UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 20-F

☐ REGISTRATION STATEMENT PURSUANTTO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

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

For the fiscal year ended December 31, 2024

OR

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

OR

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

Commission File No.: 001-40753

ICECURE MEDICAL LTD.
(Exact name of registrant as specified in its charter)

Translation of registrant's name into English: Not applicable

State of Israel
(Jurisdiction of incorporation or organization)

7 Ha'Eshel St., PO Box 3163
Caesarea, 3079504 Israel
Tel: +972.4.6230333
(Address of principal executive offices)

Eyal Shamir
Chief Executive Officer
IceCure Medical Inc.
7 Ha'Eshel St., PO Box 3163
Caesarea, 3079504 Israel
Tel: +972.4.6230333
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class	*Trading Symbol(s)*	*Name of each exchange on which registered*
Ordinary Shares, no par value	**ICCM**	**The Nasdaq Capital Market**

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

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report:

56,568,999 ordinary shares as of December 31, 2024.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act of 1934.

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 Exchange Act 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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months.

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," and emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Emerging Growth Company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, 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. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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.

Yes ☐ No ☒

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 which basis of accounting the registrant has used to prepare the financial statements included in this filing.

U.S. GAAP ☒

International Financial Reporting Standards as issued by the International Accounting Standards Board

Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

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IceCure Medical Ltd.

INTRODUCTION

We are a commercial stage medical device company focusing on the research, development and marketing of cryoablation systems and technologies based on liquid nitrogen, or LN2, for treating tumors. Cryoablation is the process by which benign and malignant tumors are ablated (destroyed) through freezing such tumors. Our proprietary cryoablation technology is a minimally invasive alternative to surgical intervention for tumors, including those found in breast, lungs, kidneys, bones and other indications. Our lead commercial cryoablation product is the ProSense system and its associated CryoProbes.

Alongside our continued efforts at improving our core technology, including our flagship product, the ProSense system, we are also focused on new product developments. This includes our next-generation single probe system, or XSense system with CryoProbes, for which we have received 510(k) regulatory clearance from the United States Food and Drug Administration, or FDA. We believe that the XSense system with CryoProbes can serve as a platform that will allow us to develop other unique CryoProbes and catheters and expand our clinical applications and is also more efficient, intuitive and user friendly compared to our existing ProSense system. We are also developing our next-generation multi-probe system, or MSense, which could enable the treatment of multiple and larger tumors (see "Item 4.B. *Business Overview – Our Products – Research and Development*" for additional information).

We believe that obtaining regulatory approval for our existing and next-generation products for specific indications will help us grow our business. As of December 31, 2024, we have received a broad range of regulatory approvals for our systems to treat tumors in the lungs, kidneys, bones and other indications. In the United States our products are cleared as a "single family" known as the "IceCure Family," which includes the IceSense3, ProSense, and MultiSense cryoablation systems, the latter of which has not been commercialized. Although our "IceCure Family" systems have regulatory clearance from the FDA for commercialization in the United States, we have yet to receive regulatory approval for such systems for treatment of malignant breast tumors, which requires a separate approval from the FDA. The FDA classifies medical devices into one of three classes (Class I, Class II, or Class III) depending on their level of risk and the types of controls that are necessary to ensure device safety and effectiveness. The class assignment is a factor in determining the type of premarketing submission or application, if any, that will be required before marketing products in the United States. On October 18, 2022, we requested that De Novo classification be accepted for our ProSense system for breast cancer indication. Because of this De Novo classification request, we will be required to accept special controls imposed by the FDA in relation to the production process and post-market monitoring. If a De Novo classification is not approved by the FDA as the regulatory pathway, the FDA will accept only pre-market approval, or PMA, in which case we would expect the timeline for marketing approvals to take longer for our associated costs to be higher relative to 510(k) or De Novo approval.

IceCure's cryoablation system currently has regulatory approval for various indications in 15 countries, including in several European countries, the U.S., and China.

We are an Israeli corporation based in Caesarea, Israel and were incorporated in Israel in 2006. On February 2, 2011, we became a public company in Israel and our Ordinary Shares were listed for trade on the Tel Aviv Stock Exchange, or the TASE. On August 26, 2021, our Ordinary Shares were listed for trade on the Nasdaq Capital Market, or Nasdaq. Our principal executive offices are located at 7 Ha'Eshel St., PO Box 3163, Caesarea, 3079504 Israel. Our telephone number in Israel is +972-4-6230333. Our website address is http://www.icecure-medical.com. The information contained on, or that can be accessed through, our website is not part of this report. We have included our website address in this report solely as an inactive textual reference.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain information included in this annual report on Form 20-F may be deemed to be "forward-looking statements," including some of the statements made under Item 3.D. "Risk Factors," Item 5 "Operating and Financial Review and Prospects," "Business" and elsewhere in this annual report constitute forward-looking statements. Forward-looking statements are often characterized by the use of forward-looking terminology such as "may," "will," "expect," "anticipate," "estimate," "continue," "believe," "predict," "should," "intend," "project" or other similar words, but are not the only way these statements are identified.

These forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, statements that contain projections of results of operations or of financial condition, expected capital needs and expenses, statements relating to the research, development, completion and use of our products, and all statements (other than statements of historical facts) that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. We have based these forward-looking statements on assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

Important factors that could cause actual results, developments and business decisions to differ materially from those anticipated in these forward-looking statements include, among other things:

- our planned level of revenues and capital expenditures;
- our available cash our ability to obtain additional funding;
- our ability to market and sell our products;
- regulatory developments in the United States and other countries;
- our plans to continue to invest in research and development to develop technology for both existing and new products;
- our ability to maintain our relationships with suppliers, manufacturers and other partners;
- our ability to internally develop new inventions and maintain and protect our European, U.S. and other patents, and other intellectual property;
- our ability to obtain and maintain regulatory approvals for our products and their associated indications for use;
- our ability to retain key executive members;
- our ability to expose and educate physicians and other medical professionals about the use cases of our products;
- our expectations regarding our tax classifications;
- interpretations of current laws and the passage of future laws;

- general market, political and economic conditions in the countries in which we operate, including those related to recent unrest and actual or potential armed conflict in Israel and other parts of the Middle East, such as the multi-front war Israel is facing; and

- those factors referred to in "Item 3.D. Risk Factors," "Item 4. Information on the Company," and "Item 5. Operating and Financial Review and Prospects", as well as in this annual report on Form 20-F generally.

Readers are urged to carefully review and consider the various disclosures made throughout this annual report on Form 20-F which are designed to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

You should not put undue reliance on any forward-looking statements. Any forward-looking statements in this annual report on Form 20-F are made as of the date hereof, and we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

In addition, the section of this annual report on Form 20-F entitled "Item 4. Information on the Company" contains information obtained from independent industry sources and other sources that we have not independently verified.

Unless otherwise indicated, all references to "we," "us," "our," the "Company" and "IceCure" refer to IceCure Medical Ltd. and its wholly owned subsidiaries, IceCure Medical Inc., a Delaware corporation, IceCure Medical HK Limited a Hong Kong corporation and IceCure (Shanghai) MedTech Co., Ltd., a subsidiary of IceCure Medical HK Limited.

Our reporting currency and functional currency is the U.S. dollar. Unless otherwise expressly stated or the context otherwise requires, references in this report to "NIS" are to New Israeli Shekels, and references to "dollars" or "$" mean U.S. dollars.

Unless derived from our financial statements or otherwise noted, amounts presented in this annual report are translated at the rate of NIS 3.647 = $1.00, the exchange rate between the NIS and the U.S. dollar reported by the Bank of Israel as of December 31, 2024.

This report contains trademarks, trade names and service marks, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent permitted under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply a relationship with, or endorsement or sponsorship of us by, these other parties.

We report our financial statements in accordance with generally accepted accounting principles in the United States, or U.S. GAAP.

Summary Risk Factors

Our business is subject to numerous risks, as more fully described in "Item 3.D. *Risk Factors*" immediately following this summary. You should read these risks in full before you invest in our securities. The following is a summary of such risks.

Risks Related to Our Financial Condition and Capital Requirements

- we have a limited operating history and we have incurred significant operating losses since our inception, and anticipate that we will incur continued losses for the foreseeable future;
- we have generated minimal revenues from product sales and may never be profitable, even if we receive regulatory approval to commercialize our products in additional geographical territories and indications; and
- we expect that we will need to raise substantial additional funding, which may not be available on acceptable terms, or at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our commercialization and product development efforts, expansion to new markets, or other activities.
- our management team concluded, and the report of our independent registered public accounting firm contains an explanatory paragraph that indicates that there are conditions that raise substantial doubts about the Company's ability to continue as a going concern.

Risks Related to Our Business and Industry

- we are highly dependent on the successful development, obtaining regulatory clearances and marketing and sale of our ProSense, XSense and our future MSense systems;
- if we fail to maintain an existing strategic relationships with Terumo Corporation or are unable to identify additional distributors of our products or any future products and technologies, our revenues may decrease;
- we are dependent upon third-party manufacturers and suppliers making us vulnerable to supply shortages and problems, increased costs and quality or compliance issues, any of which could harm our business;
- we manage our business through a small number of employees and key consultants. We may need to expand our organization and we may experience difficulties in recruiting needed additional employees and consultants, which could disrupt our operations;
- if we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks;
- we face intense competition in the market, and as a result we may be unable to effectively compete in our industry;
- our commercial success is very much dependent on third-party payors to provide adequate insurance coverage and reimbursement for the use of our systems, or any future products that we may commercialize;
- our management team has limited experience managing a U.S. reporting company; and
- our business and operations might be adversely affected by security breaches, including any cybersecurity incidents.

Risks Related to Product Development and Regulatory Approval

- our, or our partners' clinical trials may encounter delays, suspensions or other problems;
- the results of pre-clinical studies, early-stage clinical trials, data obtained from real-world use, and published third-party studies may not be indicative of results in future clinical trials and we cannot assure you that any clinical trials will yield the results we anticipate, be successful or lead to results sufficient for the necessary regulatory approvals;
- we may not receive, or may be delayed in receiving, the necessary clearances or approvals for our current products or future products in order to commercialize these products in specific countries or regions or in a specific indication, and failure to timely obtain necessary clearances or approvals for our existing or future products would adversely affect our ability to grow our business;
- preliminary data that we or others announce or publish from time to time with respect to our products may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data;
- the misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that may lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly;
- our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to immediately report to all relevant regulatory authorities, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us;
- if we do not obtain and maintain international regulatory registrations, clearances or approvals for our products, we will be unable to market and sell our products; and
- disruptions at the FDA and other government agencies could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being cleared or approved or commercialized in a timely manner or at all, which could negatively impact our business.

Risks Related to Our Intellectual Property

- if we are unable to obtain and maintain effective patent rights for our products and services, we may not be able to compete effectively in our markets. If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us; and
- third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Risks Related to the Ownership of our Securities

- our principal shareholders, officers and directors currently beneficially own approximately 47.6% of our Ordinary Shares. They will therefore be able to exert significant control over matters submitted to our shareholders for approval; and
- we may be a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes in the current taxable year or may become one in any subsequent taxable year. There generally would be negative tax consequences for U.S. taxpayers that are holders of the Ordinary Shares if we are or were to become a PFIC.

Risks Related to Israeli Law and Our Operations in Israel

- current and potential political, economic and military instability in Israel, where our headquarters, most members of management and our board of directors, research and development activities, production facilities and employees are located, including Israel's ongoing multi-front war with terrorist groups in neighboring countries, such as Hezbollah in Lebanon and Hamas in the Gaza Strip, and certain state actors such as Iran, may adversely affect our results of operations;

- the termination or reduction of tax and other incentives that the Israeli government provides to Israeli companies may increase our costs and taxes;

- we may be required to pay monetary remuneration to our Israeli employees for their inventions, even if the rights to such inventions have been duly assigned to us. We may also not be able to enforce covenants not-to-compete under current Israeli law that might result in added competition for our products;

- we received Israeli government grants for certain of our research and development activities, the terms of which may require us to pay royalties and to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. If we fail to satisfy these conditions, we may be required to pay penalties and refund grants previously received;

- provisions of Israeli law and our articles of association may delay, prevent or otherwise impede a merger with, or an acquisition of, us, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders; and

- your rights and responsibilities as a shareholder will be governed in key respects by Israeli laws, which differs in some material respects from the rights and responsibilities of shareholders of U.S. companies.

Risks Related to Enforceability of Civil Liabilities

- investors may have difficulty enforcing judgements against us, our directors and management due to certain jurisdictional constraints and challenges.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data.

[Reserved]

B. Capitalization and Indebtedness.

Not applicable.

C. Reasons for the Offer and Use of Proceeds.

Not applicable.

D. Risk Factors.

Our business faces significant risks. You should carefully consider the risks described below, together with all of the other information in this annual report on Form 20-F. The risks described below are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business operations. If any of these risks actually occurs, our business and financial condition could suffer and the price of our Ordinary Shares could decline. This report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this report and our other Securities and Exchange Commission, or SEC, filings. See "Cautionary Note Regarding Forward-Looking Statements" above.

Risks Related to Our Financial Condition and Capital Requirements

Our management has concluded that there are conditions that raise substantial doubt about our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.

Since our inception, we have accumulated losses of $105,379 thousand as of December 31, 2024. In the year ended December 31, 2024, we generated losses of $15,318 thousand and negative cash flows from operating activities of $12,563 thousand. We expect that we will continue to generate substantial operating losses and fund our operations primarily through the utilization of current financial resources, sales of our products, and additional raises of capital. These conditions raise substantial doubts about our ability to continue as a going concern. Our plan involves raising funds from existing shareholder and potential investors. There is no assurance, however, that such funding would be available to us, that it could be obtained on favorable terms, or that we will be provided with sufficient funds to continue to develop and commercialize our products.

We have a limited operating history and we have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

We are a medical device company with a limited operating history. To date, we have focused on developing our first commercial product for tumor cryoablation, the ProSense system, collecting clinical data, obtaining regulatory approvals in different geographical territories and indications and initiated our commercialization effort. We have funded our operations to date primarily through raising capital on Nasdaq, private offerings, minimal sales of our ProSense system and its components, including affiliated needles, or CryoProbes, guiding needles, or Introducers and other products, which we collectively refer to as disposables, loans, convertible loans and royalty-bearing grants that we received from the Israeli Innovation Authority, or the IIA, formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry.

We have only a limited operating history upon which you can evaluate our business and prospects. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the medical device industry. To date, we have generated minimal revenues from the sale of our ProSense system and its disposables (see "Item 5. *Operating and Financial Review and Prospects*" for additional information). We have incurred losses in each year since our inception, including operating losses of $15,696 thousand and $15,576 thousand for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $105,379 thousand. Substantially all of our operating losses resulted from costs incurred in connection with our development of our technology, business development and commercialization and from general and administrative costs associated with our operations.

Until we can generate significant revenues, if ever, we expect to satisfy our future cash needs through debt or equity financing. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate research or development plans for, or commercialization efforts with respect to our products.

Our research and development expenses may increase in connection with our planned expanded research and development efforts, including those conducted in connection with the development of our future MSense system and new types of CryoProbes, and as we seek to receive approval from applicable regulatory authorities to commence commercialization of our ProSense system for treatment in breast cancer and other indications. In addition, if we obtain marketing approval for our ProSense system for the treatment of breast cancer and other indications in different countries across the world, including the United States, and for our XSense and future MSense systems, we will likely incur significant outsourced manufacturing expenses, increased sales and marketing costs as well as costs related to obtaining medical coverage and reimbursement for our procedures, particularly in the United States. In addition, although we have certain regulatory approvals, these only allow us to conduct minimal commercialization of our products. Therefore, we will need to seek additional regulatory approvals in order to initiate commercialization, in scale, that has the potential to generate significant revenues for us. Even if we were to receive marketing approval for our ProSense, XSense and future MSense systems, we expect that we will continue to incur significant research and development expenses as we seek to improve our technology and effectively compete with our competitors and as we seek additional approvals for their use in different indications and marketing and commercialization costs.

Furthermore, in addition to such operating expenses, we expect to incur costs associated with operating as a public company subject to the rules and regulations of the SEC, which we estimate will be at least one million dollars annually. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing a medical device, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

The regulatory marketing approvals that we currently have are insufficient to generate significant revenue. Therefore, we expect to continue to incur significant losses until we are able to meaningfully commercialize our ProSense system, XSense or future MSense systems, which we may not be successful in achieving. We anticipate that our expenses will increase substantially if and as we:

- continue the research and development of our technology;
- discover that there are robust technology changes in our field;
- seek regulatory and marketing approvals for our medical devices, and more specifically, our ProSense system for treatment of breast cancer;
- subject to the receipt of the applicable regulatory approvals, establish and expand a sales, marketing, and distribution infrastructure to commercialize our current ProSense system and our future XSense and future MSense systems, and its disposables;
- seek to identify, assess, acquire, license, and/or develop other medical devices companies and subsequent generations of our current medical devices;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with respect to any of the above, including, but not limited to, failed studies, complex results, safety issues or other regulatory challenges that require longer follow-up of existing studies or additional supportive studies in order to pursue marketing approval.

The amount of any future operating losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through sales, equity or debt financings, strategic collaborations or grants. Even if we obtain regulatory approval to market our ProSense system or any future products, including the XSense and MSense systems, our future revenues will depend on the market size (geographic and indication-specific) in which any such product receives approval and our ability to achieve sufficient market acceptance, competition, pricing, reimbursement from third-party payors for our ProSense, XSense and MultiSense systems or any future product candidates. Further, the operating losses that we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Other unanticipated costs may also arise.

We have generated minimal revenues from product sales and may never be profitable, even if we receive regulatory approval to commercialize our products in additional geographical territories and indications.

Our system and its disposables are approved for marketing in a limited number of jurisdictions and for use in treatment of certain indications. In order to generate significant revenue, we will need to obtain additional regulatory approvals in jurisdictions within which we already have certain regulatory approvals and also in jurisdictions in which we currently have no regulatory approvals to market our products. Even if our ProSense or MultiSense systems or any future products are approved for marketing and sale, we anticipate incurring significant incremental costs associated with commercializing such products.

Our ProSense system and its disposables have regulatory approvals that allow us to market our system or its disposables in certain geographical areas and for specific indications. However, even with these regulatory approvals in place, we have yet to generate significant revenues and we plan to seek for additional regulatory approvals covering additional clinical indications, to allow us to increase clinical acceptance of our products by the medical community, obtain reimbursement coverage, and partner with distributors, all in order to increase commercialization efforts (see "Item 4.B. *Business Overview – Government Regulation*" for additional information). However, there can be no assurance that we will obtain regulatory approvals for all indications we have applied, or intend to apply for, or at all.

In addition to our dependency on receiving adequate regulatory approvals to market our products to our target market (geographic and indication-specific), our ability to generate significant revenues and achieve profitability also depends on our success in many areas, including but not limited to:

- complete research and development of our future MSense system and any future products in a timely and successful manner;
- obtain market acceptance, if and when approved, of our ProSense, XSense and future MSense systems and any future products from the medical community, patients and third-party payors;
- enter into agreements with commercial partners;
- obtain sufficient clinical evidence from our trials and commercial procedures, and publish such data;
- maintain and enhance a commercially viable, sustainable, scalable, reproducible and transferable manufacturing process for our ProSense, XSense and future MSense systems and any future product candidates that is compliant with current good manufacturing practices, or cGMPs, or any other applicable regulations or standards;
- establish and maintain supply and, if applicable, manufacturing relationships with third parties that can provide, in both amount and quality, adequate products to support development and the market demand for our ProSense, XSense and future MSense systems and any future products, if and when approved for marketing by regulators;
- maintain sufficient average selling price for our products and the revenues margin that we generate;
- launch and commercialize any products for which we obtain regulatory and marketing approval, either directly by establishing a sales force, marketing and distribution infrastructure, and/or with collaborators or distributors;
- accurately identifying demand for our ProSense, XSense and future MSense systems or any future products;
- ensure our products are approved for reimbursement from governmental agencies, health care providers and insurers in jurisdictions where they have been approved for marketing;
- address any competing technological and market developments that impact our technology or its prospective usage by medical professionals;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter and perform our obligations under such collaborations;
- attract, hire and retain qualified personnel; and
- locate and lease or acquire suitable facilities to support our clinical development, manufacturing facilities and commercial expansion.

In addition, even if we were to receive all of the regulatory approvals that we may seek to receive, our expenses could increase beyond expectations if we are required by the FDA, or other regulatory agencies, domestic or foreign, to change our manufacturing processes or assays or to perform studies in addition to those that we currently anticipate.

Further, if we are not able to generate significant revenues from the sale of our approved products, we may be forced to curtail or cease our operations. Due to the numerous risks and uncertainties involved in product development, it is difficult to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability.

We expect that we will need to raise substantial additional funding in order to continue our operations, which may not be available on acceptable terms, or at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our commercialization and product development efforts, expansion to new markets, or other activities.

As of December 31, 2024, our cash and cash equivalents and deposits were approximately $7.6 million, and we had working capital of $5,240 thousand and an accumulated deficit of $105,379 thousand. Our current cash and cash equivalents position is not sufficient to fund our planned operations for at least the next 12 months beyond the filing date of this Annual Report. We expect that we will require substantial additional capital to commercialize our ProSense system and to develop and commercialize our XSense and future MSense systems. In addition, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including but not limited to:

- the cost, timing and outcomes of regulatory review of ProSense system and any future products;
- the costs of maintaining our own commercial-scale GMP manufacturing facility, including costs related to obtaining and maintaining regulatory compliance, and/or engaging third-party manufacturers therefor;
- the scope, progress, results and costs of product development, testing, manufacturing, preclinical development and, if applicable, clinical trials for any other products that we may develop or otherwise obtain in the future;
- the cost of our future activities, including establishing sales, marketing and distribution capabilities for any products in any particular geography where we receive marketing approval for such products;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the level of revenues received from commercial sales of any product candidates for which we receive marketing approval.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our ProSense, XSense and future MSense systems and any future product candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. In addition, our ability to raise capital could be affected by various factors, including clinical adverse events. Moreover, the terms of any financing may adversely affect the holdings or the rights of holders of our securities 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 Ordinary Shares to decline. The incurrence of indebtedness could 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 collaborative partners 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 product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Even if we believe that we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the development or commercialization of our ProSense, XSense or future MSense systems or any other products or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, fluctuations in unemployment rates, fluctuations in inflation rates and uncertainty about economic stability. Any potential volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Inflation can adversely affect us by increasing our costs. Any significant increases in inflation and related increase in interest rates could have a material adverse effect on our business, results of operations, financial condition and our ability to raise funds.

Risks Related to Our Business and Industry

We are highly dependent on the successful development, obtaining regulatory clearances and marketing and sale of our ProSense, XSense and MultiSense systems.

Our ProSense system, our second-generation cryoablation system, is the basis of our business. As a result, the success of our business plan is highly dependent on our ability to manufacture our ProSense at a large scale, and commercialize our ProSense system for the treatment of breast cancer, and other intended uses in the field of interventional oncology (including kidney cancer, lung cancer, liver cancer and bone cancer) and our failure to do so could cause our business to fail. Successful production and commercialization of medical devices is a complex and uncertain process, dependent on the efforts of management, manufacturers, local operators, integrators, medical professionals, third-party payors, as well as general economic conditions, among other factors. Any factor that adversely impacts the production and commercialization of our ProSense system, will have a negative impact on our business, financial condition, results of operations and prospects. We have limited experience in commercializing our ProSense system and we may face several challenges with respect to our commercialization efforts, including, among others, that:

- we may not have adequate financial or other resources to complete the development of our future MSense system or any future products;
- we may not be able to manufacture our ProSense system in commercial quantities, at an adequate quality or at an acceptable cost;
- we may not be able to establish adequate sales, marketing and distribution channels for our products;
- healthcare professionals, medical providers and patients may not accept our products;
- we may not be aware of possible complications from the continued use of our ProSense system since we have limited clinical experience with respect to the actual use of our ProSense system;
- technological breakthroughs solutions in the ablation of tissues may reduce the demand for our ProSense system;
- third-party payors may not agree to reimburse sufficiently, or at all patients or healthcare providers for any or all of the procedures conducted with our ProSense system, which may adversely affect medical providers, and patients' willingness to use our ProSense system;
- we may face third-party claims of intellectual property infringement;
- we may fail to obtain or maintain regulatory clearance or approvals in our target markets (geographic and indication-specific) or may face adverse regulatory or legal actions even if regulatory approval is obtained;
- prices may adversely affect patients' willingness to use our ProSense system; and
- guidelines published by the medical community may not recommend the use of our ProSense, XSense and MultiSense systems or any future products for certain indications, which may adversely affect healthcare users willingness to use our ProSense, XSense and MultiSense systems or any future products.

If we are unable to meet any one or more of these challenges successfully, our ability to effectively commercialize our products could be limited, which in turn could have a material adverse effect on our business, financial condition and results of operations.

If we fail to maintain an existing strategic relationship with Terumo Corporation or are unable to identify additional distributors of our products or any future products and technologies, our revenues may decrease.

We expect to derive a significant amount of our revenues through our strategic relationship and distribution agreements with Terumo Corporation and its affiliates. If our relationship with Terumo Corporation is terminated or impaired for any reason and we are unable to replace this relationship with other means of distribution, it may adversely affect our future sales prospects in Japan.

We may need, or decide it is otherwise advantageous to us, to obtain the assistance of additional distributors to market and distribute our future products and technologies, as well as to market and distribute our existing ProSense, XSense and MultiSense systems, to existing or new markets or geographical areas. We may not be able to find additional distributors who will agree to and are able to successfully market and distribute our systems and technologies on commercially reasonable terms, if at all. If we are unable to establish additional distribution relationships on favorable terms, our revenues may decline. In addition, our distributors may choose to favor the products of our competitors over ours and give preference to them.

Also, our financial results are dependent upon the service efforts of Terumo Corporation. If Terumo Corporation is unsuccessful in adequately servicing our products, our sales could significantly decrease and our business, financial condition, results of operations and prospects may be adversely impacted.

Pursuant to our agreements with Terumo Corporation, we are also dependent on Terumo Corporation's efforts to obtain regulatory approval for the marketing and sale and the reimbursement of our products in Japan. If Terumo Corporation fails to obtain such approvals, it might adversely impact our future plans for sales in Japan.

Similarly, pursuant to our agreement with Beijing Turing, we will be responsible for obtaining and maintaining any and all regulatory approvals in mainland China required for marketing, promotion, distribution, sale and use of our IceSense3, ProSense, XSense and future MSense systems, with accompanying CryoProbes. If we are unable to obtain or maintain such approvals, it may adversely impact our relationship with Beijing Turing, as well as impact our future plans for sales in China.

Medical device development is costly and involves continual technological change which may render our current or future products obsolete.

The market for medical device technologies and products is characterized by factors such as rapid technological change, medical advances, changing consumer requirements, short device lifecycles, changing regulatory requirements and evolving industry standards. Any one of these factors could reduce the demand for our devices or require substantial resources and expenditures for, among other things, research, design and development, to avoid technological or market obsolescence.

Our success will depend on our ability to enhance our current technology and develop or acquire new technologies to keep pace with technological developments and evolving industry standards, while responding to changes in customer needs. A failure to adequately develop or acquire device enhancements or new devices that will address changing technologies and customer requirements adequately, or to introduce such devices on a timely basis, may have a material adverse effect on our business, financial condition and results of operations.

We might have insufficient financial resources to improve our ProSense and XSense systems or complete the development of our future MSense system, and any other future products, and advance technologies and develop new devices at competitive prices. Technological advances by one or more competitors or future entrants into the field may result in our present services or devices becoming non-competitive or obsolete, which may decrease revenues and profits and adversely affect our business and results of operations.

We may encounter significant competition across our product lines and in each market in which we will sell our products and services from various companies, some of which may have greater financial and marketing resources than we do. Our competitors may include any companies engaged in the research, development, manufacture, and marketing of non-invasive or minimally invasive solutions and technologies to treat tumors, as well as a wide range of medical device companies that sell a single or limited number of competitive products and services or participate in only a specific market segment.

We will be dependent upon success in our customer acquisition strategy.

Our business will be dependent upon success in our customer acquisition strategy. If we fail to maintain a high quality of device technology, we may fail to retain or add new customers. If we fail, our revenue, financial results and business may be significantly harmed. Our future success depends upon expanding our commercial operations in the United States, Europe and Southeast Asia, as well as entering additional markets (geography and indication-specific) to commercialize our XSense and future MSense systems and any other future products. We believe that our expanded growth will depend on the further development, regulatory approval(s) and commercialization of our ProSense, XSense and MultiSense systems. If we fail to commercialize our products in a timely manner and across a range of indications, including breast cancer, we may not be able to expand our markets or to grow our revenue, and our business and financial condition may be adversely impacted. If medical practitioners do not perceive our products to be useful and reliable, we may not be able to attract or retain new customers. A decrease in sales growth could cause us to enter into sales or distribution agreements on terms less favorable to us or cause us to license our technology on unfavorable and unexpected terms, which may have a material and adverse impact on our revenue, business, reputation, financial condition and results of operations.

We are dependent upon third-party manufacturers and suppliers making us vulnerable to supply shortages and problems, increased component and shipping costs and quality or compliance issues, any of which could harm our business.

We rely on third parties to manufacture and supply us with proprietary custom components. We rely on a limited number of suppliers who provide us materials and components as well as manufacture and assemble certain components of our products. Our suppliers may encounter problems during manufacturing for a variety of reasons, including, for example, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs and infringement of third-party intellectual property rights, any of which could delay or impede their ability to meet our requirements. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including:

- we are not currently a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- third parties may threaten or enforce their intellectual property rights against our suppliers, which may cause disruptions or delays in shipment, or may force our suppliers to cease conducting business with us;
- we may not be able to obtain an adequate supply in a timely manner or on commercially reasonable terms;
- our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of our products or cause delays in shipment;
- we may have difficulty locating and qualifying alternative suppliers;
- the costs of shipping components has increased and we may not be able to pass along such increased costs to our customers;
- we may face difficulties in performing "last time buy" procurement for "end of life" components for our systems, especially the ProSense system;
- switching components or suppliers may require product redesign, validation or verification processes and possibly submission to the FDA or other similar foreign regulatory agencies, which could significantly impede or delay our commercial activities;
- one or more of our suppliers may be unwilling or unable to supply components of our products;
- the occurrence of a fire, natural disaster or other catastrophe impacting one or more of our suppliers may affect their ability to deliver products to us in a timely manner; and
- our suppliers may encounter financial or other business hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

In addition, the product development process of cryoablation systems based on the liquid nitrogen coolant material is complex and requires unique specialists and technology for design and manufacture systems core modules and elements. We, or our partners, may experience delays in design solutions and verifications activities due to liquid nitrogen physical properties, which influences the complexity in handling, storage, and flowing of liquid nitrogen.

We consistently monitor our inventory levels and maintain recovery plans to address potential disruptions that we may encounter from our suppliers. However, we may not be able to quickly establish additional or alternative suppliers, if necessary, in part because we may need to undertake additional activities to establish such suppliers as required by the regulatory approval process. Any interruption or delay in obtaining products from our third-party suppliers, or our inability to obtain products from qualified alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to switch to competing products. Given our reliance on certain suppliers, we may be susceptible to supply shortages while looking for alternate suppliers (see "Item 4.B. *Business Overview – Production and Manufacturing*" for additional information).

We may not be able to replace our current manufacturing capabilities in a timely manner.

If our contract manufacturing facility or our in-house facility suffers any type of prolonged interruption, whether caused by regulator action, equipment failure, critical facility services failure, fire, natural disaster or any other event that causes the cessation of manufacturing activities, such as an epidemic or pandemic, we may be exposed to long-term loss of sales and profits. There are limited facilities which are capable of contract manufacturing some of our products and product candidates. Replacement of our current manufacturing capabilities may have a material adverse effect on our business and financial condition.

We are dependent upon third-party service providers. If such third-party service providers fail to maintain a high quality of service, the utility of our products could be impaired, which could adversely affect the penetration of our products, our business, operating results and reputation.

The success of certain services and products that we provide are dependent upon third-party service providers. Such service providers include manufacturers of proprietary custom components for our ProSense, XSense and MultiSense systems. As we expand our commercial activities, an increased burden will be placed upon the quality of such third-party providers. If third-party providers fail to maintain a high quality of service, our products, business, reputation and operating results could be adversely affected. In addition, poor quality of service by third-party service providers could result in liability claims and litigation against us for damages or injuries.

If we are not able to attract and retain highly skilled managerial, scientific, technical and marketing personnel, we may not be able to implement our business model successfully.

Our success depends partly on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management as well as other employees, consultants and scientific and medical collaborators. Our management team must be able to act decisively to apply and adapt our business model in the rapidly changing markets in which we will compete. In addition, we will rely upon technical and scientific employees or third-party contractors to effectively establish, manage and grow our business. Consequently, we believe that our future viability will depend largely on our ability to attract and retain highly skilled managerial, sales, scientific and technical personnel. In order to do so, we may need to pay higher compensation or fees to our employees or consultants than currently expected and such higher compensation payments may have a negative effect on our operating results. Competition for experienced, high-quality personnel in the medical device field is intense. We may not be able to hire or retain the necessary personnel to implement our business strategy. Our failure to hire and retain quality personnel on acceptable terms could impair our ability to develop new products and services and manage our business effectively.

We may need to expand our organization and we may experience difficulties in recruiting needed additional employees and consultants, which could disrupt our operations.

As our development and commercialization plans and strategies develop and because we are leanly staffed, we may need additional managerial, development, regulatory, operational, sales, marketing, financial, legal and other resources. The competition for qualified personnel in the medical device industry is intense. Due to this intense competition, we may be unable to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Our management may need to divert its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional medical device products. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize medical device products and services and compete effectively will depend, in part, on our ability to effectively manage any future growth.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenues from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

We are subject to certain U.S. and foreign anticorruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anticorruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase over time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Non-U.S. governments often impose strict price controls, which may adversely affect our future profitability.

We may be subject to rules and regulations in the United States and non-U.S. jurisdictions relating to our ProSense and MultiSense systems or any future products. In some countries, including countries of the European Union, or the EU, Japan, or China each of which has developed its own rules and regulations, pricing may be subject to governmental control under certain circumstances. In these countries, pricing negotiations with governmental agencies can take considerable time after the receipt of marketing approval for a medical device candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

For example, the Chinese government has implemented volume-based procurement policies, or VBPs, a series of centralized reforms instituted in China on both a national and regional basis designed to decrease prices for medical devices and other products. VBPs in China could result in reduced margins on covered devices and products, required renegotiation of distributor arrangements or an incurrence of inventory-related charges. As a result of VBPs, we may experience a reduction in revenues from the sales of our products in China and VBPs in China may also impact our relationship with Beijing Turing. We cannot predict future impacts of VBPs on our business and activities in China, including any expansion of VBPs to include additional products within our portfolio.

Inadequate funding for the FDA and other government agencies and/or potentially shifting priorities under the new administration could hinder the FDA's and/or those other government agencies' ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products, provide feedback on clinical trials and development programs, meet with sponsors and otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels; ability to hire and retain key personnel and accept the payment of user fees; and statutory, regulatory, and policy changes, among other factors. Average review times at the agency may fluctuate as a result. In addition, government funding of other government agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also increase the time necessary for new drugs or medical devices to be reviewed and/or approved by necessary government agencies or to otherwise respond to regulatory submissions, which would adversely affect our business. For example, the Trump Administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the medical device and pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs or treatments. Additionally, over the last several years, the US government has shut down multiple times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If funding for the FDA is reduced, FDA priorities change, or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We manage our business through a small number of employees and key consultants.

As of December 31, 2024, we had 64 full-time employees and two part time employees. Our future growth and success depend to a large extent on the continued services of members of our current management including, in particular, our VP research and development and our chief executive officer. Any of our employees and consultants may leave our company at any time, subject to certain notice periods. The loss of the services of any of our executive officers or any key employees or consultants may adversely affect our ability to execute our business plan and harm our operating results. Our operational success will substantially depend on the continued employment of senior executives, technical staff and other key personnel, especially given the intense competition for qualified personnel. The loss of key personnel may have an adverse effect on our operations and financial performance.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States or Israel.

Other than our headquarters and other operations which are located in Israel (as further described below), our business strategy incorporates significant international expansion, particularly in anticipated expansion of regulatory approvals of our products. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain regulatory approvals for the use of our products and services in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple regulatory, governmental and reimbursement regimes;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or the FCPA, its books and records provisions or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations.

We face intense competition in the market, and as a result we may be unable to effectively compete in our industry.

The major market players within the cancer cryoablation care market and our primary competitors in the United States and abroad include Boston Scientific Corporation and Siemens Healthineers. Some of these companies hold significant market share. Their dominant market position and significant control over the market could significantly limit our ability to introduce or effectively market and generate sales and capture market share.

Additionally, there are competing heat base technologies in the thermal ablation sector such as radiofrequency ablation, or RFA, microwave ablation, or MWA, and irreversible electroporation, or high-intensity focused ultrasound which are developed by entities such as NeuWave Medical, Inc., Angiodynamics, and Inisghtec Ltd.

Many of our competitors have long histories and strong reputations within the industry. They have significantly greater brand recognition, financial and human resources than we do. They also have more experience and capabilities in researching and developing medical devices, obtaining and maintaining regulatory clearances, manufacturing and marketing those products and other resources, than we do. There is a significant risk that we may be unable to overcome the advantages held by our competition, and our inability to do so could lead to the failure of our business and the loss of your investment. In addition, we may be unable to develop additional products in the future or to keep pace with developments and innovations in the market and lose market share to our competitors.

Competition in the medical devices and cancer treatment market is intense, and can lead to, among other things, price reductions, longer selling cycles, lower product margins, loss of market share and additional working capital requirements. To succeed, we must, among other critical matters, gain consumer acceptance for our ProSense, XSense and MultiSense systems, as compared to other solutions currently available in the market for the treatment of tumors and potential future medical devices incorporating our principal technology or offering other advanced cryoablation, heat ablation or other non or minimally invasive solutions. For example, since the currently accepted treatment for breast cancer is surgery, we will need to invest resources in educating the medical community and consumers, and establish strategic collaborations before we will be able to gain market acceptance for our ProSense system as a treatment to breast cancer. If our competitors offer significant discounts on certain products and solutions, we may need to lower our prices or offer other favorable terms in order to compete successfully. Moreover, any broad-based changes to our prices and pricing policies could make it difficult to generate revenues or cause our revenues to decline. Moreover, if our competitors develop and commercialize products and solutions that are more effective or desirable than products and solutions that we may develop, we may not convince our customers to use our products and solutions. Any such changes would likely reduce our commercial opportunity and revenues potential and could materially adversely impact our operating results.

Our commercial success is very much dependent on third-party payors to provide adequate insurance coverage and reimbursement for the use of our systems, or any future products that we may commercialize.

Our ProSense, XSense and MultiSense systems, and any other product in our development pipeline, is not yet approved for third-party payor coverage or reimbursement in some of the geographical markets in which we operate, or plan to operate in the future. Such reimbursement may vary based on the particular device used in providing services and is based on the identity of the third-party. Our ability to maintain a leading position in the medical device market, and specifically in the cancer care market, depends on our relationships with private third parties.

We expect to engage with federal agencies providing health coverage in the United States, such as the Centers for Medicare and Medicaid Services, or CMS, and in other countries and private third parties to allow our customers to receive reimbursement from insurance companies for our ProSense, XSense and MultiSense systems. The loss of a significant number of contracts with federal agencies or private third-parties may have an adverse effect on our revenues, which could have an adverse effect on our business, financial condition and results of operations. Over the past few years, reimbursement rates from certain third parties have declined, in some cases significantly. There can be no assurance that this trend will not continue or apply on more third parties.

In addition, private third parties may not reimburse any new procedures conducted with our products or reimburse those new clinical procedures at commercially viable rates. The failure to receive reimbursement at adequate levels for our existing or future products may adversely affect demand for those products, our revenues and expected growth. This could have an adverse effect on our business, financial condition and results of operations.

We may be subject to litigation for a variety of claims, including class actions, which could adversely affect our results of operations, harm our reputation or otherwise negatively impact our business.

We may be subject to litigation for a variety of claims, including class actions, arising from our normal business activities. These may include claims, suits, and proceedings involving labor and employment, wage and hour, commercial and other matters. The outcome of any litigation, regardless of its merits, is inherently uncertain. Any claims and lawsuits, and the disposition of such claims and lawsuits, could be time-consuming and expensive to resolve, divert management attention and resources, and lead to attempts on the part of other parties to pursue similar claims. Any adverse determination related to litigation could adversely affect our results of operations, harm our reputation or otherwise negatively impact our business. In addition, depending on the nature and timing of any such dispute, a resolution of a legal matter could materially affect our future operating results, our cash flows and our ability to raise capital.

We could become subject to product liability, warranty or similar claims and product recalls that could be expensive, divert management's attention and harm our business reputation and financial results.

Our business exposes us to an inherent risk of potential product liability, warranty or similar claims and product recalls. The medical device industry has historically been litigious, and we face financial exposure to product liability, warranty or similar claims if the use of any of our products were to cause or contribute to injury or death. There is also the possibility that defects in the design or manufacture of any of our products might necessitate a product recall. Although we plan to maintain product liability insurance, the coverage limits of these policies may not be adequate to cover future claims. In the future, we may be unable to maintain product liability insurance on acceptable terms or at reasonable costs and such insurance may not provide us with adequate coverage against potential liabilities. A product liability claim, regardless of merit or ultimate outcome, or any product recall could result in substantial costs to us, damage to our reputation, customer dissatisfaction and frustration and a substantial diversion of management attention. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

Our management team has limited experience managing a U.S. reporting company.

Most members of our management team do not have experience managing a publicly traded company in the United States, interacting with public company investors and complying with the increasingly complex laws pertaining to public companies in the United States. Although we were also a public company in Israel, our management team may not successfully or efficiently manage our transition to being a public company in the United States that is subject to significant regulatory oversight and reporting obligations under the U.S. federal securities laws and the continuous scrutiny of securities analysts and investors. These obligations and constituents will require significant attention from our senior management and could divert their attention away from the day-to-day management of our business, which could adversely affect our business, financial condition, results of operations and prospects.

Our business and operations might be adversely affected by security breaches, including any cybersecurity incidents.

We depend on the efficient and uninterrupted operation of our computer and communications systems, and those of our consultants, contractors and vendors, which we use for, among other things, sensitive company data, including our intellectual property, financial data and other proprietary business information.

While certain of our operations have business continuity and disaster recovery plans and other security measures intended to prevent and minimize the impact of IT-related interruptions, our IT infrastructure and the IT infrastructure of our consultants, contractors and vendors are vulnerable to damage from cyberattacks, computer viruses, unauthorized access, electrical failures and natural disasters or other catastrophic events. We could experience failures in our information systems and computer servers, which could result in an interruption of our normal business operations and require substantial expenditure of financial and administrative resources to remedy. System failures, accidents or security breaches can cause interruptions in our operations and can result in a material disruption of our targeted phage therapies, product candidates and other business operations. The loss of data from completed or future studies or clinical trials could result in delays in our research, development or regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur regulatory investigations and redresses, penalties and liabilities and the development of our product candidates could be delayed or otherwise adversely affected.

Even though we believe we carry commercially reasonable business interruption and liability insurance, we might suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies or for which we do not have coverage. For example, we are not insured against terrorist attacks. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay the development of our product candidates (see "Item 16.K. *Cybersecurity*" for additional information).

Our business and operations would suffer in the event of computer system failures, cyber-attacks or a deficiency in our cybersecurity.

Despite the implementation of security measures intended to secure our data against impermissible access and to preserve the integrity and confidentiality of our data, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur, it could result in a material disruption of our sales, operations, and new product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, including under data privacy laws such as the GDPR, damage to our reputation, and the further development of our new products could be delayed. (see "Item 16.K. *Cybersecurity*" for additional information).

Our business may be impacted by changes in general economic conditions.

Our business is subject to risks arising from changes in domestic and global economic conditions, including adverse economic conditions in markets in which we operate, which may harm our business. If our future customers significantly reduce spending in areas in which our technology and products are utilized, or prioritize other expenditures over our technology and products, our business, financial condition, results of operations and prospects would be materially adversely affected.

Disruption to the global economy could also result in a number of follow-on effects on our business, including a possible slow-down resulting from lower customer expenditures; inability of customers to pay for products, solutions or services on time, if at all; more restrictive export regulations which could limit our potential customer base; negative impact on our liquidity, financial condition and share price, which may impact our ability to raise capital in the market, obtain financing and secure other sources of funding in the future on terms favorable to us.

In addition, the occurrence of catastrophic events, such as hurricanes, storms, earthquakes, tsunamis, floods, medical epidemics and other catastrophes that adversely affect the business climate in any of our markets could have a material adverse effect on our business, financial condition and results of operations. Some of our operations are located in areas that have been in the past, and may be in the future, susceptible to such occurrences.

Our articles of association provide that, unless we consent to an alternative forum, the federal district courts of the United States shall be the exclusive forum for resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our shareholders' ability to choose the judicial forum for disputes with us, our directors, shareholders, or other employees.

Section 22 of the Securities Act creates concurrent jurisdiction for U.S. federal and state courts over all such Securities Act actions. Accordingly, both U.S. state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our articles of association provide that, unless we consent in writing to the selection of an alternative forum, 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. This exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act, and our shareholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder as a result of our exclusive forum provision.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to the foregoing provision of our articles of association. However, the enforceability of similar forum provisions (including exclusive federal forum provisions for actions, suits, or proceedings asserting a cause of action arising under the Securities Act) in other companies' organizational documents has been challenged in legal proceedings, and there is uncertainty as to whether courts would enforce the exclusive forum provision in our articles of association. If a court were to find the exclusive forum provision contained in our articles of association to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition, and results of operations.

Although we believe the exclusive forum provision benefit us by providing increased consistency in the application of U.S. federal securities laws or the Companies Law, as applicable, in the types of lawsuits to which they apply, such exclusive forum provision may limit a shareholder's ability to bring a claim in the judicial forum of their choosing for disputes with us or any of our directors, shareholders, officers, or other employees, which may discourage lawsuits with respect to such claims against us and our current and former directors, shareholders, officers, or other employees.

Changes in financial accounting standards may cause adverse and unexpected revenues fluctuations and impact our results of operations.

A change in accounting standards or practices could harm our operating results. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may harm our operating results or the way we conduct our business.

Risks Related to Product Development and Regulatory Approval

Our product candidates and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.

We expect our ProSense, XSense and MultiSense systems and any future products we develop to be regulated by the FDA as medical devices. Regulation in the United States may subject us to the jurisdiction of the FDA, the U.S. Department of Justice, or the DOJ, and the U.S. Health and Human Services-Office of the Inspector General, or the HHS. Outside of the United States, we may be subject to the regulation of the FDA's foreign counterparts as well as other foreign regulators. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical trials; product safety; establishment registration and device listing; marketing, sales and distribution; pre-market clearance and approval; conformity assessment procedures; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to occur, could lead to death or serious injury; post-market approval studies; and product import and export.

The regulations our product candidate is subject to are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales for any approved product. Failure to comply with applicable regulations could jeopardize our ability to sell our future products, if cleared or approved, and result in enforcement actions such as: warning or untitled letters; fines; injunctions; consent decrees; civil penalties; customer notifications; termination of distribution; recalls or seizures of products; administrative detention of medical devices believed to be adulterated or misbranded; delays in the introduction of products into the market; operating restrictions; total or partial suspension of production; refusal to grant future clearances or approvals for new products, new intended uses or modifications to our products; withdrawals or suspensions of current approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal prosecution or penalties. The occurrence of any of these events would have a material adverse effect on our business, financial condition and results of operations and could result in shareholders losing their entire investment.

Our clinical trials or the clinical trials of our partners may encounter delays, suspensions or other problems.

We, or our partners, may encounter problems in clinical trials that may cause us or the FDA or foreign regulatory agencies to delay, suspend or terminate any such clinical trials at any phase. These problems could include the possibility that we may not be able to conduct clinical trials at our preferred sites, enroll a sufficient number of patients for our clinical trials at one or more sites or begin or successfully complete clinical trials in a timely fashion, if at all. Furthermore, we, our partners, the FDA or foreign regulatory agencies may suspend clinical trials at any time if we or they believe the subjects participating in the trials are being exposed to unacceptable health risks or if we or they find deficiencies in the clinical trial process or conduct of the investigation. If clinical trials of any of our products fail, we will not be able to market the product which is the subject of the failed clinical trials. The FDA and foreign regulatory agencies could also require additional clinical trials, which would result in increased costs and significant development delays. Our, or our partners', failure to adequately demonstrate the safety and effectiveness of a product under development could delay or prevent regulatory approval of the product and could have a material adverse effect on our business, prospects, financial condition and results of operations.

The results of pre-clinical studies, early-stage clinical trials, data obtained from real-world use, and published third-party studies may not be indicative of results in future clinical trials and we cannot assure you that any clinical trials will yield the results we anticipate, be successful or lead to results sufficient for the necessary regulatory approvals.

The results of pre-clinical studies may not be predictive of the results of clinical trials, and the results of any completed clinical trials, including studies derived from real-world use and studies in published literature, or clinical trials we commence may not be successful or predictive of the results of later-stage clinical trials. Additionally, interim results during a clinical trial do not necessarily predict final results. There can be no assurance that any of our clinical trials will yield the results we anticipate, ultimately be successful or support further clinical development of any of our product candidates.

We may not receive, or may be delayed in receiving, the necessary clearances or approvals for our ProSense or MultiSense systems or future products in order to commercialize these products in specific countries or regions or in a specific indication, and failure to timely obtain necessary clearances or approvals for our existing or future products would adversely affect our ability to grow our business.

In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, or De Novo classification or approval of a pre-market approval application, or a PMA, from the FDA, unless an exemption applies. In the 510(k)-clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. The FDA may request clinical data in addition that provided from our clinical sites outside the United States. In the process of obtaining De Novo classification or PMA, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k)-clearance process may require a new 510(k) clearance. Both the PMA and the 510(k)-clearance process can be expensive, lengthy and uncertain. The FDA's 510(k)-clearance process usually takes from three to nine 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. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory clearances or approvals 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 device or other restrictions or requirements, which may limit the market for the device.

In the United States, we have received 510(k) regulatory clearance to market our ProSense system and related accessories systems for the treatment of kidney and liver tumors and XSense with CryoProbes for all indications. Specifically, FDA 510(k) clearance covers IceSense3, ProSense, XSense and MultiSense systems, including the ancillary products thereto, such as probes and ancillary products, and software updates. However, even after receiving this regulatory clearance from the FDA, we require additional approvals from the FDA in order to begin commercialization efforts capable of generating significant revenues for us.

Our 510(k) application may not be cleared by the FDA in a timely manner or at all. We have submitted for De Novo classification for approval of our ProSense system with regards to breast cancer indication. This was denied on September 16, 2023 and in response, we filed a request for supervisory review under 21 CFR 10.75 on November 15, 2023. On January 24, 2024, we received notification from the FDA that our request was affirmed since the FDA determined that there is sufficient basis to reopen the De Novo file so that we can submit new data and so that the FDA can evaluate it. In the letter, the FDA requested us to submit the full 5-year dataset from our ICE3 trial. On November 7, 2024, the FDA convened a medical device advisory committee panel, or the Advisory Panel, to review the De Novo marketing authorization request for ProSense, the decision about which is expected to be delivered by the FDA after the first quarter of 2025. The Advisory Panel included breast surgeons, interventional radiologists, breast oncologists, and representatives from the patient, consumer, and regulatory communities. The purpose of the Advisory Panel was for the FDA to obtain independent non-binding expert advice on scientific, technical and policy matters related to the potential granting of marketing authorization of ProSense for treating patients with early-stage low risk invasive breast cancer with cryoablation and adjuvant endocrine therapy. The majority of panelists voted that the benefits of ProSense outweigh the risks when used according to the proposed indications for the treatment of patients with early-stage low risk invasive breast cancer with cryoablation and adjuvant endocrine therapy. The Advisory Panel's favorable vote was based on the comprehensive body of data available on ProSense as a treatment for early-stage low risk breast cancer, including results from the ICE3 study compared with data from the current standard of care, lumpectomy, as well as testimonials and input from a broad range of key stakeholders, including women with breast cancer and their family members, patient advocacy groups, doctors, nurses and researchers. (see "Item 4.B *Business Overview*" for additional information).

If cleared, any modification to our ProSense system that has not been previously cleared for treatment of the indication for which approval was granted may require us to submit a new 510(k) premarket notification and obtain clearance, or submit a PMA and obtain FDA approval prior to implementing the change. Specifically, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We may make modifications or add additional features in the future that we believe do not require a new 510(k) clearance or approval of a PMA. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMA applications for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

The FDA can delay, limit or deny clearance or approval of a medical 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 product candidates are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or the interpretation of data from pre-clinical studies or clinical trials;
- serious and unexpected adverse effects experienced by participants in our clinical trials;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- requesting clinical data from our trials at sites located outside of the United States;
- 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 in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

In order to sell our products in member countries of the European Economic Area, or EEA, our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC) and with the Medical Device Regulations 2017/745 of the European Parliament and of the Council, which entered into force on May 26, 2021. Compliance with these requirements is a prerequisite to be able to affix the Conformité Européene, or CE, mark to our products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can issue a European Community, or EC, Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a member state of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE mark and the Notified Body number to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EEA. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products.

Preliminary data that we or others announce or publish from time to time with respect to our products may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we, or our partners, may publish or seek to publish preliminary data from ongoing clinical trials, which are based on a preliminary analysis of then-available data. Positive preliminary data may not be predictive of such trial's subsequent or overall results. Preliminary data are subject to the risk that one or more of the results and related findings and conclusions may materially change following a more comprehensive review of the data or as more data become available. Therefore, positive preliminary results in any ongoing clinical trial may not be predictive of such results in the completed trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. As a result, preliminary data that we report may differ from future results from the same clinical trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to preliminary data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, in scale, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Current and future healthcare and other legislation and regulatory reform measures may have a material adverse effect on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs or medical procedures and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the Affordable Care Act, is a sweeping measure intended to, among other things, expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Several provisions of the law may affect us and increase certain of our costs. Among the provisions of the Affordable Care Act of importance to our potential product candidates, the Affordable Care Act established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; expands eligibility criteria for Medicaid programs; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; created a new Medicare Part D coverage gap discount program; required certain Affordable Care Act marketplace and other private payor plans to include coverage for preventative services, including vaccinations recommended by the ACIP without cost share obligations (i.e., co-payments, deductibles or co-insurance) for plan members; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

In addition, other legislative changes have been adopted since the Affordable Care Act was enacted. These changes include aggregate reductions in Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect until 2031.

In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These and new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and, accordingly, our financial operations.

We anticipate that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the reimbursement our customers may receive for our products. Further, there have been, and there may continue to be, judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, the U.S. Tax Cuts and Jobs Act of 2017, or TCJA, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 26, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. Affordable Care Act Additional legislative and regulatory changes and judicial challenges to the Affordable Care Act, its implementing regulations and guidance and its policies, remain possible. However, it remains unclear how any new legislation, regulation or challenges in court might affect the prices we may obtain for any of our products for which regulatory approval is obtained. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate significant revenue, attain profitability or commercialize our products in scale.

Due to general uncertainty in the current regulatory and healthcare policy environment in the United States, and specifically regarding positions that the Trump administration may take with respect to these issues, we are unable to predict the impact of any legislative, regulatory, third-party payer or policy actions, including potential cost containment and healthcare reform measures.

In addition, the delivery of healthcare in the European Union, including the establishment and operation of health services, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay additional marketing approval of our ProSense system or any initial marketing approval for our ProSense system or any future product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval.

We are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry may be enacted in the future or what effect recently enacted federal legislation or any such additional legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in the price of our Ordinary Shares or limit our ability to raise capital or to enter into collaboration agreements for the further development and potential commercialization of our products.

Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.

Although we have certain regulatory approvals to market our ProSense system, we are still subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, import, export, registration, and listing of devices. In addition, if we receive additional regulatory approvals to market the ProSense system or regulatory approvals to market the MultiSense system or other products we will likewise remain subject to ongoing regulation. For example, we will be required to submit periodic reports to the FDA as a condition of 510(k) clearance, which we have received for our ProSense system and related accessories, for the treatment of kidney and liver tumors. These reports include information about failures and certain adverse events associated with the device after its clearance. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory clearance to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our products;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future clearances or approvals or foreign marketing authorizations of new products, new intended uses, or modifications to existing products;
- withdrawals or suspensions of product clearances or approvals, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations.

In addition, the FDA or state or foreign authorities may change their clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay clearance or approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new clearances or approvals, increase the costs of compliance or restrict our ability to maintain any approvals we are able to obtain. For example, the FDA recently announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA.

Our products must be manufactured in accordance with federal, state and foreign regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of our products must comply with the Quality System Regulation, or QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. As manufacturers of electromagnetic radiation-emitting products, we are also responsible for compliance with the radiological health regulations and certain radiation safety performance standards.

Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA or state or foreign requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us, our suppliers or our employees.

Any of these actions could significantly and negatively affect supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that may lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Advertising and promotion of our products that obtain marketing approval in the United States may be heavily scrutinized by the FDA, the DOJ, HHS, state attorneys general, members of Congress, and the public. In addition, advertising and promotion of any product that obtains approval outside of the United States may be heavily scrutinized by comparable foreign regulatory authorities.

We expect that, if cleared or approved, our products, will be cleared by the requisite regulatory authorities for specific indications. We expect to train our marketing personnel and direct sales force to not promote our devices for uses outside of the FDA-approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our devices off-label, when in the physician's independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our devices off-label. Furthermore, the use of our devices for indications other than those approved by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among healthcare providers and patients.

If the FDA or any state or foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign 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 may become subject to such actions and, if we are not successful in defending against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations. Equivalent laws and potential consequences exist in foreign jurisdictions.

In addition, if our products are cleared or approved, healthcare providers may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. 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.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to immediately report to all relevant regulatory authorities, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us 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 malfunctioned in a way that, if the malfunction were to recur, could 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, the FDA or other regulatory bodies could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

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.

Companies are 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 sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Many federal, state and foreign healthcare laws and regulations apply to medical devices. We may be subject to certain federal and state regulations, including the federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, offering, receiving, or paying any remuneration, directly or indirectly, in cash or in kind, to induce or reward purchasing, ordering or arranging for or recommending the purchase or order of any item or service for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services; the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial civil monetary penalties against an entity that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal healthcare programs to provide items or services reimbursable by a federal healthcare program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment; the federal False Statements Statute, which prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items, or services; the federal civil False Claims Act, or the FCA, which prohibits, among other things, knowingly presenting, or causing to be presented claims for payment of government funds that are false or fraudulent, or knowingly making, using or causing to be made or used a false record or statement material to such a false or fraudulent claim, or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government; and other federal and state false claims laws. The FCA prohibits anyone from knowingly presenting, conspiring to present, making a false statement in order to present, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. This law also prohibits anyone from knowingly underpaying an obligation owed to a federal program. Increasingly, U.S. federal agencies are requiring nonmonetary remedial measures, such as corporate integrity agreements in FCA settlements. The DOJ announced in 2016 its intent to follow the "Yates Memo," taking a far more aggressive approach in pursuing individuals as FCA defendants in addition to corporations.

The majority of states also have statutes similar to the federal Anti-Kickback Statute and false claims laws that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, that apply regardless of whether the payer is a government entity or a private commercial entity. The Federal Open Payments, or Physician Payments Sunshine Act, program requires manufacturers of products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, to track and report annually to the federal government (for disclosure to the public) certain payments and other transfers of value made to physicians and teaching hospitals as well as disclosure of payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations. Our failure to appropriately track and report payments to the government could result in civil fines and penalties, which could adversely affect the results of our operations. In addition, several U.S. states and localities have enacted legislation requiring medical device companies to establish marketing compliance programs, file periodic reports with the state, and/or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Other state laws prohibit certain marketing-related activities including the provision of gifts, meals or other items to certain healthcare providers. Many of these laws and regulations contain ambiguous requirements that government officials have not yet clarified. Given the lack of clarity in the laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

The medical device industry has been under heightened scrutiny as the subject of government investigations and enforcement actions involving manufacturers who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business, including arrangements with physician consultants. If our operations or arrangements are found to be in violation of such governmental regulations, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment of our operations. All of these penalties could adversely affect our ability to operate our business and our financial results.

Changes in laws or regulations relating to data protection, or any actual or perceived failure by us to comply with such laws and regulations or our privacy policies, could materially and adversely affect our business or could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

We expect to receive health information and other highly sensitive or confidential information and data of patients and other third parties (e.g., healthcare providers who refer patients for scans), which we expect to compile and analyze. Collection and use of this data might raise privacy and data protection concerns, which could negatively impact our business. There are numerous federal, state and international laws and regulations regarding privacy, data protection, information security, and the collection, storing, sharing, use, processing, transfer, disclosure, and protection of personal information and other data, and the scope of such laws and regulations may change, be subject to differing interpretations, and may be inconsistent among countries and regions we intend to operate in (e.g., the United States, the European Union and Israel), or conflict with other laws and regulations. The regulatory framework for privacy and data protection worldwide is, and is likely to remain for the foreseeable future, uncertain and complex, and this or other actual or alleged obligations may be interpreted and applied in a manner that we may not anticipate or that is inconsistent from one jurisdiction to another and may conflict with other rules or practices including ours. Further, any significant change to applicable laws, regulations, or industry practices regarding the collection, use, retention, security, or disclosure of data, or their interpretation, or any changes regarding the manner in which the consent of relevant users for the collection, use, retention, or disclosure of such data must be obtained, could increase our costs and require us to modify our services and candidate products, possibly in a material manner, which we may be unable to complete, and may limit our ability to store and process patients' data or develop new services and features.

In particular, we will be subject to U.S. data protection laws and regulations (i.e., laws and regulations that address privacy and data security) at both the federal and state levels. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. Numerous federal and state laws, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, and disclosure of health-related and other personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant civil or criminal penalties), private litigation and/or adverse publicity that could negatively affect our business. For instance, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018, which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states.

In addition, we expect to obtain health information that is subject to privacy and security requirements under the Health Information Technology for Economic and Clinical Health, or HITECH, and its implementing regulations. The Privacy Standards and Security Standards under HIPAA establish a set of standards for the protection of individually identifiable health information by health plans, health care clearinghouses and certain health care providers, referred to as Covered Entities, and the business associates with whom Covered Entities enter into service relationships pursuant to which individually identifiable health information may be exchanged. Notably, whereas HIPAA previously directly regulated only Covered Entities, HITECH makes certain of HIPAA's privacy and security standards also directly applicable to Covered Entities' business associates. As a result, both Covered Entities and business associates are now subject to significant civil and criminal penalties for failure to comply with Privacy Standards and Security Standards. As part of our normal operations, we expect to collect, process and retain personal identifying information regarding patients, including as a business associate of Covered Entities, so we expect to be subject to HIPAA, including changes implemented through HITECH, and we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA. A data breach affecting sensitive personal information, including health information, also could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

HIPAA requires Covered Entities (like many of our potential customers) and business associates, like us, to develop and maintain policies and procedures with respect to protected health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information. HITECH expands the notification requirement for breaches of patient-identifiable health information, restricts certain disclosures and sales of patient-identifiable health information and provides for civil monetary penalties for HIPAA violations. HITECH also increased the civil and criminal penalties that may be imposed against Covered Entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and its implementing regulations and seek attorney's fees and costs associated with pursuing federal civil actions. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA.

Internationally, many jurisdictions have or are considering enacting privacy or data protection laws or regulations relating to the collection, use, storage, transfer, disclosure and/or other processing of personal data, as well as certification requirements for the hosting of health data specifically. Such laws and regulations may include data hosting, data residency or data localization requirements (which generally require that certain types of data collected within a certain country be stored and processed within that country), data export restrictions, international transfer laws (which prohibit or impose conditions upon the transfer of such data from one country to another), or may require companies to implement privacy or data protection and security policies, enable users to access, correct and delete personal data stored or maintained by such companies, inform individuals of security breaches that affect their personal data or obtain individuals' consent to use their personal data. For example, European legislators adopted the EU's General Data Protection Regulation (2016/679), or GDPR, which became effective on May 25, 2018, and are now in the process of finalizing the ePrivacy Regulation to replace the European ePrivacy Directive (Directive 2002/58/EC as amended by Directive 2009/136/EC). The GDPR, supplemented by national laws and further implemented through binding guidance from the European Data Protection Board, imposes more stringent EU data protection requirements and provides for significant penalties for noncompliance. Further, the United Kingdom's initiating a process to leave the EU has created uncertainty with regard to the regulation of data protection in the United Kingdom. In particular, the United Kingdom has brought the GDPR into domestic law with the Data Protection Act 2018 which will remain in force, even if and when the United Kingdom leaves the EU.

Virtually every jurisdiction in which we expect to operate has established its own data security and privacy legal framework with which we must, and our target customers will need to, comply, including the rules and regulation mentioned above. We may also need to comply with varying and possibly conflicting privacy laws and regulations in other jurisdictions. As a result, we could face regulatory actions, including significant fines or penalties, adverse publicity and possible loss of business.

While we are preparing to implement various measures intended to enable us to comply with applicable privacy or data protection laws, regulations and contractual obligations, these measures may not always be effective and do not guarantee compliance. Any failure or perceived failure by us to comply with our contractual or legal obligations or regulatory requirements relating to privacy, data protection, or information security may result in governmental investigations or enforcement actions, litigation, claims, or public statements against us by consumer advocacy groups or others and could result in significant liability, cause our customers, partners or patients to lose trust in us, and otherwise materially and adversely affect our reputation and business. Furthermore, the costs of compliance with, and other burdens imposed by, the laws, regulations, and policies that are applicable to the businesses of our customers or partners may limit the adoption and use of, and reduce the overall demand for, our products and services. Additionally, if third parties we work with violate applicable laws, regulations, or agreements, such violations may put the data we have received at risk, could result in governmental investigations or enforcement actions, fines, litigation, claims, or public statements against us by consumer advocacy groups or others and could result in significant liability, cause our customers, partners or patients to lose trust in us, and otherwise materially and adversely affect our reputation and business. Further, public scrutiny of, or complaints about, technology companies or their data handling or data protection practices, even if unrelated to our business, industry or operations, may lead to increased scrutiny of technology companies, including us, and may cause government agencies to enact additional regulatory requirements, or to modify their enforcement or investigation activities, which may increase our costs and risks.

If we do not obtain and maintain international regulatory registrations, clearances or approvals for our products, we will be unable to market and sell our products.

Sales of our products are subject to foreign regulatory requirements that vary widely from country to country. Approval procedures vary among countries and can involve additional testing. The time required to obtain approvals may differ substantially. 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 or approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations, clearances or approvals, can be expensive and time-consuming, and we may not receive regulatory clearances 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 or approvals, if required by other countries, may be longer than that required for FDA clearance or approval, and requirements for such registrations, clearances or approvals may significantly differ from FDA requirements. If we modify our products, we may need to apply for additional regulatory clearances or approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we have received. If we are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

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

Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Over the last several years, the FDA has proposed reforms to its 510(k)-clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k)-clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) clearance pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k)-clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. In May 2019, the FDA solicited public feedback on these proposals. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

In September 2019, the FDA finalized guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA intends to develop and maintain a list device types appropriate for the "safety and performance based" pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

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 impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance or approval of our future products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval or clearance that we may have obtained and we may not achieve or sustain profitability.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable, i.e., without the need for adoption of EEA member state laws implementing them, in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. Among other things, the Medical Devices Regulation:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for follow-up regarding the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthened rules for the assessment of certain high-risk devices, which may have to undergo an additional check by experts before they are placed on the market.

These modifications may have an effect on the way we conduct our business in the EEA.

Disruptions at the FDA and other government agencies could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being cleared or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and clear or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new medical devices or modifications to cleared or approved medical devices to be reviewed and/or approved by necessary government agencies, which would adversely affect our business.

If a prolonged government shutdown occurs or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Environmental, social and corporate governance (ESG) issues, including those related to climate change and sustainability, may have an adverse effect on our business, financial condition and results of operations and damage our reputation.

There is an increasing focus from certain investors, customers, consumers, employees and other stakeholders concerning ESG matters. Additionally, public interest and legislative pressure related to public companies' ESG practices continue to grow. If our ESG practices fail to meet regulatory requirements or investor, customer, consumer, employee or other stakeholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, support for local communities, Board of Director and employee diversity, human capital management, employee health and safety practices, product quality, supply chain management, corporate governance and transparency, our reputation, brand and employee retention may be negatively impacted, and our customers and suppliers may be unwilling to continue to do business with us.

Customers, consumers, investors and other stakeholders are increasingly focusing on environmental issues, including climate change, energy and water use, plastic waste and other sustainability concerns. Concern over climate change may result in new or increased legal and regulatory requirements to reduce or mitigate impacts to the environment. Changing customer and consumer preferences or increased regulatory requirements may result in increased demands or requirements regarding plastics and packaging materials, including single-use and non-recyclable plastic products and packaging, other components of our products and their environmental impact on sustainability, or increased customer and consumer concerns or perceptions (whether accurate or inaccurate) regarding the effects of substances present in certain of our products. Complying with these demands or requirements could cause us to incur additional manufacturing, operating or product development costs.

If we do not adapt to or comply with new regulations, or fail to meet evolving investor, industry or stakeholder expectations and concerns regarding ESG issues, investors may reconsider their capital investment in our Company, and customers and consumers may choose to stop purchasing our products, which could have a material adverse effect on our reputation, business or financial condition.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain effective patent rights for our products and services, we may not be able to compete effectively in our markets. If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us.

Our success and future revenues growth will depend, in part, on our ability to protect our patent rights. In addition to the protection afforded by any patents that may be granted, historically, we have relied on trade secret protection and confidentiality agreements with our employees, consultants, and contractors to protect proprietary know-how that is not patentable or that we elect not to patent, processes that are not easily known, knowable or easily ascertainable, and for which patent infringement is difficult to monitor and enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, agreements may be breached, trade secrets may be difficult to protect, and we may not receive adequate remedies for any breach. In addition, our trade secrets and intellectual property may otherwise become known or be independently discovered by competitors or other unauthorized third parties.

There is no guarantee that the patent registration applications that we submitted with regards to our technologies will result in patent registration. In the event of failure to complete patent registration, our developments will not be proprietary, which might allow other entities to manufacture our products or design our services and compete with them.

Further, there is no assurance that all potentially relevant prior art relating to our patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our products or services, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patent applications and any future patents may not adequately protect our intellectual property, products or services and provide exclusivity for our new products or services or prevent others from designing around our claims. Furthermore, there is no guarantee that third parties will not infringe or misappropriate our patents or similar proprietary rights. In addition, there can be no assurance that we will not have to pursue litigation against other parties to assert its rights.

Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If we cannot obtain and maintain effective patent rights for our products and services, we may not be able to compete effectively, and our business and results of operations would be harmed.

We cannot provide any assurances that our trade secrets and other confidential proprietary information will not be disclosed in violation of our confidentiality agreements or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Also, misappropriation or unauthorized and unavoidable disclosure of our trade secrets and intellectual property could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets and intellectual property are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secret.

Intellectual property rights of third parties could adversely affect our ability to commercialize our products and services, and we might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

It is inherently difficult to conclusively assess our freedom to operate without infringing on third-party rights. Our competitive position may be adversely affected if existing patents or patents resulting from patent applications filed by third parties or other third-party intellectual property rights are held to cover our products or services or elements thereof, or our manufacturing or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize products or services or our product candidates (and any relevant services) unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may also be pending patent applications that if they result in issued patents, could be alleged to be infringed by our new products or services. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, be forced to abandon our new products or services or seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, U.S. patent applications filed before November 29, 2000, and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our new products or services could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our services, our new products or the use of our new products. Third-party intellectual property right holders may also actively bring infringement claims against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in pursuing the development of and/or marketing our new products or services. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing our new products or services that are held to be infringing. We might, also be forced to redesign our new products, if possible, so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing new products and services. As our industries expand and more patents are issued, the risk increases that our products and services may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, designs or methods of manufacture related to the use or manufacture of our products or services. There may be currently pending patent applications or continued patent applications that may later result in issued patents that our products or services may infringe. In addition, third parties may obtain patents or services in the future and claim that use of our technologies infringes upon these patents.

If any third-party patents were held by a court of competent jurisdiction to cover aspects of our products, processes, designs, or methods of use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products or services. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or services, or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of any patents that may issue from our patent applications or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that we were the first to file the invention claimed in our owned and licensed patents or pending applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming all other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention without undue delay in filing, is entitled to the patent, while generally outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents, all of which could have a material adverse effect on our business and financial condition.

We may be involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our intellectual property. If we were to initiate legal proceedings against a third-party to enforce a patent covering one of our products or services, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability 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 withheld relevant information from the United States Patent and Trademark Office, or the USPTO, or made a misleading statement, during prosecution. Under the Leahy-Smith Act, the validity of U.S. patents may also be challenged in post-grant and inter-parties review proceedings before the USPTO. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Derivation proceedings initiated by third parties or brought by us may be necessary to determine the priority of inventions and/or their scope with respect to our patent or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or derivative proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our new products or services to market.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our Ordinary Shares.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in, or right to compensation, with respect to our current patent and patent applications, future patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arising from conflicting obligations of consultants or others who are involved in developing our products or services. Litigation may be necessary to defend against these and other claims challenging inventorship or claiming the right to compensation. 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.

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

Filing, prosecuting, and defending patents on products and services, as well as monitoring their infringement in all countries throughout the world, would be prohibitively expensive, and our intellectual property rights in some countries can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States.

Competitors may use our technologies to develop their own products or services in jurisdictions where we have not obtained patent protection to and may export infringing products or services to territories where we have patent protection, but where patents are not enforced as strictly as they are in the United States. These products or services may compete with our products or services. Future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Risks Related to Ownership of our Securities

The market price of our Ordinary Shares may be highly volatile and fluctuate substantially, which could result in substantial loses for purchasers of our Ordinary Shares.

The trading price of our Ordinary Shares may be volatile. The market price for the Ordinary Shares may be influenced by many factors, including:

- inability to obtain the approvals necessary to commence further clinical trials;
- unsatisfactory results of clinical trials;
- announcements of regulatory approval or the failure to obtain it, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory authorities with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to the cryoablation of tumors or any other indication that we may seek to develop;
- any adverse changes to our relationship with manufacturers or suppliers;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the biotechnology industry in general;
- our commencement of, or involvement in, litigation;
- any major changes to our board of directors or management;
- our ability to recruit and retain qualified regulatory, research and development personnel;
- legislation or changes to healthcare payment systems;
- the depth of the trading market in our Ordinary Shares;
- termination or expiration of the lock-up agreements or other restrictions limiting our ability or that of any of our existing shareholders to sell our Ordinary Shares (or any other securities that we may issue, if any);

- general economic weakness, including inflation, or industry and market conditions;
- business interruptions resulting from an epidemic or pandemic, geopolitical actions, including war and terrorism, or natural disasters;
- the granting or exercise of employee stock options or other equity awards; and
- changes in investors' and securities analysts' perception of the business risks and conditions of our business.

In addition, the stock market in general, and Nasdaq Capital Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of small companies. Broad market and industry factors may negatively affect the market price of our Ordinary Shares, regardless of our actual operating performance. Further, a systemic decline in the financial markets and related factors beyond our control may cause our share price to decline rapidly and unexpectedly.

Future sales or other issuances of our Ordinary Shares could depress the market price for our Ordinary Shares.

Substantial sales of our Ordinary Shares may cause the market price of our Ordinary Shares to decline. Sales by our security holders of substantial amounts of our Ordinary Shares, or the perception that these sales may occur in the future, could cause a reduction in the market price of our Ordinary Shares or could make it more difficult for us to raise funds through the sale of equity in the future.

Future issuances of Ordinary Shares or any securities that are exercisable for or convertible into Ordinary Shares could further depress the market for our Ordinary Shares, may have an adverse effect on the market price of our Ordinary Shares and will have a dilutive effect on our existing shareholders and holders of Ordinary Shares. We expect to continue to incur research and development and general and administrative expenses and, to satisfy our funding requirements, we will need to sell additional equity securities, which may include sales of significant amounts of Ordinary Shares, which may be subject to registration rights and warrants with anti-dilutive protective provisions. The sale or the proposed sale of substantial amounts of our Ordinary Shares or other equity securities in the public markets or in private transactions may adversely affect the market price of our Ordinary Shares and our share price may decline substantially.

Our principal shareholders, officers and directors currently beneficially own approximately 47.6% of our Ordinary Shares. They will therefore be able to exert significant control over matters submitted to our shareholders for approval.

As of March 24, 2025, our principal shareholders, officers and directors beneficially own approximately 47.6% of our Ordinary Shares. This significant concentration of share ownership may adversely affect the trading price for our Ordinary Shares because investors often perceive disadvantages in owning shares in companies with controlling shareholders. As a result, these shareholders, if they acted together, could significantly influence or even unilaterally approve matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of these shareholders may not always coincide with our interests or the interests of other shareholders.

We do not know whether a market for our Ordinary Shares will be sustained or what the trading price of the Ordinary Shares will be and as a result it may be difficult for you to sell your Ordinary Shares.

Although our Ordinary Shares are listed on Nasdaq, an active trading market for the Ordinary Shares may not be sustained. It may be difficult for you to sell your Ordinary Shares without depressing the market price for the Ordinary Shares or at all. As a result of these and other factors, you may not be able to sell your Ordinary Shares at or above the price at which you purchased the shares or at all. Further, an inactive market may also impair our ability to raise capital by selling Ordinary Shares and may impair our ability to enter into strategic partnerships or acquire companies, products, or services by using our equity securities as consideration.

We have never paid cash dividends on our share capital, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never declared or paid cash dividends, and we do not anticipate paying cash dividends in the foreseeable future. Therefore, you should not rely on an investment in Ordinary Shares as a source for any future dividend income. Our board of directors has complete discretion as to whether to distribute dividends. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. In addition, the Israeli Companies Law, 5759-1999, or the Companies Law, imposes restrictions on our ability to declare and pay dividends.

Raising additional capital may cause dilution to our existing shareholders and may adversely affect the rights of existing shareholders.

We may need to raise additional capital through a combination of private and public equity offerings, debt financings and collaborations, and strategic and licensing arrangements. To the extent that we raise additional capital through the issuance of equity or otherwise including through convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Future sales of our Ordinary Shares or of securities convertible into our Ordinary Shares, or the perception that such sales may occur, could cause immediate dilution and adversely affect the market price of our Ordinary Shares.

We may be a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes in the current taxable year or may become one in any subsequent taxable year. There generally would be negative tax consequences for U.S. taxpayers that are holders of the Ordinary Shares if we are or were to become a PFIC.

Based on the projected composition of our income and valuation of our assets, we do not expect to be a PFIC for 2024, and we do not expect to become a PFIC in the future, although there can be no assurance in this regard. The determination of whether we are a PFIC is made on an annual basis and will depend on the composition of our income and assets from time to time. We will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (1) at least 75% of our gross income is "passive income" or (2) on average at least 50% of our assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account. The tests for determining PFIC status are applied annually, and it is difficult to make accurate projections of future income and assets which are relevant to this determination. In addition, our PFIC status may depend in part on the market value of the Ordinary Shares. Accordingly, there can be no assurance that we currently are not or will not become a PFIC in the future. If we are a PFIC in any taxable year during which a U.S. taxpayer holds the Ordinary Shares, such U.S. taxpayer would be subject to certain adverse U.S. federal income tax rules. In particular, if the U.S. taxpayer did not make an election to treat us as a "qualified electing fund", or QEF, or make a "mark-to-market" election, then "excess distributions" to the U.S. taxpayer, and any gain realized on the sale or other disposition of the Ordinary Shares by the U.S. taxpayer: (1) would be allocated ratably over the U.S. taxpayer's holding period for the Ordinary Shares; (2) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (3) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, if the U.S. Internal Revenues Service, or the IRS, determines that we are a PFIC for a year with respect to which we have determined that we were not a PFIC, it may be too late for a U.S. taxpayer to make a timely QEF or mark-to-market election. U.S. taxpayers that have held the Ordinary Shares during a period when we were a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC in subsequent years, subject to exceptions for U.S. taxpayer who made a timely QEF or mark-to-market election. A U.S. taxpayer can make a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. We do not intend to notify U.S. taxpayers that hold the Ordinary Shares if we believe we will be treated as a PFIC for any taxable year in order to enable U.S. taxpayers to consider whether to make a QEF election. In addition, we do not intend to furnish such U.S. taxpayers annually with information needed in order to complete IRS Form 8621 and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC. U.S. taxpayers that hold the Ordinary Shares are strongly urged to consult their tax advisors about the PFIC rules, including tax return filing requirements and the eligibility, manner, and consequences to them of making a QEF or mark-to-market election with respect to the Ordinary Shares in the event that we are a PFIC (see "Item 10.E. *Taxation—U.S. Federal Income Tax Considerations—Passive Foreign Investment Companies*" for additional information).

The JOBS Act allows us to postpone the date by which we must comply with some of the laws and regulations intended to protect investors and to reduce the amount of information we provide in our reports filed with the SEC, which could undermine investor confidence in our Company and adversely affect the market price of our Ordinary Shares.

For so long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of certain exemptions from various requirements that are applicable to public companies that are not "emerging growth companies" including:

- the provisions of the Sarbanes-Oxley Act requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;

- Section 107 of the JOBS Act, which provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. This means that an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are electing to delay such adoption of new or revised accounting standards. As a result of this adoption, our financial statements may not be comparable to companies that comply with the public company effective date;

- any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements; and

- our ability to furnish two rather than three years of income statements and statements of cash flows in various required filings.

We intend to take advantage of these exemptions until we are no longer an "emerging growth company." We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the date of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a "large accelerated filer", as defined in the rule under the Exchange Act, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We cannot predict if investors will find our Ordinary Shares less attractive because we may rely on these exemptions. If some investors find our Ordinary Shares less attractive as a result, there may be a less active trading market for the Ordinary Shares, and the trading price may be more volatile and may decline.

As a "foreign private issuer" we are subject to less stringent disclosure requirements than domestic registrants and are permitted, and may in the future elect to follow certain home country corporate governance practices instead of otherwise applicable SEC and Nasdaq requirements, which may result in less protection than is accorded to investors under rules applicable to domestic U.S. registrants.

As a foreign private issuer and emerging growth company, we may be subject to different disclosure and other requirements than domestic U.S. registrants and non-emerging growth companies. For example, as a foreign private issuer, in the United States, we are not subject to the same disclosure requirements as a domestic U.S. registrant under the Exchange Act, including the requirements to prepare and issue quarterly reports on Form 10-Q or to file current reports on Form 8-K upon the occurrence of specified significant events, the proxy rules applicable to domestic U.S. registrants under Section 14 of the Exchange Act or the insider reporting and short-swing profit rules applicable to domestic U.S. registrants under Section 16 of the Exchange Act. In addition, we intend to rely on exemptions from certain U.S. rules which will permit us to follow Israeli legal requirements rather than certain of the requirements that are applicable to U.S. domestic registrants.

We will follow Israeli laws and regulations that are applicable to Israeli companies. However, Israeli laws and regulations applicable to Israeli companies do not contain any provisions comparable to the U.S. proxy rules, the U.S. rules relating to the filing of reports on Form 10-Q or Form 8-K or the U.S. rules relating to liability for insiders who profit from trades made in a short period of time, as referred to above.

Furthermore, foreign private issuers are required to file their annual report on Form 20-F within 120 days after the end of each fiscal year, while U.S. domestic registrants that are non-accelerated filers are required to file their annual report on Form 10-K within 90 days after the end of each fiscal year. Foreign private issuers are also exempt from Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information, although we will be subject to Israeli laws and regulations having substantially the same effect as Regulation Fair Disclosure. As a result of the above, even though we are required to file reports on Form 6-K disclosing the limited information which we have made or are required to make public pursuant to Israeli law, or are required to distribute to shareholders generally, and that is material to us, you may not receive information of the same type or amount that is required to be disclosed to shareholders of a U.S. registrant.

These exemptions and leniencies will reduce the frequency and scope of information and protections to which you are entitled as an investor.

The determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, the next determination will be made with respect to us on June 30, 2025. In the future, we would lose our foreign private issuer status if a majority of our shareholders, directors or management are U.S. citizens or residents and we fail to meet additional requirements necessary to avoid loss of foreign private issuer status. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic registrant may be significantly higher.

We may be subject to securities litigation, which is expensive and could divert management attention.

In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could seriously hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

We incur significant increased costs as a result of the listing of our securities for trading on Nasdaq. As a public company in the United States, our management is required to devote substantial time to new compliance initiatives as well as compliance with ongoing U.S. requirements.

Since the listing of our Ordinary Shares on Nasdaq, we became a publicly traded company in the United States. As a public company in the United States, we incur significant accounting, legal and other expenses that we did not incur before becoming a public company in the United States. We also incur costs associated with corporate governance requirements of the SEC, as well as requirements under Section 404 and other provisions of the Sarbanes-Oxley Act. We expect these rules and regulations to increase our legal and financial compliance costs, introduce new costs such as investor relations, stock exchange listing fees and shareholder reporting, and to make some activities more time consuming and costly. The implementation and testing of such processes and systems may require us to hire outside consultants and incur other significant costs. Any future changes in the laws and regulations affecting public companies in the United States, including Section 404 and other provisions of the Sarbanes-Oxley Act, and the rules and regulations adopted by the SEC, for so long as they apply to us, will result in increased costs to us as we respond to such changes. These laws, rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including directors and officers liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers.

Sales of a significant number of shares of our Ordinary Shares in the public markets or significant short sales of our Ordinary Shares, or the perception that such sales could occur, could depress the market price of our Ordinary Shares and impair our ability to raise capital.

Sales of a substantial number of shares of our Ordinary Shares or other equity-related securities in the public markets, could depress the market price of our Ordinary Shares. If there are significant short sales of our Ordinary Shares, the price decline that could result from this activity may cause the share price to decline more so, which, in turn, may cause long holders of the Ordinary Shares to sell their shares, thereby contributing to sales of Ordinary Shares in the market. Such sales also may impair our ability to raise capital through the sale of additional equity securities in the future at a time and price that our management deems acceptable, if at all.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or the Ordinary Shares, our share price and trading volume could decline.

The trading market for the Ordinary Shares will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts and we cannot provide any assurance that analysts will cover us or provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding the Ordinary Shares, or provide more favorable relative recommendations about our competitors, the price of our Ordinary Shares would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price of our Ordinary Shares or trading volume to decline.

If we are unable to comply with the Nasdaq continued listing requirements, our Ordinary Shares could be delisted from Nasdaq, which may have a material adverse effect on our liquidity, the ability of shareholders to sell their Ordinary Shares and our ability to obtain additional financing.

Our listing on Nasdaq is conditioned on our continued compliance with Nasdaq's continued listing requirements, including maintaining a minimum bid price of $1.00 per Ordinary Share, pursuant to Nasdaq Listing Rule 5550(a)(2), or the Minimum Bid Requirement.

On July 19, 2024, we were notified by the staff of Nasdaq that we were not in compliance with the Minimum Bid Requirement as our Ordinary Shares failed to maintain a minimum bid price of $1.00 over the previous 30 consecutive business days. On January 3, 2025, the staff of Nasdaq determined that since the Company's minimum bid price had been at $1.00 or greater for ten consecutive business days from December 13, 2024 through January 2, 2025, we regained compliance with the Minimum Bid Requirement.

Even though we have regained compliance with the Minimum Bid Requirement, there can be no assurance that our share price will not again fail to satisfy the Minimum Bid Requirement or other Nasdaq continued listing requirements. If we are unable to maintain compliance with the Nasdaq continued listing requirements, Nasdaq could initiate delisting proceedings or delist our Ordinary Shares from trading on its exchange which may have a material adverse effect on us and our shareholders, including reduced liquidity with respect to our Ordinary Shares decrease our ability to issue additional securities or obtain additional financing in the future.

Risks Related to Israeli Law and Our Operations in Israel

Our principal executive offices, most of our research and development activities and other significant operations are located in Israel, and, therefore, our results may be adversely affected by political, economic and military instability in Israel, including Israel's multi-front war with terrorist groups in neighboring countries, such as Hezbollah in Lebanon and Hamas in the Gaza Strip, and state actors such as Iran, and Israel's response thereto.

Our executive offices, corporate headquarters and principal research and development facilities are located in Israel. In addition, most of our officers and directors are residents of Israel. Accordingly, political, economic and military and security conditions in Israel and the surrounding region may directly affect our business. Any conflicts, political instability, terrorism, cyberattacks or any other hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could adversely affect our operations. Ongoing and revived hostilities in the Middle East or other Israeli political or economic factors, could harm our operations.

In October 2023, Hamas terrorists infiltrated Israel's border with the Gaza Strip and conducted a series of attacks on civilian and military targets. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign commenced in the Gaza Strip. As of March 24, 2025, the ceasefire with Hamas that had been in place since January 2025 has ended, and hostilities have resumed. The continuation of the conflict has led to heightened security concerns, potential disruptions to business operations, and economic instability. There remains significant uncertainty regarding the duration and escalation of the conflict, and further military actions, restrictions, or government-imposed measures could adversely affect our operations and financial condition. Other regional hostilities, since October 7, 2023, have concurrently become more pronounced. This includes and has included a northern front war between Israel and Hezbollah, hostilities between Israel and Iran, which have included Iranian strikes against Israel in April 2024 and October 2024, and subsequent retaliation by Israel to both instances, and a continued conflict between Israel and the Houthi Movement in Yemen. Such potential disruption to our operations may include certain delays and diversions of the import of certain components for manufacturing and production as a result of reduced air travel and the attacks on container ships on the Red Sea route by the Iranian-backed Houthi Movement.

The intensity and duration of the multi-front conflict are difficult to predict, as are such conflict's economic implications on the Company's business and operations and on Israel's economy in general. The potential deterioration of Israel's economy, as a direct and indirect result of these events, may have a material adverse effect on the Company and its ability to effectively conduct its operations.

In connection with the current multi-front conflict, Israeli military reservists have been called up to perform military service. Nine of our employees have been called up as of March 24, 2025. Almost all of those employees have since returned from reserve duty as of March 24, 2025, but there can be no guarantee that they will not be called up again. Additional employees may be called up, for service, and such persons may be absent for an extended period of time. As a result, our operations may be disrupted by such absences, which in turn may materially and adversely affect our business, prospects, financial condition and results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business. A campaign of boycotts, divestment and sanctions has been undertaken against Israel, which could also adversely impact our business.

Prior to October 2023, the Israeli government pursued extensive changes to Israel's judicial system. In response to the foregoing developments, individuals, organizations and institutions, both within and outside of Israel, have voiced concerns that the proposed changes may negatively impact the business environment in Israel including due to reluctance of foreign investors to invest or transact business in Israel as well as to increased currency fluctuations, downgrades in credit rating, increased interest rates, increased volatility in securities markets, and other changes in macroeconomic conditions. To the extent that any of these negative developments do occur, they may have an adverse effect on our business, our results of operations and our ability to raise additional funds, if deemed necessary by our management and board of directors.

We expect to be exposed to fluctuations in currency exchange rates, which could adversely affect our results of operations.

We incur expenses in NIS, U.S. dollars, Euros and Chinese Yuan, or CNY, but our financial statements are denominated in U.S. dollars. Accordingly, we face exposure to adverse movements in currency exchange rates. Our revenue in the EU is denominated in Euros. Accordingly, we face exposure to adverse movements in the currency exchange rate of the U.S. dollars against the Euro, which may have a negative effect on our revenue. If the U.S. dollar strengthens against the Euro, the translation of these foreign currency denominated transactions will result in decreased revenues in U.S. dollars. Our cost of operations in Israel and in China are influenced by any movements in the currency exchange rate of the NIS and CNY. Such movements in the currency exchange rate may have a negative effect on our financial results. If the U.S. dollar weakens against the NIS and CNY, the translation of the NIS and CNY currency denominated transactions to U.S. dollar will result in increased operating expenses. Similarly, if the U.S. dollar strengthens against NIS and CNY, the translation of these NIS and CNY denominated transactions to U.S. dollars will result in decreased expenses. As exchange rates vary, sales and other operating results, when translated, may differ materially from our or the capital market's expectations.

The termination or reduction of tax and other incentives that the Israeli government provides to Israeli companies may increase our costs and taxes.

The Israeli government currently provides tax and capital investment incentives to Israeli companies, as well as grant and loan programs relating to research and development and marketing and export activities. In recent years, the Israeli government has reduced the benefits available under these programs and the Israeli governmental authorities may in the future further reduce or eliminate the benefits of these programs. We may take advantage of these benefits and programs in the future; however, there can be no assurance that such benefits and programs will be available to us. If we qualify for such benefits and programs and fail to meet the conditions thereof, the benefits could be canceled, and we could be required to refund any benefits we might already have enjoyed and become subject to penalties. Additionally, if we qualify for such benefits and programs and they are subsequently terminated or reduced, it could have an adverse effect on our financial condition and results of operations.

We may be required to pay monetary remuneration to our Israeli employees for their inventions, even if the rights to such inventions have been duly assigned to us.

We enter into agreements with our Israeli employees pursuant to which such individuals agree that any inventions created in the scope of their employment are either owned exclusively by us or are assigned to us, depending on the jurisdiction, without the employee retaining any rights. A portion of our intellectual property has been developed by our Israeli employees during their employment for us. Under the Israeli Patent Law, 5727-1967, or the Patent Law, inventions conceived by an employee during the course of his or her employment and within the scope of said employment are considered "service inventions. Service inventions belong to the employer by default, absent a specific agreement between the employee and employer otherwise. The Patent Law also provides that if there is no agreement regarding the remuneration for the service inventions, even if the ownership rights were assigned to the employer, the Israeli Compensation and Royalties Committee, or the Committee, a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for these inventions. The Committee has not yet determined the method for calculating this Committee-enforced remuneration. While it has previously been held that an employee may waive his or her rights to remuneration in writing, orally or by conduct, litigation is pending in the Israeli labor court is questioning whether such waiver under an employment agreement is enforceable. Although our Israeli employees have agreed that we exclusively own any rights related to their inventions, we may face claims demanding remuneration in consideration for employees' service inventions. As a result, we could be required to pay additional remuneration or royalties to our current and/or former employees, or be forced to litigate such claims, which could negatively affect our business.

We received Israeli government grants for certain of our research and development activities, the terms of which may require us to pay royalties and to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. If we fail to satisfy these conditions, we may be required to pay penalties and refund grants previously received.

Our research and development efforts have been financed in part through royalty-bearing grants in an aggregate amount of approximately $2.7 million (including accumulated interest) that we received from the IIA as of December 31, 2024. With respect to the royalty-bearing grants we are committed to pay royalties at a rate of 3% to 3.5% on sales proceeds from our products that were developed under IIA programs up to the total amount of grants received and bearing interest rate at the annual Secured Overnight Financing Rate, or SOFR, applicable to U.S. dollar deposits. With respect to IIA grants approved by the IIA prior to January 1, 2024 but which are outstanding thereafter, the annual interest rate is based on the 12-month SOFR, or at an alternative rate published by the Bank of Israel plus 0.71513%. For grants approved on or following January 1, 2024, the annual rate shall be the higher of (i) the 12 month SOFR plus 1%, or (ii) a fixed annual interest rate of 4%.

We are further required to comply with the requirements of the Israeli Encouragement of Industrial Research, Development and Technological Innovation Law, 5744-1984, as amended, and related regulations, or the Research Law, with respect to those past grants. When a company develops know-how, technology or products using IIA grants, the terms of these grants and the Research Law restrict the transfer or license of such know-how, and the transfer of manufacturing or manufacturing rights of such products, technologies or know-how outside of Israel, without the prior approval of the IIA. Therefore, the discretionary approval of an IIA committee would be required for any transfer or license to third parties inside or outside of Israel of know how or for the transfer outside of Israel of manufacturing or manufacturing rights related to those aspects of such technologies. We may not receive those approvals. Furthermore, the IIA may impose certain conditions on any arrangement under which it permits us to transfer technology or development.

The transfer or license of IIA-supported technology or know-how outside of Israel and the transfer of manufacturing of IIA-supported products, technology or know-how outside of Israel may involve the payment of significant amounts, depending upon the value of the transferred or licensed technology or know-how, our research and development expenses, the amount of IIA support, the time of completion of the IIA-supported research project and other factors. These restrictions and requirements for payment may impair our ability to sell, license or otherwise transfer our technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any product or technology outside of Israel. Furthermore, the consideration available to our shareholders in a transaction involving the transfer outside of Israel of technology or know-how developed with IIA funding (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to the IIA.

We may not be able to enforce covenants not-to-compete under current Israeli law that might result in added competition for our products.

We have non-competition agreements with all of our employees, all of which are governed by Israeli law. These agreements prohibit our employees from competing with or working for our competitors, generally during their employment and for up to 12 months after termination of their employment. However, Israeli courts are reluctant to enforce non-compete undertakings of former employees and tend, if at all, to enforce those provisions for relatively brief periods of time in restricted geographical areas, and only when the employee has obtained unique value to the employer specific to that employer's business and not just regarding the professional development of the employee. If we are not able to enforce non-compete covenants, we may be faced with added competition.

Provisions of Israeli law and our articles of association may delay, prevent or otherwise impede a merger with, or an acquisition of, us, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to such types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date on which a merger proposal is filed by each merging company with the Israel Registrar of Companies and at least 30 days have passed from the date on which the shareholders of both merging companies have approved the merger. In addition, a majority of each class of securities of the target company must approve a merger. Moreover, a tender offer for all of a company's issued and outstanding shares can only be completed if the acquirer receives positive responses from the holders of at least 95% of the issued share capital. Completion of the tender offer also requires approval of a majority of the offerees that do not have a personal interest in the tender offer, unless, following consummation of the tender offer, the acquirer would hold at least 98% of the Company's outstanding shares. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, claim that the consideration for the acquisition of the shares does not reflect their fair market value, and petition an Israeli court to alter the consideration for the acquisition accordingly, unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek such appraisal rights, and the acquirer or the company published all required information with respect to the tender offer prior to the tender offer's response date.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of a number of conditions, including, in some cases, a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are subject to certain restrictions. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no disposition of the shares has occurred. These provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders.

Your rights and responsibilities as a shareholder will be governed in key respects by Israeli laws, which differs in some material respects from the rights and responsibilities of shareholders of U.S. companies.

The rights and responsibilities of the holders of our Ordinary Shares are governed by our articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders in U.S. companies. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders, and to refrain from abusing its power in such company, including, among other things, in voting at a general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and related party transactions requiring shareholder approval, as well as a general duty to refrain from discriminating against other shareholders. In addition, a shareholder who is aware that it possesses the power to determine the outcome of a vote at a meeting of the shareholders or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company. There is limited case law available to assist us in understanding the nature of these duties or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our Ordinary Shares that are not typically imposed on shareholders of U.S. companies.

Risks Related to Enforceability of Civil Liabilities

Investors may have difficulty enforcing judgments against us, our directors and management.

We were incorporated in Israel. Substantially all of our executive officers and directors reside outside of the United States, and all of our assets and most of the assets of these persons are located outside of the United States. Therefore, a judgment obtained against us, or any of these persons, including a judgment based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It also may be difficult for you to effect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel. Additionally, it may be difficult for an investor, or any other person or entity, to initiate an action with respect to U.S. securities laws in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. Additionally, Israeli courts might not enforce judgments rendered outside Israel, which may make it difficult to collect on judgments rendered against us or our non-U.S. officers and directors. Moreover, an Israeli court will not enforce a non-Israeli judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases), if its enforcement is likely to prejudice the sovereignty or security of the State of Israel if it was obtained by fraud or in the absence of due process, if it is at variance with another valid judgment that was given in the same matter between the same parties, or if a suit in the same matter between the same parties was pending before a court or tribunal in Israel at the time the foreign action was brought. As a result of the difficulty associated with enforcing a judgment against us in Israel, you may not be able to collect any damages awarded by either a U.S. or foreign court.

One member of our board of directors, Mr. Yang Huang, is a citizen of and is located in China. The recognition and enforcement of foreign judgments are provided for under Chinese Civil Procedures Law. Chinese courts may recognize and enforce foreign judgments in accordance with the requirements of Chinese Civil Procedures Law based either on treaties between China and the country where the judgment is made or on principles of reciprocity between jurisdictions. China does not have any treaties or other forms of written arrangement with the United States that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to Chinese Civil Procedures Law, Chinese courts will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of Chinese laws or national sovereignty, security, or public interest. As a result, it is uncertain whether and on what basis a Chinese court would enforce a judgment rendered by a court in the United States on Mr. Huang and attempts to enforce such a judgment in China could be costly, time consuming and ultimately unsuccessful.

In addition, Mr. Vincent Chun Hung Chan, a member of our board of directors, is a citizen of both Great Britain and Hong Kong. Mr. Li Haixiang, a member of our board of directors, is a citizen of Hong Kong. Mr. Chan and Mr. Haixiang are located in Hong Kong. There is uncertainty as to whether the courts of Hong Kong would: (i) recognize or enforce judgments of United States courts obtained against us or our directors or officers predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States; or (ii) entertain original actions brought in Hong Kong against us or our directors or officers predicated upon the securities laws of the United States or any state in the United States. A judgment of a court in the United States predicated upon U.S. federal or state securities laws may be enforced in Hong Kong at common law by bringing an action in a Hong Kong court on that judgment for the amount due thereunder, and then seeking summary judgment on the strength of the foreign judgment, provided that the foreign judgment, among other things, is: (i) for a debt or a definite sum of money (not being taxes or similar charges to a foreign government taxing authority or a fine or other penalty); and (ii) final and conclusive on the merits of the claim, but not otherwise. Such a judgment may not, in any event, be so enforced in Hong Kong if (a) it was obtained by fraud; (b) the proceedings in which the judgment was obtained were opposed to natural justice; (c) its enforcement or recognition would be contrary to the public policy of Hong Kong; (d) the court of the United States was not jurisdictionally competent; or (e) the judgment was in conflict with a prior Hong Kong judgment. Hong Kong has no arrangement for the reciprocal enforcement of judgments with the United States. As a result, there is uncertainty as to the enforceability in Hong Kong, in original actions or in actions for enforcement, of judgments of United States courts of civil liabilities predicated solely upon the federal securities laws of the United States or the securities laws of any State or territory within the United States and attempts to enforce such a judgment in Hong Kong on Mr. Chan or Mr. Haixiang could be costly, time consuming and ultimately unsuccessful.

To the extent any of our directors are located in China or Hong Kong, it may be difficult for you to enforce liabilities and enforce judgments on these individuals, for you to effect service of process within the United States upon these persons, or to enforce against them judgments obtained in United States courts, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States.

As a result of the foregoing, you may have more difficulties in protecting your interests through actions against us, our officers or directors than would shareholders of a company incorporated in a jurisdiction in the United States.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company.

We are an Israeli corporation based in Caesarea, Israel and were incorporated in Israel in 2006. On February 2, 2011, we became a public company in Israel and our shares were listed for trade on the TASE. On August 26, 2021, our shares were listed for trade on Nasdaq under the symbol "ICCM." On July 24, 2023, we delisted our Ordinary Shares from the TASE.

Our principal executive offices are located at 7 Ha'Eshel St., PO Box 3163, Caesarea, 3079504 Israel. Our telephone number in Israel is +972-4-6230333. Our website address is http://www.icecure-medical.com. The information contained on our website or available through our website is not incorporated by reference into and should not be considered a part of this annual report on Form 20-F, and the reference to our website in this annual report on Form 20-F is an inactive textual reference only. IceCure Medical Inc. is our agent in the United States, and its address is 10 W Prospect Street, Suite 401, Nanuet, New York 10954.

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by the JOBS Act. As such, we are eligible to, and intend to, take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not "emerging growth companies" such as not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. We could remain an "emerging growth company" for up to five years, or until the earliest of (a) the last day of the first fiscal year in which our annual gross revenues exceeds $1.235 billion, (b) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our Ordinary Shares that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (c) the date on which we have issued more than $1 billion in nonconvertible debt during the preceding three-year period.

The SEC maintains an internet site, http://www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Our internet address is https://www.icecure-medical.com. The information on that website is not part of this Annual Report and is not incorporated by reference herein.

We are a foreign private issuer as defined by the rules under the Securities Act and the Exchange Act. Our status as a foreign private issuer also exempts us from compliance with certain laws and regulations of the SEC and certain regulations of the Nasdaq Stock Market, including the proxy rules, the short-swing profits recapture rules, and certain governance requirements such as independent director oversight of the nomination of directors and executive compensation. In addition, we are not required to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies registered under the Exchange Act.

In 2023 and 2024, our capital expenditures amounted to $480 thousand and $71 thousand, respectively. Our current capital expenditures are primarily for manufacturing facility and equipment, computers, software, research and development equipment and office improvements substantially all in Israel, and we expect to finance these expenditures primarily from cash on hand.

B. Business Overview.

We are a commercial stage medical device company focusing on the research, development and marketing of cryoablation systems, disposables and technologies based on LN2 for treating tumors. Cryoablation is the process by which benign and malignant tumors are ablated (destroyed) through freezing such tumors while in a patient's body. Our proprietary cryoablation technology is a minimally invasive alternative to surgical intervention, for tumors, including those found in breast, lungs, kidneys, bones and other indications. Our lead commercial cryoablation product is the ProSense system, as pictured below, and the associated CryoProbes.

Alongside our continued efforts at improving our core technology, including our flagship product, the ProSense system, we are also focused on new product developments. This includes our XSense system with CryoProbes for which we have received 510(k) regulatory clearance from the FDA. We believe that the XSense system with CryoProbes can serve as a platform that will allow us to develop other unique CryoProbes and catheters and expand our clinical applications, and that it is also more efficient, intuitive and user friendly. We are also developing MSense which could enable the treatment of multiple and larger tumors (see "Item 4.B. *Business Overview – Our Products – Research and Development*" for additional information).

We believe that obtaining regulatory approval for our existing and next-generation products for specific indications will help us grow our business. As of December 31, 2024, in the United States, we have a broad range of regulatory approvals for our systems to be used as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology and urology. In the United States our products are cleared as a "single family" known as the "IceCure Family," which includes the IceSense3, ProSense, XSense, and MultiSense cryoablation systems, the latter of which has not been commercialized. Although our existing, "IceCure Family" systems have regulatory clearance from the FDA for commercialization in the United States, we have yet to receive regulatory approval for such systems for treatment of malignant breast tumors, which requires separate approval from the FDA. The FDA classifies medical devices into one of three classes (Class I, Class II, or Class III) depending on their level of risk and the types of controls that are necessary to ensure device safety and effectiveness. The class assignment is a factor in determining the type of premarketing submission or application, if any, that will be required before marketing products in the United States.

On October 18, 2022, we requested that De Novo classification would be granted for our ProSense system for breast cancer indication. Because of this De Novo classification request, we would be required to accept special controls imposed by the FDA, mainly on the production process and post-market monitoring. This De Novo classification request regulatory filing with the FDA for marketing authorization was based on our ICE3 clinical trial interim analysis of ProSense for the indication of early-stage (Luminal A T1 invasive) low-risk breast cancer in patients who are at high risk to surgery (not suitable for surgical alternatives). On September 20, 2023, we received notice that the FDA denied our De Novo classification request and on November 15, 2023 we filed a request with the FDA for supervisory review under 21 CFR 10.75. On January 30, 2024, we announced that the FDA responded affirmatively to our request and determined that there is sufficient basis to reopen the De Novo file if we submit the full 5-year dataset from our ICE3 trial. On March 15, 2024, the last patient in the ICE3 trial concluded her 5 year-follow-up. 96.39% of the patients from the study were local recurrence-free with no significant device-related adverse events or complications reported. Having compiled and submitted the dataset and comparative analysis of the ICE3 results versus the data from the LUMINA study, the FDA convened a medical device advisory committee panel, or the Advisory Panel, to review the De Novo marketing authorization request for ProSense on November 7, 2024, the decision about which is expected to be delivered by the FDA after the first quarter of 2025. The Advisory Panel included breast surgeons, interventional radiologists, breast oncologists, and representatives from the patient, consumer, and regulatory communities. The purpose of the Advisory Panel was for the FDA to obtain independent non-binding expert advice on scientific, technical and policy matters related to the potential granting of marketing authorization of ProSense for treating patients with early-stage low risk invasive breast cancer with cryoablation and adjuvant endocrine therapy. The majority of panelists voted that the benefits of ProSense outweigh the risks when used according to the proposed indications for the treatment of patients with early-stage low risk invasive breast cancer with cryoablation and adjuvant endocrine therapy. The Advisory Panel's favorable vote was based on the comprehensive body of data available on ProSense as a treatment for early-stage low risk breast cancer, including results from the ICE3 study compared with data from the current standard of care, lumpectomy, as well as testimonials and input from a broad range of key stakeholders, including women with breast cancer and their family members, patient advocacy groups, doctors, nurses and researchers. See "Item 4.B. *Business Overview – Government Regulation*" and "Item 4.B. *Business Overview – Malignant Breast Tumors*" for additional information.

In order to gain market acceptance in the United States, we will require specific approval from the FDA for our ProSense system for breast cancer indication, which we hope to obtain based on the full analysis of our ICE3 trial and the Advisory Panel's positive recommendation. Other key steps to gaining market acceptance depends on the American Society of Breast Surgeons, or the ASBrS, amending their guidelines to support cryoablation as an additional option to surgery, applying for CPT I codes for cryoablation for breast cancer (with the support of the ASBrS), negotiate medical coverage for our systems from medical insurers and collaborating with a major distributor of medical devices (see ""Item 4.B. *Business Overview – Government Regulation – FDA Regulation of Medical Devices*" and "Item 3.D. *Risk Factors – Risks Related to Product Development and Regulatory Approval*" for additional information).

In addition, there is significant competition in the medical devices and cancer treatment market. Some of our competitors possess significant market share, reputations, and longevity within the industry and have greater brand recognition and financial and human resources than us. They also have more experience and capabilities in researching and developing testing devices, obtaining and maintaining regulatory clearances, manufacturing and marketing those products and other requirements, than us. Their dominant market positions and significant control over the market could significantly limit our ability to introduce or effectively market and generate sales and capture market share.

To date, we have incurred significant operating losses, generated minimal revenues from product sales, and as of December 31, 2024 and 2023, our accumulated deficit was $105.4 million and $90.1 million, respectively. We expect that we will need to raise substantial additional funding in the future (see "Item 3.D. *Risk Factors – Risks Related to Our Financial Condition and Capital Requirements*").

In the United States, Europe, Canada, China, Singapore, India, Hong Kong, Russia, Thailand, Taiwan, South Africa, Mexico, Australia, Israel, Costa Rica, and Brazil we have regulatory approvals for either our ProSense or our IceSense3 systems, or, in certain countries, both products (see "Item 4.B. *Business Overview – Our Products – Regulatory Approvals*" for additional information). In the United States, we have regulatory approval for the XSense system with CryoProbes for all the indications for which ProSense has already received the requisite FDA clearance. In addition, in order to generate significant revenue, we are applying for additional regulatory approvals for our products for specific indications in countries where we already have general regulatory approvals. For example, we filed a submission for regulatory approval for the XSense system with CryoProbes with the Medical Device Division of the Israeli Ministry of Health, or AMAR, in February 2025 and filed a submission for regulatory approval of ProSense with CryoProbes in China with the National Medical Products Administration, or the NMPA in January 2025. In these countries, we are seeking regulatory approval for the treatment of specific tumors, including those found in breast, lungs, kidneys and bones. In addition, we are seeking regulatory approvals for our systems in other countries where we believe that there is significant potential for sales of our products. In March 2023, the NMPA approved the IceSense3 disposable CryoProbes for commercial use, to be used in combination with our IceSense3 system. This approval enables us to market our disposable IceSense3 CryoProbes for commercial procedures.

The procedure using our cryoablation systems begins with the introduction of our proprietary disposable probes, through a small pea-sized incision in the skin, into the tumor while the patient is under local anesthesia and/or sedation. The probe is guided by high-resolution ultrasound (for breast tumors) or computed tomography, or CT (for other indications). For some indications guiding needles (introducers) are used to guide the probe to the tumor. Once the probe is in place, LN2 is introduced into the probe in a closed-loop circuit, so that LN2 does not enter the body, and creates a freezing zone around the tip of the probe. During the freeze cycle, an ice ball forms in the freezing zone and encompasses the tumor, ablating the cancer or benign tumor. The ice ball form can be monitored by the physician using ultrasound or CT in order to avoid causing damage to the healthy tissue surrounding the tumor. Several minutes after the procedure is completed, the ice ball thaws and, as a result thereof, there is no need for surgical removal of the dead tumor tissue as the dead tissue is naturally absorbed by the body. The entire cryoablation procedure of freeze-thaw-freeze with our ProSense system generally takes between 15 to 40 minutes, the precise time depending on the size, type and location of the tumor. The same system configuration can be used for and was designed to treat both malignant and non-malignant tumors. However, there is usually a different configuration for the probe handle between the systems used to treat breast tumors (with a primarily straight handle) and used to treat other indications (with a 90-degrees handle) due to the different imaging devices that are used in each instance (see "Item 4.B. *Business – Our Products*" for additional information). Pictured below is our system forming an ice ball (which in practice forms around the tissue within the body) in ultrasound gel.

As a minimally invasive alternative to surgery, cryoablation is much less traumatic than open surgery, and, based on current data, we believe this treatment is more affordable, entails less risk and generally results in fewer side effects and complications than open surgery. On the patient side, following procedures with our cryoablation technology, patients usually can resume normal activities within 24 hours after the procedure. In addition, the use of our technology in breast procedures eliminates the need for a post-procedure reconstruction surgery. Moreover, our procedure eliminates the need for re-excision following a lumpectomy for breast cancer, which ranges between 14% to 20% of initial lumpectomies. This data is indicated in a study published on February 21, 2019 by Liska Havel, Himani Naik, Luis Ramirez et al titled "Impact of the SSO-ASTRO Margin Guideline on Rates of Re-excision After Lumpectomy for Breast Cancer: A Meta-analysis," and a study published on May 20, 2020, in the Journal of Clinical Oncology by Mariana Chavez-MacGregor, Xiudong Lei, Nina Tamirisa. Abigail Suzanne Caudle, Sharon H. Giordano entitled "Re-excision rates among older breast cancer patients undergoing breast-conserving surgery (BCS)_ Impact of the SSO-ASTRO consensus guideline on margins". On the health provider side, procedures with our cryoablation technology for breast tumors may be carried out in a clinic, while treatment for other indications can generally be carried out as an outpatient procedure, in a CT room. As a result, the potential profit margins for health care providers and payors are greater than most of the current surgical procedures that are conducted in the operating room, which entail additional and expensive cost elements for the operating room and its staff. In addition, we believe that our LN2-based technology provides patients, medical service providers, physicians and insurers with advantages versus our competitors, especially those using heat to treat tumors, also known as thermal ablation (otherwise known as heat ablation). For example, the freezing effect on tissue from cryoablation results in less pain, and accordingly less anesthesia (which also reduces costs). A study published on April 8, 2021 by Elles M.F. van de Voort et al titled "Thermal Ablation as an Alternative for Surgical Resection of Small (≤2 cm) Breast Cancers: A Meta-Analysis" suggested that cryoablation has the lowest complication rate among breast cancer tumor procedures and the advantage of an analgesic effect. In addition, in comparison to the treatment of tumors with heat, when treating a tumor with cryoablation, the freezing does not cause evaporation of the treated tissue and therefore provides the physician conducting the treatment with a clearer view of the tissue, which we believe enables the physician to carry out the procedure more accurately with a precise view of the tumor and the treated area.

According to an investigator-led randomized phase II study on post-menopausal patients with CT1N0 breast cancer, which compared cryoablation with RFA and MWA, cryoablation achieved complete ablation rate of 94% while other ablative techniques had lower success rates. For those who underwent RFA and MWA, the complete ablation rates were 33% and 72% respectively.

On September 28, 2023, an independent study, overseen and conducted at the Breast Center of Excellence and the Department of Surgery, School of Medicine at Texas Tech University Health Sciences Center, was published called "Cryoablation Allows the Ultimate De-escalation of Surgical Therapy for Select Breast Cancer Patients" in the *Annals of Surgical Oncology*. The study's authors concluded that the success of the clinical trial analyzed in the paper showed that cryoablation is as effective as surgical resection for early-stage, low-risk tumors, is a superior alternative financially. Furthermore, they concluded, the two multi-institutional studies on cryoablation by Simmons et al. on ACOSOG Z-1072 and Fine et al. on ICE3 have shown that cryoablation ensures surgical de-escalation for small, early-stage, low-risk breast cancers. On October 17, 2023, a paper called "Cryoablation Therapy for Early-Stage Breast Cancer: Evidence and Rationale", co-authored by Robert C.Ward, MD and Alexander B. Sevrukov, MD, was published in the *Journal of Breast Imaging*. The paper describes the efficacy of less aggressive and invasive treatment of early-stage breast cancer of patients who have small, lower-risk tumors. Furthermore, it highlights the faster recovery, improved cosmetics and that it has advantage of being administered under local anesthesia.

On November 22, 2023, a study was published called "Piezo1 facilitates optimal T cell activation during tumor challenge" in *Oncolmmunology.* The study explored the role of the Piezo1 protein in regulating T-cell tumor immune-mediated rejection of soft tissue tumors through cryoablation. The data from the study show that cryoablation induces immune rejection by enhancing CD8+ T cell activation. Increased activation and responsiveness, leading to a more robust immune response against abnormal cells, was detected up to 2 weeks after cryoablation, displayed as an increase in CD25 and interferon gamma expression on CD8+ T cells.

We believe that cryoablation has already started to be recognized for its true potential, and that it represents the future of treatment for certain benign and malignant tumors. Our ongoing business strategy, as further detailed below, is focused on helping us overcome certain factors that have limited our ability to generate significant revenues, including, but not limited to, obtaining additional regulatory clearance, obtaining support of key opinion leaders and leading medical associations for the use of cryoablation (and specifically, our systems) for the treatment of tumors and other indications. In recent years, and in part due to our efforts and accomplishments, cryoablation of malignant breast tumors has been recognized for its vast potential. For example, following preliminary results of our ICE3 trial, which we presented at the yearly conference of the ASBrS in May 2018, and at the yearly RSNA conference in October 2018, the ASBrS, which, among other things, sets guidelines for breast cancer treatment, updated its guidelines on performing cryoablation procedures on breast malignant tumors in their early stages. While not cited by the ASBrS, based on our discussions with the ASBrS, we believe that the results of our study were a factor in the ASBrS decision to update these guidelines. (see "Item 4.B. *Business Overview – Our Lead Indication and Market Opportunity – Primary Indication – Breast Tumors – Malignant Breast Tumors – Multi-Site Clinical Trial of the Cryoablation System ICE3 Study – United States*" for additional information).

In addition to updating its guidelines, the ASBrS also recommend taking part in clinical trials and in registries for treating malignant breast tumors, each relating to cryoablation, to increase the knowledge and data of breast cancer cryoablation. Registries, by which uniform data is collected from patients through observational studies, represent an important stage in the commercialization of technologies and are part of the required procedure for receiving remuneration from health insurance companies.

Revenues and Growth Strategy

Our strategic objective is to be the leader in the field of cryoablation treatment for benign and malignant breast tumors and other interventional oncology indications. Using our innovative ProSense LN2 cryoablation system (and, in the future, potentially using our next generation systems) and propriety disposable probes and introducers, we intend to create a recurring revenues stream by selling single use probes to the users of our ProSense system. For tumors which are not in the breast, we also sell a disposable (single use) introducer which is used to assist with navigating the probe to the tumor.

Our revenues are based on a number of business models, which include:

- The sale of our systems and disposables to distributors and/or end users;
- Attaining end user commitments to purchase a minimum number of disposable probes per month; and
- Providing service and maintenance for our systems.

In our models, although we may sell a fixed number of systems over a period of time, the sales of the disposables are tied to the number of procedures conducted (similar to the razor/razor-blade model), and therefore, we expect to sell an increasing number of disposables as the number of procedures increases.

In order to generate significant revenues, we believe that we need to achieve each of the following milestones: (i) FDA approval for commercialization of our products for treatment of malignant tumors in breast, (ii) recommendations for the use of our products in guidelines of medical associations, such as the ASBrS, Society of Interventional Radiology, or SIR, Society of Interventional Oncology, or SIO, and others, (iii) the need to obtain category I CPT code and coverage for our products, and (iv) negotiate reimbursement with government and private insurers and payers. We believe that reaching these milestones, while focusing on our business growth strategy, will help us achieve greater revenues. Our growth strategy includes the following actions:

- Obtaining regulatory approval for our ProSense and other future systems in countries within which we do not currently have regulatory approval as well as obtaining regulatory approvals for additional indications in countries within which we already have certain approvals. Specifically, we intend to seek to obtain FDA approval to commercialize our products for the treatment of malignant breast tumors.

- Obtaining clinical data (by conducting both sponsored and independent clinical trials for our systems) and by gaining the support of these key opinion leaders.

- Expanding our distribution network for further commercialization, which may include distribution and/or license agreements or other forms of collaborative agreements.

- Obtaining the relevant approvals to allow for reimbursement to end-users of our systems.

- Having cryoablation treatment included in the recommendation guidelines as a valid treatment option of certain medical associations, such as the ASBrS.

- Continuing research and development efforts aimed at developing our MSense system. We believe that completing development of our MSense system and obtaining regulatory approval to commercialize our MSense system for a variety of indications, in the United States is necessary in order for us to grow our business.

- Continuing our efforts to obtain regulatory approval for our XSense system with CryoProbes so that we are able to commercialize it for a variety of indications so that we can grow our business.

- Obtaining guidelines from relevant professional societies in the geographic territories we operate or plan to operate.

- Expanding utilization and use of our products for breast cancer treatment by commercial sales and clinical studies around the world.

Our Lead Indication and Market Opportunity

Our lead indication is breast tumors. There are generally two types of breast tumors: those that are non-cancerous, or benign, and those that are cancerous, or malignant.

Primary Indication

Breast Tumors

The national expenditure involved in treating breast tumors (both for benign and malignant tumors), based on the National Cancer Institute increases each year. Thus, in 2015, the cost of treating breast cancer was approximately $26.8 billion in the United States – higher than any other type of cancer. This cost increased to $29.8 billion in 2020. Individual costs vary, depending on the stage of the malignancy and treatment options selected.

Benign Breast Tumors

The majority of breast tumors are benign (non-cancerous), and are generally not life-threatening compared to breast cancer. Fibroadenomas is a common type of benign breast tumors. They are solid benign (noncancerous) tumors common among women of various ages. Fibroadenoma tumors range in size and on average can be located anywhere in the breast, from the size of a marble to up to 2.5 centimeters in diameter, and tend to grow during pregnancy and breastfeeding. According to scientific publications from recent years, 10% of all women in the world suffer from fibroadenomas, and the phenomenon is particularly common among women under the age of 30 (80% of breast biopsies for women of these ages identify benign tumors). Many physicians and oncologists recommend removal of benign tumors for a variety of reasons, including: concerns that the tumor will increase in size, pain and due to concerns that the existence of a benign breast lump will make it difficult to manually discover breast cancer in the future. However, the vast majority of benign tumors are left untreated for reasons including cost and undesirable cosmetic outcomes, the latter of which, is generally not caused by treatment with our ProSense system.

Clinical Trial in Fibroadenoma (Benign Breast Tumors)

We sponsored and completed a prospective clinical trial in benign breast tumors in the Czech Republic, Israel and Germany. Between April 2009 and September 2012, data was collected from 60 procedures that were performed across four clinical sites located in Czech Republic, Israel and Germany (two sites). The IceSense3 was used to conduct the cryoablation procedures. The primary endpoint was to create an ice ball which would successfully engulf the entire tumor, as seen using ultrasound imaging. Our inclusion criteria were patients over 18 years old with core biopsy-proven breast fibroadenoma between 0.5 cm and 3.0 cm. The expected probability of success was 88%. At the one-year follow-up, in 93% of the cases, the fibroadenomas no longer existed. A June 2015 publication highlighting the data concluded that cryoablation of the fibroadenoma using a LN2 system demonstrated meaningful reduction in volume, palpability, pain and an improvement in cosmetic results from the procedure. No serious adverse events related to the IceSense3 system occurred during the clinical trial.

Malignant Breast Tumors

According to recent estimates from the American Breast Cancer Foundation's publications, breast cancer is the most commonly diagnosed cancer among American women. Of the diagnosed breast cancers, it is estimated by the American Cancer Society that 73% of breast cancers are low-risk, while according to the American Society of Clinical Oncology, localized breast cancer accounts for 63% of total breast cancer incidence. In 2025, according to the American cancer society, it is estimated that there will be a total of 376,000 new cases of invasive breast cancer and ductal carcinoma in situ (DCIS) in the United States. Furthermore, it is estimated that 42,170 women will die of breast cancer in 2025.

It is further estimated that breast cancer is the second leading cause of cancer-related death in women. Additionally, the American Cancer Society reported that the average risk of a woman in the United States of developing breast cancer during her lifetime is approximately 13%, which means that there is a one in eight chance that a woman will develop breast cancer in her lifetime. A study conducted by the American Association for Cancer Research suggests that the number of breast cancer patients may increase by 50% by 2030, which shows a significant long-term market growth potential.

Traditional treatment options for malignant breast tumors include surgery, radiation, and chemotherapy. Concerning the surgical path, most breast cancer cases will require to have some type of surgery to remove the tumor. Surgical treatment often entails either breast-conserving surgery, or BCS, in which only the part of the breast containing the cancer is removed, or mastectomy, in which the entire breast is removed, including all of the breast tissue and sometimes also nearby tissue.

Clinical Trials in Cancerous (Malignant) Breast Tumors

We completed our sponsorship of a clinical trial in cancerous breast tumors in the United States in March 2024. Our systems and probes are being used in three clinical studies initiated by investigators for malignant breast tumors in Japan, Hong Kong and China, and the Netherlands. Based on data presented from the Kameda Medical Center in Kamogawa, Japan, since May 2012, more than 600 procedures for breast cancer have been performed at the Center using our cryoablation system.

Multi-Site Clinical Trial of the Cryoablation System ICE3 Study – United States

In May 2014, we initiated a multi-site clinical trial in the United States, which included participation of 19 sites across the U.S., including Columbia University Medical Center and Mount Sinai Beth Israel. The ICE3 trial was intended to expand the clinical base for using our cryoablation system for treating low-risk, small breast cancer tumors (up to 1.5 centimeters). The primary goal of ICE3 was to assess the effectiveness by the breast tumors local recurrence rates in patients who undergo cryoablation without excision for a follow-up period of five years. The inclusion criteria were patients over 65 years old with core biopsy-proven invasive ductal carcinoma with unifocal primary disease, tumor size less than 1.5 cm, Nottingham grade 1-2, estrogen and/or progesterone receptor positive and HER2 negative and breast size adequate for safe cryoablation. ICE3 is the largest controlled multi-location clinical trial ever performed for liquid nitrogen based cryoablation of small, low-risk, early-stage malignant breast tumors without subsequently removing them.

In February 2019, the last patient was recruited. In total, 211 patients were recruited to the ICE3 trial, 206 of whom have enrolled, and 194 undergone Cryoablation according to the study protocol.

On October 18, 2022, we submitted a De Novo classification request regulatory filing with the FDA for marketing authorization based on our ICE3 clinical trial interim analysis of ProSense for the indication of early-stage (Luminal A T1 invasive) low-risk breast cancer in patients who are at high risk to surgery (not suitable for surgical alternatives), the demographic of which comprises of approximately 43,000 women in the United States annually. On September 20, 2023, we received notice that the FDA denied our De Novo classification request and on November 15, 2023, we filed a request with the FDA for supervisory review under 21 CFR 10.75. On January 30, 2024, we announced that the FDA responded affirmatively to our request and the FDA determined that there is sufficient basis to reopen the De Novo file if we submit the full 5-year dataset from our ICE3 trial. On March 15, 2024, the last patient in the ICE3 trial concluded her 5 year-follow-up. 96.39% of the patients from the study were local recurrence-free with no significant device-related adverse events or complications reported. Having compiled and submitted the dataset and comparative analysis of the ICE3 results versus the data from the LUMINA study, the FDA convened the Advisory Panel to review the De Novo marketing authorization request for ProSense on November 7, 2024, the decision about which is expected to be delivered by the FDA after the first quarter of 2025. The Advisory Panel included breast surgeons, interventional radiologists, breast oncologists, and representatives from the patient, consumer, and regulatory communities. The purpose of the Advisory Panel was for the FDA to obtain independent non-binding expert advice on scientific, technical and policy matters related to the potential granting of marketing authorization of ProSense for treating patients with early-stage low risk invasive breast cancer with cryoablation and adjuvant endocrine therapy. The majority of panelists voted that the benefits of ProSense outweigh the risks when used according to the proposed indications for the treatment of patients with early-stage low risk invasive breast cancer with cryoablation and adjuvant endocrine therapy. The Advisory Panel's favorable vote was based on the comprehensive body of data available on ProSense as a treatment for early-stage low risk breast cancer, including results from the ICE3 study compared with data from the current standard of care, lumpectomy, as well as testimonials and input from a broad range of key stakeholders, including women with breast cancer and their family members, patient advocacy groups, doctors, nurses and researchers.

The total group of Luminal A breast cancer for women in all ages, is estimated at 144,000 cases annually in the United States. We estimate that our potential market size in the U.S. is 70,000 patients if we receive marketing authorization. In the future, we intend to explore more indications for additional subgroups that are part of the total group of Luminal A breast cancer.

Data suggests the use of ProSense cryoablation in breast procedures eliminates the risk of re-excision (a second surgery). Between 14% - 20% of breast cancer surgeries result in re-excision due to the practice of requiring a margin of normal breast tissue beyond the involved malignant tissue. This is associated with greater morbidity, patient anxiety, poorer cosmetic outcomes, and increased cost.

In September 2024, an article titled "Cryoablation Without Excision for Early–Stage Breast Cancer: ICE3 Trial 5–Year Follow–Up on Ipsilateral Breast Tumor Recurrence," presenting the results of IceCure's ICE3 trial, the largest controlled multicenter clinical trial ever completed in the United States for LN2-based cryoablation of small, low-risk, early-stage malignant breast tumors as an alternative to surgery. The lead author of the study is Dr. Richard Fine, an ICE3 Investigator, who co-authored the publication with 24 doctors who are ProSense users, including co-primary investigator, Dr. Kenneth Tomkovich. 194 eligible patients received successful treatment and were included in the final results for analysis. The mean age was 74.9 years with a mean tumor size of 7.4 mm traverse and 8.1 mm sagittal. Of the 124 patients who received cryoablation and endocrine therapy, the recurrence free rate was 96.3%.

Independent Study of Cryoablation Systems – United States

An independent study, the largest multi-institutional study of women ineligible for prospective clinical trials due to patient of tumor characteristics, was published in the American Journal of Roentgenology under the title "Cryoablation of Primary Breast Cancer in Patients Ineligible for Clinical Trials: A Multi-Institutional Study". The independent study evaluated 112 patients with a median age of 71. ProSense was one of four different cryoablation systems used for procedures performed at seven U.S. institutions by seven different radiologists. The recurrence-free rates were 94.7%, 87.8%, and 81.8%, at one, two, and three years, respectively, when accounting for death, including from comorbidities, as a competing risk. Treatment with cryoablation had a low frequency of adverse events and a high frequency of procedures were technically successful.

Independent Clinical Trial of the Cryoablation System – Japan

Since May 2012, an independent clinical trial has been ongoing at the Kameda Medical Center in Kamogawa, Japan using our IceSense3 cryoablation system. So far, over 600 cryoablation procedures have been conducted using our cryoablation system (in addition to approximately 80 additional procedures with a different system). According to information reported on the International Cryosurgery Society Convention, which was held in September 2019, in 304 of the 400 patients who were treated with cryoablation between 2006 and 2019, the recurrence rate of breast cancer was lower than 1%. The inclusion criteria were patients with histologically-proven breast cancer at stage 0 (TisN0M0) or stage 1 (T1N0M0) with tumor mass and lesion (including the progress within intraductal component) less than 1.0 cm. The primary endpoints were comparing the tumor necrosis rate, cosmetic results of the procedure, clarity of imaging, safety and therapeutic effects of IceSense3 versus a competing cryoablation device.

In addition, since May 2018, an independent investigator initiated clinical trial in Japan at the St. Marianna University School of Medicine Department of Mammary Gland and Endocrine Surgery using our ProSense system. The trial's purpose was conducted in breast cancer tumors of up to 1.5 cm (in their early stages). The inclusion criteria were patients with histologically-proven breast cancer at stage 0 (TisN0M0) or stage 1 (T1N0M0), between the age of 20 and 85 years, HER2 protein expression-negative status, Ki-67 positivity of ≤ 20% and lesion spread of 1.5 cm or less. The trial was completed after the enrollment of seven patients, in which pathology was confirmed using a vacuum-assisted biopsy. In all seven patients, there was no evidence of malignant cells, and following a monitoring period of two years, all seven patients remain disease free with no clinical and imaging evidence. The primary endpoint of this clinical trial was to expand the clinical knowledge of cryoablation of cancerous breast tumors and enable to implement this technology at the St. Marianna University Hospital as a routine procedure. Based on these results, the trial received approval from the hospital to offer cryoablation for breast cancer in a commercial setting.

In April 2024, data from an independent study performed in Japan were published in an article titled "Percutaneous ultrasound-guided cryoablation for early-stage primary breast cancer: a follow-up study in Japan" in the journal *Beast Cancer*. Eighteen early-stage breast cancer patients, with a mean age of 59.0 and a mean tumor size of 9.8mm underwent treatment with ProSense and were followed for a mean of 44.3 months. No patient had local recurrence of distant metastasis in the 5 year follow up, no serious adverse events were reported and patient satisfaction was high.

In March 2025, data from an independent study performed in Japan were published in an article titled "Post-treatment patient satisfaction in early-stage breast cancer: Comparison of cryoablation versus breast conservation therapy using BREAST-Q" in the peer reviewed journal Gland Surgery. The study was conducted at the Breast Center at Kameda Medical Center in Chiba, Japan. A total of 147 breast cancer patients underwent cryoablation with ProSense. Those who underwent cryoablation reported a significantly higher satisfaction with the primary outcome (71.0±18.6 vs. 56.3±16.5) compared to breast-conserving therapy.

Independent Clinical Trial of the Cryoablation System –Hong Kong and China

Since November 2018, an independent clinical trial has been ongoing at the Queen Mary Medical Center in Hong Kong and at Hong Kong-Shenzhen University Hospital in China. According to information disclosed by the primary investigator, treatments using our ProSense cryoablation system has been performed to date in 20 patients, out of an expected total patient pool of 150, in which each patient underwent an excision after the cryoablation to examine the ablated area by pathology. Following the first phase, the remaining patients are expected to be monitored according to the standard of care without excision. The purpose of this clinical trial is to expand the clinical knowledge of cryoablation of cancerous breast tumors. The primary endpoints were to demonstrate cryosurgery's efficacy in ablating small breast cancers, safety with low morbidity and the use of PET/MRI as an effective imaging modality to assess post-treatment responses. The inclusion criteria were patients between 18 and 70 years old with core biopsy-proven T0/T1a and b breast cancer or ductal carcinoma in situ.

Independent Study of the Cryoablation System – Spain

In October 2023, we announced that University Hospital Lucus Augusti, in Lugo, Spain, conducted a study of ProSense for the cryoablation treatment of 31 patients for early-stage breast cancer patients. After a median follow-up of 10 months, cancer progression was observed only in one out of 31 patients, or a 96.8% success rate, that the lead radiologist cited as being evidence that our ProSense system is a safe and effective outpatient procedure for breast cancer.

In August 2024, we announced that University Hospital Lucus Augusti published an independent study titled "Acceptance and results of cryoablation for the treatment of early breast cancer in non-surgical patients" in the British Journal of Radiology. In evaluating the acceptance of percutaneous cryoablation treatment by patients with early-stage breast cancer who choose not to have surgery, 43 of the 45 patients offered cryoablation with ProSense, or 95.6% accepted. 36 of these, representing 39 malignant tumors (median size 24mm), proceeded to undergo cryoablation.

Independent Study of the Cryoablation System – Italy

ProSense is approved in Italy for numerous indications, including breast cancer. In February 2024, we announced new data from a preliminary independent breast cancer study conducted by Dr. Federica di Naro of Azienda Ospedaliero-Universitaria Careggi. Ultrasound-guided cryoablation using ProSense® was performed on 39 women between the ages of 60 to 92 who had biopsy-proven malignant lesions and were deemed inoperable due to advanced age and comorbidities or who refused surgery. Patients were monitored at one, three, six- and 12-months post-procedure, at which time the tumor size reduction rate was evaluated by ultrasound. At 12 months post-procedure, the effectiveness of the procedure was further evaluated by core needle biopsy on the post-procedural scar (inside the breast at the site of the tumor) and contrast enhanced mammography (CEM) to determine the presence or absence of residual tumoral cells and the effectiveness of cryoablation. The median breast cancer tumor size reduction rates reported in the study were 27.8%, 60.9% 100.0% and 100.0% at one, three, six, and 12 months post procedure respectively.

An independent study led by Dr. Franco Orsi, director of interventional radiology at the European Institute of Oncology in Milan, titled "Liquid Nitrogen-Based Cryoablation: Complication Rates for Lung, Bone and Soft Tissue Tumors" was published by Oxford University Press. The study assessed the complication rate both during and 24 hours after treatment with IceCure's cryoablation system in 85 patients who were treated for 96 lesions (tumors), 36.4% of which were lesions in bones, 18.8% in lungs, and 44.8% in soft tissue. The primary technical success rate, defined as complete tumor coverage, was 97.7% (83 of 85 patients). Patients with benign and malignant tumors were treated for either curative or palliative intent. Minor complications resolved themselves without intervention or merely required simple interventions such as drainage. The study concluded that cryoablation using an LN2-based system, is safe across various tumor sizes and locations, with only minor complications observed.

Independent Study of the Cryoablation System – Germany

An independent study on ProSense, led by Professor Thomas Vogl at the Institute of Radiology and Nuclear Medicine, University Hospital Frankfurt, at Goethe University in Germany, titled "CT-Guided Percutaneous Cryoablation of Breast Cancer: A Single-Center Experience" was published in *Cancers*. The independent study retrospectively evaluated the efficacy and safety of the system. Patients were treated in out-patient settings with curative intention for non-metastatic patients, while patients with metastases were treated to achieve local tumor control. 45 patients, with a mean age of 55, with 56 tumors, including 11 patients with recurrent tumors and 21 patients with metastatic disease, were observed at three, six, nine, and 12 months, respectively, and after the first year were followed up biannually. There were four cases of local tumor progression, representing a rate of 8.9%. There were no complications observed in any of the 56 ablations and initial complete ablation was achieved in 100% of cases.

Independent Study of the Treatment of Breast Cancer with Percutaneous Thermal Ablation – the Netherlands

An independent study initiated in March 2021 in the Netherlands aimed to assess the efficacy of RFA, MWA, and cryoablation in achieving complete tumor ablation for early-stage breast cancer patients with minimal ductal carcinoma in situ (≤ 25% of the tumor). The study was designed to inform a potential randomized phase III trial comparing thermal ablation to surgery. Cryoablation met the minimum efficacy requirements, with a 92% success rate, 0% complication rate, and 100% treatment tolerance, making it the choice for the phase III study. In contrast, MWA had a 62% efficacy and a 44% complication rate, while RFA showed the lowest efficacy at 33%. Cryoablation also demonstrated superior cosmetic outcomes and patient satisfaction compared to surgery, with the best results reported on relevant questionnaires.

Other Clinical Indications

We are targeting other tissue tumor ablation for our ProSense system, in organs such as: lungs, kidneys, bones and other organs. Our approach to these indications is to collaborate with hospitals and doctors to conduct clinical trials in order to gain additional information regarding the potential of our products to treat certain diseases. While our cryoablation products have been approved by various regulatory agencies for variety of oncology and surgical uses, we will need to validate our products in specific indications, and in certain situations in order to obtain specific regulatory approvals, and/or to collect medical data, which will be required in order to successfully market our products for these indications.

Lung Cancer

The American Cancer Society has estimated that in 2024, approximately 234,580 new cases of lung cancer will be diagnosed in the United States while an estimated of 125,170 patients will die of such cancers in the United States during 2024.

Lung Cancer Clinical Trial

Since November 2013, an independent clinical trial in cryoablation of lung tumors in non-small cell carcinoma or metastatic lesions has been ongoing at the Kameda Medical Center in Kamogawa, Japan using our cryoablation system. In 2019, this study migrated to the Kashiwa Kusei General Hospital. Based on data provided to us, this trial is an ongoing trial, and to date, more than 400 procedures have been performed using our cryoablation system.

In November 2020, the lead investigator for the trial published the results in a peer reviewed article in the European Journal of Radiology and in July 2022 in the Clinics In Oncology journal. The results of the 2020 published article covered the cryoablation treatments in 101 patients during the years 2013 through 2019. The patients with T1N0MO NSCLC (Non – small cell lung cancer) in this review were divided into four categories based on the size of maximum tumor diameter, as follows: (1) group 1: tumor size up to 0.9 cm; (2) group 2: tumor size between 1 and 1.2 cm; (3) group 3: tumor size between 1.3 and 1.7 cm; and (4) group 4: tumor size larger than 1.8 cm. Ten patients experienced local recurrences. There were no recurrences in groups 1 or 2 (0%). There was one recurrence in group 3 (4%) and nine in group 4 (33%), indicating local control to be better in smaller tumors ($p<0.001$). The 3-year recurrence-free survival rates were: 86% in group 1; 97% in group 2; 93% in group 3; and 53% in group 4, indicating survival to be better in smaller tumors ($p<0.001$). There were no serious adverse events reported. The results of the 2022 publication covered a different group of 68 patients with metastatic lung cancer during the same period of time. The three-year local control rate was 73% for all tumors and 96% and 46% in tumors <2.2 cm and ≥ 2.2 cm, respectively. Local control was not different in tumors <2.2 cm between carcinoma and sarcoma ($p=0.43$). Sarcoma showed significantly poorer local control than carcinoma in tumors ≥ 2.2 cm, of which three-year local control rate was 18% and 62%, respectively ($p<0.001$). The incidence of pneumothorax was 25%. While the average preserved pulmonary function was 98 ± 6% after cryoablation for one tumor, the treatment for multiple tumors was associated with significantly lower preservation of pulmonary function ($p=0.002$). It was concluded that cryoablation using liquid nitrogen would be one of the treatment methods for metastatic lung cancers <2.2 cm.

The results of the trial, as disclosed in the published article, were that the treatment of tumors in groups 1 and 2 through cryoablation and LN2 and local control of the tumor and the lack recurrence of the cancer was more effective than in groups 3 and 4. As part of the trial, tumors treated in groups 1 and 2 did not have local recurrence, while in groups 3 and 4, 4% and 33%, respectively, of the tumors had local recurrence. The 3-year recurrence-free survival rates were: 86% in group 1; 97% in group 2; 92% in group 3; and 53% group 4, indicating the survival to be better in smaller tumors ($p < 0.001$). No patient had treatment-related mortality. The most frequent complication was pneumothorax, with a rate of 24%, while the decrease of pulmonary function was just 3%.

The peer reviewed publication also highlighted that the use of cryoablation treatment with only one needle for the majority of the patients in the trial represented an advantage in comparison to systems that use argon gas, which usually requires the use of 2-3 needles for a procedure on the same tumors size. We believe that the publication of the results of the trial in a peer reviewed publication raises the validity of using our products for the treatment of lung tumors.

Kidney Tumors

The American Cancer Society has estimated that in 2024, approximately 81,610 new cases of kidney and renal pelvis cancer will be diagnosed in the United States, while an estimated of 14,390 patients will die of such cancers in the United States during 2024.

According to an article published in European Radiology in 2023, the cost of cryoablation of a kidney is about 77% of the cost of an open kidney surgery, also known as an open partial nephrectomy. Protocatechuic aldehyde yields a comparable health benefit at lower costs compared to open partial nephrectomy, making protocatechuic aldehyde the more dominant and cost-effective treatment.

Kidney Tumors Clinical Trials

In 2012, a clinical trial called ICESECRET (NCT02399124) Post Marketing Surveillance for PROSENSE™ a Cryotherapy Treatment of Renal Cell Carcinoma was initiated at Bnei Zion Medical Center in Haifa, Israel, in collaboration with the Shamir/Assaf Harofeh Medical Center in Be'er Ya'akov, Israel. Procedures were performed using our ProSense system for freezing and ablating kidney tumors.

According to the American Journal of Roentgenology, small renal masses, which may be malignant or benign tumors in the kidney, have been rising in incidence over the past two decades. According to the American Cancer Society, in 2022, in the United States, an estimated 79,000 new cases of kidney cancer will be diagnosed, with about 14,000 dying from the disease. Globally, there were more than 430,000 new cases of kidney cancer in 2020 and about 180,000 deaths according to World Cancer Research Fund International.

In November 2023, we announced that a study titled "Single-Probe Percutaneous Cryoablation with Liquid Nitrogen for the Treatment of T1a Renal Tumors" was published in *Cancers* and demonstrated the safety and efficacy of ProSense® in treating malignant small renal masses. The Study was authored by eight physicians in France, including interventional radiologists and urologists from Curie Institute, Paris, Nîmes University Hospital (University of Montpellier), Nîmes, and Carémeau University Hospital, Nîmes.

The objective of this retrospective study was to address the challenges of managing small renal masses, including recurrence rates, by exploring the safety and efficiency of single-probe percutaneous cryoablation as a potential solution. The causes of partial tumor response and persistent tumor residue after a T1a renal cryoablation procedure were assessed. A total of 25 patients underwent cryoablation for 26 T1a renal tumors with a median tumor size of 25.3 mm (20 to 30.7 mm) and a median RENAL nephrometry score, indicating tumor complexity, of 7 (5 to 9).

The main findings of the study were as follows:

- Disease-free survival rate was 92% (23 out of 25) at a median follow-up of 26 and a half months.
- Recurrent lesions were treated again using cryoablation, achieving a secondary local control rate of 100%.
- No patients died.
- No major complications arose.
- 92.4% of patients (N= 24) were discharged the day after surgery.

In December 2024, we announced that in our ICESECRET study of cryoablation for patients with small renal masses who cannot be offered kidney preserving surgery, there was an 88.7% recurrence-free rate. In 91 patients, 82% of the patient group, no tumor recurrence was observed. Following an additional cryoablation for the same tumor in 13 patients, the success rate was 83.8%, with a mean follow-up time of 39.6 months. In patients without a history of kidney cancer with one tumor of less than 3cm, the success rate was 88.7%. Renal function was preserved with no significant change in creatinine and hemoglobin levels relative to the baseline.

Endometriosis

In April 2023, we announced that our ProSense system was used in a single-site study conducted at the Sorbonne University Department of Interventional Radiology and Oncology at Tenon Hospital in Paris. The study was conducted by Francois H. Cornelis, MD.

Cryoprobes used in the study were of two types: our ProSense CryoProbe and Varian's V-probe. The purpose of the study was to retrospectively evaluate the pain-free survival of percutaneous (minimally invasive, through the skin) image-guided cryoablation of symptomatic extraperitoneal endometriosis, or the EE. 42 patients with a total of 47 lesions were treated. Patients were made aware that cryoablation was offered as a minimally invasive alternative to surgery, and that a surgical procedure may be performed if cryoablation failed. According to the published study, the therapeutic options thus far to avoid the progression of endometriosis and reduce symptoms have been limited to hormonal agents and wide surgical excision. During the last decades, minimally invasive techniques such as cryoablation have been suggested as a promising option to treat abdominal wall endometriosis with satisfactory outcomes and low morbidity.

Based on the following study outcome data, the study concluded that percutaneous cryoablation is a safe and effective procedure that significantly reduces pain and obtains local control of EE. The median follow-up was 13.5 months after cryoablation. The study's conclusions included:

- Efficacy rate of cryoablation to avoid secondary surgery was 92.8% per patient and 93.6% per nodule treated.
- Median pain-free survival rates were 93.75% at 6 months and 82.72% after 12 months, 24 months, and 36 months.
- Pain decreased from a median of 8/10 on the visual analogue scale to 0/10 at the last follow-up ($P < 0.0001$).
- 4 patients had an adverse event in the days following the procedure, 1 patient had a severe adverse event.

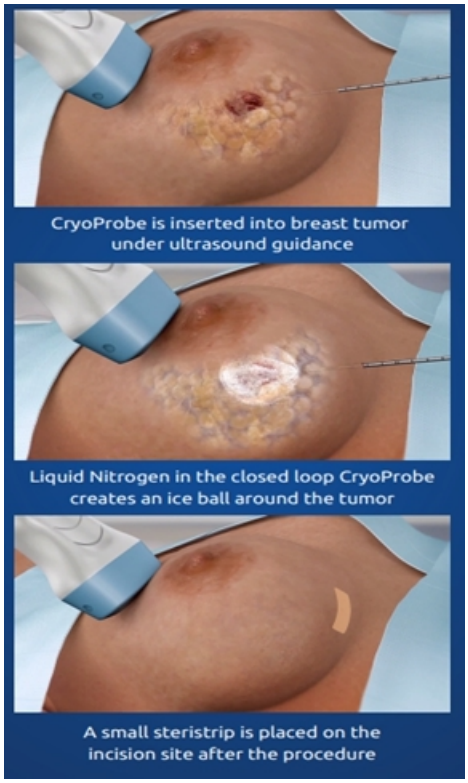
On February 29, 2024, results from an independent study conducted at University Hospital, Nimes, titled "Beyond Pain: Cryoablation of Endometriotic Nodules Using Liquid Nitrogen" were presented at the European Congress of Radiology. Seven women, between the ages of 30-45, with endometriosis in the abdominal wall and para-diaphragmatic areas were treated with ProSense cryoablation. MRI assessments, one month following the procedures, showed that hemorrhagic signals had been eliminated from and that necrotic changes developed.

Our Products

Existing Products

Our ProSense system is our second-generation cryoablation system comprised of two main parts, the main cryoablation system, our unique disposable probe, and the associated disposable introducer (guiding needle), which is used for procedures which are not in the breast. Our first product, the IceSense3 was initially designed for cryoablation of breast tumors. After identifying a number of additional possible applications for the use of our technology, such as treating lungs, kidneys, bones and other possible applications, in 2016 we launched our ProSense system as well as associated disposables (which, as shown below, are inserted into the body to conduct the freezing process). Currently, we sell ProSense in all territories in which we have regulatory approval, with the exception of China where we sell the IceSense3. In 2024, we completed the development stage of our XSense system, a more advanced system that may potentially enable the use of thinner cryoprobes and flexible probes (catheters). These capabilities may potentially enable us to expand into clinical applications such as atrial fibrillation, renal denervation and the cryoablation of pancreatic cancer through further regulatory approvals.

The following illustration demonstrates the course of the cryoablation procedure with our ProSense system in an ultrasound of the breast:



Research and Development

We are currently commercializing our single probe ProSense system and its disposables and have completed the development of our XSense system. In addition, we are also focusing on developing our next generation MSense system. We started development of our first-generation system for technical proof concept process and evaluation of clinical application in 2006. In the beginning of 2009, we started to develop our IceSense3 system, which was later improved and replaced by the ProSense. Both the IceSense3 and ProSense are commercially available systems which include technical modifications to our first-generation system in order to perform clinical procedures. We started developing what was previously known as the MultiSense system in 2016, but did not commercialize it. As of March 24, 2025, we are in the initial stages of developing the MSense.

We intend to commercialize our next generation systems, which will be our third-generation systems, subject to regulatory approvals. Our strategy is to make our next generation systems more capable, efficient and user-friendly in several aspects. The physical size of the system will have a smaller footprint, which is an important factor in CT rooms and clinics. Since our next generation MSense system will have more than one probe, it will have freezing capabilities that both our current and next generation systems do not have, such as the ability to treat regular-sized or larger tumors in more than one location simultaneously. We believe that our next generation MSense system will help us to increase our ability to penetrate the non-breast tumors market more easily and allow us to offer a more innovative product.

In the United States, we received 510(k) clearance for the XSense system with CryoProbes in June 2024 for all the indications for which ProSense has already received the requisite FDA clearance. We currently expect to submit an application for Medical Device Regulation, or MDR, approval of the XSense system with CryoProbes by the first quarter of 2026. We expect that we will submit an application to the FDA and MDR for regulatory clearance of our MSense system in 2029. Even if we complete development as planned, we do not yet know if and when we will begin to commercialize these systems or whether commercialization of such systems will lead to us generating increased revenue.

Regulatory Approvals

We have received a broad range of regulatory approvals for ProSense in the United States, Canada, Europe, China (IceSense3 system and CryoProbes only), Singapore, Hong Kong, Mexico, Australia, Israel, Colombia, Costa Rica, India (only for disposables (see "– *India*" below for additional information), Thailand, Russia, South Africa, Taiwan, Brazil and Israel. Moreover, we are pursuing additional regulatory approvals in other indications in existing countries and in other countries where we believe that there is significant potential for sales. For example, we have made submissions for regulatory approval in China (for our ProSense system, which is an upgrade to the already approved IceSense3) and the United States (for specific approval for breast cancer).

We market our ProSense for a specific indication per the rules and medical device classification in the specific territory.

United States

In the United States, we received from the FDA 510(k) clearance for our IceSense3, ProSense and MultiSense and the related disposables. On December 10, 2007, we received initial 510(k) clearance for our IceSense3 system for ablation indications specific to urology, oncology, dermatology, gynecology, general surgery, thoracic surgery and proctology. On November 29, 2010, we received 510(k) clearance for our IceSense3 system for the ablation of breast fibroadenomas under general surgery. On December 20, 2019, we received 510(k) clearance to allow us to market and sell our IceCure family (which includes Icesense3, ProSense and MultiSense) systems for the treatment of breast fibroadenomas, prostate and kidney tissue, liver metastases, tumors, skin lesions, and other indications, and treat our products as "one family of products," which means that any additional approval given by the FDA in relation to the family of products will apply automatically to the "family" as one product, without the need for FDA approval for each separate system; provided, however, that we expect to require individual approvals for our products from the FDA if we seek marketing approval for a new specific indication, as is the case for the use of these products for breast cancer.

On December 31, 2020, we submitted a pre-submission package to the FDA for approval of breast cancer indication, based on our ICE3 trial interim results for our IceCure family systems. As part of the pre-submission package, we requested that we receive approval for this indication through the 510(k) submission pathway or De Novo classification. There can be no guarantee that the FDA approves the use of any of our products for the treatment of this indication, and an approval could be given on a narrower indication than requested, or, even if approval is given to market our products, there can be no guarantee that the approval is given via the 510(k) pathway or De Novo classification, which could result in additional costs and a longer timeline until we receive any such approval. If we do not receive approval via the 510(k) pathway or De Novo classification, we may seek to receive a PMA (see "*Item 4.B. Business Overview– Government Regulation – PMA Pathway*" for additional information).

On March 31, 2021, we were granted Breakthrough Device Designation, or BDD, from the FDA for our ProSense system, for treatment for various indications, including for use in the treatment of patients with T1 invasive breast cancer and/or patients not suitable for surgical alternatives for the treatment of breast cancer.

In addition, on November 24, 2021, we submitted a pre-submission package to the FDA in which we proposed an intended use for early-stage breast cancer and high risk to surgery for our ProSense system and requested a De Novo classification. Since we were granted BDD for our ProSense system, the pre-submission package included a request for a sprint discussion under FDA procedures.

On October 18, 2022, we submitted a De Novo Classification Request regulatory filing with the FDA for marketing authorization based on our ICE3 clinical trial interim analysis of ProSense for the indication of early-stage (Luminal A T1 invasive) low-risk breast cancer in patients who are at high risk to surgery (not suitable for surgical alternatives), representing approximately 43,000 women in the United States annually. The specific indication filed is based on interim data from our ICE3 trial and is in accordance with discussions we have had with the FDA, which granted ProSense BDD on March 31, 2021, enabling closer communications regarding our regulatory filing.

On November 1, 2022, the CMS assigned payment to our ProSense breast cancer cryoablation procedures. The procedures were assigned as CPT Category III code 0581T to ambulatory payment classification 5091, Level 1 Breast/Lymphatic Surgery and Related Procedures. This payment assignment for the procedure went into effect on January 1, 2023, opening the potential for facilities to be paid, on a case-by-case basis, for these procedures subject to our receipt of FDA marketing authorization of ProSense for breast cancer. Under the temporary CPT Category III code, the ProSense procedure is priced for coverage by the CMS at approximately $3,800 for the facility fee alone. Additional coverage, including payment for the physician, is expected upon establishment of the permanent CPT Category I code, which is conditioned on several factors including our receipt of FDA marketing authorization of ProSense for breast cancer, the decision about which is expected after the first quarter of 2025.

Canada

In July 2023 we announced that Health Canada, the Canadian government's regulatory agency, approved IceCure's ProSense System, disposable CryoProbes, and introducers as cryosurgical tools for indications including: tumors (ablation of benign and malignant tumors of the lung, liver, kidneys, and musculoskeletal system, and benign tumors of the breast); general surgery; palliative intervention; and other surgeries.

Europe

In Europe, we received Conformitè Europëenne, or CE, mark approval for our ProSense cryoablation system and its disposables with indications for use as a cryosurgical tool in the fields of general surgery, dermatology, thoracic surgery, gynecology, oncology, proctology and urology, which enable us to sell our ProSense in order to perform procedures in the indications we aim to such as breast cancer, Kidney, lung, bone and other indications.

Russia

In 2020, we received regulatory approvals to market and distribute ProSense and disposables in Russia for use of our products in the treatment of benign and cancerous tumor cells through freezing in a number of organs, such as kidneys, lungs, liver and bones.

Asia and Africa

In Singapore, Hong Kong and South Africa, our ProSense system has specific approval for cryoablation of benign and malignant tumors in the breast, lung, bone and liver.

China

In China, the IceSense3 system has NMPA approval. We have received an additional five-year renewal up to June 3, 2026. On March 28, 2023, we announced that the NMPA approved our IceSense3 disposable CryoProbes for commercial use, to be used in combination with our IceSense3 system. This approval will allow us to sell our disposable IceSense3 CryoProbes for commercial procedures. In January 2025, we filed a submission for regulatory approval of our ProSense and CryoProbes in China with the NMPA.

Japan

In Japan, our ProSense and disposables are not yet approved by the Japanese regulatory authority, the Pharmaceuticals and Medical Devices Agency, or PMDA. We started to sell our products in Japan as "experimental products" under "private doctor importation" licenses in low quantities. Currently, without approval from the PMDA, we are only able to sell a limited number of ProSense systems and disposables under "private doctor importation" licenses. Following our distribution agreement with Terumo, Terumo will be responsible and bare all costs of obtaining regulatory approval for breast cancer from the PMDA to sell our products in Japan. We expect that Terumo will submit a regulatory request for breast cancer indication for our ProSense system in the second half of 2025.

Thailand

In Thailand, our products have the Ministry of Public Health approval for our ProSense system and associated disposables to treat malignant breast tumors and other intended uses.

Israel

In Israel, we have received AMAR authorization for use of our freezing technology for freezing of benign and malignant tumors, including and among others, breast, lungs, bones, kidney and other indications which enables us to market our products and will allow doctors in Israel to use our product for those indications listed above. We filed a submission for regulatory approval for our XSense system with CryoProbes with AMAR in February 2025.

Taiwan

In 2020, we received regulatory approvals to market and distribute ProSense and disposables in Taiwan for use of our products in the treatment of benign and cancerous tumor cells through freezing in a number of organs, such as kidneys, lungs, liver and bones.

India

In 2020, we received regulatory approval to commercialize our disposables in India, where our systems themselves do not require regulatory approval before commercialization. In February 2020 we received regulatory approval in India for our CryoProbes. In November 2023, CDSCO granted approval for our ProSense System.

Brazil

In 2023 we announced that our ProSense System received regulatory approval as a Class III device from the Brazilian Health Regulatory Agency, or ANVISA. Applications for both the ProSense System and its disposable CryoProbes and introducers were submitted to ANVISA by IceCure's distributor in Brazil, Ktrfios Importação e Exportação LTDA, or Ktrfios.

ProSense's indications approved by ANVISA are oncology, which includes the ablation of benign and malignant tissues in the breast, prostate, kidney, lung, liver, musculoskeletal, and skin tissue, as well as for palliative intervention and other indications. Healthcare providers are cleared to conduct procedures with ProSense, its introducers and disposable probes, and Ktrfios is cleared to both market and sell ProSense's introducers and disposable probes. ANVISA has requested that the CryoProbes also be submitted by Ktfrios for regulatory approval as a Class III device. The introducers remain a Class II device and do not require an additional regulatory submission. The probes received Class III device clearance in April 2024.

Mexico

Our ProSense system has regulatory approval from the Comisión Federal para la Protección contra Riesgos Sanitarios in Mexico. We are in the process of applying for a renewal of regulatory approval for our disposables in Mexico.

Commercialization

We began selling our IceSense3 and disposable probes in small quantities, for cryoablation of fibroadenoma in the United States in 2011. As of 2012, we began selling all of our products (IceSense3, ProSense and disposables) in the United States and other countries, with sales generated primarily by our sponsored ICE3 trial and independent clinical trials not sponsored by us. Following limited commercialization efforts that took place during our research and development phase, in 2018 and 2019, we started to increase our commercial efforts to sell our products to distributors and end users in the United States, Europe and Asia. Since then, we continued our commercialization efforts and intend to continue to commercialize our products during 2025 and beyond.

As part of our strategy of raising awareness for our products and proprietary technologies within the medical community, although no formal agreement exists, in light of the ASBrS's importance in our industry, we are operating in the United States with them as the leading organization and also with other organizations, such as the SIR, SIO, Society of Breast Imaging, and others that sets guidelines for breast cancer treatment. We are also continually seeking to collaborate with key opinion leaders in additional territories such as China, Italy, France, Spain, India, Brazil, Thailand, Hong Kong, Japan and Germany in order to create awareness and collect clinical evidence for our technology in such territories.

Our customers in the United States are hospitals, interventional radiological centers, ambulatory centers and private clinics that purchase, lease or loan the ProSense system and buy the disposables directly from us. In certain instances, we place our ProSense system in hospitals and clinics and our customers in turn commit to purchasing a minimum number of probes per year for an extended period. In other territories, excluding Japan, where we sell directly to medical facilities, we sell our products to distributors who sell medical products and procedures in our field of activity. The primary users of our products are breast surgeons, breast radiologists, and interventional radiologists. As we sell and place more cryoablation systems, we anticipate the volume of sales of our probes will materially increase as we engage in a razor/razor blades sales model (see "*Item 4.B. Business Overview – Revenues and Growth Strategy*" for additional information).

We currently have distribution agreements in Japan, Mainland China, Italy, France, Spain, Hong Kong, Taiwan, Poland, Turkey, India, Brazil, Portugal, Romania and other countries. We are reviewing new opportunities for collaboration with distributors in Germany as well. Below are the countries where we currently have distribution agreements.

United States

In the United States, we are working with leading breast surgeons and breast radiologists in order to initiate collaborations in the field of freezing malignant breast tumors. At the Radiological Society of North America, or RSNA, conference held in 2018, our freezing technology was declared one of 15 groundbreaking solutions in this field. In 2021 and 2022, our technology was also presented at the RSNA conference. Specifically, in 2021, interim data from the ICE3 clinical trial was presented and selected to be featured in a daily bulletin by RSNA. At the 2022 conference, the ProSense was featured in a poster presentation titled "To Freeze Or Not To Freeze? That Is The Question: Cryoablation For The Treatment Of Breast Cancer" by Kenneth Tomkovich, MD, Co-Primary investigator for IceCure's ICE3 clinical trial, and Diagnostic and Interventional Radiologist with Princeton Radiology, CentraState Medical Center, and Penn Princeton Medical Center in Princeton, New Jersey. In the United States, unlike in other territories, as described below, we are entering a consolidated market and, in addition to our existing growth strategy, we will need to refine our marketing approach in order to generate significant revenue.

In addition to our distribution agreements and other aspects of our product revenues and growth strategies, as described below, commercialization of our products is also highly dependent on the receipt of Current Procedural Terminology, or CPT, characterization in the United States. On July 2, 2019, our application for a CPT category III codes (0581T) describing the use of cryoablation for treating cancerous breast tumors was approved by the American Medical Association. On November 1, 2022, the CMS assigned payment to our ProSense breast cancer cryoablation procedures. The procedures were assigned as CPT Category III code 0581T to ambulatory payment classification 5091, Level 1 Breast/Lymphatic Surgery and Related Procedures. This payment assignment for the procedure went into effect on January 1, 2023, opening the potential for facilities to be paid, on a case-by-case basis, for these procedures subject to our receipt of FDA marketing authorization of ProSense for breast cancer. Under the temporary CPT Category III code, the ProSense procedure is priced for coverage by the CMS at approximately $3,800 for the facility fee alone. Additional coverage, including payment for the physician, is expected upon establishment of the permanent CPT Category I code, which is conditioned on several factors including our receipt of FDA marketing authorization of ProSense for breast cancer. We intend to pursue additional CPT category one, or CAT I, codes for breast cancer cryoablation, which is required in order to make procedures with our products eligible for reimbursement from insurance companies in the United States. Even if we are successful in obtaining approval for our products for entry into additional CPT I category codes, these changes generally take over 24 months to go into effect, usually at the start of a new calendar year.

In order to cause our products to receive entry into additional CPT I categories, we intend to work with the ASBrS and conduct registry trials to collect additional data that we believe will support the use of our system and technology as a viable treatment option for breast cancer. We believe that by conducting such trials and collecting such data, which will result in increased use of our products, and potentially additional publications regarding their use, the ASBrS may amend its guidelines and to enable our treatment system to receive CPT I approval, which could enable medical providers to receive appropriate reimbursement for treatment through our systems. At this time, it is unlikely that our ProSense (or any future system) will be eligible for rebates from insurance companies and other third-party payers without specific regulatory approvals for specific indications. Specific indications such as kidney cancer, liver cancer, bone tumors (under cryoanalgesia) have CPT I codes and reimbursement in a level of US$ 5,000-$9,000 per case. At this time, we have yet to initiate any marketing efforts for these indications.

Terumo Japan

In August 2019, we entered into an exclusive distribution agreement, or the Terumo Japan Agreement, for licensing, registration, import, marketing, sale, promotion and distribution of our ProSense system and its disposable products with breast tumors, with a leading global medical company, Terumo Corporation, or Terumo, in Japan and Singapore; provided, however, that with respect to the exclusivity clause, (i) we shall continue to have the ability to sell our system and disposables in Japan until Terumo obtains regulatory permit for marketing and distribution of our ProSense system and (ii) notwithstanding the foregoing, the exclusivity condition shall continue in force only for so long as Terumo purchases a minimum agreed upon number of products during the term of the Terumo Japan Agreement. We believe that the Terumo Japan Agreement will accelerate the commercialization of our ProSense system and associated disposables to treat malignant breast tumors in Japan and Singapore. The Terumo Japan Agreement requires Terumo to obtain necessary regulatory permits for marketing and distribution in Japan and obtaining reimbursement approvals. In Singapore, we have received the applicable regulatory approvals for our products; however, in February 2023, Termuo notified us that they suspended their distribution activities in Singapore with effect from March 31, 2023.

The Terumo Japan Agreement is for an initial term of five years from the date of receipt of regulatory approvals for the sale of the Company's products in Japan and is automatically extended for additional terms of five years each, unless a party notifies the other party of its intention to terminate the Terumo Japan Agreement at least one year prior to the end of the term, or at any time upon the mutual agreement of the parties in writing. A party shall have the right to terminate the Terumo Japan Agreement upon a breach of a material provision of the Terumo Japan Agreement by the other party or upon the insolvency of such other party, subject to certain conditions. In addition, the Terumo Japan Agreement may be terminated by either party under certain terms, including the option of revocation by the Company if Terumo does not purchase at least 60% of the minimum quantities defined in the Terumo Japan Agreement for the purchase of products and if Terumo fails to obtain the regulatory approvals on the dates stipulated in the Terumo Japan Agreement. In some cases, upon revocation or termination of the agreement, Terumo will assign to the Company the regulatory filings and regulatory approvals for the marketing and distribution of the ProSense system in Japan.

The minimum aggregate consideration that Terumo owes us under the Terumo Japan Agreement is approximately $13.2 million, of which, as of the date of this annual report on Form 20-F, we have received $4 million as proceeds for distribution rights, knowledge sharing, the first purchase order, and another $623 thousand for the sale of our products and services. Our revenues pursuant to the Terumo Japan Agreement amounted to $547 thousand in 2022, $274 thousand in 2023, and $0 in 2024.

Terumo Thailand

In December 2020, we entered into an exclusive distribution agreement with Terumo Thailand (an affiliate of Terumo), or the Terumo Thailand Agreement, for licensing, registration, import, marketing, sale, promotion and distribution of ProSense system and its disposables, in Thailand. The exclusivity condition shall continue in force only for so long as Terumo Thailand purchases a minimum agreed upon number of products during the term of the agreement. The distribution agreement is intended to accelerate the commercialization of our ProSense system and associated disposables to treat malignant and benign tumors in the breast, kidney, lung and other applications in Thailand. The agreement requires Terumo Thailand to obtain necessary regulatory permit for marketing and distribution in Thailand.

The Terumo Thailand Agreement is for an initial term of six years and is automatically extended for additional terms of six years each, unless a party notifies the other party of its intention to terminate the Terumo Thailand Agreement at least one year prior to the end of the term, or at any time upon the mutual agreement of the parties in writing. A party shall have the right to terminate the Terumo Thailand Agreement upon a breach of a material provision of the Terumo Thailand Agreement by the other party or upon the insolvency of such other party, subject to certain conditions. In addition, the Terumo Thailand Agreement may be terminated by either party under certain terms, including the option of revocation by the Company if Terumo does not purchase at least 60% of the minimum quantities defined in the Terumo Thailand Agreement for the purchase of products, and the option of revocation by Terumo Thailand if the Company discontinues its business relating to the ProSense system and its disposables or does not bring action with respect to an infringement of the exclusive distribution right within a reasonable time frame.

To date, we have received up-front payments in a total aggregate amount of $450,000 under the Terumo Thailand Agreement. The minimal aggregate consideration that Terumo Thailand owes us under the agreement is approximately $7.2 million, of which $450,000 is to be paid in three equal installments of $150,000 for the sole distribution rights, transferring the regulatory approval from our regulatory agent to Terumo Thailand and knowledge sharing and $329,000 for the first purchase order. In 2021, we received $498,000 in furtherance of the first purchase order. In 2023 and 2024 we received $14,000 and $11,000 in orders, respectively. As of March 24, 2025, Terumo Thailand has not purchased the minimum quantities pursuant to the Terumo Thailand Agreement. We are currently evaluating our commercial activities in Thailand.

Mainland China

On June 12, 2022, we signed an exclusive distribution agreement for the IceSense3 and disposable probes with Shanghai Medtronic Zhikang and Beijing Turing. Pursuant to the agreement, Shanghai Medtronic Zhikang would be the exclusive distributor of the IceSense3 and its disposable probes in mainland China for an initial period of three years, with minimum purchase targets of $3.5 million for this period. Additionally, in mainland China, Shanghai Medtronic Zhikang would not directly or indirectly invest or deal in, market, sell, promote or provide services to any product that competes with the IceSense3, during the term of the distribution agreement and for a period of six (6) months thereafter. These limitations on Shanghai Medtronic Zhikang would be limited to cryoablation and have no impact on existing or self-developed ablation treatments of Medtronic or any affiliate entity of Medtronic and/or on any country outside China. While Shanghai Medtronic Zhikang would conduct all marketing, sales, and certain professional training, Beijing Turing would be responsible for the import, installation, and after-sales service of IceSense3 systems in mainland China.

As of March 24, 2025, Shanghai Medtronic Zhikang is unlikely to fulfil its minimum purchase target of $3.5 million by April 30, 2025 and it will no longer possess the right to extend the term of the distribution agreement for three consecutive years. We are evaluating the distribution agreement in light of our commercial relationship with Shanghai Medtronic Zhikang. We currently sell our products in China through Beijing Turing.

Furthermore, under the distribution agreement's terms, we will be responsible for obtaining and maintaining any and all regulatory approvals in mainland China required for marketing, promotion, distribution, sale and use of the products issued by the NMPA, its local branches or any other government authorities. We have already obtained regulatory approvals for the IceSense3 system and for the disposable IceSense3 CryoProbes for commercial procedures. In January 2025, we filed a submission for regulatory approval of ProSense and CryoProbes in China with the NMPA.

India

As of March 24, 2025, we have two distribution partners in India, Novomed Ltd covering Maharashtra and EMT Electronics Manufacturing Technologies Ltd covering certain states in the south region of India. Our ProSense system is installed at Tata Medical Center in Mumbai, a renowned hospital for oncology in India.

Brazil

In June 2021, we entered into an exclusive distribution agreement for the sale, marketing and distribution of our products in Brazil with Ktrfios. With ANVISA regulatory approval granted in October 2023, we are collaborating with key hospitals with a view to expanding the use of our technology in Brazil.

Intellectual Property

Our intellectual property portfolio consists of 54 issued patents (16 in the United States, 22 in Europe, 5 in Great Britain, 6 in China, 4 in Japan, and 1 in Hong Kong), as further detailed in the table below.

Patent No.	Application No.	Title	Type of Patent Application	Type of Patent Protection	Expiration Date	Country	PCT No.
7967815	12/731,219	Cryosurgical Instrument with Enhanced Heat Transfer	Utility patent	Machine	03/25/2030	US	PCT/US2011/025663
102378600	201180000141.8		Utility patent	Machine	02/22/2031	China	
EP2549941	2549941		Utility patent	Machine	02/22/2031	Great Britain	
	2549941		Utility patent	Machine	02/22/2031	France	
	602011054052.1		Utility patent	Machine	02/22/2031	Germany	
	502019000004651		Utility patent	Machine	02/22/2031	Italy	
7967814	12/700,761	Cryoprobe with Vibrating Mechanism	Utility patent	Machine	02/05/2029	US	N/A
8162812	12/722,845	Combined Cryotherapy and Brachytherapy Device and Method	Utility patent	Machine and Process	03/12/2029	US	N/A

7938822	12/778,172	Heating and Cooling of Cryosurgical Instrument Using a Single Cryogen	Utility patent	Machine	05/12/2030	US	PCT/US2011/031722
103079487	201180022782.3		Utility patent	Machine	04/08/2031	China	
EP2533716	2533716		Utility patent	Machine	04/08/2031	Great Britain	
	2533716		Utility patent	Machine	04/08/2031	France	
	602011018919.0		Utility patent	Machine	04/08/2031	Germany	
	502015000073978		Utility patent	Machine	04/08/2031	Italy	
8080005	12/846,047	Closed Loop Cryosurgical Pressure and Flow Regulated System	Utility patent	Machine	06/10/2030	US	N/A
103096824	201180043677.8	Cryosurgical Instrument for Treating Large Volume of Tissue	Utility patent	Machine	09/01/2031	China	PCT/US2011/050214
EP2593028	2593028		Utility patent	Machine	09/01/2031	France	
	602011040633.7		Utility patent	Machine	09/01/2031	Germany	
8591505	13/339,506	Cryosurgical Instrument with Redirected Flow	Utility patent	Machine	05/19/2031	US	PCT/US2011/067858
103402449	201180068737.1		Utility patent	Machine	12/29/2031	China	
EP2683315	2683315		Utility patent	Machine	12/29/2031	Great Britain	
	2683315		Utility patent	Machine	12/29/2031	France	
	602011031296.0		Utility patent	Machine	12/29/2031	Germany	
	502016000113273		Utility patent	Machine	12/29/2031	Italy	
7425211	11/462,244	Cryogenic Probe for Treating Large Volume of Tissue	Utility patent	Machine	11/24/2026	US	N/A
7803154	11/832,778	Cryogenic Probe for Treating Large Volume of Tissue	Utility patent	Machine	11/24/2026	US	N/A
8709005	13/232,203	Coiled Heat Exchanger for Cryosurgical Instrument	Utility patent	Machine	12/10/2031	US	PCT/US2011/051529
103442657	201180069176.7		Utility patent	Machine	09/14/2031	China	
1190057	14103188.0		Utility patent	Machine	09/14/2031	Hong Kong	
EP2696785	2696785		Utility patent	Machine	09/14/2031	Great Britain	
	2696785		Utility patent	Machine	09/14/2031	France	
	602011031962.0		Utility patent	Machine	09/14/2031	Germany	
	502016000122670		Utility patent	Machine	09/14/2031	Italy	
9050075	14/133980		Utility patent	Machine	05/11/2031	US	

8906004	14/204,175	Coiled Heat Exchanger for Cryosurgical Instrument	Utility patent	Machine	05/11/2031	US	N/A
9808302	15/125,258	Phase Separation of Cryogen in Cryosurgical Instrument	Utility patent	Machine and Process	05/11/2031	US	PCT/US2014/064292
9039689	14/547,483	Phase Separation of Cryogen in Cryosurgical Instrument	Utility patent	Machine	01/28/2026	US	N/A
11633224	16-785,686	Cryogen Pump	Utility patent	Machine and process	06/26/2041	US	N/A
7219498	2021-12530	Cryogen Pump	Utility patent	Machine and process	01/13/2041	Japan	N/A
	21151413.8	Cryogen Pump	Utility patent	Machine and process	1/13/2041	Europe	N/A
	21151413.8	Cryogen Pump	Utility patent	Machine and process	1/13/2041	France	N/A
	21151413.8	Cryogen Pump	Utility patent	Machine and process	1/13/2041	Germany	N/A
	21151413.8	Cryogen Pump	Utility patent	Machine and process	1/13/2041	Italy	N/A
EP3868320							
	21151413.8	Cryogen Pump	Utility patent	Machine and process	1/13/2041	Switzerland	N/A
	21151413.8	Cryogen Pump	Utility patent	Machine and process	1/13/2041	The Netherlands	N/A
	21151413.8	Cryogen Pump	Utility patent	Machine and process	1/13/2041	Turkey	N/A
	21151413.8	Cryogen Pump	Utility patent	Machine and process	1/13/2041	UK	N/A
ES2919851T3	21151413.8	Cryogen Pump	Utility patent	Machine and process	1/13/2041	Spain	N/A
7465002	2022-91916	Cryogen flow control	Utility patent	Machine and process	06/06/2042	Japan	N/A
12167880		Cryogen Pump	Utility patent	Machine and process	17/02/2040	U.S.	N/A
12215811	17/866-614	Cryogenic System Connector	Utility patent	Machine and process	25/09/2042	U.S.	N/A
7612237	2023115854	Cryogenic System Connector	Utility patent	Machine and process	7/14/2043	Japan	N/A
7612233	23088275A	Cryogenic System with Multiple Immersion Pumps	Utility patent	Machine and process	30/05/2043	Japan	N/A
113243983	202110145919	Cryogen Pump	Utility patent	Machine and process	17/02/2040	China	N/A

Our intellectual property covers our technological platform, as well as innovative developments that will be used in our future products. Our patent number 8083733 relating to cryosurgical instrument with enhanced heat exchange expired in 2019 and our patents number 7137978, 7481806 and 7731711, relating to Cryosurgical instrument and its accessory system, expired in 2023. These patents are not currently used by us for the development of our current and future technology and products and the expiry has not affected our business.

In addition, to our patent portfolio, we have the following issued trademarks. We also have a number of other trademarks in the United Kingdom that we intend on abandoning.

Registration No.	Application No.	Expiration Date	Country	Mark	Renewal Due Date
4063706	77/615,741	N/A	US	ICECURE®	11/29/2030 (20 year)
4146269	85/430,438	N/A	US	ICECURE LOGO	05/22/2031 (20 year)
017884253	04/04/2018	N/A	Europe	ICECURE LOGO	04/04/2028 (10 year)
5251758	86/790,477	N/A	US	PROSENSE®	07/25/2026 (5 year)
017884265	17884265	N/A	Europe	PROSENSE®	04/04/2028 (10 year)
27566828	27566828	N/A	China	PROSENSE	02/06/2029 (10 year)
27566823	27566823	N/A	China	PROSENSE (CHINESE)	11/13/2027 (10 year)
010241305	010241305	N/A	Europe	ICECURE	09/05/2031 (10 year)
010241297	010241297	N/A	Europe	ICESENSE3	09/05/2031 (10 year)
010241263	010241263	N/A	Europe	ICESENSE	09/05/2031 (10 year)
018042365	018042365	N/A	Europe	ICECURE (NEW LOGO)	03/28/2029 (10 year)
6301784	2019-125291	N/A	Japan	PROSENSE	10/08/2030 (10 year)
6301783	2019-125290	N/A	Japan	ICECURE (ENGLISH)	10/08/2030 (10 year)
6301782	2019-125289	N/A	Japan	ICECURE (Logo)	10/08/2030 (10 year)
Allowed	90857406	N/A	US	ICECURE (New Logo)	Not yet registered
Allowed	97544323	N/A	US	XSENSE	Not yet registered
Allowed	97544323	N/A	US	MSENSE	Not yet registered
019031536	MEKW16EU	N/A	Europe	XSENSE	05/23/2034
019031469	MEKW17EU	N/A	Europe	MSENSE	05/23/2034

Production and Manufacturing

The majority of the manufacturing of the ProSense system's components is outsourced, and we complete the final assembly in our facility in Israel. The majority of the manufacturing of our disposables, including sterilization and packing is outsourced. We conduct the final inspections at our facility.

The various components of our ProSense and probes are purchased and manufactured by several vendors and subcontractors. We are engaged with approximately 90 suppliers of components for our ProSense system and its disposables. The primary suppliers for our ProSense system and disposables are Resonetics Israel LTD, J.H. Avidan LTD and Concept Group LLC.

We consistently monitor our inventory levels, manufacturing and distribution capabilities, and maintain recovery plans to address potential disruptions that we may encounter. In the future, as we scale up our sales and production further, we may implement a turnkey operation with select manufacturers for our probes.

We enter into quality agreements with our vendors and subcontractors. Pursuant to such agreements, the Company will provide the parts and raw materials and the subcontractor will provide the components and/or perform the assembly of such components and/or service in accordance with specific terms of the mutually agreed work instructions and purchase orders. The agreements define the responsibilities of each party and the regulatory and compliance requirements that apply and contain industry-standard terms and guidelines.

We entered into agreements with two contract manufacturers for the production of our XSense consoles and for the production of CryoProbes, pursuant to which the subcontractors shall be responsible for purchasing the components and raw materials, in a full turnkey model, in accordance with our specifications and work instructions. The engagements and quality agreements with these contract manufacturers set out the responsibilities of the parties and the applicable regulatory and compliance requirements and industry-standard terms and guidelines.

Competition

The medical device and tumor treatment industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Cryoablation is an alternative approach to surgically removing tumors and/or to heat ablation of tumors, such as RFA, MWA and high intensity focused ultrasound. We encounter significant competition across our product lines in each market in which we sell our products from various companies, some of which may have greater financial and marketing resources than we do. We also face competition from non-medical device companies, as pharmaceutical companies, which may offer alternative therapies and treatments. We believe that the ability of our products and services to deliver rapid minimally-invasive treatments in-office or ambulatory hospital settings serves as a key competitive advantage versus surgical and other tumor treatment solutions. In the current environment of managed care, with economically-motivated buyers, consolidation among healthcare providers, increased competition and declining reimbursement rates, we have been increasingly required to compete on the basis of price, value, reliability and efficiency, which we believe we have been able to do and hope to continue to do.

We believe that our cryoablation technology, and especially our LN2-based technology, has advantages over heat ablation technologies for breast tumors, which include, but are not limited to the below competitive advantages relative to heat ablation technologies.

- Pain: Because of the freezing effect on tissue, our procedure is less painful than heat ablation.
- Anesthesia: Due to the lower amount of pain that is generally caused by procedures from cryoablation, patients generally require less anesthesia.
- Accuracy: Image guided visualization of the cryoablation ice ball is clearer than heat ablation as the freezing does not cause evaporation, thereby allowing the cryoablation to be more accurate than thermal heat ablation. It is also safer as the boundaries of the treated area are clear under imaging with less risk of affecting healthy tissue during the ablation time.

We believe that our direct competitors for cryoablation of malignant breast tumors are Sanarus Medical, Inc. which is part of Hologic Inc., which to the best of our knowledge is not active, Galil Medical Ltd., a subsidiary of Boston Scientific Corporation and EndoCare, Inc., a subsidiary of Siemens Healthineers.

For tumors in other organs, other alternatives to surgical removal or cryoablation are available, such as thermal ablation, (including, radio frequency ablation, microwave ablation and high intensity focused ultrasound). Our primary direct competitors also include other cryoablation companies, such as Galil Medical Ltd., part of Boston Scientific Corporation, EndoCare, Inc., part of Siemens Healthineers AG, Hygea Medical Technology Co. Ltd., and Beijing Sunshine Yibang Medical Technology Co., Ltd (the latter two of which operate mainly in China) for interventional radiology. Hygea Medical Technology Co. Ltd. is a company that also uses LN2-based technology. Unlike these competitors who have a multi probe system in the market, we are still developing our MSense system. Despite this, we believe that our LN2-based cryoablation technology is superior to those of our competitors, including Galil Medical and EndoCare, for a variety of reasons, including the following:

- our cryoablation LN2 technology allows deeper freezing temperature, in the range of -50 to -170° Celsius, which results in faster and more efficient destruction of the tumor cells;
- our LN2 technology allows us to achieve lower temperatures faster, potentially leading to shorter procedures;
- our effective ablating zone for one probe is greater than that of technologies utilizing argon-based technology probes (we are able to use one probe, while argon-based technologies need more than one probe to create the same killing zone);
- Using one probe in our technology is more cost effective, less complicated, and easier to use for most physicians;
- the price of argon gas is significantly higher and less available in some territories than LN2 which makes our procedures more cost effective; and
- Argon gas is stored in a 4,500 PSI (6,000 PSI in the United States only) gas balloons, which potentially creates a risk of explosion whereas our LN2 is stored in low-pressure containers which presents less risk. The European authorities have a new directive forbidding the patient from being in the same room with Argon gas balloons for safety reasons. Argon gas supply in large balloons (70 L) requires between 2-3 balloon for an average procedure, which makes it comprehensive to handle and store. LN2 is supplied by small 2 L Dewars (for ProSense) and is easy to handle and allows for office-based procedures.

We believe that these technological advantages will enable us to compete effectively with our competitors. In addition, we believe that by completing the development, and initiating commercialization of our next generation XSense and future MSense systems will enable us to compete even more effectively with our competitors.

Government Regulation

Our products and business are subject to extensive federal, state, local and foreign laws and regulations, including those relating to the protection of the environment, health and safety and our failure to comply with applicable requirements could harm our business. Some of the pertinent laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations. In addition, these laws and their interpretations are subject to change, or new laws may be enacted.

Both federal and state governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. As indicated by work plans and reports issued by these agencies, the federal government will continue to scrutinize, among other things, the billing practices of healthcare providers and the marketing of healthcare products.

We believe that we have structured our business operations and relationships with our distributors and customers to comply with all applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert otherwise. In addition, because there is a risk that our products are used off label, we believe we are subject to increased risk of prosecution under these laws and by these entities even if we believe we are acting appropriately. We discuss below the statutes and regulations that are most relevant to our business and most frequently cited in enforcement actions.

FDA Regulation of Medical Devices

The Federal Food, Drug and Cosmetic Act, or FDCA, and FDA regulations establish a comprehensive system for the regulation of medical devices intended for human use. Our products include medical devices that are subject to these regulations, as well as other federal, state, local and foreign, laws and regulations. The FDA is responsible for enforcing the laws and regulations governing medical devices in the United States.

The FDA classifies medical devices into one of three classes (Class I, Class II, or Class III) depending on their level of risk and the types of controls that are necessary to ensure device safety and effectiveness. The class assignment is a factor in determining the type of premarketing submission or application, if any, that will be required before marketing in the United States.

- Class I devices present a low risk and are not life-sustaining or life-supporting. The majority of Class I devices are subject only to "general controls" (e.g., prohibition against adulteration and misbranding, registration and listing, good manufacturing practices, labeling, and adverse event reporting. General controls are baseline requirements that apply to all classes of medical devices.)

- Class II devices present a moderate risk and are devices for which general controls alone are not sufficient to provide a reasonable assurance of safety and effectiveness. Devices in Class II are subject to both general controls and "special controls" (e.g., special labeling, compliance with performance standards, and post market surveillance. Unless exempted, Class II devices typically require FDA clearance before marketing, through the premarket notification (510(k) process.)

- Class III devices present the highest risk. These devices generally are life-sustaining, life-supporting, or for a use that is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury. Class III devices are devices for which general controls, by themselves, are insufficient and for which there is insufficient information to determine that application of special controls would provide a reasonable assurance of safety and effectiveness. Class III devices are subject to general controls and typically require FDA approval of a premarket approval, or PMA, application before marketing.

Unless it is exempt from premarket review requirements, a medical device must receive marketing authorization from the FDA prior to being commercially marketed, distributed or sold in the United States. The most common pathways for obtaining marketing authorization are 510(k) clearance and PMA.

All of our medical device products sold in the United States are subject to regulation as medical devices under the FDCA, as implemented and enforced by the FDA. The FDA governs the following activities that we perform or that are performed on our behalf, to ensure that medical products we manufacture, promote and distribute domestically or export internationally are safe and effective for their intended uses:

- product design, preclinical and clinical development and manufacture;
- product premarket clearance and approval;
- product safety, testing, labeling and storage;
- record keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions and repair or recall of products.

510(k) Pathway

The 510(k) review process compares a new device to a legally marketed device. Through the 510(k) process, the FDA determines whether a new medical device is "substantially equivalent" to a legally marketed device (i.e., predicate device) that is not subject to PMA requirements. "Substantial equivalence" means that the proposed device has the same intended use as the predicate device, and the same or similar technological characteristics, or if there are differences in technological characteristics, the differences do not raise different questions of safety and effectiveness as compared to the predicate, and the information submitted in the 510(k) application demonstrates that the proposed device is as safe and effective as the predicate device.

To obtain 510(k) clearance, a company must submit a 510(k) application, containing sufficient information and data to demonstrate that its proposed device is substantially equivalent to a legally marketed predicate device. These data generally include non-clinical performance testing (e.g., software validation, animal testing electrical safety testing), but may also include clinical data. Typically, it takes three to twelve months for the FDA to complete its review of a 510(k) submission; however, it can take significantly longer and clearance is never assured. During its review of a 510(k) application, the FDA may request additional information, including clinical data, which may significantly prolong the review process. After completing its review of a 510(k) application, the FDA may issue an order, in the form of a letter, that finds the device to be either (i) substantially equivalent and states that the device can be marketed in the United States, or (ii) not substantially equivalent and states that device cannot be marketed in the United States. 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 requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) clearance or de novo classification, any modification that could significantly affect the safety or effectiveness of the device, or that would constitute a major change in its intended use, including significant modifications to any of our products or procedures, requires submission and clearance of a new 510(k) application or de novo classification or approval of a PMA. The FDA relies on each manufacturer to make and document this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. Modifications meeting certain conditions may be candidates for a streamlined FDA review known as Special 510(k) review, which the FDA intends to process within 30 days of receipt. If a device modification requires the submission of a 510(k) application, but the modification does not affect the intended use of the device or alter the fundamental technology of the device, then summary information that results from the design control process associated with the cleared device can serve as the basis for clearing the application. A Special 510(k) allows a manufacturer to declare conformity to design controls without providing new data. When a modification involves a change in material, the nature of the "new" material will determine whether a traditional or Special 510(k) is necessary. An Abbreviated 510(k) is another type of 510(k) process that is intended to streamline the review of data through the reliance on one or more FDA-recognized consensus standards, special controls established by regulation, or FDA guidance documents. In most cases, an Abbreviated 510(k) includes one or more declarations of conformity to an FDA-recognized consensus standard. We may also make minor product enhancements that we believe do not require new 510(k) clearances. If the FDA disagrees with our determination regarding whether a new 510(k) clearance was required for these modifications, we may need to cease marketing and/or recall the modified device. The FDA may also subject us to other enforcement actions, including, but not limited to, issuing a warning letter or untitled letter to us, seizing our products, imposing civil penalties, or initiating criminal prosecution.

De Novo Pathway

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified as Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification procedure. This procedure allows a manufacturer whose novel device is automatically classified as Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in July 2012, a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the de novo classification pathway by permitting manufacturers to request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. We originally obtained marketing authorization for our system using the de novo classification process after receiving a not substantially equivalent determination following the submission of a 510(k) premarket notification. We have subsequently used the 510(k) clearance process to obtain authorization from the FDA for changes to our marketed system.

PMA Pathway

Unlike the comparative standard of the 510(k) pathway and the De Novo Pathway, the PMA process requires an independent demonstration of the safety and effectiveness of a device. PMA is the most stringent type of device marketing application required by the FDA. PMA is based on a determination by the FDA that the PMA contains sufficient valid scientific evidence to ensure that the device is safe and effective for its intended use(s). A PMA application generally includes extensive information about the device including the results of clinical testing conducted on the device and a detailed description of the manufacturing process.

After a PMA application is accepted for review, the FDA begins an in-depth review of the submitted information. FDA regulations provide 180 days to review the PMA and make a determination; however, in reality, the review time is normally longer (e.g., one to three years). During this review period, the FDA may request additional information or clarification of information already provided. In addition, during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the data supporting the application and provide recommendations to the FDA as to whether the data provide a reasonable assurance that the device is safe and effective for its intended use. The FDA generally will conduct a preapproval inspection of the manufacturing facility to ensure compliance with Quality System Regulation, or QSR, which imposes comprehensive development, testing, control, documentation and other quality assurance requirements for the design and manufacturing of a medical device.

Based on its review, the FDA may (i) issue an order approving the PMA, (ii) issue a letter stating the PMA is "approvable" (e.g., minor additional information is needed), (iii) issue a letter stating the PMA is "not approvable," or (iv) issue an order denying PMA. A company may not market a device subject to PMA review until the FDA issues an order approving the PMA. As part of a PMA, the FDA may impose post-approval conditions intended to ensure the continued safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution, and requiring the collection of additional clinical data. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including withdrawal of the approval.

Most modifications to a device having completed PMA, including changes to the design, labeling, or manufacturing process, require prior approval before being implemented. Prior approval is obtained through submission of a PMA supplement. The type of information required to support a PMA supplement and the FDA's time for review of a PMA supplement vary depending on the nature of the modification.

Breakthrough Devices Program

The goal of the BDP is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the FDA's mission to protect and promote public health.

The Breakthrough Devices Program offers manufacturers an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission.

On November 15, 2021, the CMS announced the repeal of a proposed rule that would have provided a new Medicare coverage pathway in efforts to bring new and innovative technologies to beneficiaries sooner, start the process of accelerating the coverage of new, innovative breakthrough devices to Medicare beneficiaries and provide a four-year provisional reimbursement coverage period. We are working to understand current Medicare requirements and polices for coverage, coding and payment of breakthrough devices and how our ProSense system will be treated as a result of this rule repeal. CMS has stated that they are considering other coverage pathways for breakthrough devices, however no timeline for such other pathways has been announced. We expect that we will still be required to apply for CPT I codes under regular approval procedures in order to receive reimbursement.

Clinical Trials

A clinical trial is typically required to support a PMA application or de novo classification, and is sometimes required for a 510(k) pre-market notification. Clinical trials of medical devices in the United States are governed by the FDA's Investigational Device Exemption, or IDE, regulation. This regulation places significant responsibility on the sponsor of the clinical study including, but not limited to, choosing qualified investigators, monitoring the trial, submitting required reports, maintaining required records, and assuring investigators obtain informed consent, comply with the study protocol, control the disposition of the investigational device, submit required reports, etc.

Clinical trials of significant risk devices (e.g., implants, devices used in supporting or sustaining human life, devices of substantial importance in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health) require FDA and Institutional Review Board, or IRB, approvals prior to starting the trial. FDA approval is obtained through submission of an Investigational Device Exemption, or IDE, application. Clinical trials of non-significant risk, or NSR, devices, (i.e., devices that do not meet the regulatory definition of a significant risk device) only require IRB approval before starting. The clinical trial sponsor is responsible for making the initial determination of whether a clinical study is significant risk or NSR; however, IRB and/or FDA reviewer may review this decision and disagree with the determination.

An IDE application must be supported by appropriate data, such as performance data, animal and laboratory testing results, showing that it is safe to evaluate the device in humans and that the clinical study protocol is scientifically sound. There is no assurance that submission of an IDE will result in the ability to commence clinical trials. Additionally, after a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to an unacceptable health risk.

As noted above, the FDA may require a company to collect clinical data on a device in the post-market setting.

The collection of such data may be required as a condition of PMA. The FDA also has the authority to order, via a letter, a post-market surveillance study for certain devices at any time after they have been cleared or approved.

Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the United States. Similarly, in Europe the clinical study must be approved by a local ethics committee and in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

Pervasive and Continuing FDA Regulation

After a device is placed on the market, regardless of its classification or premarket pathway, numerous additional FDA requirements generally apply. These include, but are not limited to:

- Establishment registration and device listing requirements;
- QSR, which governs the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of finished devices;
- Labeling requirements, which mandate the inclusion of certain content in device labels and labeling, and generally require the label and package of medical devices to include a unique device identifier, and which also prohibit the promotion of products for uncleared or unapproved, i.e., "off-label," uses;
- Medical Device Reporting regulation, which requires that manufacturers and importers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and
- Reports of Corrections and Removals regulation, which requires that manufacturers and importers report to the FDA recalls (i.e., corrections 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; manufacturers and importers must keep records of recalls that they determine to be not reportable.

The FDA enforces these requirements by inspection and market surveillance. Failure to comply with applicable regulatory requirements can result in an enforcement action by the FDA, which may include, but is not limited to, the following sanctions:

- untitled letters or warning letters;
- fines, injunctions and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for 510(k) clearance or premarket approval of new products;
- withdrawing 510(k) clearance or premarket approvals that are already granted; and
- criminal prosecution.

We are subject to unannounced device inspections by the FDA, as well as other regulatory agencies overseeing the implementation of and compliance with applicable state public health regulations. These inspections may include our suppliers' facilities. We cannot assure that we have adequately complied with all regulatory requirements or that one or more of the referenced sanctions will not be applied to us as a result of a failure to comply.

International Regulation

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we must obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. The European Union/European Economic Area, or the EU/EEA, requires a CE conformity mark in order to market medical devices. Many other countries, such as Australia, India, New Zealand, Pakistan and Sri Lanka, accept CE or FDA clearance or approval, although others, such as Brazil, Canada, China and Japan require separate regulatory filings.

In the EU and the EEA, devices are required to comply with the essential requirements of the EU Medical Devices Directive being replaced by MDR 2017/745 which allowed the marketing of medical devices in the EU, under MDD until May 26, 2024. Compliance with these requirements entitled us to affix the CE conformity mark to our medical devices, without which they cannot be commercialized in the EU and EEA. To demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I), where the manufacturer can issue a CE Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the Medical Devices Directive, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization accredited at the European Commission to conduct conformity assessments. The Notified Body would typically audit and examine the quality system for the manufacture, design and final inspection of our devices before issuing a certification demonstrating compliance with the essential requirements. Based on this certification we can draw up a CE Declaration of Conformity which allows us to affix the CE Mark to our products.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation, which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable (i.e., without the need for adoption of EEA member State laws implementing them) in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and in vitro diagnostic devices and ensure a high level of safety and health while supporting innovation.

The MDR, which became effective on May 26, 2021, does the following:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

These modifications may have an impact on the way we design and manufacture products and the way we conduct our business in the EEA. We are progressing in our plans to meet the new requirements.

Further, the advertising and promotion of our products in the EU and the EEA is subject to the laws of individual EU and EEA member states implementing the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other EU and EEA member state laws governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

We are in the process of implementing the new MDR requirements to conform with the European requirements.

We have received AMAR approval in Israel. In addition, we received approval from the MedCert Zertifizierungs und Prufungsgsesellschaft fur die Medizin GmbH of Germany, and are entitled to print the CE Mark on our products, after having examined the EU Technical File for each new product.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, CMS, other divisions of the Department of Health and Human Services, the Department of Justice, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety and Health Administration, the Environmental Protection Agency, and state and local governments. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair completion laws.

The distribution of medical device products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of medical device products.

Third-Party Payors Coverage and Reimbursement

Procedures using our products to treat breast cancer are not reimbursed currently by private or governmental third-party payors in the United States. On November 1, 2022, the CMS assigned our ProSense breast cancer cryoablation procedures with CPT Category III code 0581T to ambulatory payment classification 5091, Level 1 Breast/Lymphatic Surgery and Related Procedures. This payment assignment for the procedure went into effect on January 1, 2023, opening the potential for facilities to be paid, on a case-by-case basis, for these procedures subject to our receipt of FDA marketing authorization of ProSense for breast cancer. Under the temporary CPT Category III code, the ProSense procedure is priced for coverage by the CMS at approximately $3,500 for the facility fee alone. The Company may request an extension to the temporary CPT Category III code, which is due to expire in February 2029. Additional coverage, including payment for the physician, is expected upon establishment of the permanent CPT Category I code, which is conditioned on several factors, including our receipt of FDA marketing authorization of ProSense for breast cancer.

We intend to seek reimbursement through private and governmental third-party payors in the future, although significant uncertainty exists as to whether coverage and reimbursement of such procedures will be approved. In both the United States and foreign markets, our ability to expand utilization of the system and to attract commercialization partners depends, in part, on the availability of adequate coverage and reimbursement from third-party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, and private health insurers. Medicare is a federally funded program managed by the CMS, through local contractors that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured, that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations or other guidelines that govern its individual program. Each payor, whether governmental or private, has its own process and standards for determining whether it will cover and reimburse a procedure or a particular product. Since private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations, achieving favorable CMS coverage and reimbursement is often a significant gating issue for successful introduction of a new product. The competitive position of our systems will depend, in part, upon the extent of coverage and adequate reimbursement for the procedures in which such products are used.

Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage policies and reimbursement rates are attained for procedures using our products, less favorable coverage policies and reimbursement rates may be implemented in the future.

State and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding, and otherwise affect the prices we may obtain for any of our products for which we may obtain regulatory approval, or the frequency with which any such products is prescribed or used.

In addition, in some foreign countries, the proposed pricing for a medical device must be approved before it may be lawfully marketed. The requirements governing medical device pricing vary widely from country to country. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Historically, products launched in the EU do not follow price structures of the United States and generally tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our distributors and the potential profitability of any of our product candidates in those countries could be negatively affected.

Other Healthcare Laws and Compliance Requirements

Healthcare providers, physicians, and third-party payors will affect the utilization of any products for which we obtain marketing approval. Our future arrangements with healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any device for which we obtain marketing approval. In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the CMS, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. The applicable laws and regulations include the federal Anti-Kickback Statute, the False Claims Act, and the Health Insurance Portability and Accountability Act of 1996, or HIPAA.

- The Anti-Kickback Statute makes it illegal for any person, including a device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, or order of a particular device, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it.

- The Federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $10,957 and $21,916 for each separate false claim and the potential for exclusion from participation in federal healthcare programs. Conduct that violates the False Claims Act also may implicate various federal criminal statutes. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute also are deemed false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law.

- HIPAA which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, also imposes certain obligations, including contractual terms and technical safeguards, with respect to maintaining the privacy, security and transmission of individually identifiable health information.

- HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, 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.

- The Federal Physician Payments Sunshine Act within the Affordable Care Act, and its implementing regulations, which requires that certain manufacturers of devices and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members; and

- Analogous state and foreign fraud and abuse laws and regulations, such as anti-kickback and false claims laws, which may apply to sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third party payor, including commercial insurers, and state 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 federal laws, thus complicating compliance efforts. Such laws are generally broad and are enforced by various state agencies and private actions.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information, which are applicable to "business associates"—independent contractors or agents of HIPAA covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity.

Current and future legislation

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

U.S. Regulation

The Affordable Care Act has had, and is expected to continue to have, a significant impact on the healthcare industry. The Affordable Care Act was designed to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the Affordable Care Act expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. There remain judicial, Congressional and executive branch challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing or delaying penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, delaying the implementation of certain Affordable Care Act-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. Additionally, on December 15, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the individual mandate was repealed by Congress. Further, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari and on June 17, 2021, decided that the plaintiffs lacked standing to challenge the individual mandate, leaving unresolved the question of whether the mandate is constitutional.

We continue to evaluate the effect that the Affordable Care Act has on our business. Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. However, the CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2031. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 26, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. In addition, on August 16, 2022, President Biden signed the IRA into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. Affordable Care Act Additional legislative and regulatory changes and judicial challenges to the Affordable Care Act, its implementing regulations and guidance and its policies, remain possible.

It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and any healthcare reform measures of the Trump administration will impact the Affordable Care Act. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The Affordable Care Act, as well as other federal, state and foreign healthcare reform measures that have been and may be adopted in the future, could harm our future revenues.

Additional laws and regulations governing international operations

Since we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any United States individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain 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.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-United States nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our presence outside of the United States, requires dedicating additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on the United States exchanges for violations of the FCPA's accounting provisions.

Post-Marketing Regulations

Following clearance or approval of a new product, a company and the product are subject to continuing regulation by the FDA and other federal and state regulatory authorities, including, among other things, monitoring and recordkeeping activities, reporting to applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting for uses or in patient populations not described in the product's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the products or labeling or changes of site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

Our research and development efforts were financed in part through royalty-bearing grants from the Israel Innovation Authority, or the IIA. As of December 31, 2024, we have received the aggregate amount of approximately $2.7 million (including accumulated interest) from the IIA for the development of our products. With respect to such grants, we are committed to pay certain royalties up to the total grant amount, including accumulated interest. As of December 31, 2024, we paid approximately $695 thousand. Regardless of any royalty payment, we are further required to comply with the requirements of the Research Law, with respect to those past grants. When a company develops know-how, technology or products using IIA grants, the terms of these grants and the Research Law restrict the transfer of such know-how, and the transfer of manufacturing or manufacturing rights of such products, technologies or know-how outside of Israel, without the prior approval of the IIA. This may restrict our ability to move the production of our products outside of Israel, or to sell intellectual property and other know-how. Further, should we move our production outside of Israel, we may be subject to repayment of 120% or more of the grants.

The royalty rate we have undertaken to pay the IIA is 3.5%, and in any event up to the level of the grant, including accumulated interest, being linked to the exchange rate of the U.S. dollar and bearing Libor interest. Starting from the second half of 2017, new directives were introduced, according to which small companies (up to an annual turnover of $70 million) are to pay royalties of 3%.

The total sum of royalties, including accumulated interest, we are required to repay the IIA, as of December 31, 2024 was approximately $1.98 million, net, after deducting the sums we paid as royalties to the IIA.

C. Organizational Structure.

We have three wholly-owned subsidiaries: IceCure Medical Inc., IceCure Medical HK Limited and IceCure (Shanghai) MedTech Co., Ltd., a Chinese company fully owned by the subsidiary in Hong Kong.

IceCure Medical Inc. is our wholly-owned subsidiary incorporated in the State of Delaware. IceCure Medical Inc. is engaged in business development, marketing, managing clinical trial and selling our products in the United States.

IceCure Medical HK Limited is our wholly-owned subsidiary incorporated in Hong Kong. IceCure Medical HK Limited serves as a holding company for IceCure (Shanghai) MedTech Co., Ltd. Currently, there is no other activity in IceCure Medical HK.

IceCure (Shanghai) MedTech Co., Ltd., a subsidiary fully owned by IceCure Medical HK Limited, started its operations on January 1, 2021, and is engaged in obtaining regulatory approvals, business development, and marketing activities in China.

D. Property, Plant and Equipment.

Our headquarters are located at 7 Ha'Eshel St., Caesarea, 3079504, Israel, where we currently occupy approximately 879 square meters (approximately 9,461 square feet). We lease our facilities and our lease is due to end in July 2026.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

A. Operating Results.

The following discussion and analysis of our results of operations and financial condition should be read in conjunction with our consolidated financial statements and the related notes included elsewhere in this annual report on Form 20-F. The discussion below contains forward-looking statements that are based upon our current expectations and are subject to uncertainty and changes in circumstances. Actual results may differ materially from these expectations due to inaccurate assumptions and known or unknown risks and uncertainties, including those identified in "Cautionary Note Regarding Forward-Looking Statements" and under "Item 3.D. Risk Factors" elsewhere in this annual report on Form 20-F. Our discussion and analysis for the year ended December 31, 2023 compared to the year ended December 31, 2022 can be found in our annual report on Form 20-F for the fiscal year ended December 31, 2023, filed with the SEC on April 3, 2024.

Overview

We are a commercial stage medical device company focusing on the research, development and marketing of cryoablation systems and technologies based on LN2 for treating tumors. Cryoablation is the process by which benign and malignant tumors are ablated (destroyed) through freezing such tumors while in a patient's body. Our proprietary cryoablation technology is a minimally invasive alternative to surgical intervention, for tumors, including those found in breast, lungs, kidneys, bones and other indications. Our lead commercial cryoablation product is the ProSense system. We sell our IceSense3 and its associated CryoProbes in China.

Alongside our continued efforts at improving our core technology, including our flagship product, the ProSense system, we are also focused on new product developments. This includes our XSense system with CryoProbes for which we have received 510(k) regulatory clearance from the FDA. We believe that the XSense system with CryoProbes can serve as a platform that will allow us to develop other unique CryoProbes and catheters and expand our clinical applications, and that it is also more efficient, intuitive and user friendly compared to our existing ProSense system. We are also developing MSense which could enable the treatment of multiple and larger tumors (see "Item 4.B. *Business Overview – Our Products – Research and Development*" for additional information).

Components of Operating Results

Revenues

Our revenues primarily consist of (i) selling or placing our ProSense and IceSense3 systems and selling their disposables and related services; and (ii) revenues from granting the exclusive distribution rights to our products in Japan to Terumo Corporation, which also include providing technical, regulatory and clinical materials and support in obtaining regulatory approvals in Japan.

Cost of Revenues

Our cost of revenues consists primarily of salaries and related personnel expenses, materials for production of our products, subcontractors' expenses and other related production expenses.

Gross Margin

Gross margin, or gross profit as a percentage of revenue, is affected by a variety of factors which influence our revenues and the cost of goods sold. Revenues are affected mostly by the number of products we sell and the varying ratio between selling and placing systems, different selling prices depending on sales channels, territories and the mix of products and currency fluctuation, mainly the U.S. Dollar against the Euro and revenue recognition from granting exclusive distribution rights in Japan. The cost of revenues is affected mostly by the changes in cost of materials and import costs, subcontractors' costs, cost of personal, and currency fluctuation, mainly the U.S. Dollar against the NIS. Our gross margin is also affected by production volumes and production efficiency.

Operating Expenses

Our current operating expenses consist of three components — research and development expenses, marketing and sales expenses and general and administrative expenses. To ensure that we are well-positioned to achieve our near-term objectives, we implemented an expense reduction plan setting out reductions in non-revenue generating research and development and general and administrative costs, lowering monthly cash expenditure, and ensuring that we can meet our primary goals in 2025.

Research and Development Expenses

Our research and development expenses consist primarily of salaries and related benefits, subcontractors' expenses, materials and other related research and development expenses, clinical studies and regulation expenses.

Our research and development expenses might increase as we continue to develop our new products, pursue new regulatory indications in the United States and other territories, collect updated clinical data, and recruit additional research and development and regulation employees.

Sales and Marketing

Our sales and marketing expenses consist primarily of salaries and related benefits, payments to consultants, costs associated with conventions, travel and other marketing and sales expenses.

We expect that our sales and marketing expenses will materially increase as we continue to enhance our market penetration efforts and recruit additional sales and marketing employees.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, professional services fees for accounting, legal, directors' fees, facilities, and associate costs, insurance and other general and administrative expenses. Our general and administrative expenses might increase as a result of the expansion of our business.

Financial expense and income

Financial expenses and income consist primarily of interest income from deposits and exchange rate differences on cash and cash equivalents, deposits and other assets and liabilities which are denominated in NIS and EUR.

Comparison of the Years Ended December 31, 2024 and 2023

Results of Operations

The following table summarizes our results of operations for the periods presented.

	Year Ended December 31,	
U.S. dollars in thousands	**2024**	**2023**
Revenues	$ 3,291	$ 3,229
Cost of revenues	1,840	1,929
Gross profit	$ 1,451	$ 1,300
Research and development expenses	7,096	8,273
Marketing and sales expenses	6,296	4,437
General and administrative expenses	3,755	4,166
Operating loss	$ 15,696	$ 15,576
Finance income, net	(378)	(924)
Net loss and comprehensive loss	$ 15,318	$ 14,652
Basic and diluted net loss per share	$ 0.30	$ 0.32

Revenues

The following table summarizes our revenues through types for the periods presented. The period-to-period comparison of results is not necessarily indicative of results for future periods.

	Year Ended December 31,	
U.S. dollars in thousands	**2024**	**2023**
Disposables	$ 1,828	$ 1,503
Systems	1,363	1,452
Exclusive distribution agreement and other services	100	274
Total	$ 3,291	$ 3,229

Our revenues for the year ended December 31, 2024 increased by $62 thousand, or 2%, to $3,291 thousand, compared to $3,229 thousand for the year ended December 31, 2023. Our total revenue from sales of systems and disposables for the year ended December 31, 2024, increased by 8% to $3,191 thousand, compared to $2,955 thousand for the year ended December 31, 2023, an increase of $236 thousand. Sales of disposables for the year ended December 31, 2024 increased to $1,828 thousand, compared to $1,503 thousand for the year ended December 31, 2023, an increase of $325 thousand, or 22%. Sales of systems for the year ended December 31, 2024 were $1,363 thousand, compared to $1,452 thousand for the year ended December 31, 2023, a decrease of $89 thousand, or 6%. Revenue recognition from our exclusive distribution agreement in Japan and other services for the year ended December 31, 2024 decreased to $100 thousand compared to $274 thousand for the year ended December 31, 2023, a decrease of $174 thousand, or 64%.

The following table summarizes our revenues by geographic region for the periods presented. The period-to-period comparison of results is not necessarily indicative of results for future periods.

U.S. dollars in thousands	Year Ended December 31, 2024	2023
United States	$ 870	$ 751
Japan	481	480
India	413	109
China	41	440
Israel	30	30
Other	1,456	1,419
Total	$ 3,291	$ 3,229

Our revenue in the United States amounted to $870 thousand for the year ended December 31, 2024, compared to $751 thousand for the year ended December 31, 2023, an increase of approximately $119 thousand, or 16%. Our revenue in Japan, including revenue recognition from exclusive distribution rights and other services and revenue from the sale of products, amounted to $481 thousand for the year ended December 31, 2024, compared to $480 thousand for the year ended December 31, 2023. Our revenue in India amounted to $413 thousand for the year ended December 31, 2024, compared to $109 thousand for the year ended December 31, 2023, an increase of approximately $304 thousand, or 279%. Our revenue in China amounted to $41 thousand for the year ended December 31, 2024, compared to $440 thousand for the year ended December 31, 2023, a decrease of approximately $399 thousand, or 91%. Our sales in Israel and other territories, including Europe, amounted to $1,486 thousand for the year ended December 31, 2024, compared to $1,449 thousand for the year ended December 31, 2023, an increase of $37 thousand of 3%.

Cost of Revenues and Gross Profit

The following table summarizes our cost of revenues for the periods presented, as well as presenting the gross profit as a percentage of total revenues. The period-to-period comparison of results is not necessarily indicative of results for future periods.

U.S. dollars in thousands	Year Ended December 31, 2024	2023
Raw materials, subcontractors, and auxiliary materials (including changes in inventories)	$ 832	$ 905
Payroll and related benefits (including share-based compensation))	585	551
Depreciation	186	161
Royalties to IIA	99	96
Shipping	44	42
Others	94	174
Total	$ 1,840	$ 1,929
Gross profit	$ 1,451	$ 1,300
Gross margin %	44%	40%

Our cost of revenues for the year ended December 31, 2024 decreased by 5% to $1,840 thousand, compared to $1,929 thousand for the year ended December 31, 2023, whereas our gross profit for the year ended December 31, 2024 increased by $151 thousand, or 12%, to $1,451 thousand, compared to $1,300 thousand in the year ended December 31, 2023. The decrease in our cost of revenues in 2024 was primarily attributable to a decrease in raw material costs, subcontractor costs and auxiliary material costs, which was partially offset by an increase in payroll and related benefits costs. The increase in gross profit and gross margin was primarily attributable to the increase in sales of our disposables, which generates a higher gross margin then our systems.

Research and development expenses

The following table summarizes our research and development costs for the periods presented. The period-to-period comparison of results is not necessarily indicative of results for future periods.

	Year Ended December 31,	
U.S. dollars in thousands	**2024**	**2023**
Payroll and related benefits (including share-based compensation)	$ 5,436	$ 5,395
Raw materials, subcontracted work and consulting	734	1,593
Clinical trials	181	436
Others	745	849
Total	$ 7,096	$ 8,273

Research and development, or R&D, expenses decreased by 14% to $7,096 thousand, compared to $8,273 thousand in 2023. The decrease is primarily due to a reduction in our development expenses for the XSense system, and a decrease in costs of clinical trial and regulatory compliance.

Sales and marketing expenses

The following table summarizes our sales and marketing costs for the periods presented. The period-to-period comparison of results is not necessarily indicative of results for future periods.

	Year Ended December 31,	
U.S. dollars in thousands	**2024**	**2023**
Payroll and related benefits (including share-based compensation)	$ 2,639	$ 2,239
Consultants and professional services	2,518	987
Travel	426	354
Conferences	286	323
Sales Commissions	96	49
Advertising and promotion	32	92
Others	299	393
Total	$ 6,296	$ 4,437

Selling and marketing expenses for the year ended December 31, 2024 increased by 42% to $6,296 compared to $4,437 thousand in 2023. The increase in selling and marketing expenses in 2024 compared to 2023 is attributable mainly to costs associated with consultants and professional services related to the reopening of our De Novo classification approval case with the FDA and the associated convening of the Advisory Panel and an increase in payroll and related benefits expenses, which reflects our strategy regarding the expansion of our marketing activities, primarily in the United States.

General and administrative expenses

The following table summarizes our general and administrative costs for the periods presented. The period-to-period comparison of results is not necessarily indicative of results for future periods.

	Year Ended December 31,	
U.S. dollars in thousands	**2024**	**2023**
Professional services	$ 1,955	$ 1,996
Payroll and related benefits (including share-based compensation)	1,624	1,886
Others	176	284
Total	$ 3,755	$ 4,166

General and administrative expenses for the year ended December 31, 2024 decreased by 10% to $3,755 thousand, compared to $4,166 thousand for the year ended December 31, 2023. This decrease is primarily attributable to a decrease in directors and officers insurance costs and other costs.

Operating loss

Based on the foregoing, our operating loss increased from $15,576 thousand for the year ended December 31, 2023 to $15,696 thousand for the year ended December 31, 2024.

Finance income, net

Finance income, net for the year ended December 31, 2024 was $378 thousand, compared to $924 thousand for the year ended December 31, 2023. The decrease in our net financial income is primarily attributable to the decrease in our short-term deposits and the income from interest on such short-term deposits.

Net loss

Net loss for the year ended December 31, 2024 increased by 5% to $15,318, compared to $14,652 thousand for the year ended December 31, 2023. The increase is primarily attributable to the increase in operation expenses which was mostly offset by the increase in gross profit, and a decrease in net financial income.

B. Liquidity and Capital Resources.

Overview

Since our inception through December 31, 2024, we have funded our operations principally from public offerings and private placements of our securities, loans, revenues from sale of products and distribution agreements, and grants received from the IIA. As of December 31, 2024, we had $7.6 million in cash and cash equivalents, including short-term deposits.

Our primary recurring use of cash is payment of our operating costs, which consist primarily of employee-related expenses, such as compensation and benefits, as well as to our suppliers and subcontractors for components and services provided for our products and research and development, general operating expenses for sales and marketing, facilities and overhead costs, general and administrative and capital expenditures.

The table below presents our cash flows for the periods indicated.

USD in thousands	**2024**	**2023**
Net cash used in operating activities	(12,563)	(12,550)
Net cash provided by (used in) investing activities	446	(684)
Net cash provided by financing activities	9,187	83
Net increase (decrease) in cash and cash equivalents	(2,930)	(13,151)

Operating Activities

Cash flows from operating activities consist primarily of loss adjusted for various non-cash items, including depreciation and amortization and share-based compensation expenses. In addition, cash flows from operating activities are impacted by changes in operating assets and liabilities, which include inventories, accounts receivable, other assets, accounts payable and other current liabilities.

Net cash used in operating activities for the year ended December 31, 2024 increased by $13 thousand to $12,563 thousand, compared to $12,550 thousand for year ended December 31, 2023, which reflects an increase in 2024 cash operational activities compared to 2023.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2024, was $446 thousand compared to net cash of $684 thousand used for the year ended December 31, 2023. Net cash used in investing activities for year ended December 31, 2024 is attributable to a withdrawal of short-term deposits of $529 thousand, which are offset, in part, by the purchase of property and equipment for $71 thousand and investment in restricted deposits of $12 thousand. The net cash provided by investing activities for the year ended December 31, 2023 is attributable to the purchase of property and equipment for $480 thousand and to investment in short-term deposits of $500 thousand, which are offset, in part, by the realization of restricted deposits of $296 thousand.

Financing Activities

Net cash provided by financing activities increased by $9,104 to $9,187 thousand for the year ended December 31, 2024, compared to $83 thousand for the year ended December 31, 2023. The increase is primarily attributable to the issuance of Ordinary Shares, net of issuance costs, through use of our at-the-market, or ATM, facility.

Financial Arrangements

As of December 31, 2024, our credit arrangements include grants from the IIA.

Since 2022, we have funded our operations mainly through public offerings, raising an aggregate amount of net proceeds of $24 million.

On December 23, 2022, we announced the closing of a “best efforts” public offering of 8,787,880 Ordinary Shares at a public offering price of $1.65 per share. After deducting placement agent fees, commissions and other offering expenses, our net proceeds from this offering were $13.6 million. Several of our long-term institutional shareholders, including Epoch Partner Investments Limited, or Epoch, participated in the transaction on the same terms as other investors.

On January 12, 2024, we entered into an equity distribution agreement with Maxim Group LLC, or Maxim, as sales agent, pursuant to which we may offer and sell Ordinary Shares having an aggregate offering price of up to $9,700,000 from time to time through Maxim, otherwise known as an ATM facility. The Ordinary Shares were offered and sold pursuant to our currently effective registration statement on Form F-3 (File No. 333-267272), the prospectus contained therein and the prospectus supplement filed with the SEC dated January 12, 2024. We paid Maxim a commission equal to 2.5% of the gross sales price per share sold pursuant to the terms of the agreement and provided Maxim with customary indemnification and contribution rights. We reimbursed Maxim for certain specified expenses. As of December 31, 2024, we had sold 10,764,315 Ordinary Shares pursuant to the ATM facility, having aggregate gross proceeds of $9.7 million and aggregate net proceeds of $9.2 million.

On January 13, 2025, we entered into a second equity distribution agreement with Maxim as sales agent, pursuant to which we may offer and sell Ordinary Shares having an aggregate offering price of up to $13,960,500 from time to time through Maxim. The Ordinary Shares will be offered and sold pursuant to our currently effective registration statement on Form F-3 (File No. 333-267272), the prospectus contained therein and the prospectus supplement filed with the SEC dated January 13, 2024. We will pay Maxim a commission equal to 2.5% of the gross sales price per share sold pursuant to the terms of the agreement and will provide Maxim with customary indemnification and contribution rights. We also agreed to reimburse Maxim for certain specified expenses. As of March 24, 2025, we have sold 2,047,277 Ordinary Shares pursuant to the ATM facility, having aggregate gross proceeds of $2.8 million and aggregate net proceeds of $2.6 million.

In addition, since our inception, we received an aggregate of $2.7 million (including accumulated interest) from the IIA.

Current Outlook

We have financed our operations to date primarily through proceeds from sales of our Ordinary Shares and convertible securities, sales of our products and grants from the IIA. We have incurred losses and generated negative cash flows from operations since inception in 2006.

We expect that we will continue to generate substantial operating losses and fund our operations primarily through the utilization of current financial resources, sales of our products, and additional raises of capital. These conditions raise substantial doubts about our ability to continue as a going concern. Our plan involves raising funds from existing shareholder and potential investors. There is no assurance, however, that such funding would be available to us, that it could be obtained on favorable terms, or that we will be provided with sufficient funds to continue to develop and commercialize our products.

We expect to generate revenues from the sale of our products and other revenues in the future. However, we do not expect these revenues to support all of our operation in the near future. We expect our expenses to increase in the future in connection with our ongoing activities, particularly as we continue the development of our MSense system and continue our commercialization efforts. Furthermore, we expect to incur additional costs associated with operating as a public company listed on Nasdaq. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

As of December 31, 2024, our cash and cash equivalents, including short-term deposits, were $7.6 million, and we had working capital of $5,240 thousand and an accumulated deficit of $105,379 thousand. As of March 24, 2025, the Company's cash, cash equivalents, and short-term deposits were approximately $6.0 million. The Company's current cash and cash equivalents position is not sufficient to fund its planned operations for at least the next 12 months beyond the filing date of this Annual Report. Such conditions raise substantial doubts about the Company's ability to continue as a going concern. Management's plan includes raising funds from existing shareholders and/or outside potential investors. However, there is no assurance such funding will be available to the Company or that it will be obtained on terms favorable to the Company or will provide the Company with sufficient funds to successfully complete the development of, and to commercialize, its products. The financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount and classification of liabilities that may be required should the Company be unable to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of these uncertainties; however, we expect that we will require substantial additional capital to continue the development of, and to commercialize our products. In addition, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future capital requirements will depend on many factors, including:

- our ability to sell our products according to our plans;
- the progress and cost of our research and development activities;
- the costs associated with the manufacturing our products;

- the costs of clinical trials and obtaining regulatory approvals;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the cost of our commercialization efforts, marketing, sales and distribution of our products the potential costs of contracting with third parties to provide marketing and distribution services for us or for building such capacities internally; and
- the magnitude of our general and administrative expenses.

Until we can generate significant recurring revenues and profit, we expect to satisfy our future cash needs through debt or equity financings. We cannot be certain that additional funding will be available to us when needed, on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate research or development plans, and/or commercialization efforts and/or regulatory efforts with respect to our products in different territories.

C. Research and development, patents and licenses, etc.

For a description of our research and development programs and the amounts that we have incurred over the last two years pursuant to those programs, please see "Item 5.A. Operating Results— Operating Expenses— Research and Development Expenses" and "Item 5.A. Results of Operations— Comparison of the year ended December 31, 2024 to the year ended December 31, 2023— Research and Development Expenses, net."

D. Trend Information

Current geopolitical tensions resulting from Israel's multi-front war have affected companies in Israel and around the world. Inflation in the United States, Israel and around the world has affected, and may continue to affect, the cost of labor and the prices of goods and services from third-party vendors on which we rely. In many instances, we have had to increase the prices at which we sell our products and services to offset these higher costs. We cannot predict impacts, trends and uncertainties involving the global economy and Israel's multi-front war related to economic activity, our supply chain, our third-party partners and the extent to which our revenue, income, profitability, liquidity, or capital resources may be materially and adversely affected. See also "*Our principal executive offices, most of our research and development activities and other significant operations are located in Israel, and, therefore, our results may be adversely affected by political, economic and military instability in Israel, including Israel's multi-front war with terrorist groups in neighboring countries, such as Hezbollah in Lebanon and Hamas in the Gaza Strip, and state actors such as Iran, and Israel's response thereto"*.

E. Critical Accounting Estimates

We prepare our financial statements in accordance with U.S. GAAP. At the time of the preparation of the financial statements, our management is required to use estimates, evaluations, and assumptions which affect the application of the accounting policy and the amounts reported for assets, obligations, income, and expenses. Any estimates and assumptions are continually reviewed. The changes to the accounting estimates are credited during the period in which the change to the estimate is made.

Use of estimates in the preparation of financial statements:

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Management believes that the estimates, judgments and assumptions used are reasonable based upon information available at the time they are made. Actual results could differ from those estimates.

We describe our significant accounting policies more fully in Note 2 to our financial statements for the year ended December 31, 2024, included elsewhere in this annual report on Form 20-F. We believe that the accounting policies below are critical in order to fully understand and evaluate our financial condition and results of operations.

Inventories

We value our inventories at the lower of cost or market, with cost determined with weighted average cost of historical purchases and market based upon net realizable value. The valuation of our inventories requires management to make costing and market estimates. For work in process goods, we are required to estimate the cost to completion of the products and the prices at which we will be able to sell the products. For finished goods, we must assess the prices at which we believe the inventory can be sold. Inventories are also adjusted for estimated obsolescence and written down to net realizable value based upon estimates of future demand, technology developments, and market conditions.

Revenue recognition

Revenue is measured as the amount of consideration we expect to be entitled to, in exchange for transferring products or providing services to our customers and is recognized when or as performance obligations under the terms of contracts with our customers are satisfied. ASC 606 prescribes a five-step model for recognizing revenue from contracts with customers: (i) identify contract(s) with the customer; (ii) identify the separate performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the separate performance obligations in the contract; and (v) recognize revenue when (or as) each performance obligation is satisfied.

At contract inception, once the contract is determined to be within the scope of ASC 606, we assess whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services. We then allocate the transaction price (the amount of consideration the Company expects to be entitled to from a customer in exchange for the promised goods or services) to each performance obligation and recognizes the associated revenue when (or as) each performance obligation is satisfied.

Revenues from product sales are recognized upon the transfer of control, which is generally upon shipment or delivery.

Provisions for discounts, rebates and sales incentives to customers, returns and other adjustments are provided for in the period the related sales are recorded. Sales incentives to customers are not material.

Deferred revenue represents amounts received by us for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management.

The following table sets forth information regarding our executive officers, key employees and directors as of the date of this annual report:

Name	Age	Position
Ron Mayron	61	Chairman of the Board of Directors
Eyal Shamir	64	Chief Executive Officer, Director
Ronen Tsimerman	55	Chief Financial Officer, Chief Operation Officer
Naum Muchnik	48	Vice President, Research, Development and Engineering
Tlalit Bussi Tel-Tzure	53	Vice President, Business Development and Global Marketing
Galit Malik	52	Vice President, Operations and Services
Shay Levav	48	Vice President, Regulatory, Quality Assurance and Clinical Applications
Merav Nir Dotan	56	Vice President, Human Resources
Shad Good	47	Vice President, Sales for North America
Li Haixiang	52	Director
Vincent Chun Hung Chan [(5)]	61	Director
Yang Huang	46	Director
Sharon Levita [(1)(2)(3)(4)(5)]	57	Director
Oded Tamir [(1)(2)(3)(4)(5)]	69	Director

(1) Member of the Compensation Committee
(2) Member of the Audit Committee and Financial Statement Examination Committee
(3) External Director (as defined under Israeli law)
(4) Independent Director (as defined under Israeli law)
(5) Independent Director (as defined under Nasdaq Stock Market rules)

Ron Mayron, Chairman of the Board of Directors

Mr. Ron Mayron has served as Chairman of our board of directors since December 2017. Mr. Mayron has served as chairman of the board of directors of Resymmetry Ltd. from July 2016 to January 2022, InnoCan Pharma Corporation (CSE: INNO, FWB: IP4, OTC: INNPF) since November 2017, Virility Medical LTD from October 2019 to March 2023 and as a member of the board of directors of G-Med Ltd. since September 2015, Kaizen Bio-Tec Ltd. since May 2017, Simplivia Ltd. since May 2019, Kadimastem LTD (TASE: KDST) from December 2020 to December 2023, Entera Bio Ltd. (NASDAQ: ENTX) from March 2021 to July 2024 and DNA Biomedical Solutions (TASE: DNA) from March 2021 to May 2023, Ir-Med, Inc. (OTC:IRME) since March 2021, NureXone (CDNX) from December 2021 to July 2023. Mr. Mayron has also served as the founder and chief executive officer of RonMed Ltd. Prior to that, Mr. Mayron served as a member of the board of directors of EclipeIR (USA) Inc. from June 2016 to September 2019 and BioLight Life Sciences Investments Ltd. (TASE: BOLT) from August 2015 to July 2024. Mr. Mayron also served in various positions at Teva Pharmaceutical Industries Ltd. (NYSE: TEVA, TASE: TEVA) from 1993 to 2014, including as vice president–Israel and Africa and chief executive officer of Teva Israel from 2009 to 2013. Mr. Mayron received his B.Sc. in industrial and management engineering from Ben-Gurion University of the Negev, Israel and MBA from Tel-Aviv University, Israel. Mr. Mayron also completed a special senior management and global leadership programs at the Massachusetts Institute of Technology (M.I.T), Boston and managerial skills for international business and executive international marketing programs at Insead University, France.

Eyal Shamir, Chief Executive Officer and Director

Mr. Eyal Shamir has served as our Chief Executive Officer since September 2016 and on our board of directors since December 2017. Mr. Shamir has over 20 years of experience as chief executive officer of medical device companies. He has served as chief executive officer of Erika Carmel Ltd. from May 2013 to August 2016, Tadbik Pack Ltd. from January 2011 to December 2012 and Hanita Lenses Ltd. from 2006 to 2010. Mr. Shamir received his B.A. in economics and business management from the Hebrew University, Israel and his MBA from the College of Management Academic Studies, Israel.

Ronen Tsimerman, Chief Financial Officer and Chief Operation Officer

Mr. Ronen Tsimerman has served as our Chief Financial Officer since May 2017 and as our Chief Operation Officer since May 2018. Mr. Tsimerman has over 20 years of experience as chief financial officer of public and private companies. He has served as chief financial officer of Insuline Medical Ltd. from June 2015 to May 2017, as chief financial officer of Mer-Group Broadband division (TASE: CMER) from 2005 to 2013 and as vice president of finance of Mer-Group Telecom Division from 2013 to 2014. Mr. Tsimerman received his bachelor's degree in business and MBA from The College of Management, Israel.

Naum Muchnik, Vice President, Research, Development and Engineering

Mr. Naum Muchnik has served as our Vice President, Research, Development and Engineering since March 2018. Prior to that, Mr. Muchnik has served as operations and service manager of Medasense Biometrics Ltd. from August 2016 to March 2018 and as research and development mechanical team leader and project leader of GE Healthcare – Ultrasound. Mr. Muchnik received his M.Sc. in technology management from the Holon Technology Institute, Israel and Bachelor of Technology in mechanical engineering from the Ort Braude Academic College, Israel.

Tlalit Bussi Tel-Tzure, Vice President, Business Development and Global Marketing

Ms. Tlalit Bussi Tel-Tzure has served as our Vice President, Business Development and Global Marketing, since December 2018. Ms. Bussi Tel-Tzure has more than 20 years of sales, business developments and marketing of medical device companies. She has served as vice president of marketing of DiA Imaging Analysis Ltd. form April 2017 to December 2018, and as vice president of sales and marketing of Medical Compression System Ltd. from September 2012 to August 2017. Ms. Bussi Tel-Tzure received her Bachelor of Science from the Hebrew University, Israel and her MBA from the Heriot-Watt University, United Kingdom.

Galit Malik, Vice President, Operations and Services

Ms. Galit Malik has served as our Vice President, Operations and Service since December 2022. Prior to that she has served as our Director of Operations and Service from February 2019 to December 2022. Before joining the Company, Ms. Galit Malik served as the Corporate Director of Supply Chain of Mazor Robotics (acquired by Medtronic) from March 2017 to October 2018 and as its Corporate Purchasing and Logistics manager from January 2008 to March 2017. She has also served as its Office Manager, Buyer, and logistics specialist from May 2003 to January 2008. Ms. Malik received her bachelor's degree from the Open University of Israel, and her master's degree from Haifa University, Israel.

Shay Levav, Vice President, Regulatory and Quality Assurance and Clinical Applications

Mr. Shay Levav has served as our Vice President, Regulatory and Quality Assurance and Clinical Applications since September 2020. Before joining the Company, Mr. Levav has served as a member on the board of directors of Applied Spectral Imaging from December 2018 to August 2020 and as its quality and regulatory affairs manager since January 2015 to December 2018. He has also served as commercialization business manager of Carestream Health Inc. from 2012 to 2015, as its operations quality manager since 2001 to 2012, and service engineer since 2000 to 2001. Mr. Levav holds a B.A. from the Ruppin Academy Center, Israel.

Merav Nir Dotan, Vice President, Human Resources

Mrs. Merav Nir Dotan has served as our Vice President, Human Resources, since November 2021. Mrs. Nir Dotan has over two decades of experience in human resources and organizational management. Mrs. Nir Dotan was previously Vice President of Human Resources at Hanita Lenses, a medical device manufacturer and provider of intraocular lens solutions for cataract surgery, from 2009 to 2020. In addition, from December 2020 through January 2022, Mrs. Nir Dotan worked part time for RNR-Sys, a consulting and project management company. Mrs. Nir Dotan has a Master of Science in Organizational Behavior from Tel Aviv University and received her undergraduate degree in Human Resources from Ben-Gurion University of the Negev.

Shad Good, Vice President, Sales for North America

Mr. Shad Good, has served as Vice President, Sales for North America since September 19, 2023. Before joining the Company, Mr. Good was VP of Sales at UV-Concepts Inc from April 2022 to August 2023. From July 2017 to March 2022, Mr. Good was Senior Director of Sales, U.S., at Mammotome, an operating company of Danaher Corporation, where he led sales for the company's minimally invasive breast biopsy systems and built a sales organization for the successful launch of an emerging technology, a wire-free device for lumpectomies. Mr. Good holds a B.S. in Marketing from Miami University of Ohio.

Li Haixiang, Director

Mr. Li Haixiang has served on our board of directors since December 2024. Mr. Haixiang is the founder and managing partner of Virtus Inspire Ventures, a boutique venture capital firm that provides seed, venture and growth-stage funding to early-stage technology companies. Mr. Haixiang has been an independent non-executive director at AVO Insurance Company Holding since August 2018 and an independent non-executive director at FUTU Holding Limited since March 2019. Mr. Haixiang has been a sole director at Chestnut Hill Ventures Limited since September 2015, a sole director at Virtus Inspire International Limited since August 2020, a sole director at Virtus Inspire Capital Limited since May 2012, a sole director at Virtus Inspire Ventures GP Limited since June 2015, a sole director at Virtus Inspire Ventures Management Limited since June 2015, a sole director at Sapientia Investment Consulting Limited since March 2021, a sole director at the Kwan Limited since October 2021, a sole director at Virtus Inspire Aurora Limited since March 2021, a sole director at Virtus Inspire Partners Limited since March 2021, a sole director at Virtus Inspire SG Limited since October 2021, a sole director at VI Capital Pte Limited since June 2022, a sole director at VIPC 1 Limited since August 2022, a sole director at Virtus Inspire Holding Limited since February 2023, and a sole director at Virtus Inspire Group Limited since February 2023. Mr. Haixiang received a BA from South China University of Technology and an MA from China Europe International Business School. Mr. Li Haixiang has the voting and dispositive power over the shares held by Epoch, which amounts to a 44.1% stake as of March 24, 2025.

Vincent Chun Hung Chan, Director

Mr. Vincent Chun Hung Chan has served on our board of directors since December 2022. Mr. Chan has been a venture partner at Beyond Ventures since August 2024 and a venture capital manager in China and Hong Kong since October 2023 and was a Senior Managing Director and Head of Asia of Samena Capital Hong Kong Limited from 2016 to 2022. From 1991 to 2016, he served several leading private equity investment companies including HSBC Equity Management Limited, Suez Asia Holdings (Hong Kong) Limited, JAFCO Investment (Asia Pacific) Ltd and Spring Capital Asia, Limited. Mr. Chan has been an independent non-executive director of CN Logistics International Holdings Limited since September 2020, and an independent non-executive director of Hywin Holdings Ltd. (Nasdaq: HYW) since June 2022. Mr. Chan is currently the Director and Treasurer of the Hong Kong Venture Capital and Private Equity Association. Mr. Chan has been a member of the Main Board and GEM Listing Review Committees of the Stock Exchange of Hong Kong from 2020 to 2024. He was previously a member of the Main Board and GEM Listing Committee of the Stock Exchange of Hong Kong from May 2007 to May 2012. He was also a member of the Public Shareholders Group of the Hong Kong Securities and Futures Commission from July 2005 to March 2011. Mr. Chan received a Bachelor of Arts degree from the University of Hong Kong in November 1986 and a master's degree in business administration from the Manchester Business School (then known as the Victoria University of Manchester) in the United Kingdom in July 1988. He was admitted as a chartered financial analyst of the Institute of Chartered Financial Analysts, United States in September 1993.

Yang Huang, Director

Mr. Yang Huang has served on our board of directors since April 2020. Mr. Huang has 20 years of senior sales and marketing management experience in the field of medical devices. Mr. Huang has also served as operation directors of Virtus Inspire Ventures, a private equity fund, since July 2019 and as a corporate representative of IceCure (Shanghai) MedTech Co., Ltd. since July 2020, Prior to that, Mr. Huang has served as business unit director of Olympus (Beijing) Sales & Service Co., Ltd. from November 2016 to July 2019 and as business unit director of B. Braun MEDICAL (SHANGHAI) International Trading Co., Ltd. from January 2015 to November 2016. He also served as business unit head for Stryker from September 2013 through January 2015 and as sales manager at Johnson & Johnson from October 2000 through August 2013. Mr. Huang has graduated from Cheung Kong Graduate School of Business, China and Zhejiang Medical University, China.

Sharon Levita, Director

Ms. Sharon Levita has served on our board of directors as an external director since September 2019. Ms. Levita has also served as chief financial officer at ForSight Robotics Ltd. since September 2023. Prior to that, Ms. Levita served as business development and strategy director at Medtronics from February 2020 to August 2023, as vice president operations and site leader of Mazor, as part of Medtronic, from December 2018 to January 2020 and as chief financial officer and vice president business operations of Mazor Robotics Ltd. from February 2008 to December 2018. Ms. Levita received her B.A in economics and accounting from the University of Haifa and her M.A in business administration from the Bar-Ilan University. Ms. Levita is also a certificated public accountant in Israel.

Oded Tamir, Director

Mr. Oded Tamir has served on our board of directors since September 2013. Mr. Tamir has also served as executive chairman of the board of directors of Fertigo Medical Ltd. since November 2018, as a member of the advisory board of Biodesign Israel, a Stanford University program for medical entrepreneurship and innovation, since June 2018. Prior to that, Mr. Tamir has served as executive chairman of Imedis AI Ltd. from November 2018 to September 2020, and as president and chief executive officer of RADLogics Inc. from June 2013 to December 2016. Mr. Tamir is the co-founder of Insightec Ltd., where he served as the chief financial officer and chief operating officer for 15 years. Mr. Tamir received his B.Sc. in economics and business management from the Technion – Israel Institute of Technology, Israel completed advanced accounting studies at the University of Haifa, Israel executive development management program at the Technion – Institute of Management, Israel, graduated the advanced directors' program of Deloitte Israel & Co., and executive education and training program at the John F. Welch Leadership Development Center, New York.

Family Relationships

There are no family relationships between any members of our executive management and our directors.

Arrangements for Election of Directors and Members of Management

With the exception of our director, Yang Huang, who was appointed by Epoch, one of our shareholders, there are no arrangements or understandings with major shareholders, customers, suppliers or others pursuant to which any of our executive management or our directors were selected (see "*Item 7.B. Major Shareholders and Related Party Transactions"* for additional information).

B. Compensation

The following table presents all compensation paid by us to each of our five most highly compensated senior managers for the year ended December 31, 2024. The table does not include any amounts we paid to reimburse any of such persons for costs incurred in providing us with services during this period.

All amounts reported in the tables below reflect the cost to the Company, in thousands of U.S. Dollars, for the year ended December 31, 2024.

Name and Principal Position	Cost of Salary, Bonuses, Pension, Retirement and Other Similar Benefits[1]	Share Based Compensation[1]	Total[1]
Eyal Shamir, *Chief Executive Officer*	$ 443,139	69,546	512,685
Shad Good, *VP Sales for North America*	$ 398,034	32,891	430,925
Ronen Tsimerman, *Chief Financial Officer and Chief Operation Officer*	$ 313,004	74,077	387,081
Shay Levav, *VP Regulatory and Quality Assurance and Clinical Applications*	$ 274,458	55,255	329,713
Tlalit Bussi Tel-Tzure, *VP Business Development and Global Marketing*	$ 272,763	52,181	324,944
Total	$ 1,701,398	283,950	1,985,348

(1) Amounts presented are the aggregate of USD amounts translated at the NIS-USD exchange rate for each pay period for the relevant employee during the reporting period.

Employment Agreements with Executive Officers

We have entered into written employment agreements with each of our executive officers. All of these agreements contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable law. In addition, we have entered into agreements with each executive officer and director pursuant to which we have agreed to indemnify each of them up to a certain amount and to the extent that these liabilities are not covered by directors' and officers' insurance.

For a description of the terms of our options and option plans, see "Item 6.E. Share Ownership" below.

Differences between the Companies Law and Nasdaq Requirements

Companies incorporated under the laws of the State of Israel whose shares are publicly traded, including companies with shares listed on Nasdaq, are considered public companies under Israeli law and are required to comply with various corporate governance requirements under Israeli law relating to such matters as the composition and responsibilities of the audit committee and the compensation committee (subject to certain exceptions that we intend to utilize), and a requirement to have an internal auditor. These requirements are in addition to the corporate governance requirements imposed by the rules of the Nasdaq Stock Market and other applicable provisions of U.S. securities laws to which we are subject as a foreign private issuer. Under the Nasdaq Stock Market Rules, a foreign private issuer may generally follow its home country rules of corporate governance in lieu of the comparable requirements of the Nasdaq Rules, except for certain matters including the composition and responsibilities of the audit committee.

C. Board Practices

Introduction

Our board of directors presently consists of seven members, including two external directors required to be appointed under the Companies Law. We believe that Ms. Sharon Levita, Mr. Oded Tamir and Mr. Vincent Chun Hung Chan are "independent" for purposes of the Nasdaq Stock Market rules. Our articles of association provide that the number of board of directors' members (including external directors) shall be set by the general meeting of the shareholders provided that it will consist of not less than five (5) and not more than eleven (11). Pursuant to the Companies Law, the management of our business is vested in our board of directors. Our board of directors may exercise all powers and may take all actions that are not specifically granted to our shareholders or to management. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our board of directors. Our Chief Executive Officer is appointed by, and serves at the discretion of, our board of directors, subject to the employment agreement that we have entered into with him, which was approved by our shareholders. All other executive officers are appointed by our Chief Executive Officer. Their terms of employment are subject to the approval of the compensation committee and of the board of directors, and are subject to the terms of any applicable employment agreements that we may enter into with them.

Each director, except external directors, will hold office until the next annual general meeting of our shareholders following his or her appointment, or until he or she resigns or unless he or she is removed by a majority vote of our shareholders at a general meeting of our shareholders or upon the occurrence of certain events, in accordance with the Companies Law and our articles of association.

In addition, under certain circumstances, our articles of association allow our board of directors to appoint directors to fill vacancies on our board of directors or in addition to the acting directors (subject to the limitation on the number of directors), until the next annual general meeting or special general meeting in which directors may be appointed or terminated. External directors may be elected for up to two additional three-year terms after their initial three-year term under the circumstances described below, with certain exceptions as described in "External Directors" below. External directors may be removed from office only under the limited circumstances set forth in the Companies Law (see "*Item 6.C. Directors, Senior Management and Employees – Board Practices – External Directors"* below).

Under the Companies Law, any shareholder holding at least one percent of our outstanding voting power may request at an annual meeting of shareholders to nominate a director. However, any such shareholder may make such a request only if a notice of such shareholder's intent to make such nomination has been given to our board of directors. Any such notice must include certain information, including the consent of the proposed director nominee to serve as our director if elected, and a declaration that the nominee signed declaring that he or she possesses the requisite skills and has the availability to carry out his or her duties. Additionally, the nominee must provide details of such skills, and demonstrate an absence of any limitation under the Companies Law that may prevent his or her election, and affirm that all of the required election-information is provided to us, pursuant to the Companies Law.

However, under regulations promulgated under the Israeli Companies Law for Israeli companies whose shares are traded on stock exchanges outside of Israel, or the Exemptions Regulations, one or more shareholders of such a company may request the company's board of directors to include the appointment of a candidate for a position on the board of directors or the termination of a board member as an item on the agenda of a future general meeting (if the company sees fit), provided that the shareholder hold at least five percent (5%) of the voting rights of the company, instead of one percent (1%) required in the past.

Under the Companies Law, our board of directors must determine the minimum number of directors who are required to have accounting and financial expertise. In determining the number of directors required to have such expertise, our board of directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our board of directors has determined that the minimum number of directors of our company who are required to have accounting and financial expertise is one.

The board of directors must elect one director to serve as the chairman of the board of directors to preside at the meetings of the board of directors and may also remove that director as chairman. Pursuant to the Companies Law, neither the chief executive officer nor any of his or her relatives is permitted to serve as the chairman of the board of directors, and a company may not vest the chairman or any of his or her relatives with the chief executive officer's authorities. In addition, a person who reports, directly or indirectly, to the chief executive officer may not serve as the chairman of the board of directors; the chairman may not be vested with authorities of a person who reports, directly or indirectly, to the chief executive officer; and the chairman may not serve in any other position in the company or a controlled company, but he or she may serve as a director or chairman of a controlled company. However, the Companies Law permits a company's shareholders to determine, for a period not exceeding three years from each such determination, that the chairman or his or her relative may serve as chief executive officer or be vested with the chief executive officer's authorities, and that the chief executive officer or his or her relative may serve as chairman or be vested with the chairman's authorities. Such determination of a company's shareholders requires either: (1) the approval of at least a majority of the shares of those shareholders present and voting on the matter (other than controlling shareholders and those having a personal interest in the determination) (shares held by abstaining shareholders shall not be considered); or (2) that the total number of shares opposing such determination does not exceed 2% of the total voting power in the company. Currently, we have a separate chairman and chief executive officer.

The board of directors may, subject to the provisions of the Companies Law, delegate some of its powers to committees of the board, and it may, from time to time, revoke such delegation or alter the composition of any such committees, subject to certain limitations. Unless otherwise expressly provided by the board of directors, the committees shall not be empowered to further delegate such powers. The composition and duties of our audit committee, financial statement examination committee and compensation committee are described below.

The board of directors oversees how management monitors compliance with our risk management policies and procedures, and reviews the adequacy of the risk management framework in relation to the risks faced by us. The board of directors is assisted in its oversight role by an internal auditor. The internal auditor undertakes both regular and ad hoc reviews of risk management controls and procedures, the results of which are reported to our audit committee.

External Directors

Under the Companies Law, an Israeli company whose shares have been offered to the public or whose shares are listed for trading on a stock exchange in or outside of Israel is required to appoint at least two external directors to serve on its board of directors. External directors must meet stringent standards of independence. As of the date hereof, our external directors are Ms. Sharon Levita and Mr. Oded Tamir.

According to regulations promulgated under the Companies law, at least one of the external directors is required to have "financial and accounting expertise," unless another member of the audit committee, who is an independent director under the Nasdaq Stock Market rules, has "financial and accounting expertise," and the other external director or directors are required to have "professional expertise." An external director may not be appointed to an additional term unless: (1) such director has "accounting and financial expertise;" or (2) he or she has "professional expertise," and on the date of appointment for another term there is another external director who has "accounting and financial expertise" and the number of "accounting and financial experts" on the board of directors is at least equal to the minimum number determined appropriate by the board of directors. We have determined that both Ms. Sharon Levita and Mr. Oded Tamir have accounting and financial expertise.

A director with accounting and financial expertise is a director who, due to his or her education, experience and skills, possesses a high degree of proficiency in, and an understanding of, business – accounting matters and financial statements, such that he or she is able to understand the financial statements of the company in depth and initiate a discussion about the manner in which financial data is presented. A director is deemed to have "professional expertise" if he or she holds an academic degree in certain fields or has at least five years of experience in one of the said fields or in certain senior positions.

External directors are elected by a majority vote at a shareholders' meeting, as long as either:

- at least a majority of the shares held by shareholders who are not controlling shareholders and do not have personal interest in the appointment (excluding a personal interest that did not result from the shareholder's relationship with the controlling shareholder) have voted in favor of the proposal (shares held by abstaining shareholders shall not be considered); or

- the total number of shares voted against the election of the external director, does not exceed 2% of the aggregate voting rights of the company.

The term "control" is defined in the Companies Law as the ability to direct the activities of the company, other than by virtue of being an office holder. A shareholder is presumed to be a controlling shareholder if the shareholder "holds" (within the meaning of the Companies Law) 50% or more of the voting rights in a company or has the right to appoint 50% or more of the directors of the company or its general manager. With respect to certain matters (for example: interested party transactions), a controlling shareholder is deemed to include a shareholder that holds 25% or more of the voting rights in a public company if no other shareholder holds more than 50% of the voting rights in the company, but excludes a shareholder whose power derives solely from his or her position as a director of the company or from any other position with the company.

The Companies Law provides for an initial three-year term for an external director. Thereafter, an external director may be reelected by shareholders to serve in that capacity for up to two additional three-year terms, provided that:

(1) his or her service for each such additional term is recommended by one or more shareholders holding at least one percent of the company's voting rights and is approved at a shareholders meeting by a disinterested majority, where the total number of shares held by non-controlling, disinterested shareholders voting for such reelection exceeds two percent of the aggregate voting rights in the company and subject to additional restrictions set forth in the Companies Law with respect to the affiliation of the external director nominee as described below; or

(2) his or her service for each such additional term is recommended by the board of directors and is approved at a shareholder meeting by the same disinterested majority required for the initial election of an external director (as described above); or

(3) the external director offered his or her service for each such additional term and was approved in accordance with the provisions of section (1) above.

The term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including the Nasdaq Stock Market, may be extended indefinitely in increments of additional three-year terms, in each case provided that the audit committee and the board of directors of the company confirm that, in light of the external director's expertise and special contribution to the work of the board of directors and its committees, the reelection for such additional period(s) is beneficial to the company, and provided that the external director is reelected subject to the same shareholder vote requirements as if elected for the first time (as described above). Prior to the approval of the reelection of the external director at a general shareholders meeting, the company's shareholders must be informed of the term previously served by him or her and of the reasons why the board of directors and audit committee recommended the extension of his or her term.

The Companies Law provides that a person is not qualified to serve as an external director if (i) the person is a relative of a controlling shareholder of the company, or (ii) if that person or his or her relative, partner, employer, another person to whom he or she was directly or indirectly subordinate, or any entity under the person's control, has or had, during the two years preceding the date of appointment as an external director: (a) any affiliation or other disqualifying relationship with the company, with any person or entity controlling the company or a relative of such person, or with any entity controlled by or under common control with the company; or (b) in the case of a company with no shareholder holding 25% or more of its voting rights, had at the date of appointment as an external director, any affiliation or other disqualifying relationship with a person then serving as chairman of the board or chief executive officer, with a holder of 5% or more of the issued share capital or voting power in the company or with the most senior financial officer.

The term "relative" is defined under the Companies Law as a spouse, sibling, parent, grandparent or descendant; spouse's sibling, parent or descendant; and the spouse of each of the foregoing persons.

Under the Companies Law, the term "affiliation" and the similar types of disqualifying relationships include (subject to certain exceptions):

- an employment relationship;

- a business or professional relationship even if not maintained on a regular basis (excluding insignificant relationships);
- control; and
- service as an office holder, excluding service as a director in a private company prior to the initial public offering of its shares if such director was appointed as a director of the private company in order to serve as an external director following the initial public offering.

The term "office holder" is defined under the Companies Law as a general manager, chief business manager, deputy general manager, vice general manager, any other person assuming the responsibilities of any of these positions regardless of that person's title, a director and any other manager directly subordinate to the general manager.

In addition, no person may serve as an external director if that person's position or professional or other activities create, or may create, a conflict of interest with that person's responsibilities as a director or otherwise interfere with that person's ability to serve as a director or if the person is an employee of the Israel Securities Authority or of an Israeli stock exchange. A person may furthermore not continue to serve as an external director if he or she received direct or indirect compensation from the company including amounts paid pursuant to indemnification and/or exculpation contracts or commitments and insurance coverage, other than for his or her service as an external director as permitted by the Companies Law and the regulations promulgated thereunder.

Following the termination of an external director's service on a board of directors, such former external director and his or her spouse and children may not be provided a direct or indirect benefit by the company, its controlling shareholder or any entity under its controlling shareholder's control. This includes engagement as an office holder or director of the company or a company controlled by its controlling shareholder or employment by, or provision of services to, any such company for consideration, either directly or indirectly, including through a corporation controlled by the former external director. This restriction extends for a period of two years with regard to the former external director and his or her spouse or child and for one year with respect to other relatives of the former external director.

External directors may be removed only by a special general meeting of shareholders called by the board of directors after the board has determined the occurrence of circumstances allow such dismissal, at the same special majority of shareholders required for their election or by a court, and in both cases only if the external directors cease to meet the statutory qualifications for their appointment or if they violate their duty of loyalty to our company. In the event of a vacancy created by an external director which causes the company to have fewer than two external directors, the board of directors is required under the Companies Law to call a shareholder meeting as soon as possible to appoint such number of new external directors in order that the company thereafter will have two external directors.

External directors may be compensated only in accordance with regulations adopted under the Companies Law.

If at the time at which an external director is appointed all members of the board of directors who are not controlling shareholders or relatives of controlling shareholders of the company are of the same gender, the external director to be appointed must be of the other gender. A director of a company may not be appointed as an external director of another company if at the same time a director of such other company is acting as an external director of the first company.

Under regulations promulgated pursuant to the Companies Law, a company with no controlling shareholder whose shares are listed for trading on specified exchanges outside of Israel, including Nasdaq, may adopt exemptions from various corporate governance requirements of the Companies Law, so long as such company satisfies the requirements of applicable foreign country laws and regulations, including applicable stock exchange rules, that apply to companies organized in that country and relating to the appointment of independent directors and the composition of audit and compensation committees. Such exemptions include an exemption from the requirement to appoint external directors and the requirement that an external director be a member of certain committees, as well as exemption from limitations on directors' compensation. As of the Date hereof, the Company have a controlling shareholder and therefore cannot use such exemptions.

Independent Directors Under the Companies Law

An "independent director" is either an external director or a director who meets the same non-affiliation criteria as an external director (except for (i) the requirement that the director be an Israeli resident (which does not apply to companies such as ours whose securities have been offered outside of Israel or are listed outside of Israel) and (ii) the requirement for accounting and financial expertise or professional qualifications), as determined by the audit committee, and who has not served as a director of the company for more than nine consecutive years. For these purposes, ceasing to serve as a director for a period of two years or less would not be deemed to sever the consecutive nature of such director's service.

Regulations promulgated pursuant to the Companies Law provide that a director in a public company whose shares are listed for trading on specified exchanges outside of Israel, including Nasdaq, who qualifies as an independent director under the relevant non-Israeli rules and who meets certain non-affiliation criteria, which are less stringent than those applicable to independent directors as set forth above, would be deemed an "independent" director pursuant to the Companies Law provided: (i) he or she has not served as a director for more than nine consecutive years; and (ii) he or she has been approved as such by the audit committee. For these purposes, ceasing to serve as a director for a period of two years or less would not be deemed to sever the consecutive nature of such director's service.

Furthermore, pursuant to these regulations, such company may reappoint a person as an independent director for additional terms, beyond nine years, which do not exceed three years each, if each of the audit committee and the board of directors determine, in that order, that in light of the independent director's expertise and special contribution to the board of directors and its committees, the reappointment for an additional term is in the company's best interest.

Alternate Directors

Our articles of association provide, as allowed by the Companies Law, that any director may, subject to the conditions set thereto including approval of the nominee by our board of directors, appoint a person as an alternate to act in his place, to remove the alternate and appoint another in his place and to appoint an alternate in place of an alternate whose office is vacated for any reason whatsoever. Under the Companies Law, a person who is not qualified to be appointed as a director, a person who is already serving as a director or a person who is already serving as an alternate director for another director, may not be appointed as an alternate director. Nevertheless, a director who is already serving as a director may be appointed as an alternate director for a member of a committee of the board of directors so long as he or she is not already serving as a member of such committee, and if the alternate director is to replace an external director, he or she is required to be an external director and to have either "financial and accounting expertise" or "professional expertise," depending on the qualifications of the external director he or she is replacing. A person who does not have the requisite "financial and accounting experience" or the "professional expertise," depending on the qualifications of the external director he or she is replacing, may not be appointed as an alternate director for an external director. A person who is not qualified to be appointed as an independent director, pursuant to the Companies Law, may not be appointed as an alternate director of an independent director qualified as such under the Companies Law. Unless the appointing director limits the time or scope of the appointment, the appointment is effective for all purposes until the appointing director ceases to be a director or terminates the appointment.

Committees of the Board of Directors

Our board of directors has established four standing committees, the audit committee, the compensation committee, and the financial statement examination committee.

Audit Committee

Under the Companies Law, we are required to appoint an audit committee. The audit committee must be comprised of at least three directors, including all of the external directors (one of whom must serve as chair of the committee). The audit committee may not include the chairman of the board; a controlling shareholder of the company or a relative of a controlling shareholder; a director employed by or providing services on a regular basis to the company, to a controlling shareholder or to an entity controlled by a controlling shareholder; or a director who derives most of his or her income from a controlling shareholder.

In addition, a majority of the members of the audit committee of a publicly traded company must be independent directors under the Companies Law. Our audit committee is comprised of Ms. Sharon Levita, Mr. Oded Tamir and Mr. Vincent Chan. Ms. Levita serves as the chair of our audit committee.

Under the Companies Law, our audit committee is responsible for, among other things:

(i) determining whether there are deficiencies in the business management practices of our company, and making recommendations to the board of directors to improve such practices;

(ii) determining whether to approve certain related party transactions (including transactions in which an office holder has a personal interest and whether such transaction is extraordinary or material under Companies Law) and establishing the approval process for certain transactions with a controlling shareholder or in which a controlling shareholder has a personal interest (see "*Item 6.C. Directors, Senior Management and Employees – Board Practices – Approval of Related Party Transactions under Israeli law"*);

(iii) determining the approval process for transactions that are "non-negligible" (i.e., transactions with a controlling shareholder that are classified by the audit committee as non-negligible, even though they are not deemed extraordinary transactions), as well as determining which types of transactions would require the approval of the audit committee, optionally based on criteria which may be determined annually in advance by the audit committee;

(iv) examining our internal controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of its responsibilities;

(v) examining the scope of our auditor's work and compensation and submitting a recommendation with respect thereto to our board of directors or shareholders, depending on which of them is considering the appointment of our auditor;

(vi) establishing procedures for the handling of employees' complaints as to deficiencies in the management of our business and the protection to be provided to such employees; and

(vii) where the board of directors approves the working plan of the internal auditor, examining such working plan before its submission to the board of directors and proposing amendments thereto.

Our audit committee may not conduct any discussions or approve any actions requiring its approval (see "*Item 6.C. Directors, Senior Management and Employees – Board Practices – Approval of Related Party Transactions under Israeli law"*), unless at the time of the approval a majority of the committee's members are present, which majority consists of independent directors under the Companies Law, including at least one external director.

Our board of directors has adopted an audit committee charter setting forth, among others, the responsibilities of the audit committee consistent with the rules of the SEC and Nasdaq Listing Rules (in addition to the requirements for such committee under the Companies Law), including, among others, the following:

- oversight of our independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of our independent registered public accounting firm to the board of directors in accordance with Israeli law;
- recommending the engagement or termination of the person filling the office of our internal auditor, reviewing the services provided by our internal auditor and reviewing effectiveness of our system of internal control over financial reporting;
- recommending the terms of audit and non-audit services provided by the independent registered public accounting firm for pre-approval by our board of directors; and
- reviewing and monitoring, if applicable, legal matters with significant impact, finding of regulatory authorities' findings, receive reports regarding irregularities and legal compliance, acting according to "whistleblower policy" and recommend to our board of directors if so required.

Nasdaq Stock Market Requirements for Audit Committee

Under the Nasdaq Stock Market rules, we are required to maintain an audit committee consisting of at least three members, all of whom are independent and are financially literate and one of whom has accounting or related financial management expertise.

As noted above, the members of our audit committee include Ms. Sharon Levita and Mr. Oded Tamir who are external directors, and Mr. Vincent Chan who is an independent director, each of whom is "independent," as such term is defined in under Nasdaq Stock Market rules. Ms. Levita serves as the chair of our audit committee. All members of our audit committee meet the requirements for financial literacy under the Nasdaq Stock Market rules. Our board of directors has determined that each member of our audit committee is an audit committee financial expert as defined by the SEC rules and has the requisite financial experience as defined by the Nasdaq Stock Market rules.

Financial Statement Examination Committee

Under the Companies Law, the board of directors of a public company in Israel must appoint a financial statement examination committee, which consists of members with accounting and financial expertise or the ability to read and understand financial statements. Our financial statement examination committee is comprised of Ms. Sharon Levita, Mr. Oded Tamir and Mr. Vincent Chan. The function of a financial statements examination committee is to discuss and provide recommendations to its board of directors (including the report of any deficiency found) with respect to the following issues: (1) estimations and assessments made in connection with the preparation of financial statements; (2) internal controls related to the financial statements; (3) completeness and propriety of the disclosure in the financial statements; (4) the accounting policies adopted and the accounting treatments implemented in material matters of the company; and (5) value evaluations, including the assumptions and assessments on which evaluations are based and the supporting data in the financial statements.

Compensation Committee

Under the Companies Law, the board of directors of any public company must establish a compensation committee. The compensation committee must be comprised of at least three directors, including all of the external directors, who must constitute a majority of the members of the compensation committee. Each compensation committee member that is not an external director must be a director whose compensation is in accordance with the amount paid to an external director of the Company. The compensation committee is subject to the same Companies Law restrictions as the audit committee as to: (a) who may not be a member of the committee; and (b) who may not be present during committee deliberations as described above.

Our compensation committee is acting pursuant to a written charter, and consists of Ms. Sharon Levita, Mr. Oded Tamir and Mr. Vincent Chan. Our compensation committee complies with the provisions of the Companies Law, the regulations promulgated thereunder, and our articles of association, on all aspects referring to its independence, authorities and practice. Our compensation committee follows home country practice as opposed to complying with the compensation committee membership and charter requirements prescribed under the Nasdaq Stock Market rules.

Our compensation committee reviews and recommends to our board of directors: with respect to our executive officers' and directors': (1) annual base compensation (2) annual incentive bonus, including the specific goals and amounts; (3) equity compensation; (4) employment agreements, severance arrangements, and change in control agreements and provisions; (5) retirement grants and/or retirement bonuses; and (6) any other benefits, compensation, compensation policies or arrangements.

The duties of the compensation committee include the recommendation to the company's board of directors of a policy regarding the terms of engagement of office holders, to which we refer as a compensation policy. Such policy must be adopted by the company's board of directors, after considering the recommendations of the compensation committee. The compensation policy is then brought for approval by our shareholders, which requires a special majority. Under the Companies Law, the board of directors may adopt the compensation policy if it is not approved by the shareholders, provided that after the shareholders oppose the approval of such policy, the compensation committee and the board of directors revisit the matter and determine that adopting the compensation policy would be in the best interests of the company. Our compensation policy was approved by our shareholders on March 3, 2022. The Current compensation policy expired on March 3, 2025. On March 23, 2025, the Company's compensation committee and the board of directors approved a new compensation policy which will be effective as of and subject to the approval of the company's shareholders of the Company. The Company is currently in the process of convening a special general meeting for the approval of the compensation policy.

The compensation policy must serve as the basis for decisions concerning the financial terms of employment or engagement of executive officers and directors, including exculpation, insurance, indemnification or any monetary payment or obligation of payment in respect of employment or engagement. The compensation policy must relate to certain factors, including advancement of the company's objectives, the company's business and its long-term strategy, and creation of appropriate incentives for executives. It must also consider, among other things, the company's risk management, size and the nature of its operations. The compensation policy must furthermore consider the following additional factors:

- the education, skills, expertise and accomplishments of the relevant director or executive;
- the director's or executive's roles and responsibilities and prior compensation agreements with him or her;
- the relationship between the cost of the terms of service of an office holder and the average median compensation of the other employees of the company (including those employed through manpower companies), including the impact of disparities in salary upon work relationships in the company;
- the possibility of reducing variable compensation at the discretion of the board of directors; and the possibility of setting a limit on the exercise value of non-cash variable compensation; and
- as to severance compensation, the period of service of the director or executive, the terms of his or her compensation during such service period, the company's performance during that period of service, the person's contribution towards the company's achievement of its goals and the maximization of its profits, and the circumstances under which the person is leaving the company.

The compensation policy must also include the following principles:

- with the exception of office holders who report directly to the chief executive officer, the link between variable compensation and long-term performance and measurable criteria;
- the relationship between variable and fixed compensation, and the ceiling for the value of variable compensation at the time of its grant;
- the conditions under which a director or executive would be required to repay compensation paid to him or her if it was later shown that the data upon which such compensation was based was inaccurate and was required to be restated in the company's financial statements;
- the minimum holding or vesting period for variable, equity-based compensation; and
- maximum limits for severance compensation.

The compensation policy must also consider appropriate incentives from a long-term perspective.

The compensation committee is responsible for: (1) recommending the compensation policy to a company's board of directors for its approval (and subsequent approval by the shareholders); and (2) duties related to the compensation policy and to the compensation of a company's office holders, including:

- recommending whether a compensation policy should continue in effect, if the then-current policy has a term of greater than three years (approval of either a new compensation policy or the continuation of an existing compensation policy must in any case occur every three years);

- recommending to the board of directors periodic updates to the compensation policy;
- administering the clawback policy;
- assessing implementation of the compensation policy;
- determining whether the terms of compensation of certain office holders of the company need not be brought to approval of the shareholders; and
- determining whether to approve the terms of compensation of office holders that require the committee's approval.

Our compensation policy is designed to promote our long-term goals, work plan and policy, retain, motivate and incentivize our directors and executive officers, while considering the risks that our activities involve, our size, the nature and scope of our activities and the contribution of an officer to the achievement of our goals and maximization of profits, and align the interests of our directors and executive officers with our long-term performance. To that end, a portion of an executive officer compensation package is targeted to reflect our short and long-term goals, as well as the executive officer's individual performance. On the other hand, our compensation policy includes measures designed to reduce the executive officer's incentives to take excessive risks that may harm us in the long-term, such as limits on the value of cash bonuses and equity-based compensation, limitations on the ratio between the variable and the total compensation of an executive officer and minimum vesting periods for equity-based compensation.

Our compensation policy also addresses our executive officer's individual characteristics (such as his or her respective position, education, scope of responsibilities and contribution to the attainment of our goals) as the basis for compensation variation among our executive officers, and considers the internal ratios between compensation of our executive officers and directors and other employees. Pursuant to our compensation policy, the compensation that may be granted to an executive officer may include: base salary, annual bonuses, equity-based compensation, benefits and retirement and termination of service arrangements. All cash bonuses (including special bonuses and one-time bonuses) are limited to a maximum amount linked to the executive officer's base salary. In addition, our compensation policy provides for maximum permitted ratios between the total variable (cash bonuses and equity based compensation) and non-variable (base salary) compensation components, in accordance with an officer's respective position with the company.

An annual cash bonus may be awarded to executive officers upon the attainment of pre-set periodic objectives and individual targets. The chairman or Chief Executive Officer may be granted with a discretionary bonus of up to an immaterial portion of the annual bonus (as defined in the compensation policy). Other subordinate office holders may be granted with discretionary bonuses of up to three (3) monthly salaries. Our Chief Executive Officer will be entitled to recommend performance objectives to such executive officers, and such performance objectives will be approved by our compensation committee (and, if required by law, by our board of directors).

The performance measurable objectives of our Chief Executive Officer will be determined annually by our compensation committee and board of directors. A less significant portion of Chief Executive Officer's annual cash bonus may be based on a discretionary evaluation of the Chief Executive Officer's respective overall performance by the compensation committee and the board of directors based on quantitative and qualitative criteria.

The equity-based compensation under our compensation policy for our executive officers (including members of our board of directors) is designed in a manner consistent with the underlying objectives in determining the base salary and the annual cash bonus, with its main objectives being to enhance the alignment between the executive officers' interests with our long-term interests and those of our shareholders and to strengthen the retention and the motivation of executive officers in the long term. Our compensation policy provides for executive officer compensation in the form of share options, Restricted Share Units, or RSUs, and or any other equity-based compensation in accordance with our share incentive plan then in place. Equity-based compensation granted to executive officers shall be subject to vesting periods in order to promote long-term retention of the awarded executive officers. The equity-based compensation shall be granted from time to time and be individually determined and awarded according to the performance, educational background, prior business experience, qualifications, role and the personal responsibilities of the executive officer.

In addition, our compensation policy contains compensation recovery provisions which allows us under certain conditions to recover bonuses paid in excess, enables our Chief Executive Officer to approve an immaterial change in the terms of employment of an executive officer (provided that the changes of the terms of employment are in accordance our compensation policy) and allows us to exculpate, indemnify and insure our executive officers and directors subject to certain limitations set forth thereto.

Our compensation policy also provides for compensation to the members of our board of directors either: (i) in accordance with the amounts provided in the Companies Regulations (Rules Regarding the Compensation and Expenses of an External Director) of 2000, as amended by the Companies Regulations (Relief for Public Companies Traded in Stock Exchange Outside of Israel) of 2000, as such regulations may be amended from time to time; or (ii) in accordance with the amounts determined in our compensation policy.

Internal Auditor

Under the Companies Law, the board of directors of an Israeli public company must appoint an internal auditor nominated by the audit committee. Our internal auditor is Mr. Doron Cohen (Fahn Kanne Control Management Ltd, Grant Thornton). The role of the internal auditor is to examine, among other things, whether a company's actions comply with the law and proper business procedure. The audit committee is required to oversee the activities, and to assess the performance of the internal auditor as well as to review the internal auditor's work plan. An internal auditor may not be an interested party or office holder, or a relative of any interested party or office holder, and may not be a member of the company's independent accounting firm or its representative. The Companies Law defines an interested party as a holder of 5% or more of the outstanding shares or voting rights of a company, any person or entity that has the right to appoint at least one director or the general manager of the company or any person who serves as a director or as the general manager of a company. Our internal auditor is not an interested party in the Company, and not our employee.

Remuneration of Directors

Under the Companies Law, remuneration of directors is subject to the approval of the compensation committee, thereafter by the board of directors and thereafter, unless exempted under the regulations promulgated under the Companies Law, by the general meeting of the shareholders. In case the remuneration of the directors is in accordance with regulations applicable to remuneration of the external directors then such remuneration shall be exempt from the approval of the general meeting. Where the director is also a controlling shareholder, the requirements for approval of transactions with controlling shareholders apply.

Fiduciary Duties of Office Holders

The Companies Law imposes a duty of care and a duty of loyalty on all office holders of a company.

The duty of care requires an office holder to act with the level of skill with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of care of an office holder includes a duty to use reasonable means to obtain:

- information on the advisability of a given action brought for his approval or performed by him by virtue of his position; and
- all other important information pertaining to these actions.

The duty of loyalty of an office holder requires an office holder to act in good faith and for the benefit of the company, and includes a duty to:

- refrain from any conflict of interest between the performance of his duties in the company and his performance of his other duties or personal affairs;
- refrain from any action that is competitive with the company's business;
- refrain from exploiting any business opportunity of the company to receive a personal gain for himself or others; and
- disclose to the company any information or documents relating to the company's affairs which the office holder has received due to his position as an office holder.

Insurance

Under the Companies Law, a company may obtain insurance for any of its office holders against the following liabilities incurred due to acts he or she performed as an office holder, if and to the extent provided for in the company's articles of association:

- breach of his or her duty of care to the company or to another person, to the extent such a breach arises out of the negligent conduct of the office holder;
- a breach of his or her duty of loyalty to the company, provided that the office holder acted in good faith and had reasonable cause to assume that his or her act would not prejudice the company's interests; and
- a financial liability imposed upon him or her in favor of another person.

We currently have directors' and officers' liability insurance, providing total coverage of $14 million. Such insurance also includes side A directors' and officers' liability insurance, for the benefit of all of our directors and officers.

Indemnification

The Companies Law and the Israeli Securities Law, 5728-1968, or the Securities Law, provide that a company may indemnify an office holder against the following liabilities and expenses incurred for acts performed by him or her as an office holder, either pursuant to an undertaking made in advance of an event or following an event, provided its articles of association include a provision authorizing such indemnification:

- a financial liability imposed on him or her in favor of another person by any judgment concerning an act performed in his or her capacity as an office holder, including a settlement or arbitrator's award approved by a court;
- reasonable litigation expenses, including attorneys' fees, expended by the office holder (a) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (1) no indictment (as defined in the Companies Law) was filed against such office holder as a result of such investigation or proceeding; and (2) no financial liability as a substitute for the criminal proceeding (as defined in the Companies Law) was imposed upon him or her as a result of such investigation or proceeding, or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; or (b) in connection with a monetary sanction;
- reasonable litigation expenses, including attorneys' fees, expended by the office holder or imposed on him or her by a court: (1) in proceedings that the company institutes, or that another person institutes on the company's behalf, against him or her; (2) in a criminal proceedings of which he or she was acquitted; or (3) as a result of a conviction for a crime that does not require proof of criminal intent; and
- expenses incurred by an office holder in connection with an Administrative Procedure under the Securities Law, including reasonable litigation expenses and reasonable attorneys' fees. An "Administrative Procedure" is defined as a procedure pursuant to chapters H3 (Monetary Sanction by the Israeli Securities Authority), H4 (Administrative Enforcement Procedures of the Administrative Enforcement Committee) or I1 (Arrangement to prevent Procedures or Interruption of procedures subject to conditions) to the Securities Law.

The companies Law also permits a company to undertake in advance to indemnify an office holder, provided that if such indemnification relates to financial liability imposed on him or her, as described above, then the undertaking should be limited and shall detail the following foreseen events and amount or criterion:

- to events that in the opinion of the board of directors can be foreseen based on the company's activities at the time that the undertaking to indemnify is made; and
- in amount or criterion determined by the board of directors, at the time of the giving of such undertaking to indemnify, to be reasonable under the circumstances.

We have entered into indemnification agreements with all of our directors and with all members of our office holders. Each such indemnification agreement provides the office holder with indemnification permitted under applicable law and up to a certain amount, and to the extent that these liabilities are not covered by directors and officer's insurance.

Exculpation

Under the Companies Law, an Israeli company may not exculpate an office holder from liability for a breach of his or her duty of loyalty, but may exculpate in advance an office holder from his or her liability to the company, in whole or in part, for damages caused to the company as a result of a breach of his or her duty of care (other than in relation to distributions), but only if a provision authorizing such exculpation is included in its articles of association. Our articles of association provide that we may exculpate, in whole or in part, any office holder from liability to us for damages caused to the company as a result of a breach of his or her duty of care, but prohibit an exculpation from liability arising from a company's transaction in which our controlling shareholder or officer has a personal interest. Subject to the aforesaid limitations, under the indemnification agreements, we exculpate and release our office holders from any and all liability to us related to any breach by them of their duty of care to us to the fullest extent permitted by law.

Limitations

The Companies Law provides that we may not exculpate or indemnify an office holder nor enter into an insurance contract that would provide coverage for any liability incurred as a result of any of the following: (1) a breach by the office holder of his or her duty of loyalty unless (in the case of indemnity or insurance only, but not exculpation) the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice us; (2) a breach by the office holder of his or her duty of care if the breach was carried out intentionally or recklessly (as opposed to merely negligently); (3) any act or omission committed with the intent to derive an illegal personal benefit; or (4) any fine, monetary sanction, penalty or forfeit levied against the office holder.

Under the Companies Law, exculpation, indemnification and insurance of office holders in a public company must be approved by the compensation committee and the board of directors and, with respect to certain office holders or under certain circumstances, also by the shareholders.

Our articles of association permit us to exculpate (subject to the aforesaid limitation), indemnify and insure our office holders to the fullest extent permitted or to be permitted by the Companies Law.

The foregoing descriptions summarize the material aspects and practices of our board of directors. For additional details, we also refer you to the full text of the Companies Law, as well as of our articles of association, which is an exhibit to this annual report on Form 20-F, and is incorporated herein by reference.

There are no service contracts between us or any of our subsidiaries, on the one hand, and our directors in their capacity as directors, on the other hand, providing for benefits upon termination of service.

Approval of Related Party Transactions under Israeli Law

General

Under the Companies Law, we may approve an action by an office holder from which the office holder would otherwise have to refrain, as described above, if:

- the office holder acts in good faith and the act or its approval does not cause harm to the company; and
- the office holder disclosed the nature of his or her interest in the transaction (including any significant fact or document) to the company at a reasonable time before the company's approval of such matter.

Disclosure of Personal Interests of an Office Holder

The Companies Law requires that an office holder disclose to the company, promptly, and, in any event, not later than the board meeting at which the transaction is first discussed, any direct or indirect personal interest that he or she may have and all related material information known to him or her relating to any existing or proposed transaction by the company, including without limitations, any material document or fact regarding such transaction. If the transaction is an extraordinary transaction, the office holder must also disclose any personal interest held by:

- the office holder's relatives; or
- any corporation in which the office holder or his or her relatives holds 5% or more of the shares or voting rights, serves as a director or general manager or has the right to appoint at least one director or the general manager.

An office holder is not, however, obliged to disclose a personal interest if it derives solely from the personal interest of his or her relative in a transaction that is not considered an extraordinary transaction. Under the Companies Law, an extraordinary transaction is a transaction:

- not in the ordinary course of business; or
- not on market terms; or
- that is likely to have a material effect on the company's profitability, assets or liabilities.

The Companies Law does not specify to whom within us nor the manner in which required disclosures are to be made. We require our office holders to make such disclosures to our board of directors.

Under the Companies Law, once an office holder complies with the above disclosure requirement, the board of directors may approve a transaction between the company and an office holder, or a third party in which an office holder has a personal interest, unless the articles of association provide otherwise and provided that the transaction is in the company's interest. If the transaction is an extraordinary transaction in which an office holder has a personal interest, first the audit committee and then the board of directors, in that order, must approve the transaction. Under specific circumstances, shareholder approval may also be required. Generally, a person who has a personal interest in a matter which is considered at a meeting of the board of directors or the audit committee may not be present at such a meeting unless the chairman of the audit committee or board of directors (as applicable) determines that he or she should be present in order to present the transaction that is subject to approval. A director who has a personal interest in a transaction, which is considered at a meeting of the board of directors or the audit committee, may not be present at this meeting or vote on this matter, unless a majority of members of the board of directors or the audit committee, as the case may be, has a personal interest. If a majority of the board of directors has a personal interest, then shareholder approval is generally also required.

Disclosure of Personal Interests of a Controlling Shareholder

Under the Companies Law, the disclosure requirements that apply to an office holder also apply to a controlling shareholder of a public company. Extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, including a private placement in which a controlling shareholder has a personal interest, as well as transactions for the provision of services whether directly or indirectly by a controlling shareholder or his or her relative, or a company such controlling shareholder controls, and transactions concerning the terms of engagement and compensation of a controlling shareholder or a controlling shareholder's relative, whether as an office holder or an employee, require the approval of the audit committee or the compensation committee, as the case may be, the board of directors and a majority of the shares voted by the shareholders of the company participating and voting on the matter in a shareholders' meeting. In addition, the shareholder approval must fulfill one of the following requirements, or a Special Majority:

- at least a majority of the shares held by shareholders who are not controlling shareholders and have no personal interest in the transaction and are voting at the meeting must be voted in favor of approving the transaction, excluding abstentions; or

- the shares voted by shareholders who vote against the transaction represent no more than 2% of the voting rights in the company.

In addition, any extraordinary transaction with a controlling shareholder or in which a controlling shareholder has a personal interest with a term of more than three years requires the abovementioned approval every three years; however, such transactions not involving the receipt of services or compensation can be approved for a longer term, provided that the audit committee determines that such longer term is reasonable under the circumstances.

The Companies Law requires that every shareholder that participates, in person, by proxy or by voting instrument, in a vote regarding a transaction with a controlling shareholder, must indicate in advance or in the ballot whether or not that shareholder has a personal interest in the vote in question. Failure to indicate such personal interest will result in the invalidation of that shareholder's vote.

The term "controlling shareholder" is defined in the Companies Law as a shareholder with the ability to direct the activities of the company, other than by virtue of being an office holder. A shareholder is presumed to be a controlling shareholder if the shareholder holds 50% or more of the voting rights in a company or has the right to appoint 50% or more of the directors of the company or its general manager. In the context of a transaction involving a shareholder of the company, a controlling shareholder also includes a shareholder who holds 25% or more of the voting rights in the company if no other shareholder holds more than 50% of the voting rights in the company. For this purpose, the holdings of all shareholders who have a personal interest in the same transaction will be aggregated.

Approval of the Compensation of Directors and Executive Officers

The compensation of, or an undertaking to indemnify, insure or exculpate, an office holder who is not a director requires the approval of the company's compensation committee, followed by the approval of the company's board of directors, and, if such compensation arrangement or an undertaking to indemnify, insure or exculpate is inconsistent with the company's stated compensation policy, or if the said office holder is the chief executive officer of the company (subject to a number of specific exceptions), then such arrangement is subject to the approval of our shareholders, subject to a Special Majority requirement.

Directors. Under the Companies Law, the compensation of our directors requires the approval of our compensation committee, the subsequent approval of the board of directors and, unless exempted under the regulations promulgated under the Companies Law, the approval of the general meeting of our shareholders. If the compensation of our directors is inconsistent with our stated compensation policy, then, provided that those provisions that must be included in the compensation policy according to the Companies Law have been considered by the compensation committee and board of directors, shareholder approval by a Special Majority will be required.

Executive officers other than the chief executive officer. The Companies Law requires the approval of the compensation of a public company's executive officers (other than the chief executive officer) in the following order: (i) the compensation committee, (ii) the company's board of directors, and (iii) only if such compensation arrangement is inconsistent with the company's stated compensation policy, the company's shareholders by a Special Majority. However, if the shareholders of the company do not approve a compensation arrangement with an executive officer that is inconsistent with the company's stated compensation policy, the compensation committee and board of directors may override the shareholders' decision if each of the compensation committee and the board of directors provide detailed reasons for their decision, including regarding to the shareholders of the Company objection.

Chief executive officer. Under the Companies Law, the compensation of a public company's chief executive officer is required to be approved by: (i) the company's compensation committee; (ii) the company's board of directors, and (iii) the company's shareholders by a Special Majority. However, if the shareholders of the company do not approve the compensation arrangement with the chief executive officer, the compensation committee and board of directors may override the shareholders' decision if each of the compensation committee and the board of directors provides detailed reasons for their decision. In addition, the compensation committee may exempt the engagement terms of a candidate to serve as the chief executive officer from shareholders' approval, if the compensation committee determines that the compensation arrangement is consistent with the company's stated compensation policy, that the chief executive officer did not have a prior business relationship with the company or a controlling shareholder of the company, and that subjecting the approval to a shareholder vote would impede the company's ability to attain the candidate to serve as the company's chief executive officer (and provide detailed reasons for the latter).

The approval of each of the compensation committee and the board of directors, with regard to the office holders and directors above, must be in accordance with the company's stated compensation policy; however, under special circumstances, the compensation committee and the board of directors may approve compensation terms of a chief executive officer that are inconsistent with the company's compensation policy provided that they have considered those provisions that must be included in the compensation policy according to the Companies Law and that shareholder approval was obtained by a Special Majority requirement.

Duties of Shareholders

Under the Companies Law, a shareholder has a duty to refrain from abusing his power in the company and to act in good faith and in an acceptable manner in exercising his rights and performing his obligations toward the company and other shareholders, including, among other things, in voting at general meetings of shareholders (and at shareholder class meetings) on the following matters:

- amendment of the articles of association;
- increase in the company's authorized share capital;
- merger; and
- the approval of related party transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from oppressing other shareholders. The remedies generally available upon a breach of contract will also apply to a breach of the above-mentioned duties, and in the event of oppression of other shareholders, additional remedies are available to the injured shareholder.

In addition, any controlling shareholder, any shareholder that knows that its vote can determine the outcome of a shareholder vote and any shareholder that, under a company's articles of association, has the power to appoint or prevent the appointment of an office holder, or has another power with respect to a company, is under a duty to act with fairness towards the company. The Companies Law does not describe the substance of this duty except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness, taking the shareholder's position in the company into account.

D. Employees

As of December 31, 2022, we had 65 full-time employees and 7 part-time employees. As of December 31, 2023, we had 71 full-time employees and 6 part-time employees. As of December 31, 2024, we had 64 full-time employees and two part-time employees. The majority of our employees are located in Israel.

Our employees are not represented by labor unions or covered by collective bargaining agreements. We believe that we maintain good relations with our employees. However, in Israel, we are subject to certain Israeli labor laws, regulations and national labor court precedent rulings, as well as certain provisions of collective bargaining agreements applicable to us by virtue of extension orders issued in accordance with relevant labor laws by the Israeli Ministry of Economy and which apply such agreement provisions to our employees even though they are not part of a union that has signed a collective bargaining agreement.

All of our employment and consulting agreements include employees' and consultants' undertakings with respect to non-competition and assignment to us of intellectual property rights developed in the course of employment and confidentiality. With respect to our employees in Israel, the enforceability of such provisions is limited by Israeli law.

E. Share Ownership

See "Item 7.A. Major Shareholders" below.

Employee Equity Incentive Plan

We maintain two equity incentive plans, the 2006 plan and the 2024 plan. As of March 24, 2025, the number of options allotted in the 2006 plan is 3,510,615. In addition, the number of options that have vested and have not yet been exercised or expired in the 2006 plan is 2,682,647. 1,038,675 options and 834,666 RSUs were allotted in the 2024 plan.

Our 2006 plan was adopted by our board of directors in May 2017 and expires in May 2027. Our employees, directors, officer, consultants, advisors, suppliers and any other person or entity whose services are considered valuable to us are eligible to participate in this plan. Our 2024 plan was adopted by our board of directors in February 2024 and expires in February 2034. Our employees, directors, officer, consultants, advisors, suppliers and any other person or entity whose services are considered valuable to us are eligible to participate in this plan. In April 2024, our board of directors adopted an addendum to our 2024 plan to confer eligibility for participation in and permit the grant of awards under the 2024 plan for any U.S. employees, directors, officers, consultants, advisors, suppliers and any other persons or entities whose services are considered valuable to us in accordance with the treatment of qualified incentive stock options and non-qualified incentive stock options under U.S. federal taxation law under Internal Revenue Code of 1986 (U.S. Code: Title 26).

Our ESOP plans are administered by our board of directors, regarding the granting of options and the terms of option grants (and regarding our 2024 plan, also the granting of restricted share units and restricted shares), including exercise price, method of payment, vesting schedule, acceleration of vesting and the other matters necessary in the administration of these plan. Eligible Israeli employees, officers and directors, would qualify for provisions of Section 102(b)(2) of the Israeli Income Tax Ordinance (New Version), 5721–1961, or the Tax Ordinance. Pursuant to such Section 102(b)(2), qualifying options and shares issued upon exercise of such options are held in trust and registered in the name of a trustee selected by the board of directors. The trustee may not release these options or shares to the holders thereof for two years from the date of the registration of the options in the name of the trustee. Under Section 102, any tax payable by an employee from the grant or exercise of the options is deferred until the transfer of the options or Ordinary Shares by the trustee to the employee or upon the sale of the options or Ordinary Shares, and gains may qualify to be taxed as capital gains at a rate equal to 25%, subject to compliance with specified conditions. Our Israeli non-employee service providers and controlling shareholders may only be granted options under Section 3(i) of the Tax Ordinance, which does not provide for similar tax benefits. The ESOP also permits the grant to Israeli grantees of options that do not qualify under Section 102(b)(2).

Upon termination of employment without Cause, as defined in both ESOP plans, all unvested awards will expire, and all vested options will generally be exercisable for three (3) or nine (9) months, depending on the plan, respectively, following termination, or such other period as determined by the plan administrator, subject to the terms of the ESOP plans and the governing award agreement.

Upon termination of employment due to death, retirement or disability, all the vested awards at the time of termination will be exercisable for twenty-four (24) or twelve (12) months, depending on the plan, respectively, following termination, or such other period as determined by the plan administrator, subject to the terms of the ESOP plans and the governing award agreement.

F. Disclosure of a Registrant's Action to Recover Erroneously Awarded Compensation.

Not applicable.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders.

The following table sets forth information regarding beneficial ownership of our Ordinary Shares as of March 24, 2025, by:

- each person, or group of affiliated persons, known to us to be the beneficial owner of more than 5% of our outstanding Ordinary Shares;
- each of our directors and executive officers; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to Ordinary Shares. Ordinary Shares issuable under share options or warrants that are exercisable within 60 days after March 24, 2025, are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options or warrants but are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

We are not controlled by another corporation, by any foreign government or by any natural or legal persons except as set forth herein, and there are no arrangements known to us which would result in a change in control of our company at a subsequent date. Except as indicated in footnotes to this table, we believe that the shareholders named in this table have sole voting and investment power with respect to all shares shown to be beneficially owned by them, based on information provided to us by such shareholders. Unless otherwise noted below, each beneficial owner's address is: c/o IceCure Medical Ltd., 7 Ha'Eshel St., PO Box 3163, Caesarea, 3079504 Israel.

	No. of Shares Beneficially Owned	Percentage Owned
Holders of more than 5% of our voting securities:		
Epoch Partner Investments Limited[1]	25,846,597[2]	44.1%
Directors and senior management who are not 5% holders:		
Li Haixiang	25,846,597[2]	44.1%
Eyal Shamir*	590,314	1.0%
Ronen Tsimerman	355,080	**
Ron Mayron*	278,023	**
Tlalit Bussi Tel-Tzure	191,812	**
Shay Levav	141,861	**
Naum Muchnik	140,423	**
Yang Huang	113,438	**
Merav Nir Dotan	88,938	**
Galit Malik	79,668	**
Shad Good	28,453	**
Oded Tamir*	20,000	**
Sharon Levita*	-	**
Vincent Chun Hung Chan*	-	**
All directors and senior management as a group (14 persons)	27,874,607	47.6%

* Indicates director of the Company.

** Less than 1%.

(1) Mr. Li Haixiang, who has the voting and dispositive power over the shares held by Epoch, is also a member of our board of directors.

(2) Includes 25,846,597 Ordinary Shares. Mr. Li Haixiang has the voting and dispositive power over the shares held by Epoch. The mailing address of Mr. Li Haixiang is 70/F Two International Finance Centre, Suite 7013, Central, Hong Kong. This information is based on the information contained in the Schedule 13G/A filed by Epoch on November 14, 2024.

Changes in Percentage Ownership by Major Shareholders

Over the course of 2024, there was a decrease in the percentage ownership of Epoch (from 52.6% to 45.7%), due to a dilution as a result of public offerings during 2024, including issuances of Ordinary Shares under the ATM facility.

Over the course of 2023, there were no major increases in the percentage ownership of any of our major shareholders. There was a decrease in the percentage ownership of Epoch to 52.6% of our issued and outstanding share capital, or 24,049,707 shares.

Over the course of 2022, there were no major increases in the percentage ownership of our major shareholders. On the other hand, there were decreases in the percentage ownership of Epoch whose percentage ownership in the Company decreased to 52.7% of our issued and outstanding share capital, or 24,049,707 shares, and Alpha Capital Anstalt, whose percentage ownership in the Company decreased below 5% to 0.789% of our issued and outstanding share capital, or 290,378 shares.

Record Holders

Based on a review of information provided to us by our transfer agent, as of March 24, 2025, there were six holders of record of our Ordinary Shares.

The Company is not controlled by another corporation, by any foreign government or by any natural or legal persons except as set forth herein, and there are no arrangements known to the Company which would result in a change in control of the Company at a subsequent date.

B. Related Party Transactions.

Employment Agreements

We have entered into written employment agreements with each of our executive officers. All of these agreements contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable law. In addition, we have entered into agreements with each executive officer and director pursuant to which we have agreed to indemnify each of them up to a certain amount and to the extent that these liabilities are not covered by directors' and officers' insurance. Members of our senior management are eligible for bonuses each year. The bonuses are payable upon meeting objectives and targets that are set by our Chief Executive Officer and approved annually by our board of directors that also set the bonus targets for our Chief Executive Officer.

Options

Since the inception of the ESOP, we have granted options to purchase our Ordinary Shares to our officers and certain of our directors. Such option agreements may contain acceleration provisions upon certain merger, acquisition, or change of control transactions, as defined in the ESOP or in the stated compensation policy, as the case may be. We describe our option plans under "Item 6.E. Share Ownership –Equity Incentive Plan." If the relationship between us and an executive officer or a director is terminated, except for Cause (as defined in the various option plan agreements and the ESOP), options that are vested will generally remain exercisable for three or nine months after such termination, depending on the plan.

Sale of Ordinary Shares

On December 21, 2022, in connection with a "best efforts" public offering, we entered into a securities purchase agreement with certain investors, including our controlling shareholder, Epoch, pursuant to which we agreed issued an aggregate of 8,787,880 Ordinary Shares, at a price to the public of $1.65 per share. As part of this public offering, we sold 4,242,424 Ordinary Shares to Epoch at $1.65 per share, resulting in gross proceeds from Epoch to us of approximately $7 million.

On January 12, 2024, we entered into an equity distribution agreement, with Maxim, as sales agent, pursuant to which we may offer and sell Ordinary Shares having an aggregate offering price of up to $9,700,000 from time to time through Maxim. The Ordinary Shares were offered and sold pursuant to our currently effective registration statement on Form F-3 (File No. 333-267272), the prospectus contained therein and the prospectus supplement filed with the SEC dated January 12, 2024. We were not obligated to sell any Ordinary Shares under the ATM facility. We paid Maxim a commission equal to 2.5% of the gross sales price per share sold pursuant to the terms of the agreement and provided Maxim with customary indemnification and contribution rights. We reimbursed Maxim for certain specified expenses. Epoch invested $2.5 million into this equity distribution agreement. As of December 31, 2024, we sold 10,764,315 Ordinary Shares pursuant to the ATM facility, having aggregate gross proceeds of $9.7 million and aggregate net proceeds of $9.2 million.

On January 13, 2025, we entered into a second equity distribution agreement with Maxim as sales agent, pursuant to which we may offer and sell Ordinary Shares having an aggregate offering price of up to $13,960,500 from time to time through Maxim. The Ordinary Shares will be offered and sold pursuant to our currently effective registration statement on Form F-3 (File No. 333-267272), the prospectus contained therein and the prospectus supplement filed with the SEC dated January 13, 2024. We will pay Maxim a commission equal to 2.5% of the gross sales price per share sold pursuant to the terms of the agreement and will provide Maxim with customary indemnification and contribution rights. We also agreed to reimburse Maxim for certain specified expenses. As of March 24, 2025, we have sold 2,047,277 Ordinary Shares pursuant to the ATM facility, having aggregate gross proceeds of $2.8 million and aggregate net proceeds of $2.6 million.

C. Interests of Experts and Counsel.

None.

ITEM 8. FINANCIAL INFORMATION.

A. Consolidated Statements and Other Financial Information.

See “Item 18. Financial Statements.”

Legal Proceedings

On July 29, 2021, we were informed that a motion to certify a claim as a class action was filed against the Company in Israel with the Haifa District Court by Shalom Benamo. In the motion, the plaintiff claims that the Company’s reports filed on the TASE electronic filing site, the MAYA, and on the ISA electronic filing site, the MAGNA, are not in compliance with applicable accessibility guidelines, and therefore the Company prevents or reduces the access of people with disabilities to such reports. The plaintiff seeks damages in a total amount of NIS 5,000,000. On March 5, 2023, the motion was dismissed by the Tel-Aviv Jaffa District Court.

On July 5, 2021, we were informed that a motion to certify a claim as a class action was filed in Israel with the Tel Aviv District Court by Amir Yosef Brot, who claims to be a shareholder of the Company. The plaintiff's claim is against the Company, the members of the board of directors, the controlling shareholder and the investors who took part in the private placement that was approved by our shareholders on March 7, 2021. In the motion, the plaintiff claims, *inter alia*, that we conducted a private placement of securities to the controlling shareholder and the investors at a significant discount to the Company's share price at the time, that the share price did not reflect material information that was allegedly in the Company's possession and which was also brought to the attention of the investors, and that there were alleged defects in the manner of approving the private placement by our shareholders. After a review of the motion, we believe that the motion is without merit and that the factual description and the data underlying the motion are incorrect and/or imprecise. At this stage of the claim and after a review of the motion and the responses that were submitted by the parties, the Company believes that the motion is without merit and that the factual description and the data underlying the motion are incorrect and/or imprecise.

Dividends

We have never declared or paid any cash dividends on our Ordinary Shares and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

The Companies Law imposes further restrictions on our ability to declare and pay dividends, including repurchases of shares which are considered dividends under the Companies Law. Under the Companies Law, we may declare and pay dividends only if, upon the determination of our board of directors, there is no reasonable concern that the distribution will prevent us from being able to meet the terms of our existing and foreseeable obligations as they become due, or Solvency Criteria. Under the Companies Law, the distribution amount is further limited to the greater of retained earnings or earnings generated over the two most recent years legally available for distribution according to our then last reviewed or audited financial statements, provided that the end of the period to which the financial statements relate is not more than six months prior to the date of distribution, or the Earnings Criteria. In the event that we do not meet such earnings criteria, we may seek the approval of a court in order to distribute a dividend. The court may approve our request if it is convinced that there is no reasonable concern that the payment of a dividend will prevent us from satisfying our existing and foreseeable obligations as they become due. However under new exemption applicable as of March 12, 2024, an Israeli company whose shares are listed outside of Israel, is permitted to perform distribution in a way of repurchasing its own shares, even if the Earnings Criteria is not met, without the need for court's approval. The exemption is subject to certain conditions, including, among others: (i) The distribution meets the Solvency Criteria; and (ii) no rejection was filed by any of the company's creditors to the court. If any creditor objects to the distribution, the company will be required to obtain the court's approval for the distribution.

Payment of dividends may be subject to Israeli withholding taxes. See "Item 10.E. Taxation", for additional information.

B. Significant Changes.

No significant change, other than as otherwise described in this annual report on Form 20-F, has occurred in our operations since the date of our consolidated financial statements included in this annual report on Form 20-F.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details.

Our Ordinary Shares have been trading on Nasdaq under the symbol "ICCM" since August 2021.

B. Plan of Distribution.

Not applicable.

C. Markets.

Our Ordinary Shares are listed on Nasdaq .

D. Selling Shareholders.

Not applicable.

E. Dilution.

Not applicable.

F. Expenses of the Issue.

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital.

Not applicable.

B. Memorandum and Articles of Association.

A copy of our articles of association is attached as Exhibit 3.1 to this annual report. The information called for by this Item is set forth in Exhibit 3.1 to this annual report and is incorporated by reference into this annual report.

C. Material Contracts.

We have not entered into any material contract within the two years prior to the date of this Annual Report, other than contracts entered into in the ordinary course of business, as otherwise described herein in "Item 4.A. History and Development of the Company" above, "Item 4.B. Business Overview" above, "Item 6.C Board Practices – Indemnification," "Item 6.E Share Ownership – Equity Incentive Plan," "Item 7.A. Major Shareholders," or "Item 7.B. Related Party Transactions," above, or as otherwise described below:

Pursuant to our December 2022 offering, on December 21, 2022, we entered into a placement agency agreement A.G.P. and Brookline, together with A.G.P., the Placement Agents, pursuant to which A.G.P. agreed to serve as lead placement agent and Brookline agreed to serve as co-placement agent for the issuance and sale of the Ordinary Shares. We agreed to pay the Placement Agents an aggregate cash fee equal to 7% of the gross proceeds received by us from the sale of the Ordinary Shares in the Offering, however in the case of certain identified investors the Company agreed to pay a cash fee equal to 3% of the gross proceeds received by us from such investors. Pursuant to the Placement Agency Agreement, we also agreed to pay the Placement Agents $50 thousand for accountable expenses and $10 thousand for non-accountable expenses. The Placement Agency Agreement has indemnification and other customary provisions for transactions of this nature.

On January 12, 2024, we entered into an equity distribution agreement, with Maxim Group LLC, as sales agent, pursuant to which we may offer and sell Ordinary Shares having an aggregate offering price of up to $9,700,000 from time to time through Maxim Group LLC. The Ordinary Shares will be offered and sold pursuant to our currently effective registration statement on Form F-3 (File No. 333-267272), the prospectus contained therein and the prospectus supplement filed with the SEC dated January 12, 2024. We will pay Maxim Group LLC a commission equal to 2.5% of the gross sales price per share sold pursuant to the terms of the agreement and will provide Maxim Group LLC with customary indemnification and contribution rights. We also agreed to reimburse Maxim Group LLC for certain specified expenses. As of December 31, 2024, we sold 10,764,315 Ordinary Shares pursuant to the ATM facility, having aggregate gross proceeds of $9.7 million and aggregate net proceeds of $9.2 million.

On January 13, 2025, we entered into a second ATM facility with Maxim as sales agent, pursuant to which we may offer and sell Ordinary Shares having an aggregate offering price of up to 13,960,500.

D. Exchange Controls

There are currently no Israeli currency control restrictions on payments of dividends or other distributions with respect to our Ordinary Shares or the proceeds from the sale of the shares, except for the obligation of Israeli residents to file reports with the Bank of Israel regarding certain transactions. However, legislation remains in effect pursuant to which currency controls can be imposed by administrative action at any time.

The ownership or voting of our Ordinary Shares by non-residents of Israel, except with respect to citizens of countries that are in a state of war with Israel, is not restricted in any way by our memorandum of association or amended and restated articles of association or by the laws of the State of Israel.

E. Taxation.

Israeli Tax Considerations and Government Programs

The following is a description of the material Israeli income tax consequences of the ownership of our Ordinary Shares. The following also contains a description of material relevant provisions of the current Israeli income tax structure applicable to companies in Israel, with reference to its effect on us. To the extent that the discussion is based on new tax legislation which has not been subject to judicial or administrative interpretation, there can be no assurance that the tax authorities will accept the views expressed in the discussion in question. The discussion is not intended, and should not be taken, as legal or professional tax advice and is not exhaustive of all possible tax considerations.

The following description is not intended to constitute a complete analysis of all tax consequences relating to the ownership or disposition of our Ordinary Shares. Shareholders should consult their own tax advisors concerning the tax consequences of their particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign or other taxing jurisdiction.

General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax. As of December 2024, the corporate tax rate is 23%. However, the effective tax rate payable by a company that derives income from a "Preferred Enterprise" (as discussed below) may be considerably less. Capital gains derived by an Israeli company are generally subject to the prevailing corporate tax rate.

Capital gains derived by an Israeli resident company are subject to tax at the prevailing corporate tax rate. Under Israeli tax legislation, a corporation will be considered as an "Israeli resident company" if it meets one of the following: (i) it was incorporated in Israel; or (ii) the control and management of its business are exercised in Israel.

Law for the Encouragement of Industry (Taxes), 5729-1969

The Encouragement of Industry (Taxes) Law, 5729-1969, generally referred to as the Industry Encouragement Law, provides several tax benefits for "Industrial Companies."

The Industry Encouragement Law defines an "Industrial Company" as an Israeli resident-company, of which 90% or more of its income in a given tax year, other than income from defense loans, is derived from an "Industrial Enterprise" located in Israel owned by it. An "Industrial Enterprise" is defined as an enterprise whose principal activity in a given tax year is industrial production.

The following corporate tax benefits, among others, are available to Industrial Companies:

- amortization of the cost of purchased a patent, rights to use a patent, and know-how, which are used for the development or advancement of the company, over an eight-year period, commencing on the year in which such rights were first exercised;
- under limited conditions, an election to file consolidated tax returns with related Israeli Industrial Companies; and
- expenses related to a public offering are deductible in equal amounts over three years.

Eligibility for benefits under the Industry Encouragement Law is not contingent upon approval of any governmental authority.

Tax Benefits and Grants for Research and Development

General. The IIA, an independent publicly funded agency, was created to provide a variety of practical tools and funding platforms aimed at effectively addressing the dynamic and changing needs of the local and international innovation ecosystem. The IIA acts under the Law for the Encouragement of Research, Development and Technological Innovation in the Industry 1984, or the Innovation Law, and the related IIA rules and regulations. Companies that receive funding from the IIA are subject to certain liabilities of the Innovation Law, mainly pertaining to the know-how that was developed with the support of the IIA within the framework of an R&D funding program, and/or its derivatives (herein: "IIA-supported know-how"), and/or to the products derived from the technology that was developed with the support of the IIA within the framework of an R&D funding program, and/or its derivatives, or IIA-supported products.

Ownership Structure. Any change of ownership of an IIA-supported company must be reported to the IIA prior to the execution of change of ownership. A change in the company's ownership, in which a foreign entity becomes a stakeholder in the company, requires the IIA approval and the new shareholder's signature on an undertaking letter acknowledging the company's liabilities to the Innovation Law.

Royalty payment. Companies supported by the IIA are required to pay royalties on income generated from IIA-supported products, until the full refund of the grant. For companies whose grants were approved by the IIA prior to July 2017, the grant was previously linked to the US dollar and bored a fixed LIBOR rate as published on the first day each year until December 31, 2023. From January 1, 2024, these same IIA grants have been linked to SOFR or an alternative rate published by the Bank of Israel, plus 0.71513%.

Until July 2017, the rate of the royalties' repayment was 3% of related income in the first three years, and 3.5% from the 4th year, onward. As of July 2017, the rate of the royalties' refund for companies with total revenues of under $70M at the year preceding the application date, has changed to 3%.

On January 1, 2025, Amendment No. 9 to the Interest and Linkage Law was instated, in which the term "Linkage differences and interest" no longer exists. Therefore, the new default for an addition to a sum of money is Shekel interest, which relates to both maintaining the value of the money and compensating the creditor (the Shekel interest rate includes the linkage component). According to the Interest and Linkage Law, charges incurred up to December 31, 2024, will accrue interest and linkage differences, as defined prior to the law's amendment, until December 31, 2024. Charges incurred on this date and afterwards, will accrue Shekel interest until they are fully repaid.

Manufacturing location. The manufacturing location (including assembly) is determined based on the manufacturing declaration located in the grant application submitted for supporting R&D, or the Manufacturing Declaration. The transfer of manufacturing activity outside Israel may be subject to the prior approval of the IIA and may result in an increased royalty payment's rate and an increased total royalty payment, which will be calculated based on the deviation from the company's Manufacturing Declaration. Cumulative deviation of under 10% requires notification of the IIA, while 10% or more requires pre-approval.

The rate of royalty payment due to overseas manufacturing is increased as follows: If the foreign company will be given the rights to only manufacture the IIA-supported products, an additional 1% will be incurred (e.g., instead of paying 3%, the company will pay 4%). However, if the foreign company will be given the rights to both manufacture and distribute the IIA-supported products, the royalties rate may be higher. The increased royalty rate will apply for revenues associated with manufacturing outside of Israel only. In general, royalties will be paid from the final sale price to the client and not from the inter-company transfer price. The company will have to keep paying royalties until it reaches the new royalty liability ceiling.

The increased repayment is calculated according to the percentage of the manufacturing activities that are carried out outside of Israel out of the total cumulative manufacturing activities both in Israel and abroad, as described in the following table:

Percentage of manufacturing activities performed outside of Israel, cumulatively	The increased payment to the Israel Innovation Authority
Up to 50%	120% of the received grants + interest
50% – 90%	150% of the received grants + interest
90% or more	300% of the received grants + interest

If the manufacturing is performed outside of Israel by us, the rate of royalties payable on revenues from the sale of products manufactured outside of Israel will increase by 1% over the regular rates. If the manufacturing is performed outside of Israel by a third party, the rate of royalties payable by us on those revenues will be equal to the ratio obtained by dividing the amount of the grants received from the IIA and our total investment in the project that was funded by these grants. The transfer of no more than 10% of the manufacturing capacity in the aggregate outside of Israel is exempt under the Research Law from obtaining the prior approval of the IIA. A company requesting funds from the IIA also has the option of declaring in its IIA grant application an intention to perform part of its manufacturing outside Israel, thus avoiding the need to obtain additional approval. On January 6, 2011, the Research Law was amended to clarify that the potential increased royalties specified in the table above will apply even in those cases where the IIA approval for transfer of manufacturing outside of Israel is not required, namely when the volume of the transferred manufacturing capacity is less than 10% of total capacity or when the company received an advance approval to manufacture abroad in the framework of its IIA grant application. For applications to manufacture abroad, submitted to the IIA after October 25, 2023, the maximum increased liability is up to 150% of the IIA grants, plus interest accrued thereon, instead of 300%.

Know-how location. To the extent a company wishes to transfer its IIA-supported know-how outside of Israel, it must be preapproved by the IIA and the company may be required to pay an additional payment to the IIA, or the Fee, as described below. This Fee (which also relates to programs that are absolved of royalty payment) is calculated according to the ratio between the total grants received from the IIA and the total financial R&D expenses invested in the related know-how (including the received grants), multiplied by the transaction price of the IIA-supported know-how, or the Basic Amount.

The Basic Amount minus the received grants is depreciated at a rate of 1/7 per annum, as of the fourth year from the end of the last supported file in each program. As a result, when transferring IIA-supported know-how after 10 years or more, the maximum payment to the IIA will be only the total sum of the received grants plus interest, minus paid royalties.

However, the aforementioned formula has minimum and maximum limits. The minimum amount of the payment is the total sum of grants received plus interest. The maximum amount shall be no higher than 6 times the total sum of grants received plus interest. In the case that the IIA-supported company retains its R&D center in Israel for at least 3 consecutive years, following the year of transferring the IIA-supported know-how outside of Israel, while maintaining at least 75% of its R&D employment in Israel ((in relation to the R&D the Company had for the six (6) months before the know-how was transferred) – the payment will be limited to 3 times the total sum of grants received plus interest.

Transferring IIA-supported know-how outside of Israel according to the Innovation Law (including paying the Fee where necessary) releases the IIA-supported company from all liabilities to the IIA.

Transfer of know-how to another Israeli entity is subject to signature of the recipient Israeli entity on a formal IIA issued undertaking document, to comply with the provisions of the Innovation Law, including the restrictions on the transfer of know-how and the obligation to pay royalties.

According to the above, these liabilities should be taken into account when we consider whether to outsource manufacturing, engage in change of control transactions or otherwise transfer our know-how outside of Israel, and may require us to obtain the pre-approval of the IIA for certain actions and transactions and pay additional payments to the IIA. In particular, any change of control and any change of ownership of our Ordinary Shares that would make a non-Israeli citizen or resident an "interested party," as defined in the Innovation Law, requires a prior written notice to the IIA in addition to any payment that may be required of us for transfer of manufacturing or know-how outside of Israel. If we fail to comply with the Innovation Law, we may be subject to criminal charges or to mandatory repayment of grants received by us (together with interest and penalties).

Tax Benefits for Research and Development

Israeli tax law allows, under certain conditions, a tax deduction for expenditures, including capital expenditures, for the year in which they are incurred. Expenditures are deemed related to scientific research and development projects, if:

- The expenditures are approved by the relevant Israeli government ministry, determined by the field of research;
- The research and development must be for the promotion of the company; and
- The research and development is carried out by or on behalf of the company seeking such tax deduction.

The amount of such deductible expenses is reduced by the sum of any funds received through government grants for the finance of such scientific research and development projects. No deduction under these research and development deduction rules is allowed if such deduction is related to an expense invested in an asset depreciable under the general depreciation rules of the Tax Ordinance. Expenditures not so approved are deductible in equal amounts over three years.

From time to time, we may apply the IIA for approval to allow a tax deduction for all research and development expenses during the year incurred. There can be no assurance that such application will be accepted.

Taxation of our Shareholders

Capital Gains Taxes Applicable to Non-Israeli Resident Shareholders. A non-Israeli resident who derives capital gains from the sale of shares in an Israeli resident company might be exempt from Israeli tax upon meeting the following terms: (1) the shares sold were purchased after January 1, 2009; (2) the capital gain is not derived from the permanent establishment of the foreign resident in Israel; (3) the purchase of shares was not from a relative; (4) and the shares are not traded on the stock exchange in Israel. In addition, A foreign resident might be exempt from capital gains tax in Israel from a sale of securities traded on the stock exchange In Israel if the capital gain is not derived from a permanent establishment of the foreign resident in Israel and the shares were purchased by the foreign resident before the listing day on the stock exchange.

Additionally, a sale of securities by a non-Israeli resident may be exempt from Israeli capital gains tax under the provisions of an applicable tax treaty. For example, under Convention Between the Government of the United States of America and the Government of the State of Israel with respect to Taxes on Income, as amended, or the United States-Israel Tax Treaty, the sale, exchange or other disposition of shares by a shareholder who is a United States resident (for purposes of the treaty) holding the shares as a capital asset and is entitled to claim the benefits afforded to such a resident by the U.S.-Israel Tax Treaty, or a Treaty U.S. Resident, is generally exempt from Israeli capital gains tax unless: (i) the capital gain arising from such sale, exchange or disposition is attributed to real estate located in Israel; (ii) the capital gain arising from such sale, exchange or disposition is attributed to royalties; (iii) the capital gain arising from the such sale, exchange or disposition is attributed to a permanent establishment in Israel, under certain terms; (iv) such Treaty U.S. Resident holds, directly or indirectly, shares representing 10% or more of the voting capital during any part of the 12-month period preceding the disposition, subject to certain conditions; or (v) such Treaty U.S. Resident is an individual and was present in Israel for 183 days or more during the relevant taxable year.

In some instances where our shareholders may be liable for Israeli tax on the sale of their Ordinary Shares, the payment of the consideration may be subject to the withholding of Israeli tax at source. Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale.

Taxation of Non-Israeli Shareholders on Receipt of Dividends. Non-Israeli residents are generally subject to Israeli income tax on the receipt of dividends paid on our Ordinary Shares at the rate of 25%, which tax will be withheld at source, unless relief is provided in a treaty between Israel and the shareholder's country of residence. With respect to a person who is a "substantial shareholder" at the time of receiving the dividend or on any time during the preceding twelve months, the applicable tax rate is 30%. A "substantial shareholder" is generally a person who alone or together with such person's relative or another person who collaborates with such person on a permanent basis, holds, directly or indirectly, at least 10% of any of the "means of control" of the corporation. "Means of control" generally include the right to vote, receive profits, nominate a director or an executive officer, receive assets upon liquidation, or order someone who holds any of the aforesaid rights how to act, regardless of the source of such right. However, a distribution of dividends to non-Israeli residents is subject to withholding tax at source at a rate of 20% if the dividend is distributed from income attributed to a Preferred Enterprise, unless a reduced tax rate is provided under an applicable tax treaty. For example, under the United States-Israel Tax Treaty, the maximum rate of tax withheld at source in Israel on dividends paid to a holder of our Ordinary Shares who is a Treaty U.S. Resident is 25%. However, generally, the maximum rate of withholding tax on dividends, not generated by a Preferred Enterprise, that are paid to a United States corporation holding 10% or more of the outstanding voting capital throughout the tax year in which the dividend is distributed as well as during the previous tax year, is 12.5%, provided that not more than 25% of the gross income for such preceding year consists of certain types of dividends and interest. Notwithstanding the foregoing, dividends distributed from income attributed to a "Preferred Enterprise" are not entitled to such reduction under the tax treaty but are subject to a withholding tax rate of 15% for a shareholder that is a U.S. corporation, provided that the condition related to our gross income for the previous year (as set forth in the previous sentence) is met. If the dividend is attributable partly to income derived from a Preferred Enterprise, and partly to other sources of income, the withholding rate will be a blended rate reflecting the relative portions of the two types of income. We cannot assure you that we will designate the profits that we may distribute in a way that will reduce shareholders' tax liability.

U.S. Federal Income Tax Considerations

THE FOLLOWING SUMMARY IS INCLUDED HEREIN FOR GENERAL INFORMATION AND IS NOT INTENDED TO BE, AND SHOULD NOT BE CONSIDERED TO BE, LEGAL OR TAX ADVICE. EACH U.S. HOLDER SHOULD CONSULT WITH HIS OR HER OWN TAX ADVISOR AS TO THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND SALE OF ORDINARY SHARES, INCLUDING THE EFFECTS OF APPLICABLE STATE, LOCAL, FOREIGN OR OTHER TAX LAWS AND POSSIBLE CHANGES IN THE TAX LAWS.

Subject to the limitations described in the next paragraph, the following discussion summarizes the material U.S. federal income tax consequences to a "U.S. Holder" arising from the purchase, ownership and sale of the Ordinary Shares. For this purpose, a "U.S. Holder" is a holder of Ordinary Shares that is: (1) an individual citizen or resident of the United States, including an alien individual who is a lawful permanent resident of the United States or meets the substantial presence residency test under U.S. federal income tax laws; (2) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) or a partnership (other than a partnership that is not treated as a U.S. person under any applicable U.S. Treasury regulations) created or organized under the laws of the United States or the District of Columbia or any political subdivision thereof; (3) an estate, the income of which is includable in gross income for U.S. federal income tax purposes regardless of source; (4) a trust if a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust; or (5) a trust that has a valid election in effect to be treated as a U.S. person to the extent provided in U.S. Treasury regulations.

This summary is for general information purposes only and does not purport to be a comprehensive description of all of the U.S. federal income tax considerations that may be relevant to a decision to purchase our Ordinary Shares. This summary generally considers only U.S. Holders that will own our Ordinary Shares as capital assets. Except to the limited extent discussed below, this summary does not consider the U.S. federal tax consequences to a person that is not a U.S. Holder, nor does it describe the rules applicable to determine a taxpayer's status as a U.S. Holder. This summary is based on the provisions of the Internal Revenues Code of 1986, as amended, or the Code, final, temporary and proposed U.S. Treasury regulations promulgated thereunder, administrative and judicial interpretations thereof, (including with respect to the Tax Cuts and Jobs Act of 2017), and the U.S.-Israel Income Tax Treaty, all as in effect as of the date hereof and all of which are subject to change, possibly on a retroactive basis, and all of which are open to differing interpretations. We will not seek a ruling from the IRS with regard to the U.S. federal income tax treatment of an investment in our Ordinary Shares by U.S. Holders and, therefore, can provide no assurances that the IRS will agree with the conclusions set forth below.

This discussion does not address all of the aspects of U.S. federal income taxation that may be relevant to a particular U.S. holder based on such holder's particular circumstances and in particular does not discuss any estate, gift, generation-skipping, transfer, state, local, excise or foreign tax considerations. In addition, this discussion does not address the U.S. federal income tax treatment of a U.S. Holder who is: (1) a bank, life insurance company, regulated investment company, or other financial institution or "financial services entity;" (2) a broker or dealer in securities or foreign currency; (3) a person who acquired our Ordinary Shares in connection with employment or other performance of services; (4) a U.S. Holder that is subject to the U.S. alternative minimum tax; (5) a U.S. Holder that holds our Ordinary Shares as a hedge or as part of a hedging, straddle, conversion or constructive sale transaction or other risk-reduction transaction for U.S. federal income tax purposes; (6) a tax-exempt entity; (7) real estate investment trusts or grantor trusts; (8) a U.S. Holder that expatriates out of the United States or a former long-term resident of the United States; or (9) a person having a functional currency other than the U.S. dollar. This discussion does not address the U.S. federal income tax treatment of a U.S. Holder that owns, directly or constructively, at any time, Ordinary Shares representing 10% or more of our voting power. Additionally, the U.S. federal income tax treatment of partnerships (or other pass-through entities) or persons who hold Ordinary Shares through a partnership or other pass-through entity are not addressed.

Each prospective investor is advised to consult his or her own tax adviser for the specific tax consequences to that investor of purchasing, holding or disposing of our Ordinary Shares, including the effects of applicable state, local, foreign or other tax laws and possible changes in the tax laws.

Taxation of Dividends Paid on Ordinary Shares

We do not intend to pay dividends in the foreseeable future. In the event that we do pay dividends, and subject to the discussion under the heading "Passive Foreign Investment Companies" below and the discussion of "qualified dividend income" below, a U.S. Holder, other than certain U.S. Holder's that are U.S. corporations, will be required to include in gross income as ordinary income the amount of any distribution paid on Ordinary Shares (including the amount of any Israeli tax withheld on the date of the distribution), to the extent that such distribution does not exceed our current and accumulated earnings and profits, as determined for U.S. federal income tax purposes. The amount of a distribution which exceeds our earnings and profits will be treated first as a non-taxable return of capital, reducing the U.S. Holder's tax basis for the Ordinary Shares to the extent thereof, and then capital gain. We do not expect to maintain calculations of our earnings and profits under U.S. federal income tax principles and, therefore, U.S. Holders should expect that the entire amount of any distribution generally will be reported as dividend income.

In general, preferential tax rates for "qualified dividend income" and long-term capital gains are applicable for U.S. Holders that are individuals, estates or trusts. For this purpose, "qualified dividend income" means, inter alia, dividends received from a "qualified foreign corporation." A "qualified foreign corporation" is a corporation that is entitled to the benefits of a comprehensive tax treaty with the United States which includes an exchange of information program. The IRS has stated that the U.S.-Israel Tax Treaty satisfies this requirement, and we believe we are eligible for the benefits of that treaty.

In addition, our dividends will be qualified dividend income if our Ordinary Shares are readily tradable on Nasdaq or another established securities market in the United States. Dividends will not qualify for the preferential rate if we are treated, in the year the dividend is paid or in the prior year, as a PFIC, as described below under "Passive Foreign Investment Companies." A U.S. Holder will not be entitled to the preferential rate: (1) if the U.S. Holder has not held our Ordinary Shares for at least 61 days of the 121-day period beginning on the date which is 60 days before the ex-dividend date, or (2) to the extent the U.S. Holder is under an obligation to make related payments on substantially similar property. Any days during which the U.S. Holder has diminished its risk of loss on our Ordinary Shares are not counted towards meeting the 61-day holding period. Finally, U.S. Holders who elect to treat the dividend income as "investment income" pursuant to Code section 163(d)(4) will not be eligible for the preferential rate of taxation.

The amount of a distribution with respect to our Ordinary Shares will be measured by the amount of the fair market value of any property distributed, and for U.S. federal income tax purposes, the amount of any Israeli taxes withheld therefrom. Cash distributions paid by us in NIS will be included in the income of U.S. Holders at a U.S. dollar amount based upon the spot rate of exchange in effect on the date the dividend is includible in the income of the U.S. Holder, and U.S. Holders will have a tax basis in such NIS for U.S. federal income tax purposes equal to such U.S. dollar value. If the U.S. Holder subsequently converts the NIS into U.S. dollars or otherwise disposes of it, any subsequent gain or loss in respect of such NIS arising from exchange rate fluctuations will be U.S. source ordinary exchange gain or loss.

Taxation of the Disposition of Ordinary Shares

Except as provided under the PFIC rules described below under "Passive Foreign Investment Companies," upon the sale, exchange or other disposition of our Ordinary Shares, a U.S. Holder will recognize capital gain or loss in an amount equal to the difference between such U.S. Holder's tax basis for the Ordinary Shares in U.S. dollars and the amount realized on the disposition in U.S. dollar (or its U.S. dollar equivalent determined by reference to the spot rate of exchange on the date of disposition, if the amount realized is denominated in a foreign currency). The gain or loss realized on the sale, exchange or other disposition of Ordinary Shares will be long-term capital gain or loss if the U.S. Holder has a holding period of more than one year at the time of the disposition. Individuals who recognize long-term capital gains may be taxed on such gains at reduced rates of tax. The deduction of capital losses is subject to various limitations.

Passive Foreign Investment Companies

Special U.S. federal income tax laws apply to U.S. taxpayers who own shares of a corporation that is a PFIC. We will be treated as a PFIC for U.S. federal income tax purposes for any taxable year that either:

- 75% or more of our gross income (including our pro rata share of gross income for any company, in which we are considered to own 25% or more of the shares by value), in a taxable year is passive; or

- At least 50% of our assets, averaged over the year and generally determined based upon fair market value (including our pro rata share of the assets of any company in which we are considered to own 25% or more of the shares by value) are held for the production of, or produce, passive income.

For this purpose, passive income generally consists of dividends, interest, rents, royalties, annuities and income from certain commodities transactions and from notional principal contracts. Cash is treated as generating passive income.

The tests for determining PFIC status are applied annually, and it is difficult to make accurate projections of future income and assets which are relevant to this determination. In addition, our PFIC status may depend in part on the market value of our Ordinary Shares. Accordingly, there can be no assurance that we currently are not or will not become a PFIC.

Based on the projected composition of our income and valuation of our assets, we do not expect to be a PFIC for 2024, and we do not expect to become a PFIC in the future, although there can be no assurance in this regard. If we currently are or become a PFIC, each U.S. Holder who has not elected to mark the shares to market (as discussed below), would, upon receipt of certain distributions by us and upon disposition of our Ordinary Shares at a gain: (1) have such distribution or gain allocated ratably over the U.S. Holder's holding period for the Ordinary Shares, as the case may be; (2) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (3) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, when shares of a PFIC are acquired by reason of death from a decedent that was a U.S. Holder, the tax basis of such shares would not receive a step-up to fair market value as of the date of the decedent's death, but instead would be equal to the decedent's basis if lower, unless all gain were recognized by the decedent. Indirect investments in a PFIC may also be subject to these special U.S. federal income tax rules.

The PFIC rules described above would not apply to a U.S. Holder who makes a QEF election for all taxable years that such U.S. Holder has held the Ordinary Shares while we are a PFIC, provided that we comply with specified reporting requirements. Instead, each U.S. Holder who has made such a QEF election is required for each taxable year that we are a PFIC to include in income such U.S. Holder's pro rata share of our ordinary earnings as ordinary income and such U.S. Holder's pro rata share of our net capital gains as long-term capital gain, regardless of whether we make any distributions of such earnings or gain. In general, a QEF election is effective only if we make available certain required information. The QEF election is made on a shareholder-by-shareholder basis and generally may be revoked only with the consent of the IRS. We do not intend to notify U.S. Holders if we believe we will be treated as a PFIC for any tax year. In addition, we do not intend to furnish U.S. Holders annually with information needed in order to complete IRS Form 8621 and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC. Therefore, the QEF election will not be available with respect to our Ordinary Shares.

In addition, the PFIC rules described above would not apply if we were a PFIC and a U.S. Holder made a mark-to-market election. A U.S. Holder of our Ordinary Shares which are regularly traded on a qualifying exchange, including Nasdaq, can elect to mark the Ordinary Shares to market annually, recognizing as ordinary income or loss each year an amount equal to the difference as of the close of the taxable year between the fair market value of the Ordinary Shares and the U.S. Holder's adjusted tax basis in the Ordinary Shares. Losses are allowed only to the extent of net mark-to-market gain previously included income by the U.S. Holder under the election for prior taxable years.

U.S. Holders who hold our Ordinary Shares during a period when we are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC. U.S. Holders are strongly urged to consult their tax advisors about the PFIC rules.

Tax on Net Investment Income

U.S. Holders who are individuals, estates or trusts will generally be required to pay a 3.8% Medicare tax on their net investment income (including dividends on and gains from the sale or other disposition of our Ordinary Shares), or in the case of estates and trusts on their net investment income that is not distributed. In each case, the 3.8% Medicare tax applies only to the extent the U.S. Holder's total adjusted income exceeds applicable thresholds.

Tax Consequences for Non-U.S. Holders of Ordinary Shares

Except as provided below, an individual, corporation, estate or trust that is not a U.S. Holder referred to below as a non-U.S. Holder, generally will not be subject to U.S. federal income or withholding tax on the payment of dividends on, and the proceeds from the disposition of, our Ordinary Shares.

A non-U.S. Holder may be subject to U.S. federal income tax on a dividend paid on our Ordinary Shares or gain from the disposition of our Ordinary Shares if: (1) such item is effectively connected with the conduct by the non-U.S. Holder of a trade or business in the United States and, if required by an applicable income tax treaty is attributable to a permanent establishment or fixed place of business in the United States; or (2) in the case of a disposition of our Ordinary Shares, the individual non-U.S. Holder is present in the United States for 183 days or more in the taxable year of the disposition and other specified conditions are met.

In general, non-U.S. Holders will not be subject to backup withholding with respect to the payment of dividends on our Ordinary Shares if payment is made through a paying agent, or office of a foreign broker outside the United States. However, if payment is made in the United States or by a U.S. related person, non-U.S. Holders may be subject to backup withholding, unless the non-U.S. Holder provides an applicable IRS Form W-8 (or a substantially similar form) certifying its foreign status, or otherwise establishes an exemption.

The amount of any backup withholding from a payment to a non-U.S. Holder will be allowed as a credit against such holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Information Reporting and Withholding

A U.S. Holder may be subject to backup withholding at a rate of 24% with respect to cash dividends and proceeds from a disposition of Ordinary Shares. In general, backup withholding will apply only if a U.S. Holder fails to comply with specified identification procedures. Backup withholding will not apply with respect to payments made to designated exempt recipients, such as corporations and tax-exempt organizations. Backup withholding is not an additional tax and may be claimed as a credit against the U.S. federal income tax liability of a U.S. Holder, provided that the required information is timely furnished to the IRS.

A U.S. Holder with interests in "specified foreign financial assets" (including, among other assets, our Ordinary Shares, unless such Ordinary Shares are held on such U.S. Holder's behalf through a financial institution) may be required to file an information report with the IRS if the aggregate value of all such assets exceeds $50,000 on the last day of the taxable year or $75,000 at any time during the taxable year (or such higher dollar amount as may be prescribed by applicable IRS guidance); and may be required to file a Report of Foreign Bank and Financial Accounts, or FBAR, if the aggregate value of the foreign financial accounts exceeds $10,000 at any time during the calendar year. You should consult your own tax advisor as to the possible obligation to file such information report.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to certain information reporting requirements of the Exchange Act, applicable to foreign private issuers and under those requirements will file reports with the SEC. The SEC maintains an Internet website that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are also available to the public through the SEC's website at www.sec.gov.

As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act. However, we will file with the SEC, within 120 days after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and may submit to the SEC, on a Form 6-K, unaudited quarterly financial information.

We maintain a corporate website at http://www.icecure-medical.com. Information contained on, or that can be accessed through, our website and the other websites referenced above do not constitute a part of this annual report on Form 20-F. We have included these website addresses in this annual report on Form 20-F solely as inactive textual references.

I. Subsidiary Information.

Not applicable.

J. Annual Report to Security Holders.

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

In the ordinary course of our operations, we are exposed to certain market risks, primarily changes in foreign currency exchange rates and interest rates.

Quantitative and Qualitative Disclosure About Market Risk

We are exposed to market risks 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. Our current investment policy is to invest available cash in bank deposits with banks that have a credit rating of at least A-minus. Currently, a substantial majority of our cash is held in our operating cash bank account. Given the current low rates of interest we receive, we will not be adversely affected if such rates are reduced. Our market risk exposure is primarily a result of NIS/U.S. dollar exchange rates, which is discussed in the following paragraph.

Foreign Currency Exchange Risk

Our functional and reporting currency is the U.S. dollar. Although the U.S. dollar is our functional currency, a significant portion of our expenses are denominated in NIS and a relatively small portion of our expenses is denominated in Euros, and currently most of our revenues are denominated in U.S. dollars. Therefore, our foreign currency exposures give rise to market risk associated with exchange rate movements of the U.S. dollar, mainly against the NIS and the Euro. Our NIS and Euro expenses consist principally of payroll to our employees in Israel, payments made to subcontractors for purchasing components to our products, research and development activities and marketing and sales activities. We anticipate that a significant portion of our expenses will continue to be denominated in currencies other than the U.S. dollar. If the U.S. dollar fluctuates significantly against either the NIS or the Euro, it may have a negative impact on our results of operations.

Due to the fact that exchange rates between the U.S. dollar and the NIS (as well as between the U.S. dollar and other currencies) fluctuate continuously, such fluctuations have an impact on our results and period-to-period comparisons of our results. The effects of foreign currency remeasurements are reported in our consolidated statements of operations. In order to reduce some of this currency exposure, we keep cash balances in NIS. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

As of December 31, 2024, we did not enter into any hedging transactions, but we may do so in the future. Even if we do enter into such hedge transactions in the future, we cannot guarantee that such measures will effectively protect us from adverse effects due to the impact of fluctuations in currency exchange rates.

In addition, we have balance sheet exposure arising from assets and liabilities denominated in currencies other than the U.S. dollar, mainly in NIS and Euros. Any change of the conversion rates between the U.S. dollar and these currencies may create financial gain or loss.

The tables below provide information as of the dates indicated regarding our foreign currency-denominated monetary assets and liabilities as of December 31, 2024 (U.S. dollars in thousands).

Assets:	
NIS	$ 1,972
EUR	388
Other currencies	44
Total	2,404
Liabilities:	
NIS	3,518
EUR	-
Other currencies	46
Total	3,564
Net Liabilities	1,160

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities.

Not applicable.

B. Warrants and rights.

Not applicable.

C. Other Securities.

Not applicable.

D. American Depositary Shares

Not applicable.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2024, or the Evaluation Date. Based on such evaluation, those officers have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be included in periodic filings under the Exchange Act and that such information is accumulated and communicated to management, including our principal executive and financial officers, as appropriate to allow timely decisions regarding required disclosure.

(b) Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based principally on the framework and criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission as of the end of the period covered by this report. Based on that evaluation, our management has concluded that our internal control over financial reporting was effective as of December 31, 2024, at providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

(c) Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to an exemption for EGCs provided in the JOBS Act.

(d) Changes in Internal Control over Financial Reporting

During the year ended December 31, 2024, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

The members of our audit committee include Ms. Sharon Levita and Mr. Oded Tamir, who are external directors, and Mr. Vincent Chan, each of whom is "independent" as such term is defined in under Nasdaq Stock Market rules. Ms. Levita serves as the chair of our audit committee. All members of our audit committee meet the requirements for financial literacy under the Nasdaq Stock Market rules. Our board of directors has determined that each member of our audit committee is an audit committee financial expert as defined by the SEC rules and has the requisite financial experience as defined by the Nasdaq Stock Market rules.

ITEM 16B. CODE OF ETHICS

We have adopted a written code of ethics that applies to our officers and employees, including our principal executive officer, principal financial officer, principal controller and persons performing similar functions as well as our directors. Our Code of Business Conduct and Ethics is posted on our website at www.icecure-medical.com. Information contained on, or that can be accessed through, our website does not constitute a part of this annual report on Form 20-F and is not incorporated by reference herein. If we make any amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the code, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC including the instructions to Item 16B of Form 20-F. We have not granted any waivers under our Code of Business Conduct and Ethics.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Brightman Almagor Zohar & Co., a firm in the Deloitte Global Network, has served as our principal independent registered public accounting firm for each of the two years ended December 31, 2024 and 2023.

The following table provides information regarding fees paid by us to Brightman Almagor Zohar & Co. and/or other member firms of Deloitte Global Network for all services, including audit services, for the years ended December 31, 2024 and 2023.

	Year Ended December 31,	
	2024	**2023**
Audit fees [1]	$ 140	$ 140
Audit-related fees [2]	$ 90	$ 13
Tax fees [3]	-	-
All other fees	-	-
Total	$ 230	$ 153

(1) Includes professional services rendered in connection with the audit of our annual financial statements and review of our interim financial statements.

(2) Includes professional services rendered in connection with comfort letters and consents.

(3) Tax fees are the aggregate fees billed (in the year) for professional services rendered for tax compliance and tax advice other than in connection with the audit.

Pre-Approval of Auditors' Compensation

Our audit committee charter sets forth, among others, the responsibilities of the audit committee consistent with the rules of the SEC and Nasdaq Listing Rules (in addition to the requirements for such committee under the Companies Law), including, among others, the following:

- oversight of our independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of our independent registered public accounting firm to the board of directors in accordance with Israeli law;
- recommending the engagement or termination of the person filling the office of our internal auditor, reviewing the services provided by our internal auditor and reviewing effectiveness of our system of internal control over financial reporting;
- recommending the terms of audit and non-audit services provided by the independent registered public accounting firm for pre-approval by our board of directors; and
- reviewing and monitoring, if applicable, legal matters with significant impact, finding of regulatory authorities' findings, receive reports regarding irregularities and legal compliance, acting according to "whistleblower policy" and recommend to our board of directors if so required.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

Under Nasdaq rules, we may elect to follow certain corporate governance practices permitted under the Companies Law in lieu of compliance with corresponding corporate governance requirements otherwise imposed by the Nasdaq Stock Market rules for U.S. domestic issuers.

In accordance with Israeli law and practice and subject to the exemption set forth in Rule 5615 of the Nasdaq Stock Market rules, we have elected to follow the provisions of the Companies Law, rather than the Nasdaq Stock Market rules, with respect to the following requirements:

- *Distribution of periodic reports to shareholders; proxy solicitation*. As opposed to the Nasdaq Stock Market rules, which require listed issuers to make such reports available to shareholders in one of a number of specific manners, Israeli law does not require us to distribute periodic reports directly to shareholders, and the generally accepted business practice in Israel is not to distribute such reports to shareholders but to make such reports available through a public website. In addition to making such reports available on a public website, we currently make our audited consolidated financial statements available to our shareholders at our offices and will only mail such reports to shareholders upon request. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules.

- *Quorum*. While the Nasdaq Stock Market rules require that the quorum for purposes of any meeting of the holders of a listed company's common voting stock, as specified in the company's bylaws, be no less than 33 1/3% of the company's outstanding common voting stock, under Israeli law, a company is entitled to determine in its articles of association the number of shareholders and percentage of holdings required for a quorum at a shareholders meeting. Our articles of association provide that a quorum of two or more shareholders holding at least two (2) shareholders, in person or by proxy, holding at least 25% of the voting rights. in person or by proxy is required for commencement of business at a general meeting. However, the quorum set forth in our articles of association with respect to an adjourned meeting consists of at least one shareholder present in person or by proxy.

- *Nomination of our directors.* With the exception of directors elected by our board of directors and external directors, our directors are elected by an annual or special meeting of our shareholders (i) to hold office until the next annual meeting following his or her election or (ii) for three-year term, as described below under "Management—Board Practices—External Directors." The nominations for directors, which are presented to our shareholders by our board of directors, are generally made by the board of directors itself, in accordance with the provisions of our articles of association and the Companies Law. Nominations need not be made by a nominating committee of our board of directors consisting solely of independent directors, as required under the Nasdaq Stock Market rules.

- *Compensation of officers.* Israeli law and our articles of association do not require that the independent members of our board of directors (or a compensation committee composed solely of independent members of our board of directors) determine an executive officer's compensation, as is generally required under the Nasdaq Stock Market rules with respect to the chief executive officer and all other executive officers. Instead, compensation of executive officers is determined and approved by our compensation committee and our board of directors, and in certain circumstances by our shareholders, either in consistency with our office holder compensation policy or, in special circumstances in deviation therefrom, taking into account certain considerations stated in the Companies Law (see "Item 6.C. *Directors, Senior Management and Employees - Board Practices - Approval of Related Party Transactions under Israeli Law*" for additional information).

- *Independent Directors*. Under the Israeli Companies Law, we would be required to include on our board of directors at least two members, each of whom qualifies as an external director, and as to whom special qualifications and other provisions would be applicable. We would also be required to include one such external director on each of our board committees. However, as we do not have a controlling shareholder, and we comply with the requirements of the Nasdaq Stock Market with respect to the composition of our board and such committees, we therefore are exempt from the Israeli Companies Law requirements with respect thereto, including the appointment of external directors. We are required, however, to ensure that all members of our audit committee are "independent" under the Nasdaq Rules, and we must also ensure that a majority of the members of our audit committee are "independent directors" as defined in the Israeli Companies Law. Furthermore, Israeli law does not require, and our independent directors do not conduct regularly scheduled meetings at which only they are present, as otherwise required by the Nasdaq Stock Market rules.

- *Shareholder approval.* We will seek shareholder approval for all corporate actions requiring such approval under the requirements of the Companies Law, rather than seeking approval for corporation actions in accordance with Nasdaq Listing Rule 5635. In particular, under this Nasdaq Stock Market rule, shareholder approval is generally required for: (i) an acquisition of shares/assets of another company that involves the issuance of 20% or more of the acquirer's shares or voting rights or if a director, officer or 5% shareholder has greater than a 5% interest in the target company or the consideration to be received; (ii) the issuance of shares leading to a change of control; (iii) adoption/amendment of equity compensation arrangements (although under the provisions of the Companies Law there is no requirement for shareholder approval for the adoption/amendment of the equity compensation plan); and (iv) issuances of 20% or more of the shares or voting rights (including securities convertible into, or exercisable for, equity) of a listed company via a private placement (and/or via sales by directors/officers/5% shareholders) if such equity is issued (or sold) at below the greater of the book or market value of shares. By contrast, under the Companies Law, shareholder approval is required for, among other things: (i) transactions with directors concerning the terms of their service or indemnification, exemption and insurance for their service (or for any other position that they may hold at a company), for which approvals of the compensation committee, board of directors and shareholders are all required, (ii) extraordinary transactions with controlling shareholders of publicly held companies, which require the special approval, and (iii) terms of employment or other engagement of the controlling shareholder of us or such controlling shareholder's relative, which require special approval. In addition, under the Companies Law, a merger requires approval of the shareholders of each of the merging companies.

- *Approval of Related Party Transactions.* All related party transactions are approved in accordance with the requirements and procedures for approval of interested party acts and transaction as set forth in the Companies Law, which requires the approval of the audit committee, or the compensation committee, as the case may be, the board of directors and shareholders, as may be applicable, for specified transactions, rather than approval by the audit committee or other independent body of our board of directors as required under the Nasdaq Stock Market rules (see "Item 6.C. *Directors, Senior Management and Employees - —Board Practices—Approval of Related Party Transactions under Israeli Law*" for additional information).

- *Annual Shareholders Meeting.* As opposed to the Nasdaq Stock Market Rule 5620(a), which mandates that a listed company hold its annual shareholders meeting within one year of the company's fiscal year-end, we are required, under the Companies Law, to hold an annual shareholder meeting each calendar year and within 15 months of the last annual shareholders meeting.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

ITEM 16J. INSIDER TRADING POLICIES

We have adopted an insider trading policy governing the purchase, sale and other transactions in our securities that applies to our directors, senior management, employees, consultants, contractors and other covered persons, including immediate family members and entities controlled by any of the foregoing persons.

This policy prohibits, among other things, insider trading and certain speculative transactions in our securities (including short sales, buying put and selling call options and other hedging or derivative transactions in our securities) and establishes a regular blackout period schedule during which directors, senior management, employees, and other covered persons may not trade in our securities, as well as certain pre-clearance procedures that our directors and officers, our subsidiaries and/or affiliates must observe prior to effecting any transaction in our securities.

We believe that this policy is reasonably designed to promote compliance with applicable insider trading laws, rules and regulations, and listing standards applicable to us. A copy of this policy is filed as Exhibit 11.1 to this Form 20-F.

ITEM 16K. CYBERSECURITY.

Our board of directors recognizes the critical importance of maintaining the trust and confidence of our customers, clients, business partners, and employees. Our board of directors oversees our risk management program, and cybersecurity represents an important component of our overall approach to risk management. Our cybersecurity policies, standards, processes, and practices are based on recognized frameworks established by the National Institute of Standards and Technology, the International Organization for Standardization, and other applicable industry standards. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security, reliability, and availability of the information that we collect and store by identifying, preventing, and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Risk Management and Strategy

As part of the critical elements of our overall risk management approach, our cybersecurity program is focused on the following key areas:

- Governance: Our board of directors' oversight of cybersecurity risk management is supported by the management committee, which includes our Chief Executive Officer, Chief Financial Officer and Vice President Operations and Services) which regularly interacts with the Company's outsourced virtual Chief Information Security Officer, or vCiso, other members of management and outside counsel.

- Collaborative Approach: The Company has implemented a comprehensive, cross-functional approach to identifying, preventing, and mitigating cybersecurity threats and incidents, while also implementing controls that provide for the prompt escalation of certain cybersecurity incidents so that decisions regarding the public disclosure and reporting of such incidents can be made by management promptly.

- Technical Safeguards: The Company deploys technical safeguards that are designed to protect the Company's information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality, and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence.

- Education and Awareness: The Company provides regular, mandatory cybersecurity threat training to all employees so that they are aware of how to address cybersecurity threats and to communicate the Company's evolving information security policies, standards, processes, and practices.

- Incident Response and Recovery Planning: The Company has established and maintains comprehensive incident response and recovery plans that fully address the Company's response to a cybersecurity incident, and such plans are tested and evaluated regularly.

- SEC Regulation: The Company analyzes quantitative and qualitative factors of any security incident in terms of impact and reasonably likely effects. If our board of directors and management committee, with the assistance of legal counsel, determine that the nature, scope and timing of such incident has materially affected or would be reasonably likely to materially affect the Company's business strategy, results of operations or financial condition, the Company would deem such incident to be material in accordance with Regulation SCI.

- Third-Party Risk Management: The Company maintains a risk-based approach to identifying and overseeing cybersecurity risks presented by third parties, including vendors, service providers, and other external users of the Company's systems, as well as the systems of third parties that could adversely impact our business in the event of a cybersecurity incident affecting those third-party systems.

We engage in the periodic assessment and testing of our policies, standards, processes, and practices that are designed to address cybersecurity threats and incidents. These efforts include a wide range of activities, including audits, assessments, and other exercises focused on evaluating the effectiveness of our cybersecurity measures and planning. We engage third parties to perform assessments on our cybersecurity measures, including information security maturity assessments, audits, and independent reviews of our information security control environment and operating effectiveness.

The results of such assessments, audits, and reviews are reported to and reviewed by the management committee and are reported to our board of directors. Company adjusts its cybersecurity policies, standards, processes, and practices as necessary based on the information provided by these assessments, audits, and reviews.

Governance

Our board of directors oversees our risk management process, including the management of risks arising from cybersecurity threats. Our management committee receives regular reports and updates on cybersecurity risks, which address a wide range of topics including recent developments, evolving standards, vulnerability assessments, third-party and independent reviews, the threat environment, technological trends and information security considerations arising concerning our peers and third parties. Our board of directors also receives prompt and timely information regarding any cybersecurity incident that meets established reporting thresholds, as well as updates regarding any such incident until it has been addressed. On an annual basis, the board of directors discusses our approach to cybersecurity risk management with members of our management committee and our audit committee meets with the cybersecurity specialists to discuss cybersecurity policy.

The vCISO, in coordination with our Management Committee, works collaboratively with the Company to implement a program designed to protect the Company's information systems from cybersecurity threats and to promptly respond to any cybersecurity incidents by the Company's incident response and recovery plans. To facilitate the success of the Company's cybersecurity risk management program, the IT team is deployed to address cybersecurity threats and respond to cybersecurity incidents. Through ongoing communications with these teams, the vCISO and our management committee monitor the prevention, detection, mitigation, and remediation of cybersecurity threats and incidents in real-time.

Our vCISO, Mr. Roni Goldberg, has seven years of experience in the information security and risk management field for enterprise-grade level organizations with over 10,000 employees. Mr. Roni Goldberg is a certified Chief Information Security Officer from the Technion (Israel Institute of Technology), a certified Information Systems Security Professional from the ISC*2 organization which validates expertise in designing, implementing, and managing top-tier cybersecurity programs, and has a certified Sophos Security Architecture qualification. Mr. Roni Goldberg has strong expertise in Risk Management, building and maintaining security programs, and managing IT security and rich experience in security standards of NIST risk management and other cybersecurity frameworks, SANS, ISO/IEC 27001, ITIL, and privacy.

Cybersecurity threats have not materially affected us and are reasonably likely to affect the Company, including its business strategy, results of operations, or financial condition.

PART III

ITEM 17. FINANCIAL STATEMENTS

We have elected to provide financial statements and related information pursuant to Item 18.

ITEM 18. FINANCIAL STATEMENTS

The consolidated financial statements and the related notes required by this Item are included in this annual report on Form 20-F beginning on page F-1.

ITEM 19. EXHIBITS.

Exhibit Number	Exhibit Description
2.1*	Description of Securities.
3.1	Articles of Association of IceCure Medical Ltd. (incorporated herein by reference to Exhibit 1.1 to our Registration Statement on Form F-1 (File No. 333-258660) filed with the SEC on August 9, 2021).
4.1	Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.1 to our Registration Statement on Form F-1 (File No. 333-258660) filed with the SEC on August 9, 2021).
4.2	IceCure Medical Stock Option Plan (incorporated herein by reference to Exhibit 10.2 to our Registration Statement on Form F-1 (File No. 333-258660) filed with the SEC on August 9, 2021).
4.3	IceCure Medical Remuneration Policy (incorporated herein by reference to Exhibit 10.3 to our Registration Statement on Form F-1 (File No. 333-258660) filed with the SEC on August 9, 2021).
4.4^	Distribution Agreement, dated August 29, 2019, by and between IceCure Medical Ltd. and Terumo Corporation (incorporated herein by reference to Exhibit 10.5 to our Registration Statement on Form F-1 (File No. 333-258660) filed with the SEC on August 9, 2021).
4.5^	Distribution Agreement, dated December 31, 2020, by and between IceCure Medical Ltd. and Terumo (Thailand) Company Limited (incorporated herein by reference to Exhibit 10.6 to our Registration Statement on Form F-1 (File No. 333-258660) filed with the SEC on August 9, 2021).
4.6	Exclusive Distribution Agreement, dated June 12, 2022, by and between IceCure (Shanghai) MedTech Co., Ltd., Shanghai Medtronic Zhikang Medical Devices Co., Ltd. and Beijing Turing Medical Technology Co., Ltd. (incorporated herein by reference to Exhibit 10.1 to our Registration Statement on Form F-3 (File No. 333-267272) filed with the SEC on September 2, 2022).
4.7	Exclusive Distribution Agreement, dated June 12, 2022, by and between IceCure Medical Ltd., IceCure (Shanghai) MedTech Co., Ltd. and Beijing Turing Medical Technology Co., Ltd. (incorporated herein by reference to Exhibit 10.2 to our Registration Statement on Form F-3 (File No. 333-267272) filed with the SEC on September 2, 2022).
4.8	Equity Distribution Agreement by and between IceCure Medical Ltd., and Maxim Group LLC, dated January 12, 2024 (incorporated herein by reference to Exhibit 10.1 to our Report of Foreign Private Issuer on Form 6-K (File No. 001-40753) filed with the SEC on January 12, 2024).
4.9	Equity Distribution Agreement by and between IceCure Medical Ltd., and Maxim Group LLC, dated January 13, 2025 (incorporated herein by reference to Exhibit 10.1 to our Report of Foreign Private Issuer on Form 6-K (File No. 001-40753) filed with the SEC on January 13, 2025).
4.10	IceCure Medical Ltd. 2024 Employee Equity Incentive Plan (incorporated herein by reference to Exhibit 4.9 to Form 20-F, filed with the SEC on April 3, 2024).
4.11	IceCure Medical Ltd U.S. Addendum to the 2024 Employee Equity Incentive Plan (incorporated herein by reference to Exhibit 99.2 to our Report of Foreign Private Issuer on Form 6-K (Filed No. 001-40753) filed with the SEC on April 15, 2024).
8.1	List of Subsidiaries (incorporated herein by reference to Exhibit 21.1 to our Registration Statement on Form F-1 (File No. 333-258660) filed with the SEC on December 3, 2021).
11.1*	Insider Trading Policy.
12.1*	Certification of the Chief Executive Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934.
12.2*	Certification of the Chief Financial Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934.
13.1%	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350.
13.2%	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350.
15.1*	Consent of Brightman Almagor Zohar & Co., a firm in the Deloitte Global Network, independent registered public accounting firm.
97.1	Clawback Policy (incorporated herein by reference to Exhibit 97.1 to Form 20-F, filed with the SEC on April 3, 2024).
101*	The following financial information from the Registrant's Annual Report on Form 20-F for the year ended December 31, 2024, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance sheets as of December 31, 2024, December 31, 2023 and December 31, 2022; (ii) Consolidated Statements of Comprehensive Loss as of December 31, 2024, December 31, 2023 and December 31, 2022; (iii) Consolidated Statement of Changes in Shareholders' Equity as of December 31, 2024, December 31, 2023 and December 31, 2022; (iv) Consolidated Statements of Cash Flows as of December 31, 2024, December 31, 2023 and December 31, 2022; and (v) Notes to the consolidated financial statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed herewith.

% Furnished herewith.

^ Certain confidential information contained in this exhibit, has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K, because it (i) is not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on Form 20-F filed on its behalf.

ICECURE MEDICAL LTD.

Date: March 27, 2025

By: /s/ Eyal Shamir
Eyal Shamir
Chief Executive Officer

ICECURE MEDICAL LTD.

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2024

ICECURE MEDICAL LTD.

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2024

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of IceCure Medical Ltd.

Opinion on the Financial Statements

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

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1.B to the financial statements, the Company's lack of sufficient revenues and substantial operating losses raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 1.B to the financial statements. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Basis for Opinion

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

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

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

/s/ Brightman Almagor Zohar & Co.
Certified Public Accountants
A Firm in the Deloitte Global Network

Tel Aviv, Israel
March 27, 2025

We have served as the Company's auditor since 2006.

ICECURE MEDICAL LTD.

CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share data and per share data)

	Note	As of December 31, 2024	As of December 31, 2023
ASSETS			
CURRENT ASSETS			
Cash and cash equivalents		7,564	10,533
Short-term deposit		-	529
Trade receivables		221	103
Inventory	3	1,988	2,275
Prepaid expenses and other receivables	4	981	744
Total current assets		10,754	14,184
NON-CURRENT ASSETS			
Right of use assets	5	524	679
Property and equipment, net	6	1,252	1,513
Prepaid expenses and other long-term assets		46	34
Total non-current assets		1,822	2,226
TOTAL ASSETS		12,576	16,410
LIABILITIES AND SHAREHOLDERS' EQUITY			
CURRENT LIABILITIES			
Trade payables		1,232	502
Lease liabilities	5	298	223
Employees and other current liabilities	7	3,984	3,146
Total current liabilities		5,514	3,871
NON-CURRENT LIABILITIES			
Long term lease liabilities	5	161	376
Total non-current liabilities		161	376
Commitments and contingencies	8		
SHAREHOLDERS' EQUITY			
Ordinary shares, no par value; Authorized 2,500,000,000 shares; Issued and outstanding: 56,568,999 shares and 45,729,684 shares as of December 31, 2024 and December 31, 2023, respectively	9	-	-
Additional paid-in capital		112,280	102,224
Accumulated deficit		(105,379)	(90,061)
Total shareholders' equity		6,901	12,163
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY		12,576	16,410

The accompanying notes are an integral part of the consolidated financial statements.

ICECURE MEDICAL LTD.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(U.S. dollars in thousands, except share data and per share data)

	Note	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Revenues	10	3,291	3,229	3,085
Cost of revenues	11	1,840	1,929	1,640
Gross profit		1,451	1,300	1,445
Research and development expenses	12	7,096	8,273	9,123
Sales and marketing expenses	13	6,296	4,437	3,204
General and administrative expenses	14	3,755	4,166	5,857
Operating loss		15,696	15,576	16,739
Finance expenses (income), net		(378)	(924)	239
Net loss and comprehensive loss		15,318	14,652	16,978
Basic and diluted net loss per share		0.30	0.32	0.46
Weighted average number of shares outstanding used in computing basic and diluted net loss per share		50,876,790	45,638,030	37,016,631

The accompanying notes are an integral part of the consolidated financial statements.

ICECURE MEDICAL LTD.

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
(U.S. dollars in thousands, except share and warrants data and per share data)

	Ordinary shares		Pre-funded warrants		Additional paid- in	Accumulated	Total shareholders'
	Number	Amount	Number	Amount	capital	deficit	equity
Balance as of December 31, 2021	**35,780,335**	**-**	1,034,000	**-**	**85,389**	**(58,431)**	**26,958**
Issuance of restricted ordinary shares	21,000	-	-	-	6	-	-
Issuance of ordinary shares, net of issuance cost of $931	8,787,880	-	-	-	13,569	-	13,569
Pre-funded warrants exercised	1,034,000	-	(1,034,000)	-	1	-	1
Options exercised	219	-	-	-	1	-	1
Share-based compensation expenses	-	-	-	-	1,865	-	1,871
Loss for the year	-	-	-	-	-	(16,978)	(16,978)
Balance as of December 31, 2022	**45,623,434**	**-**	-	**-**	**100,831**	**(75,409)**	**25,422**
Options exercised	106,250	-	-	-	83	-	83
Share-based compensation expenses	-	-	-	-	1,310	-	1,310
Loss for the year	-	-	-	-	-	(14,652)	(14,652)
Balance as of December 31, 2023	**45,729,684**	**-**	**-**	**-**	**102,224**	**(90,061)**	**12,163**
Issuance of ordinary shares, net of issuance cost of $487	10,764,315	-	-	-	9,187	-	9,187
Issuance of restricted ordinary shares	75,000	-	-	-	-	-	-
Share-based compensation expenses	-	-	-	-	869	-	869
Loss for the year	-	-		-	-	(15,318)	(15,318)
Balance as of December 31, 2024	**56,568,999**	**-**	**-**	**-**	**112,280**	**(105,379)**	**6,901**

The accompanying notes are an integral part of the consolidated financial statements.

ICECURE MEDICAL LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands, except share data and per share data)

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Cash flows from operating activities:			
Net loss	(15,318)	(14,652)	(16,978)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	332	323	248
Share-based compensation	869	1,310	1,865
Exchange rate changes in cash and cash equivalents and deposit	39	(25)	359
Non-cash short-term interest on deposits	-	(29)	-
Changes in assets and liabilities:			
Decrease (increase) in trade receivables	(118)	(25)	378
Decrease (increase) in inventory	287	582	(902)
Decrease (increase) in prepaid expenses and other receivables	(237)	496	1,050
Decrease in right of use assets	271	182	245
Increase (decrease) in trade payables	730	(212)	(167)
Decrease in lease liabilities	(256)	(191)	(312)
Increase (decrease) in employees and other current liabilities	838	(309)	540
Decrease in other long-term liabilities	-	-	(618)
Net cash used in operating activities	(12,563)	(12,550)	(14,292)
Cash flows from investing activities:			
Investment in short-term deposits	(1,373)	(500)	-
Withdrawal of short-term deposits	1,902	-	-
Withdrawal of (investment in) restricted deposits	(12)	296	-
Purchase of property and equipment	(71)	(480)	(891)
Net cash provided by (used in) investing activities	446	(684)	(891)
Cash flows from financing activities:			
Issuance of ordinary shares, net of issuance costs	9,187	-	13,569
Issuance of restricted ordinary shares	-	-	6
Exercise of pre-funded warrants	-	-	1
Exercise of options to ordinary shares	-	83	1
Net cash provided by financing activities	9,187	83	13,577
Increase (decrease) in cash and cash equivalents	(2,930)	(13,151)	(1,606)
Cash and cash equivalents beginning of the year	10,533	23,659	25,621
Effect of foreign exchange rate on cash and cash equivalents	(39)	25	(356)
Cash and cash equivalents end of the year	7,564	10,533	23,659
Non-cash activities			
Obtaining a right-of-use asset in exchange for a lease liability	116	193	-

The accompanying notes are an integral part of the consolidated financial statements.

NOTE 1 - GENERAL

A. Description of the Company:

IceCure Medical Ltd. ("IceCure Medical Ltd.", the "Company", "we" or "our") is a medical device Company incorporated in Israel.

On February 2, 2011, we became a public company in Israel and our ordinary shares were listed for trade on the Tel Aviv Stock Exchange ("TASE"). On August 26, 2021, our ordinary shares were listed for trade on the Nasdaq Capital Market ("Nasdaq") under the symbol "ICCM." On July 24, 2023, we delisted our ordinary shares from the TASE.

Since its establishment, IceCure Medical Ltd., and its wholly-owned subsidiaries, IceCure Medical Inc. in the United States (the "U.S. Subsidiary"), IceCure Medical HK Limited in Hong Kong (the "Hong Kong Subsidiary") and IceCure (Shanghai) MedTech Co., Ltd. in China (the "Chinese Subsidiary", and together with the Company, U.S. Subsidiary and Hong Kong Subsidiary, the "Group"), have been engaged in the research, development and commercialization of minimally invasive medical devices for cryoablation (freezing) of tumors in the human body, using its propriety liquid nitrogen Cryoablation technology, as an alternative to surgical intervention to remove the tumor. The Company received regulatory approvals for marketing its products in the United States, Europe and other territories.

The U.S. Subsidiary was established on April 6, 2011 in the State of Delaware and is engaged in business development, marketing, clinical trial management and sale of the Company's products in the United States. The Hong Kong Subsidiary was established on September 26, 2018 and commenced its activity in 2021. The Chinese Subsidiary was established on July 14, 2020 and is wholly owned by the Hong Kong Subsidiary. The Chinese Subsidiary in China commenced its operation on January 1, 2021 and is engaged in business development, obtaining regulatory approvals and marketing activities for the Company's products.

The Group's activities are subject to significant risks and uncertainties, including failing to secure additional funding to commercialize its technology, obtaining regulatory approvals, and developing and obtaining regulatory approval for its next generation systems. In addition, the Group is subject to risks from, among other things, competition associated with the industry in general, other risks associated with financing, liquidity requirements, rapidly changing customer requirements and limited operating history.

B. Going Concern:

As of December 31, 2024, the Company has accumulated losses of $105,379. In the year ended December 31, 2024, the Company generated losses of $15,318, and negative cash flows from operating activities of $12,563.

To date, management expects the Company to continue to generate substantial operating losses and fund its operations primarily through utilization of its current financial resources, sales of its products, and additional raises of capital.

NOTE 1 - GENERAL (Cont.)

B. Going Concern (Cont.):

Such conditions raise substantial doubts about the Company's ability to continue as a going concern. Management's plan to continue as a going concern includes raising funds from existing shareholders and/or new investors. However, there is no assurance such funding will be available to the Company or that it will be obtained on terms favorable to the Company or will provide the Company with sufficient funds to successfully obtain regulatory approvals or complete the development of, and to commercialize, its products. These financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount and classification of liabilities that may be required should the Company be unable to continue as a going concern.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

A. Use of estimates:

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments, and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Management believes that the estimates, judgments and assumptions used are reasonable based upon information available at the time they are made. Actual results could differ from those estimates.

B. Financial statements in U.S. dollars and functional currency:

The functional currency of the Company and its subsidiaries is the U.S. dollar ("USD" or "dollar" or "$") since the dollar is the currency of the primary economic environment in which the Company has operated and expects to continue to operate in the foreseeable future. Most of the Company's revenues are derived from sales outside of Israel, which are based primarily on dollar.

In addition, the majority of the Company's equity raising is denominated in dollars. Thus, the functional currency of the Company and certain subsidiaries is the dollar.

Transactions and balances denominated in dollars are presented at their original amounts. Transactions and balances denominated in foreign currencies have been re-measured to dollars in accordance with the provisions of Accounting Standards Codification ("ASC") 830-10, "Foreign Currency Translation".

All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the statements of comprehensive loss as financial income or expenses, as appropriate.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Cont.)

C. Principles of consolidation:

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation. Profits from intercompany sales, not yet realized outside the Group, were also eliminated.

D. Cash and cash equivalents:

Cash equivalents are short-term highly liquid investments that are readily convertible into cash with original maturities of three months or less.

E. Trade Receivables:

Trade receivables are recorded at the invoiced amount, are unsecured, and do not bear interest. Accounts receivable are stated at their net realizable value, net of allowances. The allowance for credit loss is based on the Company's periodic assessment of the collectability of the accounts based on a combination of factors, including historical loss data, customer specific information, current market conditions and reasonable and supportable forecasts of future economic conditions to inform adjustments to historical loss data. Allowance for credit loss for the year ended December 31, 2024 is $3. No allowance for credit loss was recorded for the years ended December 31, 2023 and 2022.

F. Inventories:

Inventories are stated at the lower of cost, determined by the weighted average method, or market based on net realizable value. Inventories are adjusted for estimated excess and obsolescence and written down to net realizable value based upon estimates relating to historical usage rates, product end-of-life dates, technological obsolescence and product introductions.

G. Property and equipment:

Property and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets. The annual depreciation rates are as follows:

	%
Systems and equipment	15 - 20
Computers and software	33
Office furniture and equipment	7 - 15
Leasehold improvements	Over the shorter of the related lease period or the useful lives of the asset

The Company periodically performs impairment testing on its long-lived assets either annually or whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Cont.)

H. Leases:

We determine if an arrangement is a lease at inception. Operating lease assets are presented as operating lease right of use ("ROU") assets, and corresponding operating lease liabilities are presented as lease liabilities within current liabilities (current portions), and as long-term lease liabilities within non - current liabilities (long-term portions), on our consolidated balance sheets.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the remaining lease payments over the lease term at the commencement date. The rates implicit in our leases are not reasonably determinable and, we use our incremental borrowing rate. We calculate the incremental borrowing rate to reflect the interest rate that we would have to pay to borrow on a collateralized basis an amount equal to the lease payments in a similar economic environment over a similar term, and we consider our historical borrowing activities and market data in this determination. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. Our lease terms may include options to extend the lease when it is reasonably certain that we will exercise that option. Lease expense is recognized on a straight-line basis over the lease term.

Some of our leases contain variable lease payments, which are expensed as incurred unless those payments are based on an index or rate. Variable lease payments based on an index or rate are initially measured using the index or rate in effect at lease commencement and included in the measurement of the lease liability; thereafter, changes to lease payments due to rate or index updates are recorded as rent expense in the period incurred. Our lease agreements do not contain any material residual value guarantees or material restrictive covenants. In addition, we do not have any related party leases.

I. Contingencies:

The Company accounts for its contingent liabilities in accordance with ASC Topic 450, Contingencies ("ASC 450"). A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter.

J. Revenue recognition:

Revenue is measured as the amount of consideration the Company expects to be entitled to, in exchange for transferring products or providing services to its customers and is recognized when or as performance obligations under the terms of contracts with the Company's customers are satisfied. ASC 606 prescribes a five-step model for recognizing revenue from contracts with customers: (i) identify contract(s) with the customer; (ii) identify the separate performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the separate performance obligations in the contract; and (v) recognize revenue when (or as) each performance obligation is satisfied.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Cont.)

J. Revenue recognition (Cont.):

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services. When a contract has more than one performance obligation, the Company allocates the transaction price (the amount of consideration the Company expects to be entitled to from a customer in exchange for the promised goods or services) to each performance obligation and recognizes the associated revenue when (or as) each performance obligation is satisfied.

Revenues from product sales are recognized upon the transfer of control, which is generally upon shipment or delivery.

Provisions for discounts, rebates and sales incentives to customers, returns and other adjustments are provided for in the period the related sales are recorded. Sales incentives to customers are not material.

Deferred revenue represents amounts received by the Company for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met.

As of December 31, 2024, and 2023, the Company's deferred revenue balance is $334 and $187 (out of which $334 and $187 are presented as current), respectively.

For further analysis of the Company's main revenue contract, see Note 10 below.

K. Share-based compensation:

The Company applies ASC 718, "Share-Based Payment," which requires the measurement and recognition of compensation expenses for all share-based payment awards, including stock options, made to employees and directors under the Company's stock plans based on estimated fair values.

ASC 718-10 requires companies to estimate the fair value of share-based payment awards on the date of grant. The portion of the share value of the award that is ultimately expected to vest is recognized as share-based compensation expenses over the requisite service periods in the Company's consolidated statements of comprehensive loss.

The Company estimates the fair value of stock options granted using a Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires a number of assumptions, the most significant of which are the expected stock-price volatility and the expected option term (the time from the grant date until the options are exercised or expire). The Company's calculations of the expected volatility were based upon actual historical stock-price movements over the period, which was equal to the expected option term.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Cont.)

K. Share-based compensation (Cont.):

The expected option term was calculated for options granted to employees and directors in accordance with ASC 718-10-S99, using the "simplified" method, and grants to non-employees were based on the contractual term. Historically, the Company has not paid out dividends and has no foreseeable plans to do so. The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with an equivalent term. Changes in the determination of each of the inputs can affect the fair value of the options granted and the results of operations of the Company.

L. Research and development costs:

Research and development costs are charged to the consolidated statements of comprehensive loss as incurred. Grants for funding approved research and development projects are recognized at the time the Company is entitled to such grants, on the basis of the costs incurred and applied as a deduction from the research and development expenses.

M. Severance pay:

Under Israeli employment laws, all of the Company's employees in Israel are included under Section 14 of the Severance Compensation Act, 1963 ("Section 14"). Pursuant to Section 14, these employees are entitled to monthly deposits at a rate of 8.33% of their monthly salary, made on their behalf by the Company. Payments in accordance with Section 14 exempt the Company from any future severance pay liabilities in respect of those employees. The aforementioned deposits are not recorded as an asset in the Company's consolidated balance sheets.

N. Income taxes:

The Company accounts for income taxes utilizing the asset and liability method in accordance with ASC 740, "Income Taxes." Current tax liabilities are recognized for the estimated taxes payable on tax returns for the current year. Deferred tax liabilities or assets are recognized for the estimated future tax effects attributable to temporary differences between the income-tax bases of assets and liabilities and their reported amounts in the consolidated financial statements and for tax loss carry forwards and are measured using the enacted tax rates and laws, that will be in effect when the differences are expected to reverse. Measurement of current and deferred tax liabilities and assets is based on provisions of enacted tax laws, and deferred tax assets are reduced, if necessary, by the amount of tax benefits, the realization of which is not considered more likely than not based on available evidence. As of December 31, 2024, the Company had a full valuation allowance against deferred tax assets.

ASC 740-10 requires a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. The Company has not recorded any liability for uncertain tax positions for the year ended December 31, 2024.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Cont.)

O. Fair value of financial instruments:

The Company applies ASC 820, "Fair Value Measurements and Disclosures" ("ASC 820"), pursuant to which fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date.

The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

The carrying values of cash and cash equivalents, trade accounts receivable, prepaid expenses and other receivables, other long-term assets, trade accounts payable, other current liabilities and other long-term liabilities approximate their fair value due to the short-term maturity of these instruments.

When determining the fair value measurements for assets and liabilities required to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact and considers assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions and risk of nonperformance.

P. Concentrations of credit risk:

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, deposit and trade accounts receivables.

The management believes that the financial institutions that hold the Company's investments are corporations with high credit standing. Accordingly, management believes that low credit risk exists with respect to these financial investments.

The Company's trade receivables are derived from sales to customers located primarily in the Americas, Asia Pacific, and Europe. The Company performs ongoing credit evaluations of its customers' financial condition. Under certain circumstances, the Company may require advance payments.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Q. Segment Reporting:

The chief operating decision maker (the "CODM") of the Company is the Chief Executive Officer ("CEO"). The CODM reviews financial information presented on a consolidated basis for purposes of allocating resources and evaluating financial performance. Accordingly, management has determined that the Company operates in one reportable segment.

R. Basic and diluted net loss per share:

Basic net loss per share is computed based on the weighted-average number of ordinary shares outstanding during each year. Diluted net loss per share is computed based on the weighted-average number of ordinary shares outstanding during each year, plus the dilutive potential of the ordinary shares considered outstanding during the year, in accordance with ASC 260-10, "Earnings Per Share", using the treasury stock method. All outstanding stock options were excluded from the calculation of the diluted loss per share for the years ended December 31, 2024, 2023 and 2022 because all such securities have an anti-dilutive effect.

S. Comprehensive loss:

The purpose of reporting comprehensive income (loss) is to report a measure of all changes in equity of an entity that result from recognized transactions and other economic events of the period resulting from transactions from non-owner sources.

T. Recently issued accounting pronouncements:

As an "emerging growth company," the Jumpstart Our Business Startups Act ("JOBS Act") permits the Company to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. The Company has elected to use this extended transition period under the JOBS Act.

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB"), or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

In November 2023, the FASB issued Accounting Standards Update ("ASU") 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. The ASU expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly reviewed by the chief operating decision maker ("CODM") and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. The ASU also allows, in addition to the measure that is most consistent with U.S. GAAP, the disclosure of additional measures of segment profit or loss that are used by the CODM in assessing segment performance and deciding how to allocate resources. The ASU is effective for the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2024, or Annual Report, and subsequent interim periods, with early adoption permitted. As part of this Annual Report, the Company adopted ASU 2023-07, which was applied retrospectively to all prior periods presented. Refer to Note 16 herein for further details regarding this adoption.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Cont.)

T. Recently issued accounting pronouncements (Cont.):

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This ASU requires disclosure of specific categories in the rate reconciliation and additional information for reconciling items that meet a quantitative threshold. The amendment also includes other changes to improve the effectiveness of income tax disclosures, including further disaggregation of income taxes paid for individually significant jurisdictions. This ASU is effective for public business entities for fiscal years beginning after December 15, 2024 and for entities other than public business entities for fiscal years beginning after December 15, 2025. Early adoption is permitted. Adoption of this ASU should be applied on a prospective basis, although retrospective application is permitted. The Company is currently evaluating the impact of adopting this ASU on its consolidated financial statements and disclosures.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40), Disaggregation of Income Statement Expenses. This update aims to enhance the transparency of financial reporting by requiring public business entities to provide disaggregated disclosure of certain income statement expense captions into specified categories in disclosures in the footnotes to the financial statements. The ASU is effective for annual fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. Adoption of this ASU should be applied on a prospective basis, although retrospective application is permitted. The Company is currently evaluating the impact of adopting this ASU on its consolidated financial statements and disclosures.

(U.S. dollars in thousands, except share data and per share data)

NOTE 3 - INVENTORY

Composition:

	As of December 31, 2024	As of December 31, 2023
Raw materials	1,408	1,391
Work in progress	231	316
Finished goods	349	568
	1,988	2,275

NOTE 4 - PREPAID EXPENSES AND OTHER RECEIVABLES

Composition:

	As of December 31, 2024	As of December 31, 2023
Tax authorities	157	114
Prepaid expenses	657	512
Advanced payables	136	107
Other	31	11
	981	744

NOTE 5 - LEASES

The Company leases approximately 879 square meters in Caesarea, Israel.

To secure the lease payments, the Company provided a bank guarantee of $31.

In addition, the Company leases vehicles under various operating lease agreements.

As of December 31, 2024, and 2023, total ROU assets were approximately $524 and $679 and the lease liabilities for operating leases were approximately $459 and $599, respectively.

Supplemental cash flow information related to operating leases was as follows:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Cash payments for operating leases	296	246	242

(U.S. dollars in thousands, except share data and per share data)

NOTE 5 - LEASES (Cont.)

The maturities of operating lease liabilities and the reconciliation of undiscounted cash flows for operating lease liabilities as of December 31, 2024, were as follows:

2025	304
2026	194
2027	31
2028	-
Undiscounted cash flows for operating leases	529
Less: amount representing interest	(70)
Operating lease liabilities	459

The weighted average lease term and weighted average discount rate as of December 31, 2024, was as follows:

Operating leases weighted average remaining lease term (in years)	1.48
Operating leases weighted average discount rate	7.5%

NOTE 6 - PROPERTY AND EQUIPMENT, NET

Composition:

	As of December 31, 2024	As of December 31, 2023
Cost		
Systems and equipment	2,016	1,965
Computers and software	440	426
Office furniture and equipment	135	132
Leasehold improvements	212	209
	2,803	2,732
Less - accumulated depreciation		
Systems and equipment	920	664
Computers and software	410	375
Office furniture and equipment	68	58
Leasehold improvements	153	122
	1,551	1,219
Property and Equipment, Net	1,252	1,513

Depreciation and amortization expenses for the years ended December 31, 2024, 2023 and 2022 were $332, $323 and $248, respectively.

(U.S. dollars in thousands, except share data and per share data)

NOTE 7 - EMPLOYEES AND OTHER CURRENT LIABILITIES

Composition:

	As of December 31, 2024	As of December 31, 2023
Deferred revenues	334	187
Provision for royalties to IIA	46	47
Payroll and social benefits	2,037	1,362
Vacation and recuperation provision	720	630
Accrued expenses and others	847	920
	3,984	3,146

NOTE 8 - COMMITMENTS AND CONTINGENCIES

A. Israeli Innovation Authority (the "IIA"):

The Company undertook to pay royalties to the IIA in respect of grants it received from the IIA for the years 2006 through 2014 for participation in research and development costs. According to the terms of the grants, the IIA was entitled to receive royalties at the rate of 3% of the revenue, up to the amount of the grants received, including accumulated interest.

The liability to the IIA shown in Note 7 is calculated based on the Company's revenue from products developed with grants from the IIA.

As of December 31, 2024, based on 2024 second half revenue, the Company recorded a liability for royalties which amounted to $46.

As of December 31, 2024, the Company has no open application for grants to the IIA.

Total grants received by the Company from the Israeli Innovation Authority ("IIA"), including accumulated interest, amounted to approximately $2,676 ($1,980 net of royalties paid). The grants were previously linked to the exchange rate of the dollar, and bore the London Interbank Offered Rate until December 31, 2023. From January 1, 2024, these IIA grants are linked to the 12-month Secured Overnight Financing Rate or at an alternative rate published by the Bank of Israel plus 0.71513%.

B. Liens:

The Company pledged a deposit in the amount of NIS 114 (approximately $31) to secure a bank guarantee issued in connection with a lease agreement. In addition, the Company pledged a deposit in the amount of $15 to secure a bank guarantee issued in connection with a credit card issued. The deposits are presented in the consolidated balance sheets as a non-current asset under "Prepaid expenses and other long-term assets".

NOTE 8 - COMMITMENTS AND CONTINGENCIES (Cont.)

C. Class Action:

On July 5, 2021, the Company was informed that a motion (the "motion") to certify a claim as a class action was filed against it and the members of the Company's board of directors (the "Board"), the controlling shareholder and the investors who took part in the private placement that was approved by the general meeting on March 7, 2021 (the "investors"). The motion to certify was filed with the Tel Aviv District court by a shareholder of the Company (the "Plaintiff").

In the motion, the plaintiff claims, inter alia, that the Company made a private placement of securities to the controlling shareholder and the investors at a significant discount on the share price at that time, which did not reflect the material information that was allegedly in the Company's possession and which was also brought to the attention of the investors. The motion also alleged defects in the manner of approving the private placement at the meeting of the Company's shareholders.

The Plaintiff estimated the amount of his individual claim at a sum of approximately NIS 30,000 thousand (USD 8,226), the amount of the class action, insofar as it will be qualified as such, at a sum of approximately NIS 163,459 thousand (USD 44,820) for the class damages that the Plaintiff claims had their shares diluted unlawfully, and at a sum of approximately NIS 234,349 thousand (USD 64,258), for damage that was supposedly caused to the shareholders due to a sale at less than the allegedly full market price.

At this stage of the claim and after a review of the motion and the responses that were submitted by the parties, the Company believes that the motion is without merit and that the factual description and the data underlying the motion are incorrect and/or imprecise.

NOTE 9 - SHAREHOLDERS' EQUITY

A. Ordinary shares:

(1) The ordinary shares confer upon the holders the right to receive notice to participate and vote in general meetings of shareholders of the Company, the right to receive dividends, if declared, and the right to participate in the distribution of the surplus assets of the Company in an event of liquidation.

(2) Public and private placements:

On June 3, 2022, 1,034,000 pre-funded warrants issued as part of our public offering, that closed on December 8, 2021, were exercised into 1,034,000 ordinary shares at an exercise price of $0.001 per share.

On July 18, 2022, the Company issued 21,000 restricted ordinary shares to a consultant of the Company. The shares were restricted from any offer, sale, contract for sale, encumbrance, grant of any options for the sale of or otherwise disposed of for a period of 12 months from July 1, 2022. With respect to this grant the Company recorded share-based compensation expenses in the amount of $34, included in sales and marketing expenses in the consolidated statements of comprehensive loss.

On December 23, 2022, the Company raised $14,500 (gross) through a public offering of 8,787,880 ordinary shares, at a price to the public of $1.65 per share, gross, in lieu of ordinary shares.

After deducting closing costs underwriting discounts and fees, the Company received proceeds of approximately $13,569.

On January 12, 2024, we entered into an equity distribution agreement (the "Agreement"), with Maxim Group LLC ("Maxim"), as sales agent, pursuant to which we offered and sold ordinary shares having an aggregate offering price of up to $9,700 from time to time through Maxim. Maxim received commission equal to 2.5% of the gross sales price per share sold pursuant to the terms of the Agreement. We also provided Maxim with customary indemnification and contribution rights and agreed to reimburse Maxim for certain specified expenses. We sold 10,764,315 ordinary shares under the Agreement, having aggregate gross proceeds of $9,674 and aggregate net proceeds of $9,187.

On August 18, 2024, the Company issued 75,000 restricted ordinary shares to a consultant of the Company. The shares shall be restricted from any offer, sale, contract for sale, encumbrance, grant of any options for the sale of or otherwise disposed of for a period of 12 months from August 18, 2025. For the year ended December 31, 2024, the Company recorded share-based compensation expenses in the amount of $17, included in sales and marketing expenses in the consolidated statements of comprehensive loss.

(U.S. dollars in thousands, except share data and per share data)

NOTE 9 - SHAREHOLDERS' EQUITY (Cont.)

B. Shares, options and RSUs for employees and non-employees:

(1) The fair value of options granted was estimated using the Black-Scholes option pricing model, and based on the following assumptions:

	For the year ended December 31, 2024	For the year ended December 31, 2023	For the year ended December 31, 2022
Exercise price	$0.74 - $0.88	$1.22 - $1.37	$1.78 - $3.61
Expected volatility	119.5%	119.4% - 132.3%	91.0% - 91.6%
Risk-free interest	4.39% - 4.4%	3.86% - 4.34%	0.92% - 2.43%
Expected life of up to (years)	5.5 - 7	5.06 -7.02	5.56 - 6.25

(2) The following table summarizes the changes in options granted to employees, officers, members of the Board and non-employees for the years ended December 31, 2024, 2023 and 2022:

	Number of Share Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)
Balance as of January 1, 2022	1,336,480	$ 1.64	7.03
Granted	1,806,316	$ 3.3	
Expired	(3,380)	$ 3.43	
Forfeited	(63,262)	$ 2.04	
Exercised	(219)	$ 1.64	
Balance as of December 31, 2022	3,075,935	$ 2.55	7.8
Granted	1,157,940	$ 1.29	
Expired	(89,194)	$ 2.48	
Forfeited	(319,810)	$ 2.42	
Exercised	(106,250)	$ 2.87	
Balance as of December 31, 2023	3,718,621	$ 2.07	7.41
Granted	1,087,078	$ 0.86	
Expired	(67,162)	$ 3.53	
Forfeited	(147,825)	$ 1.89	
Exercised	-	-	
Balance as of December 31, 2024	4,590,712	$ 1.76	7.43
Exercisable at the end of year	2,368,762	$ 1.98	5.68

As of December 31, 2024, there are a total of 244,926 outstanding and exercisable options for which the aggregated positive intrinsic value is $100.

The weighted average fair value of options granted during the year ended December 31, 2024, was $0.64 per share.

(U.S. dollars in thousands, except share data and per share data)

NOTE 9 - SHAREHOLDERS' EQUITY (Cont.)

B. Shares, options and RSUs for employees and non-employees (cont.):

(3) The following table summarizes the changes in RSUs granted to employees, officers and members of the Board for the years ended December 31, 2024:

	Number of Share Options
Balance as of December 31, 2023	-
Granted	862,950
Expired	-
Forfeited	(22,711)
Exercised	-
Balance as of December 31, 2024	840,239

(4) Options and RSUs granted during 2024, 2023 and 2022:

(a) On January 12, 2022, the Company granted 1,720,660 options to purchase an aggregate of 1,720,660 ordinary shares to 59 optionees of the Company, as follows: 333,992 options to the Company's chief executive officer, the chairman of the Board and a member of the Board, 443,674 options to five officers of the Company and 942,994 options to 51 employees of the Company, at an exercise price of $3.61 per share. The options granted to the chief executive officer, chairman of the Board, Board member and the officers will vest as follows: a quarter after one year and the rest will vest in 12 equal quarterly installments over a period of three years from January 12, 2022. The options granted to the 51 employees will vest in four equal installments over a period of four years from the date of grant. The options are exercisable for 10 years from the date of grant.

On March 23, 2022, the Company granted 30,434 options to purchase an aggregate of 30,434 ordinary shares to five officers of the Company, as follows: 13,720 options for the Company's chief executive officer, and 16,714 options for four officers, at an exercise price of $2.73 per share. The options will vest as follows: a quarter after one year and the rest will vest in 12 equal quarterly installments over a period of three years from March 23, 2022. The options are exercisable for 10 years from the date of grant.

(b) On July 4, 2022, the Company granted to a consultant of the company 55,222 options to purchase an aggregate of 55,222 ordinary shares, at an exercise price of $1.78 per share. The options will vest as follows: eight equal quarterly installments over a period of two years from October 4, 2022. The options are exercisable for 10 years from the date of grant.

NOTE 9 - SHAREHOLDERS' EQUITY (Cont.)

B. Shares, options and RSUs for employees and non-employees (cont.):

(c) On February 19, 2023, the Company granted 1,107,940 options to purchase an aggregate of 1,107,940 ordinary shares to 76 option-holders of the Company, as follows: (i) 172,321 options to the Company's chief executive officer, the chairman of the Board and a member of the Board; (ii) 252,371 options to six officers of the Company; (iii) 641,836 options to 66 employees of the Company; and (iv) 41,412 options to a consultant of the Company, at an exercise price of $1.37 per share. The options granted to the chief executive officer, chairman of the Board, a Board member and the officers will vest as follows: a quarter after one year and the balance will vest in 12 equal quarterly installments over a period of three years from February 19, 2024. The options granted to the 66 employees will vest in four equal installments over a period of four years from the date of grant. The options granted to a consultant of the Company will vest in six equal quarterly installments from January 4, 2023. The options are exercisable for 10 years from the date of grant.

(d) On August 14, 2023, the Company granted 50,000 options to purchase an aggregate of 50,000 ordinary shares to an officer of the Company at an exercise price of $1.22 per share. The options will vest as follows: a quarter after one year, and the rest will vest in 12 equal quarterly installments over a period of three years from August 14, 2024. The options are exercisable for 10 years from the date of grant.

(e) On July 2, 2024, the Company granted 1,072,614 options to purchase an aggregate of 1,072,614 ordinary shares to 67 optionees of the Company, as follows: (i) 543,778 options to seven officers of the Company; and (ii) 528,836 options to 60 employees of the Company, at exercise prices of $0.74-$0.88 per share. One quarter of the options granted to the officers will vest after one year and the remain 75% will vest in twelve (12) equal quarterly installments over a period of three years from July 2, 2025. The options granted to the 60 employees will vest in four equal installments over a period of four years from the date of grant.

In addition, the Company granted 862,950 RSUs, as follows: (i) 453,149 RSUs to seven officers of the Company; and (ii) 409,801 RSUs to 60 employees of the Company. The RSUs granted to the officers and employees will vest on the same terms as the options, commencing on the earliest date of: (i) the Company receiving FDA authorization for its ProSense system for breast cancer treatment or (ii) the consummation of an equity investment in the Company of at least $15M following the date of the grant. The total fair value of these RSU grants is $634. As of December 31, 2024, it is not probable that the performance conditions will be achieved. Accordingly, no share-based compensation expenses were recognized with respect to these RSU grants.

(U.S. dollars in thousands, except share data and per share data)

NOTE 9 - SHAREHOLDERS' EQUITY (Cont.)

B. Shares, options and RSUs for employees and non-employees (cont.):

(4) The total share-based compensation expenses for employees and non-employees the Company recognized for share-based payments is as follows:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Cost of revenues	84	79	137
Sales and marketing	146	167	208
Research and development	335	513	785
General and administrative	304	551	735
	869	1,310	1,865

As of December 31, 2024, the total unrecognized share-based compensation cost related to non-vested share options grant arrangements under the plan was $884. This cost is expected to be recognized over the remaining vesting period of 3.5 years until the end of June 30, 2028.

As of December 31, 2024, the total unrecognized share-based compensation cost related to RSUs grant arrangements under the plan was $634. This cost is expected to be recognized over the vesting period when achievement of the performance conditions will be probable.

(U.S. dollars in thousands, except share data and per share data)

NOTE 10 - REVENUES

The Company's revenues are derived primarily from the sale of systems and disposables. Revenues from warranty and services are not material and therefore are included in revenue from systems in the following table.

Composition:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Systems	1,363	1,452	1,002
Disposables	1,828	1,503	1,336
Exclusive distribution agreement and other services	100	274	747
	3,291	3,229	3,085

For maintenance agreements that provide service beyond the Company's standard warranty and other service agreements, revenue is recognized over the contract term. A time-based measure of progress appropriately reflects the transfer of services to the customer. Payment terms between the Company and its customers vary by the type of customer and the territory of sale. The term between invoicing and the payment due date is not significant.

Exclusive distribution agreement in China

On June 12 2022, the Chinese Subsidiary signed an exclusive sales and distribution agreement (the "Distribution Agreement") for systems and disposables with Shanghai Medtronic Zhikang Medical Devices Co. Ltd. ("Shanghai Medtronic Zhikang") and Beijing Turing for an initial term of 36 months, with a minimum purchase target of $3.5 million within this term. Pursuant to the Distribution Agreement, the Chinese Subsidiary will sell the Company's products to Beijing Turing, which will import the Company's products from Israel to mainland China and resell them to Shanghai Medtronic Zhikang. Shanghai Medtronic Zhikang will be responsible for, among other matters: (i) marketing and promoting the products within mainland China; and (ii) holding professional medical education events for the Company's products in mainland China. Beijing Turing will be responsible for warehousing, logistics, warranty services, training, and other support and after sale services.

Under the terms of the Distribution Agreement, if Shanghai Medtronic Zhikang meets the accumulated three-year minimum purchase target, it will then have the right to extend the term of the Distribution Agreement for three consecutive years subject to an agreement on a new minimum purchase target. The Distribution Agreement may be terminated in certain circumstances, including in the event of default, material breach or insolvency. To date, Shanghai Medtronic Zhikang is unlikely to fulfil its minimum purchase target of $3.5 million by April 30, 2025 and it will no longer possess the right to extend the term of the Distribution Agreement for three consecutive years. We are evaluating the distribution agreement and commercial relationship with Shanghai Medtronic Zhikang. We currently sell our products in China through Beijing Turing.

Furthermore, under the Distribution Agreement's terms, the Chinese Subsidiary will be responsible for obtaining and maintaining any and all regulatory approvals in mainland China required for marketing, promotion, distribution, sale and use of the Company's products, issued by mainland China's National Medical Products Association, its local branches or any other government authorities. The Chinese Subsidiary has already obtained regulatory approvals for the IceSense3 systems and disposable CryoProbes for commercial procedures and filed for a regulatory approval for its ProSense system.

NOTE 10 - REVENUES (Cont.)

Exclusive distribution agreement in Japan

On August 30, 2019, the Company entered into an exclusive distribution agreement (the "Terumo Agreement") with Terumo Corporation ("Terumo"), in which Terumo will be appointed as an exclusive distributor of the Company's products in Japan.

The Terumo Agreement is for a period of five years from the date of the receipt of regulatory approvals for the sale of the Company's products in Japan, which will be extended automatically for an additional period of five years each, unless either party notifies the other party of its intention to terminate the agreement at least one year prior to the end of the period of the Terumo Agreement (either the initial five year period or any of the renewal periods). The Terumo Agreement can be canceled in certain circumstances. Pursuant to the Terumo Agreement, Terumo will be responsible and will bear the costs of performing the activities that are required, including clinical research, insofar as they may be required, for the purpose of receiving the regulatory approvals in Japan.

As of December 31, 2024, the Company believes that Terumo will submit a request for regulatory approval in the second half of 2025.

In addition, milestones have been set, for which, if met, the Company will receive the following amounts (that were identified by the Company as variable consideration):

(1) $250 will be paid to the Company upon the submission of an application for regulatory approval for the products in Japan;

(2) $250 will be paid to the Company upon the receipt of regulatory approval in Japan; and

(3) $500 will be paid to the Company upon the receipt of approval for medical reimbursement for the procedure in Japan

A total amount of $4,250 was allocated to the identified performance obligations as follows:

Systems and disposables – $866 were allocated based on the sale price of these products to similar customers in similar contracts.

Submission of an application for regulatory approval – $250 were allocated based on a standalone selling price of the submission fee.

Assistance in obtaining the regulatory approval – $3,134 were allocated based on the residual approach since the Company has not yet established a price for this service and has not sold it on a standalone basis.

The Company recognizes revenues from sales of systems and disposables when the control is transferred to Terumo and recognizes revenue from assistance in obtaining the regulatory approval over the estimated period as evaluated by the Company.

As of December 31, 2024, the total amount of revenue recognized from this agreement is $4,000.

(U.S. dollars in thousands, except share data and per share data)

NOTE 11 - COST OF REVENUES

Composition:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Payroll and related benefits (including share-based compensation)	585	551	896
Raw materials subcontractors and auxiliary materials	832	905	298
Shipping	44	42	48
Royalties to the IIA	99	96	93
Depreciation	186	161	111
Others	94	174	194
	1,840	1,929	1,640

NOTE 12 - RESEARCH AND DEVELOPMENT EXPENSES

Composition:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Payroll and related benefits (including share-based compensation)	5,436	5,395	5,969
Materials, subcontracted work and consulting	734	1,593	1,742
Clinical trials	181	436	495
Others	745	849	917
	7,096	8,273	9,123

NOTE 13 - SALES AND MARKETING EXPENSES

Composition:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Payroll and related benefits (including share-based compensation)	2,639	2,239	1,599
Consulting and professional services	2,518	987	566
Travel	426	354	274
Advertising and promotion expenses	32	92	74
Sales commissions	96	49	13
Conferences	286	323	301
Others	299	393	377
	6,296	4,437	3,204

(U.S. dollars in thousands, except share data and per share data)

NOTE 14 - GENERAL AND ADMINISTRATIVE EXPENSES

Composition:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Payroll and related benefits (including share-based compensation)	1,624	1,886	2,262
Professional services	1,955	1,996	3,369
Others	176	284	226
	3,755	4,166	5,857

NOTE 15 - TAXES ON INCOME

A. General:

The Company and its subsidiaries are assessed for tax purposes on an unconsolidated basis. Each of the Company's subsidiaries is subject to the tax rules prevailing in its country of incorporation.

B. Corporate Taxation:

The Company is subject to Israeli corporate tax rate of 23% for the years ended December 31, 2024, 2023 and 2022.

The U.S. subsidiary is subject to U.S. federal tax rate of 21% for the years ended December 31, 2024, 2023 and 2022.

The Chinese subsidiary is subject to a progressive tax rate in China of 2.5% up to taxable income of one million RMB, 5% on taxable income between one million RMB to three million RMB and 25% on taxable income higher than three million RMB, for the year ended December 31, 2024, 2023 and 2022.

C. Net loss carryforward:

As of December 31, 2024, the Company has an accumulated tax loss carryforward of approximately $93,625 in Israel, which may be carried forward and offset against taxable income in the future for an indefinite period.

D. Tax assessments

The Company received final tax assessments in Israel through the year ended December 31, 2019.

(U.S. dollars in thousands, except share data and per share data)

NOTE 15 - TAXES ON INCOME (Cont.)

E. Deferred income taxes:

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

Significant components of the Company's deferred tax assets are as follows:

	As of December 31, 2024	As of December 31, 2023
Net loss carryforward	21,534	18,608
Other reserves and allowance	165	145
Total deferred tax assets	21,699	18,753
Valuation allowance	(21,699)	(18,753)
Net deferred tax asset	-	-

As of December 31, 2024, the Company has provided valuation allowances of $21,699 in respect of deferred tax assets resulting from tax loss carryforward and other temporary differences. Management currently believes that because the Company has a history of losses, it is more likely than not that the deferred tax regarding the loss carryforward and other temporary differences will not be realized in the foreseeable future.

F. Effective tax expense (benefit):

The components of loss before tax and a reconciliation of the Company's tax expense to the Company's theoretical statutory tax benefit are as follows:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Loss before taxes:			
Local	15,187	14,652	16,952
Foreign[1]	131	*	26
Net loss, as reported in the consolidated statements of comprehensive loss	15,318	14,652	16,978
Israeli statutory income tax rate	23%	23%	23%
Theoretical tax benefit	3,523	3,370	3,905
Losses and other items for which a valuation allowance was provided or benefit from loss carryforwards	(3,523)	(3,370)	(3,905)
Income tax expense	-	-	-

* Lowerthan $1K

1 Foreign is amount related to the US & China Subsidiaries.

(U.S. dollars in thousands, except share data and per share data)

NOTE 16 - SEGMENT REPORTING, GEOGRAPHIC AND SIGNIFICANT CUSTOMER INFORMATION

The Company has identified one reportable and operating segment that designs, develops, manufactures and markets cryoablation medical devices. The CODM assesses the performance of the Company and decides how to allocate resources based upon consolidated net comprehensive loss that is also reported within the consolidated statements of comprehensive loss. The measure of segment assets that is reviewed by the CODM is reported within the consolidated balance sheet as consolidated total assets. Significant expense categories provided to the CODM are those presented in the consolidated statements of comprehensive loss and in Notes 11-14.

The following table sets forth reporting revenue information by geographic region:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
United States	870	751	604
Japan	481	480	1,130
India	413	109	47
China	41	440	104
Israel	30	30	30
Other[2]	1,456	1,419	1,170
	3,291	3,229	3,085

The following table sets forth reporting property and equipment information by geographic region:

	As of December 31, 2024	As of December 31, 2023
Israel	933	1,084
United States	319	429
	1,252	1,513

The following table is a summary of customer concentrations as a percentage of revenue:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Customer A	*	*	25%
Customer B	*	14%	*
Customer C	13%	*	*

* Lowerthan 10%

2 No country included in Others represents more than 10% of consolidated revenues.

NOTE 17 - SUBSEQUENT EVENTS

The following are the significant events that took place subsequent to December 31, 2024:

On January 13, 2025, we entered into a second equity distribution agreement with Maxim as sales agent, pursuant to which we may offer and sell ordinary shares having an aggregate offering price of up to $13,960 from time to time through Maxim. The ordinary shares will be offered and sold pursuant to our currently effective registration statement on Form F-3 (File No. 333-267272), the prospectus contained therein and the prospectus supplement filed with the Securities Exchange Commission dated January 13, 2024. We will pay Maxim a commission equal to 2.5% of the gross sales price per share sold pursuant to the terms of the agreement and will provide Maxim with customary indemnification and contribution rights. We also agreed to reimburse Maxim for certain specified expenses. As of March 24, 2025, we have sold 2,047,277 ordinary shares pursuant to the equity distribution agreement, having aggregate gross proceeds of $2,755 and aggregate net proceeds of $2,571.

Exhibit 2.1

Description of Share Capital

The following description of IceCure Medical Ltd. (the "Company") share capital, provisions of articles of association ("Articles") as may be amended and restated from time to time, and Israeli law are summaries and do not purport to be complete, and is qualified in its entirety by reference to, the provisions of our Articles as well as the Israeli law and any other documents referenced in the summary and from which the summary is derived.

General

As of December 31, 2024, our authorized share capital consisted of 2,500,000,000 Ordinary Shares, with no par value per share, of which 56,568,999 were issued and outstanding as of such date. All of our outstanding Ordinary Shares have been validly issued, fully paid and non-assessable.

Our registration number with the Israeli Registrar of Companies is 513787804.

Name of exchange on which registered

Our ordinary shares have been listed on Nasdaq Capital Market ("Nasdaq") under the symbol "ICCM" since August 26, 2021.

The Powers of the Directors

Our board of directors shall direct our policy and shall supervise the performance of our Chief Executive Officer and his actions. Our board of directors may exercise all powers that are not required under the Israeli Companies Law, 5759-1999 (the "Companies Law") or under our Articles to be exercised or taken by our shareholders.

Pre-emptive Rights

The Company's Ordinary Shares are not redeemable and are not subject to any preemptive right.

Limitations or Qualifications

Not applicable.

Other Rights

Not applicable.

Rights of the Shares

The Company's Ordinary Shares shall confer upon the holders thereof:

- equal right to attend and to vote at all of the Company's general meetings, whether regular or special, with each Ordinary Share entitling the holder thereof, which attends the meeting and participates in the voting, either in person or by a proxy or by a written ballot, to one vote;
- equal right to participate in distribution of dividends, if any, whether payable in cash or in bonus shares, in distribution of assets or in any other distribution, on a per share pro rata basis; and
- equal right to participate, upon the Company's dissolution, in the distribution of the Company's assets legally available for distribution, on a per share pro rata basis.

Election of Directors

Under our Articles, the board of directors will be no less than five (5) and no more than eleven (11), unless the general meeting resolves otherwise.

Pursuant to our Articles, our directors are elected at an annual general meeting of our shareholders, and in certain events, in a special meeting of our shareholders and serve on the board of directors until the next annual general meeting (except for external directors) or until they resign or until they cease to act as board members pursuant to the provisions of our Articles or any applicable law, upon the earlier.

Pursuant to the Companies Law, other than the external directors, for whom special election requirements apply under the Companies Law, the vote required to appoint a director is a simple majority vote of holders of our voting shares, participating and voting at the relevant meeting. In addition, our Articles allow our board of directors to appoint directors to fill vacancies and/or as an addition to the board of directors (subject to the maximum number of directors) to serve until the next annual general meeting.

External directors are elected for an initial term of three years, may be elected for up to two additional terms of three years each under certain circumstances, and may be removed from office pursuant to the terms of the Companies Law.

External directors are elected by a majority vote at a shareholders' meeting, as long as either:

- at least a majority of the shares held by shareholders who are not controlling shareholders and do not have a personal interest in the appointment (excluding a personal interest that did not result from the shareholder's relationship with the controlling shareholder) have voted in favor of the proposal (shares held by abstaining shareholders shall not be considered); or

- the total number of shares voted against the election of the external director, does not exceed 2% of the aggregate voting rights of the Company.

Notwithstanding the above, the term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including the Nasdaq Stock Market, may be extended indefinitely in increments of additional three-year terms, in each case provided that the audit committee and the board of directors of the Company confirmed and presented to the general shareholders meeting that, in light of the external director's expertise and special contribution to the work of the board of directors and its committees, the reelection for such additional period(s) is beneficial to the Company, and provided that the external director is reelected subject to the same shareholder vote requirements as if elected for the first time (as described above). Prior to the approval of the re-election of the external director at a general shareholders meeting, our shareholders must be informed of the term previously served by him or her and of the reasons why the board of directors and audit committee recommended the extension of his or her term.

Annual and Special Meetings

Under Companies Law, the Company is required to hold an annual general meeting of our shareholders once every calendar year, at such time and place which shall be determined by the Company's board of directors, which must be held no later than 15 months after the date of the previous annual general meeting. All general meetings other than the annual general meeting of shareholders are referred to in our Articles as special general meetings. Our board of directors may call special meetings whenever it sees fit at such time and place, as it may determine. In addition, the Companies Law provide that our board of directors is required to convene a special meeting upon the written request of: (a) any two of the Company's directors or of one quarter of the members of the board of directors in office at such time; and/or (b) one or more shareholders holding, in the aggregate, either (a) 5% or more of our outstanding issued shares and 1% or more of our outstanding voting power or (b) 5% or more of our outstanding voting power (the "**Non Exempted Holding**"). However, in accordance with the regulations promulged under the Companies Law relating to Israeli companies whose shares are listed on foreign stock exchanges (the **"Exemptions Regulations")**, the board of directors of an Israeli company whose shares are listed outside of Israel, shall convene a special meeting at the request of one or more shareholders holding at least ten percent (10%) of the issued and outstanding share capital instead of five percent (5%) in the past, and at least one percent (1%) of the voting rights in the Company, or one or more shareholders holding at least ten percent (10%) of the voting rights in the Company, provided that if the law applicable to companies incorporated in the country which the Company is listed for trade establishes a right to demand convening of such a meeting for those holding a percentage of holdings lower than ten percent (10%), then the Non Exempted Holding shall apply.

Under the Companies Law, one or more shareholders holding at least 1% of the voting rights may request that the board of directors include a matter in the agenda of a general meeting to be convened in the future, provided that it is appropriate to discuss such a matter at the general meeting. However, under the Exemptions Regulations, one or more shareholders of an Israeli company whose shares are listed outside of Israel, may request our board of directors to include an appointment of a candidate for a position on the board of directors or the termination of a board member, as an item on the agenda of a future general meeting (if the Company sees fit), provided that the shareholder hold at least 5% of the voting rights of the Company (instead of 1% in the past). Any such shareholder may make such a request for nomination of directors only if a notice of such shareholder's intent to make such nomination has been given to our board of directors in accordance with the regulations promulgated under the Companies Law and our Articles. Any such notice must include certain information, including the consent of the proposed director nominee to serve as our director if elected, and a declaration that the nominee signed declaring that he or she possesses the requisite skills and has the availability to carry out his or her duties. Additionally, the nominee must provide details of such skills, demonstrate an absence of any limitation under the Companies Law that may prevent his or her election, and affirm that all of the required election-information is provided to us, pursuant to the Companies Law.

Subject to the provisions of the Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which according to the Companies Law may be between four (4) and sixty (60) days prior to the date of the meeting, as applicable according to the matters on the general meetings agenda. According to the Companies Law, resolutions regarding the following matters must be passed at a general meeting of our shareholders:

- amendments to our Articles;
- the exercise of the Board's powers by a general meeting if the Board is unable to exercise its powers and the exercise of any of its powers is required for the Company's proper management;
- appointment or termination of the Company's auditors;
- appointment of directors (other than with respect to circumstances specified in the our Articles of association);
- approval of acts and transactions requiring general meeting approval pursuant to the provisions of the Companies Law and any other applicable law;
- increases or reductions of the Company's authorized share capital;
- a merger (as such term is defined in the Companies Law).
- dissolution of the Company by the court, voluntary dissolution, or by voluntary dissolution in an expedited procedure.

Notices

The Companies Law require that a notice of any annual or special general shareholders meeting be provided at least 14 or 21 days prior to the meeting, as the case may be, and if the agenda of the meeting includes certain matters prescribed under the Companies Law and the regulations promulgated thereafter, among others, the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, approval of the chairman of the board or his relative to serve as the general manager or to exercise his powers and approval of the general manager or his relative serve as the chairman of the board or to exercise his powers, or an approval of a merger, notice must be provided at least 35 days prior to the meeting.

Voting rights

Each shareholder shall have one vote for each share held, provided that votes may be cast in person, by proxy, or by written ballot as permitted under our Articles. In the case of jointly held shares, the vote shall be cast in accordance with the priority of shareholders as prescribed in our Articles.

Quorum

As permitted under the Companies Law and our Articles, the quorum required for our general meetings consists of two or more shareholders who are present in person or by proxy and who hold or represent at least twenty-five percent (25%) of the voting rights in the Company. If half an hour has elapsed from the date set for the meeting and the quorum has not been found valid, the meeting will be postponed to the business day after the day of the meeting, to the same time and to the same place or to another day, time and place as determined by the board of directors. The Company will announce through the immediate report of the postponement of the meeting and the date of the postponed meeting. If a quorum was not present at such adjourned meeting, one shareholder, at least, who is present in person or by proxy, will constitute a quorum, unless the meeting was convened upon requisition of shareholders. If a special general meeting was summoned following the request of a shareholder according to applicable law, and within half an hour a legal quorum shall not have been formed, the meeting shall be cancelled.

Access to Corporate Records

Under the Companies Law, shareholders are entitled to have access to: minutes of the Company's general meetings; our shareholders register and principal shareholders register, Articles and annual audited financial statements; and any document that the Company is required by law to file publicly with the Israeli Companies Registrar or the Israel Securities Authority. These documents are publicly available and may be found and inspected at the Israeli Registrar of Companies. In addition, shareholders may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Companies Law. The Company may deny this request if the Company believes it has not been made in good faith or if such denial is necessary to protect the Company's interest or protect a trade secret or patent.

Adoption of Resolutions

Our Articles provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required under the Companies Law or our Articles. A shareholder may vote in a general meeting in person, by proxy, by a written ballot when applicable.

Changes in capital

Our Articles enable us to increase or reduce our authorized share capital. Any such changes are subject to the provisions of the Companies Law and must be approved by a resolution duly adopted by our shareholders at a general meeting. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings or profits, require the approval of both our Board of Directors and an Israeli court.

Exclusive Forum

Our Articles provide that unless the Company consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, or the Securities Act and that any person or entity purchasing or otherwise acquiring any interest in any security of the Company, shall be deemed to have notice of and consented to this exclusive forum provision.

Limitations on the Rights to Own Ordinary Shares

There are no limitations on the right to own our securities.

Provisions Restricting Change in Control of the Company

There are no specific provisions of our Articles that would have an effect of delaying, deferring or preventing a change in control of the Company or that would operate only with respect to a merger, acquisition or corporate restructuring involving us (or any of our subsidiaries). However, as described below, certain provisions of the Companies Law may have such effect.

Mergers

The Companies Law includes provisions that allow a merger transaction and requires that each company that is a party to the merger have the transaction approved by its board of directors and, unless certain requirements described under the Companies Law are met, a vote of the majority of shareholders, and, in the case of the target company, also a majority vote of each class of its shares. For purposes of the shareholder vote of each party, unless a court rules otherwise, the merger will not be deemed approved if shares representing a majority of the voting power present at the shareholders meeting and which are not held by the other party to the merger (or by any person or group of persons acting in concert who holds 25% or more of the voting power or the right to appoint 25% or more of the directors of the other party) vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger will be subject to the same Special Majority approval that governs all extraordinary transactions with controlling shareholders instead. Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that as a result of the merger the surviving company will be unable to satisfy the obligations of any of the parties to the merger, and may further give instructions to secure the rights of creditors. If the transaction would have been approved by the shareholders of a merging company but did not receive the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the petition of holders of at least 25% of the voting rights of a company. For such petition to be granted, the court must find that the merger is fair and reasonable, taking into account the value of the parties to the merger and the consideration offered to the shareholders. In addition, a merger may not be completed unless at least (1) 50 days have passed from the time that the requisite proposals for approval of the merger were filed with the Israeli Registrar of Companies by each merging company and (2) 30 days have passed since the merger was approved by the shareholders of each merging company.

Special Tender Offer

The Companies Law also provides that, subject to certain exceptions, an acquisition of shares in an Israeli public company must be made by means of a "special" tender offer if as a result of the acquisition (1) the purchaser would become a holder of 25% or more of the voting rights in a company, unless there is already another holder of at least 25% or more of the voting rights in a company or (2) the purchaser would become a holder of 45% or more of the voting rights in a company, unless there is already a holder of more than 45% of the voting rights in a company. These requirements do not apply if, in general, the acquisition (1) was made in a private placement that received shareholders' approval, subject to certain conditions, (2) was from a holder of 25% or more of the voting rights in a company which resulted in the acquirer becoming a holder of 25% or more of the voting rights in a company, or (3) was from a holder of more than 45% of the voting rights in a company which resulted in the acquirer becoming a holder of more than 45% of the voting rights in a company. A "special" tender offer must be extended to all shareholders. In general, a "special" tender offer may be consummated only if (1) at least 5% of the voting power attached to a company's outstanding shares will be acquired by the offeror and (2) the offer is accepted by a majority of the offerees who notified a company of their position in connection with such offer (excluding the offeror, controlling shareholders, holders of 25% or more of the voting rights in a company or anyone on their behalf, or any person having a personal interest in the acceptance of the tender offer). If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

However, under the Exemption Regulations, the aforesaid limitations regarding a special tender offer do not apply for an Israeli company whose shares are listed outside of Israel, provided that if the applicable law as applicable to companies incorporated in the country which a company is listed for trade, provide a restriction on the acquisition of control of any proportion of a company or that the acquisition of control of any proportion requires the purchaser to also offer a purchase offer to shareholders from among the public.

Full tender offer

If, as a result of an acquisition of shares, the acquirer will hold more than 90% of an Israeli public company's outstanding shares or of certain class of shares, the acquisition must be made by means of a tender offer for all of the outstanding shares, or for all of the outstanding shares of such class, as applicable. In general, if less than 5% of the outstanding shares, or of applicable class, are not tendered in the tender offer and more than half of the offerees who have no personal interest in the offer tendered their shares, all the shares that the acquirer offered to purchase will be transferred to it by operation of law. However, a tender offer will also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of a company or of the applicable class of shares. Any shareholders that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may request, by petition to an Israeli court, (i) appraisal rights in connection with a full tender offer, and (ii) that the fair value should be paid as determined by the court, for a period of six months following the acceptance of the offer. However, the acquirer is entitled to stipulate, under certain conditions, that tendering shareholders will forfeit such appraisal rights.

Tax Considerations for Acquisitions

Lastly, Israeli tax law treats some acquisitions, such as stock-for-stock exchanges between an Israeli company and a foreign company, less favorably than U.S. tax laws. For example, Israeli tax law may, under certain circumstances, subject a shareholder who exchanges his Ordinary Shares for shares in another corporation to taxation prior to the sale of the shares received in such stock-for-stock swap.

Differences Between Law of Different Jurisdictions

Not applicable.

Borrowing Powers

Pursuant to the Companies Law and our Articles, the Board may exercise all powers and take all actions that are not required under law or under our Articles to be exercised or taken by the shareholders.

Changes in the Company's Capital

The general meeting may, by a simple majority vote of our shareholders attending the general meeting:

- increase our registered share capital by the creation of new shares from the existing class or a new class, as determined by the general meeting;
- cancel registered share capital which has not yet been issued, provided that there is no commitment of the Company to issue such Shares;
- consolidate and divide all or any of our share capital into shares of larger nominal value than our existing shares;
- subdivide our existing shares or any of them, our share capital or any of it, into shares of smaller nominal value than is fixed; and
- reduce our share capital and any fund reserved for capital redemption in any manner, and with and subject to any incident authorized, and consent required, by the Companies Law.

Debt Securities

The Company does not have any debt securities that are registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Other Securities

The Company does not have any other securities that are registered under Section 12 of the Securities Exchange Act.

Exhibit 11.1

ICECURE MEDICAL LTD.
INSIDER TRADING POLICY

EFFECTIVE JANUARY 12 , 2022

AMENDED MARCH 26, 2025

I. Introduction

This policy determines acceptable transactions in the securities of IceCure Medical Ltd. (the "***Company***") by our employees, directors, consultants and other related persons. This policy arises from the Company's status as a public company whose shares are traded on the Nasdaq Capital Market under the symbol "ICCM". During the course of your employment, directorship or consultancy with the Company, you may receive important information that is not yet publicly available ("***Inside Information***"), about the Company or about other publicly-traded companies with which the Company has business dealings. Because of your access to this Inside Information, you may be in a position to profit financially by engaging in any transaction involving the Company's securities, or securities of another publicly-traded company, or to disclose such information to a third party who does so profit or which you may have reasonable belief to assume will use the Inside Information (a "***Tippee***").

In addition, the Company itself must comply with securities laws applicable to its own securities trading activities, and must not engage in any transaction involving a purchase or sale of its securities, including any offer to purchase or offer to sell or otherwise dispose of its securities, when it is in possession of material nonpublic information concerning the Company, other than in compliance with applicable law, subject to the policies and procedures adopted by the Company and the exceptions listed in Section III(c) of this policy to the extent applicable.

II. Insider Trading Policy

A. *Securities Transactions*

Use of Inside Information by someone for personal gain, or to pass on, or "tip," the Inside Information to someone who uses it for personal gain, is illegal, regardless of the quantity of shares, and is therefore prohibited. You can be held liable both for your own transactions and for transactions effected by a Tippee, or even a Tippee of a Tippee. Furthermore, it is important that the appearance of insider trading in securities be avoided. The only exception is that transactions directly with the Company, *e.g.,* option exercises for cash or purchases under a Trading Plan (as defined below), are permitted. However, the subsequent sale (including the sale of shares in a cashless exercise program) or other disposition of such shares is fully subject to these restrictions.

B. *Inside Information*

As a practical matter, it is sometimes difficult to determine whether you possess Inside Information. The key to determining whether nonpublic information you possess about a public company is Inside Information is whether dissemination of the information would likely affect the market price of the company's shares or would likely be considered important, or "material," by investors who are considering trading in that company's shares. Certainly, if the information makes you want to trade, it would probably have the same effect on others. Remember, both positive and negative information can be material. If you possess Inside Information, you may not trade in a company's shares, advise anyone else to do so or communicate the information to anyone else until you know that the information has been publicly disseminated. This means that in some circumstances, you may have to forego a proposed transaction in a company's securities even if you planned to execute the transaction prior to learning of the Inside Information and even though you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting. "***Trading***" includes engaging in short sales, transactions in put or call options, hedging transactions and other inherently speculative transactions, for your own account or for others.

Although by no means an all-inclusive list, information about the following items may be considered to be Inside Information until it is publicly disseminated:

- financial results or forecasts;
- confirming or updating previous disclosures or analysts' reports;
- major product or technological developments;
- results of pre-clinical studies and clinical trials of the Company's product candidates;
- major contract awards or cancellations;
- M&A activity, including acquisitions or dispositions of assets or divisions;
- pending public or private sales of debt or equity securities;
- declaration of share splits, dividends or changes in dividend policy;
- top management or control changes;
- possible tender offers or proxy fights;
- significant write-offs;
- significant litigation or settlements;
- impending bankruptcy;
- gain or loss of a significant license agreement or other contracts with customers or suppliers;
- pricing changes or discount policies;
- cybersecurity risks and incidents;

- corporate partner relationships or joint venture developments; and

- governmental actions or regulations.

For information to be considered publicly disseminated, it must be widely disclosed through a press release or U.S. Securities Exchange Commission filing, and a sufficient amount of time must have passed to allow the information to be fully disclosed. Generally speaking, information will be considered publicly disseminated after two full trading days have elapsed since the date of public disclosure of the information. For example, if an announcement of Inside Information of which you were aware was made *prior* to trading on Wednesday, then you may execute a transaction in the Company's securities on Friday.

III. Trading by Directors, Officers and Other Employees

We require directors, officers and other employees to do more than refrain from insider trading. We require that they limit their transactions in the Company's shares to defined time periods following public dissemination of quarterly (if applicable) interim and annual financial results and notify, and receive approval from, the Chief Financial Officer prior to engaging in transactions in the Company's shares and observe other restrictions designed to minimize the risk of apparent or actual insider trading.

A. Covered Insiders

The provisions outlined in this policy apply to all directors, officers and employees of the Company. Generally, any entities or family members of those individuals whose trading activities are controlled or influenced by any of such persons should be considered to be subject to the same restrictions.

B. Window Period

Generally, except as set forth in this paragraphs B, C, and D of this policy, directors, officers and other employees may buy or sell securities of the Company only during a "*Window Period*" that opens after two full trading days have elapsed after the public dissemination of the Company's annual, interim, quarterly (if applicable) financial results and closes on the last trading day two weeks before the end of the quarter. This Window Period may be closed early or may not open if, in the judgment of the Company's Chief Financial Officer, there exists undisclosed information that would make trades by members of the Company's directors, officers or employees inappropriate. It is important to note that the fact that the Window Period has closed early or has not opened should be considered Inside Information. A director, officer or other employee who believes that special circumstances require him or her to trade outside the Window Period should consult with the Company's Chief Financial Officer. Permission to trade outside the Window Period will be granted only where the circumstances are extenuating and there appears to be no significant risk that the trade may subsequently be questioned.

C. Exceptions to Window Period

1. *Option/Warrant Exercises*. Other than as provided in paragraph III.C.3 below, directors, officers and other employees may exercise options/warrants for cash granted under the Company's equity incentive plans without restriction to any particular period in light of information then available to the public. However, the subsequent sale of the shares (including sales of shares in a cashless exercise) acquired upon the exercise of options/warrants is subject to all provisions of this policy.

2. *10b5-1 Automatic Trading Programs*. Rule 10b5-1 under the U.S. Securities Exchange Act of 1934, as amended (the "***Exchange Act***") provides an affirmative defense from insider trading liability under the U.S. federal securities laws for transactions in the Company's securities made pursuant to, and in compliance with, a written plan established by a director, officer or other employee that meets the requirements of Rule 10b5-1 (a "***Trading Plan***") that meets each of the following requirements: (a) the Trading Plan is adopted by the insider during a Window Period and when the insider is not in possession of material non-public information; (b) the Trading Plan is followed by the insider; (c) the Trading Plan either (i) specifies the amount of securities to be sold and the date on which the securities are to be sold, (ii) includes a written formula or algorithm, or computer program, for determining the amount of securities to be sold and the price at which and the date on which the securities are to be purchased or sold, or (iii) does not permit the insider to exercise any subsequent influence over how, when, or whether to effect sales; provided, in addition, that any other person who, pursuant to the plan, does exercise such influence must not have been aware of the material non-public information when doing so; (d) the Trading Plan includes a representation from the insider adopting the plan that such insider (i) is not aware of any Inside Information about the Company or its securities and (ii) is adopting the Trading Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b-5 under the Exchange Act; (e) the Trading Plan provides that trading under it cannot begin until the later of (i) 90 days after the adoption of the Trading Plan or (ii) two business days following the disclosure of the Company's financial results in a Report of Foreign Private Issuer on Form 6-K or Annual Report on Form 20-F (such period being referred to as the "cooling-off period", but, in either case, not to exceed 120 days following the adoption of the Trading Plan, and provided that if the insider is not a director or officer of the Company, such cooling-off period shall be at least 30 days rather than the longer periods set forth above); (f) at the time it is adopted the Trading Plan conforms to all other requirements of Rule 10b5-1 then in effect; (g) the Trading Plan was reviewed by the Company prior to establishment, solely to confirm compliance with this policy and the securities laws; and (h) the Trading Plan allows for the cancellation of a transaction and/or suspension of such Trading Plan upon notice and request by the Company to the individual if any proposed trade (i) fails to comply with applicable laws (*e.g.*, exceeding the number of shares that may be sold under Rule 144 under the U.S. Securities Act of 1933, as amended ("***Rule 144***")) or (ii) would create material adverse consequences for the Company. The Company must be notified of the establishment of any such Trading Plan, any amendments to such Trading Plan and the termination of such Trading Plan.

3. *Former Employees*. Former employees of the Company who have left the Company and still own securities of the Company that have not been forfeited shall contact the Company's Chief Financial Officer to discuss trading outside the Window Period on a case-by-case basis.

D. Pre-Clearance and Advance Notice of Transactions

In addition to the requirements of paragraph B above, directors, officers and other employees that the Clearing Officer (as defined below) deems to have routine access to material non-public information may not engage in any transaction in the Company's securities, including any purchase or sale in the open market, loan or other transfer of beneficial ownership without first obtaining pre-clearance of the transaction from the Company's Chief Financial Officer (the "***Clearing Officer***"), at least two business days in advance of the proposed transaction. The Clearing Officer will then determine whether the transaction may proceed. Pre-cleared transactions not completed within five business days shall require new pre-clearance under the provisions of this paragraph. The Company may, at its discretion, shorten such period of time.

Advance notice of gifts or an intent to exercise an outstanding share option shall be given to the Clearing Officer. To the extent possible, advance notice of upcoming transactions to be effected pursuant to an established Trading Plan under Section III.C.2 above shall also be given to the Clearing Officer.

E. Prohibition of Speculative or Short-term Trading

No director, officer or other employee may engage in short sales, transactions in put or call options, hedging transactions, margin accounts or other inherently speculative transactions with respect to the Company's shares at any time.

F.ControlShares

Directors and officers should take care not to violate the restrictions on sales by control persons (under Rule 144) and should file any notices of sale required by Rule 144.

G. Rule 144 and Section 16 Matters for Directors and Officers

Directors and officers of the Company must also comply with Rule 144, or another applicable exemption from registration. The practical effect of Rule 144 is that directors and officers who sell the Company's securities may be required to comply with a number of requirements including holding period, volume limitation, manner of sale and U.S. Securities and Exchange Commission filing requirements. The Company may provide separate memoranda and other appropriate materials to its directors and officers regarding compliance with Rule 144. In addition, if the Company is no longer considered a "foreign private issuer", the directors and officers who transact in Company securities have to report such transactions through the filing of Form 4s with the U.S. Securities and Exchange Commission. The Company will advise such persons if they are subject to the requirements of Form 4 and the reporting requirements of Section 16 of the Exchange Act.

IV. Duration of Policy's Applicability

This policy continues to apply to your transactions in the Company's shares or the securities of other publicly traded companies engaged in business transactions with the Company even after your employment, directorship or consultancy with the Company has terminated. If you are in possession of Inside Information when your relationship with the Company concludes, you may not trade in the Company's shares or the securities of any such other company until the information has been publicly disseminated or is no longer material.

V. Penalties

Anyone who effects transactions in the Company's securities or the securities of other public companies engaged in business transactions with the Company (or provides information to enable others to do so) on the basis of Inside Information is subject to both civil liability and criminal penalties, as well as disciplinary action by the Company. An employee, director or consultant who has questions about this policy should contact his or her own attorney or our Chief Financial Officer, Ronen Tsimerman, at ronent@icecure-medical.com.

* * *

Adopted/last amended: **MARCH 26 , 2025** Board meeting

Exhibit 12.1

CERTIFICATION PURSUANT TO EXCHANGE ACT RULE 13a-14(a) or 15d-14(a)

I, Eyal Shamir, certify that:

1. I have reviewed this annual report on Form 20–F of IceCure Medical Ltd. (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent function):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: March 27, 2025

/s/ Eyal Shamir
Eyal Shamir
Chief Executive Officer

Exhibit 12.2

CERTIFICATION PURSUANT TO EXCHANGE ACT RULE 13a-14(a) or 15d-14(a)

I, Ronen Tsimerman, certify that:

1. I have reviewed this annual report on Form 20–F of IceCure Medical Ltd. (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent function):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: March 27, 2025

/s/ Ronen Tsimerman
Ronen Tsimerman
Chief Financial Officer

Exhibit 13.1

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350

In connection with the filing of the Annual Report on Form 20-F for the period ended December 31, 2024 (the "Report") by IceCure Medical Ltd. (the "Company"), the undersigned, as the Chief Executive Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, that, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 27, 2025

/s/ Eyal Shamir
Eyal Shamir
Chief Executive Officer

Exhibit 13.2

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350

In connection with the filing of the Annual Report on Form 20-F for the period ended December 31, 2024 (the "Report") by IceCure Medical Ltd. (the "Company"), the undersigned, as the Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, that, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 27, 2025

/s/ Ronen Tsimerman
Ronen Tsimerman
Chief Financial Officer

Exhibit 15.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statements Nos. 333-258660 and 333-267272 on Form F-3 and Nos. 333-262620, 333-264578, 333-270982, and 333-281587 on Form S-8 of our report dated March 27, 2025, relating to the consolidated financial statements of IceCure Medical Ltd. appearing in this Annual Report on Form 20-F for the year ended December 31, 2024.

/s/ Brightman Almagor Zohar & Co.
Certified Public Accountants
A Firm in the Deloitte Global Network

Tel Aviv, Israel
March 27, 2025