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

FORM 20-F

☐ **REGISTRATION STATEMENT PURSUANT TO 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**

For the transition period from _____ to

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

Date of event requiring this shell company report

Commission file number: 001-35165

BrainsWay Ltd.
(Exact name of Registrant as specified in its charter)

Israel
(Jurisdiction of incorporation or organization)

16 Hartum Street, RAD Tower, 14th Floor, Har HaHotzvim, Jerusalem, 9777516, Israel
(Address of principal executive offices)

Ido Marom
Chief Financial Officer
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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
American Depositary Shares each representing two Ordinary Shares (1)	BWAY	NASDAQ Global Market
Ordinary Shares, par value NIS 0.04 per share	BWAY	Tel Aviv Stock Exchange

(1) Evidenced by American Depositary Receipts

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: 37,626,427 Ordinary Shares.

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 Securities 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 Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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. ☒

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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Introduction

Unless the context otherwise requires, all references to "BrainsWay," "we," "us," "our," the "Company" and similar designations refer to BrainsWay Ltd., a limited liability company incorporated under the laws of the State of Israel, and its consolidated subsidiaries. The term "including" means "including but not limited to", whether or not explicitly so stated. The "BrainsWay" name and design logo are our registered trademarks. BrainsWay also asserts all rights, including but not limited to trademark rights, with respect to the term "Deep TMS." Solely for convenience, the trademarks, service marks, and trade names referred to in this Annual Report are without the ® and TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks, and trade names. This Annual Report contains additional trademarks, service marks, and trade names of others, which are the property of their respective owners. All trademarks, service marks, and trade names appearing in this Annual Report are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies' trademarks, service marks or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Financial and Other Information

The term "NIS" refers to New Israeli Shekels, the lawful currency of the State of Israel, the terms "dollar", "US$", "$" or "USD" refer to U.S. dollars, the lawful currency of the United States of America. Our functional and presentation currency is the U.S. dollar. Unless otherwise indicated, U.S. dollar amounts herein (other than amounts originally receivable or payable in dollars) have been translated for the convenience of the reader from the original NIS amounts at the representative rate of exchange as of December 31, 2024 ($1 = NIS 3.647). The dollar amounts presented should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated. Foreign currency transactions in currencies other than U.S. dollars are translated in this Annual Report into U.S. dollars using exchange rates in effect at the date of the transactions.

Statistical Information

This Annual Report includes statistics and other data relating to markets, market sizes, and other industry data pertaining to our business that we obtained from industry publications, surveys, and other information available to us. Industry publications and surveys generally state that the information contained therein has been obtained from sources believed to be reliable. Market data and statistics are inherently predictive, speculative and are not necessarily reflective of actual market conditions. Such statistics are based on market research, which itself is based on sampling and subjective judgments by both the researchers and the respondents, including judgments about what types of products and transactions should be included in the relevant market. In addition, the value of comparisons of statistics for different markets is limited by many factors, including that (i) the markets are defined differently, (ii) the underlying information was gathered by different methods, and (iii) different assumptions were applied in compiling the data. Likewise, market size calculations and definitions are based on shifting and sometimes limited assumptions, including, but not limited to, relating to pricing models for our products. In addition, the sections of this Annual Report titled "*Item 4. Information on the Company*" contain information obtained from independent industry and other sources that we may not have independently validated. Accordingly, the market statistics included in this Annual Report should be viewed with caution. We believe that information from these industry publications included in this Annual Report is reliable.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements under the sections titled "*Item 3. Key Information—Risk Factors*," "*Item 4. Information on the Company*," "*Item 5. Operating and Financial Review and Prospects*" and elsewhere in this Annual Report may include forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. You should not put undue reliance on any forward-looking statements. Unless we are required to do so under U.S. federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements.

Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to:

- market perception and acceptance of Deep Transcranial Magnetic Stimulation, or Deep TMS™, technology (Deep TMS) and patient satisfaction with the effectiveness and benefits of Deep TMS;
- availability of reimbursement from third-party payors, including insurance companies and Medicare;
- the adequacy of our existing capital to meet our future capital requirements;
- our ability to commercialize Deep TMS, including internationally, by ourselves or through third-party distributors;
- our ability to develop enhancements to our Deep TMS system through our research and development efforts;
- our reliance on third parties to conduct our clinical trials and manufacture our product candidates for clinical testing;
- our ability to complete and obtain favorable results from existing clinical trials, and to launch and successfully complete new clinical trials, for Deep TMS indications;
- our ability to obtain and comply with regulatory approvals of Deep TMS and enhancements to our Deep TMS system within our anticipated timeframes, or at all;
- our ability to obtain and maintain adequate protection of our intellectual property, including intellectual property licensed to us; and
- our ability to operate within the changing market conditions caused by geopolitical instability, wars, economic downturns, disrupted supply chains and global pandemics.

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. [Reserved]

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should carefully consider the risks we describe below, in addition to the other information set forth elsewhere in this Annual Report, including our financial statements and the related notes beginning on page F-1. The risks and uncertainties described below in this Annual Report on Form 20-F for the year ended December 31, 2024 are not the only risks we face. We may face additional risks and uncertainties not currently known to us or that we currently deem to be immaterial. Any of the risks described below or incorporated by reference in this Form 20-F, and any such additional risks, could materially adversely affect our reputation, business, financial condition or results of operations.

Summary of Risk Factors

The following is a summary of some of the principal risks we face. The list below is not exhaustive, and investors should read this "Risk Factors" section in full.

Financial Condition and Capital Requirement Risks

- We have a history of operating losses. Although during the year ended December 31, 2024 we achieved an operating profit, we may incur losses in the future and no longer be profitable and we cannot ensure that our existing capital will be sufficient to meet our capital requirements.

Business, Economic and Industry risks

- Our success depends on Deep TMS as a safe treatment option for patients, as well as market perception and acceptance of TMS generally.
- Our long-term growth depends on our ability to increase market penetration and further commercialize Deep TMS, as well as develop enhancements and features to the Deep TMS system through our research and development efforts and obtain regulatory clearances for additional indications, products and/or labeling expansions. If we fail to do so, we may be unable to achieve future growth.
- We operate in a very competitive environment and if we are unable to compete successfully against our existing or potential competitors, our revenues and operating results may be negatively affected.
- We are dependent on physicians and if we are unable to adequately train physicians and other treatment providers and operators or if they use the Deep TMS inadequately, we may be unable to achieve our expected growth.
- Failure to secure or maintain adequate coverage and reimbursement of our Deep TMS system for the currently authorized indications and other indications for which we obtain FDA authorization in the future, if any, may make physicians reluctant to use or recommend Deep TMS and have a material adverse effect on our sales, results of operations, and financial condition.
- We rely on third parties, including suppliers for some components used in manufacturing our Deep TMS products, distributors to market and promote our products internationally and third parties to conduct our clinical trials, which exposes us to uncertainty and instability.
- Clinical trials involve a lengthy and expensive process with an uncertain outcome, which may delay or cause us to abandon the development of Deep TMS for additional indications.
- Our collaboration arrangements may not be successful, which could adversely affect our ability to develop and commercialize our products.

- We bear the risk of product liability lawsuits and warranty claims which might harm our business, may not be covered by our insurance policies or may exceed our insurance policy coverage, and we may not have enough funds to cover such claims or lawsuits damages.

- Our operations could be affected in the event of further geopolitical instability, war, supply chain disruptions, unfavorable market or political conditions, global pandemic or other outbreaks or other negative global trends or disruptions.

- Our reliance on the use of technology may adversely affect our business if we become subject to cyber-terrorism or other compromises and shut-downs or if we experience significant disruptions in our information technology systems, and security and privacy breaches may expose us to liability and harm our reputation and business.

- We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, and/or through the licensing of products or technologies from third parties. The failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could harm our business.

Government Regulatory Risks

- Our products 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 or to obtain and/or maintain needed clearances could harm our business.

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

- If treatment guidelines for the clinical conditions we are targeting change or the standard of care evolves, we may need to redesign and seek new marketing authorizations from the FDA for one or more of our products.

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

- Deep TMS may cause or contribute to adverse medical events that we are required to report to the FDA, 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 or our distributors do not obtain and maintain international regulatory registrations or approvals for Deep TMS, we will be unable to market and sell our products outside of the United States.

- We are subject to certain federal, state, and foreign fraud and abuse laws, health information privacy and security laws, and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

- Healthcare policy changes, including legislation reforming the U.S. healthcare system, could harm our cash flows, financial condition, and results of operations.

Intellectual Property Risks

- We depend on our intellectual property, and our future success is dependent on our ability to protect our intellectual property and not infringe on the rights of others.
- The duration of our patent rights may not be sufficient to effectively protect our products and business.
- Our right to the essential intellectual property upon which the Deep TMS technology is based derives from in-license agreements with government agencies and research institutions, the termination of which would prevent us from commercializing Deep TMS.
- The license agreements for our critical patents and related intellectual property impose significant monetary obligations and other requirements on us that may adversely affect our ability to successfully execute our business plan.
- The key patents that underlie Deep TMS technology are subject to the U.S. government's royalty free usage rights on a worldwide basis for any discovery based on such patents, which may have unexpected, adverse consequences on the market for our product.
- 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.
- Legal proceedings or third-party claims of intellectual property infringement and other challenges, whether with or without merit, may require us to spend substantial time and money and could prevent us from developing or commercializing Deep TMS.

Foreign Country Risks

- The Israeli government grants that we received require us to meet several conditions, may restrict our ability to manufacture our Deep TMS systems and transfer relevant know-how outside of Israel and require us to pay royalties, including increased royalties if we manufacture our Deep TMS systems outside of Israel or payment of a redemption fee if we transfer relevant know-how outside of Israel.
- We have manufacturing, assembly and other significant functions that are located in Israel and, therefore, our business and operations may be adversely affected by political, economic and military conditions in Israel.
- Exchange rate fluctuations between the U.S. dollar, the New Israeli Shekel and other foreign currencies may negatively affect our future results of operations.
- The price of our American Depositary Shares, or ADSs, may be volatile and may fluctuate due to factors beyond our control.
- The significant share ownership position of several of our officers, directors, and entities affiliated with certain of our directors, including Valor, may limit your ability to influence corporate matters.

Risks Related to our Financial Condition and Capital Requirements

We have a history of operating losses. Although during the year ended December 31, 2024 we achieved an operating profit, we may incur losses in the future and no longer be profitable and we cannot ensure that our existing capital will be sufficient to meet our capital requirements.

We have incurred net losses since our inception until and including the year ended December 31, 2023, largely reflecting research and development, general and administrative expenses, and sales and marketing expenses. We have reached a net income of $2.9 million for the year ended December 31, 2024 but experienced net losses of $4.2 million and $13.3 million for the years ended December 31, 2023 and 2022, respectively. As a result of ongoing losses since our inception, as of December 31, 2024, we had an accumulated deficit of $98.3 million. While we have sold and leased Deep TMS systems and/or installed Deep TMS Systems under revenue generating pay-per-use models in various markets over the last few years, we may continue to incur significant sales and marketing, research and development, product development, regulatory and other expenses as we continue to pursue our commercialization efforts to increase adoption of Deep TMS and expand existing relationships with our customers, to obtain regulatory clearances or approvals for Deep TMS in additional countries and for additional or broader indications, and to develop new enhancements or features to our existing Deep TMS systems. These expenses, along with potential declines in our revenues, may cause us to once again incur operating losses in the future. The net losses we may incur may fluctuate significantly from period to period. We will need to continue to generate additional revenues and to carefully manage our expenses to sustain profitability on an annual basis, and even if we continue to achieve profitability for a certain period, we cannot be sure that we will remain profitable for any substantial period of time. A failure to maintain profitability on an annual basis, or achieve profitability should we incur operating losses in the future, could negatively impact the value of our shares.

We believe that our existing capital and other sources of liquidity will be sufficient to meet our capital requirements. To date we have funded our operations primarily through offerings of our securities, through research and development grants from the Israel Innovation Authority and other sources, and through sales and leases of our Deep TMS systems as well as revenue generated through pay-per-use models on certain installed systems and services provided to our customers. We expect to continue generating revenues primarily through sales, leases, pay-per-use fees, service fees and other potential income generated by the commercial distribution of Deep TMS systems for approved indications.

The adequacy of our available funds to meet our operating and capital requirements will depend on many factors, including our ability to achieve revenue growth and maintain favorable operating margins; our ability to increase the market share of Deep TMS and expand our operations and offerings, including our sales and marketing efforts; the cost, progress and results of our future research, product development and clinical programs for additional enhancements to Deep TMS and future indications for the system; the costs and timing of obtaining regulatory approvals for future indications or expanded labeling for existing indications of Deep TMS; our ability to improve or maintain coverage and reimbursement arrangements with third-party and government payors; the terms and conditions of commercial agreements for marketing and distribution of Deep TMS; the effect of competing technological and market developments; and costs incurred in enforcing and defending certain of the patents and other intellectual property rights upon which our technologies are based, to the extent such rights are breached or challenged.

On November 5, 2024, we consummated a private placement of 2,103,745 ADSs and warrants to purchase 1,500,000 ADSs to Valor BrainsWay Holdings, LLC, or Valor, for aggregate immediate gross proceeds of approximately $20 million. We cannot be certain that in the future alternative financing sources will be available to us at such times or in the amounts we need or whether we can negotiate commercially reasonable terms or at all, or that our actual cash requirements will not be greater than anticipated. Any issuance of additional equity or equity-linked securities could be dilutive to our existing shareholders, and any new equity securities could have rights, preferences, and privileges superior to those of holders of the Ordinary Shares or ADSs. For example, in connection with the private placement to Valor, we amended our Articles of Association to provide Valor the right to designate for nomination one or two members to our Board of Directors, depending on the percentage of their holdings. Moreover, future debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt, pay dividends, repurchase our shares, make investments and engage in merger, consolidation, or asset sale transactions. If we are unable to obtain future financing through the methods we described above or through other means, our business may be materially impaired and we may be unable to complete our business objectives and may be required to cease operations, curtail one or more product development or commercialization programs, significantly reduce expenses, sell assets, seek a merger or joint venture partner, file for protection from creditors, or liquidate all our assets.

Risks Related to our Business and Industry

Our success depends on Deep TMS as a safe treatment option for patients, as well as market perception and acceptance of TMS generally.

Our business currently depends entirely on the success of Deep TMS, our proprietary TMS solution. TMS is an emerging treatment option for patients. As a result, physician and patient awareness of TMS therapy as a treatment option for applicable brain disorders, and experience with TMS therapies, is limited. Because the market for TMS therapy is still developing and contains a limited number of market participants, sales of Deep TMS could be negatively impacted by unfavorable market reactions to TMS generally, Deep TMS in particular, and/or negative developments in the industry. For example, with respect to Deep TMS in particular, in February 2020, we announced that a multicenter study of our Deep TMS system for Post-Traumatic Stress Disorder (PTSD) was discontinued after interim results showed subjects treated with the H-Coil that was involved in the study (i.e., the same as that used in our multicenter OCD study) did not demonstrate sufficient efficacy relative to the sham group. While there is prior and subsequent contrary data supporting the potential for positive outcomes in PTSD with other H-Coils we manufacture, further research would be needed to scientifically corroborate this hypothesis.

If the use of our Deep TMS system or other TMS therapies results in serious adverse events (e.g., seizures), or such products malfunction or are misused, patients and physicians may attribute such negative events to TMS and/or Deep TMS, which may adversely affect market adoption of this form of therapy. For example, a paper titled "Seizure risk with repetitive TMS: Survey results from over a half-million treatment sessions" published in 2021 in Brain Stimulation claims that Deep TMS appears to be associated with a higher relative seizure risk than with generic figure-8 coil TMS. While the authors of the paper themselves cite numerous reasons to view the results with caution and while the claims in the paper were based on a small data set obtained from an informal survey which appear to be inconsistent with other more comprehensive studies, we may nonetheless be unable to successfully educate the public about these often nuanced and technical publication deficiencies and thus the overall safety of our technology. These reported findings may have a negative effect on market perception of the effectiveness of the TMS therapy in general, and by extension Deep TMS. In addition, if patients undergoing treatment with any available TMS solutions perceive the benefits to be inadequate or the administration of TMS to be too burdensome or inconvenient, and/or if adverse events and/or factors such as discomfort and noise with available TMS solutions are too numerous or severe compared to the relevant rates of alternative therapies or pharmaceutical options, it will be difficult to demonstrate the value of Deep TMS to patients and physicians. Moreover, psychiatrists may find it difficult or expensive to train existing employees and/or hire additional staff, allocate sufficient space or operate our device given that psychiatry is a field not traditionally associated with medical equipment treatment options. As a result of any one or a combination of these reasons, demand for and the use of Deep TMS may decline or may not increase at the pace or to the levels we expect.

Even if TMS therapy is widely accepted by physicians and patients, our success will depend in large part on our ability to educate and train physicians and patients, and to successfully demonstrate the safety, tolerability, ease of use, efficacy, cost effectiveness and other advantages of Deep TMS. We have been engaging in an active marketing campaign to raise awareness of Deep TMS and its benefits, but we cannot be assured that these efforts will be successful or that they will not prove to be too costly. Physicians may find patient set up and the subsequent procedures for future treatment sessions to be difficult or complicated compared to competing treatment methods. Any of these factors could slow market adoption of Deep TMS.

Our long-term growth depends on our ability to increase market penetration and further commercialize Deep TMS, as well as develop enhancements and features to the Deep TMS system through our research and development efforts. If we fail to do so, we may be unable to achieve future growth.

Our strategy depends on our ability to further commercialize and increase market penetration of Deep TMS for MDD (including reduction of comorbid anxiety symptoms, commonly referred to as anxious depression), OCD, and smoking addiction, develop and seek regulatory approvals of Deep TMS for new indications or for expanded labeling of current authorized indications, and add new enhancements or features for the Deep TMS system. These goals are also designed to respond to changing customer demands, competitive pressures, and technologies. Our industry is characterized by intense competition, including from other existing treatment options, a growing number of Traditional TMS competitors, rapid technological changes, new product and treatment protocol introductions and enhancements, price competition, and evolving industry standards. It is important that we anticipate changes in technology and market demand, as well as physician practices to successfully develop, obtain clearance or approval, if required, and successfully introduce new, enhanced, and competitive technologies and treatment protocols to meet our prospective customers' needs on a timely and cost-effective basis.

We might be unable to further commercialize Deep TMS for approved indications or develop, obtain or maintain regulatory clearances or approvals to market Deep TMS for new indications, different treatment protocols or expanded labeling for current indications, or to develop and obtain regulatory approvals for enhancements or new features for the Deep TMS system. Furthermore, our clearances on existing indications could be jeopardized by increased regulatory requirements in different territories. Additionally, Deep TMS for MDD (including reduction of comorbid anxiety symptoms, commonly referred to as anxious depression), OCD, smoking addiction, and any future indications, even if cleared, might not be sufficiently accepted by physicians or the third-party payors who reimburse for the procedures performed with our products. Potential customers may not qualify for credit arrangements with us and/or our third party financing vendors. Likewise, we may be unable to devise pricing strategies that are attractive to customers, and even when we do, our customers may not always have the financial resources to meet their contractual commitments, which can negatively impact our ability to collect on open debts accrued by customers, especially in cases of default by larger customers and/or multi-system orders. The success of any new or expanded indications, enhancements, features or treatment protocols for the Deep TMS system will depend on numerous additional factors, including but not limited to, our ability to properly identify and anticipate clinician and patient needs; demonstrate the benefits associated with the use of Deep TMS when compared to the products and devices of our competitors; demonstrate the safety and efficacy of new or expanded indications and treatment protocols, and develop and obtain regulatory approvals or clearances of Deep TMS for such indications, enhancements, features or treatment protocols, to the extent required; and to adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties.

If we do not develop and obtain regulatory clearances or approvals for new or expanded indications, enhancements, features or treatment protocols in time to meet market demand, or if there is insufficient demand for these indications, enhancements, features or treatment protocols, our results of operations will suffer. Our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new indication for Deep TMS, any enhancements to the Deep TMS system or any other innovation. In addition, even if we are able to develop enhancements or new features for Deep TMS, these enhancements or features may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or enhancements or features.

Furthermore, we must carefully manage our introduction of new indications. If potential customers believe such indications will be subject to additional future enhancements or features or may become available at a more attractive price, they may delay purchases until such indications are available. We may also have excess or obsolete inventory as we upgrade to newer models of our products and/or transition to new indications, and we have limited experience in managing product transitions.

We operate in a very competitive environment and if we are unable to compete successfully against our existing or potential competitors, our revenues and operating results may be negatively affected.

Our Deep TMS systems for MDD (including reduction of comorbid anxiety symptoms, commonly referred to as anxious depression), OCD, smoking addiction, and any future indications are or will be subject to intense competition. The industry in which we operate is subject to rapid change and is highly sensitive to the introduction of new products or other market activities of current or new industry participants. Our ability to compete successfully will depend on our ability to develop and obtain regulatory clearances or approvals of Deep TMS for indications that reach the market in a timely manner, to receive adequate coverage and reimbursement from third-party payors, and to successfully demonstrate to physicians and patients the merits of Deep TMS compared to the products of our competitors. If we are not successful in convincing others of the merits of Deep TMS or educating them on the use of the Deep TMS system, they may not use our system or use them effectively and we may be unable to increase our revenues.

Deep TMS competes with several existing Traditional TMS competitors, including Neuronetics, Magventure, Neurocare (MAG & More), Cloud TMS, Magstim, Nexstim Yingchi, Sebers (Remed/Blossom), Magnus Medical, NeuroQuore, and BTL. Competing TMS therapy companies have developed or may develop treatments that have improved efficacy when compared to our products or that require a less significant investment of resources from physicians. Likewise, psychiatrists and other customers may not be able to easily compare Deep TMS to our focal TMS competitors given limited data from head-to-head studies and marketing campaigns and tactics employed by competitors which may have access to greater resources than we do.

We also face competition from pharmaceutical and other companies, many of which have greater resources than we do, that develop competitive products, such as anti-depressant medications (including but not limited to a nasal spray utilizing the drug esketamine, which was approved in 2022 by the FDA for use in conjunction with an oral antidepressant) and to a lesser degree, ECT, home-use alternatives such as transcranial direct current stimulation (TDCS) devices, prescription digital therapeutics (PDTs), and other neuromodulation treatment options. Our commercial opportunity could be reduced or eliminated if these competitors develop and commercialize anti-depressant medications or other treatments that are safer or more effective than Deep TMS, or are offered at more competitive prices, are more easily administered to patients or are otherwise more attractive to our customers and patients. At any time, these and other potential market entrants may develop treatment alternatives that may make Deep TMS less competitive.

We also note that competition varies based on the indication, and some of the indications we are advancing may face marketability challenges based on existing treatment options. For example, there are a variety of smoking cessation products currently available on the market, including nicotine patch treatment. Electronic cigarettes, or e-cigarettes, are also widely available substitutes for tobacco smoking. Deep TMS for smoking cessation may not be a marketable alternative to these existing options, particularly to the extent smokers need to pay out-of-pocket given the unavailability of reimbursement for this indication.

Our competitors may also develop and patent processes or products earlier than we can or obtain domestic or international regulatory clearances or approvals for competing products or processes, including treatment protocols, more rapidly than we can, which could impair our ability to develop and commercialize similar products. Furthermore, our educational efforts to distinguish between Deep TMS and traditional TMS may not be sufficiently effective, and our competitors may therefore succeed in obtaining regulatory pathways for their products based on our clinical data without having to invest in clinical trials themselves. In addition, we compete with our competitors to engage the services of independent distributors outside the United States, both those presently working with us and those with whom we hope to work as we expand.

Furthermore, our competitors may be seeking predicate FDA approvals in various psychiatric and neurological indications, and TMS products of various companies are frequently used off-label, and in certain circumstances, are marketed outside of the United States for other indications. Additionally, if either TMS competitors or other medical device or pharmaceutical companies introduce new and disruptive products or forms of therapy, our market share may be reduced and our financial performance and ability to compete may be significantly impacted. These competitors may have obtained or seek to obtain expansions of existing clearances and indications before we do. For example, in March 2024, one of our competitors received clearance from the FDA effectively expanding its existing MDD clearance to cover adolescent patients aged 15-21 and allowing it to treat these patients with its device as an adjunct form of therapy.

Moreover, our relationships with large clinic networks, which we rely on, can be jeopardized (and thus impact on our installed base and future assumed revenue streams) depending on developments with these networks and/or by the deepening of relationships between these networks and our competitors, thus leading to potential financial difficulties that may negatively affect our revenues. For example, we had to remove devices and pursue collections from a clinic network with whom we have had a relationship after the network had accrued an outstanding debt. Moreover, any exclusivity or other commercial arrangements between our competitors and large clinic networks we also work with may hinder the deployment of our Deep TMS systems in such networks. We are further exposed to the risk that our competitors, some of whom have more financial resources than us, may enter into exclusive relationships, acquire or merge with clinic networks, thereby strengthening the relationship between them and the clinic network and making it more difficult for us to maintain a business relationship with such clinic networks. For example, in January 2023 GreenBrook TMS Inc., which owns approximately 95 treatment centers offering TMS therapy in the Unites States, entered into an exclusive relationship with Neuronetics, Inc., one of our competitors. Thereafter, in December 2024, Neuronetics acquired all of the issued and outstanding shares of Greenbrook. Furthermore, any financial instability of these networks can have an adverse effect on our revenues. In addition, our competitors may be acquired by enterprises that have more established distribution networks than we do, thus gaining an integral distribution advantage over us.

We are dependent on physicians and if we are unable to adequately train physicians and other treatment providers and operators or if they use the Deep TMS inadequately, we may be unable to achieve our expected growth.

There is a learning process involved for treatment providers to become proficient in the use of our Deep TMS systems, which requires us to spend considerable time and resources for training. It is critical to the success of our commercialization efforts to train a sufficient number of physicians and to provide them with adequate, ongoing instruction and training in the use of our Deep TMS systems. This training process generally requires physicians to review and study product materials and engage in hands-on training sessions. This training process may also take longer than expected or be more complicated than the physicians or their personnel are comfortable with and may therefore affect our ability to increase sales. Convincing physicians to dedicate the time and energy necessary for adequate training is challenging, and we may not be successful in these efforts.

The use of our Deep TMS system to treat OCD requires a special procedure to provoke the patient to exhibit symptoms of OCD while the patient is treated with Deep TMS. This procedure requires special training and may make the treatment more difficult to apply than alternative treatments, as the treatment must be tailored for the condition of each patient. As a result, this may lead to a variability of the overall results and between patients, which could discourage use of Deep TMS for OCD. In addition, if the physicians and operators do not apply the treatment of OCD patients properly or experience difficulties in the use of the system for OCD, this could reduce the level of satisfaction with this system for OCD, and adversely affect our revenues and our operating results.

To the extent our customer physicians do not properly diagnose or select appropriate patient candidates for Deep TMS treatment and/or utilize unprescribed protocols it could result in variability of the treatment efficacy and results for the patient. Our ability to generate significant revenues from Deep TMS relies on physicians' and patients' satisfaction with the effectiveness of Deep TMS and if physicians or patients are not satisfied with the results of Deep TMS, our reputation, and future results of operations may be adversely affected.

We may be unable to predict and/or manage our anticipated growth effectively, which could make it difficult to execute our business strategy and we may even be unable to forecast our future growth accurately.

We intend to continue to grow our business operations and may experience periods of rapid growth and expansion. This anticipated growth could create a strain on our organizational, administrative and operational infrastructure, including our supply chain operations, quality control, technical support and customer service, sales force management and general and financial administration. These risks increase as we expand into new countries, each entailing varied and often time-consuming regulatory challenges and requirements. We may be unable to maintain the quality, regulatory infrastructure, or delivery timelines of our products or customer service, or satisfy customer demand if our business grows too rapidly. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, and our reporting systems and procedures. We may implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain and failure to complete this in a timely and efficient manner could harm our business.

As our commercial operations and sales volume grow, we will need to continue to increase our workflow capacity for our supply chain, regulatory expansion, customer service, training and education personnel, billing, accounting reporting and general process improvements and expand our internal quality assurance program, among other things. Our current workforce may not be sufficient to handle our expanding growth and we will be required to expand and train additional personnel as we increase our sales efforts. We may not successfully implement these increases in scale or the expansion of our personnel, which could harm our business.

Moreover, we may be unable to predict future growth related to Deep TMS for MDD (including reduction of comorbid anxiety symptoms, commonly referred to as anxious depression), OCD, smoking addiction, and other psychiatric indications because some of these disorders are inherently difficult to diagnose and there are frequent co-morbidities (overlap) in these disorders that complicate treatment methods. Diagnosis for psychiatric disorders, such as MDD and OCD, is based on an individual's reported experiences and mental status examination, and accordingly is subject to significant error. For example, it is estimated that about half of the individuals in the United States who experience a major depressive episode annually are not diagnosed correctly. In addition, there is a rising trend in which primary care providers, rather than mental health professionals, prescribe anti-depressant medications. While we view this as an overall positive development for the industry, any errors in diagnosing the underlying condition can impact the appropriateness – and thus efficacy – of any treatments administered, including Deep TMS. In addition, the H-Coils for our Deep TMS systems may prove to be interchangeable in some respects, and clinicians may be able to treat patients with multiple disorders in the same procedure. With respect to comorbidities, there is a high rate of tobacco use amongst patients suffering from mental health conditions such as depression and anxiety. Approximately 3 of every 10 cigarettes smoked by adults in the United States are smoked by persons with mental health conditions. As a result of the foregoing factors, the addressable market for Deep TMS for MDD (including reduction of comorbid anxiety symptoms, commonly referred to as anxious depression), OCD, and smoking addiction, may be smaller than we currently anticipate, and predictions for our future growth may prove to be inaccurate. This may have a materially adverse effect on our future results of operations.

If our sales and customer support teams or independent third-party distributors and agents are not sufficiently skilled or fail to reach additional markets and adequately promote, market and sell or lease our Deep TMS systems, our revenues could significantly decrease and we may not generate sufficient revenues to sustain profitability.

As of December 31, 2024, we had 120 employees, including 53 employees in sales and marketing. Our operating results are directly dependent upon the sales and marketing efforts of our sales and customer support team and on our independent third-party distributors and agents outside of the United States. If our employees or our independent distributors and agents fail to adequately promote, market and sell or lease our Deep TMS systems, our revenues could significantly decrease and/or fail to meet our targets.

In addition, our future revenues will largely depend on our ability to successfully execute our marketing efforts and adequately address our customers' needs. In certain territories, it is or will be necessary to expand our sales force, including by hiring additional sales representatives or distributors with specific technical backgrounds that can support our customers' needs.

As we develop and seek regulatory clearances for new indications, enhancements, features and treatment protocols and increase our marketing efforts, we will need to expand the reach of our marketing and sales networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled employees, and distributors with significant technical knowledge in various areas. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, or if we experience high turnover in our sales force in the future, new hires may not become as productive as may be necessary to maintain or increase our sales. If we are unable to expand our sales and marketing capabilities domestically and internationally, we may be unable to effectively commercialize our Deep TMS systems, which could harm our business.

Failure to secure or maintain adequate coverage and reimbursement of our Deep TMS system for the currently authorized indications and other indications for which we obtain FDA authorization in the future, if any, may make physicians reluctant to use or recommend Deep TMS and have a material adverse effect on our sales, results of operations, and financial condition.

Patients generally rely on third-party payors to reimburse all or part of the costs associated with outpatient treatment services. Patients may, thus, be unwilling to undergo, and physicians may be unwilling to prescribe, a given course of treatment in the absence of adequate coverage and reimbursement. Accordingly, our ability to successfully commercialize our Deep TMS system depends significantly on the extent to which treatment sessions using Deep TMS are covered and reimbursed by government healthcare programs, such as Medicare and Medicaid (among others), commercial health insurers, managed care organizations, and other third-party payors.

Third-party payors are increasingly examining the medical necessity and cost effectiveness of medical products and services, in addition to safety and efficacy. Significant uncertainty exists as to the reimbursement status of any newly approved (or cleared) products or therapies, which represent novel approaches to treatment of a disease, addiction, or condition, such as Deep TMS for smoking addiction. Even if a third-party payor covers a particular treatment that uses Deep TMS, the resulting reimbursement rate may not be adequate to cover a provider's cost to purchase or lease the Deep TMS system or ensure such transaction is profitable for the provider. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a treatment is neither experimental nor investigational, and is safe, effective, and medically necessary, appropriate for the specific patient, cost-effective, supported by peer-reviewed medical journals and included in clinical practice guidelines.

In the United States, there is no uniform policy of coverage and reimbursement among third-party payors, including private insurers. Therefore, coverage and reimbursement for treatments can differ significantly from payor to payor. However, many third-party payors often rely upon Medicare coverage policies and payment limitations in setting their own coverage and reimbursement policies and methodologies. Private insurance coverage for Deep TMS as a treatment for MDD generally requires 1 to 4 prior failures of anti-depressant medications.

Medicare coverage for Deep TMS as a treatment for MDD generally requires that certain specified clinical criteria relating to medical necessity are met and documented. In particular, subject to variations by payor and locale, under applicable payor policies, Deep TMS may be covered for MDD if: (i) prescribed by a licensed physician, knowledgeable in the use of TMS (ii) as a treatment for an adult with a confirmed diagnosis of MDD and no contraindications, (iii) where there is sufficient documentation of failure of between 1 and 2 previous medication trials (depending on the relevant Medicare Administrative Contractor policy). Other relevant coverage factors considered under these policies include resistance to treatment with psychopharmacologic agents for depression, history of response to repetitive TMS, and whether the individual is a candidate for electroconvulsive therapy (ECT) and TMS is less burdensome to the patient. Reimbursement for Deep TMS as an MDD treatment is also generally limited to 36 treatment sessions.

Since 2021, there has been emerging reimbursement coverage for Deep TMS for the treatment of OCD. While the criteria for this emerging Deep TMS for OCD coverage varies with each payor, generally coverage requires the failure of a combination of between two and four medication trials of two different classes (with most requiring two failed trials), for specified periods, and may also require a trial of psychotherapy, before qualifying for reimbursement. Maintaining the reimbursement coverage obtained since 2021 and obtaining coverage from additional payors may be difficult, and payors may condition coverage on the satisfaction of varied criteria.

Obtaining adequate reimbursement of Deep TMS for smoking addiction, or for any future indications or expanded labeling of currently approved indications or different treatment protocols, as applicable, may be difficult unless there is sufficient published clinical data to support clinical efficacy and cost effectiveness based upon the treatment continuum of care. Currently, there is no third-party coverage of Deep TMS as a treatment for smoking addiction, as payors that have evaluated Deep TMS for smoking addiction coverage have not yet concluded that it is a reasonable and necessary therapy for smoking addiction. In October 2023 the Clinical TMS Society, an influential peer group, published the first coverage recommendations for smoking. While this is an important first step toward educating payors, ongoing efforts advocating for coverage will be required, which may be expensive and time-consuming. Therefore, it may take significant time to obtain sufficient reimbursement coverage of Deep TMS for smoking addiction. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement compared to existing approved biologics and other therapies. There may be significant delays in obtaining coverage and reimbursement for newly approved therapies in the United States, and coverage may be more limited than the indications for which the product is approved by the FDA or similar regulatory authorities outside the United States. Further, there is no guarantee that Deep TMS will ever be adequately covered or reimbursed for smoking addiction, if at all, or any other future indication for which we obtain authorization, if any. Nonetheless, the availability of reimbursement coverage in any given indication is not always the exclusive path to commercialization, and we may pursue and/or develop cash-pay, corporate wellness programs, and/or other alternate models in order to monetize these indications.

In addition, the U.S. federal government and state legislatures have continued to implement cost containment programs, including price controls and restrictions on coverage and reimbursement. To contain costs, governmental healthcare programs and third-party payors are increasingly challenging the price, scrutinizing the medical necessity, and reviewing the cost-effectiveness of medical treatments. Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets have government-managed healthcare systems that govern reimbursement for psychiatric treatments and procedures and certain markets, including Japan, impose additional criteria that must be met (such as the need for approval by sometimes insular medical societies) before coverage may be practically obtained even on approved procedures. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods.

If adequate levels of reimbursement from third-party payors outside of the United States are not obtained, international sales and lease transactions for the Deep TMS system may not materialize or grow significantly.

The marketability of Deep TMS may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, which may delay or cause us to abandon the development of Deep TMS for additional indications.

We are currently at various stages of completed, ongoing or planned clinical trials of Deep TMS for new indications and/or seeking expanded labeling for existing indications. Development of medical devices includes pre-clinical studies and sometimes clinical trials, and is a long, expensive, and uncertain process, subject to delays and failure at any stage. Clinical trials for Deep TMS involve certain specific risks, including factors related to trial design and patient enrollment. Additionally, if we are unable to recruit a sufficient number of patients for our clinical trials, we may be unable to generate sufficient data to support marketing authorization. Moreover, our research and development, pre-clinical and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities. We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials, which would cause us or regulatory authorities to delay or suspend clinical trials, or delay the analysis of data from completed or ongoing clinical trials. We estimate that clinical trials involving various indications of Deep TMS will continue for several years; however, such trials may also take significantly longer to complete and may cost more money than we have expected.

Furthermore, the data obtained from the studies and trials may be inadequate to support regulatory authorizations or to enable market acceptance of certain indications of Deep TMS. Failure can occur at any stage of testing, and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of the current, or a future, version of Deep TMS for any particular indication, including but not limited to delays in securing clinical investigators or trial sites for the clinical trial and in obtaining institutional review board and other regulatory approvals to commence a clinical trial; slower than anticipated patient recruitment and enrollment; negative or inconclusive results from clinical trials; unforeseen safety issues; an inability to monitor patients adequately during or after treatment; placement of a clinical trial on hold by the FDA, institutional review boards/ethics committees or other regulatory authorities; changes in governmental regulations or administrative actions, including governmental changes in permissible endpoints or other measures utilized in clinical trials; problems with investigator or patient compliance with the trial protocols; the FDA or other regulators disagreeing as to the design, protocol or implementation of our clinical trials; exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials; the quality of the products falling below acceptable standards; and the inability to manufacture sufficient quantities of our products to commence or complete clinical trials.

Additionally, the FDA or other regulatory entities may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to demonstrate safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay authorization of additional indications, expansion of labeling for existing indications or new treatment protocols for Deep TMS. A number of companies in the medical device and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after seeing promising results in earlier clinical trials. We do not know whether any clinical trials we or our clinical partners may conduct will demonstrate adequate efficacy and safety to result in regulatory authorization to market new indications for Deep TMS. In addition, the results of our past clinical trials of Deep TMS may not be predictive of future trial results. If later-stage clinical trials involving Deep TMS for new indications, expansion of labeling for existing indications or new treatment protocols do not produce favorable results, our ability to obtain regulatory authorization for such indications, expansion or treatment protocols may be adversely impacted, which will have a material adverse effect on our business, financial condition, and results of operations.

We rely on third parties, including suppliers for some components used in manufacturing our Deep TMS products, distributors to market and promote our products internationally and third parties to conduct our clinical trials, which exposes us to uncertainty and instability.

We rely on suppliers for most of the components used in manufacturing Deep TMS, including the computer controlling the stimulator, the helmet, and the arm of the helmet, and we may not have sufficient contractual assurances for the long-term supply of these components. We remain dependent on a single outsourcing company utilized for the manufacture of certain components in our newer systems, including our proprietary stimulator, and other third parties for various other components. For us to be successful, our suppliers and contract manufacturer must be able to provide us with components in sufficient quantities, in compliance with quality and regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. While these suppliers have generally met our overall demand requirements, we experienced certain challenges with specific product orders (including but not limited to orders of important capacitors for use within our proprietary stimulator) not conforming with the times and specifications initially set, which has in turn necessitated contingency measures – such as increased inventory orders and/or lengthened order periods – to compensate for future possible risks in this regard. Moreover, the willingness of these third parties to continue meeting our demands going forward may be limited for several reasons, including our lack of long-term agreements with those suppliers, geopolitical factors, internal capabilities, our relative importance as a customer of those suppliers, or, as applicable, their ability to produce the components for or provide assembly services to manufacture our Deep TMS systems. An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these components, if we cannot obtain an acceptable substitute for these components, if changes are made to the specifications of components which are incompatible with our systems, and/or if any mitigation plan involving alternative suppliers (which may include the need to transfer aspects of manufacturing or assembly from one geographical location to another) is delayed or unsuccessful. In addition, we have experienced, and may continue to experience, supply chain issues, which are in part related to, or exacerbated by, geopolitical instability and military threats on shipping routes and/or on regions in which our manufacturing activities take place. See "*—Our operations could be affected in the event of further geopolitical instability, war, supply chain disruptions, unfavorable market or political conditions, global pandemic or other outbreaks or other negative global trends or disruptions*." and "*—We have manufacturing, assembly and other significant functions that are located in Israel and, therefore, our business and operations may be adversely affected by political, economic and military conditions in Israel*."

Any transition to a new supplier or contract manufacturer could be time-consuming and expensive, may result in interruptions to our operations and product delivery, could affect the performance specifications of Deep TMS or could require that we modify the design of our systems. If we are required to change our contract manufacturer, we will be required to verify that the new manufacturer maintains facilities, procedures, and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture Deep TMS systems in a timely manner. If the change in manufacturer results in a significant change to any product, a new 510(k) clearance from the FDA or similar non-U.S. regulatory authorization may be necessary before we implement the change, which could cause a substantial delay. We cannot assure you that we will be able to identify and engage alternative suppliers or contract manufacturers on similar terms or without delay. Furthermore, our contract manufacturer could require us to move to a different production facility. The occurrence of any of these events could harm our ability to meet the demand for Deep TMS systems in a timely and cost-effective manner.

In addition, we rely, and expect to rely in the future, on a network of third-party distributors and agents to market and distribute our products in international markets. We are assessing the opportunity to continue expanding into other international markets. We may face significant challenges and risks in managing a geographically dispersed distribution network. We have limited ability to control any third-party distributors and agents. Our distributors and agents may be unable to successfully market, lease, and sell our products and may not devote sufficient time and resources to support the marketing, sales, education, and training efforts that we believe enable the products to develop, achieve or sustain market acceptance. Additionally, in some international jurisdictions, we rely on our distributors to manage the regulatory process, while complying with all applicable rules and regulations, and we are dependent on their ability to do so effectively. Moreover, if a dispute arises with a distributor or if a distributor is terminated by us or goes out of business, it may take time to locate an alternative distributor, to seek appropriate regulatory approvals with the new distributor and to train new personnel to market our products, and our ability to sell those systems in the region formerly serviced by such terminated distributor could be harmed. Any of these factors could reduce our revenues from affected markets, increase our costs in those markets or damage our reputation. In addition, if an independent distributor or agent were to depart and be retained by one of our competitors, we may be unable to prevent that distributor or agent from helping competitors solicit business from our existing customers, which could further adversely affect our sales. As a result of our reliance on third-party distributors and agents, we may be subject to disruptions and increased costs due to factors beyond our control, including labor strikes, third-party error, and other issues. If the services of any of our distributors or agents become unsatisfactory, we may experience delays in meeting our customers' demands, and we may be unable to find a suitable replacement on a timely basis or on commercially reasonable terms. Any failure to deliver products or services in a timely manner may damage our reputation and could cause us to lose existing or potential customers.

We also rely on third parties in our clinical trials, which are managed by our own staff and personnel as well as by certain third parties, including clinical trial sites, medical institutions, clinical research organizations, or CROs, and private practices, for, among other things, site monitoring, statistical work, and electronic data capture. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with applicable protocols, and legal, regulatory, and scientific standards, including current good clinical practices, or cGCPs, which are set forth in regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for clinical trials. If we or any such third parties fail to comply with applicable cGCPs, the clinical data generated in such trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before granting a marketing authorization for any particular indication. In addition, if such third parties do not devote sufficient time and resources to our clinical trials or otherwise fail to carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they assist in obtaining is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory authorization for or successfully commercialize Deep TMS for a specified indication.

We face risks associated with our international business.

We currently market and sell Deep TMS systems outside of the United States in various countries and/or intend to market and expand the commercialization of Deep TMS in other international markets, including Canada, Europe, Australia, and various Middle Eastern, Central/South American, and Asian countries. We are also assessing the opportunity to expand into other international markets. However, our expansion plans may not be realized, or if realized, may not be successful. We expect each market to have particular regulatory hurdles to overcome, and future developments in these markets, including the uncertainty relating to governmental policies and regulations, could harm our business. In addition, the sale, lease, and shipment of our Deep TMS systems across international borders, as well as the purchase of components and products from international sources, subjects us to extensive U.S. and other foreign governmental trade, import, export, regulatory, and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. We expect our international activities will be dynamic over the foreseeable future as we continue to pursue opportunities in international markets.

Our international business operations are subject to a variety of risks, including but not limited to difficulties in staffing and managing foreign and geographically dispersed operations, to the extent we establish non-U.S. operations; differing and multiple payer reimbursement regimes, government payors or patient self-pay systems; difficulties in determining and creating the proper sales pathway in new, international markets; compliance with various U.S. and international laws and regulations, including export control laws and the U.S. Foreign Corrupt Practices Act of 1977 (FCPA) and similar international laws, anti-money laundering laws and differing regulatory requirements for obtaining marketing authorizations for our products in non-U.S. jurisdictions; changes in, or uncertainties relating to, foreign rules and regulations that may impact our ability to sell our products, perform services or repatriate profits to the United States; tariffs and trade barriers, export regulations, sanctions, and other regulatory and contractual limitations on our ability to sell our products in certain foreign markets; potential adverse tax consequences, including imposition of limitations on or increase of withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures; imposition of differing labor laws and standards; armed conflicts or economic, political, and/or social instability in foreign countries and regions; fluctuations in foreign currency exchange rates; supply lags, inefficiencies, difficulty managing expenses in our local currency in the event that its value diverges from that of the currencies of the jurisdictions where we earn income, and other risks created by any sourcing, manufacture, assembly and/or production of our products/components outside of the U.S., while commercial activities are largely focused in the U.S.; an inability, or reduced ability, to protect our intellectual property, including any effect of compulsory licensing imposed by government action; and availability of government subsidies or other incentives that benefit competitors in their local markets that are not available to us.

Tariff policies and potential countermeasures could increase our costs and disrupt our supply chain, which could negatively impact the results of our operations.

U.S. President Trump has increased, and has indicated his willingness to continue to increase, the use of tariffs by the U.S. to accomplish certain U.S. policy goals. Such tariffs and any countermeasures could increase the cost of raw materials and components necessary for our operations, disrupt our supply chain and create additional operational challenges. Further, it is possible that government policy changes and related uncertainty about policy changes could increase market volatility. Because of these dynamics, we cannot predict the impact of any future changes to the U.S.'s or other countries' trading relationships or the impact of new laws or regulations adopted by the U.S. or other countries on our business. Such changes in tariffs and trade regulations could have a material adverse effect on our financial condition, results of operations and cash flows.

Our collaboration arrangements may not be successful, which could adversely affect our ability to develop and commercialize our products.

We are currently involved in a number of research and development collaborations with third parties relating to the development of new technologies and additional uses of Deep TMS. These and any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. If any of our collaboration arrangements are not successful, it could have a material adverse effect on our business, financial condition, and results of operations.

Collaborations are subject to numerous risks, which may include that collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations; collaborators may elect not to pursue development and commercialization of our products or not to continue or renew development or commercialization programs based on trial or test results, may change their strategic focus due to the acquisition of competitive products or may independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates; availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities; a collaborator with marketing, manufacturing, and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities; we could grant exclusive rights to our collaborators that would prevent us from collaborating with others; we may be forced to terminate, litigate, and/or renegotiate arrangements with our collaborators due to default on their obligations to us or due to their improper maintaining or defending our intellectual property rights or their use of our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; our collaborators may have claims that we breached our obligations to them which may result in termination, renegotiation, litigation or delays in performance of such arrangements; disputes may arise between us and a collaborator that causes the delay or termination of the research, development, and/or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources; collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products; collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

We bear the risk of product liability lawsuits and warranty claims which might harm our business, may not be covered by our insurance policies or may exceed our insurance policy coverage, and we may not have enough funds to cover such claims or lawsuits damages.

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture, sale, promotion, and use of medical devices for the treatment of MDD (including reduction of comorbid anxiety symptoms, commonly referred to as anxious depression), OCD, smoking addiction, and other potential indications. Our treatments are designed for patients who suffer from significant psychiatric, and neurological disorders, and addictions, and these patients are more likely to experience significant adverse health outcomes, which could increase the risk of product liability lawsuits. Furthermore, if physicians and other operators are not sufficiently trained in the use of our Deep TMS systems, they may misuse or ineffectively use our system, which may result in unsatisfactory patient outcomes. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to the patients.

Regardless of their merit or eventual outcome, product liability claims may result in decreased demand for Deep TMS; injury to our reputation and brand; significant litigation costs or substantial monetary awards to or costly settlements with patients; product recalls; loss of revenues; the inability to commercialize new indications, enhancements, or features; and diversion of management attention from pursuing our business strategy.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include public liability, employer's liability, property, third party liability, umbrella, workers' compensation, products and clinical trial liability, and directors' and officers' liability. We do not know, however, if these policies will provide us with adequate levels of coverage, particularly in light of the dynamic and changing risk profile we face as a result of new business models, territories and ventures we pursue. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage, our business could suffer. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, a recall of some of our products, whether or not related to a product liability claim, could result in significant costs and loss of customers.

In addition, we bear the risk of warranty claims on the products we supply, often for the entire contract term for systems which we lease to customers, and generally for at least one year for Deep TMS systems we sell to customers. There can be no assurance that we will have sufficient funds, devices, components and/or personnel to cover future warranty claims. We may not be successful in claiming recovery of relevant components from our suppliers or vendors in the event of a successful warranty claim against us by a customer and, to the extent recovered, such recovery from our vendor or supplier may not be adequate. In addition, warranty claims brought by our customers related to third-party components may arise after the termination of the warranty period we are eligible to receive from our suppliers, which could result in costs to us.

We could be negatively impacted by violations of applicable anti-corruption laws or violations of our internal policies designed to ensure ethical business practices.

We operate in a number of countries throughout the world, and we may operate in countries that may not have the strong commitment to anti-corruption and ethical behavior that is required by U.S. laws or by our corporate policies. We are subject to the risk that we, our U.S. employees or any future employees or consultants located in other jurisdictions, or any third parties such as our distributors that we engage to do work on our behalf in foreign countries may take action determined to be in violation of anti-corruption laws in any jurisdiction in which we conduct business, including the FCPA. The FCPA generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments, offers or promises to foreign officials for the purpose of obtaining or retaining business or other advantages. In addition, the FCPA imposes recordkeeping and internal controls requirements on publicly traded corporations and their foreign affiliates, which are intended to, among other things, prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made.

We will face significant risks if we fail to comply with the FCPA and other laws that prohibit improper payments, offers or promises of payment to foreign governments and their officials and political parties by us and other business entities for the purpose of obtaining or retaining business or other advantages. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses operating in such countries engage in business practices that are prohibited by the FCPA or other laws and regulations. We have implemented or are in the process of implementing company policies relating to compliance with the FCPA and similar laws. However, such policies may not be effective at preventing all potential FCPA or other violations. Although our agreements with our international distributors state our expectations for our distributors' compliance with U.S. laws, including the FCPA, and provide us with various remedies upon any non-compliance, including the ability to terminate the agreement, our distributors may not comply with U.S. laws, including the FCPA.

Any violation of the FCPA or any similar anti-corruption law or regulation could result in substantial fines, sanctions, civil and/or criminal penalties and curtailment of operations in certain jurisdictions, and might harm our business, financial condition, or results of operations.

Our operations could be affected in the event of further geopolitical instability, war, supply chain disruptions, unfavorable market or political conditions, global pandemic or other outbreaks or other negative global trends or disruptions.

In recent years, we experienced and continue to experience supply chain and shipping delays, shortages and challenges due to geopolitical instability and military threats on global shipping routes, forcing us to adapt our production line, forecasting and other logistical processes to address these challenges. Further global and regional geopolitical instability could exacerbate disruptions to production, cause additional delays in the supply and delivery of products used in our operations, negatively impact the planned pace of clinical trials, R&D and business initiatives, disrupt the marketplace in which we operate, and may have material adverse effects on our operations, sales, revenues, collection from accounts and ability to raise funds. Our third-party suppliers source certain components and materials of our Deep TMS systems from various countries, and any continued geopolitical instability may adversely impact their development, manufacture, and supply processes. For example, the recent disruptions to traditional trade routes by the Houthis have necessitated reliance on more expensive shipping alternatives which increased our lead times and costs of production. Additionally, we have seen a significate rise in the price of many of the electronic components needed for our system. The extent to which the geopolitical instability impacts our results will depend on future developments, which are highly uncertain and cannot be predicted.

In addition, we have experienced, and may continue to experience, disruptions to the transportation channels used in our supply chain and distribution operations, including increased airport and shipping port congestion, a lack of transportation capacity, increased fuel expenses, import or export controls or delays, and labor disputes or shortages. Transport operators are exposed to various risks, such as extreme weather conditions, natural disasters, work stoppages, personnel shortages, and operating hazards, as well as interstate and international transportation requirements. If we experience transportation problems, or if there are other significant changes in the cost of these services, we may not be able to arrange efficient alternatives and timely means to obtain raw materials or ship products to our customers. Disruptions in our container shipments may result in increased costs, including the additional use of air freight to meet demand. Congestion in ports can affect previously negotiated contracts with shipping companies, resulting in unexpected increases in shipping costs and reduction in our profitability. For example, since late 2023, we needed to utilize more expensive air shipping methods in order to ensure timely delivery of capacitors, head caps, and certain other components in our systems to avoid delays caused by the recent Houthi disruptions to traditional trade routes. In addition, the geopolitical instability caused by the Ukraine war and by the Israel-Gaza and Israel-Hezbollah war (and related tensions with Israel's other neighboring countries) has resulted in several disruptions and delays in our global transportation channels, manpower and other challenges at our outsourced manufacturer (which relies heavily on facilities and personnel located near the Israel-Lebanon border, a region particularly susceptible to any skirmishes and other outbreaks of violence between Israel and Hezbollah and/or other northern neighbors), as well as quantity limits and price increases. See "*—We rely on third parties, including suppliers for some components used in manufacturing our Deep TMS products, distributors to market and promote our products internationally and third parties to conduct our clinical trials, which exposes us to uncertainty and instability*." and "*—We have manufacturing, assembly and other significant functions that are located in Israel and, therefore, our business and operations may be adversely affected by political, economic and military conditions in Israel*."

In the period following the COVID-19 global pandemic, as part of the global supply chain crisis, we have seen a significant rise in the price of many of the electronic components needed for our systems. These price increases – which were initially caused by supply and demand factors, and, in some cases, shortages relating to these parts across the globe – have subsequently remained elevated despite the fact that many of these challenges have since improved. On a related point, the lead time for receiving certain specific electronic components shipped by suppliers has also increased in recent years, compelling us to increase buffer inventory levels to ensure that future demand for our systems can be timely met. These risks may be further exacerbated in light of geopolitical events, including the ongoing conflict between Russia and Ukraine, the Israel-Gaza war, the Israel-Hezbollah war and potential related tensions with Israel's other neighboring countries.

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner, and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our products on a timely basis.

Worldwide economic and political conditions have also been adversely impacted by continued political instability and military hostilities in multiple geographies including the conflict between Ukraine and Russia, the Israel-Gaza war, the Israel-Hezbollah war and potential related tensions with Israel's other neighboring countries. These conditions have made and may continue to make it difficult for our customers and potential customers to afford our products, and could cause our customers to stop using our products or to use them less frequently. If that were to occur, our revenue may decrease and our performance may be negatively impacted. In addition, the pressure on consumers to absorb more of their own healthcare costs has resulted in some cases in higher deductibles and limits on durable medical equipment, which may cause seasonality in purchasing patterns. Furthermore, during economic uncertainty, some customers experience job losses and may continue to have issues gaining timely access to sufficient health insurance or credit, which could result in their unwillingness to purchase products or impair their ability to make timely payments to us. A recession, depression or other sustained adverse market event could materially and adversely affect our business and the value of our Ordinary Shares or ADSs.

We cannot predict the reoccurrence of any economic slowdown or the future strength of the economy, worldwide, in the United States, in Israel, or in our industry. These and other economic factors could have a material adverse effect on our business, financial condition and results of operations.

Our reliance on the use of technology may adversely affect our business if we become subject to cyber-terrorism or other compromises and shut-downs or if we experience significant disruptions in our information technology systems, and security and privacy breaches may expose us to liability and harm our reputation and business.

We depend on our information technology systems for the efficient functioning of our business accounting, data storage, compliance, purchasing, and inventory management. While we will attempt to mitigate interruptions, we may experience difficulties in implementing upgrades to our information technology systems, which would impact our business operations, or experience difficulties in operating our business during the upgrade, either of which could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain, and otherwise adequately service our customers. In the event we experience significant disruptions as a result of the current implementation of our information technology systems, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our results of operations and cash flows.

We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a materially adverse effect on our business.

We rely heavily on our internal computer and information technology systems. Our information technology systems may be subject to cyber-terrorism or other compromises and shut-downs, which may result in unauthorized access to our proprietary information, destruction of our data or disability, degradation or sabotage of our systems, often through the introduction of computer viruses, cyber-attacks, and other means, and could originate from a variety of sources, including internal or unknown third parties. We cannot predict what effects such cyber-attacks or compromises or shut-downs may have on our business, and the consequences could be material. Cyber incidents may remain undetected for an extended period, which could exacerbate these consequences. If our information systems or other technology are compromised, it could have a material adverse effect on our business.

In addition, as part of our business operations, we may receive and process information about our customers, partners and, potentially, their patients, including protected health information (PHI), and we may configure our devices to collect, transmit or store or contract with third parties to collect, transmit or store our customers' data, including PHI. PHI, a subset of "individually identifiable information," is defined under the federal level by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information and Technology for Economic and Clinical Health Act of 2009 (HITECH), including applicable implementing regulations. HIPAA, along with various analogous laws at the state level, governs the protection and confidentiality of PHI, and other sensitive information, as applicable (as more fully described below). To the extent we, or third parties we contract with, collect, store or transfer PHI, we may be required to safeguard PHI in accordance with HIPAA. Furthermore, to the extent we qualify as a business associate under HIPAA, we may be directly subject to HIPAA's Privacy Rule.

While we implemented security measures relating to our operations, generally, those measures may not prevent security breaches that could harm our business or expose us to liability under HIPAA and/or applicable state or foreign privacy laws. Advances in computer capabilities, inadequate technology or facility security measures or other factors may result in a compromise or breach of our systems and any data we store and process. Our security measures may be breached as a result of actions by third parties or employee error or malfeasance, among many other possibilities. A party who is able to circumvent our security measures or exploit inadequacies in our security measures, could, among other things, misappropriate proprietary information, including information about our customers and their patients, cause the loss or disclosure of some or all of this information, cause interruptions in our or our customers' operations or expose our customers to computer viruses or other disruptions or vulnerabilities. Any compromise of our systems or the data we store or process could implicate reporting requirements, civil penalties, and other enforcement actions under applicable laws, result in a loss of confidence in the security of our software, damage our reputation, disrupt our business, lead to legal liability, and adversely affect our results of operations. Moreover, a compromise of our systems could remain undetected for an extended period of time, exacerbating the impact of that compromise. Actual or perceived vulnerabilities may lead to claims against us by our customers, their patients or other third parties, including federal, state and foreign governmental authorities. While our customer agreements typically contain provisions that seek to limit our liability, there is no assurance these provisions will be enforceable and effective under applicable law. In addition, the cost and operational consequences of implementing further data protection measures could be significant.

We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, and/or through the licensing of products or technologies from third parties. The failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could harm our business.

Our success depends in part on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures, technologies, and market pressures. Accordingly, from time to time, we may consider opportunities to acquire, make investments in or license other technologies, products, and businesses that may enhance our capabilities, complement our current products, or expand the breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses, and other alliances involve numerous risks, including but not limited to difficulty assimilating or integrating acquired or licensed technologies, products or business operations; issues maintaining uniform standards, procedures, controls, and policies; unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill; diversion of management's attention from our core business and disruption of ongoing operations; adverse effects on existing business relationships with suppliers, distributors, and customers; risks associated with entering new markets in which we have limited or no experience; potential losses related to investments in other companies; potential loss of key employees of the acquired businesses; and increased legal and accounting compliance costs.

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms or at all or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers or distributors.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures, languages, legal and regulatory environments, currency risks and the particular economic, political and regulatory risks associated with specific countries.

To finance any acquisitions, investments or strategic alliances, we may choose to issue Ordinary Shares, ADSs or other equity-linked securities as consideration, which could dilute the ownership of our shareholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our Ordinary Shares or ADSs is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our shares as consideration.

Risks Related to Employee Matters

If we are not able to retain our key management, or attract and retain qualified scientific, technical, and business personnel, our ability to implement our business plan may be adversely affected.

Our success largely depends on the skill, experience, and effort of our senior management. The loss of the service of any of these persons would likely result in a significant loss in the knowledge and experience that we possess and could significantly delay or prevent successful product development and other business objectives. Our ability to achieve our strategic growth plans depends in part on our ability to recruit and maintain talented sales and operations team members. New hires are often subject to a time intensive educational onboarding period before they can successfully identify potential customer leads and close sales. This can lead to delays before we can ramp up our commercial initiatives and achieve sales targets. It can also divert attention from our existing sales leadership and personnel who are needed to train these new hires. Additionally, we experienced certain challenges in hiring and/or maintaining employees that we believe are related to current and previous trends in the workforce. We believe that these events have created a climate of volatility in employment relations throughout the economy and in our company, which has affected or may affect our ability to recruit, train and retain employees, including skilled sales professionals. The employee turnover we historically experienced, including in our salesforce, has limited our ability to ramp up our sales and marketing force as quickly as would have otherwise been possible. There is intense competition between numerous medical device, pharmaceutical, and biotechnology companies, universities, governmental entities, and other research institutions, all of whom are seeking to employ qualified individuals in the technical fields in which we operate, and we may not be able to attract and retain the qualified personnel necessary for the successful development and commercialization of Deep TMS.

Employment litigation and unfavorable publicity could negatively affect our future business.

Employees may, from time to time, bring lawsuits against us regarding injury, creating a hostile workplace, discrimination, payment of wage and overtime, sexual harassment, and other employment issues. In recent years there has been an increase in the number of discrimination and harassment claims generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these claims have had a significant negative impact on some businesses. Companies that have faced employment or harassment related lawsuits have had to terminate management or other key personnel, and have suffered reputational harm that has negatively impacted their sales. If we were to face any employment related claims, our business could be negatively affected.

Under applicable employment laws, we may not be able to enforce covenants not to compete.

Our employment agreements generally include covenants not to compete. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work. For example, Israeli courts have required employers seeking to enforce covenants not to compete to demonstrate that the competitive activities of a former employee will harm one of a limited number of material interests of the employer, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such an interest will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees and our competitiveness may be diminished.

Risks Related to Government Regulation

Our products 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 or to obtain and/or maintain needed clearances could harm our business.

We are subject to extensive regulation in the United States and elsewhere, including by the FDA, FTC, and their foreign counterparts. 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; marketing, sales and distribution; premarket clearance and approval; 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 recur, could lead to death or serious injury; post-market approval studies; and product import and export.

The regulations to which we are subject are complex and stringently enforced. 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. The FDA enforces these regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. Furthermore, various service offerings which may be included under certain existing or potential pricing models, including but not limited to device operation services performed by technicians engaged directly by us, could increase the risk profile and/or regulatory burden associated with our business. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

An element of our strategy is to continue to upgrade our Deep TMS systems, add new enhancements and features, pursue next-generation equipment versions utilizing our patented technology, expand clearance or approval of the Deep TMS System to include new indications or broader application and introduce different treatment plans. In the United States, before we can market a new medical device, claim new or expanded indications for use or introduce a significant modification to an existing product, or implement new treatment plans, we must first receive either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, premarket approval application (PMA) or *de novo* classification, from the FDA, unless an exemption applies. In the PMA process, 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. However, some devices are automatically subject to the PMA pathway regardless of the level of risk they pose because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that FDA review such devices in accordance with the *de novo* classification procedure, which allows a manufacturer whose novel device would otherwise require a PMA prior to marketing to request down-classification of the device on the basis that the device presents low or moderate risk. If the FDA grants the *de novo* classification request, the applicant will then receive authorization to market the device. This device type can then be used as a predicate device for future 510(k) submissions. 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 a 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.

We received marketing authorization of our MDD and smoking addiction indications through the 510(k) clearance process and have made various expansions to our MDD indication, including, in 2021, a clearance for a shortened three-minute depression protocol and a labeling expansion for anxious depression through subsequent 510(k) clearances. In 2022, we extended our FDA clearance for MDD (including anxious depression) to our H7 Coil, also via the 510(k) process. This does not include our shortened three-minute depression protocol, which continues only to apply for our H1 Coil. In 2024, we expanded the FDA labeling for our system to treat late-life (ages 69-86) MDD indications. We also received marketing authorization of our OCD indication through the *de novo* classification process. Several competitors have obtained 510(k) clearance for their TMS device for an OCD indication, using our *de novo* classification as a predicate device in their submission, and others may follow suit. The process of obtaining regulatory authorization to market a medical device can be costly and time consuming, and we may not be able to successfully obtain authorizations on a timely basis, if at all.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including: we may be unable to demonstrate to the FDA's satisfaction that the product or modification is substantially equivalent to the proposed predicate device or is safe and effective for its intended use; the data from our pre-clinical studies and clinical trials may be insufficient to support authorization, where required; and the manufacturing process or facilities we use may not meet applicable requirements. The FDA may also, instead of accepting a 510(k) submission, require us to submit a PMA, which is typically a much more complex, lengthy, and burdensome application than a 510(k) submission. To support a PMA, the FDA would likely require that we conduct one or more clinical studies to demonstrate that the device is safe and effective. In some cases, such studies may be requested for a 510(k) as well. We may not be able to meet the requirements to obtain 510(k) clearance or PMA approval (or a *de novo* classification request), in which case the FDA may not grant any necessary clearances or approvals. In addition, the FDA may place significant limitations upon the intended uses of our products as a condition to a 510(k) clearance, PMA approval or *de novo* classification. Product applications can also be denied or withdrawn due to failure to comply with regulatory requirements or the occurrence of unforeseen problems following clearance or approval. Any delays or failure to obtain FDA clearance or approval of new products we develop, any limitations imposed by the FDA on new product use or the costs of obtaining FDA clearance or approvals could have a material adverse effect on our business, financial condition, and results of operations.

Even if granted, a 510(k) clearance, *de novo* classification, or PMA imposes substantial restrictions on how our devices may be marketed or sold, and the FDA continues to place considerable restrictions on our products and operations. For example, the manufacture of medical devices must comply with the FDA's Quality System Regulation (QSR). In addition, manufacturers must register their manufacturing facilities, list their products with the FDA, and comply with requirements relating to labeling, marketing, complaint handling, adverse event and medical device reporting, reporting of corrections and removals, and import and export restrictions. The FDA monitors compliance with the QSR and these other requirements through periodic inspections. If our facilities or those of our suppliers are found to be in violation of applicable laws and regulations, or if we or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions: untitled letters, warning letters, fines, injunctions, consent decrees, and civil penalties; customer notifications or repair, replacement, refunds, recalls, detention or seizure of our products; operating restrictions or partial suspension or total shutdown of production; refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products; withdrawing 510(k) marketing clearances, PMA approvals and/or *de novo* classifications that have already been granted; refusing to provide Certificates for Foreign Government; refusing to grant export approval for our products; or pursuing criminal prosecution. Any of these sanctions could impair our ability to produce or commercialize our products in a cost-effective and timely manner in order to meet our customers' demands and could have a material adverse effect on our reputation, business, results of operations, and financial condition. We may also be required to bear other regulatory compliance costs or take other actions that may have a negative impact on our sales and our ability to generate profits.

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 authorization of our future products under development or impact our ability to modify our currently marketed products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new 510(k) clearances or other classifications or approvals, increase the costs of compliance or restrict our ability to maintain our current clearances and *de novo* authorization. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action in the United States, especially with the new Trump administration, which has already implemented a number of policy changes that are likely to impact our industry. In addition to substantive policy changes, the new Trump administration's push for deregulation, a reduction of federal funding, and a reduction of the federal workforce in agencies including in the Department of Health and Human Services ("DHHS") may lead to delays in approvals or clearances, unpredictable enforcement, abrupt policy changes, and many other forms of regulatory volatility that may destabilize our industry and could have a material adverse effect on our business.

In order to sell our products in member countries of the European Economic Area (EEA), or in countries that also rely on the CE Mark outside the EEA, our products must comply with the General Safety and Performance Requirements of the Medical Device Regulation (Regulation 2017/745) and the ISO 13485:2016 standard for Medical devices (Quality management systems, Requirements for regulatory purposes). Compliance with these requirements is a prerequisite to be able to affix the CE Mark to our products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the General Safety and Performance 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 an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the Medical Devices Regulation, a conformity assessment procedure requires the intervention of an organization accredited by a Member State of the EEA to conduct conformity assessments, 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. We are audited and certified for ISO 13485, Quality Management System, under the Medical Device Single Audit Program (MDSAP), which means that we undergo a single audit of our quality management systems (QMS) to satisfy the regulatory requirements of multiple jurisdictions, such as the United States (FDA), Canada (Health Canada), Brazil (ANVISA), Japan (PMDA) and Australia (TGA). In order to market class II (or above) medical devices in Canada, an MDSAP certificate is mandatory. 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 General Safety and Performance Requirements. This certificate entitles the manufacturer to affix the CE Mark to its medical devices after having prepared and signed a related EC Declaration of Conformity. 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 device, which would prevent us from selling them within the EEA and may have an impact on our marketing authorizations in other countries.

We or our distributors will also need to obtain, or retain, regulatory approval in other foreign jurisdictions in which we plan to or currently market and sell our products, and we or they may not obtain such approvals as necessary to commercialize our products in those territories. Regulatory marketing authorizations in these foreign jurisdictions typically require device testing, conformance to classification requirements, pre-market requests to authorize commercialization, and in some cases, inspections and/or a local presence in the territory for the approval holder.

Any modification to a 510(k)-cleared product 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 *de novo* classification, or possibly, a PMA. Modifications to products that have been approved through the PMA process generally require premarket FDA approval. Similarly, certain modifications made to products cleared through a 510(k) or authorized through the *de novo* classification process may require a new 510(k) clearance. Each of the PMA, *de novo* classification and the 510(k) clearance processes can be expensive, lengthy, and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can be 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 filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. The *de novo* process generally takes between 4 months and one year.

Despite the time, effort and cost invested by us in an FDA approval or clearance process, a device may eventually not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory authorizations could harm our business. Furthermore, even if we are granted regulatory authorizations, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.

Any modifications to our existing products may require new 510(k) clearance; however, future modifications may be subject to the substantially more costly, time-consuming, and uncertain PMA process. 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 cause our sales to decline and our expenses to increase.

The FDA requires every manufacturer to make the modification 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 authorizations are necessary. We made modifications to our products in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510(k) clearances were not required. We may make modifications or add additional enhancements or features in the future that we believe do not require a new 510(k) clearance, *de novo* classification or a PMA. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications, *de novo* classifications or PMAs for modifications to our previously authorized products for which we have concluded that new authorizations are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain appropriate regulatory authorization, and we may be subject to significant regulatory fines or penalties. In addition, the FDA may not authorize our products for the indications that are necessary or desirable for successful commercialization or could require clinical trials to support any modifications. Any delay or failure in obtaining required regulatory authorizations would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Our products must be manufactured in accordance with any applicable federal, state and/or foreign regulations, and we could be forced to recall our installed systems 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 FDA's 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. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. Compliance with the QSR is necessary to receive FDA clearance or approval to market new products and is necessary for a manufacturer to be able to continue to market cleared or approved devices in the United States. 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. Foreign regulatory authorities also impose manufacturing quality requirements, that may differ from the FDA requirements, with which we must comply.

Additionally, the FDA substantively revised the QSR regulation in 2024, which is now titled the Quality Management System Regulation ("QMSR"). If the new Trump administration continues the Biden administration's efforts to implement the revision and maintain the current schedule, this new regulation will likely become effective February 2, 2026.

We or our third-party suppliers may fail to take the necessary steps to comply with applicable regulations, including regulatory changes, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA or foreign jurisdiction 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 or clearances; 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 of Deep TMS for additional indications or any other clearances or approvals we may seek; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us or our employees. Any of these actions could significantly and negatively impact supply of our Deep TMS systems. 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 suffer reduced revenues and increased costs.

If treatment guidelines for the clinical conditions we are targeting change or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for one or more of our products.

If treatment guidelines for the clinical conditions we are targeting or the standard of care for such conditions evolves, we may need to redesign our Deep TMS systems and seek new marketing authorizations from the FDA. Our existing 510(k) and *de novo* clearances from the FDA are based on current treatment guidelines. Additionally, if treatment guidelines change so that different treatments become desirable, the clinical utility of one or more of our indications could be diminished and our business could suffer.

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

The Deep TMS system has been authorized for marketing by the FDA only for MDD (including reduction of comorbid anxiety symptoms, commonly referred to as anxious depression), OCD, and smoking addiction indications. We train our commercial organization to not promote our products for uses outside of the FDA-authorized indications for use, known as "off-label uses." However, we cannot guarantee that all of our employees, representatives, and agents will abide by our marketing policies. If the FDA determines that our promotional materials, training or other marketing activities constitute promotion of an off-label or unapproved 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, 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 laws prohibiting false claims for reimbursement.

Moreover, even if we, and all our employees, contractors, and agents, market our products in compliance with applicable FDA regulations, such regulations do not apply to the practice of medicine, and we cannot prevent a physician from prescribing and/or using our products off-label when, in the physician's independent professional medical judgment, he or she deems it appropriate. Similarly, we cannot prevent patients from using our products off-label. There may be increased risk of injury to patients if physicians attempt to prescribe, or patients attempt to use, Deep TMS off-label. Furthermore, the use of Deep TMS for MDD (including reduction of comorbid anxiety symptoms, commonly referred to as anxious depression), OCD or smoking addiction other than as stated on product labeling, or for indications other than those authorized by the FDA, may not be effective to treat such conditions, which could harm our reputation in the marketplace among physicians and patients. There are similar risks if Deep TMS is prescribed or used off-label with respect to non-U.S. regulatory approvals.

Deep TMS may cause or contribute to adverse medical events that we are required to report to the FDA, 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, it 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 could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in clearance of future products.

The FDA and foreign regulatory bodies have the authority to require, and in the United States companies are expected to voluntarily implement, 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. An FDA recall, whether mandatory or voluntary, may be based on a finding that there is reasonable probability that the device could cause serious injury or death. 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. If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies, and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

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 authorization for the device before we may market or distribute the corrected device. Seeking such authorization 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 untitled letters or warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of corrective actions, even if they are not reportable to the FDA. We may initiate voluntary corrective actions for our products in the future that we determine do not require notification to 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 adverse event involving Deep TMS systems could result in voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as exposing us to private litigation, would require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

If we or our distributors do not obtain and maintain international regulatory registrations or approvals for Deep TMS, we will be unable to market and sell our products outside of the United States.

Sales of our Deep TMS systems outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. While the regulations of some countries may not impose barriers to marketing and selling Deep TMS systems or only require notification, others require that we or our distributors obtain the approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or approvals, can be expensive and time-consuming, and we or our distributors may not receive regulatory approvals in each country in which we plan to market Deep TMS or we may be unable to do so on a timely basis. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for FDA authorization, and requirements for such registrations, clearances or approvals may significantly differ from FDA requirements. If we modify our Deep TMS systems, we or our distributors may need to apply for additional regulatory 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 or our distributors have received. If we or our distributors 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 authorization by the FDA and/or the permission to affix the CE Mark does not ensure clearance or approval by regulatory authorities in other jurisdictions, and clearance or approval by one or more foreign regulatory authorities does not ensure clearance or approval by the FDA, the EU and/or the regulatory authorities in other foreign countries. However, a failure or delay in obtaining regulatory clearance or approval in one country may have a negative effect on the regulatory process in others.

We are subject to certain federal, state, and foreign fraud and abuse laws, health information privacy and security laws, and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims, physician self-referral, anti-inducement, and physician transparency laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations involve substantial costs. Our business practices and relationships with providers and patients are subject to scrutiny under these laws. We may also be subject to patient information privacy and security regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- the federal healthcare Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arrangement for, or recommendation of, a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The federal government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal healthcare Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exceptions and regulatory safe harbors to the federal healthcare Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration to those who prescribe, purchase, or recommend medical device products, including by providing discounts, or engaging individuals as speakers, consultants, or advisors, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as reimbursement support programs, educational or research grants, or charitable donations;

- the federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal government funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Private individuals, commonly known as "whistleblowers," can bring civil False Claims Act *qui tam* actions, on behalf of the government and themselves and may share in amounts paid by the entity to the government in recovery or settlement. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of $14,308 to $28,619 per false or fraudulent claim or statement. As noted above, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the federal civil False Claims Act. Many pharmaceutical and medical device manufacturers have been investigated and have reached settlements for substantial amounts under the federal civil False Claims Act in connection with alleged off-label promotion of their products and allegedly providing free products to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, manufacturers can be held liable under the federal civil False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. There are also criminal penalties, including imprisonment and criminal fines, for making or presenting false, fictitious or fraudulent claims to the federal government;

- the federal Physician Self-Referral Law, commonly known as the Stark Law, which prohibits physicians from referring Medicare and Medicaid patients to healthcare entities in which they or any of their immediate family members have ownership interests or other financial arrangements, if these entities provide certain designated health services reimbursable by Medicare or Medicaid, unless an exception applies. The Stark Law also prohibits entities that provide designated health services reimbursable by Medicare and Medicaid from billing the Medicare and Medicaid programs for any items or services that result from a prohibited referral and requires the entities to refund amounts received for items or services provided pursuant to the prohibited referral on a timely basis. Sanctions for violating the Stark Law include denial of payment, civil monetary penalties and exclusion from the federal healthcare programs. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim and may result in civil penalties and additional penalties under the federal False Claims Act;

- the federal Anti-Inducement Law (also known as the Civil Monetary Penalties Law), which prohibits a person from offering or transferring remuneration to a Medicare or State healthcare program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State healthcare program;

- HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statements or representations, 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. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the federal Physician Payments Sunshine Act under the Patient Protection and Affordable Care Act (PPACA), which requires certain manufacturers of drugs, medical devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and group purchasing organizations, as well as ownership and investment interests held by physicians and their immediate family members. Since January 2022, applicable manufacturers are also required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives;

- HIPAA, as amended by HITECH, and their respective implementing regulations, impose privacy, security, and breach reporting obligations with respect to PHI upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers and their respective business associates that perform services on their behalf that involve PHI. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make HIPAA compliance as well as 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 HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions; and

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; state laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those applicable to us in the United States; state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

These laws and regulations, among other things, constrain our business, marketing, and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with physicians or other potential purchasers of our products. We also entered into consulting agreements with physicians, which are subject to these laws. Further, while we do not submit claims and our customers will make the ultimate decision on how to submit claims, we may provide reimbursement guidance and support regarding our products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

To enforce compliance with healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. For example, U.S. federal and state regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, including pursuing novel theories of liability under these laws. These government agencies have recently increased regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient support programs, including bringing criminal charges or civil enforcement actions under the federal healthcare Anti-Kickback statute, federal civil False Claims Act, the healthcare fraud statute, and the HIPAA privacy provisions. Responding to investigations can be time and resource consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to.

If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to administrative, civil and criminal penalties, damages, fines, disgorgement, substantial monetary penalties, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, additional reporting obligations, and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, reputational harm, and the curtailment or restructuring of our operations.

Healthcare policy changes, including legislation reforming the U.S. healthcare system, could harm our cash flows, financial condition, and results of operations.

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, 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, revisions, or reinterpretations of existing regulations may impose additional costs, lengthen review times of any future products, or make it more difficult to 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.

For example, in March 2010, the PPACA was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may impact our business, the PPACA establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models; and expands the eligibility criteria for Medicaid programs.

Some of the provisions of the PPACA have yet to be implemented, and there have been judicial and Congressional challenges to modify, limit, or repeal certain aspects of the PPACA since its enactment and it has continued to evolve. During his first term as president, President Trump supported the repeal of all or portions of the PPACA, and in January 2017, he signed Executive Orders designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA to the maximum extent permitted by law. Due to such efforts, certain elements of the PPACA have been invalidated or suspended, which has, in turn, led to additional challenges against the law as a whole. For example, the Tax Cuts and Jobs Act of 2017 included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA 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". As a result, there is significant uncertainty regarding future healthcare reform and its impact on our operations. In December 2018, a district court in Texas held that the individual mandate is unconstitutional and that the rest of the PPACA is, therefore, invalid. On appeal, the Fifth Circuit Court of Appeals affirmed the holding on the individual mandate but remanded the case back to the lower court to reassess whether and how such holding affects the validity of the rest of the PPACA. The Fifth Circuit's decision on the individual mandate was appealed to the U.S. Supreme Court. On June 17, 2021, the Supreme Court held that the plaintiffs (comprised of the state of Texas, as well as numerous other states and certain individuals) did not have standing to challenge the constitutionality of the PPACA's individual mandate and, accordingly, vacated the Fifth Circuit's decision and instructed the district court to dismiss the case. As a result, the PPACA will remain in-effect in its current form for the foreseeable future; however, we cannot predict what additional challenges may arise in the future, the outcome thereof, or the impact any such actions may have on our business, and there is even greater uncertainty given the recent election of President Trump for a second term.

The Biden administration also introduced various measures in 2021 focusing on healthcare and drug pricing, in particular. For example, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. 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 PPACA. On the legislative front, the American Rescue Plan Act of 2021 was signed into law on March 11, 2021, which, in relevant part, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source drugs and innovator multiple source drugs, beginning January 1, 2024. And, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (with negotiated drug prices beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation, and replaces the Part D coverage gap discount program with a new discounting program beginning in 2025. The IRA also authorizes the United States Department of Health and Human Services (DHHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. We cannot yet assess the impact that the IRA will have on the medical-products industry, but it will likely be significant.

There is seemingly constant evolution with regard to healthcare in the United States, and we cannot predict what healthcare programs and regulations may be implemented or changed at the federal and/or state level or the effect of any future legislation or regulation on our business or that of our current or prospective customers, suppliers, and/or the U.S. healthcare industry as a whole.

It is possible that such recent and/or future initiatives could have an adverse effect on our ability to obtain or maintain approvals and/or successfully commercialize products in the United States in the future. For example, any changes that reduce or impede the ability to obtain reimbursement for the type of products we currently market, or may commercialize in the future, as applicable, in the United States would likely have an adverse effect on our business and profitability.

Our employees, consultants, distributors, agents, and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, consultants, distributors, agents, and other commercial partners may engage in inappropriate, fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the regulations of the FDA and other U.S. healthcare regulators, as well as non-U.S. regulators, including by violating laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete, and accurate reporting of financial information or data. In particular, sales, marketing, and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. It is not always possible to identify and deter misconduct by our employees, distributors, agents, and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Efforts to ensure that the activities of these parties will comply with applicable healthcare laws and regulations involve substantial costs. These risks may be more pronounced, and we may find that the processes and policies we have implemented are not effective at preventing misconduct. If any actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

Risks Related to Our Intellectual Property

We depend on our intellectual property, and our future success is dependent on our ability to protect our intellectual property and not infringe on the rights of others.

Our success depends, in part, on our ability to obtain sufficient patent protection and/or licensing rights for Deep TMS (including, but not limited to, the various H-Coils utilized in our devices and various product features/capabilities), maintain the confidentiality of our trade secrets and know-how, operate without infringing on the proprietary rights of others, and prevent others from infringing our proprietary rights. Our success also depends, in part, on the ability of the U.S. Public Health Service, or PHS, which refers collectively to the National Institutes of Health, or NIH, the Centers for Disease Control and Prevention, or CDC, and the FDA, as agencies of the PHS within the DHHS, and Yeda Research and Development Company Ltd., or Yeda, the technology transfer arm of the Weizmann Institute of Science, from whom we license essential intellectual property upon which the Deep TMS technology is based, to obtain sufficient patent protection for such intellectual property, maintain the confidentiality of related trade secrets and know-how, operate without infringing on or violating the proprietary rights of others, and prevent others from infringing or violating the Company’s owned and/or in-licensed intellectual property.

We and our licensors try to protect our proprietary position by, among other things, filing U.S., European, and other patent applications related to Deep TMS, as well as to inventions and improvements that may be important to the continuing development of Deep TMS. While we generally apply for patents in those countries where we intend to make or have made, use, sell, or import patented products, we may not accurately predict all of the countries where patent protection will ultimately be desirable. If we fail to timely file a patent application in any such country, we may be precluded from doing so at a later date. In addition, we cannot assure you that any of our future processes or product indications will be patentable or enforceable even if patented; our processes or product indications will not infringe upon the patents of third parties; or we will have the resources to defend against charges of patent infringement or other violation or misappropriation of intellectual property by third parties or to protect our own intellectual property rights against infringement, misappropriation or violation by third parties.

Because the patent position of medical device companies involves complex legal and factual questions, we cannot predict the validity and enforceability of patents with certainty. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in our patents (including patents owned by or licensed to us). Our issued patents may not provide us with any competitive advantages, may be held invalid or unenforceable as a result of legal challenges by third parties or could be circumvented. Our competitors may also independently develop formulations, processes, technologies, methods or products similar to ours or design around or otherwise circumvent patents issued to, or licensed by, us. Thus, any patents that we own or license from others may not provide any protection against competitors. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in patents being issued. If these patents are issued, they may not be of sufficient scope to provide us with meaningful protection. The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford relatively limited protection, and may not adequately protect our rights or permit us to gain or keep our competitive advantage.

Patent rights are territorial; thus, the patent protection we do have exists only in those countries in which we have been issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the United States and the European Union. Therefore, we cannot assure you that the patents issued to us or to our licensors, if any, as a result of foreign patent applications will have the same scope of coverage as our or our licensors' U.S. patents. Competitors may successfully challenge our patents, produce similar products that do not infringe our patents, or produce products in countries where we have not applied for patent protection or that do not respect our patents. Furthermore, it is not possible to know the scope of claims that will be allowed in published applications and it is also not possible to know which claims of granted patents, if any, will be deemed enforceable in a court of law. A failure to obtain sufficient intellectual property protection in any foreign country could materially and adversely affect our business, results of operations, and future prospects. Moreover, we may participate in opposition proceedings to determine the validity of our foreign patents or our competitors' foreign patents, which could result in substantial costs and divert management's resources and attention. Additionally, due to uncertainty in patent protection law, we have not filed applications in many countries where significant markets exist.

Changes in patent law and regulations in other countries or jurisdictions or changes in governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, in Europe, beginning June 1, 2023, European applications and patents may be subjected to the jurisdiction of the Unified Patent Court (UPC) for a single pan-European infringement action or revocation proceeding. European applications will for now have the option in certain circumstances, upon grant of a patent, of becoming a Unitary Patent that will be subject to the jurisdiction of the UPC. This is a significant change in European patent practice. As the UPC is a new court system with few decisions rendered, there is little precedent for parties to rely on at the court, increasing the uncertainty. The UPC may provide our competitors with a new forum to seek to centrally revoke our European patents if we do not opt our patents out of the UPC where permitted, and allows for the possibility of a competitor to obtain pan-European injunctions with their own UPC-designated European patents. As a single court system can invalidate a European patent, we, where applicable, may opt out of the UPC and as such, each European patent would then need to be challenged in each individual country and each infringement action pursued in each country.

After the completion of development and registration of our patents, third parties may still act to manufacture and/or market products that infringe our patent protected rights, and we may not have adequate resources to enforce our patents. Any such manufacturing and/or marketing of products that infringe our patent rights may significantly harm our business, results of operations and prospects.

In addition, due to the extensive time needed to develop, test, and obtain regulatory approval for new indications of Deep TMS, any patents that protect these indications may expire early during the commercialization process. This may reduce or eliminate any market advantages that such patents may give us. Following patent expiration, we may face increased competition through the entry of competing products into the market and a subsequent decline in market share and profits.

Moreover, our business interests may change, or our licensors may disagree with the scope of our license grants. In such cases, litigation could impede our ability to commercialize the technology, or such licensing arrangements may result in the development, manufacturing, marketing, and sale by our licensors of products substantially similar to our products, causing us to face increased competition, which could reduce our market share and significantly harm our business, results of operations and prospects.

The duration of our patent rights may not be sufficient to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the duration of a patent, and the protection it affords, is limited. Even if patents covering our technologies, products, or product candidates are obtained, once the patent life has expired, we may be open to competition. Patents covering some of our core technology have expired or will expire within the next five years. In particular, the earliest of our U.S. patents on Deep TMS expired in January 2024. See "*Business—Intellectual Property*." In addition, although upon issuance in the United States a patent can be extended based on certain delays caused by the United States Patent and Trademark Office (USPTO), this extension can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our technologies, products, and product candidates, our business, and results of operations will be adversely affected.

Our right to the essential intellectual property upon which the Deep TMS technology is based derives from in-license agreements with government agencies and research institutions, the termination of which would prevent us from commercializing Deep TMS.

We have in-licensing agreements with the PHS and Yeda. There is no assurance that the in-licenses or related rights on which we base our technology will not be terminated due to a material breach of the underlying agreements or some other failure to meet the terms of agreement, such as a failure on our part to make certain progress milestone payments set forth in the terms of the licenses or to comply with manufacturing obligations under these agreements, or otherwise expire. There is no assurance that we will be able to renew or renegotiate our license agreements on acceptable terms if and when such agreements terminate. We cannot guarantee that any in-license is enforceable or will not be terminated in the future. The termination of any in-license or our inability to practice such technology and/or to enforce our rights under any in-license would materially and adversely affect our ability to commercialize our Deep TMS systems.

The license agreements for our critical patents and related intellectual property impose significant monetary obligations and other requirements on us that may adversely affect our ability to successfully execute our business plan.

We depend upon license agreements with the PHS and Yeda for our intellectual property rights to Deep TMS technology. Deep TMS was developed by our founders, among others, prior to our founding over the course of their work for the PHS. The key family of patents and patent applications upon which the unique coil of Deep TMS technology is based is owned by the DHHS (based on an assignment of the related rights from the PHS) and is exclusively in-licensed to us under a license agreement with the PHS. A second family of patent applications covering additional functions of Deep TMS (including the multichannel stimulator that we are developing for use in a more advanced version of our system), which is jointly owned by us with the NIH and Yeda, is also licensed to us under the PHS license agreement and our license agreement with Yeda.

Our license agreement with Yeda was made within the context of research we commissioned at the Weizmann Institute involving Deep TMS. This agreement provides for in-licensed rights relating to our second and third families of patent applications, which cover additional characteristics of Deep TMS (including several Deep TMS coils, multi-channel stimulation, and methods of use), as well as in-licensed rights to rotational field TMS, which involves the perpendicular placement of two coils over the head operated with a phase lag which causes a rotating induced electric field that enables stimulation of neurons in various orientations.

These agreements provide us an exclusive (subject to certain standard exceptions and such as described below), worldwide license, with a right to sublicense, subject to the approval of PHS and Yeda, as applicable, for the life of the relevant patents (in the case of Yeda, on a per country basis or until the 15-year anniversary of the first commercial sale (per country) of a product developed on the basis of the agreement, if later for the development, creation, use, import, offer, and sale of any product or treatment that relates to Deep TMS technology and that is developed on the basis of such patents or (in the case of the agreement with Yeda) such research. These agreements require us, as a condition to the maintenance of our license and other rights, to make milestone and royalty payments and satisfy certain performance obligations, including with respect to manufacturing. If we were to receive a notice of non-compliance under any of these agreements, we would need to either obtain appropriate waivers and/or cure such non-compliance, which may require us to modify our operations.

The first patent family upon which our Deep TMS products are based, which is owned by the DHHS (based on an assignment of the related rights from the PHS) and is exclusively in-licensed to us under a license agreement with the PHS, expired in the U.S. in January 2024, and a divisional patent within this family will expire in the U.S. in 2026. See "*Business—Intellectual Property.*" While we have secured additional patents which we believe extend the protection of our products into future years, we cannot be certain that this protection will completely compensate for the expiration of this underlying patent.

All of the above-described obligations impose significant financial and logistical burdens upon our ability to carry out our business plan. Furthermore, if we do not meet such obligations in a timely manner, we could lose the rights to our proprietary technology, which would have a material adverse effect on our business, financial condition, and results of operations.

In certain cases, we may rely on our licensors to conduct prosecution, maintenance and/or defense of patents on our behalf. Our ability to ensure that these patents are properly prepared, prosecuted, maintained, enforced or defended is therefore limited, which may adversely affect our licensed intellectual property rights. Any failure by our licensors to properly prepare, prosecute, maintain, enforce, and defend patents or other licensed rights could materially harm our ability to protect our products and prevent infringement of intellectual property rights by competitors, thereby materially reducing our potential profits.

The key patents that underlie our Deep TMS technology are subject to the U.S. government's royalty free usage rights on a worldwide basis for any discovery based on such patents, which may have unexpected, adverse consequences upon the market for our product.

Under our PHS license agreement, the U.S. government possesses an irrevocable, nonexclusive, nontransferable royalty-free license for the practice of inventions based on the inventions upon which our Deep TMS technology is based, for the benefit of the U.S. government, foreign governments, or international organizations under any existing or future treaty or agreement applicable to the U.S. government at such time. Furthermore, the PHS may grant, or may cause us to grant, nonexclusive research licenses, for the purpose of encouraging basic research at academic or corporate facilities (but, in the case of any license to a commercial entity, subject to our right to object if we believe that such license would adversely impact the exclusivity of our rights under the agreement). The PHS may also require us to grant sublicenses to responsible applicants if the public health and safety so require, subject to our right to demonstrate that any such sublicense will not materially increase the availability to the public of our licensed rights or that such public health and safety requirements may be otherwise met without any such sublicense.

No material limits have been placed on the license held by the U.S. government for its own (or for its treaty partners' or agreement counter-parties') benefit, and it is possible that the U.S. government, a foreign government or an international organization could even commercialize a product on the basis of this license and the related technology. We cannot provide assurance that these rights will not be exploited in a manner that infringes upon any otherwise enforceable exclusive licenses we hold to the PHS-owned patents, that does not develop or advance products that compete with our own, or that does not otherwise adversely impact our business. Because our rights with respect to the PHS-owned patents are critical to Deep TMS-based technologies and systems, any unexpected consequences from the U.S. government's or other third party's exploitation of such rights could have an adverse impact on the market for Deep TMS and, hence, on our business, financial condition, and results of operations.

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.

In addition to filing patent applications, we generally try to protect our trade secrets, know-how, technology, and other proprietary information by entering into confidentiality or non-disclosure agreements with parties that have access to it, such as our development and/or commercialization partners, employees, contractors, and consultants. We also enter into agreements that require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees, advisors, research collaborators, contractors, and consultants while we employ or engage them. However, we cannot assure you that these agreements will provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use, misappropriation or disclosure of such trade secrets, know-how or other proprietary information because these agreements can be difficult and costly to enforce or may not provide adequate remedies. Any of these parties may breach the confidentiality agreements and willfully or unintentionally disclose our confidential information, or our competitors might learn of the information in some other way. The disclosure to, or independent development by, a competitor of any trade secret, know-how or other technology not protected by a patent could materially adversely affect any competitive advantage we may have over any such competitor.

To the extent that any of our employees, advisors, research collaborators, contractors or consultants independently develop, or use independently developed, intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises with respect to any proprietary right, enforcement of our rights can be costly and unpredictable, and a court may determine that the right belongs to a third party.

Legal proceedings or third-party claims of intellectual property infringement and other challenges, whether with or without merit, may require us to spend substantial time and money and could prevent us from developing or commercializing Deep TMS.

The medical device industry is characterized by competing intellectual property and a substantial amount of litigation over patent rights. In particular, our competitors in both the United States and abroad, many of whom have substantially greater resources and have made substantial investments in competing technologies, have been issued patents and filed patent applications with respect to their products, methods and processes and may apply for other patents in the future. The large number of patents, the rapid rate of new patent issuances, and the complexities of the technology involved increase the risk of patent litigation.

Our commercial success depends upon our ability, and the ability of any third party with which we may partner, to develop, manufacture, market and sell Deep TMS, and use our patent-protected technologies without infringing the patents of third parties. We face risks that there may be patents issued to third parties that relate to Deep TMS and technology of which we are not aware or that we must challenge to continue our operations as currently contemplated.

The development, manufacture, use, offer for sale, sale or importation of Deep TMS and any planned future-generation products may infringe on the claims of third-party patents or violate other intellectual property rights. The nature of claims contained in unpublished patent filings around the world is unknown to us and it is not possible to know which countries patent holders may choose for the extension of their filings under the Patent Cooperation Treaty, or other mechanisms. For example, because patent applications do not publish for at least 18 months, if at all, and can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that Deep TMS would infringe. Therefore, there is a risk that we could adopt a technology without knowledge of a pending patent application, which technology would infringe a third-party patent once that patent is issued. Also, because the claims of published patent applications can change between publication and patent grant, published applications that initially do not appear to be problematic may issue with claims that potentially cover our products, technology or methods.

Determining whether a product infringes a patent involves complex legal and factual issues and the outcome of patent litigation is often uncertain. Even though we have conducted research of issued patents, no assurance can be given that patents containing claims covering our products, technology or methods do not exist, have not been filed or could not be filed or issued.

The cost to us of any intellectual property litigation or other infringement proceeding, even if resolved in our favor, could be substantial. Any claims of patent infringement, even those without merit, could be expensive and time consuming to defend; cause us to cease making, licensing or using products that incorporate the challenged intellectual property; require us to redesign, reengineer or rebrand Deep TMS, if feasible; cause us to stop engaging in normal operations and activities, including developing new indications for Deep TMS; and divert management's attention and resources. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation or defense of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may also absorb significant management time. Consequently, we may not be able to manufacture, use, offer for sale, sell or import our Deep TMS systems in the event of an infringement action.

Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. 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.

In the event of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could potentially limit our competitive advantage. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement or other claims, we are unable to enter into licenses on acceptable terms. This inability to enter into licenses could harm our business significantly.

In addition, because of our developmental stage, claims that Deep TMS infringes on the patent rights of others are more likely to be asserted after commencement of commercial sales incorporating our technology.

In addition to infringement claims against us, we may become a party to other patent litigation or proceedings before regulatory agencies, including post-grant review, inter parties review, interference or re-examination proceedings filed with the U.S. Patent and Trademark Office that challenge our patent rights or the patent rights of our licensors. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings can be substantial and the outcome can be uncertain. An adverse determination in these proceedings could weaken or invalidate the patent claims that cover our technology and Deep TMS, which could harm our business significantly and dissuade companies from collaborating with us or permit third parties to directly compete with the same technology.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other medical device, biotechnology and/or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employees', consultants' or independent contractors' former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact 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.

Obtaining and maintaining patent protection depends on compliance with various procedures and other requirements, and our patent protection could be reduced or eliminated in case of non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications are due to the relevant patent agencies in several stages over the lifetime of the patents and/or patent applications. The relevant patent agencies require compliance with a number of procedural, documentary, fee payment and other requirements during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which the failure to comply with the relevant requirements can result in the abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and know-how in the relevant jurisdiction, which could have a material adverse effect on our business, prospects, financial condition and results of operation.

Risks Related to Our Functions in Israel

We have manufacturing, assembly and other significant functions that are located in Israel and, therefore, our business and operations may be adversely affected by political, economic and military conditions in Israel.

Certain material aspects of our business are located in Israel, including our headquarters, our research and development and our manufacturing and assembling. See "*—We rely on third parties, including suppliers for some components used in manufacturing our Deep TMS products, distributors to market and promote our products internationally and third parties to conduct our clinical trials, which exposes us to uncertainty and instability*." In addition, 71 of our employees are located in Israel. Accordingly, our business will be directly influenced by the political, economic, and military conditions affecting Israel at any given time. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries. These conflicts involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. In addition, Israel faces threats from more distant neighbors, in particular Iran. A change in the security and political situation in Israel and in the economy could impede our ability to raise the funds required to finance our research and development plans and to create joint ventures with third parties, and could otherwise have a material adverse effect on our business, operating results, and financial condition.

Our facilities, and those of some of our suppliers including the outsourced contract manufacturer for our newer systems, are in range of rockets that may be fired from Lebanon, Syria or the Gaza Strip into Israel. In the event that our facilities are damaged as a result of hostile action or hostilities otherwise disrupt the ongoing operation of our facilities, our research and development activities, and our ability to deliver products to customers could be materially and adversely affected. Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although the Israeli government is currently committed to covering the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, there can be no assurance that this government coverage will be maintained, or if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business, financial condition, and results of operations.

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against this terrorist organization commenced in parallel to its continued rocket and terror attacks. In addition, in October 2023, Hezbollah, a terror group based in Lebanon, commenced extensive rocket attacks on northern Israel and other areas within the State of Israel. The personnel and facilities of our outsourced manufacturer, located near the Israel-Lebanon border, were particularly susceptible throughout 2024 to the risks and instabilities posed by the outbreaks of violence that occurred between Israel and Hezbollah during this period. Although a temporary ceasefire with Hezbollah was reached in late 2024, the clash between Israel and Hezbollah in Lebanon may escalate in the future into a greater regional conflict. Additionally, a Yemeni rebel group, the Houthis, launched a series of attacks on global shipping routes in the Red Sea, causing disruptions of supply chain and also launched rockets and drones in an attempt to reach Israeli military and civilian targets. These geopolitical developments may adversely affect our ability to continue carrying out various administrative, research, operational and commercial functions and activities both in Israel and globally.

In addition, popular uprisings in various countries in the Middle East and North Africa are affecting the political stability of those countries. Such instability may lead to deterioration in the political and trade relationships that exist between the State of Israel and these countries. Furthermore, some countries restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies if hostilities involving Israeli or political instability in the region continue or intensify. Such restrictions may seriously limit our ability to sell Deep TMS to customers in those countries. In addition, there have been increased efforts by activists to cause companies and consumers to boycott Israeli products. Such efforts, particularly if they become more widespread, may materially and adversely impact our ability to sell our products.

Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or significant downturns in the economic or financial condition of Israel could adversely affect our operations and product development, cause our revenues to decrease, and adversely affect the share price of publicly traded companies having functions in Israel, such as us.

Moreover, in recent years Israel has been facing political instability with the rapid changing of its government. Between the years 2018 and 2022, five elections were held for the Israeli Parliament as a result of a failure to constitute a government. In addition, in 2022 a proposed dramatic and controversial legal reform that would drastically change the way that the High Court of Justice would function and shift the balance of power between the Knesset and other government bodies caused significant backlash in Israel, including civil protests and demonstrations, which continued and intensified in connection with the October 2023 attacks on Israel and the hostages taken by Hamas and other militant groups in the Gaza Strip. Any continuations or exacerbations of instability in Israel's security, political and/or economic environments might deter potential and current investors from investing in Israeli based companies such as BrainsWay.

Exchange rate fluctuations between the U.S. dollar, the New Israeli Shekel and other foreign currencies may negatively affect our future revenues.

While a substantial portion of our revenues is and will continue to be generated in U.S. dollars and our financial records are maintained in U.S. dollars, we incur a significant portion of our expenses in currencies other than U.S. dollars, such as NIS. As a result, our financial results have been and may continue to be affected by fluctuations in the applicable exchange rates of currencies in the U.S., Israel, and other countries in which our products and services may be sold.

Our operations may be affected by negative labor conditions in Israel.

Strikes and work-stoppages occur relatively frequently in Israel. If Israeli trade unions threaten additional strikes or work-stoppages and such strikes or work-stoppages occur, those may, if prolonged, have a material adverse effect on the Israeli economy and on our business, including our ability to deliver products to our customers and to receive raw materials from our suppliers in a timely manner.

Our operations could be disrupted as a result of the obligation of some of our personnel to perform military service.

Members of our senior management and several of our key employees reside in Israel, and although most of them are no longer required to perform reserve duty, some may be required to perform annual military reserve duty, and may be called for active duty under emergency circumstances at any time. Since the initiation of the Israel-Gaza war, several of our Israel-based employees were drafted to the Reserves for purposes of the war effort, including five employees in 2023 and four in 2024. These employees hail from different departments across our organization, including R&D, manufacturing, and finance. While some of these employees have been released, should they be re-drafted, or should the war expand and/or other circumstances occur that would result in additional employees being drafted into the reserves, certain Israel-based functions, primarily including our R&D and scientific operations could be impacted. These impacts could include delays in our ability to rollout next generation products, and/or any planned redesigned components, features and/or capabilities on our existing products.

The termination or reduction of tax and other incentives that the Israeli Government provides to domestic companies may increase the costs involved in operating a company in Israel.

The Israeli government currently provides tax and capital investment incentives to domestic 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 have indicated that the government may in the future further reduce or eliminate the benefits of those programs. In connection with the increased defense expenses due to the Israel-Gaza war and other hostilities in Israel since October 2023, additional budget cuts could be implemented, resulting in termination or reduction of grants and other benefits. We may take advantage of these benefits and programs in the future, however, there is no assurance that such benefits and programs would continue to be available in the future to us. If such benefits and programs were terminated or further reduced, it could have an adverse effect on our business, operating results, and financial condition.

The Israeli government grants that we received require us to meet several conditions, may restrict our ability to manufacture our Deep TMS systems and transfer relevant know-how outside of Israel and require us to pay royalties, including increased royalties if we manufacture our Deep TMS systems outside of Israel or payment of a redemption fee if we transfer relevant know-how outside of Israel.

We have received royalty-bearing grants from the government of Israel through the Israel Innovation Authority (IIA) (formerly the Office of the Chief Scientist of the Ministry of Economy and Industry), for the financing of a portion of our research and development expenditures in Israel. When know-how is developed using IIA grants, the Encouragement of Research, Development and Technological Innovation in Industry Law 5744-1984, or the Innovation Law, the IIA's rules and guidelines as well as the terms of each of these grants, impose an obligation to pay royalties from any income deriving from a product developed, in whole or in part, directly or indirectly, in the framework of a research and development program funded by the IIA, including any derivatives and related services. Therefore, we are required to pay low single-digit royalties on the sale of those of our products developed with this funding, which payments shall not exceed, in the aggregate, the amount of the grant received (in U.S. dollars), plus interest at an annual rate based on LIBOR. In addition, the Innovation Law restricts our ability to manufacture our products, and transfer know-how developed as a result of the IIA's funded research and development, outside of Israel. In certain cases, transfer of the IIA funded know-how outside of Israel requires pre-approval by the IIA, which may also impose certain conditions, including payment of a redemption fee calculated according to the formulas provided in the IIA's rules and guidelines, or the Redemption Fee, which differentiate between certain situations (while in no event will the Redemption Fee be more than six (6) times the grants received from the IIA plus interest). In addition, we may need or deem it beneficial to us to manufacture our products outside of Israel, in which case prior approval from the IIA is required (such approval is not required for the transfer of less than 10% of the manufacturing capacity in the aggregate), and we would be required to pay royalties at an accelerated rate and would be subject to payment of increased royalties, as defined under the IIA's rules and regulations (up to, in the aggregate, 300% of the amount of the grant received (dollar linked), plus interest at annual rate based on LIBOR, depending on the manufacturing volume that is performed outside Israel less royalties already paid to the IIA). Accordingly, we may be limited in our ability to manufacture outside of Israel, and the manufacture of our products outside of Israel could have a material adverse effect on our business and results of operations.

The IIA has also published rules and guidelines with respect to the grant to a foreign entity of the right to use know-how that was developed using the IIA's grants, or Funded Know-How, in a manner that does not entirely prevent the IIA funded company from using the Funded Know-How, which include a requirement to receive the IIA's prior approval. This approval is subject to payment to the IIA in accordance with the formulas stipulated in these rules.

In addition, we may transfer Funded Know-How to another Israeli company, provided that the acquiring company assumes all of our responsibilities toward the IIA (the transfer would still require IIA approval, and is subject to the obligation to pay royalties to the IIA from the income of such sale transaction, but will not be subject to the payment of the Redemption Fee).

The obligation to comply with the Innovation Law and with the IIA's rules and guidelines (including with respect to the restriction of the transfer of Funded Know-How and manufacturing rights outside of Israel) remains in effect even after full repayment of the amount of royalties payable pursuant to the grants. Once a Redemption Fee is paid on a transfer of Funded Know-How outside Israel, all obligations towards the IIA (including the royalty obligation) cease. We are also subject to reporting obligations towards the IIA including submitting during the R&D approved program period periodic reports pertaining to the progress of research and development, submitting reports on income derived from products developed using grants from the IIA and, in certain circumstances, reports regarding change in the holding in our company and change of control. Furthermore, in the event of any change of control or any change in the holding of voting rights or rights to appoint directors or the CEO a result of which any non-Israeli citizen or non-Israeli resident becomes an "Interested Party" in our company, the non-Israeli citizen or non-Israeli resident shall comply with all the restrictions imposed on us and our obligations pursuant to Innovation Law and the IIA's rules and guidelines. See "*Management—Internal Auditor*" for definition of Interested Party. In addition, the government of State of Israel may from time to time audit sales of products that it claims incorporate technology funded via IIA programs, and this may lead to additional royalties being payable on additional product candidates. Moreover, under certain circumstances, further offerings of our shares to the public in any stock exchange whether in Israel or abroad, is subject to the approval of the IIA.

These restrictions may impair our ability to enter into agreements covering IIA Funded Know-how without the approval of the IIA, and we cannot be certain that such approval will be obtained on terms that are acceptable to us, or at all. Furthermore, in the event that we undertake a transaction involving the transfer to a non-Israeli entity of know-how developed with IIA funding pursuant to a merger or similar transaction, or in the event we undertake a transaction involving the licensing of the IIA's Funded Know-How, the consideration available to our shareholders may be reduced by the amounts we are required to pay to the IIA. Any approval, if given, will generally be subject to additional financial obligations. Failure to comply with the requirements under the IIA's rules and guidelines and the Innovation Law may subject us to mandatory repayment of grants received by us (together with interest and penalties), as well as expose us to criminal proceedings.

Enforcing a U.S. judgment against us and our current senior management and directors, or asserting U.S. securities law claims in Israel, may be difficult.

We are incorporated in Israel. Our directors and some members of our management reside in Israel (and most of our assets reside outside of the United States). Therefore, a judgment obtained against us or any of these persons in the United States, including one 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 may also be difficult 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.

Even if an Israeli court agrees to hear such a claim, it may determine that Israeli, and not U.S., law is applicable to the claim. Under Israeli law, if U.S. law is found to be applicable to such a claim, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would be governed by Israeli law. There is little binding case law in Israel addressing these matters.

Israeli law and tax considerations may delay, prevent or make difficult an acquisition of us, which could prevent a change of control and negatively affect the price of the ADSs.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for certain transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions (see Exhibit 2.3 attached to this Annual Report). These provisions of Israeli law may delay, prevent or make difficult an acquisition of us, which could prevent a change of control, and therefore would potentially depress the price of the ADSs.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders, especially for those shareholders whose country of residence does not have a tax treaty with Israel which exempts such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free stock 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.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

We have entered into assignment of invention agreements with our employees who engage in research and development pursuant to which such individuals agree to assign to us all rights to any inventions created during and as a result of their employment or engagement with us. A significant portion of our intellectual property has been developed by our employees in the course and as a result of their employment by us. Under the Israeli Patent Law, 5727-1967, or the Patent Law, inventions conceived by an employee during the scope of his or her employment with a company and as a result thereof are regarded as "service inventions," which belong to the employer absent a specific agreement between the employee and employer giving the employee service invention rights. The Patent Law also provides that if there is no agreement between an employer and an employee with respect to the employee's right to receive compensation for such "service inventions," 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 his or her service inventions and the scope and conditions for such remuneration. Israeli case law clarifies that the right to receive consideration for "service inventions" can be waived by the employee and that in certain circumstances, such waiver does not necessarily have to be explicit. In order to determine the scope and validity of such wavier, the Committee will examine, on a case-by-case basis, the general contractual framework between the parties, using interpretation rules of the general Israeli contract laws. Further, the Committee has not yet determined one specific formula for calculating this remuneration (but rather uses the criteria specified in the Patents Law). As such, and although our employees have agreed to assign to us service invention rights, we may face claims demanding remuneration in consideration for assigned inventions. As a consequence of such claims, 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.

The government tax benefits that we currently are entitled to receive require us to meet several conditions and may be terminated or reduced in the future.

Some of our operations in Israel may entitle us to certain tax benefits under the Law for the Encouragement of Capital Investments, 5719-1959, or the Investment Law, once we begin to generate taxable income. If we do not meet the requirements for maintaining these benefits, they may be reduced or cancelled and the relevant operations would be subject to Israeli corporate tax at the standard rate, which is currently set at 23%. In addition to being subject to the standard corporate tax rate, we could be required to refund any tax benefits that we may receive in the future, plus interest and penalties thereon. Even if we continue to meet the relevant requirements, the tax benefits that our current "Technology Enterprise" is entitled to may not apply in the future at their current levels or at all. If these tax benefits were reduced or eliminated, the amount of taxes that we pay would likely increase, as all of our operations would consequently be subject to corporate tax at the standard rate, which could adversely affect our results of operations. Additionally, if we increase our activities outside of Israel, for example, by way of acquisitions, our increased activities may not be eligible for inclusion in Israeli tax benefits programs. See "*Material Tax Considerations—Israeli Tax Considerations and Government Programs*" for additional information concerning these tax benefits.

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

The rights and responsibilities of our shareholders 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. corporations. For example, 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 the company, including, among other things, 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. In addition, a shareholder who is aware that it possesses the power to determine the outcome of a shareholder vote 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 our shareholders that are not typically imposed on shareholders of U.S. corporations.

Risks Related to the ADSs and Ordinary Shares

The price of the ADSs may be volatile and may fluctuate due to factors beyond our control.

The share price of publicly traded medical device companies has been highly volatile and is likely to remain highly volatile in the future. The market price of the ADSs or Ordinary Shares on either The Nasdaq Global Market, or Nasdaq, or the Tel Aviv Stock Exchange, or TASE, may fluctuate significantly due to a variety of factors, including but not limited to, positive or negative results of testing and clinical trials by us, strategic partners, and competitors; delays in entering into strategic relationships with respect to development and/or commercialization of Deep TMS or entry into strategic relationships on terms that are not deemed to be favorable to us; technological innovations or commercial product introductions by us or competitors; changes in government regulations; developments concerning proprietary rights, including patents and litigation matters; public concern relating to the commercial value or safety of Deep TMS; financing or other corporate transactions; publication of research reports or comments by securities or industry analysts; general market conditions in the medical device industry or in the economy as a whole; or other events and factors, many of which are beyond our control.

These, and other market and industry factors, may cause the market price and demand for the ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ADSs and may otherwise negatively affect the liquidity of the ADSs. In addition, stock markets in general, and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

The significant share ownership position of several of our officers, directors, and entities affiliated with certain of our directors, including Valor, may limit your ability to influence corporate matters.

Our officers, directors, and entities affiliated with certain of our directors beneficially own or control, directly or indirectly, approximately 35.46% of our outstanding Ordinary Shares as of March 31, 2025. Following a private placement of ADSs and warrants to purchase ADSs, consummated on November 5, 2024, Valor and its affiliates own ADSs representing in the aggregate approximately 13.86% of our outstanding share capital as of March 31, 2025 and Valor also holds currently exercisable warrants to purchase additional ADSs that, if exercised in full, will increase the aggregate holdings of Valor and its affiliates to 20.2% of our outstanding share capital as of March 31, 2025. Valor also has the right, among other rights, to designate (i) one nominee to our Board of Directors as long as it, together with its affiliates, beneficially holds at least 10% of our outstanding share capital or (ii) two nominees to our Board of Directors as long as it, together with its affiliates, beneficially holds at least 20% of our outstanding share capital. Accordingly, our officers, directors, Valor and their affiliates are able to significantly influence, though not independently determine, the outcome of matters required to be submitted to our shareholders for approval, including decisions relating to the election of our Board of Directors, and the outcome of any proposed merger or consolidation of our company. These interests may not be consistent with those of our other shareholders. In addition, these persons' and Valor's significant interest in us may discourage third parties from seeking to acquire control of us, which may adversely affect the market price of the ADSs and our Ordinary Shares.

Holders of ADSs may be subject to limitations on the transfer of their ADSs and the withdrawal of the underlying Ordinary Shares.

ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason, subject to the right of ADS holders to cancel their ADSs and withdraw the underlying Ordinary Shares. Temporary delays in the cancellation of the ADSs and withdrawal of the underlying Ordinary Shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of Ordinary Shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our Ordinary Shares. In addition, ADS holders may not be able to cancel their ADSs and withdraw the underlying Ordinary Shares when they owe money for fees, taxes, and similar charges, and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of Ordinary Shares or other deposited securities. See Exhibit 2.3 attached to this Annual Report.

We and the depositary are entitled to amend the deposit agreement and to change the rights of ADS holders under the terms of such agreement, or to terminate the deposit agreement, without the prior consent of the ADS holders.

We and the depositary are entitled to amend the deposit agreement and to change the rights of the ADS holders under the terms of such agreement, without the prior consent of the ADS holders. We and the depositary may agree to amend the deposit agreement in any way we decide is necessary or advantageous to us or to the depositary. Amendments may reflect, among other things, operational changes in the ADS program, legal developments affecting ADSs or changes in the terms of our business relationship with the depositary. In the event that the terms of an amendment are materially disadvantageous to ADS holders, ADS holders will only receive 30 days' advance notice of the amendment, and no prior consent of the ADS holders is required under the deposit agreement. Furthermore, we may decide to direct the depositary to terminate the ADS facility at any time for any reason. For example, terminations may occur when we decide to list our Ordinary Shares on a non-U.S. securities exchange and determine not to continue to sponsor an ADS facility or when we become the subject of a takeover or a going-private transaction. If the ADS facility will terminate, ADS holders will receive at least 90 days' prior notice, but no prior consent is required from them. Under the circumstances that we decide to make an amendment to the deposit agreement that is disadvantageous to ADS holders or terminate the deposit agreement, the ADS holders may choose to sell their ADSs or surrender their ADSs and become direct holders of the underlying Ordinary Shares, but will have no right to any compensation whatsoever.

ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our Ordinary Shares provides that, to the fullest extent permitted by law, holders and beneficial owners of ADSs irrevocably waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to the ADSs or the deposit agreement.

If this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently, and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement, and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

If you or any other holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under federal securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any substantive provision of the U.S. federal securities laws, and the rules and regulations promulgated thereunder.

ADS holders will not have the same voting rights as the holders of our Ordinary Shares and may not receive voting materials in time to be able to exercise their right to vote.

Holders of the ADSs will not be able to exercise voting rights attaching to the Ordinary Shares represented by the ADSs. Under the terms of the deposit agreement, holders of the ADSs may instruct the depositary to vote the Ordinary Shares underlying their ADSs. Otherwise, holders of ADSs will not be able to exercise their right to vote unless they withdraw the Ordinary Shares underlying their ADSs to vote them in person or by proxy in accordance with applicable laws and regulations and our articles of association. Even so, ADS holders may not know about a meeting far enough in advance to withdraw those Ordinary Shares. If we ask for the instructions of holders of the ADSs, the depositary, upon timely notice from us, will notify ADS holders of the upcoming vote and arrange to deliver our voting materials to them. Upon our request, the depositary will mail to holders a shareholder meeting notice that contains, among other things, a statement as to the manner in which voting instructions may be given. We cannot guarantee that ADS holders will receive the voting materials in time to ensure that they can instruct the depositary to vote the Ordinary Shares underlying their ADSs. A shareholder is only entitled to participate in, and vote at, the meeting of shareholders, provided that it holds our Ordinary Shares as of the record date set for such meeting and otherwise complies with our articles of association. In addition, the depositary's liability to ADS holders for failing to execute voting instructions or for the manner of executing voting instructions is limited by the deposit agreement. As a result, holders of ADSs may not be able to exercise their right to give voting instructions or to vote in person or by proxy, and they may not have any recourse against the depositary or us if their Ordinary Shares are not voted as they have requested or if their shares cannot be voted.

Our Ordinary Shares and ADSs are traded on different markets and this may result in price variations.

Our Ordinary Shares have been traded on the TASE since January 4, 2007, and the ADSs have been traded on The Nasdaq Global Market since April 16, 2019. Trading in our securities on these markets takes place in different currencies (dollars on the Nasdaq and NIS on the TASE), and at different times (resulting from different time zones, different trading days, and different public holidays in the United States and Israel). The trading prices of our securities on these two markets may differ due to these and other factors. Any decrease in the price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

We do not have any current plans to pay dividends in the near term.

We do not have any current plans to pay any cash dividends in the near term. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of the ADSs will be the investors' sole source of gain for at least the next several years. In addition, Israeli law limits our ability to declare and pay dividends, and may subject us to certain Israeli taxes. For more information, see "*Item 8.A. Financial Information—Consolidated Statements and Other Financial Information—Dividend Policy*."

The price of the ADSs may rely on the research and reports of equity research analysts.

The trading market for the ADSs may rely on the research and reports that equity research analysts publish about us and our business. The price of the ADSs could decline if one or more securities analysts downgrade the ADSs or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

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

In the past, U.S.-listed companies that have experienced volatility in the market price of their securities, including many life sciences and biotechnology companies, have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Regardless of the merits or the ultimate results of such litigation, securities litigation brought against us could result in substantial costs and divert our management's attention from other business concerns, which could have a material adverse effect on our results of operations.

As a foreign private issuer whose shares are listed on The Nasdaq Global Market, we follow certain home country corporate governance practices instead of certain Nasdaq requirements.

As a foreign private issuer whose shares are listed on The Nasdaq Global Market, we are permitted to follow certain home country corporate governance practices instead of certain requirements of the rules of The Nasdaq Global Market. Although we established a quorum requirement such that the quorum for any meeting of shareholders is two or more shareholders holding at least 33 and 1/3% of our voting rights, which complies with Nasdaq requirements, pursuant to the "foreign private issuer exemption" we established a quorum for an adjourned meeting, if the meeting is adjourned for lack of quorum, of two or more shareholders holding any percentage of our voting rights. We also follow Israeli corporate governance practice in lieu of Nasdaq Marketplace Rule 5635(c), which requires shareholder approval for certain dilutive events (such as issuances that will result in a change of control, certain transactions other than a public offering involving issuances of a 20% or greater interest in us and certain acquisitions of the shares or assets of another company), and prior to an issuance of securities when a stock option or purchase plan is to be established or materially amended or other equity compensation arrangement made or materially amended, pursuant to which stock may be acquired by officers, directors, employees or consultants. Otherwise, we comply with the rules generally applicable to U.S. domestic companies listed on The Nasdaq Global Market. However, we may in the future decide to use the foreign private issuer exemption with respect to some or all of the other Nasdaq corporate governance rules. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on The Nasdaq Global Market may provide less protection than is accorded to investors of domestic issuers.

By contrast, under the Israeli Companies Law, shareholder approval is required (subject to certain limited exceptions) for, among other things: (a) transactions with directors concerning the terms of their service (including indemnification, exemption, and insurance for their service or for any other position that they may hold at a company); (b) extraordinary transactions with controlling shareholders of publicly held companies; (c) terms of office and employment or other engagement of a controlling shareholder, if any, or such controlling shareholder's relative; (d) approval of transactions with the company's Chief Executive Officer with respect to his or her terms of employment, whether in accordance with the approved compensation policy of the company or not, or transactions with officers of the company not in accordance with the approved compensation policy; (e) approval of the compensation policy of the company for "office holders"(as such term is defined in the Israeli Companies Law); and (f) certain private placements involving the issuance of 20% or more of our total voting rights, or private placements as a result of which a person will become a controlling shareholder of the company. In addition, under the Israeli Companies Law, a merger requires approval of the shareholders of each of the merging companies.

In addition, as a foreign private issuer, we are exempt from the rules and regulations under the United States Securities Exchange Act of 1934, as amended, or the Exchange Act, related to the furnishing and content of proxy statements, and our officers, directors, and principal shareholders are 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 early as domestic companies whose securities are registered under the Exchange Act.

We may lose our foreign private issuer status which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting, and other expenses.

We are a foreign private issuer, and therefore are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. In order to maintain our current status as a foreign private issuer, either (a) a majority of our Ordinary Shares and ADSs (calculated together) must be owned of record, directly or indirectly, by non-residents of the United States or (b)(i) a majority of our senior management or directors may not be U.S. citizens or residents, (ii) more than 50 percent of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. If we were to lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the costs we incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our Board of Directors.

We may incur increased costs as a result of operating as a public company in the United States, and our management may be required to devote substantial time to new compliance initiatives.

As a public company whose ADSs are listed in the United States, and particularly as we no longer qualify as an emerging growth company and/or may lose our foreign private issuer status, we incur accounting, legal and other expenses that we did not incur prior to our listing on Nasdaq and registration with the SEC, including costs associated with our reporting requirements under the Exchange Act. We also incur costs associated with corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act), as well as rules implemented by the SEC and The Nasdaq Global Market, and provisions of Israeli corporate law applicable to public companies, and the rules of the TASE. These rules and regulations may increase our legal and financial compliance costs, introduce new costs such as investor relations, increased insurance premiums and stock exchange listing fees, and may make some activities more time-consuming and costly. Our board members and other personnel may need to devote a substantial amount of time to these initiatives. We are constantly evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

Changes in the laws and regulations affecting public companies will result in increased costs to us as we respond to their requirements. These laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. 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 senior management. We cannot predict or estimate the amount or timing of additional costs we may incur in order to comply with such requirements.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of the ADSs and Ordinary Shares.

Our management is required to assess the effectiveness of our internal controls and procedures and disclose changes in these controls on an annual basis. Additionally, as we are no longer an emerging growth company effective December 31, 2024 and are deemed to be an accelerated filer, pursuant to Section 404(b) of the Sarbanes-Oxley Act we are required to include an auditor attestation on our internal control over financial reporting in the annual report.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. To maintain the effectiveness of our disclosure controls and procedures and our internal control over financial reporting, we expect that we will need to continue enhancing existing, and possibly implement new, financial reporting and management systems, procedures and controls to manage our business effectively and support our growth in the future. The process of evaluating our internal control over financial reporting will continue to require an investment of substantial time and resources, including by our Chief Executive Officer, Chief Financial Officer and other members of our senior management. The determination and any remedial actions required could divert internal resources and take a significant amount of time and effort to complete and could result in us incurring additional costs that we did not anticipate, including the hiring of outside consultants. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner or to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion or issues an adverse opinion in its attestation as to the effectiveness of our internal control over financial reporting required by Section 404(b), investors may lose confidence in the accuracy and completeness of our financial reports and the trading price of the ADSs and Ordinary Shares could be negatively affected. We could also become subject to investigations by Nasdaq or the TASE, the SEC or other regulatory authorities, which could require additional financial and management resources.

Irrespective of compliance with Section 404, any failure of our internal controls could have a material adverse effect on our stated results of operations and harm our reputation. As a result, we may experience higher than anticipated operating expenses, as well as higher independent auditor fees during and after the implementation of these changes. If we are unable to implement any of the required changes to our internal control over financial reporting effectively or efficiently, it could adversely affect our operations, financial reporting and/or results of operations and could result in an adverse opinion on internal controls from our independent auditors.

Risks Related to Tax Matters

We may be a passive foreign investment company for U.S. federal income tax purposes, which generally would result in certain adverse U.S. federal income tax consequences to our U.S. shareholders.

In general, a non-U.S. corporation is a "passive foreign investment company" (a PFIC) for any taxable year in which (i) 75% or more of its gross income consists of passive income (the "income test") or (ii) 50% or more of the average quarterly value of its assets consists of assets that produce, or are held for the production of, passive income (the "asset test"). Generally, "passive income" includes interest, dividends, rents, royalties, certain gains, and cash is a passive asset for PFIC purposes.

We have not made a formal determination as to whether we would be classified as a PFIC for the current taxable year or previous taxable years, and do not plan to make such a determination for subsequent years. The determination of whether we are a PFIC depends on the particular facts and circumstances (such as the valuation of our assets, including goodwill and other intangible assets), and may also be affected by the application of the PFIC rules, which are subject to differing interpretations. The fair market value of our assets is expected to depend, in part, upon (i) the market price of the ADSs, which is likely to fluctuate, and (ii) the composition of our income and assets, which will be affected by how, and how quickly, we spend any cash that is raised in any financing transaction.

If we were a PFIC for any taxable year during which a U.S. shareholder owned the ADSs, such U.S. shareholder generally will be subject to certain adverse U.S. federal income tax consequences, including increased tax liability on gains from dispositions of the ADSs and certain distributions and a requirement to file annual reports with the Internal Revenue Service. In light of the foregoing, no assurance can be provided that we are not currently a PFIC or that we will not become a PFIC in any future taxable year. Prospective investors should consult their own tax advisers regarding our PFIC status. See "Material Tax Considerations—Certain U.S. Federal Income Tax Considerations—Passive Foreign Investment Company Considerations."

ITEM 4. INFORMATION ON THE COMPANY

A. *History and Development of the Company*

Our legal and commercial name is BrainsWay Ltd. We are a public company that was incorporated under the laws of the State of Israel in November 2006. We completed our initial public offering on the TASE on January 4, 2007, and on April 16, 2019 we completed the listing of the ADSs on The Nasdaq Global Market. Our Ordinary Shares are currently listed on the TASE under the symbol "BWAY", and the ADSs are currently listed on The Nasdaq Global Market under the symbol "BWAY". Our Israel-based principal executive offices are located at 16 Hartum Street, RAD Tower, 14th Floor, Har HaHotzvim, Jerusalem 9777516, Israel, and our telephone number is +972-2-582-4030. We also have U.S. offices located in Boston and plan to move to New Jersey.

The Securities and Exchange Commission, or SEC, maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at http://sec.gov.

Our web site address is http://www.brainsway.com. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report.

Our capital expenditures for the years ended December 31, 2024, 2023, and 2022 were approximately $3.8 million, $2.3 million and $1.7 million, respectively. Our current capital expenditures primarily involve purchase of equipment and system components in both Israel and the United States. Our research and development costs for the years ended December 31, 2024, 2023, and 2022 amounted to $7.2 million, $6.7 million and $7.7 million, respectively. These research and development costs primarily consisted of expenses incurred in connection with the development of our existing and future indication pipeline, and the development of our Deep TMS system. We expect our capital expenditures and research and development costs to remain significant as we continue our research and development efforts and advance our existing and planned clinical pipeline, in the United States and other strategic markets. We anticipate our capital expenditures and research and development costs in 2025 to be financed from our existing cash and cash equivalents, including the proceeds from the private placement of ADSs and warrants that closed on November 5, 2024, and from our ongoing sales and leases of our Deep TMS systems. For the near future, our investments will mainly remain in the United States and Israel, where our operations and research and development facilities are currently located.

B. Business Overview

BrainsWay is a global leader in advanced noninvasive neurostimulation treatments for mental health disorders. The Company is boldly advancing neuroscience with its proprietary Deep Transcranial Magnetic Stimulation (Deep TMS™) platform technology to improve health and transform lives. We are dedicated to leading through superior science and building on what we believe to be an unparalleled body of clinical evidence. We are the first and only TMS company to be cleared by the U.S. Food and Drug Administration (FDA) for three separate mental health disorder indications based on clinically proven efficacy as demonstrated in pivotal randomized placebo-controlled studies. Current indications include major depressive disorder (MDD) (including reduction of comorbid anxiety symptoms, commonly referred to as anxious depression), obsessive-compulsive disorder (OCD), and smoking addiction.

We have also received CE Mark for a variety of psychiatric and neurological indications. We are focused on increasing global awareness of and broad access to Deep TMS. Deep TMS uses magnetic pulses to stimulate neurons and consequently modulates the physiological activity of the brain. Our technology can either increase brain activity in neuronal networks which are hypoactive, or alternatively decrease brain activity in neuronal networks which are hyperactive. Our proprietary electromagnetic coils, which we refer to as H-Coils, are designed to safely stimulate deep and broad brain regions, which we believe provides an advantage over other available TMS products, which we refer to collectively as Traditional TMS, that generally use a "figure 8" design. In the United States, we sell our Deep TMS system for the treatment of MDD (including reduction of comorbid anxiety symptoms, commonly referred to as anxious depression) and OCD and have also been marketing our products for the treatment of smoking addictions since 2023. We believe that our Deep TMS technology has the potential to be safe and effective for the treatment of a wide range of additional psychiatric, neurological, and addiction disorders. Additional clinical trials of Deep TMS in various psychiatric, neurological, and addiction disorders are underway or planned.

MDD is a common and debilitating mental disorder characterized by physiological symptoms, such as sleep disturbance and changes in appetite, emotional symptoms, such as sadness, despair, emptiness, self-hate, and critique, and cognitive symptoms, such as difficulty concentrating, memory dysfunction, suicidal thinking, and faulty judgment of reality. According to a 2018 study cited by the World Health Organization (WHO), depression affects approximately 300 million people worldwide, with the rate of depression increasing in developed countries. The U.S. National Institute of Mental Health (NIMH) estimates that 21.0 million adults in the United States suffer from a major depressive episode in 2021. Based on 2006-2007 data from the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) study, we estimate that approximately 7 million adult MDD patients in the United States are considered treatment-resistant (i.e., do not achieve remission after four trials of anti-depressant medication), of which we estimate that approximately 6.3 million or more are currently eligible to receive reimbursement for Deep TMS from either governmental or private insurers. Assuming a course of treatment per patient of 33 treatment sessions and a price paid to us per treatment session of $70 (which has historically served as our benchmark price per treatment session), we believe our total annual addressable market opportunity for MDD in the United States is approximately $14.6 billion.

Comorbid anxiety symptoms are common in patients with major depressive disorder. Between sixty and ninety percent of patients with depression have moderate to severe anxiety. As noted above, in the United States, an estimated 21.0 million adults experienced at least one major depressive episode in 2021. Therefore, considering the rate of comorbidity, we estimate that 12.6 to 18.9 million adults experience moderate to severe anxiety in addition to their primary diagnosis of depression. Common anxiety symptoms include nervousness, feelings of panic, increased heart rate, rapid breathing, sweating, insomnia, trembling, and difficulty focusing or thinking clearly. The economic burden in the United States for major depressive disorder totaled $333 billion per year between 2010 and 2018.

OCD is a common, chronic, and long-lasting disorder in which a person has uncontrollable, reoccurring thoughts (obsessions) and behaviors (compulsions) that he or she feels the urge to repeat over and over in a manner that can interfere with all aspects of life, such as work, school, and personal relationships. Based on data from the NIMH, we estimate that approximately 3.1 million adults in the United States suffer from OCD annually. We believe that approximately half of the patients (1.5 million) that have sought help would be considered treatment-resistant (i.e., not having achieved ≥30% improvement of their symptoms from medications and psychotherapy). Assuming our emerging OCD coverage ultimately reaches target of 90% of adults in the United States covered by private health insurance (as with MDD), and assuming a course of treatment per patient of 29 treatment sessions and a price paid to us per treatment session of $70 (which is our benchmark price per treatment session), we believe our total addressable market opportunity for OCD in the United States is approximately $2.7 billion.

Smoking is one of the leading causes of death in developed countries. The addiction to nicotine, similar to the addiction to drugs and alcohol, involves modulation of the brain reward system and causes uncontrollable desire to smoke. 480,000 U.S. adults die from smoking each year. Cigarette smoking has been found to harm nearly every organ system in the body and is the leading cause of preventable death in the U.S. and of disease burden worldwide (Rostron, BL, Chang CM, Pechacek TF. Estimation of cigarette smoking-attributable morbidity in the United States, *JAMA Intern Med*. 2014;174(12):1922-1928). According to the CDC, approximately 28.3 million U.S. adults smoked cigarettes in 2021, with 68% stating they want to quit and 55% actually attempting to quit. Of those attempting to quit, 7.6 million made a serious attempt to quit (i.e., using medication or counseling). Of those smokers attempting to quit either with or without medical assistance, 2.9 million were successful. Reimbursement is not currently available for Deep TMS for smoking addiction, and it is therefore premature to assess the amount of money our customers might be able to collect from potential payors, and willing to pay us, for treatment for this indication. That said, assuming a course of treatment per patient of 18 treatment sessions, and assuming an average price paid to us per treatment session of $50, we believe our total annual addressable market opportunity for smoking addiction in the United States is approximately between $3.9 and $4.1 billion.

Our first commercial H1 Coil Deep TMS product received clearance from the FDA in 2013 for the treatment of MDD in adult patients who have failed to achieve satisfactory improvement from anti-depressant medication in the current episode. Our pivotal trial for MDD demonstrated statistically significant response and remission rates of 38.4% and 32.6%, respectively, in week five of Deep TMS treatment of 20 minutes per session, compared to 21.4% and 14.6%, respectively, after sham treatment. Our Deep TMS system for MDD is currently marketed to and installed at psychiatrists' offices and other facilities principally in the United States and in certain other countries throughout the world.

Additionally, in April 2021, we received FDA clearance for a shorter 3-minute "Theta-Burst" protocol for our MDD treatment. In support of our successful application to the FDA for this protocol, we submitted safety and efficacy data from 146 subjects who had received either the standard Deep TMS protocol or Theta Burst Deep TMS. Clearance was obtained after it was demonstrated that subjects in both groups experienced a statistically and clinically meaningful reduction in depression scores, and the results met the equivalence criteria needed for clearance of the shorter treatment. We believe that certain patients and providers can benefit from these shorter treatment sessions and that this protocol has the potential to expand access to care by providing patients with added flexibility in selecting courses of treatment that may fit better with their lifestyle.

In August 2021, the FDA cleared an expansion of our existing MDD clearance to include the noninvasive treatment of anxiety symptoms among subjects with MDD, commonly referred to as anxious depression. In support of our application for this labeling expansion, we demonstrated statistically significant results from three randomized controlled trials and open label studies which found favorable outcomes with Deep TMS when compared to sham or medication as a standard of care. The data from the three randomized controlled trials studies of Deep TMS demonstrated effect sizes ranging from 0.34 (when compared to sham) to 0.90 (when compared to medication).

In August 2022, based on a randomized, double-blind, controlled multicenter, non-inferiority study of our H1 and H7 Coils, the Company's MDD clearance, which had previously applied to its H1 Coil, was extended to also apply to its H7 Coil. The Deep TMS H7 Coil had been previously cleared for use in treating obsessive-compulsive disorder since 2018, and with this new clearance it can be marketed for the treatment of MDD (including anxious depression). The FDA's grant of clearance was based on its review of successful results from a randomized, double-blind, controlled multicenter trial completed by the Company. The study, which included 144 subjects, found overall efficacy rates for the H7 Coil that were comparable to those achieved with BrainsWay's H1 Coil.

Following receipt of this clearance, a publication of the study in The Journal of Clinical Investigation (JCI) Insight included a retrospective analysis of the study results which identifies preliminary predictors that could help optimize treatment based on individual patients' attributes. This analysis examined clinician rating scales and EEG data revealing intriguing differences between the patient treatment of the two coils. Categorizing patients according to "clusters" of clinical depressive and anxiety baseline symptoms derived from a subset of the Hamilton Depression Rating Scale (HDRS-21) resulted in two subject groups: One with higher severity of the cluster, which on average responded better to the H1 Coil, and another with lower severity of the cluster, which on average responded better to the H7 Coil. This analysis also showed that brain activity measured during the first treatment session correlated with the clinical outcomes ultimately achieved after the full course of treatment. This finding suggests that specific brain patterns observed in an individual's response to either coil during the early stages of treatment might be predictive of the longer-term outcome of treatment with that coil.

In May 2024, the FDA cleared an expansion of our existing MDD clearance allowing for the treatment of patients with late life depression. The expanded clearance covers MDD patients ages 22 to 86, changing the previous upper age limit of 68. This expanded clearance makes our Deep TMS the first and only form of TMS indicated for the treatment of patients over the age of 68 suffering from MDD, including those with comorbid anxiety symptoms. Our application to the FDA included study data showing, for example, that MDD patients over 68 years of age who were treated with our H1 Coil demonstrated 69% and 62% response and remission rates, respectively, using the HDRS-21, and 65% and 35% response and remission rates, respectively, using the self-administered Patient Health Questionnaire-9 (PHQ-9).

We were the first medical device company to offer an FDA-authorized noninvasive treatment for OCD, the marketing authorization for which we received in August 2018 as an adjunct therapy for adult patients suffering from OCD. Our pivotal trial for OCD demonstrated statistically significant response and partial response rates of 38.1% and 54.8%, respectively, after six weeks of daily active Deep TMS treatment of 19 minutes per session, compared to 11.1% and 26.7%, respectively, after sham treatment. We remain the only company to have proven clinical efficacy for this indication based on a randomized, double-blind, placebo-controlled, multicenter trial, and our competitors that have since obtained FDA clearance for this indication have done so in part relying on our clinical data.

We are the first and only TMS company to offer an FDA-cleared treatment for smoking addiction, which also represents the first FDA clearance for any TMS device in the addiction space. We received this clearance from the FDA in August 2020 for use of our Deep TMS system as an aid in short-term smoking cessation in adults. Our pivotal trial for smoking addiction demonstrated statistically significant results, with a 28.4% Continuous Quit Rate (CQR) – defined as abstinence from smoking for any 4-week period during the study – achieved among patients who completed the full course of therapy, compared with 11.7% of completers undergoing sham treatment.

We believe that Deep TMS represents a platform technology with the potential to treat a variety of other psychiatric, neurological and addiction disorders. We are actively conducting and/or planning clinical trials in new areas, including neurological and/or addiction disorders.

Our current customers are principally doctors, hospitals, and medical centers in the field of psychiatry. Treatment with Deep TMS is typically performed as an office-based procedure using our Deep TMS system, which consists of our proprietary H-Coil helmet, as well as several other components, including a stimulator, cooling system, positioning arm and an operator interface. A course of treatment for MDD typically requires 20 treatment sessions five times a week over a period of four weeks, and thereafter up to 24 additional maintenance-continuation sessions twice weekly over a period of up to 12 weeks. The standard Deep TMS treatment protocol for OCD requires 29 treatment sessions over six weeks. A course of treatment for smoking addiction typically requires 18 treatment sessions, comprised of treatment five times a week over a period of three weeks, followed by treatment once per week for an additional three weeks. Each standard MDD, OCD or smoking addiction session lasts 20 minutes, 19 minutes, and 18 minutes, respectively. For Deep TMS for MDD, the FDA has also cleared a 3 minute “Theta Burst” treatment protocol. Patients may experience some discomfort during treatment and must use earplugs to reduce exposure to the loud sounds produced by the device. The treatment requires no anesthesia, hospitalization or sedation, and no systemic side effects are associated with the therapy.

We estimate that over 90% of the total private insurer adult covered lives in the United States have coverage for reimbursement of MDD treatment with Deep TMS. In addition, our MDD treatment (including for reduction of anxiety symptoms, commonly referred to as anxious depression) with Deep TMS is eligible for reimbursement from Medicare. Deep TMS treatment for MDD reimbursement coverage is generally available after between one and four failed (inadequate response or intolerable) trials of anti-depressant medications. However, there is an increasing trend to reduce the number of prior failed medication treatments required to qualify for coverage and thus to place Deep TMS for MDD earlier within the continuum of care. We are actively engaged in efforts to work with payors to facilitate a continuation of this trend.

In 2021, for the first time, several payors issued policies and coverage determinations allowing for reimbursement coverage applicable to Deep TMS for OCD, with over 90 million covered lives in the U.S. eligible for coverage as of March 2023. Positive coverage decisions for Deep TMS for OCD have been issued by Centene Corporation (with 26 million covered lives), Health Care Service Corporation (HCSC) (with 17 million covered lives), TriCare (with 9.6 million covered lives), Cigna Corporation (with 17 million covered lives), Highmark (with 6.8 million covered lives), Premera (with 2.6 million covered lives) and LifeWise (with 2.2 million covered lives). Additionally, one of the seven Medicare Administrative Contractors (MACs) in the US, Palmetto GBA, has published its final Local Coverage Determination (LCD) in 2022 extending coverage applicable to Deep TMS treatment for OCD. While the criteria for Deep TMS for OCD coverage varies with each payor, generally, coverage requires the failure of between two and four medication trials before qualifying for reimbursement. Our strategy is to look for ways to facilitate increased coverage for OCD treatment by more payors, including both commercial and governmental.

Reimbursement is not yet available for Deep TMS for smoking addiction. In October 2023, the Clinical TMS Society (CTMSS), an influential peer group, published the first coverage recommendations for TMS for smoking addiction.

In Israel, in June 2022, for the first time the Israeli Ministry of Health has approved coverage applicable to our Deep TMS system for the treatment of MDD. The inclusion of the treatment within Israel's health basket of essential medical services means that the country's health funds must now make the treatment available to qualifying patients free of charge. Qualifying patients include adults over the age of 21 with depression who either have not responded to two prior antidepressants or are intolerant to other treatment alternatives. Coverage may be provided for up to 40 treatment sessions, which are to be administered in hospitals. Moreover, in Australia, in November 2021, for the first time, coverage applicable to Deep TMS for MDD was granted for adults over the age of 18. Coverage in Australia is available for 35 treatment sessions.

The United States is our primary and most strategic market, representing approximately 81% of our revenues for the year ended December 31, 2024 and approximately 75% of our revenues for each of the years ended December 31, 2023 and 2022. We operate in the United States through our wholly owned subsidiary, BrainsWay USA Inc, as a direct marketing and sales channel, where we currently have existing sales, marketing, and support infrastructure. We generate revenue from various flexible pricing models that are designed to maximize market penetration. For the year ended December 31, 2024, we generated revenues in the United States of $33.2 million, an increase of 38.9% as compared to $23.9 million for the year ended December 31, 2023.

On a consolidated basis, we generated revenue from leasing, one of our two main categories of activity, of $14.5 million, $8.5 million and $9.2 million for the years ended December 31, 2024, 2023 and 2022, respectively. Our revenue from sales, our other main category of activity, was $22.4 million, $20.4 million and $16.2 million for the years ended December 31, 2024, 2023 and 2022, respectively. Our revenue from sale-related and other services, was $4.1 million, $2.9 million and $1.8 million for the years ended December 31, 2024, 2023 and 2022, respectively.

Our Deep TMS Platform

Our proprietary Deep TMS technology is intended for noninvasive treatment of psychiatric, neurological, and addiction disorders. The system includes an H-Coil uniquely designed to transmit electric current flows at varying rates, creating an electromagnetic field that serves to depolarize cortical neurons and activate neural networks in certain areas of the brain in accordance with the operating frequency, with the effect of treating the disorder associated with that area of the brain. Our innovative technology is capable of stimulating deeper and broader regions of the brain than any other commercially available TMS product.

We have developed a number of H-Coils with differing configurations, building upon our technology with important changes for each coil. For different regions of the brain which are known to be associated with specific brain disorders, we offer different H-Coils that are designed to influence the neurological networks of those regions. For example, we have two H-Coils, targeting different brain regions, that may be used for MDD (including anxious depression), one H-Coil used for OCD, and one H-Coil used for smoking addiction. Some of our H-Coils are also able to treat more than one indication. The H-Coils transmit pulses which are generated by a power supply, known as a stimulator. We developed our own proprietary stimulator that is more advanced than our previously used third-party stimulator and improves our approved Deep TMS systems through its user-friendly software interface and other features. We expanded our FDA clearances in MDD, OCD, and smoking addiction, which had previously applied to our older model systems with third-party stimulators, to also include current systems which incorporate our proprietary stimulator. In addition, we are currently developing and initiated clinical testing of our next generation multichannel device, which includes our patented "rotational field" TMS or "Deep TMS 360°™" technology. The patented multichannel aspect of this technology allows for simultaneous modulation of different areas of the brain with independent stimulation parameters, and the patented rotational field aspect employs a method of stimulation that enables activation of a greater number of neurons in the brain via two orthogonal TMS coils which are placed perpendicular to each other and operated with a time lag in order to induce a circularly rotating electric field. This enables stimulation of neurons in various orientations, in contrast to currently available TMS devices which stimulate only neurons parallel to the induced field. We recently launched two new feasibility studies involving this next generation device, one in the neurological field of post-stroke rehabilitation, and the other for OCD using an accelerated protocol. Furthermore, in an August 2024 article in the Brain Stimulation Journal, our first pilot data on the efficacy of our rotational field technology was published. This feasibility study involved 12 depression patients and compared the efficacy of our rotational field helmet with that of our H7-Coil. Albeit via a small sample size, the data demonstrated significantly greater improvement with the rotational field helmet in the depressive symptoms as reflected by the HDRS-17 rating scale compared to the H7-Coil. We plan to further study the safety, efficacy and various possible applications for this next generation technology and believe it has the potential to make our Deep TMS systems even more attractive to clinicians, researchers and patients.

Our Deep TMS system is comprised of the various key components, as illustrated below. Each system can accommodate two helmets, and a third helmet can be incorporated using a separate auxiliary stand.

The key components of our Deep TMS system are:

- Helmet, including proprietary H-Coil
- Stimulator, which provides the power supply and source of the Deep TMS electromagnetic field
- Graphic User Interface (GUI)
- One or More Arm(s)/Positioning Device(s)
- Cooling System
- Movable Medical Cart

We believe our Deep TMS platform has many advantages relative to other TMS systems. Our H-Coil is a flexible device encased in a helmet that fits securely around the patient's head. This, together with the proprietary structure of our H-Coil, means that a much larger surface area of the head is in contact with the H-Coil than would be in contact with a figure 8-style coil. Furthermore, if the patient moves his or her head, the helmet—and thus the H-Coil—moves along with it, eliminating the need for features which prevent the patient from moving his or her head during therapy. In contrast, all other currently available TMS products, which we refer to as Traditional TMS, generally utilize a variation of a figure 8 coil that is placed adjacent to the scalp of the patient and needs to be specifically positioned and attached to the head in order to deliver focal stimulation of the desired area of the brain. Whereas some figure 8 coils are handheld by the operator, others are attached to an apparatus designed to minimize the ability of the patient to move the head away from the relevant portion of the coil during therapy, which would prevent the patient from achieving the required stimulation. These features either alert the operator in the event of a shift of the patient's head away from the coil, or actually fasten the coil next to the patient's head. In either case, only a small surface area on the patient's head is likely to come into contact with the figure 8 coil. Traditional TMS is limited to stimulating relatively narrower and shallower areas of the brain, and the manual positioning of the figure 8 coil in Traditional TMS may cause inaccuracies in the region treated. Studies suggest that the figure 8 coil misses the target in a substantial number of patients.

A course of treatment for MDD typically requires 20 treatment sessions five times a week over a period of four weeks, and thereafter up to 24 additional maintenance-continuation sessions twice weekly over a period of up to 12 weeks. The standard Deep TMS treatment protocol for OCD requires 29 treatment sessions over six weeks. The clearance for this indication is categorized as an adjunct therapy, which means that it should be administered in conjunction with other first-line therapies and/or medications, as determined in the independent medical judgment of the treating healthcare professional on a case-by-case basis. A course of treatment for smoking addiction typically requires 18 treatment sessions, comprised of treatment five times a week over a period of three weeks, followed by treatment once per week for an additional three weeks. A standard MDD, OCD or smoking addiction session lasts 20, 19 and 18 minutes, respectively. For Deep TMS for MDD, the FDA has also cleared a 3 minute "Theta Burst" treatment protocol. The protocols for OCD and smoking addiction also require a short provocation procedure (i.e., triggering of OCD or smoking symptoms, as relevant), to ensure that Deep TMS is calibrated to treat the particular needs of the patient, which is then followed by a Deep TMS session. The treatments are typically office-based procedures performed in private clinics, hospitals, universities, and other medical centers. As with Traditional TMS, Deep TMS is contraindicated for patients with metallic objects or implanted stimulator devices in or near the head, including cochlear implants, deep brain stimulators, other implanted electrodes or stimulators, aneurysm clips or coils, stents, bullet fragments, jewelry, and hair barrettes. During treatment, the patient must use earplugs to reduce exposure to the loud sounds produced by the device.

We believe that Deep TMS has additional advantages over Traditional TMS because it is capable of stimulating deeper and broader areas of the brain. Studies have shown that while Traditional TMS devices create an electromagnetic field estimated to penetrate the cortical surface of the brain up to depths in the range of 0.7 centimeters to 1.0 centimeters, Deep TMS creates a magnetic field with a slower and more gradual deterioration that reaches depths of approximately 1.5 to 2 centimeters for BrainsWay's H-Coils. Studies have also shown that BrainsWay's H1 Coil has the capacity for total stimulated brain volume of 17 cm3 compared to 3 cm3 for the figure 8 coil used in Traditional TMS. We believe this deeper and broader penetration of Deep TMS provides an advantage over Traditional TMS because of its potential to address a wider variety of brain disorders, and for a given disorder, to stimulate more relevant brain structures.

The training for operation of a Deep TMS system is relatively simple and generally requires a day of training which includes classroom lectures as well as a number of hours of practice providing treatment. The OCD and smoking training protocols also include tailored provocation procedures tailored to provoke the specific obsessions, compulsions, or addictions, as relevant, of the subject.

Competitive Strengths

- ***Deep TMS technology has advantages over Traditional TMS***

We believe that Deep TMS, with our proprietary H-Coil design, allows for deeper and broader penetration of regions of the brain compared to Traditional TMS, permitting Deep TMS to address a wider variety of psychiatric, neurological, and addiction disorders. We believe that this deeper and broader penetration provides us with the opportunity to address more indications with potentially greater clinical efficiency because Deep TMS stimulates a larger portion of the brain and is less sensitive to coil orientation and position during treatment. In addition, Deep TMS is administered at stimulation levels that we believe are as safe and tolerable as Traditional TMS.

- ***We have obtained FDA marketing authorizations of Deep TMS for MDD (including anxious depression), OCD, and smoking addiction***

We are the only manufacturer of a TMS device to have been cleared by the FDA for three separate mental health disorder indications based on clinically proven efficacy which was demonstrated in pivotal randomized placebo-controlled studies conducted on the device: MDD, for which our H1 Coil device was cleared by the FDA in 2013, (and which clearance was expanded in August 2021 to include reduction of comorbid anxiety symptoms, or anxious depression, and then again in May 2024 allowing for treatment of MDD patients ages 69-86) and for which our H7 Coil received 510(k) clearance from the FDA in August 2022; OCD, for which our device was classified by FDA as a Class II device in a *de novo* classification in August 2018; and smoking addiction, for which our device was cleared for short term treatment in August 2020. For MDD (including anxious depression), we are one of only two TMS companies that have performed clinical studies supporting an FDA clearance. For OCD, we are the only company to have received such clearance based on clinical data from a pivotal study on the device. We remain the only company to have proven clinical efficacy for OCD based on a randomized, double-blind, placebo-controlled, multicenter trial, while other competitors that have since obtained FDA clearance for this indication, have done so in part relying on our clinical data. For smoking addiction, and indeed addictions generally, we are the first and only TMS company to have received FDA clearance.

- ***Our clinical data supports the efficacy and safety of Deep TMS***

We believe that our clinical data supports the efficacy and safety of Deep TMS, which could accelerate its market acceptance by clinicians. Our pivotal trial for MDD demonstrated statistically significant response and remission rates of 38.4% and 32.6%, respectively, in week five of Deep TMS treatment of 20 minutes per session, compared to 21.4% and 14.6%, respectively, after sham treatment. Our pivotal trial for OCD demonstrated statistically significant response and partial response rates of 38.1% and 54.8%, respectively, after six weeks of daily active Deep TMS treatment of 19 minutes per session, compared to 11.1% and 26.7%, respectively, after sham treatment. Post-marketing data on Deep TMS for OCD published in 2021 found that 58.4% of those who completed 29 sessions achieved response, and 73% of patients, including those who did and did not complete the full course of therapy, demonstrated response at least once prior to the conclusion of treatment. Our pivotal trial for smoking addiction demonstrated a statistically significant difference in reaching the Continuous Quit Rate (CQR), defined as 4 weeks of continuous abstinence from smoking at any point during the study. Among the 168 participants in the study who completed three weeks of Deep TMS or sham treatment, plus the mandatory additional three weeks of follow-up (reaching the six-week endpoint), the CQR was 28.4% in the treatment group, compared to 11.7% in the sham group (p=0.007). Overall, Deep TMS treatment was safe and well-tolerated by patients in these trials.

With respect to our MDD labeling expansion which now includes anxious depression, data from 573 patients who had undergone Deep TMS treatment in 11 studies, including both randomized controlled trials (RCT) and open-label studies, which was submitted by us in support of our application to the FDA, demonstrated a treatment effect that was consistent, robust, and clinically meaningful for decreasing anxiety symptoms in adult patients suffering from major depressive disorder. An analysis of our data found favorable outcomes with Deep TMS when compared to sham or medication as standard of care. For example, using the Cohen's d statistical method, data from the 3 randomized studies of Deep TMS demonstrated effect sizes ranging from 0.34 (when compared to sham) to 0.90 (when compared to medication). As a reference, published articles from approximately 16,000 subjects in over 70 studies of drug-based anxiety treatments – including studies of standard-of-care medications frequently prescribed for patients suffering from anxious depression and general anxiety disorder – report effect sizes ranging from 0.2 – 0.37.

- ***We have a commercial track record for MDD and OCD***

We have an established commercial footprint in the United States for Deep TMS for MDD, including our own sales, marketing, and support employees. We estimate that over 90% of total private insurer covered lives in the United States have coverage for reimbursement of MDD treatment with Deep TMS. In addition, our MDD treatment with Deep TMS is eligible for reimbursement from all Medicare Administrative Contractors (MACs), and our OCD treatment is currently covered by one of the seven MACs. We are also currently selling Deep TMS for MDD in Canada, Europe, Asia, India, Israel, and certain other countries. We received reimbursement coverage applicable to Deep TMS in Australia in November 2021 and in Israel in June 2022. We are also increasing our commercialization efforts for Deep TMS for OCD. Our installed base of Deep TMS systems for MDD facilitates faster expansion into OCD because clinicians who already have a Deep TMS system only need to lease or purchase an add-on arm and helmet to the existing system. In 2021, for the first time, several payors issued policies and coverage determinations allowing for reimbursement coverage applicable to Deep TMS for OCD, with over 90 million covered lives in the U.S. eligible for coverage as of March 2024. Positive coverage decisions for Deep TMS for OCD have been issued by Centene Corporation (with 26 million covered lives), Health Care Service Corporation (HCSC) (with 17 million covered lives), TriCare (with 9.6 million covered lives), Cigna Corporation (with 17 million covered lives), Highmark (with 6.8 million covered lives), Premera (with 2.6 million covered lives) and LifeWise (with 2.2 million covered lives). Additionally, one of the seven Medicare Administrative Contractors (MACs) in the US, Palmetto GBA, published a final Local Coverage Determination (LCD) in 2022 extending coverage applicable to Deep TMS for OCD. While the criteria for this emerging Deep TMS for OCD coverage varies with each payor, generally, coverage requires the failure of between two and four medication trials before qualifying for reimbursement. Our strategy is to look for ways to facilitate increased coverage for OCD treatment by more payors, including both commercial and governmental. After the receipt of FDA clearance for our Deep TMS product for smoking addiction, we initiated a clinical data collection effort to facilitate a long-term commercial plan for this product.

- ***Our flexible pricing models are designed to achieve market penetration***

We market our products utilizing two basic pricing models: (i) a fixed-fee lease model enabling unlimited use; and (ii) a sales or purchase model. We also offer and/or are considering offering a pay per use model to certain customers in certain territories. Warranty and support are either included (in varying degrees and for varying periods) or may be purchased as part of all pricing models. Additional potential revenues may be derived from extended warranty fees paid for the system for service coverage beyond the standard included warranty period, and from variable or usage fees based on the number of treatments performed with the system. We are also able to leverage our platform technology, which includes the ability to treat multiple indications using different H-coil helmets, to facilitate transactions utilizing combined pricing models often involving a single system with one or more add-on helmets. We believe that our different pricing models offer flexibility and allow for increased market acceptance among clinics and psychiatric professionals. Based on our commercial data, and depending on insurer reimbursement rates, we believe our psychiatrist customers for MDD systems can generate up to approximately $10,000 of gross revenues per patient, and in some cases more, for a course of treatment using our system. While OCD coverage is still emerging, we believe that our customers can generate up to approximately $8,800 of gross revenues per OCD patient.

- ***Deep TMS has potential application to a range of psychiatric, neurological, and addiction disorders***

Our clinical studies, including various feasibility studies, suggest that our Deep TMS system has the potential to serve as a platform technology that can address a potentially wide variety of other psychiatric, neurological, and addiction disorders by using the appropriate H-Coil structure for different targeted brain regions. We are the first and only TMS company to be cleared by the FDA for three separate mental health disorder indications based on clinically proven efficacy as demonstrated in pivotal randomized placebo-controlled studies. Current indications include MDD, OCD, and smoking addiction. Moreover, in August 2021, we received 510(k) clearance from the FDA expanding our MDD indication to also include treatment of depressed patients for the reduction of comorbid anxiety symptoms (commonly referred to as anxious depression). In 2021 we also received a clearance for a shortened three-minute depression protocol and a labeling expansion for anxious depression through subsequent 510(k) clearances. In 2022, the FDA extended the clearance of our H7 Coil to include the treatment of MDD (including anxious depression). Our shortened three-minute depression protocol, however, continues only to apply for our H1 Coil. In 2024, we received FDA clearance for an expansion of our existing MDD clearance allowing for the treatment of patients within the 69-86 age range suffering from late life depression.

Beyond our existing indications, we are also considering further clinical trials in other neurological and/or addiction areas.

Our Strategy

We are currently focused on expanding the commercialization of Deep TMS with respect to MDD, OCD and smoking addiction. In September 2021, we received a 510(k) clearance from the FDA for expansion of our Deep TMS MDD treatment also to include treatment for reduction of anxiety symptoms, commonly referred to as anxious depression. In August 2022, we received FDA clearance for treating anxious depression with our H7 Coil, which had been previously cleared for treating OCD. In May 2024, we received FDA clearance for an expansion of our existing MDD clearance allowing for the treatment of patients within the 69-86 age range suffering from late life depression. In addition, we are actively engaged in research for other potential applications for Deep TMS for patients suffering from neurological conditions and addictions. For each potential indication, we assess and evaluate our technology's efficacy, safety, patent status, market potential, and development and regulatory pathways. Our systematic approach to evaluating and developing applications for Deep TMS allows us to continually build upon our clinical pipeline, and advance those applications with the greatest clinical effect and revenue potential. We also plan to advance other technological innovations in the neuromodulation space for the improvement of our products. For example, we are currently developing and initiated clinical testing of our next generation multichannel device, which includes our patented "rotational field" TMS or "Deep TMS 360°™" technology, allowing for simultaneous modulation of different areas of the brain and stimulation of neurons in various orientations to cover a greater number of neurons.

Specific elements of our strategy include the following:

- ***Increase the full-scale commercialization of Deep TMS for MDD, OCD and smoking addiction***

We are continuing to scale up our commercialization of Deep TMS for MDD as we seek to further penetrate the MDD market, including based on the FDA-cleared treatment to anxious depression (received in September 2021) and the H7 Coil cleared by the FDA in August 2022 for such treatment. We continue to focus our principal commercial activity on the U.S. market in light of the market size and wide range of insurance coverage. In addition, we continue our full-scale commercialization of Deep TMS for OCD, which is the first noninvasive medical device FDA-authorized for the treatment of OCD, with reimbursement coverage for this indication obtained since 2021 from payors covering over 90 million covered lives in the United States. After the receipt of FDA clearance for our products for smoking addiction, we initiated a clinical data collection effort to facilitate and support the long-term viability of the commercial plan for this product.

- ***Pursue additional indications and technological innovations for Deep TMS***

We are considering expanding the application of Deep TMS to other areas including neurological and/or addiction disorders. We intend to progress these plans ourselves and through our relationships with third-party researchers and clinical institutions in conducting clinical trials for additional psychiatric, neurological, and addiction disorders. With this approach, we address psychiatric, neurological, and addiction disorders that we believe present some of the most promising market opportunities for Deep TMS.

- ***Expand reimbursement coverage for Deep TMS for OCD, smoking addiction and other approved indications in the future***

A key prerequisite to the successful market acceptance of Deep TMS is securing sufficient insurance/third-party payor coverage. The scope and level of coverage are also key factors in our ability to penetrate the market and to expand further use of our Deep TMS system by healthcare providers and facilities for the benefit of the larger patient population. Our MDD treatment with Deep TMS is widely eligible for reimbursement, including from Medicare, subject to the satisfaction of certain clinical criteria. We aim to achieve similar levels of reimbursement for Deep TMS for OCD. We also aim to secure coverage in various jurisdictions outside of the United States, For example in 2021 and in 2022, favorable coverage decisions applicable to TMS for MDD were issued in Australia and Israel, respectively. Although there is not currently any reimbursement for smoking addiction, in October 2023 the Clinical TMS Society, an influential peer group, published the first coverage recommendations for smoking. We believe that our ability to secure coverage from payors will be a key factor in the long-term success of this indication.

- ***Develop innovative enhancements and features for our Deep TMS systems***

We continue to develop innovative enhancements and features for our Deep TMS systems to expand the applicability of Deep TMS to additional indications and improve the capabilities of the systems for approved indications. For example, in December 2021 we displayed a future version of the platform that will serve as the basis for our next generation Deep TMS system, which includes our patented "rotational field" TMS or "Deep TMS 360°™" technology, allowing for simultaneous modulation of different areas of the brain and stimulation of neurons in various orientations to cover a greater number of neurons. Our novel rotational field technology involves the operation of two orthogonal coils to induce a rotating field in the brain, allowing for stimulation of neurons in various orientations. We have recently begun to test the clinical efficacy of this next generation technology in 2 new feasibility studies – one for post-stroke rehabilitation, and the other for OCD using an accelerated protocol. We further believe these enhancements hold the potential to make Deep TMS even more attractive for clinicians, researchers, and patients, and may serve to better position its use in neurology.

- ***Increase our international commercial footprint***

We are working to expand our existing commercial footprint in Europe, Asia, Latin America, Australia, and the broader Middle East, and to pursue commercialization in additional markets. We currently have distribution and agent agreements in various territories, including, notably, Canada, Italy, Spain, Czech Republic, Japan, South Korea, Taiwan, Thailand, Greece, and India. In Israel, we directly distribute to our customers.

We obtained regulatory approval with the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan, which is a precondition to receiving reimbursement coverage under the Japanese National Health Insurance Plan. After working extensively with our Japanese distributor with the relevant bodies in Japan, in 2024 we succeeded in updating the guidelines issued by the Japanese Society of Psychology and Neurology to include coverage for Deep TMS. Commercial sales of our systems thus commenced in 2024, and our Japanese distributor has initiated a Post Marketing Study (PMS) in Japan to assess the efficacy and safety of our treatment on the local population, which is a required commercialization criteria for this territory.

Deep TMS for MDD

Disease Overview

MDD is a common and debilitating mental disorder characterized by physiological symptoms, such as sleep disturbance and changes in appetite, emotional symptoms, such as sadness, despair, emptiness, self-hate and critique, and cognitive symptoms, such as difficulty concentrating, memory dysfunction, suicidal thinking, and faulty judgment of reality. MDD is expressed differently, and in different intensities, among patients, and significantly impacts the functioning in all aspects of life. Patients are often not diagnosed due to low levels of awareness of the disease and its symptoms by the patient and the family doctor involved, or due to prejudice related to psychotherapy. In order to be diagnosed with MDD, a patient must display symptoms that are present most of the day, nearly every day, for at least two weeks. A diagnosis of MDD is established by clinical interview, and an assessment of whether a patient reports a collection of the relevant symptoms.

MDD is a recurrent disease and follows a fluctuating course over an individual's lifetime, with periods of remission and relapse. If an initial episode of MDD is resolved, the return of depressive symptoms during the first nine months thereafter is referred to as a relapse of the illness and is generally considered to be part of the same depressive episode. When depressive symptoms return more than twelve months after the initial episode of MDD is resolved, it is considered to be a recurrence of the illness and is deemed a new and distinct episode. A response to treatment is commonly measured as a clinically significant decrease in symptoms on a standardized rating scale from baseline scores. When a patient shows no or nearly no symptoms, the patient is referred to as being in remission. Experiencing one episode of MDD places an individual at an estimated 50% risk of experiencing an additional episode of MDD. Approximately 80% of those individuals who have experienced two episodes of MDD will experience an additional episode.

In people with MDD, the complex system of neuronal communication does not function properly. One of the most important discoveries in neuroscience has been the recognition that improper regulation of one or more of the three major neurotransmitters, serotonin, norepinephrine, and dopamine, plays a key role in a patient's depression. This understanding has guided psychiatric drug development and the treatment of depression for more than three decades by placing a major focus on targeting chemically-based mechanisms. The relatively recent introduction of TMS as a targeted, circuit-based treatment option has reintroduced the importance of electrical mechanisms in restoring proper function to neuronal pathways to treat depression.

Market Information

According to the WHO, an estimated 280 million people worldwide including 21.0 million individuals in the United States develop a major depressive episode within a given year. We estimate that there are 69 million depression patients in India, 71 million in China, 37 million in Europe, and 6 million in Japan. MDD is one of the most prevalent mental illnesses across all demographics. According to the Clinical Psychology Review, MDD follows a chronic course of repeated bouts of remission and recurrence in about 50% of people affected. The chronic nature of MDD makes it the leading cause of years lost to disability in the world, and MDD patients are more likely to commit suicide. According to the American Journal of Psychiatry, roughly 2% of MDD patients treated as outpatients, and 4% of those hospitalized because of their condition, commit suicide. In addition, studies suggest that some patients exhibit a higher mortality rate even after controlling for suicide. Due to the prevalence and severity of MDD, the treatment of the disorder is a pressing concern for mental health professionals.

We focus on the population segment for whom conventional treatment (medicinal and/or psychotherapy) of MDD has not provided the required clinical response, as patients who are treatment-resistant are entitled to reimbursement for Deep TMS treatment. It is customary to assess that approximately half of the sufferers from the illness do not respond to the first medicinal treatment, and that one-third do not find conventional solutions to their suffering at all. In addition, even among patients who receive medicinal treatment that is found effective, many suffer from severe side effects that cause them to abandon the treatment and be left with their depressive condition. We aim to meet the enormous need of these groups of treatment-resistant patients and provide effective, non-medicinal treatment which is not accompanied by the systemic side effects of the medication on the one hand and the electroconvulsive therapy (ECT) treatments on the other hand (such as damage to memory).

Treatment Options for MDD

Treatment for patients diagnosed with MDD varies by disease severity. For patients with mild to moderate depression, first line treatment is usually psychotherapy (the treatment of mental disorders by psychological means), especially if the patient is able to identify particular stressors or sources of depressive symptoms. For some of these patients, pharmacotherapy (anti-depressant medication) may be used to supplement psychotherapy. For patients with moderate depression, pharmacotherapy with or without psychotherapy is the recommended initial treatment. TMS is a second line therapy for the treatment of a patient who has failed to achieve satisfactory improvement from prior pharmacotherapy. For patients with severe depression and later stage treatment, somatic treatments such as ECT may be an option.

The central group of anti-depressant medicines is the selective serotonin reuptake inhibitors (SSRI) and selective serotonin and norepinephrine reuptake (SNR).

A significant systematic review of the existing evidence linking serotonin levels to depression was published in *Nature* in July of 2022. The review concluded that "[t]he main areas of serotonin research provide no consistent evidence of there being an association between serotonin and depression, and no support for the hypothesis that depression is caused by lowered serotonin activity or concentrations." The review, however, did not refute the body of evidence showing that randomized clinical trials (RCTs) comparing SSRIs to placebo have consistently demonstrated statistical significance in reducing depression. As such, there has not been an appreciable change in prescribing patterns. Thus, SSRIs are effective for some patients in treating depression, but there is a gap in understanding as to why.

Positive data published in May 2023 in the Journal of Psychiatric Research demonstrated compelling data with respect to the effectiveness of Deep TMS for MDD, showing a high response rate from patients in an average period of 16 sessions or 21 days after beginning treatment with Deep TMS.

A publication in October 2023 in the Psychiatry Research journal published new real-world post-marketing data demonstrating the efficacy of accelerated Deep TMS for the treatment of major depressive disorder (MDD). The standard FDA-cleared Deep TMS protocol involves one treatment session per day, five days a week for 4 weeks, followed by a maintenance period. However, there has been recent interest in "accelerated" dosing schedules which involve multiple sessions each day to allow for quicker overall treatment time. Data collected using this approach to treat depression was compiled from clinical sites and analyzed in this study. Key findings from this post-marketing study included data demonstrating efficacy of Deep TMS administered over multiple sessions each day to allow for quicker overall treatment time for depression patients. Following publication of these post-marketing results, in June 2024 we announced the launch of a prospective, randomized, controlled, multicenter clinical trial evaluating an accelerated treatment protocol for our Deep TMS system to treat MDD. The clinical trial is anticipated to enroll over 100 patients with MDD who will be split into two groups – one receiving a novel accelerated treatment protocol featuring an acute phase over several treatment days, and the other receiving the FDA-cleared standard-of-care protocol which entails an acute phase over several weeks. The design of this non-inferiority trial, which was determined in discussion with the FDA, aims to compare the outcomes achieved with the accelerated Deep TMS protocol versus the current standard-of-care Deep TMS protocol.

The limitations of anti-depressant medications in MDD treatment were demonstrated in the STAR*D study, a large clinical trial funded by the NIMH that enrolled more than 4,000 adult MDD patients at 41 clinical sites to examine the outcomes to a sequenced series of anti-depressant medication attempts that mimicked best practices. In the study, only 36.8% and 30.6% of patients achieved remission in their first and second medication attempts, respectively. In addition, 30-40% of MDD patients did not experience a meaningful response to anti-depressant medication. An analysis conducted in 2020 which was based on the STAR*D study further reinforced the limitations of anti-depressant medications in MDD treatment, finding that only 21% of patients achieve remission with medication and that 58% achieved no meaningful benefit with a second step switch to a monoaminergic antidepressant. This means that there is still a significant number of patients who could benefit from an alternative treatment such as Deep TMS.

TMS has been used as an antidepressant therapy since 2008. Currently, TMS for MDD is generally recommended for treatment-resistant MDD patients. Until recently payors typically required that patients fail multiple antidepressant medications prior to receiving TMS; however, there has been a trend which continued in recent years to reduce the number of required failures to one or two medication failures before qualifying for TMS. Based on research showing that TMS is effective in treating depressive symptoms in patients earlier within the continuum of care, many payors have now reduced the number of prior failed medication trials needed to qualify for Deep TMS for MDD. Specifically, about 90 million covered lives in the US with commercial coverage now qualify for Deep TMS for MDD after two to three failed medication trials, and approximately 42 million lives in the US with Medicare reimbursement coverage qualify after just one to two failed medication trials.

Drug side effects play a decisive role in treatment selection and modification, as each class of drugs is associated with a host of side effects, some more severe or more common than others. For many patients, the side effects associated with pharmacological treatments for depression are a primary reason underlying low compliance and, subsequently, low efficacy of treatment. The most common side effects include gastrointestinal symptoms, sedation, insomnia, weight changes, sexual dysfunction, nervousness, sleep disruption, nausea, headaches, and cardiovascular or neurological effects. Side effects may also cause patients not to adhere to the treatment or to abandon it. On initiation of anti-depressant pharmacotherapy, close monitoring for response to treatment and development of side effects is essential. In addition, correlation was discovered between consumption of SSRI medications and actualization of suicidal thoughts in youth, and some SSRI group medicines require strict diets and medical supervision. In August 2022, the FDA has approved AUVELITY (dextromethorphan HBr -bupropion HCl) extended-release tablets for the treatment of MDD in adults. AUVELITY is the first and only oral N-methyl D-aspartate (NMDA) receptor antagonist approved for the treatment of MDD. The most common side effects of the recently approved NMDA treatment include dizziness, headache, diarrhea, somnolence, dry mouth, sexual dysfunction, and hyperhidrosis.

For TMS, however, no significant side effects have been observed, other than mild headaches for a short period of up to a few hours after the treatment, and rare instances of short seizures. The few side effects associated with TMS treatment is considered one of its main advantages. The most common side effect of Deep TMS treatment is short-lasting mild pain or discomfort around the site of coil application. This side effect usually only lasts during the first week of treatment. Other adverse reactions such as jaw and face pain, muscle pain, spasm or twitching, and neck pain were reported as mild or moderate and were also resolved shortly after treatment, as well as seizures in certain patients. The less severe side effects associated with Deep TMS make it an attractive option for patients.

Alternatives to pharmacological and TMS-based treatments include ECT, vagal nerve stimulation (VNS), and deep brain stimulation (DBS). ECT, the main psychotherapy alternative to TMS, is a therapy in which patients are administered brief electric currents through the brain. ECT is a noninvasive treatment carried out by a doctor under full anesthesia and muscle relaxant medicines, and patients often undergo partial hospitalization with recovery time lasting from hours to even days. While fewer treatment sessions are required (6-12 sessions) compared to TMS (20-30 sessions), each session lasts approximately an hour compared to the Deep TMS sessions that are typically about 20 minutes each. While ECT has high proven efficacy (70-75%) for patients with MDD, ECT's potential for serious side effects, as well as negative stereotypes surrounding the treatment, often cause patients to be reluctant to undergo ECT. In addition, ECT affects the entire brain, including parts which do not need treatment, and may cause permanent cognitive damage, including memory loss. ECT may have significant and relatively severe side effects, the most common of which are cognitive and memory loss, changes in blood pressure, muscle pains, nausea, changes in mood, headaches, and pain or discomfort. ECT is currently approved for treatment-resistant depression, severe mania, schizophrenia, bipolar disorder, aggression or agitation in patients with dementia, and catatonia. It is provided usually in cases of severe MDD, where medicinal treatment is ineffective or impossible and in instances where the depression constitutes a risk to the life of the patient.

VNS and DBS are invasive therapies that can have serious side effects. Both involve implanted devices, which require surgery. In DBS, two electrodes are surgically implanted in the brain and a pulse generator is implanted into the patient's chest. The electrodes produce electrical impulses that can regulate the electrical activity of the brain. In VNS, a pulse generator is implanted on the upper left side of the chest to stimulate the vagus nerve. VNS and DBS include surgical related risks, such as infection or local damage to the recurrent laryngeal nerve, which may lead to permanent voice alteration.

Prescription Digital Therapeutics, or PDTs, are a new therapeutic class of products designed to directly treat diseases with software. Certain PDTs are prescribed by healthcare providers after evaluation by the FDA for safety and efficacy testing via randomized clinical trials. Digital therapeutic companies, such as Pear Therapeutics, Inc., offer and/or are exploring products across a variety of therapeutic areas including substance abuse, insomnia, and depression. These products can also include cognitive behavioral therapy (CBT) techniques designed to improve disease outcomes.

Deep TMS for MDD—Our Clinical Trials

Phase III Trial Measuring Efficacy and Safety of Deep TMS

We completed a Phase III trial at 20 different sites in the United States, Canada, Israel, and Germany to test the efficacy and safety of using Deep TMS to treat MDD between 2009 and 2013. The therapeutic effect was clinically meaningful in both patients who failed one to two medications and patients who failed three or more medications, indicating that Deep TMS is effective in an even more treatment-resistant population.

Based on these results, we filed a 510(k) application to the FDA for Deep TMS using BrainsWay's H1 Coil. In 2013, the FDA cleared Deep TMS for the treatment of MDD in adult patients who have failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode.

(a) Trial Design

This randomized, double-blind, placebo-controlled, multicenter trial investigated the efficacy and safety of Deep TMS in 212 treatment-resistant adult MDD patients. Enrolled subjects were randomized in a 1:1 ratio to undergo either monotherapy with active Deep TMS or with a sham. For active Deep TMS treatment, BrainsWay's H-Coils was used at 120% stimulation intensity and a frequency of 18 Hz.

The trial was designed with three phases. The first phase was a wash-out phase in which patients slowly stopped any anti-depressants, mood stabilizers, or antipsychotics that they were previously taking. This phase lasted one to two weeks. The second phase was a four-week acute treatment phase in which patients received daily treatment with Deep TMS or a sham. The treatments were administered in a five-day sequence each week during the second phase. Measurements in respect of this phase were taken in week five. The final phase was a 12-week maintenance-continuation phase in which patients received two treatments per week of Deep TMS or a sham. Measurements in respect of the final phase were taken in week 16.

The primary efficacy endpoint was a change in the 21-question Hamilton Depression Rating Scale (HDRS) at week five (following the end of the acute treatment phase). The secondary efficacy endpoints were response and remission rates at week five. Response was defined as a reduction of at least 50% from baseline HDRS score. Remission was defined as a total HDRS score of less than 10. Tertiary efficacy endpoints included a change in HDRS score from baseline to week 16 and the response and remission rates at week 16. Safety was assessed at every treatment and additional safety evaluations included auditory threshold tests and cognitive evaluations.

Inclusion and exclusion criteria required patients to meet the following criteria:

- Antidepressant medication-free (following washout period)
- Failure to respond to one to four antidepressant trials or not tolerant of at least two antidepressant treatments in the current episode
- Diagnosed with MDD with a single or recurrent episode
- Duration of current episode must be at least one month but less than seven years
- Score of at least four on the Clinical Global Impression Severity of Illness (CGI-S)
- Score of at least 20 on the HDRS
- No current (or within past year) diagnosis of other Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) Axis I disorders (e.g., PTSD, OCD, other mood disorders, eating disorders, psychotic disorders, or dissociative disorders)
- No history or increased risk of seizures

During analysis, the study results were analyzed in two separate groups: the intention-to-treat (ITT) and per-protocol (PP) analysis sets. The ITT group included all subjects who met the eligibility criteria and received at least one Deep TMS treatment. Some of these patients, however, were not administered the treatment at the specified stimulation intensity of 120%. The PP patients included all subjects from the ITT group who received the protocol-specified treatment and stimulation intensity. Baseline demographic, clinical and safety assessments were performed on the ITT analysis set. Primary efficacy analysis was performed only on the PP group.

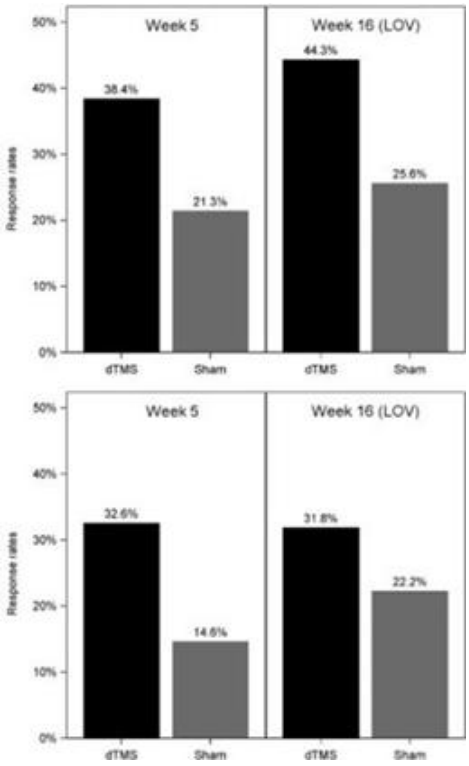
(b) Trial Results

The primary efficacy endpoint was a change in the HDRS total score from baseline through week five. The change was measured as the slope of a graph of time point versus HDRS score. The estimated slope for the Deep TMS treatment group was −6.39 while the estimated slope for the sham treatment group was −3.28. The difference between groups was statistically significant (p = 0.008) for the PP group.

The secondary efficacy endpoints were response and remission rates through week five. As shown in Figure 1, response rates were 38.4% at week five for the Deep TMS group and 21.4% at the same time point for the sham group. Remission rates were 32.6% for the Deep TMS group and 14.6% for the sham group. The difference between groups was statistically significant for both response and remission rates (p = 0.0138 and p = 0.0051, respectively).

The tertiary efficacy endpoints were changes in HDRS scores, response, and remission rates at week 16 compared to baseline (see Figure 1 below). The difference in slope between Deep TMS and sham groups was 2.47, which was statistically significant (p = 0.0259). Additionally, the response rates at week 16 were 44.3% for the Deep TMS group and 25.6% for the sham group, which demonstrated a statistically significant difference between the groups (p = 0.0086). Remission rates at week 16 were 31.8% for the Deep TMS group and 22.2% for the sham group, which was a nonsignificant difference between groups (p = 0.1492).

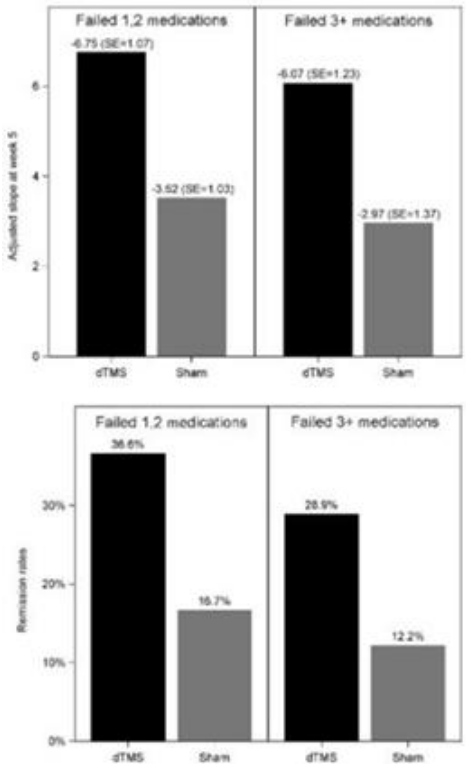
Figure 1. Response and Remission Rates for Deep TMS and Sham Groups at Week 5 and Week 16



Source: Levkovitz et al., 2015

For the group of patients who failed one to two medications, remission rates were 36.6% in the Deep TMS group and 16.7% in the sham group. This was a statistically significant difference (p = 0.032). For the group of patients who failed three or more medications, remission rates were 28.9% for the Deep TMS group and 12.2% for the sham group. This difference was just outside of significance (p = 0.057). The data suggest that Deep TMS treatment can achieve high rates of remission even in patients who have been more resistant to medications.

Figure 2. HDRS Score Change (Slope) and Remission Rates for Deep TMS and Sham Groups in Subpopulations of Patients Who Failed 1 to 2 Medications versus Patients Who Failed 3+ Medications



Source: Levkovitz et al., 2015

(c) Safety Results

Overall, Deep TMS treatment was safe and well-tolerated by patients. The most common reported side effects within the Deep TMS group are as follows: 26.7% of patients experienced headaches, 5.0% experienced application site pain, and 3.0% experienced application site discomfort. The most common reported side effects within the sham group are as follows: 18.9% of patients experienced headaches, 3.6% experienced insomnia, and 2.7% of patients experienced back pain. One subject experienced a seizure, following excessive consumption of alcohol on the night before treatment that was not reported to the treating physician or operator at the time of treatment. This was considered device-related, albeit with the caveat that withdrawal from alcohol may have led to a reduction of seizure threshold and consequently to this seizure during Deep TMS.

Longer-Term Remission and Response

As demonstrated by our pivotal multicenter study for MDD (as described above), and in another third-party study (Harel et al. (2014)), MDD patients who achieved remission or response after an acute course of Deep TMS treatment of 20 sessions over four weeks were able to sustain the therapeutic effect by continuing to undergo Deep TMS treatment beyond the treatment course. Additionally, our trial and the Harel study showed that among MDD patients who did not achieve a response after an acute course of Deep TMS treatment, the longer such patients continued to undergo Deep TMS therapy, the more likely they were to achieve remission or response. This result was also demonstrated in another study examining the results of our multicenter trial (Yip et al. (2017)), which found that 72.7% of the patients who did not achieve response after an acute course of treatment achieved a response within the next 12 weeks (which involved twice weekly Deep TMS treatment), of which 60.6% achieved response within the first four weeks. These studies suggest that Deep TMS may continue to be effective beyond the standard acute treatment course, potentially broadening its clinical applicability.

Real world data further demonstrates the benefits of Deep TMS for MDD: In a peer-reviewed post-marketing study published in Psychiatry Research in 2023, we demonstrated that patients who had received 30 or more Deep TMS treatments achieved an 82% response rate and a 65% remission rate. In the study, BrainsWay collected an aggregate data set from 1,753 patients across 21 clinics, of which 1,351 patients met the inclusion criteria for the analysis. All patients were treated with our H1 Coil utilizing either a standard protocol (typically 18Hz, 20-minutes long) or a shorter intermittent theta burst (iTBS) protocol. Outcomes were measured with clinician-based scales (HDRS-21) and/or patient self-administered questionnaires designed specifically for depression (PHQ-9, BDI-II). This analysis also showed that the average patient achieved sustained response at 16 sessions, or 21 days after beginning treatment. The results found similar efficacy rates among patients undergoing the standard protocol and those who had been administered an iTBS protocol. Data from questionnaires which are not specific to depression, and thus less relevant for assessing depression changes, were intentionally excluded.

Use of H7 Coil for treatment of MDD

Our randomized, double-blind, controlled multicenter, non-inferiority study of our H1 and H7 Coils trial, which included 144 subjects, found overall efficacy rates for the H7 Coil which were comparable to those achieved with our H1 Coil. Based on this trial, our MDD clearance, which had previously applied to our H1 Coil, was extended by the FDA to also apply to our H7 Coil, which until this clearance was used only for treatment of OCD.

Furthermore, following receipt of this clearance, a publication of the study in *The Journal of Clinical Investigation (JCI) Insight* included a retrospective analysis of the study results which identify preliminary predictors that could help optimize treatment based on individual patients' attributes. This analysis examined clinician rating scales and EEG data revealing intriguing differences between the patient treatment of the two coils. Categorizing patients according to "clusters" of clinical depressive and anxiety baseline symptoms derived from a subset of the Hamilton Depression Rating Scale (HDRS-21) resulted in two subject groups: One with higher severity of the cluster, which on average responded better to the H1 Coil, and another with lower severity of the cluster, which on average responded better to the H7 Coil. This analysis also showed that brain activity measured during the first treatment session correlated with the clinical outcomes ultimately achieved after the full course of treatment. This finding suggests that specific brain patterns observed in an individual's response to either coil during the early stages of treatment might be predictive of the longer-term outcome of treatment with that coil.

Deep TMS for OCD

Disease Overview

OCD is a common, chronic, and long-lasting disorder in which a person has uncontrollable, reoccurring thoughts (obsessions) and behaviors (compulsions) that he or she feels the urge to repeat over and over in a manner that can interfere with all aspects of life, such as work, school, and personal relationships.

Individuals with OCD exhibit obsessions, compulsions, or both. Obsessions are reoccurring ideas, thoughts, or impulses that cause anxiety that individuals experience excessively and without cause. Compulsions are defined as repetitive behaviors or thoughts that are performed on a strict schedule and appear to have a purpose to the patient exhibiting the behavior or thought. Even if an individual is aware that the thoughts are inappropriate or irrelevant, he or she still might not be able to suppress the thought or the corresponding action. Obsessions tend to be related to contamination, cleanliness, or orderliness, and so compulsions frequently involve cleaning, washing, counting, arranging things in a particular way, or repeatedly checking on things. These symptoms can interfere with all aspects of life, such as work, school, and personal relationships. While a wide spectrum of individuals may exhibit OCD-like symptoms, in order to be diagnosed with OCD, he or she must exhibit symptoms that cause severe distress or disrupt a person's functioning for more than one hour per day.

OCD can severely disrupt an individual's daily functioning, and many individuals suffering from OCD have a lower quality of life and significantly more mental distress compared to unaffected individuals. A survey of OCD patients found that 73% of patients have weakened family relationships, 62% have weakened friendships, and 40% are chronically underemployed or unemployed. Patients with both OCD and MDD, a frequent combination of disorders, experience the most severely impacted quality-of-life. Additionally, individuals with OCD may feel embarrassment or shame regarding their obsessions and compulsions, contributing to the low treatment-seeking rate of approximately 36%.

Market Information

Despite variances in estimates of the incidence of the disorder, we believe that a majority of research reports that 2% of the global population suffers from OCD sometime during their lifetime. According to the National Institute of Mental Health, approximately 1.2% of the adult population in the United States suffers from OCD over their lifetime. Based on these data, we estimate that approximately 3.1 million adults in the United States suffer from OCD annually, and approximately half (i.e., 1.5 million) are treatment resistant. Of the total OCD population, 50.6% of cases are characterized as having severe impairment. Another 34.8% of adults with OCD had moderate impairment, and 14.6% had mild impairment. The average age of onset is 19 years old.

There is a significant overlap of patients experiencing MDD and those experiencing OCD. Researchers found that MDD was 10 times more prevalent in OCD patients compared to the general population. Additionally, roughly 30% of OCD patients have concurrent OCD and MDD at the time of evaluation, and 60 to 80% of OCD patients experience a depressive episode over the course of their lifetime. Frequently, depressive symptoms follow OCD, which suggests that the depressive symptoms occur as a response to the distress caused by OCD.

Treatment Options for OCD

OCD is generally considered to be one of the most difficult psychiatric diseases to treat. The wide variability in the expression of the disease and the frequent co-morbidity (simultaneous presence) with MDD and other anxiety disorders has complicated the development of an effective, targeted treatment for OCD. The accepted treatment for OCD is medicinal treatment, psychotherapy or a combination of both. However, up to 40% of patients do not respond to these treatments sufficiently.

While 60-70% of patients respond or partially respond to treatment with antidepressant medications such as SRIs or SSRIs, there is a high relapse rate of approximately 60% when medications are stopped. The high relapse rate suggests that pharmacological treatments should be continued over an extended period of time in order to have continued effect. In addition, when testing a new pharmacological treatment on a patient, it takes 10 to 12 weeks to determine if the medication is bringing about clinically significant improvements in symptoms. Over half of patients experience a 25% to 35% decrease in symptoms within 10 to 12 weeks, but symptoms rarely disappear entirely. In addition, 40-60% of OCD patients do not experience a meaningful response to pharmacological treatment.

Deterrents to treatment include the often-severe side effects of medications. Tricyclic antidepressant medication, generally considered to be an effective first-line OCD treatment, is known for its particularly strong side effect profile. The medication can cause heightened risk of seizures, weight gain, sleepiness, tremor, dry mouth, nausea, constipation, visual changes, sweating, and sexual dysfunction. All other OCD medications may cause similar side effects, which make it challenging for patients to retain a high quality of life while also working toward disease remission. Upon initiation of pharmacological treatment for OCD, it is critical to closely monitor for development of any adverse effects.

Psychotherapy can be an effective treatment for adults and children with OCD. The treatment may involve controlled exposure to the source of the obsession and practice of refraining from performance of the compulsion. Research shows that certain types of psychotherapy, including cognitive behavior therapy (CBT) and other related therapies (e.g., habit reversal training) can be as effective as medication for many individuals. Research also shows that a type of CBT called Exposure and Response Prevention (EX/RP) is effective in reducing compulsive behaviors in OCD, even in people who did not respond well to antidepressant medication. For many patients EX/RP is the add-on treatment of choice when antidepressant medication does not effectively treat OCD symptoms.

Deep TMS presents a novel, FDA-authorized treatment for OCD. In August 2018, the FDA classified and provided marketing authorization for Deep TMS for OCD as an adjunct treatment (i.e., to be used in conjunction with first-line treatment, such as antidepressant medication or CBT) for adult patients suffering from OCD. Deep TMS has the unique ability to simultaneously influence a network of specific regions in the brain related to OCD. In addition, it offers a direct effect over deep regions in the brain associated with the disorder. The effects of the treatment begin within a relatively short time period and the duration of the entire treatment plan is shorter compared to a medicinal treatment. Deep TMS therapy for OCD has not demonstrated any systemic side effects, and we believe that Deep TMS presents an attractive alternative to existing treatment options for OCD because antidepressant medications, due to their side effects, often lead to cessation of treatment by the patient and as a result, relapse of OCD symptoms.

Positive data published in February 2022 in the Journal of Psychiatric Research demonstrated the relative cost-effectiveness of Deep TMS for refractory OCD patients when compared with other treatments within the treatment continuum, which includes outpatient medication, CBT, as well as more intensive, facility-based approaches. The data suggest that Deep TMS is a cost-effective alternative, and particularly indicate that it may serve as an incremental strategy to employ when higher intensity strategies, such as facility-based approaches, are either unavailable, not financially feasible, or have extended waits for admission.

Since 2021, several payors issued policies and coverage determinations allowing for reimbursement coverage applicable to Deep TMS for OCD. While the criteria for this emerging Deep TMS coverage varies with each payor, generally, coverage requires the failure of between two and four medication trials before qualifying for reimbursement.

The NIMH is supporting research into new treatment approaches for people whose OCD does not respond well to the usual therapies. These new approaches include combination and add-on (augmentation) treatments, as well as novel techniques such as deep brain stimulation (DBS).

Deep TMS for OCD — Our Clinical Trials

Phase III Trial Measuring Efficacy and Safety

We completed a Phase III trial at 11 sites in the United States, Israel, and Canada to test the efficacy and safety of Deep TMS as a treatment for OCD, which was conducted from 2014 through 2017. In this trial, Deep TMS met its safety and efficacy endpoints and based on these results, we filed a *de novo* application to the FDA for the Deep TMS (using our H7 Coil) in this indication. In August 2018, the FDA classified and granted marketing authorization for Deep TMS as an adjunct treatment for adult patients with OCD to be used together with other first-line therapies.

(a) Trial Design

This double blind, placebo-controlled trial tested the efficacy and safety of Deep TMS in the treatment of 94 treatment-resistant OCD patients. Enrolled subjects were randomized to either treatment with active Deep TMS or a sham. Deep TMS for OCD was used for all treatment sessions, each of which lasted 18.3 minutes. Our H7 Coil is specifically used in OCD treatment because it targets the anterior cingulate cortex, a region believed to be affected by OCD.

The trial consisted of three phases. The first phase, lasting one to two weeks, was the screening phase, during which antidepressant medications other than SSRIs were tapered down and washed out (i.e., to make sure that patients take during the trial only medications that were approved by the protocol (such as SSRIs), and that they remained stable on these medications). Following the screening phase, patients entered into a six-week treatment phase. During the first five weeks of the treatment phase, patients received five consecutive sessions per week, followed by one week with four sessions (29 total treatment sessions). The third phase was the follow-up, in which patients were assessed in week six after their final treatment.

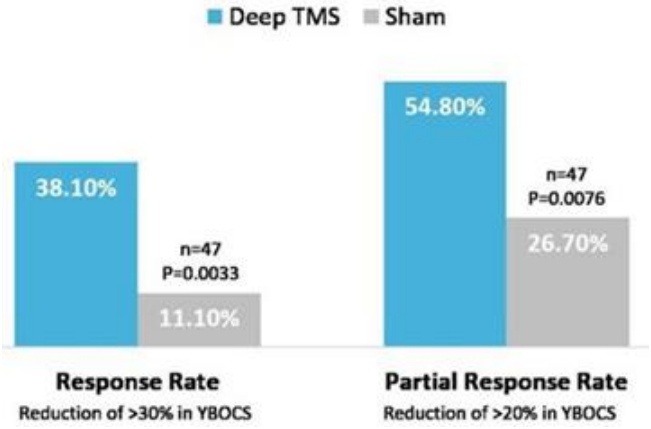
The primary endpoint measure was the Yale-Brown Obsessive Compulsive Scale (YBOCS), which is a score ranging from 0 to 40, with higher scores indicating greater severity of OCD symptoms. The secondary efficacy endpoint measures were response rate at weeks 6 and 10, partial response rate at weeks 6 and 10, and remission rates at week 6. Secondary safety endpoint measures included the number of adverse events, physical and cognitive evaluations, and vital signs.

Inclusion and exclusion criteria required patients to be diagnosed with OCD, have a YBOCS score of greater than 20, and not be diagnosed with any severe personality disorders.

(b) Trial Results

After six weeks of treatment, the Deep TMS treatment group had statistically significant improvement in YBOCS score compared to the sham treatment group. The adjusted mean YBOCS score decreased by 6.04 points in the Deep TMS group and by 3.27 points in the sham control group. The difference between the slopes of 2.78 points across six weeks between the treatment arms was statistically significant (p-value: 0.0127), and the effect size at week six assessment was 0.69. As shown in Figure 3, 38.1% of the Deep TMS treatment group achieved a response compared to 11.1% of the sham treatment group. Furthermore, 54.8% of the Deep TMS treatment group achieved a partial response, compared to 26.7% of the sham treatment group. The differences between groups were statistically significant for both response rate (p = 0.0033) and partial response rate (p = 0.0076).

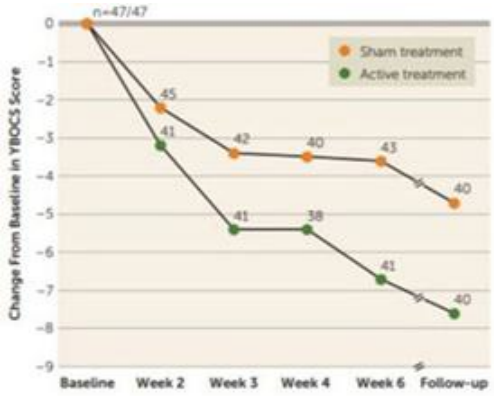
Figure 3. Response and Partial Response Rates for Deep TMS and Sham Treatment Groups



One month after the end of treatment (10 weeks after baseline), patients retained clinical improvement of symptoms, and these measures (YBOCS change and response rate) were significantly better in the Deep TMS group compared to the sham group (p=0.03 for YBOCS change and p=0.0057 for response rate).

Figure 4 highlights the continued decrease in unadjusted mean YBOCS score from baseline over the ten-week period.

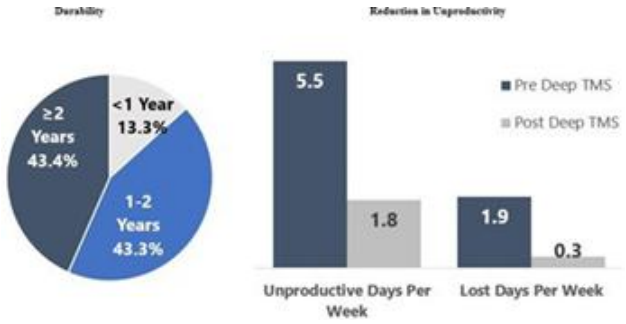
Figure 4. Total YBOCS Score Change from Baseline over 10-Weeks for Deep TMS and Sham Treatment Groups



Real world data further demonstrates the benefits of Deep TMS for OCD: In a post-marketing study, published as a peer-reviewed paper, the overall first and sustained response rates were 72.6% and 52.4%, respectively. The response rate was 57.9% in patients who had YBOCS scores after the FDA-cleared protocol of 29 Deep TMS sessions. First response was achieved in average after 18.5 sessions (SD = 9.4) or 31.6 days (SD = 25.2). Onset of sustained one-month response was achieved in average after 20 sessions (SD = 9.8) or 32.1 days (SD = 20.5). Average YBOCS scores demonstrated continuous reduction with increasing numbers of sessions. The results indicate that in real-world clinical practice, the majority of OCD patients benefitted from our therapy, and the onset of improvement usually occurs within 20 sessions. Extending the treatment course beyond 29 sessions resulted in continued reduction of OCD symptoms, raising the prospect of value for extended treatment protocols in non-responders.

A study published in November 2021 in the Brain Stimulation journal demonstrates the durability of Deep TMS for OCD and the significant reduction in functional disability experienced by those who have undergone our therapy for this disorder. To evaluate durability, clinical sites from our pivotal trial, as well as other clinical sites contributing post-marketing data, conducted follow up assessments with patients that had met response criteria following treatment with our H1 Coil. Durability was defined as the elapsed time from the end of the Deep TMS treatment course until there was a change in ongoing treatment. Data revealed that of the 60 subjects evaluated from seven clinical sites, 52 demonstrated durability of one year or more (86.7%), 26 of which showed two or more years of durability. The data also showed that patients exhibited a significant reduction in disability, with self-reported unproductive days per week dropping from 5.5 days (±0.4) to 1.8 days (±0.4), and self-reported lost days per week dropping from 1.9 (±0.6) to 0.3 days (±0.2).

Figure 5. OCD Durability and Reduction in Unproductivity



Deep TMS for Smoking Addiction

Disease Overview

Smoking is one of the leading causes of death in developed countries. The addiction to nicotine, similar to the addiction to drugs and alcohol, activates the limbic system and causes uncontrollable desire to smoke. According to the World Health Organization (WHO), 1.3 billion people globally use tobacco, primarily cigarette smoking. Globally, more than 8 million people die from smoking each year: 7 million from direct use and 1.2 million from second-hand smoke. Approximately 34 million U.S. adults smoke cigarettes, and 480,000 die from smoking each year. Repeated nicotine use leads to tobacco use disorder (TUD), characterized by craving and withdrawal, compulsive use despite negative consequences, repeated relapses, and is associated with multiple health problems and failed attempts to cease. Smoking causes about 90% of all lung cancer deaths.

Market Information

The global nicotine replacement therapy (NRT) market was estimated at $2.6 billion in 2019, and this market value is anticipated to increase as a result of the increasing incidence of chronic, smoking-related diseases. Chantix (Varenicline), the leading smoking cessation pharmaceutical from Pfizer, had sales of $1.1 billion worldwide in 2019, $899 million from the United States. Considering the U.S. market, there are 34 million cigarette smokers. Each year, 55% attempt to quit smoking (81% of which are motivated to quit). Only 29% of adult smokers that attempt to quit report using medication (e.g. NRT, Varenicline, Buproprion), and less than 10% of smokers quit within a given year with varied long-term success.

Treatment Options for Smoking Addiction

One of the most common smoking addiction options is nicotine replacement therapy (NRT), which is the affixing of patches to the body or the chewing of gum which secrete decreasing concentrations of nicotine in a manner which may assist physical withdrawal. However, this method does not treat the psychological-behavioral component of the addiction, and therefore there is a high probability that the patient will return to smoking if nicotine patch treatment is discontinued. A study found that 93% of over-the-counter NRT users relapse and return to smoking within six months.

First line treatment options include antidepressants such as Zyban (bupropion) and Chantix (varenicline). Studies have found advantageous abstinence rates compared to placebo. Yet, recent studies using objective measures found very low quit rates. A recent meta-analysis found that 20% of smokers treated with medications remained abstinent for one year, compared to 12% with placebo. The medications may frequently be associated with undesirable adverse events.

There are studies that indicate that combination of psychological support with pharmacotherapy may increase the chances to quit smoking. Although there is not currently any reimbursement coverage for TMS therapy as a treatment for smoking addiction, in October 2023, the Clinical TMS Society (CTMSS), an influential peer group, published the first coverage recommendations for smoking addiction treatment using TMS. With this new coverage guidance for insurers, CTMSS now recommends TMS coverage for individuals with a confirmed diagnosis of Tobacco Use Disorder (TUD) who failed two alternative treatment methods, cannot tolerate drugs, or have other comorbid medical conditions (secondary to TUD) such as COPD, artery disease and lung cancer.

Deep TMS for Smoking Addiction – Our Clinical Trials

Deep TMS presents a novel, FDA-authorized treatment for smoking addiction. In August 2020, the FDA classified and provided marketing authorization for the use of Deep TMS as an aid in short-term smoking cessation in adults. Deep TMS has the unique ability to simultaneously influence a network of specific regions in the brain associated with reward and craving. The effects of the treatment begin within a relatively short time period and the duration of the entire treatment plan is shorter compared to a medicinal treatment. Deep TMS therapy for smoking cessation has not demonstrated any systemic side effects, and we believe that Deep TMS presents an attractive alternative to existing treatment options for smoking cessation because antidepressant medications, due to their side effects, often lead to cessation of treatment by the patient and as a result, relapse to smoking.

We concluded with positive results a pivotal multicenter trial assessing the safety and efficacy of Deep TMS as an aid in smoking cessation in adults suffering from chronic smoking addiction.

The trial was a randomized, double-blind, multicenter study designed to evaluate the safety and efficacy of Deep TMS treatment as an aid in reducing cigarette smoking in individuals suffering from chronic smoking addiction. It was conducted at 14 sites, primarily in the U.S., and enrolled 262 eligible subjects randomized into two groups: an active treatment group treated with our proprietary H4 Coil targeting addiction-related brain circuits, and a sham control group. The primary endpoint of the study was a comparison between the two groups of the four-week continuous quit rate (CQR), representing abstinence during a consecutive four-week period. Weekly abstinence was defined as a subject's self-report (in a diary) of no smoking, confirmed by urine tests indicating abstinence from smoking. The participants in the study were highly addicted to smoking, with a history of smoking on average for over 26 years and multiple failed attempts to quit. All of the subjects in the study had at least one prior unsuccessful attempt to quit smoking before being enrolled in the trial. Over 68% of the subjects had undertaken at least three prior unsuccessful attempts, and over 25% had undertaken at least five prior unsuccessful attempts.

Participants received three weeks of daily Deep TMS (or sham) treatment followed by one session per week for three more weeks (for a total of 18 treatments over six weeks). Assessment visits, including questionnaires and the collection of urine samples, were performed weekly from week two until week six. In addition, subjects were asked to keep a record of their smoking behavior on a diary card. Patients reporting abstinence at 6 weeks were invited for a long follow-up (L-UP) visit at 4 months.

Of the 169 participants in the study who actually completed three weeks of Deep TMS or sham treatment, plus the mandatory additional three weeks of follow-up (reaching the six-week endpoint), the CQR was 28.0% in the treatment group compared to 11.7% in the sham group (p=0.007). The primary endpoint was defined based on the CQR among those subjects who received at least one Deep TMS (or sham) treatment session and had at least one post-baseline assessment, even if not completing the treatment period. Within this cohort (ITT-E, which consisted of 234 participants and included dropouts) the CQR was 19.4% in the treatment group and 8.7% in the sham group (p= 0.0174).

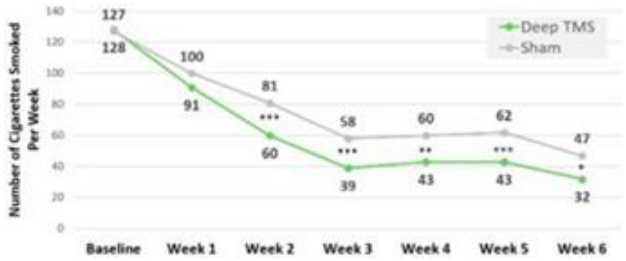
The Overall 4-week continuous quit rate (CQR) is shown in the figure below for the active Deep TMS and sham groups, within the ITT-E and completers (CO) cohorts.

Figure 6. Overall 4-week Continuous Quit Rates for Deep TMS and Sham Treatment Groups

An important secondary endpoint was the reduction in the number of cigarettes smoked. At baseline, the average number of cigarettes smoked per week was 123 for the active group and 139 for the sham group. After 3 weeks of treatment, the average number of cigarettes smoked per week was reduced to 38 in the active group and 57 in the sham group (p= 0.0018, active vs. sham). By the sixth week of the study, the average number of cigarettes smoked per week declined to 31 for the active group and 48 for the sham group (p=0.0125, active vs. sham).

The numbers of cigarettes per week, from baseline to the 6-week time-point, are shown in the figure below for the two groups. As can be seen, the difference between the Deep TMS and sham group is significant starting from week 2.

Figure 7. Number of Cigarettes Smoked for Deep TMS and Sham Treatment Groups



Sales and Marketing

United States

The United States is our primary and most strategic market, representing approximately 81% of our revenues for the year ended December 31, 2024 and approximately 75% of our revenues for the years ended December 31, 2023 and 2022. We operate in the United States through our wholly owned subsidiary, BrainsWay USA Inc., as a direct marketing and sales channel, engaging in the marketing, sales, support, and logistics independently in the United States. As of December 31, 2024, we had 49 U.S. employees, including 47 sales, marketing and service/operations employees, 1 general and administrative employee, and 1 medical affairs employee.

In the United States, we sell or lease Deep TMS systems by one of the following two methods: (i) a fixed-fee lease model in which the Deep TMS system is leased to a customer for a fixed annual fee, generally with a term of between 48 to 60 months, for unlimited use; and (ii) a sales or purchase model in which the Deep TMS system is sold to the customer for a fixed purchase price. sales or purchase model. We also utilize and/or are planning to utilize other commercial models, including those based on a pay per use model, with certain customers in certain territories. Additional potential revenues may be derived from extended warranty fees paid for the system for service coverage beyond the standard included warranty period, and from variable or usage fees based on the number of treatments performed with the system. We are also able to leverage our platform technology, which includes the ability to treat multiple indications using different H-Coil helmets, to facilitate transactions utilizing combined pricing models often involving a single system with one or more add-on helmets. These flexible offerings are designed to facilitate market penetration by addressing the differing clinical needs and risk tolerance among our customer base.

As of December 31, 2024, approximately 43% of our global Deep TMS systems installed base for MDD utilized the fixed-fee lease model, and approximately 57% utilized the sales model. We generally commercialize Deep TMS for OCD utilizing a leasing or purchase model, and often as part of a combined offering with our MDD system.

Following our receipt of FDA clearance for smoking addiction, we completed controlled and limited market releases of our system for this indication, and are currently in the process of a clinical data collection effort to facilitate a long term commercial plan for this product.

The training for operation of our Deep TMS system is not complex and requires about a day of training which includes theoretical learning and a number of practical hours of practice of placing the helmet on the head of the patient and providing treatment. Deep TMS for OCD requires additional training on triggering the patient's OCD symptoms prior to administration of the treatment. Similarly, Deep TMS for smoking addiction involves a provocation procedure which triggers each individual smoker's craving for his or her preferred cigarette brand prior to the administration of therapy.

After installation of our system, we offer high quality service, technical support, and repair to customers. Customers leasing the device generally receive support including maintenance and warranty for repairs and replacements during the full term of the lease. In contrast, customers purchasing the device receive this support for the first year following purchase. Thereafter, the warranty and support can be extended on a yearly basis by paying a set fee.

Our marketing activities include, amongst other things, corporate presence in major commercial and professional conferences, press releases, advertising, participation in open house and other similar events, social media, Search Engine Optimization (SEO), and other internet-based promotional campaigns, and release of both direct and online marketing materials, which are all designed to increase the use of our systems for the authorized indications.

Commencing the year ended December 31, 2024, we increased our marketing efforts directed at large clinic networks or chains and enterprise accounts and on multi-unit sales. While these transactions account for an increasing portion of our installed-base and commercial pipeline, there is a correlating increased financial risk imposed by our reliance on these deals, particularly in the event of customer default or delays in payment. See the section titled "*Risk Factors – Our long-term growth depends on our ability to increase market penetration and further commercialize Deep TMS, as well as develop enhancements and features to the Deep TMS system through our research and development efforts. If we fail to do so, we may be unable to achieve future growth*."

Outside of the United States

Approximately 19% of our revenues for the fiscal year ended December 31, 2024 and approximately 25% of our revenues for the fiscal years ended December 31, 2023 and 2022, were generated outside of the United States. A significant part of our sales outside the United States are made indirectly with local distributors and agents. Most of our sales outside the United States are made via the purchase model, although we lease some of our Deep TMS systems as well, and in Israel we have several sites who have enlisted under a pay-per-use model. Our primary focus is on selling to hospitals, medical centers and clinics dealing with the treatment of psychiatric neurological and addiction illnesses and disorders.

Our non-U.S. sales are managed both by our internal team in Israel and by local agents in various countries. In Israel, we do not use a distributor and our sales team distributes directly to our customers. We have exclusive distribution agreements in various territories, including, notably, in Canada, Japan, South Korea, Thailand, Taiwan, the Philippines, Italy, Spain, Czech Republic, Greece and India, and are seeking new distribution partners for other strategic markets. Under our distribution agreements, the distributor typically receives an exclusive right to commercialize our Deep TMS system in the relevant territory. The exclusivity is contingent upon fulfillment of certain quotas, or pre-defined minimum orders of a number of systems per period. We have the right to cancel the exclusivity of the distributor if the distributor fails to fulfill the set targets. The distributor is required to pay us for each Deep TMS system installed in the territory.

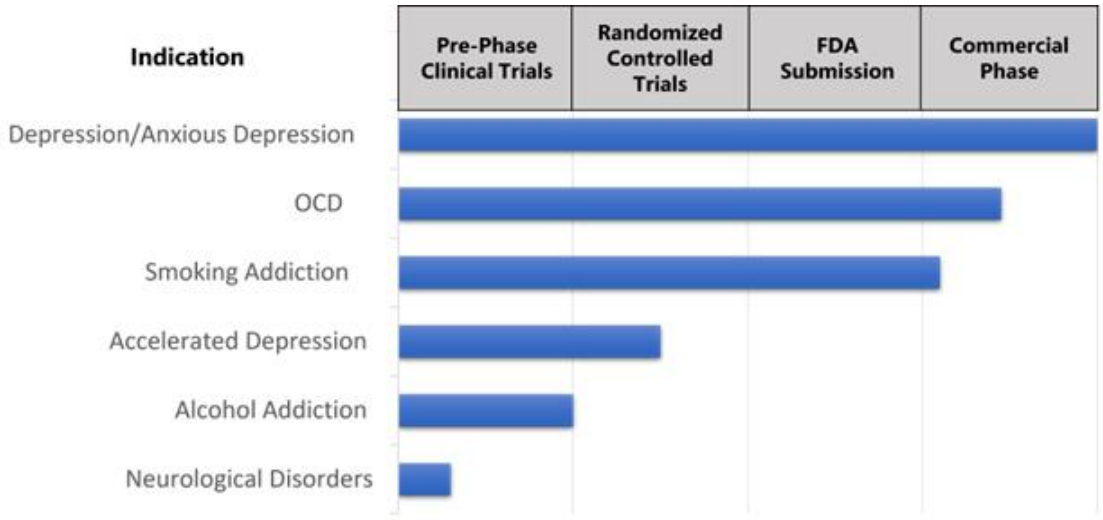
The duration of these agreements varies between distributors and ranges between three and ten years. In territories in which we use a local distributor, the distributor is generally responsible for obtaining and maintaining the regulatory approvals required for marketing of Deep TMS systems in the territory and for the installation, training, and maintenance of the systems in the relevant territory. In Japan, we have obtained PMDA regulatory approval for our Deep TMS system, which is a precondition to receiving reimbursement coverage under the Japanese National Health Insurance Plan. After working extensively with our Japanese distributor with the relevant bodies in Japan, in 2024 we succeeded in updating the guidelines issued by the Japanese Society of Psychology and Neurology to include coverage for Deep TMS. Commercial sales of our systems thus commenced in 2024, and our Japanese distributor has initiated a Post Marketing Study (PMS) in Japan to assess the efficacy and safety of our treatment on the local population, which is a required commercialization criteria for this territory.

In October 2024, we received orders for 15 Deep TMS systems to be used by mental health centers in Taiwan and South Korea. In June 2024, we entered into an exclusive multi-year distribution agreement with a specialty distributor serving both the acute hospital and non-acute healthcare spaces with minimum quantity orders which increase successively over several years, starting with 11 Deep TMS systems to be ordered in 2024.

We aim to increase our marketing and sales outside the United States by means of cultivating and supporting our existing distributors, and by considering other strategic opportunities in various markets. Success of penetration in each country is contingent on a variety of factors, including, among others, the strength and capabilities of the distribution partner, the existence of regulatory approvals, the availability of reimbursement, the support of key opinion leaders, and the ability of customers to adopt our technology.

Our Clinical Pipeline

Set forth below is a table presenting the status of our currently planned clinical pipeline:



Additional Potential Deep TMS Applications

Our primary focus for additional potential applications for Deep TMS include neurological and/or addiction disorders. For instance, we announced pilot study results from a randomized, placebo-controlled, double-blind study on the safety and efficacy of Deep TMS in reducing alcohol consumption and craving in adults with Alcohol Use Disorder (AUD). Analyzing data from 46 subjects, the study demonstrated that subjects in the active group had an average of 2.9% heavy drinking days (defined as a day on which four or more drinks were consumed for women, or five or more drinks for men) compared to 10.6% heavy drinking days in the sham group. We are currently considering pursuing further alcohol treatment research including via our rotational field technology.

In December 2024, positive pilot data was released from an independent, third-party study conducted at Stanford University evaluating an accelerated protocol using our Deep TMS technology to treat AUD patients. The outcomes were reported in a publication in the Brain Stimulation journal titled, "Accelerated deep TMS in alcohol use disorder: A preliminary pilot trial targeting the dorsal anterior cingulate cortex increases neural target engagement and abstinence." The study compared outcomes achieved in a residential treatment program on a group of AUD patients treated with our H7-Coil (n=5) using an "accelerated" protocol of multiple sessions of Deep TMS per day over several days, with those achieved in a previously collected sample of data from patients in the same program (n=39) who had undergone other forms of treatment not involving Deep TMS. In the follow-up period after treatment, subjects receiving accelerated Deep TMS showed notably better improvements when compared to those treated by other means. The better outcomes were seen in several important areas, including lower percentages of heavy drinking days (3% v. 22%) and regular drinking days (15% v. 28%), as well as lower relapse rates (60% v. 74%). The study also reported neuroimaging MRI changes in brain activity and connectivity in areas of the brain implicated in addiction disorders and believed to be predictive of AUD relapse. Shortly following publication of the pilot study, the U.S. National Institutes of Health (NIH) awarded approximately $1.5 million to the same research team to explore the efficacy of our Deep TMS system in treating substance use addictions, underscoring the possibility of utilizing Deep TMS as a noninvasive treatment modality within the broader addiction space.

We have conducted clinical trials evaluating Deep TMS for a variety of neurological and psychiatric conditions and believe further investigation could pave the way for marketing authorizations in new indications in the United States and expand the potential for treatment to a wider range of patients. Recent areas of focus include post-stroke rehabilitation and OCD treatment using an accelerated protocol, which we are currently exploring via 2 new feasibility studies utilizing our next generation "Rotational Field" TMS (or "Deep TMS 360°™") system. Factors that contribute to how we prioritize the pursuit of certain clinical studies include, but are not limited to, the strength of our feasibility clinical data, market potential, required budget, and ease of conduct of the trial. However, there is no guarantee that we will ultimately be successful in obtaining marketing clearance for the indications prioritized for further study or any other new indications.

Competition

The industry for the treatment of mental health diseases, disorders, and other conditions is intensely competitive. Our currently marketed Deep TMS system is, and any future indications, expansions or new treatment methods we develop and commercialize will be, subject to intense competition. Our Deep TMS system for MDD competes with existing antidepressant drugs, other TMS therapies and to a lesser degree, more invasive treatments such as ECT, VNS, and DBS. Our Deep TMS system for OCD also competes with existing medications and other available treatments. The industry in which we operate is subject to rapid change and is highly sensitive to the introduction of new products or other market activities of current or new industry participants. Certain competitors may be larger and have greater resources than us, and may develop treatment options that receive faster regulatory approvals and/or are more rapidly adopted by clinicians and patients or may expand their operations by partnering with, or acquiring, healthcare providers, mental health clinic chains or other mental health service providers. Our competitors compete with us on the basis of efficacy and safety, regulatory approvals, price and availability of reimbursement from third-party payors, ease of use/administration of the treatment option, reputation, and market trends. Key competitive factors affecting the commercial success of the Deep TMS system are likely to be efficacy, safety and tolerability, reliability, convenience and time frame of administration, market acceptance of our products relative to alternative treatments, and availability and scope of reimbursement.

Competitors that sell other forms of TMS therapy for MDD include Neuronetics, MagVenture, Magstim, Neurocare (MAG & More), Cloud TMS, Nexstim, Yingchi Medical, Sebers, Magnus Medical, NeuroQuore, and BTL that compete directly with us. Their systems are typically based on traditional TMS utilizing a figure-8 coil and are generally FDA-cleared for MDD. MagVenture and Neuronetics have also received FDA clearance for OCD, although these competitors did not conduct randomized, controlled studies as a predicate to receiving such clearance. By contrast, our unique Deep TMS H-Coils are designed to address a number of different brain disorders. Several competitors have obtained 510(k) clearance for their TMS device for an OCD indication, using our *de novo* classification as a predicate device in their submission, and others may follow suit. We remain the only company to have proven clinical efficacy for this indication based on a randomized, double-blind, placebo-controlled, multicenter trial, while other competitors that have since obtained FDA clearance for this indication, have done so in part relying on our clinical data. BrainsWay remains the only company currently with marketing authorizations for MDD, OCD, and the treatment of smoking addiction.

Another competitive issue we face within the TMS field arises from increasing interest in "accelerated" dosing schedules which involve multiple sessions each day to allow for quicker overall treatment time. For example, one TMS competitor has developed a depression protocol involving 50 sessions of TMS over a 5-day period with the assistance of functional MRI targeting. This protocol, involving a total treatment period that is significantly shorter than traditional TMS protocols, has gained increasing commercial traction in the market. The appeal of the protocol has increased with the FDA's grant of clearance in September 2022 to the TMS competitor offering the protocol, and with payors issuing specialized inpatient reimbursement codes applicable to the protocol. We accumulated our own data for several years demonstrating the potential efficacy of various accelerated Deep TMS protocols, followed by an October 2023 peer-reviewed publication in the Psychiatry Research Journal and our June 2024 launch of a prospective, randomized, controlled, multicenter clinical trial on accelerated Deep TMS for depression.

We also face competition from pharmaceutical and other companies that develop competitive products, such as antidepressant medications (including but not limited to a nasal spray utilizing the drug esketamine approved by the FDA for use in conjunction with an oral antidepressant), with certain competitive advantages such as widespread market acceptance, ease of patient use and well-established reimbursement. We also face competition from the SAINT™ Neuromodulation protocol (Magnus Medical), a brain stimulation technique for treatment of neuropsychiatric disorders, which received an FDA clearance for the treatment of MDD in adults who have failed to achieve satisfactory improvement from prior antidepressant medications in the current episode. Magnus Medical launched its SAINT Neuromodulation System in 2024 with this protocol being their main offering. In addition, we may face competition from ketamine, which is used as an anesthetic to treat a variety of brain disorders. Currently in clinical trials, there are a number of psychedelics including lysergic acid diethyamide (LSD), psilosybin, DMT, and methylendioxymethamphetatmine (MDMA) showing early promise in the treatment of mental health conditions like depression and PTSD. Our commercial opportunity could be reduced or eliminated if these competitors develop and commercialize antidepressant medications or other treatments that are safer, more effective or more convenient than Deep TMS. At any time, these and other potential market entrants may develop treatment alternatives that may render our products uncompetitive or less competitive. In addition, we could face competition by the recently approved AUVELITY (dextromethorphan HBr -bupropion HCl) extended-release tablets for the treatment of MDD in adults, which are the first and only oral N-methyl D-aspartate (NMDA) receptor antagonist approved for the treatment of MDD.

We are also subject to competition from invasive neuromodulation therapies such as ECT, VNS, and DBS. Major players in this space include Abbott, Boston Scientific Corporation, LivaNova, and Medtronic. For example, the VNS system developed by Cyberonics (now LivaNova) is FDA-approved for MDD.

For smoking addiction, there are a wide range of prescription and over-the-counter (OTC) short term aids in smoking cessation. Two prescription medications that are synonymous with the market are Chantix® (varenicline) and Zyban (buproprion). OTC nicotine replacement therapies continue to play a major role in a multi-modal approach to smoking cessation, with common forms ranging from chewing gums, to lozenges, to transdermal patches.

Digital therapeutics, including prescription digital therapeutics (PDTs), are also gaining popularity in the space of mental health treatments given the availability and affordability of smart phones. For all of the conditions we address in the United States, there are numerous popular phone applications to help reinforce the multi-modal treatment algorithms.

In addition, we may face competition in the future from other noninvasive treatments for MDD (including anxious depression), OCD, and smoking addiction. Examples of noninvasive treatment options in early development include low-intensity and low-frequency ultrasound (LIFU), transcranial laser therapy, and infrared therapy. We cannot predict whether any of these or any other treatment options will succeed in clinical trials or be commercially marketable in the future.

Intellectual Property

See "*Item 5. Operating and Financial Review and Prospects—C. Research and Development, Patents and Licenses*."

Government Grants

As of December 31, 2024, we have received grants from the IIA in an aggregate amount of approximately $13.4 million. We are currently required to pay 3% royalties of sales of our Deep TMS products, which payment obligations do not currently exceed the amount of the grant received (in U.S. dollars), plus interest at an annual rate equal to the LIBOR rate. As of December 31, 2024, we have paid royalties to the IIA in an aggregate amount of approximately $6.2 million (including amounts in respect of accrued interest), with remaining outstanding royalties of up to $10.1 million.

In addition, we received from MAGNET approvals for grants in an aggregate amount of NIS 8.2 million (approximately $2.2 million based on the NIS to USD exchange rate as of December 31, 2024). There is no requirement to repay the grants or pay royalties thereon.

Manufacturing and Supply

We manage all aspects of product supply through our Jerusalem and/or U.S.-based operations teams. We manufacture our proprietary H-Coils and outsource the manufacture of certain components, including the stimulator, the computer controlling the stimulator, cooling system, the helmet, and the arm of the helmet, which are produced and tested to our specifications. We assemble Deep TMS systems at our headquarters in Jerusalem, U.S. warehouses and/or installation sites. In some cases, we rely on third-party providers to provide components used in existing products and we expect to continue to do so for future products. Our production activities also include manually assembling certain components of our devices for all required clinical and commercial quantities, and the integration of all components into a functioning Deep TMS system.

We rely on suppliers for most of the components used in manufacturing Deep TMS, including the computer controlling the stimulator, the helmet, and the arm of the helmet. In addition, we rely on the outsourcing company utilized for the manufacture of our newer systems, including our proprietary stimulator and various other components. We manage our arrangements with our third-party manufacturers and suppliers to adjust delivery schedules and quantities of components to match our changing manufacturing requirements. We forecast our component needs based on historical trends, current utilization patterns, and sales forecasts of future demand. We establish our relationships with our third-party manufacturers and suppliers through supplier contracts and purchase orders. In most cases, these supplier relationships may be terminated by either party upon short notice. The prices that we pay for sourced components vary depending on various factors, including the cost of the raw materials required for those components, our required delivery times, and shipping costs.

In order to mitigate the risks related to a single-source of supply, we qualify alternative suppliers when possible, maximize the use of commercial, off the shelf components and materials, minimize specialized or proprietary manufacturing processes, and develop contingency plans for responding to disruptions, including maintaining adequate inventory of any critical components. For further discussion of the risks related to our supply chain, see "*Risk Factors – Our operations could be affected in the event of further geopolitical instability, war, supply chain disruptions, unfavorable market or political conditions, global pandemics or other outbreaks or other negative global trends or disruptions*". To date, the supply of finished products to our customers and clinicians has not been materially adversely affected as a result of component supply issues.

We are subject to extensive governmental regulation in connection with the manufacture of our devices. We must ensure that all of the processes, methods, and equipment are compliant with the current Quality System Regulations (QSR) for devices on an ongoing basis, mandated by the FDA and other regulatory authorities, and must conduct extensive audits of vendors, contract laboratories and suppliers. We comply with such regulatory requirements. Certain of our foreign marketing authorizations require compliance of said manufacturing process with the ISO 13485 standard and with the Medical Device Single Audit Program (MDSAP), with which we are compliant.

Reimbursement

We estimate that over 90% of the total private insurer adult covered lives in the United States have coverage for reimbursement of MDD treatment with Deep TMS, available after one to four failed (inadequate response or intolerable) trials of antidepressant medications. In addition, our MDD treatment with Deep TMS is eligible for reimbursement from Medicare, and is available after one to two failed trials of psychopharmacologic agents (such as antidepressant medications) and subject to the satisfaction of other clinical criteria. Typically, payors (including Medicare) will provide reimbursement for up to 36 treatment sessions of Deep TMS for MDD, although the maximum number of covered sessions varies by insurer and/or location.

Recently, United HealthCare has updated their Medicare Advantage policy in states covered by National Government Services Medicare to allow non-physician practitioners, like nurse practitioners, to order and administer TMS Therapy to their patients with MDD in states where they have scope of practice to do so. Similarly, Aetna nationwide commercial plans (with 16.8 million covered lives), recently allowed TMS treatment to be ordered and administered by behavioral health nurse practitioners for patients with MDD, and has removed the previously required four-month psychotherapy trial before a patient becomes eligible to receive an initial course of treatment with TMS. BlueCross BlueShield of Michigan (with 4.7 million covered lives) and BlueCross BlueShield of Louisiana (with 1.1 million covered lives) have also issued healthcare policies updates reducing the number of failed medication trails from four down to two prior to TMS treatment eligibility.

In recent years there has been emerging reimbursement coverage for Deep TMS for the treatment of OCD, with over 90 million covered lives eligible for coverage as of March 2025. Positive coverage decisions for Deep TMS for OCD have been issued by Centene Corporation (with 26 million covered lives), Health Care Service Corporation (HCSC) (with 17 million covered lives), TriCare (with 9.6 million covered lives), Cigna Corporation (with 17 million covered lives), Highmark (with 6.8 million covered lives), Premera (with 2.6 million covered lives) and LifeWise (with 2.2 million covered lives). Additionally, one of the seven Medicare Administrative Contractors (MACs) in the US, Palmetto GBA, published a final Local Coverage Determination (LCD) in 2022 extending coverage applicable to Deep TMS for OCD. While the criteria for this emerging Deep TMS for OCD coverage varies with each payor, generally, coverage requires the failure of between two and four medication trials before qualifying for reimbursement. Our strategy is to look for ways to facilitate increased coverage for OCD treatment by more payors, including both commercial and governmental. In addition, there is currently an out-of-pocket market for our Deep TMS systems for OCD. Deep TMS for smoking addiction is not currently eligible for reimbursement. We plan to seek to obtain coverage as we progress in our commercialization for this indication. In October 2023 the Clinical TMS Society, an influential peer group, published the first coverage recommendations for smoking addiction, which we have highlighted as part of our efforts to educate payors.

The sale or lease of a medical device utilized for in-office medical treatments depend, in part, on the extent to which such treatments using that device will be covered by third-party payors, such as government healthcare programs (e.g., Medicare), private insurance, and managed healthcare organizations. Even if a third-party payor covers a particular treatment, the resulting reimbursement payment rates may not be adequate to cover a provider's cost to purchase such medical device or ensure that purchase or lease will be profitable for the provider. Additionally, patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the treatment and may be unwilling to undergo such treatment in the absence of coverage and adequate reimbursement.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a treatment is: neither experimental nor investigational; safe, effective, and medically necessary; appropriate for the specific patient; cost-effective; supported by high quality evidence published in peer reviewed medical journals; included in clinical practice guidelines; and supported by medical community acceptance and demand.

Physician reimbursement under Medicare generally is based on a defined fee schedule, or the Physician Fee Schedule, through which payment amounts are determined by the relative values of the service rendered in a physician office setting or by a physician in a facility setting. Medicare coverage for TMS also has specific patient history requirements. Medicare coverage for Deep TMS generally requires one to four failed (inadequate response or intolerable) trials of psychopharmacologic agents (such as antidepressant medications).

In the United States, there is no uniform policy of coverage and reimbursement among private third-party payors. Reimbursement rates from private payors vary depending on the procedure performed, the commercial payor, contract terms, and other factors. Private third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Private insurance coverage for Deep TMS has traditionally required three to four failures of antidepressant medications. However, many payors have now reduced the number of prior failed medication trials needed to qualify for Deep TMS for MDD. Specifically, 194 million covered lives in the U.S. with commercial coverage now qualify for Deep TMS for MDD after two to three failed medication trials, and all Medicare Administrative Contractors (MACs) have issued Local Coverage Determinations (LCDs) qualifying approximately 62 million lives in the U.S. for Medicare reimbursement after just one to two failed medication trials.

Coverage and reimbursement for treatments can differ significantly from payor to payor. Decisions regarding the extent of coverage and amount of reimbursement to be provided for an in-office treatment are made on a plan-by-plan basis. One payor's determination to provide coverage for a specific treatment does not assure that other payors will also provide coverage and adequate reimbursement.

In addition, the U.S. federal government and state legislatures have continued to implement cost containment programs, including price controls and restrictions on coverage and reimbursement. Governmental and private insurers are increasingly challenging the price, examining the medical necessity, and reviewing the cost-efficacy of medical services. Adoption of price controls and cost containment measures by any such payors, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our market opportunity and reduce our revenues.

Private insurers currently cover treatments using our Deep TMS system for MDD, and there is now emerging coverage from various payors for Deep TMS therapy for OCD. We are actively engaged in efforts to facilitate increased coverage for OCD treatment by more payors, including both commercial and governmental. Reimbursement is not yet available for Deep TMS for smoking addiction or for therapies currently under development for other indications.

Nonetheless, we can provide no assurances that we will be able to obtain a wide range reimbursement coverage for OCD nor any reimbursement coverage for smoking addiction, and even if obtained, we can provide no assurance that the coverage will be at the same levels as we have for MDD.

We are also working to include Deep TMS in additional insurance coverage policies in the United States and in other jurisdictions in which we operate. In regions where we have appointed a local distributor, where reasonable, it is typically required under our agreements that the distributor utilize efforts to obtain reimbursement coverage for Deep TMS in the relevant territory on our behalf.

In June 2022, for the first time, the Israeli Ministry of Health approved coverage applicable it our Deep TMS system for the treatment of depression. The inclusion of the treatment within Israel's health basket of essential medical services means that Israel's health funds must now make the treatment available to qualifying patients free of charge. Qualifying patients include adults over the age of 21 with depression who have either not responded to two prior antidepressants, or who are intolerant to other treatment alternatives. Coverage may be provided for up to 40 treatment sessions, which are to be administered in hospitals. In addition, in September 2024, the Israel Ministry of Defense's Rehabilitation Department granted approval for the reimbursement of Deep TMS therapy for qualifying patients with PTSD at Israeli public hospitals. In Australia, in November 2021, for the first time, coverage applicable to Deep TMS for MDD was granted for adults over the age of 18. Coverage in Australia is available for 35 treatment sessions.

Government Regulation

United States

Our products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. Our products are subject to regulation as medical devices under the U.S. Federal Food, Drug and Cosmetic Act (FDCA), as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification or premarket approval, or PMA. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and efficacy. Class I includes devices with the lowest risk to the patient and are those for which safety and efficacy can be assured by adherence to the FDA's general controls for medical devices, which include compliance with the applicable portions of the QSR facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's general controls, and special controls as deemed necessary by the FDA to ensure the safety and efficacy of the device. These special controls can include performance standards, post-market surveillance, patient registries, special labeling requirements, premarket data requirements and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA.

Our Deep TMS system is classified as a Class II medical device. For MDD, smoking addiction, and subsequently granted applications relating to MDD (including a 3-minute Theta Burst protocol, a labeling expansion to include reduction of comorbid anxiety symptoms among depressed patients and an expansion of the labeling for late-life MDD), we obtained FDA marketing authorization through the 510(k) clearance process. For OCD, we obtained FDA marketing authorization through the *de novo* classification process. Subsequent changes made to our Deep TMS system will be made through one or more of the various existing FDA review pathways.

510(k) Marketing Clearance Pathway

To obtain 510(k) clearance, we must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes nine to 12 months, but may take significantly longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the *de novo* classification 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.

Premarket Approval Process

A PMA application must be submitted if the medical device is in Class III (although the FDA has the discretion to continue to allow certain pre-amendment Class III devices to use the 510(k) process) or cannot be cleared through the 510(k) process. A PMA application must be supported by, among other things, extensive technical, pre-clinical, clinical trials, manufacturing, and labeling data to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA application is submitted and filed, the FDA begins an in-depth review of the submitted information, which typically takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA will usually be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the QSR, which imposes extensive design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale, distribution, and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMA applications or supplements are required for significant modifications to the manufacturing process, labeling of the product and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an original PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

De novo Classification Process

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 substantially equivalent predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification process. This process 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 to a predicate device. The 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 obtained marketing authorization for the OCD indication for our Deep TMS system using the direct *de novo* request classification process. We have used the 510(k) clearance process to obtain authorization from the FDA for changes to our marketed Deep TMS system, including applications extending our clearances to our proprietary stimulator, and expansions to our MDD indication which now allow us to market a shorter 3 minute depression protocol as well the ability to market our MDD therapy for the reduction of comorbid anxiety symptoms among depressed patients, and we received an extension for the FDA clearance of our H7 Coil for treatment of MDD (including anxious depression). In June 2024, the FDA granted us an expanded indication for our Deep TMS system allowing for the treatment of patients with MDD ages 22 to 86, changing the previous upper age limit of 68. This represented our 10th FDA clearance and made our Deep TMS the first and only form of TMS indicated for the treatment of patients over the age of 68 suffering from MDD, including those with comorbid anxiety symptoms.

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) premarket notification. Clinical trials for significant risk devices generally require submission of an application for an Investigational Device Exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the investigational protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA as well as the appropriate institutional review boards (IRBs), at the clinical trial sites, and the informed consent of the patients participating in the clinical trial is obtained. 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. Any trials we conduct must be conducted in accordance with FDA regulations as well as other federal regulations and state laws concerning human subject protection and privacy. Moreover, the results of a clinical trial may not be sufficient to obtain clearance or approval of the product.

Changes to Marketed Devices

After a device receives 510(k) marketing clearance, or *de novo* classification, any modification that could significantly affect its safety or efficacy, or that would constitute a major change or modification in its intended use, will require a new 510(k) marketing clearance or, depending on the modification, a *de novo* classification or PMA. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications today are accomplished by a manufacturer documenting the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for every change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

Post-market Regulation

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

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the design, manufacturing, and distribution process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced, and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling;
- FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury or serious adverse events, if the malfunction were to recur;

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

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

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

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

We may be subject to similar foreign laws that may include applicable post-marketing requirements such as safety surveillance and risk-benefit analysis. Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation, and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, our manufacturing operations, and the recall or seizure of our products. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

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

- recalls, withdrawals, or administrative detention or seizure of our products;

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

- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;

- withdrawing 510(k) clearances or PMA approvals that have already been granted;

- refusal to grant export or import approvals for our products; or

- criminal prosecution.

U.S. and Foreign Healthcare Laws and Compliance Requirements

Healthcare providers, physicians, and third-party payors play a primary role in the recommendation, prescription, and payment for medical treatments. A medical device manufacturer's arrangements with third-party payors, providers, and patients may expose it to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect its business or the financial arrangements and relationships through which it markets, sells and distributes its products. Even if a medical device manufacturer does not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal, and state healthcare laws and regulations are applicable to its business. In addition, portions of our business may be subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). To the extent we provide any covered entity customers with services that involve the use or disclosure of protected health information (PHI) we may be required to enter into business associate agreements. Business associates are also directly liable for compliance with HIPAA. The laws that may affect a medical device manufacturer's ability to operate include, but are not limited to:

- the federal healthcare Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or providing remuneration (broadly interpreted to include anything of value), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arrange for or recommend a good or service for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare and Medicaid. The government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. Moreover, the government may assert that a claim for reimbursement that includes items resulting from a violation of the federal healthcare Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exceptions and regulatory safe harbors to the federal healthcare Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration to those who prescribe, purchase, or recommend medical device products, including discounts, or engaging individuals as speakers, consultants, or advisors, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as reimbursement support programs, educational or research grants, or charitable donations;

- the federal civil False Claims Act (FCA), which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal government funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Private individuals, commonly known as "whistleblowers," can bring FCA *qui tam* actions, on behalf of the government and themselves, and may share in amounts paid by the entity to the government in recovery or settlement. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of $14,308 to $28,619 per false or fraudulent claim or statement. Many pharmaceutical and medical device manufacturers have been investigated and have reached substantial settlements under the FCA in connection with alleged off label promotion of their products and allegedly providing free products to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, a claim including items or services resulting from a violation of the federal healthcare Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Moreover, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. There are also criminal penalties, including imprisonment and criminal fines, for making or presenting false, fictitious or fraudulent claims to the federal government;

- the federal Physician Self-Referral Law, commonly known as the Stark Law, which prohibits physicians from referring Medicare and Medicaid patients to healthcare entities in which they or any of their immediate family members have ownership interests or other financial arrangements, if these entities provide certain designated health services reimbursable by Medicare or Medicaid, unless an exception applies. The Stark Law also prohibits entities that provide designated health services reimbursable by Medicare and Medicaid from billing the Medicare and Medicaid programs for any items or services that result from a prohibited referral and requires the entities to refund amounts received for items or services provided pursuant to the prohibited referral on a timely basis. Sanctions for violating the Stark Law include denial of payment, civil monetary penalties and exclusion from the federal healthcare programs. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim and may result in civil penalties and additional penalties under the federal False Claims Act;

- the federal Anti-Inducement Law (also known as the Civil Monetary Penalties Law), which prohibits a person from offering or transferring remuneration to a Medicare or State healthcare program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State healthcare program;

- HIPAA, which prohibits and imposes criminal liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement 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. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their implementing regulations, which imposes privacy, security, transmission, and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, including health plans, healthcare clearinghouses, and certain healthcare providers and their respective business associates that perform services on their behalf that involve 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 HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, created under the PPACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers were also required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and

- foreign and state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; state laws that require device manufacturers to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and other federal and state laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus requiring additional compliance efforts and data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those in the United States (such as the European Union, which adopted the General Data Protection Regulation, which became effective in May 2018).

Because of the breadth of these laws and the narrowness of their statutory exceptions and regulatory safe harbors, it is possible that some of a medical device manufacturer's business activities could be subject to challenge under one or more of these laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations on some issues. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that business arrangements with third parties comply with applicable healthcare laws and regulations is costly and time consuming. If a medical device manufacturer's operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to it, it may be subject to civil, criminal and administrative penalties, damages, fines, disgorgement, substantial monetary penalties, individual imprisonment, exclusion from governmental funded healthcare programs, such as Medicare and Medicaid, additional reporting obligations and oversight if it becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of operations, any of which could adversely affect the ability of a medical device manufacturer to operate its business and the results of its operations.

United States Healthcare Reform

In the United States, a number of legislative and regulatory proposals have been considered or enacted to change the healthcare system in ways that could affect a medical device manufacturer's business. Among policy makers and governmental and private insurers in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. For example, in 2010, the PPACA was enacted, which includes measures to significantly change the way healthcare is financed by both governmental and private insurers, and significantly impacts the medical device industry. Among other ways in which it may impact a medical device manufacturer's business, the PPACA:

- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical efficacy research in an effort to coordinate and develop such research;

- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models; and

- expands the eligibility criteria for Medicaid programs.

Some of the provisions of the PPACA have yet to be implemented, and there have been judicial and Congressional challenges to modify, limit, or repeal certain aspects of the PPACA since its enactment and it has continued to evolve. During his first term as president, President Trump supported the repeal of all or portions of the PPACA, and in January 2017, he signed Executive Orders designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA to the maximum extent permitted by law. Due to such efforts, certain elements of the PPACA have been invalidated or suspended, which has, in turn, led to additional challenges against the law as a whole. For example, the Tax Cuts and Jobs Act of 2017 included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA 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". As a result, there is significant uncertainty regarding future healthcare reform and its impact on our operations. In December 2018, a district court in Texas held that the individual mandate is unconstitutional and that the rest of the PPACA is, therefore, invalid. On appeal, the Fifth Circuit Court of Appeals affirmed the holding on the individual mandate but remanded the case back to the lower court to reassess whether and how such holding affects the validity of the rest of the PPACA. The Fifth Circuit's decision on the individual mandate was appealed to the U.S. Supreme Court. On June 17, 2021, the Supreme Court held that the plaintiffs (comprised of the state of Texas, as well as numerous other states and certain individuals) did not have standing to challenge the constitutionality of the PPACA's individual mandate and, accordingly, vacated the Fifth Circuit's decision and instructed the district court to dismiss the case. As a result, the PPACA will remain in-effect in its current form for the foreseeable future; however, we cannot predict what additional challenges may arise in the future, the outcome thereof, or the impact any such actions may have on our business, and there is even greater uncertainty given the recent election of President Trump for a second term.

The Biden administration also introduced various measures in 2021 with a focus on healthcare and drug pricing, in particular. For example, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. 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 PPACA. On the legislative front, the American Rescue Plan Act of 2021 was signed into law on March 11, 2021, which, in relevant part, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source drugs and innovator multiple source drugs, beginning January 1, 2024. And, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (with negotiated drug prices beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program beginning in 2025. The IRA also authorizes the United States Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. We cannot yet assess the impact that the IRA will have on the medical-products industry, but it will likely be significant.

There is seemingly constant evolution with regard to healthcare in the United States, and we cannot predict what healthcare programs and regulations may be implemented or changed at the federal and/or state level or the effect of any future legislation or regulation on our business or that of our current or prospective customers, suppliers, and/or the U.S. healthcare industry as a whole.

It is possible that recent and/or future initiatives could have an adverse effect on our ability to obtain or maintain approvals and/or successfully commercialize products in the United States in the future. For example, any changes that reduce, or impede the ability to obtain, reimbursement for the type of products we currently market, or may commercialize in the future (as applicable), in the United States would likely have an adverse effect on our business and profitability.

Outside of the United States

In addition to U.S. regulations, we are subject to a variety of regulations in other jurisdictions governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA clearance or approval for a product, we must obtain authorization before commencing clinical trials or obtain marketing authorization or approval of our products under the comparable regulatory authorities of countries outside of the United States. The marketing authorization process varies from country to country and the time may be longer or shorter than that required for FDA clearance or approval.

We also have received European Conformity (CE) marking in the European Economic Area (EEA) and in Israel for MDD, OCD, and smoking addiction, and 11 other indications in psychiatry, addiction treatment, and neurology. Additional regulatory approvals have also been obtained for Deep TMS in various other existing and potential territories, including, for example, in Canada and India. Sales and marketing of medical devices outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. The time required to obtain appropriate marketing authorizations from other foreign authorities may be longer or shorter than that required for FDA approval. Whether or not we have obtained FDA approval, our Deep TMS systems may be subject to different regulatory requirements in other jurisdictions. The foreign regulatory approval process includes all the risks associated with FDA regulation, as well as country-specific risks and regulations.

Employees

Our employees include professionals with extensive experience in medical device development and applications, neurology and psychopathology, pre-clinical experimentation, clinical development, and business development. As of December 31, 2024, we had 120 employees, of which 49 were based in the United States and 71 were based outside of the United States (in Israel). Our U.S. employee base includes 47 employees in sales, marketing, and service/operations, 1 employee in medical affairs, and 1 general and administrative employee. Our Israeli employee base includes 31 employees in clinical trials, research and development, production, quality control, and service/operations, 6 employees in sales and marketing, and 34 general,administrative and operations employees.

While none of our employees are party to any collective bargaining agreements, certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists' Associations) are applicable to our employees by order of the Israel Ministry of Labor. Such orders are part of the employment related laws and regulations which apply to our employees and set certain mandatory terms of employment. Such mandatory terms of employment primarily concern the length of the workday, minimum daily wages, pension plan benefits for all employees, insurance for work-related accidents, procedures for dismissal of employees, severance pay and other conditions of employment. We generally provide our employees with benefits and working conditions beyond the required minimums.

We have never experienced an employment-related work stoppage and we believe our relationship with our employees is good.

Environmental Matters

We are subject to various environmental, health and safety laws and regulations, including those governing noise emissions. We believe that our business, operations, and facilities are being operated in compliance in all material respects with applicable environmental and health and safety laws and regulations. Based on information currently available to us, we do not expect environmental costs and contingencies to have a material adverse effect on us. Significant expenditures could be required in the future, however, if we are required to comply with new or more stringent environmental or health and safety laws, regulations or requirements.

Legal Proceedings

We are named as a co-defendant in a lawsuit by a patient alleging hearing loss following his enrollment in one of our clinical studies and we are vigorously defending this matter. There are also various employment-related claims (brought by former employees) and collection matters (stemming from debt accrued by certain of our customers, including larger national/enterprise customers and/or customers with multi-system orders).

C. Organizational Structure

Our three subsidiaries, all of which wholly-owned, are: BrainsWay, Inc., incorporated in Delaware on March 31, 2003; Brain Research and Development Services Ltd., incorporated in Israel on August 13, 2003; and BrainsWay USA Inc., incorporated in Delaware on November 24, 2014.

D. Property, Plants and Equipment

We have leased offices in Jerusalem, Israel, since November 2007. In 2024, we moved to a new building (across the street from our previous location) owned by an affiliate of our previous landlord and which was built according to our custom specifications. Our new headquarters consist of approximately 1,730 square meters, including administrative offices, research operations, central laboratory, and a warehouse. The initial lease term of the new space is 5 years beginning from the date we moved into the new space (which occurred on July 14, 2024), with an automatic extension period of another 5 years unless terminated prior thereto. Under the terms of the agreement, lease payments and management fees are pre-set according to an escalating price structure per year of the term, such that in the first year of the lease, the fees, including management fees, will amount to approximately $48,730 plus value added tax, or VAT, per month, in the aggregate, and are paid in NIS and are linked to the Israeli consumer price index. By the fifth year of the lease term, these fees will amount to approximately $58,280 plus VAT per month, in the aggregate.

We previously leased an office space in Boston, MA, where our previous CEO and CFO resided, in a space comprised of 3,976 square feet leased at a rate of $8,118 per month and this lease expired in November 2024 and was not renewed. We are currently searching for a new location for our US offices that will be ideally suited to meet our present needs.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this Annual Report. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, particularly those in "Item 3. Key Information—D. Risk Factors."

Company Overview

BrainsWay is a global leader in advanced noninvasive neurostimulation treatments for mental health disorders. We are boldly advancing neuroscience with our proprietary Deep Transcranial Magnetic Stimulation (Deep TMS™) platform technology to improve health and transform lives. We are dedicated to leading through superior science and building on what we believe to be an unparalleled body of clinical evidence. We are the first and only TMS company to be cleared by the FDA for three separate mental health condition indications based on clinically proven efficacy as demonstrated in pivotal randomized placebo-controlled studies. Current indications include major depressive disorder (MDD), including reduction of comorbid anxiety symptoms, commonly referred to as anxious depression, obsessive-compulsive disorder (OCD), and smoking addiction. We have also received CE Mark for a variety of psychiatric and neurological indications. We are focused on increasing global awareness of, and broad access to, Deep TMS. Deep TMS uses magnetic pulses to stimulate neurons and consequently modulates the physiological activity of the brain. Our technology can either increase brain activity in neuronal networks which are hypoactive, or alternatively decrease brain activity in neuronal networks which are hypoactive. Our proprietary electromagnetic coils, which we refer to as H-Coils, are designed to safely stimulate deep and broad brain regions, which we believe provides an advantage over other available TMS products, which we refer to collectively as Traditional TMS, that generally use a "figure 8" design. In the United States, we sell our Deep TMS system for the treatment of MDD (including reduction of comorbid anxiety symptoms, commonly referred to as anxious depression), OCD and smoking addictions. We believe that our Deep TMS technology has the potential to be safe and effective for the treatment of a wide range of additional psychiatric, neurological, and addiction disorders. Additional clinical trials of Deep TMS in various psychiatric, neurological, and addiction disorders are underway or planned.

Our first commercial H1 Coil Deep TMS product received clearance from the FDA in 2013 for the treatment of MDD in adult patients who have failed to achieve satisfactory improvement from anti-depressant medication in the current episode. Our Deep TMS system for MDD is currently marketed to and installed at psychiatrists' offices and other facilities principally in the United States and in certain other countries throughout the world. In addition, our second Deep TMS commercial product received FDA marketing authorization in August 2018 as an adjunct therapy for adult patients suffering from OCD, and we currently market this product to the same general clientele as our MDD systems. Furthermore, our third Deep TMS commercial product received FDA marketing authorization in August 2020 as a short-term therapy for smoking addiction. Moreover, in August 2021, we received 510(k) clearance from the FDA for our Deep TMS for its use for the reduction of comorbid anxiety symptoms in adult patients with depression. In August 2022, we received 510(k) clearance from the FDA for the use of our H7 Coil to treat MDD (including anxious depression). In 2024, we received FDA clearance for an expansion of our existing MDD clearance allowing for the treatment of patients within the 69-86 age range suffering from late life depression. Our sales and marketing efforts are currently focused in the United States, where we generated approximately 81% of our revenues in the year ended December 31, 2024.

We believe that Deep TMS represents a platform technology that provides for an opportunity to develop additional Deep TMS products for a variety of psychiatric, neurological, and addiction disorders. We are planning clinical trials for other indications, including neurological and/or addiction disorders.

Our current customers are principally doctors, hospitals, and medical centers in the field of psychiatry. Treatment with Deep TMS is typically performed as an office-based procedure using our Deep TMS system, which consists of our proprietary H-Coil helmet, as well as several other components, including a stimulator, cooling system, positioning arm and an operator interface. A course of treatment for MDD typically requires 20 treatment sessions (five times a week over a period of four weeks) and thereafter up to 24 additional maintenance-continuation sessions (twice weekly over a period of up to 12 weeks). The standard Deep TMS treatment protocol for OCD requires 29 treatment sessions over six weeks. A course of treatment for smoking addiction typically requires 18 treatment sessions, comprised of treatment five times a week over a period of three weeks, followed by treatment once per week for an additional three weeks. Each standard MDD, OCD or smoking addiction session lasts 20 minutes, 19 minutes, and 18 minutes, respectively. For Deep TMS for MDD, the FDA has also cleared a 3 minute "Theta Burst" treatment protocol. Patients may experience some discomfort during treatment and must use earplugs to reduce exposure to the loud sounds produced by the device. The treatment requires no anesthesia, hospitalization or sedation and no systemic side effects are associated with this therapy.

In the United States, we sell or lease Deep TMS systems by one of the following two methods: (i) a fixed-fee lease model in which the Deep TMS system is leased to a customer for a fixed annual fee, generally with a term of between 48 and 60 months, for unlimited use; and (ii) a sales or purchase model in which the Deep TMS system is sold to the customer for a fixed purchase price. Additional potential revenues may be derived from extended warranty fees paid for the system for service coverage beyond the standard included warranty period, and from variable or usage fees based on the number of treatments performed with the system. We are also able to leverage our platform technology, which includes the ability to treat multiple indications using different H-Coil helmets, to facilitate transactions utilizing combined pricing models often involving a single system with one or more add-on helmets. These flexible offerings are designed to facilitate market penetration by addressing the differing clinical needs and risk tolerance among our customer base. We commercialize Deep TMS for OCD based generally on either the sale model, or as part of a fixed-fee lease model together with our MDD system. Following our receipt of FDA clearance for smoking addiction, we completed controlled and limited market releases of our system for this indication, and are currently in the process of a clinical data collection effort to facilitate a long term commercial plan for this product.

As of December 31, 2024, we had an installed base of approximately 1,353 Deep TMS systems, whereby 578 systems were leased from us, and an additional 775 systems were sold by us prior to December 31, 2024. Our installed base increased by 252 systems during 2024. In addition, as of December 31, 2024, we had shipped 743 H7 Coils as additional coils attached to certain of our new and existing systems following our receipt in August 2018 of marketing approval from the FDA for our OCD system.

For the year ended December 31, 2024, our revenues were $41.0 million compared to $31.8 million for the year ended December 31, 2023, representing an increase of 29% over the revenues generated in 2023. Our net income for the year ended December 31, 2024 was $2.9 million, compared to net loss of $4.2 million for the year ended December 31, 2023.

As of December 31, 2024, we had an accumulated deficit of $98.4 million. Our primary sources of capital to date have been from public offerings in Israel and in the United States, and private placements of our securities, grants from the Israel Innovation Authority (IIA), borrowings under our credit facilities, the lease and sale and commercialization of our products and services.

We expect our research, development, and clinical trials expenses to increase in connection with our ongoing activities, particularly as we continue to develop next generation technology (including in the areas of multichannel and rotational field TMS), rollout additional features on our current platform (including beta testing of additional remote capabilities), pursue future confirmatory trials and data collection efforts for existing indications, and seek FDA clearance for new indications such as fatigue in MS, addictions (including alcohol, cocaine and/or opioid addiction), pain and other potential psychiatric and neurological indications. On November 5, 2024 we consummated a private placement of 2,103,745 ADSs and warrants to purchase 1,500,000 ADSs to Valor, for aggregate immediate gross proceeds of approximately $20 million. We believe that our existing cash resources will be sufficient to enable us to fund our operating expenses and capital expenditure requirements in the foreseeable future.

Components of Our Results of Operations

Revenues

We derive our revenues from the lease and sale of our Deep TMS systems. We offer the following main pricing models:

- *Sale Model:* The Deep TMS system is sold to the customer for a fixed purchase price.
- *Fixed-fee Lease Model:* The customer leases the Deep TMS system and pays a fixed annual or monthly fee for the term of the lease (generally between 48 and 60 months).

Additional revenues may be generated from certain customers in certain territories who are or may potentially be under a Pay Per Use model, whereby the customer pays a fixed fee per every patient session during which the system is used. Further potential revenues may be derived from extended warranty fees paid for the system for service coverage beyond the standard included warranty period, which is generally for one year, and from variable or usage fees based on the number of treatments performed with the system.

We are also able to leverage our platform technology, which includes the ability to treat multiple indications using different H-Coil helmets, to facilitate transactions utilizing combined pricing models often involving a single system with one or more add-on helmets.

Our revenues from the operating leases of our Deep TMS systems are recognized on a straight-line method over the term of the lease. Usage based fees, if applicable, are recognized as revenue when we are entitled to receive such revenue. Our revenues from sales are recognized when control of the system is transferred to the customer, generally upon delivery of the system.

Cost of revenues and gross margin

Our cost of revenues includes a significant component for the Deep TMS systems that we sell under our sales model. The cost of revenues for systems that we sell primarily consists of the costs of raw materials, including components purchased from our third-party contract manufacturers, and manufacturing and assembly of the components that we perform ourselves. The entire cost of the Deep TMS system is recognized upon such sales. While we have previously used a third-party stimulator for our Deep TMS systems, we developed and have received FDA clearance for our own proprietary stimulator for MDD (in May 2018), OCD (in March 2019), and smoking addiction (in April 2021).

In the case of our other models, including our fixed-fee lease model, where we maintain ownership of the Deep TMS systems and place our systems at sites for use by our customers, rather than selling them outright. Cost of revenue for these models includes a significant component of depreciation of the Deep TMS systems. We expect to continue to own our Deep TMS systems that have been placed under these models for the foreseeable future, which allows us to maintain our relatively low cost of revenues for those systems.

The cost of revenues for systems that we lease or sell also includes costs related to personnel, royalties to PHS and Yeda, shipping, and our operations department. We expect our cost of revenues to increase in absolute dollars to the extent our revenues increase.

Research and development expenses, net

Research and development expenses, net, consist primarily of personnel expenses, including salaries and related benefits and share-based compensation for employees, laboratory materials, regulatory costs, patents, facility costs, and travel expenses, as well as expenses associated with outsourced professional scientific development services, and the costs of multi-center and other clinical trials.

We expect to continue to incur research and development expenses for the foreseeable future as we advance the development of our Deep TMS technology for various neurological and/or addiction disorders, as well as for various hardware and software development projects related to the Deep TMS system.

Selling and marketing expenses

Selling and marketing expenses consist of marketing and commercial activities related to the sale and lease of our Deep TMS systems, as well as personnel expenses, including salaries and related benefits, sales commissions and share-based compensation for employees, collection fees and facility costs. Other significant sales and marketing costs include conferences, trade shows, and promotional and marketing activities, including direct and online marketing, SEO, earned media, practice support programs, media campaigns and travel expenses.

While we anticipate relative stability in current headcount levels for our existing commercial organization, we plan on investing additional resources including certain added roles to align with our strategic and growth initiatives.

General and administrative expenses

General and administrative expenses consist primarily of personnel expenses, including salaries and related benefits, share-based compensation, and travel expenses for employees in executive, finance, information technology, legal, and human resource functions. General and administrative expenses also include the cost of insurance, allowance for doubtful accounts, professional services, including legal and accounting fees, as well as administrative costs, including corporate facility costs.

General and administrative costs also include, but are not limited to, accounting, legal, human resources, consulting, investor relations, listing fees on The Nasdaq Global Market, costs associated with reporting and compliance in the United States, as well as director and officer insurance premiums, as a result of becoming a public company in the United States. We anticipate that our general and administrative expenses will decrease as we realign our corporate activities.

Finance income

Our finance income consists primarily of interest earned on our bank deposits, and remeasurement of warrants.

Finance expenses

Our finance expenses consist primarily of financing costs related to our outstanding liability to the IIA on account of grants received for financing our research and development activity, as well as expenses related to bank charges and foreign currency exchange transactions.

Income Taxes Expense

Our income taxes expense is derived primarily from income generated from the sales and lease of our Deep TMS systems from our U.S. subsidiary. During the year ended December 31, 2024, we recorded deferred tax assets in respect of temporary differences in the U.S. subsidiary.

Critical Accounting Policies and Estimates

The preparation of financial statements, in conformity with IFRS, requires companies to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and disclosure of contingent assets and liabilities at and as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates and judgments are subject to an inherent degree of uncertainty, and actual results may differ. Our significant accounting policies are more fully described in Note 2 to our financial statements included elsewhere in this Annual Report. Critical accounting estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances, and are particularly important to the portrayal of our financial position and results of operations. Our estimates are primarily guided by observing the following critical accounting policies:

Allowance for Doubtful Accounts based on Expected Credit Losses on Trade Receivables

We apply a simplified approach and measure the loss allowance in respect of our short-term financial assets, trade receivables, in an amount equal to the lifetime expected credit losses.

We record an allowance for doubtful accounts based on expected credit losses for trade receivables. The allowance rates are based on days past due for our various customers. The allowance is initially based on our historical observed default rates as well as forward-looking information. At each reporting date, the historical observed default rates are updated and changes in the forward-looking estimates are analyzed. The amount of the allowance is sensitive to changes in circumstances and forecasted economic conditions.

Impairment of inventory:

The net realizable value is determined based on management's evaluation including forecasts and estimates as to the amounts expected to be realized from the sale or use of inventory. The possible effects on the financial statements are the recognition of impairment loss or the reversal of impairment loss.

Determining the Fair Value of an Unquoted Financial Asset or Liability - for the Warrants Liability

The fair value of unquoted financial assets or liability in Level 3 of the fair value hierarchy is determined using valuation techniques, generally using future cash flows discounted at current rates applicable for items with similar terms and risk characteristics. Changes in estimated future cash flows and estimated discount rates, after consideration of risks such as liquidity risk, credit risk and volatility, are liable to affect the fair value of these assets of liability.

Recent Accounting Pronouncements

The recent accounting pronouncements are set forth in Note 2 to our audited consolidated financial statements beginning on page F-1 of this Annual Report.

A. Operating Results

Quarterly Results of Operations

The following tables show our unaudited quarterly statements of operations for the periods indicated. We have prepared this quarterly information on a basis consistent with our audited financial statements.

Three months ended	**March 31**	**June 30**	**Sep. 30**	**Dec. 31**	**March 31**	**June 30**	**Sep. 30**	**Dec. 31**	**March 31**	**June 30**	**Sep. 30**	**Dec. 31**
	2024				**2023**				**2022**			
	Statement of Operations (in U.S dollars thousands)											
Revenues	9,095	10,005	10,502	11,414	6,625	7,829	8,302	9,029	7,970	8,006	5,168	6,033
Cost of revenues	2,283	2,468	2,781	2,903	1,792	2,095	2,131	2,290	1,867	2,192	1,341	1,729
Gross profit	**6,812**	**7,537**	**7,721**	**8,511**	**4,833**	**5,734**	**6,171**	**6,739**	**6,103**	**5,814**	**3,827**	**4,304**
Research and development expenses, net	1,626	1,711	1,809	2,044	1,785	1,902	1,544	1,434	1,576	1,731	2,220	2,151
Selling and marketing expenses	3,827	3,796	4,108	4,472	4,912	3,983	3,602	3,959	4,146	4,552	4,751	4,750
General and administrative expenses	1,266	1,444	1,523	1,564	1,803	1,192	1,158	1,162	1,863	1,539	1,726	1,726
Total Operating expenses	6,719	6,951	7,440	8,080	8,500	7,077	6,304	6,555	7,585	7,822	8,697	8,627
Total operating income (loss)	**93**	**586**	**281**	**431**	**(3,667)**	**(1,343)**	**(133)**	**184**	**(1,482)**	**(2,008)**	**(4,870)**	**(4,323)**
Finance income (expenses), net	190	117	456	1,305	1,407	(135)	(38)	(221)	(324)	(329)	(99)	401
Income (loss) before income taxes	**283**	**703**	**737**	**1,736**	**(2,260)**	**(1,478)**	**(171)**	**(37)**	**(1,806)**	**(2,337)**	**(4,969)**	**(3,922)**
Income taxes (tax benefit)	172	103	75	188	171	185	59	(164)	187	113	70	(55)
Net income (loss) and Comprehensive income (loss)	**111**	**600**	**662**	**1,548**	**(2,431)**	**(1,663)**	**(230)**	**127**	**(1,993)**	**(2,450)**	**(5,039)**	**(3,867)**

Our quarterly revenues and operating results have varied in the past and are expected to vary in the future due to numerous factors. We believe that period-to-period comparisons of our operating results are not necessarily meaningful and should not be relied upon as indications of future performance.

Year ended December 31, 2024 compared to year ended December 31, 2023

Revenues

Our total revenues increased by $9.2 million, or 29%, from $31.8 million for the year ended December 31, 2023 to $41.0 million for the year ended December 31, 2024. The increase in revenues is primarily attributed to an increase in leases and sales of our Deep TMS systems to customers. Revenues from sales and leases were 55% and 35%, respectively, of the revenues for the year ended December 31, 2024, compared to 64% and 27%, respectively, of the revenues for the year ended December 31, 2023.

Cost of revenues and gross margin

Our cost of revenues was $10.4 million for the year ended December 31, 2024 compared to $8.3 million for the year ended December 31, 2023. The increase of $2.1 million, or 26% is primarily attributed to an increase in sales volumes. There has been no material change in our gross margin as a percentage of revenue for the last three years.

Research and development expenses, net

Our research and development expenses, net, were $7.2 million for the year ended December 31, 2024 compared to $6.7 million for the year ended December 31, 2023. The increase of $0.5 million, or 7%, is primarily attributed to an increase in headcount and in investments in clinical trial and post-marketing studies.

Selling and marketing expenses

Our selling and marketing expenses were $16.2 million for the year ended December 31, 2024 compared to $16.5 million for the year ended December 31, 2023. The decrease of $0.3 million, or 2%, is primarily attributed to a decrease in the costs of the commercial team in the United States. These cost savings included decreased headcounts and costs associated with same, recruiting expenses, advertising and promotional expenses. The Company also improved its cost effectiveness for marketing expenses by targeting the investments to specific groups and growing markets.

General and administrative expenses

Our general and administrative expenses were $5.8 million for the year ended December 31, 2024 compared to $5.3 million for the year ended December 31, 2023. The increase of $0.5 million, or 9%, is primarily attributed to termination of equity awards and related forfeiture of share-based payments in 2023 in connection with the restructuring process that occurred in 2023.

Finance expenses, net

Our finance income, net, was $2.0 million for the year ended December 31, 2024 compared to finance income, net of $1.0 million for the year ended December 31, 2023. The increase of $1.0 million is primarily attributed to remeasurement of warrants.

For information on the impact of currency fluctuations on the company, please see "*Item 11. Quantitative and Qualitative Disclosures About Market Risk*" below.

Year ended December 31, 2023 compared to year ended December 31, 2022

For comparison of fiscal year 2023 to fiscal year 2022 please see "*Management's Discussion and Analysis of Financial Condition and Results of Operations - Year ended December 31, 2023 compared to year ended December 31, 2022*" section in our annual report on form 20-F for the year ended December 31, 2023 filed with the SEC on March 28, 2024.

For more information regarding governmental economic, fiscal, monetary or political policies or factors that have materially affected, or could materially affect, directly or indirectly, the Company's operations in Israel, please see also "*Item 3D. Risk Factors—Risks Related to Our Functions in Israel*."

B. Liquidity and Capital Resources

As of December 31, 2024, we had cash, cash equivalents, restricted cash and short-term deposits of $69.6 million and an accumulated deficit of $98.4 million, compared to cash, cash equivalents, restricted cash and short-term deposits of $46.3 million, and an accumulated deficit of $101.3 million as of December 31, 2023. We incurred positive cash flows from operating activities of $10.3 million and positive cash flows from operating activities of $1.3 million for the years ended December 31, 2024 and 2023, respectively. We incurred operating losses from our inception through the year ended December 31, 2023, and reached a net profit in the year ended December 31, 2024 mainly due to an increase in sales. Our primary sources of capital to date have been from public offerings in the U.S. and Israel and private placements of our securities, grants from the IIA, and leases and sales of our Deep TMS systems. From inception through December 31, 2024, we raised approximately $149 million from placements of our securities and exercise of options.

Our primary contractual obligations consist of liabilities in respect of research and development grants received from the IIA, royalties in respect of license agreements for the use of some of our intellectual property with Yeda and PHS, as well as lease liabilities in respect of corporate facilities and vehicles. For information about our contractual obligations, see Notes 11 and 12 to our financial statements included in this Annual Report.

We expect our revenues to increase in connection with our ongoing activities, particularly as we expand the marketing of our Deep TMS system for MDD, OCD, and smoking addiction. In November 2024, we raised approximately $20 million in immediate proceeds from a private placement of 2,103,745 ADSs and warrants to purchase 1,500,000 ADSs to Valor. Accordingly, based on our current business plan, we believe that our cash and cash equivalents as of December 31, 2024 and the anticipated revenues from sales of our products will be sufficient to fund our operating expenses and capital expenditure requirements in the foreseeable future.

Cash flows

The table below summarizes our cash flow activities for the indicated periods:

	Year Ended December 31,	
(in U.S dollars thousands)	**2024**	**2023**
Net cash provided by operating activities	10,298	1,284
Net cash provided by (used in) investing activities	30,311	(37,409)
Net cash provided by (used in) financing activities	18,263	(1,026)
Exchange rate differences on cash and cash equivalents	(47)	90
Increase (decrease) in cash and cash equivalents	58,825	(37,061)

Operating Activities

Net cash provided by operating activities was $10.3 million during the year ended December 31, 2024, compared to $1.3 million provided by operating activities during the year ended December 31, 2023. The increase of $9.0 million is primarily attributed to net profit in 2024 compared to a net loss in 2023.

Investing Activities

Net cash provided by investing activities was $30.3 million during the year ended December 31, 2024, compared to $37.4 million used in investing activities during the year ended December 31, 2023. The increase in cash provided by investing activities is mainly due to the transfer of $35 million that as of December 31, 2023 were held in bank deposits for a duration of over three months and as of December 31, 2024 were held in bank deposits for a duration of less than three months. This resulted in a change in the way these amounts are classified from “short term deposits” (in the year ended December 31, 2023) to “cash and cash equivalents” (in the year ended December 31, 2024).

Financing Activities

Net cash provided by financing activities was $18.3 million during the year ended December 31, 2024, compared to $1.0 million used in financing activities during the year ended December 31, 2023. The change is primarily attributed to the proceeds from the private placement to Valor in 2024.

Government Grants

As of December 31, 2024, our wholly owned subsidiary, Brain Research and Development Services Ltd., received grants from the IIA in an aggregate amount of approximately $13.4 million. Brain Research and Development Services Ltd. is currently required to pay 3% royalties of sales of our Deep TMS products, which payment obligations do not currently exceed the amount of the grant received (in U.S. dollars), plus interest at an annual rate equal to the LIBOR rate. As of December 31, 2024, Brain Research and Development Services Ltd. paid royalties to the IIA in an aggregate amount of approximately $6.2 million (including amounts in respect of accrued interest), with remaining outstanding royalties of up to $10.1 million. In the event of failure of a project that was partly financed by the IIA, we would not be obligated to pay any royalties or repay the amounts received.

Research and development grants received from the IIA are recognized upon receipt as a liability if future economic benefits are expected from the project that will result in royalty-bearing sales. The amount of the liability for the loan is first measured at fair value using a discount rate that reflects a market rate of interest that reflects, in turn, the appropriate degree of risks inherent in our business. If no economic benefits are expected from the research activity, the grants received are recognized as a reduction of the related research and development expenses. In that event, the royalty obligation is treated as a contingent liability in accordance with IAS 37, "Provisions, Contingent Liabilities, and Contingent Asset."

At the end of each reporting period, we evaluate whether there is a reasonable assurance that the received grants will not be repaid based on our best estimate of future sales and, if so, no liability is recognized, and the grants are recorded against a corresponding reduction in research and development expenses.

Additionally, in 2013, the MAGNET committee of the IIA (MAGNET) approved the activities of the consortium for the development plan of a brain stimulator and monitor tool, which we refer to as the Consortium, of which we are one of the participants. As part of the Consortium, Brain Research and Development Services Ltd. received from MAGNET approvals for grants in an aggregate amount of NIS 8.2 million (approximately $2.25 million based on the NIS to USD exchange rate as of December 31, 2024). There is no requirement to repay the grants or pay royalties thereon. Such non-royalty-bearing grants from the MAGNET program for funding approved research and development projects are recognized when there is reasonable assurance that the grants will be received and we will comply with all related conditions, on the basis of the costs incurred, and are presented as a deduction from research and development expenses.

Outstanding Warrants

In connection with the private placement to Valor, consummated on November 5, 2024, we issued Valor a warrant to purchase 1,500,000 ADSs, or the Valor Warrant, at an exercise price of $9.50686 per ADS, or the Valor Warrant Exercise Price. The Valor Warrant became exercisable upon issuance thereof at the closing of the Valor investment and will remain exercisable for 18 months after the initial issuance date, or the Exercise Period. Under the Valor Warrant, if at any time during the Exercise Period, the ADS closing price of any thirty (30) consecutive trading day period exceeds the Valor Warrant Exercise Price by 40% or more, Valor shall be required to fully exercise the Valor Warrant within five (5) trading days. Valor may also exercise the Valor Warrant, in whole or in part, at any time during the Exercise Period, by means of a "cashless exercise" according to the formula set forth in the Valor Warrant.

C. Research and Development, Patents, and Licenses

For descriptions of our research and development policies for the years 2023 and 2022, please see the "*Item 5.C Research and Development, Patents, and Licenses*" sections in our annual reports on Form 20-F filed with the SEC on March 28, 2024 and March 27, 2023, respectively.

Intellectual Property

The core technology of our Deep TMS based on H-Coils is covered by our patents.

Our intellectual property portfolio consists principally of patents and pending patent applications related to our Deep TMS technology that are either exclusively licensed to us for commercialization on a worldwide basis from (1) agencies of the U.S. Public Health Service (PHS) within the U.S. Department of Health and Human Services (DHHS), and (2) Yeda Research and Development Company Limited (Yeda), the commercialization arm of the Weizmann Institute for Science (Weizmann Institute) or are owned by us. These include a total of 34 issued U.S. patents, 1 pending U.S. patent application, and 60 issued patents and 10 pending patent applications in other jurisdictions (treating Europe as one jurisdiction).

Our strategy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development of our business. Our intellectual property rights outside of the United States are principally in Europe (France, Italy, Sweden, UK, and Germany), Canada, Australia, Japan, Hong Kong, and Israel. Patents related to our Deep TMS technology may provide future competitive advantages with claims related to aspects of the structure of our coils and methods of administration of treatment for applications of such technology. We also rely on our trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position. We look to defend our Deep TMS technology by asserting our intellectual property rights, where it is determined to be necessary, to preserve our rights and gain the benefit of our technological investments. We seek to obtain patents in connection with the technology that we developed as part of our strategy for protection of our intellectual property, including technology covered under our license agreements with the PHS and Yeda.

The claiming strategy in each of our patent applications is based on the advice of our patent counsel and our business model and business needs are taken into consideration. We file patent applications containing claims seeking protection of our proprietary technologies and products, as well as all new applications and/or uses we discover or develop for existing technologies and products, assuming these are strategically valuable. We continuously assess the number and types of patent applications, as well as the pending and issued patent claims, to ensure that appropriate coverage and value are obtained for our systems and methods, given the governing law and the corresponding patent office rules and regulations. In addition, claims may be modified during patent prosecution or additional claims added to meet our intellectual property and business needs.

Patents and Patent Applications

Our first group of patents (Patent Family A) relates to the H-Coil technology in general: This includes coverage for the H-Coil for MDD, the H-Coil for OCD, the H-Coil for smoking addiction, and for future products we are developing. This group of patents has been exclusively licensed to us from the PHS, and includes two issued U.S. patents and eight issued patents in other jurisdictions. The issued patents are set to expire in 2026 in the U.S. and expired in 2021 outside the U.S. These coils are also covered by additional patents which extend until later dates as detailed further in this section.

Our second group of patents (Patent Family B) relates to additional design features of BrainsWay's H-Coil for MDD, H-Coil for smoking addiction, and also covers some future products we are developing. This group of patents has been licensed to us from the PHS and from Yeda, and includes six issued U.S. patents and eleven issued patents in other jurisdictions. The issued patents in this group are set to expire in 2025-2028 in the U.S. and in 2026 in other countries, not taking into account any potential patent term adjustment or extension that may be available in the future. These coils are also covered by additional patents which extend until later dates as detailed further in this section.

Our third group of patents (Patent Family C) relates to a family of central base coils including BrainsWay's H-Coil for OCD (which is also cleared for MDD), and also some future products that we are developing. Patent Family C is owned by us, and includes three issued U.S. patents, and eleven issued patents in other jurisdictions. The issued patents are set to expire in 2033 in the U.S., and in 2034 in other countries, not taking into account any potential patent term adjustment or extension that may be available in the future.

Our fourth group of patents (Patent Family D) relates to a family of unilateral coils including some future products we are developing. Patent Family D is owned by us, and includes one issued U.S. patent, and five issued patents in other jurisdictions. The issued patents are set to expire in 2033 in the U.S., and in 2034 in other countries, not taking into account any potential patent term adjustment or extension that may be available in the future.

Our fifth group of patents (Patent Family E) consists of utility model patent applications and other patent applications which provide coverage of several H-Coils, including those used in BrainsWay's MDD and OCD systems. Patent Family E is owned by us, and includes two issued Chinese Utility Model patents, one issued patent in the U.S., five issued patents in other jurisdictions, and two pending patent applications in other jurisdictions. The issued patents are set to expire in 2039.

Our sixth group of patents (Patent Family F) relates to a family of circular coils including BrainsWay's H-Coils for MDD and smoking, as well as some other future products we are developing. Patent Family F is owned by us, and includes two issued U.S. patents, and seven issued patents in other jurisdictions. The issued patents are set to expire in 2033 in the U.S. and in 2034 in other countries, not taking into account any potential patent term adjustment or extension that may be available in the future.

Our seventh group of patents (Patent Family G) relates to real-time closed-loop brain stimulation and includes one issued U.S. patent and three pending patent applications in other jurisdictions. The issued patent is set to expire in 2038.

Our eighth group of patents (consisting of additional families of issued patents and pending patent applications) relates to a multichannel stimulator we are developing as an enhancement to our Deep TMS system, which we see as the next generation of our products, several H-Coil designs which may be future products, capabilities to address additional medical conditions such as the need to open the blood brain barrier, and biomarker research using Deep TMS with an EEG that we are currently conducting. These include seven issued U.S. patents, and fifteen issued or allowed patents in other jurisdictions. The issued patents in these families are set to expire in 2029, 2031, 2033, and between 2037 and 2039, not taking into account any potential patent term adjustment or extension that may be available in the future.

In addition to the list of patents noted above, we own an additional group of U.S. patents that relates to multichannel stimulation and was acquired from TMS Innovations, LLC in 2019. We believe these patents will enable us to broaden the scope of capabilities in the multichannel stimulator we are developing. The issued patents are set to expire between 2028 and 2035, not taking into account any potential patent term adjustment or extension that may be available in the future.

In addition to the list of patents noted above, in January 2020 we exercised our option to exclusively license the rights to certain patents relating to rotational field TMS from Yeda. This group of patents includes two issued U.S. patents and four issued patents in other jurisdictions. The issued patents are set to expire in 2032 in the U.S. and in 2030 in other jurisdictions, not taking into account any potential patent term adjustment or extension that may be available in the future.

In addition to the list of patents noted above, we own another family of patent applications which provide coverage of several H-Coils, including those used in our MDD and OCD systems, and of aspects of rotational field TMS. This patent family is owned by us, and includes one pending patent application in the U.S., and five pending patent applications in other jurisdictions.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions that may vary from one jurisdiction to another. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We can provide no assurance that our patent applications or those patent applications that we in-license will result in the issuance of any corresponding patents (other than any allowed patent applications, which normally result in the issuance of a patent after the applicant has paid the required issue fee). The inability of any such patent applications to be allowed may harm our ability to protect our intellectual property, our ability to compete in the neuromodulation market, and our results of operations. Our issued patents and those that may be issued in the future, or those licensed to us, may be challenged, narrowed, circumvented or found to be invalid or unenforceable, which could limit our ability to stop competitors from marketing related products. Neither we nor our licensors can be certain that we were the first to invent or first to file for the inventions claimed in our owned or licensed patents or patent applications which may also affect our ability to assert the patents against others. In addition, our competitors may design around our patents or any technology developed by us, and the rights granted under any issued patents may not provide us with any meaningful competitive advantages against these competitors. Furthermore, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before our future product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. See "*Item 3.D. Risk Factors—Risk Relating to Intellectual Property*."

License Agreements

The core technology for Deep TMS is exclusively licensed to us for commercialization on a worldwide basis from the PHS and Yeda.

PHS License Agreement

The initial discoveries of the Deep TMS technology and the feasibility studies for implementation of the technology were carried out in the framework of research performed at NIH by the scientific founders of our Company prior to its formation. The rights for such discoveries are owned by the DHHS and are now licensed to us by the PHS, an agency within the DHHS. Subsequent to these discoveries, applications were filed for registration of Patent Family A and Patent Family B (described under "—Patents" above) covering the H-Coils developed in the course of this research.

In 2003, we entered into a license agreement with the PHS, pursuant to which we were granted (i) an exclusive license to develop, manufacture, use, import and sell any product or treatment which is created or based on the patents and which deals with TMS and (ii) the right to enter into sublicense agreements, subject to approval of the PHS. The U.S. government was granted an irrevocable, nonexclusive, nontransferable royalty-free license for use of any invention in connection with the patents, throughout the world, for the benefit of the U.S. government, a foreign government and other international organization under the provisions of a treaty or agreement applicable to the U.S. government at such time. In addition, the PHS is entitled to grant academic or commercial bodies a nonexclusive license for use of the patents for advancement of basic research only, subject to our consent.

We are required to pay royalties consisting of 2% from payments received from sales or leases of our Deep TMS systems and/or portions thereof using the licensed technology (beyond the first $10 million in cumulative sales, a milestone which has passed). In addition, we are required to pay a royalty of 8% from the net cash proceeds we receive from any sublicenses, so long as the underlying intellectual property is valid and enforceable in the relevant territory. Moreover, there is a one-time $10,000 fee relating to certain new FDA approvals associated with these patents.

The PHS is responsible for registration and defense of Patent Family A, subject to indemnification by us for registration expenses. We are responsible for registration and defense of the Patent Family B and are required to bear all related expenses.

The PHS license agreement is valid up until the expiration of the last to expire of the licensed patent rights under the agreement. The PHS may cancel the agreement in the event of, among others, (i) a fundamental breach by us, (ii) we enter into involuntary liquidation proceedings or shall become insolvent, (iii) we have not achieved our milestones under the agreement (all of which have been achieved as of the date hereof), (iv) we have maliciously made a false statement or has omitted a material fact in an application for a license or in any other report required under the agreement, (v) we do not make the product based upon the patents accessible to the public after commencement of the commercial marketing of the product, (vi) we are unable to bring the product to a level of safety which it must reach in order to license the product or (vii) we do not manufacture the licensed products substantially in the United States without reasonable justification, in each case, subject to a 90-day cure period (other than in respect of clause (ii) above). We may cancel the agreement at any time with 60 days' notice, subject to payment of any outstanding royalties.

If the PHS license agreement is terminated as a result of the expiration of the first registered patent under the agreement (as described above), we may continue to market and sell the products and processes in any country in which the patent is expired, without an obligation to pay royalties or any other payment whatsoever to the PHS.

Yeda License Agreement

In 2005, we entered into a research and licensing agreement with Yeda, which, as amended from time to time, we refer to as the Yeda license agreement, pursuant to which we licensed certain technologies developed at the Weizmann Institute in studies conducted by Prof. Abraham Zangen, our scientific founder and neurobiological advisor, in the field of treatment of depression using TMS technology. Under the Yeda license agreement, all of the rights, including the rights to registration of patents, rights and inventions, information and/or other results which shall arise from the research, referred to as the "licensed technology", remain exclusively owned by Yeda. The Yeda license agreement grants us an exclusive license to use the licensed technology, throughout the world, for performance of research and development, manufacture, commercialization, and sale of systems for medical treatment in the field of TMS treatment. The license is valid with regard to every product up to the expiration or revocation date of the latest patent registered under the agreement in a particular country, provided that the date of expiry of the license shall be extended to a period of 15 years commencing on the date of first commercial sale of the product in such country. Yeda reserves the right to make use of the information which shall be developed for academic and research purposes only, including its publication, subject to various restrictions set forth in the agreement. We have agreed to lend to Yeda, without consideration, one Deep TMS system, which it shall use for academic research purposes only. We have the right to grant sublicenses subject to the fulfillment of conditions specified in the agreement.

Under the terms of the Yeda license agreement, we are required to pay 1% of net sales on systems which are based on certain patents (which include technology licensed from PHS). Additionally, we are required to pay 2% of net sales (beyond the first $10 million in cumulative sales, a milestone which has passed), for products which are based solely on certain patents licensed exclusively from Yeda. In addition, in the event we receive income from products which are sublicensed, we would be required to pay a royalty of up to 8% on the net cash proceeds received from such sublicenses, so long as the underlying intellectual property is valid and enforceable in the relevant territory. Moreover, the Yeda license agreement provides for certain one-time fees relating to certain new FDA approvals associated with these patents.

In January 2020, we exercised our right to add the additional rotational field TMS innovation to the Yeda license agreement. To the extent products based on this technology are commercialized we will have to pay Yeda royalties, either at increased rates ranging from 1.6%-2% in addition to the previously determined rates for "combined products" (which also include innovations covered by previous agreements), or at a fixed rate of 5% for products based exclusively on the rotational field TMS.

In addition to customary termination rights of a party due to material breach by the other party, Yeda has the right to terminate the Yeda license agreement in the event that Yeda receives notice or a claim from the PHS that performance of the research constitutes breach of a patent of the PHS. We have agreed to indemnify Yeda in respect of any such claim or demand from the PHS. To the best of our knowledge, the Yeda license agreement and performance of the research thereunder do not breach the terms of our license agreement with the PHS.

In any event of termination of the Yeda agreement, all of the rights in the licensed technology will be returned to Yeda, and we are required to grant Yeda a nonexclusive license, without consideration, in perpetuity, throughout the world for all information developed by it or which shall arise from the development of the products under the agreement, including any license or application for license submitted by us in connection with the products. Following the expiry of the latest patent in such country with regard to such product, we would be entitled to continue to manufacture and sell such product in such country without payment of royalties to Yeda.

Trade Secrets and Know-How

We may rely, in some circumstances, on trade secrets and know-how to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, through confidentiality agreements and assignment of inventions agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, such agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

D. Trend Information

Trend information is included throughout the other sections of this Item 5. In addition, in the aftermath of the COVID-19 global pandemic, quarantine mandates, and the ensuing global supply chain crisis, we have seen a rise in the price of many of the electronic components needed for our systems. These price increases are largely attributable to supply and demand factors, and in some cases, shortages, relating to these parts across the globe. On a related point, the lead time for receiving electronic components shipped by suppliers has increased significantly in recent years amid the worldwide supply chain crisis, and the subsequent shipping disruptions caused by the war between Ukraine and Russia, the Israel-Gaza and the Israel-Hezbollah conflicts and Houthi attacks on shipping routes. This was particularly true in 2024, when far fewer carriers operated flights into and outside of Israel. All of this has compelled us to significantly increase inventory levels and/or to utilize more expensive shipping methods to ensure that future demand for our systems can be timely met.

E. Critical Accounting Estimates

Not applicable.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management Recent Developments

In connection with the consummation of the private placement of the ADSs and warrants to purchase ADSs on November 5, 2024, Mr. Yossi Ben Shalom resigned from our Board of Directors and Mr. Jonathan Shulkin was appointed as a member of our Board of Directors.

The following table sets forth the name, age and position of each of our executive officers and directors as of the date of this Annual Report.

Name	Age	Position
Executive Officers		
Hadar Levy	51	Chief Executive Officer
Ido Marom	49	Chief Financial Officer
Gilead Moiseyev, PhD	53	Chief Technology Officer
Yiftach Roth, PhD	55	Chief Scientist
Colleen Hanlon, PhD	45	Vice President of Medical Affairs
Directors:		
Ami Boehm	55	Chairman of the Board
Dr. David Zacut[3]	72	Vice Chairman of the Board
Avner Hagai[2][4]	68	Director
Eti Mitrany[1][2]	54	Director
Karen Sarid[1][2][3]	73	Director
Prof. Abraham Zangen	54	Director
Avner Lushi[1][4]	58	Director
Jonathan Shulkin[4]	50	Director

(1)Member of our audit committee.
(2)Member of our compensation committee.
(3)Member of our executive committee.
(4)Member of our nomination committee.

Executive Officers

Hadar Levy has served as our Chief Executive Officer since February 13, 2023. Prior to this, Mr. Levy served as our Senior Vice President and General Manager North America since May 2020, and before that as Chief Financial Officer from September 2014 to May 2020. Mr. Levy also serves as a director in ReWalk Robotics Ltd. (Nasdaq listed) since July 2022. Prior to joining us, from August 2011 to September 2014 Mr. Levy served as Chief Financial Officer of the Latin American Division at Amdocs; and from 2008 to 2011, served as Chief Financial Officer & Vice President of Business Development of Notalvision. Prior to this position, he served as Controller of GE Healthcare Israel. Mr. Levy holds a BA in Economics and Accounting from Ruppin and an LLM from Bar Ilan University. Mr. Levy is a Certified Public Accountant.

Ido Marom has served as our Chief Financial Officer since May 2023. Prior to joining the Company, he served as CFO of Surgical Theater Inc., a start-up medical technology company since 2019. Prior to this, he served as Finance Director – Commercial Finance Business Officer at Amdocs, a global market leader in the communication and media industry. Previously, he served as CFO and Chief Operating Officer of The Jewish Agency in North America and as Vice President of Finance of Ness Technologies, a global provider of IT services. Mr. Marom is a Certified Public Accountant and holds a BA in Accounting and Finance from Haifa University, Israel.

Gilead Moiseyev has served as our Chief Technology Officer since March 2024. Prior to BrainsWay, Gilead spent five years at Magenta Medical as Chief Operating Officer, developing a percutaneously implanted, expandable, coronary pump. Before Magenta, Gilead spent 16 years at Medinol, where he helped develop and bring to market an array of both coronary and peripheral systems. Mr. Moiseyev holds a B.Sc. in Mechanical Engineering, an M.Sc. in Computational Mechanics and a Ph.D. in Computational Mechanics, all from the Technion, Israel.

Yiftach Roth is one of our scientific founders and key inventors of the Deep TMS technology. Dr. Roth has led and/or participated in our key scientific and Research and Development initiatives since May 2006. In 2010, Dr. Roth became our Chief Scientist. From 2003 through 2006, Dr. Roth worked in the Advanced Technology Center of the Chaim Sheba Medical Center at Tel Hashomer as a researcher in the field of Magnetic Resonance Imaging (MRI). Dr. Roth holds B.Sc. and M.Sc. degrees in Physics and a Ph.D. in Medical Physics from Tel Aviv University. Dr. Roth is the brother-in-law of Professor Zangen, a director and scientific consultant for the Company.

Colleen Hanlon has served as our Vice President Medical Affairs since November 2022. Prior to joining the Company, she spent nine years as a faculty member in the Department of Psychiatry at the Medical University of South Carolina (2010-2019), before being recruited to design, build, and manage a Neuromodulation Program as a tenured professor in the Departments of Cancer Biology and Translational Neuroscience at Wake Forest School of Medicine (2019-2022). She has experience leading multidisciplinary clinical research programs bridging neurology, psychiatry and pain. She has published over 100 articles, authored over 10 book chapters, been involved in hiring and managing over 50 people, mentored over 80 trainees, delivered over 100 invited talks and educational sessions globally. Recognized as a leader and pioneer in the field of brain imaging and brain stimulation research for addiction, Dr. Hanlon received over $13 million from the National Institute of Health to develop neural-circuit based therapeutics, like Transcranial Magnetic stimulation (TMS) for patients with a variety of psychiatric and neurologic disorders – including addiction, pain, and stroke rehabilitation. Dr. Hanlon received a B.S. from the University of Florida in 2001 and a Ph.D. in Neurobiology from Duke University in 2005.

Directors

Ami Boehm has served as a member of our Board of Directors since January 12, 2023, and as Chairman of our Board of Directors since February 2023. Mr. Boehm has deep expertise in providing strategic advice for companies operating in multiple global industries. From 2004 until 2022, he served as a partner at FIMI Opportunity Funds, Israel's leading private equity firm. As a partner at FIMI, Mr. Boehm has sourced and led dozens of control equity investments, and led improvement processes of FIMI's portfolio companies and strategic activities of the portfolio companies in Israel, China, Europe and the U.S. Mr. Boehm currently serves as Chairman of the board of directors of Gilat Satellite Networks Ltd. (Nasdaq and TASE listed), and a director at Leumi Partners and the IL Investors Forum. Mr. Boehm also previously served as chairman or director of numerous other public and private companies, including Ormat Technologies, Inc. (NYSE and TASE listed), TAT Industries Ltd. (Nasdaq and TASE listed), Kamada Ltd. (Nasdaq and TASE listed), Rekah Pharmaceutical Industries Ltd. (TASE listed), Novolog Ltd. (TASE listed), Hamlet Ltd. (TASE listed), Galam Ltd., and Greenstream Ltd., and has worked closely with management teams across the continuum of business and corporate development activities. Mr. Boehm received a Master of Business Administration from Northwestern University and Tel-Aviv University, a Bachelor of Law from Tel-Aviv University, and a Bachelor of Economics from Tel-Aviv University.

Dr. David Zacut has served as Vice-Chairman of our Board of Directors since February 2023. Prior to that he served as our Chairman of the Board of Directors since our inception. Dr. Zacut is a member of our executive committee, and has been providing consulting services to Brain Research and Development Services Ltd. since May 2001. Since 1983, Dr. Zacut has been working as a senior practicing physician at Hadassah Hospital, and from 1994 through 2003, he served as a managing director of several large medical centers. In addition, Dr. Zacut serves as a director of several private companies, including Brain Research and Development Services Ltd. Dr. Zacut holds an M.D. degree from the Hebrew University of Jerusalem.

Avner Hagai has served as a member of our Board of Directors since November 2006 and currently serves as a member of our compensation committee and our nomination committee. He currently serves as a director at several companies, including at Prisma F.S. Ltd., a building management company (where he has served since 2002), and previously served as a director at Hofit Kibbutz Kinneret Ltd., a plastics manufacturer. Mr. Hagai established A.A. Glass Ltd., an automotive glass and services company, where he has served as a director since 1984.

Eti Mitrany has served as a member of our Board of Directors since June 2016, and currently serves as chairperson of our compensation committee and a member of our audit committee. Ms. Mitrany is an executive with over 25 years of global experience in the life sciences industry. Ms. Mitrany currently serves as the CEO of the IL Investors Forum, Chairwoman at Derma Gene Ltd. and a member of Maccabi Healthcare Council. From April 2021 until December 2022, she served as CFO and Head of Corporate Strategy at CytoReason, a life sciences AI company developing a computational model of the human body. From 2012 until January 2020, she served as Senior Vice President, Head of the Corporate Economic Department at Teva Pharmaceuticals, with global responsibility for Teva's business planning and analysis. Prior to that, Ms. Mitrany held various positions at Teva, including serving as CFO of its global specialty business (commercial, R&D, and new ventures), head of Financial Planning & Analysis of the global branded business, and global CFO of Copaxone (a multiple sclerosis treatment) and various other specialty products. Ms. Mitrany received her BA in Economics and an MBA in Finance, both from Tel-Aviv University.

Karen Sarid has served as a member of our Board of Directors since December 2017, currently serves as chairperson of our audit committee, and is a member of our compensation committee and our executive committee. Between March 2014 and July 2017, Ms. Sarid served as VP Beauty and Dental and as Chairman of China activities at Syneron Medical Ltd. Between January 2012 and August 2013 Ms. Sarid served as President of Alma Lasers Ltd. Ms. Sarid currently serves as a director of Eva Visual Ltd. She holds a BA in Economics and Accounting from the University of Haifa.

Prof. Abraham Zangen has served as a member of our Board of Directors since June 2019. Prof. Zangen is the Head of the Brain Stimulation and Behavior Lab and the Chair of the PsychoBiology Brain Program at Ben-Gurion University in Israel. His research is directed at identifying and understanding altered neuroplasticity in psychiatric disorders, primarily depression, addiction and ADHD, utilizing brain stimulation, and imaging techniques to explore mechanisms and potential clinical applications. He co-developed, along with Dr. Yiftach Roth, the Deep TMS coil which serves as our platform technology. Professor Zangen has published over 150 peer reviewed articles, reviews, and book chapters. He has been awarded numerous prizes for his scientific achievements, including the Medical Futures Innovation Award in London, the Sieratzki Prize for Advances in Neuroscience, and the Juludan Prize at the Technion. He has also received several distinguished research grants, including from the National Institutes of Health, H2020 and the Israel Science Foundation. Professor Zangen is the brother-in-law of Dr. Yiftach Roth, who serves as our Chief Scientific Officer and a co-developer of our Deep TMS technology.

Avner Lushi has served as a member of our Board of Directors since January 2020 and currently serves as a member of our audit committee and our nomination committee. Mr. Lushi co-founded the Guangzhou Sino-Israel Bio-industry Investment Fund (GIBF) which focuses on introducing Israeli and western life sciences companies to the Chinese market (and related investments), where he also serves as a Managing Partner & CEO. Between 2004 and 2015 Mr. Lushi served as a Partner and Managing Director of Israel Healthcare Ventures (IHCV), a life sciences venture capital fund. From 2001 to 2005, he co-founded and served as CEO of Life Sciences Transaction Support Ltd. (LTS), a PwC subsidiary dealing with life sciences investment banking. Since 2005, Mr. Lushi served as an independent board member at ten public companies, of which he remains a board member in Ginegar Plastic Product Ltd. (TASE listed). In addition, as part of his role at GIBF, he serves as a board member of Silexion Therapeutics Corp. (Nasdaq listed) and of several private companies. From 1997 to 2001, prior to turning to the private sector, he held increasingly senior roles within the Israeli Prime Minister's Chamber and the Israeli Supreme Court. Mr. Lushi holds an LLM in Law from the Hebrew University of Jerusalem, and an LLB in Law and a BA in Economics from the Haifa University.

Jonathan Shulkin has served as a member of our Board of Directors since November 2024. Mr. Shulkin has over 25 years of experience in private equity investing. Mr. Shulkin is a Partner and Co-President of Valor Equity Partners, the Fund Manager for Valor Siren Ventures I L.P. (together with its parallel funds, "VSV I") and Valor Siren Ventures II L.P. (together with its parallel funds, "VSV II") and as a member of all Valor Equity Partners Investment Committees. Mr. Shulkin oversees Valor Equity Partners' Scale Group, Finance, and People Teams. Currently, Mr. Shulkin is a Director of several Valor Equity Partners growth fund and VSV portfolio companies, including Gopuff, Misfits Market, Spot & Tango, and Rarefied Atmosphere. Prior to Valor, from 1998 until 2001 Mr. Shulkin was part of MG Capital's Investment and Portfolio Team. During his tenure at MG Capital, he worked on acquisition teams focused on executing transactions in the electronic connector industry. Mr. Shulkin served in operational roles at MG Capital's portfolio companies, including Chief Operating Officer of Connector Service Corporation's Plating Division, where he managed the business through 100% growth over a 12-month period. Mr. Shulkin also served as President of Electronic Plating Service and Chief Operating Officer for Amax Plating, Electronic Plating Service, and Associated Plating Company. Prior to joining MG Capital, from 1997 to 1998 Mr. Shulkin worked with Bain & Company as an Associate Consultant. At Bain, he worked on assignments for various Fortune 500 clients in Texas and Australia. Mr. Shulkin holds a B.B.A. in Accounting (with honors) from the University of Texas at Austin.

B. Compensation

The aggregate compensation paid, and benefits-in-kind granted to or accrued on behalf of all of our directors and officers for their services to us, in all capacities, during the year ended December 31, 2024, was approximately $4.9 million. Out of that amount, $3 million was paid as salary, $1 million was attributed to the value of the equity-based awards granted to senior management during 2024 and approximately $0.3 million was attributed to retirement plans. No additional amounts have been set aside or accrued by us to provide pension, retirement, or similar benefits.

The compensation terms for our directors and officers are derived from their employment agreements and/or board/shareholder approvals, and comply with our Compensation Policy for office holders, which was most recently approved by our shareholders on June 17, 2024, or the Compensation Policy. On November 14, 2023, our directors adopted the Policy for Recovery of Erroneously Awarded Compensation, or the Compensation Recovery Policy, which provides for certain incentive-based compensation awarded to our officers to be recovered in the event that we are required to prepare an accounting restatement to correct material noncompliance with any financial reporting requirement to which we are subject. This description of the Compensation Recovery Policy is qualified by reference to the full text of such policy, which is filed as an exhibit hereto.

The table and summary below outline the actual compensation granted or paid to our five highest compensated officers during the year ended December 31, 2024.

Name and position of director or officer	Base Salary or Other Payments[1]	Value of Social benefit[2]	Value of Equity Based Compensation Granted[3][4]	All Other Compensation[5]	Total
Hadar Levy, CEO	$ 276,427	$ 72,674	$ 261,809	$ 193,394	$ 804,304
Ido Marom, CFO	$ 178,696	$ 50,941	$ 92,378	$ 73,562	$ 395,577
Colleen Hanlon, PhD, VP of Medical	$ 240,248	$ 27,240	$ 28,177	$ 60,000	$ 355,665
Michael Cohen, VP US Sales	$ 191,620	$ 50,592	$ 30,971	$ 155,226	$ 428,409
Ross Mitchell, VP Marketing	$ 195,371	$ 51,321	$ 19,685	$ 40,800	$ 307,177

(1) "Base Salary or Other Payments" means the aggregate yearly gross monthly salaries or other payments with respect to our senior management and members of the board of directors which was actually paid during the year ended December 31, 2024.

(2) "Social Benefits" include payments to the National Insurance Institute, advanced education funds, managers' insurance and pension funds; vacation pay; and recuperation pay as mandated by Israeli law.

(3) Value of Equity Based Compensation Granted consists of the fair value of the equity-based compensation granted during the year ended December 31, 2024 in exchange for the directors' and officers' services recognized as an expense in profit or loss and is carried to the accumulated deficit under equity. The total amount is recognized as an expense over the vesting period of the RSUs and/or options.

(4) Hadar Levy was granted 320,000 options on February 13, 2023 subject to a 4-year vesting period and 187,500 options on March 5, 2024 subject to a 4-year vesting period.

(5) "All Other Compensation" includes, among other things, bonuses, car-related expenses (including tax gross-up) and communication expenses.

Certain equity-based compensation listed in the table above was granted pursuant to an equity incentive plan. For information regarding the terms of our equity incentive plans, please see the section titled "Award Plans" under Item 6.E.

In addition, all of our directors and executive officers are covered under our directors' and executive officers' liability insurance policies and were granted letters of indemnification and exculpation by us. For information on exemption and indemnification letters granted to our directors and officers, please see "*Item 6.C.—Board Practices—Exculpation, Insurance and Indemnification of Directors and Officers*."

Employment Agreements

We have entered into written employment or service agreements with each member of our senior management. 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 laws.

Director Compensation

As of the date of the filing of this annual report, we pay our non-executive directors (i.e., all directors other than Mr. Boehm and Prof. Zangen) an annual cash fee of NIS 133,000. Additionally, as of the date of the filing of this annual report, we pay a cash fee of NIS 2,480 per meeting of the Board and any committee thereof, which is increased to (i) NIS 4,020 in the case of a committee chairperson; or (ii) NIS 4,390 in the case of a director determined to be an expert.

Ami Boehm serves as an active chairman of our Board of Directors. During his term as Chairman of the Board in the year ended December 31, 2023, Mr. Boehm received a monthly compensation of NIS 22,500 plus VAT for his term in office (calculated based on 30% capacity of a NIS 75,000 full capacity role). As approved by our shareholders at the 2024 AGM, commencing January 1, 2024 Mr. Boehm's monthly compensation was increased (as approved by our shareholders) to NIS 30,000 plus VAT (calculated based on 40% capacity of a NIS 75,000 full capacity role) and Mr. Boehm is paid a monthly amount of NIS 5,000 as reimbursement of reasonable per diem expenses, including traveling expenses and expenses associated with attending meetings. In addition, as approved by our shareholders at the 2024 AGM, Mr. Boehm was granted: (i) 75,000 options to purchase our Ordinary Shares at an exercise price equal to NIS 11.17 per share (the closing price of our Ordinary Shares on the TASE on March 4, 2024, the last trading day before our Board of Directors approved such grant); and (ii) 37,500 restricted share units, or RSUs. Both the grant of options and the grant of RSUs are subject to a four-year vesting period, with the first 25% vesting on the date falling 12 months following the March 5, 2024 vesting commencement date, and the remaining 75% vesting in 12 equal quarterly portions until the end of the four year period from the vesting commencement date, provided, in each case that Mr. Boehm continues to be a member of our Board of Directors at the time of each such vesting date.

At our 2024 AGM, our shareholders also approved the grant to each of our directors then in office (other than Mr. Boehm), including Dr. David Zacut, Mr. Avner Hagai, Ms. Eti Mitrany, Ms. Karen Sarid, Prof. Abraham Zangen, Mr. Yossi Ben Shalom and Mr. Avner Lushi: (i) 25,000 options to purchase our Ordinary Shares at an exercise price equal to NIS 11.17 per share (the closing price of our Ordinary Shares on the TASE on March 4, 2024, the last trading day before our Board of Directors approved such grant); and (ii) 12,500 RSUs. Both the grant of options and the grant of RSUs are subject to a four-year vesting period, with the first 25% vesting on the date falling 12 months following the March 5, 2024 vesting commencement date, and the remaining 75% vesting in 12 equal quarterly portions until the end of the four year period from the vesting commencement date, provided, in each case that the relevant grantee continues to be a member of our Board of Directors at the time of each such vesting date. Following his resignation from our Board of Directors in November 2024, we entered into a consultancy agreement with Mr. Ben Shalom and the grants discussed above will continue vesting for as long as the consultancy agreement is in effect.

The grants to our directors (including our Chairman of the Board) shall otherwise be in accordance with our 2019 Amended and Restated Share Incentive Plan and in compliance with all applicable laws. For more information, please see our proxy statement in connection with the 2024 AGM, submitted to the SEC on May 9, 2024.

We also have a consultancy agreement with Prof. Zangen, a director and scientific founder of the Company. For more information, see "*Item 7.B. Related Party Transactions.*"

The table and summary below outline the actual compensation granted or paid to our directors during the year ended December 31, 2024.

Name of director	Annual Basis Compensation	Annual Per meeting compensation	Value of Equity Based Compensation Granted[1]	All Other Compensation[2]	Total
Ami Boehm	$113,544	-	$162,166	-	$275,710
Dr. David Zacut	$35,955	$4,291	$38,052	-	$78,298
Prof. Abraham Zangen	$56,727	-	$38,052	$13,194	$107,973
Karan Sarid	$35,955	$19,464	$38,052	-	$93,471
Eti Mitrany	$35,955	$12,106	$38,052	$448	$86,561
Avner Lushi	$35,955	$7,643	$38,052	$674	$82,324
Yossi Ben Shalom[3]	$26,967	$2,682	$38,052	-	$67,701
Avner Hagai	$35,955	$6,034	$38,052	-	$80,041
Jonathan Shulkin[3]	$8,989	$805	-	-	$9,794

(1)Mainly attributed to expenses for the granting of options.
(2)Mainly attributed to car expenses and reimbursements of travel expenses.
(3)Mr. Jonathan Shulkin was appointed as a member of our Board of Directors on November 5, 2024, replacing Mr. Ben Shalom who resigned effective as of such date. Therefore, the table does not reflect the full-year compensation for these directors.

Compensation Policy

In general, under the Israeli Companies Law, a public company must have a compensation policy for its "office holders" approved by the board of directors after receiving and considering the recommendations of the compensation committee. In addition, the compensation policy requires the approval of the general meeting of the shareholders. In public companies such as our Company, shareholder approval requires one of the following: (i) the majority of shareholder votes counted at a general meeting, which must include the majority of all of the votes of those shareholders who are non-controlling shareholders and do not have a personal interest in the approval of the compensation policy, who vote at the meeting (excluding abstentions) or (ii) the total number of votes against the proposal among the shareholders mentioned in paragraph (i) does exceed two percent (2%) of the voting rights in the company. Under special circumstances, the board of directors may approve the compensation policy despite the objection of the shareholders on the condition that the compensation committee and then the board of directors decide, on the basis of detailed arguments and after discussing again the compensation policy, that approval of the compensation policy, despite the objection of the meeting of shareholders, is for the benefit of the company. An "office holder" is defined under the Israeli Companies Law as a general manager, chief business manager, vice general manager, any other person assuming the responsibilities of any of the foregoing positions without regard to such person's title, and a director, or manager directly subordinate to the general manager. Each person identified as a director or member of our senior management in the first table in this Item is an office holder

The compensation policy must be based on certain considerations, must include certain provisions, and needs to reference certain matters as set forth in the Israeli Companies Law.

The compensation policy must serve as the basis for decisions concerning the financial terms of employment or engagement of office holders, 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, business plan, long-term strategy, and creation of appropriate incentives for office holders. 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, experience, expertise, and accomplishments of the relevant office holder;
- the office holder's position, responsibilities, and prior compensation agreements with him or her;
- the ratio between the cost of the terms of employment of an office holder and the cost of the employment of other employees of the company, including employees employed through contractors who provide services to the company, in particular the ratio between such cost, the average, and median salary of the employees of the company, as well as the impact of such disparities on the work relationships in the company;
- if the terms of employment include variable components—the possibility of reducing variable components at the discretion of the board of directors and the possibility of setting a limit on the value of variable equity-based components not settled in cash; and
- if the terms of employment include severance compensation—the term of employment or office of the office holder, the terms of his or her compensation during such period, the company's performance during such period, his or her individual contribution to the achievement of the company goals and the maximization of its profits and the circumstances under which he or she is leaving the company.

The compensation policy must also include, among others:

- with regards to variable components in the terms of office and employment:
  - with the exception of office holders who report directly to the chief executive officer, determining the variable components on long-term performance basis and on measurable criteria; however, the company may determine that an immaterial part of the variable components of the compensation package of an office holder shall be awarded based on non-measurable criteria, if such amount is not higher than three monthly salaries per annum, while taking into account such office holder contribution to the company;
  - the ratio between variable and fixed components, as well as the limit of the values of variable components at the time of their payment. However, with respect to variable equity-based components that are not settled in cash, the limit of their value at the time of grant.
- a condition under which the office holder will return to the company, according to conditions to be set forth in the compensation policy, any amounts paid as part of his or her terms of employment, if such amounts were paid based on information later to be discovered to be wrong, and such information was restated in the company's financial statements;
- the minimum holding or vesting period of variable equity-based components to be set in the terms of office or employment, as applicable, while taking into consideration long-term incentives; and
- a limit to retirement grants.

Our compensation policy is designed to promote retention and motivation of directors and senior management, incentivize superior individual excellence, align the interests of our directors and senior management with our long-term performance and provide a risk management tool. 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 limitations on the value of cash bonuses and equity-based compensation to a maximum number of monthly salaries, 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 senior management, and considers the internal ratios between compensation of our senior management and directors and other employees. Pursuant to our compensation policy, the compensation that may be granted to an executive officer may include: base salary, exemption indemnification and insurance subject to certain limitations set forth therein, annual bonuses and other cash bonuses (such as a signing bonus and special bonuses with respect to any special achievements, such as outstanding personal achievement, outstanding personal effort or outstanding company performance), equity-based compensation, social benefits, retirement, and termination of service arrangements. All cash bonuses to executive officers ("Annual Target Bonus", "Overachievement Bonus" and "Special Bonus") are limited to a maximum amount linked to the executive officer's base salary. In addition, the total equity-based compensation components may not exceed 200% of each executive officer's base salary with respect to any given calendar year.

An annual cash bonus may be awarded to senior management upon the attainment of pre-set periodic objectives and individual targets. The annual cash bonus that may be granted to our senior management will be based on performance objectives and a discretionary evaluation of the executive officer's overall performance by our compensation committee and board of directors and subject to minimum thresholds. Up to 25% of the annual cash bonus that may be granted to senior management may be based on a discretionary evaluation. Furthermore, our chief executive officer will be entitled to recommend performance objectives, and such performance objectives will be approved by our compensation committee (and, if required by law, by our board of directors).

The equity-based compensation under our compensation policy for our officers and 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 officers' and directors' interests with our long-term interests and those of our shareholders, and to strengthen the retention and the motivation of senior management in the long term. Our compensation policy provides for officers and directors compensation in the form of share options or other equity-based awards, such as restricted shares and restricted share units (RSUs), in accordance with our Share Incentive Plan then in place. All equity-based incentives granted to officers and directors shall be subject to vesting periods in order to promote long-term retention of the awarded officer or director. 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 officer or director. Our compensation policy limits the number of outstanding securities exercisable or convertible into shares to 10% of our issued and outstanding share capital on a fully diluted basis.

In addition, our compensation policy contains compensation recovery provisions, which allows us under certain conditions to recover bonuses paid in excess, and includes provisions enabling 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 with our compensation policy).

Our compensation policy also provides for compensation to the members of our Board of Directors (except for directors that are employed by us, or provide services, directly or through companies in their control, to us in another role) either (i) for external directors, if any, in accordance with the amounts provided in the Companies Regulations (Rules Regarding the Compensation and Expenses of an External Director), 2000, as amended by the Companies Regulations (Relief for Public Companies Traded in Stock Exchange Outside of Israel), 2000, as such regulations may be amended from time to time, or (ii) for all other directors, in accordance with the amounts determined in our compensation policy.

Our amended and restated compensation policy was last approved by our shareholders at the 2024 AGM and is valid for a period of three years according to the Israeli Companies Law.

C. Board Practices

Appointment of Directors and Terms of Officers

Our Board of Directors consists of eight (8) directors, all of whom qualify as "independent" under applicable U.S. securities laws and Nasdaq listing rules. The term of office of each director is until the next annual general meeting of our shareholders.

Number and Appointment of Directors

Our articles of association provide that the number of directors on our Board of Directors will be not less than four (4) but no more than eight (8) directors, including the Valor Designee(s) (as explained below) and not including any external directors to the extent required to be appointed by the Israeli Companies Law. The number of directors also does not include up to two (2) additional directors who may be appointed by our Board of Directors whose term of office would expire as of the first annual meeting of shareholders after their appointment, provided that they may be reappointed by our Board of Directors for one additional term of office and provided that they may be reappointed by the annual general meeting. Each appointed director, other than external directors, if any, shall serve as a member of the Board of Directors until the next annual general meeting. The term of a director shall terminate at the next annual general meeting, unless he or she is reelected at the annual general meeting. Pursuant to our articles of association, 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.

Valor Designee(s)

Our articles of association were most recently amended at the extraordinary general meeting held on November 5, 2024 in connection with the approval of the private placement to Valor. As amended, our articles of association provide the following in connection with Valor's rights to designate and remove members of our Board of Directors:

- so long as Valor beneficially holds, directly or indirectly, or together with (i) its manager, managing member, officer or director, (ii) its members, or (iii) any Person who, directly or indirectly, controls, is controlled by, or is under common control with Valor, including any fund now or hereafter existing that is controlled by one or more general partners, managers, managing members or investment advisers of, or shares the same management company or investment adviser with, Valor (each of the foregoing (i), (ii) and (iii), a "Valor Affiliate" and collectively, "Valor Affiliates"), at least 10% of our issued and outstanding share capital (for the avoidance of any doubt, including by means of holding (through bank, broker, depository other nominee of otherwise) ADSs), Valor shall have the right to designate one nominee to our Board of Directors. In addition, so long as Valor beneficially holds, directly or indirectly, or together with Valor Affiliates, at least 20% of our issued and outstanding share capital as set forth above, Valor shall have the right to designate an additional nominee (i.e., a total of 2 nominees) to our Board of Directors, or the Valor Designee(s);

- except as required by applicable law, our Board of Directors shall not take any action to remove from his or her office or replace any Valor Designee, provided, however, that in the event that we shall take, or be required to take, any action which may cause Valor and the Valor Affiliates to beneficially own, directly or indirectly, less than 20% or 10%, as the case may be, of our issued and outstanding share capital, we shall give Valor a written notice, or the Dilution Notice, promptly following such action in reasonable detail. In the event that after the lapse of a 60 trading day period following such Dilution Notice, Valor and the Valor Affiliates beneficially own, directly or indirectly, less than 20% or 10%, as the case may be, of our issued and outstanding share capital, the board seat of the applicable Valor Designee(s) appointed in accordance with our articles of association, shall automatically terminate. Valor's rights to designate one or two Valor Designee(s), as the case may be, to our Board of Directors, and our obligations in connection thereto, shall be immediately reinstated once Valor and the Valor Affiliates beneficially own, directly or indirectly, at least 10% or 20%, as the case may be, of our issued and outstanding share capital, however, in the event that Valor and the Valor Affiliates shall beneficially own, directly or indirectly, less than 20% or 10%, as the case may be, of our issued and outstanding share capital due to a sale initiated by Valor or Valor Affiliates of our share capital or ADSs held by Valor or Valor Affiliates, then the board seat of the applicable Valor Designee(s) appointed in accordance with our articles of association shall automatically terminate and shall not be reinstated. Valor is required to notify us in writing promptly following such sale that impacts its rights under our articles of association in reasonable detail;

- Valor shall have the right to the fullest extent permissible by applicable law, to cause our Board of Directors to remove any Valor Designee. Without derogative from the foregoing, Valor shall have the right to the fullest extent permissible by applicable law to require us not to include and remove in our notice of general meeting, proxy statement and proxy card (or any equivalent thereof) and/or recommend to our shareholders to vote against, the appointment of any person nominated to our Board of Directors to replace any Valor Designee at any time. In the event any Valor Designee ceases to be a member of our Board of Directors for any reason (other than in connection with a reduction in the number of directors that Valor is entitled to designate), our Board of Directors shall promptly appoint an alternate member of the Board of Directors designated by Valor to fill such vacancy and appoint such Valor Designee to all committees on which the prior Valor Designee served;

- other than the Valor Designee(s), Valor shall not, directly or indirectly, propose to the general meeting of our shareholders, any additional member (whether affiliated to Valor or any other person) to our Board of Directors unless it proposes a special tender offer (as required under Israeli Companies Law) following which it would hold more than 45% of the voting rights of us; and

- in the event that Valor is entitled to designate Valor Designee(s) to our Board of Directors and any such Valor Designee(s) have not been appointed to our Board of Directors by our shareholders or otherwise, our Board of Directors shall promptly take all required action in order to appoint such Valor Designee(s) to our Board of Directors pursuant to its authority to appoint up to two additional members of the Board of Directors as set forth above.

General

Under Israeli law, the chief executive officer of a public company may not serve as the chairman of the board of directors of the company unless approved by a special majority of our shareholders as required under the Israeli Companies Law.

In addition, under the Israeli Companies Law, our Board of Directors must determine the minimum number of directors who are required to have financial and accounting expertise. Under applicable regulations, a director with financial and accounting expertise is a director who, by reason of his or her education, professional experience, and skills, has a high level of proficiency in and understanding of business accounting matters and financial statements. He or she must be able to thoroughly comprehend the financial statements of the company and initiate debate regarding the manner in which financial information is presented. In determining the number of directors required to have such expertise, the 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 we should have at least two directors with the requisite financial and accounting expertise.

In connection with the consummation of the Valor private placement and based on Valor's rights pursuant to our articles of association, on November 5, 2024 Mr. Jonathan Shulkin was appointed to be a member of our Board of Directors as a Valor Designee. As the maximum number of board members pursuant to our amended articles of association is eight, Mr. Ben Shalom resigned from his position on our Board of Directors to enable the appointment of Mr. Shulkin.

There are no arrangements or understandings between us, on the one hand, and any of our directors, on the other hand, providing for benefits upon termination of their employment or service as directors of our Company.

Independent and External Directors - Israeli Companies Law Requirements

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, nomination process and majority requirements and other provisions would be applicable. We would also be required to include one such external director on each of our board committees and all of the external directors would be required to be members of our audit committee and our compensation committee.

Under the Israeli Companies Law, a person may not be appointed as an external director if he or his relative, partner, employer or any entity under his control has or had during the two years preceding the date of appointment any affiliation with the company, any entity controlling the company or any entity controlled by the company or by this controlling entity or, in a company that does not have a controlling shareholder, in the event that he has affiliation, at the time of his appointment, to the chairman of the board, chief executive officer, a 5% shareholder or the highest ranking officer in the financial field. The term "affiliation" includes: an employment relationship, a business or professional relationship maintained on a regular basis, control, and service as an office holder. No person can serve as an external director if the person's position or other business creates, or may create, conflicts of interest with the person's responsibilities as an external director, or if the person is an employee of the Israel Securities Authority or of an Israeli stock exchange. In addition, an individual may not be appointed as an external director if she or he, or her or his relative, partner, employer, supervisor, or an entity she or he controls, has other than negligible business or professional relations with any of the persons with which the external director may not be affiliated, even if such relations are not routine, or if she or he received any consideration, directly or indirectly, in addition to the remuneration to which she or he are entitled and to reimbursement of expenses, for acting as a director in the company.

Under regulations promulgated under the Israeli Companies Law, Israeli companies whose shares are traded on stock exchanges such as the Nasdaq that do not have a controlling shareholder (as defined therein) and which comply with the requirements of the jurisdiction where the company's shares are traded with respect to the appointment of independent directors and the composition of an audit committee and compensation committee, may elect not to follow the Israeli Companies Law requirements with respect to the composition of its audit committee and compensation committee and the appointment of external directors. As we do not have a controlling shareholder, and as we comply with the requirements of the Nasdaq with respect to the composition of our board and such committees, we resolved to apply these exemptions from the Israeli Companies Law requirements with respect thereto, including the appointment of external directors.

Committees

Our Board of Directors has established four standing committees, the audit committee, the compensation committee, the nomination committee, and the executive committee.

Audit Committee

Israeli Companies Law Requirements

Under the Israeli Companies Law, the board of directors of any public company must also appoint an audit committee comprised of at least three directors, including all of the external directors (if any). The audit committee may not include:

- the chairman of the board of directors;
- a controlling shareholder or a relative of a controlling shareholder;
- any director employed by us or by one of our controlling shareholders or by an entity controlled by our controlling shareholders (other than as a member of the board of directors); or
- any director who regularly provides services to us, to one of our controlling shareholders or to an entity controlled by our controlling shareholders.

According to the Israeli Companies Law, the majority of the members of the audit committee, as well as the majority of members present at audit committee meetings, are required to be "independent" (as defined below), and the chairperson of the audit committee are required to be an external director. Any persons disqualified from serving as a member of the audit committee may not be present at the audit committee meetings, unless the chairperson of the audit committee has determined that such person is required to be present at the meeting or if such person qualifies under one of the exemptions of the Israeli Companies Law.

The term "independent director" is defined under the Israeli Companies Law as an external director or a director who meets the following conditions, and who is appointed or classified as such according to the Israeli Companies Law: (1) the conditions for his or her appointment as an external director (as described above) are satisfied, and the audit committee approves the director having met such conditions, and (2) he or she has not served as a director of the company for over nine consecutive years with any interruption of up to two years of his or her service not being deemed a disruption to the continuity of his or her service.

Pursuant to regulations promulgated under the Israeli Companies Law, we comply with the requirements of Nasdaq with respect to the composition of our audit committee and compensation committee, and do not follow the Israeli Companies Law requirements with respect to the composition of such committees, such as those described above. See the section titled "Directors and Senior Management" under Item 6.A above.

SEC and Nasdaq Listing Requirements

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

Rule 10A-3 of the Exchange Act requires that all members of an audit committee meet the independence criteria set forth in such rule. The independence requirements of Rule 10A-3 of the Exchange Act implement two basic criteria for determining independence:

- audit committee members are barred from accepting directly or indirectly any consulting, advisory or other compensatory fee from the issuer or an affiliate of the issuer, other than in the member's capacity as a member of the board of directors and any board committee; and

- audit committee members may not be an "affiliated person" of the issuer or any subsidiary of the issuer apart from her or his capacity as a member of the board of directors and any board committee.

The SEC has defined "affiliate" for non-investment companies as "a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified." The term "control" is intended to be consistent with the other definitions of this term under the Exchange Act, as "the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise." A safe harbor has been adopted by the SEC, under which a person who is not an executive officer or 10% shareholder of the issuer would be deemed not to have control of the issuer.

In accordance with the Sarbanes-Oxley Act of 2002 and the Nasdaq Listing Rules, the audit committee is directly responsible for the appointment, compensation, and performance of our independent auditors. In addition, the audit committee is responsible for assisting the board of directors in reviewing our annual financial statements, the adequacy of our internal control and our compliance with legal and regulatory requirements. The audit committee also oversees our major financial risk exposures and policies for managing such potential risks, discusses with management and our independent auditor significant risks or exposure and assesses the steps management has taken to minimize such risk.

The members of our audit committee include Karen Sarid, Eti Mitrany, and Avner Lushi, with Karen Sarid serving as chairperson. All members of our audit committee meet the requirements for financial literacy under the Nasdaq Listing Rules. Our Board of Directors has determined that each of Karen Sarid, Eti Mitrany, and Avner Lushi is an audit committee financial expert as defined by the SEC rules and all members of the audit committee have the requisite financial experience as defined by the Nasdaq Listing Rules. In addition, each of the members of the audit committee is "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act.

Approval of Transactions with Related Parties

The approval of the audit committee is required to effect specified actions and transactions with office holders and controlling shareholders and their relatives, or in which they have a personal interest. See the section titled "Duties of Directors and Officers and Approval of Specified Related Party Transactions under the Israeli Companies Law" below. The audit committee may not approve an action or a transaction with a controlling shareholder or with an office holder unless at the time of approval the audit committee meets the composition requirements under the Israeli Companies Law (including the exemptions provided thereunder).

Audit Committee Charter

Our Board of Directors adopted an audit committee charter setting forth the responsibilities of the audit committee consistent with the rules of the SEC and the Nasdaq corporate governance rules, which include:

- retaining and terminating our independent auditors, subject to board of directors and shareholder ratification;
- overseeing the independence, compensation, and performance of our independent auditors;
- the appointment, compensation, retention, and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services;
- pre-approval of audit and non-audit services to be provided by the independent auditors;
- reviewing with management and our independent directors our financial statements prior to their submission to the SEC; and
- approval of certain transactions with office holders and controlling shareholders, as described below, and other related party transactions.

Additionally, under the Israeli Companies Law, the role of the audit committee includes the identification of irregularities in our business management, among other things, by consulting with the internal auditor or our independent auditors and suggesting an appropriate course of action to the board of directors. In addition, the audit committee or the board of directors, as set forth in the articles of association of the company, is required to approve the yearly or periodic work plan proposed by the internal auditor. The audit committee is required to assess the company's internal audit system and the performance of its internal auditor. The Israeli Companies Law also requires that the audit committee assess the scope of the work and compensation of the company's external auditor. In addition, the audit committee is required to determine whether certain related party actions and transactions are "material" or "extraordinary" for the purpose of the requisite approval procedures under the Israeli Companies Law and whether certain transactions with a controlling shareholder will be subject to a competitive procedure or other procedures. The audit committee charter states that in fulfilling its role the committee is empowered to conduct or authorize investigations into any matters within its scope of responsibilities. Under the Israeli Companies Law, a company whose audit committee's composition also meets the requirements set for the composition of a compensation committee (as further detailed below) may have one committee acting as both audit and compensation committees.

Compensation Committee

Israeli Companies Law Requirements

Under the Israeli Companies Law, public companies are required to appoint a compensation committee in accordance with the guidelines set forth thereunder.

The compensation committee must consist of at least three members. All of the external directors, if any, must serve on the committee and constitute a majority of its members, and the remaining members must be directors whose compensation is in accordance with the regulations for compensation of external directors under the Israeli Companies Law. The chairperson of the compensation committee must be an external director, if any. In addition, members of the compensation committee may not include directors who are disqualified from serving as members of the audit committee (as described above).

Our compensation committee, which consists of Eti Mitrany, Avner Hagai, and Karen Sarid, assists our Board of Directors in determining compensation for our directors and officers. Eti Mitrany serves as Chairperson of the committee.

Pursuant to regulations promulgated under the Israeli Companies Law, we comply with the requirements of Nasdaq with respect to the composition of our audit committee and compensation committee, and do not follow the Israeli Companies Law requirements with respect to the composition of such committees, such as those described above. See the section titled "Directors and Senior Management" under Item 6.C above.

In accordance with the Israeli Companies Law, the roles of the compensation committee are, among others, as follows:

- to recommend to the board of directors the compensation policy for directors and officers, and to recommend to the board of directors once every three years whether the compensation policy that had been approved should be extended for a period of more than three years;
- to recommend to the board of directors updates to the compensation policy, from time to time, and examine its implementation;
- to decide whether to approve the terms of office, and employment of directors and officers that require approval of the compensation committee; and
- to decide whether the compensation terms of the chief executive officer, which were determined pursuant to the compensation policy, will be exempted from approval by the shareholders because such approval would harm the ability to engage the chief executive officer.

In addition to the roles mentioned above our compensation committee also makes recommendations to our Board of Directors regarding the awarding of employee equity grants.

In addition to the above, our compensation committee is entitled to agree to prior notice periods for resignation or dismissal within the context of certain acceleration events, and to agree to up to 12 months full payment of the compensation package and fringe benefits, upon termination by us of an engagement with an officer or an employee.

Nasdaq Listing Requirements

Under the Nasdaq Listing Rules, we are required to maintain a compensation committee consisting of at least two members, all of whom are independent.

Under SEC and Nasdaq Listing Rules, there are heightened independence standards for members of the compensation committee, including a prohibition against the receipt of any compensation from us other than standard supervisory board member fees. Although foreign private issuers are not required to meet this heightened standard, our Board of Directors has determined that all of our compensation committee members meet this heightened standard.

Compensation Committee Charter

Our Board of Directors adopted a compensation committee charter setting forth the responsibilities of the compensation committee consistent with the requirements of the Israeli Companies Law, the rules of the SEC and the Nasdaq corporate governance rules, which include:

- recommending to the board of directors for its approval (i) a compensation policy for officers and directors, (ii) once every three years, whether to extend the compensation policy, subject to receipt of the required corporate approvals (either a new compensation policy or the continuation of an existing compensation policy must in any case occur every three years); and (iii) periodic updates to the compensation policy. In addition, the compensation committee is required to periodically review the implementation of the compensation policy;
- approving transactions relating to the terms of office and employment of office holders (within the meaning of the Companies Law), which require the approval of the compensation committee pursuant to the Companies Law;
- reviewing and approving the granting of options and other incentive awards to the extent such authority is delegated by the board of directors; and
- reviewing, evaluating and making recommendations regarding the compensation and benefits for our non-employee directors.

Nomination Committee

In March 2022, our Board of Directors appointed a nomination committee, comprised of Avner Lushi, Avner Hagai and Jonathan Shulkin. Avner Lushi serves as the Chairperson of the committee.

Nasdaq Listing Requirements

The Nasdaq Listing Rules require that director nominees be selected or recommended for the board's selection either by a nomination committee composed solely of independent directors or by a majority of independent directors, in a vote in which only independent directors participate, subject to certain exceptions.

Our Nomination Committee assumed the responsibility for recommending to the Board nominees for election (including re-election) to our Board of Directors, in lieu of the recommendation by our independent directors. Our Board of Directors has determined that all of our nomination committee members are independent under applicable rules.

Consistent with the requirements of the Nasdaq Rules, our Nomination Committee is responsible for:

- identifying potential new candidates for service on our Board of Directors, taking into account, inter alia, the candidate's applicable experience, expertise and/or familiarity with our field of business, as well as the candidate's ethical character, independent judgment and industry reputation;
- conducting appropriate inquiries into the backgrounds and qualifications of potential candidates for service as directors; and
- reviewing and resolving whether or not to approve arrangements with respect to such candidates.

Executive Committee

In 2021, our Board of Directors appointed an executive committee, comprised of Dr. David Zacut and Karen Sarid. The roles of the executive committee are:

- to oversee the implementation of the business strategy of our company; and
- to exercise such other duties as the board may resolve from time to time.

Attendance in Board Meetings

The following table sets forth the attendance rate for each of the members of our Board of Directors during 2024:

Name	Percentage of Meetings Attended
Ami Boehm	100%
David Zacut	100%
Avner Hagai	100%
Eti Mitrany	100%
Karen Sarid	100%
Prof. Abraham Zangen	87.5%
Jonathan Shulkin[(1)]	100%
Avner Lushi	100%

(1)Appointed on November 5, 2024.

Our Board of Directors takes an active role in supervising the risk management of the Company and follows our internal policies and procedures.

Internal Auditor

Under the Israeli Companies Law, the board of directors of a public company must appoint an internal auditor based on the recommendation of the audit committee. The role of the internal auditor is, among other things, to examine whether a company's actions comply with applicable law and orderly business procedure. Under the Israeli Companies Law, the internal auditor may not be an interested party or an office holder or a relative of an interested party or of an office holder, nor may the internal auditor be the company's independent auditor or the representative of the same.

An "interested party" is defined in the Israeli Companies Law as (i) a holder of 5% or more of the issued share capital or voting power in a company, (ii) any person or entity who has the right to designate one or more directors or to designate the chief executive officer of the company, or (iii) any person who serves as a director or as a chief executive officer of the company.

Mr. Doron Cohen of Fahn Kanne Control Management Ltd. (Grant Thornton Israel) serves as our internal auditor.

Duties of Directors, Officers and Shareholders and Approval of Specified Related Party Transactions under the Israeli Companies Law

Fiduciary Duties and Duty of Care of Office Holders

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

The duty of care of an office holder is based on the duty of care set forth in connection with the tort of negligence under the Israeli Torts Ordinance (New Version) 5728-1968. This duty of care requires an office holder to act with the degree of proficiency with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of care includes, among other things, a duty to use reasonable means, in light of the circumstances, to obtain:

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

The fiduciary duty incumbent on an office holder requires him or her to act in good faith and for the benefit of the company, and includes, among other things, the duty to:

- refrain from any act involving a conflict of interest between the performance of his or her duties in the company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the business of the company;
- refrain from exploiting any business opportunity of the company for the purpose of gaining a personal advantage for himself or herself or others; and
- disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

We may approve an act specified above which would otherwise constitute a breach of the office holder's fiduciary duty, provided that the office holder acted in good faith, the act or its approval does not harm the company, and the office holder discloses his or her personal interest, including any material fact or document, a reasonable time before consideration of the approval of such act. Any such approval is subject to the terms of the Israeli Companies Law, setting forth, among other things, the appropriate bodies of the company entitled to provide such approval, and the methods of obtaining such approval.

Disclosure of Personal Interest of an Office Holder and Approval of Transactions

The Israeli Companies Law requires that an office holder disclose to the company without delay any personal interest that he or she may have and all related material information or documents relating to any existing or proposed transaction by the company. An interested office holder's disclosure must be made without delay and in any event no later than the first meeting of the board of directors at which the transaction is considered. An office holder is not obliged to disclose such information if the personal interest of the office holder derives solely from the personal interest of his or her relative in a transaction that is not considered an extraordinary transaction.

Under the Israeli Companies Law, once an office holder has complied with the above disclosure requirement, a company may approve a transaction between the company and the office holder or a third party in which the office holder has a personal interest. However, a company may not approve a transaction or action that is not to the company's benefit.

Under the Israeli Companies Law, unless the articles of association of a company provide otherwise, a transaction with an office holder or with a third party in which the office holder has a personal interest, which is not an extraordinary transaction, requires approval by the board of directors. If the transaction considered is an extraordinary transaction with an office holder or third party in which the office holder has a personal interest, then audit committee approval is required prior to approval by the board of directors. For the approval of compensation arrangements with directors and senior management, see the sections titled "Compensation Policy" under Item 6.B above and "Approval of Terms of Office and Employment of Office Holders" below.

Any persons who have a personal interest in the approval of a transaction that is brought before a meeting of the board of directors or the audit committee, except for a transaction with an office holder or with a third party in which the office holder has a personal interest, which is not an extraordinary transaction, may not be present at the meeting or vote on the matter. However, if the chairman of the board of directors or the chairman of the audit committee has determined that the presence of an office holder with a personal interest is required, such office holder may be present at the meeting for the purpose of presenting the matter. Notwithstanding the foregoing, a director who has a personal interest may be present at the meeting, and vote on the matter if a majority of the directors or members of the audit committee have a personal interest in the approval of such transaction. If a majority of the directors at a board of directors meeting have a personal interest in the transaction, such transaction also requires approval of the shareholders of the company.

A "personal interest" is defined under the Israeli Companies Law as the personal interest of a person in an action or in a transaction of the company, including the personal interest of such person's relative or the interest of any other corporate body in which the person and/or such person's relative is a director or general manager, a 5% shareholder or holds 5% or more of the voting rights, or has the right to appoint at least one director or the general manager, but excluding a personal interest stemming solely from the fact of holding shares in the company. A personal interest also includes (1) a personal interest of a person who votes according to a proxy of another person, including in the event that the other person has no personal interest, and (2) a personal interest of a person who gave a proxy to another person to vote on his or her behalf regardless of whether or not the discretion of how to vote lies with the person voting.

An "extraordinary transaction" is defined under the Israeli Companies Law as any of the following:

- a transaction other than in the ordinary course of business;
- a transaction that is not on market terms; or
- a transaction that may have a material impact on the company's profitability, assets or liabilities.

Disclosure of a Personal Interest of a Controlling Shareholder and Approval of Transactions

The Israeli Companies Law also requires that a controlling shareholder disclose to the company without delay any personal interest that he or she may have and all related material information or documents relating to any existing or proposed transaction by the company. A "controlling shareholder" for purposes of the approval of transactions is defined by the Israeli Companies Law as a shareholder holding the ability to direct the actions of the company, other than by virtue of being a director or holding a position with the company, including a shareholder holding twenty five percent or more of the voting rights of the company if there is no other shareholder holding over fifty percent of the voting rights of the company.

A controlling shareholder's disclosure must be made without delay and in any event no later than the first meeting of the board of directors at which the transaction is considered. 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, and the terms of engagement of the company, directly or indirectly, with a controlling shareholder or a controlling shareholder's relative (including through a corporation controlled by a controlling shareholder), regarding the company's receipt of services from the controlling shareholder, and if such controlling shareholder is also an office holder or employee of the company, regarding his or her terms of employment, require the approval of each of (i) the audit committee or the compensation committee, as applicable, (ii) the board of directors, and (iii) the shareholders, in that order. In addition, the shareholder approval must fulfill one of the following requirements:

- a majority of the shares held by shareholders who have no personal interest in the transaction and are voting at the meeting, excluding abstentions, must be voted in favor of approving the transaction; or

- the shares voted by shareholders who have no personal interest in the transaction who vote against the transaction represent no more than two percent (2%) of the voting rights in the company.

In addition, an extraordinary transaction with a controlling shareholder or in which a controlling shareholder has a personal interest, and an engagement of the company, directly or indirectly, with a controlling shareholder or a controlling shareholder's relative (including through a corporation controlled by a controlling shareholder), regarding the company's receipt of services from the controlling shareholder, and if such controlling shareholder is also an office holder or employee of the company, regarding his or her terms of employment, in each case with a term of more than three years, requires the abovementioned approvals every three years; however, 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 Israeli 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 proxy card whether or not that shareholder has a personal interest in the vote in question. Failure to so indicate will result in the invalidation of that shareholder's vote. Pursuant to an exemption available to companies such as the Company under regulations promulgated under the Israeli Companies Law, a shareholder may notify the company that he or she does not have a personal interest by virtue of providing her or his vote to the company if the voting instrument provides that by virtue of voting the shareholder declares that he or she does not have a personal interest in approving the resolution, other than a personal interest that was disclosed to the company.

Duties of Shareholders

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

- an amendment to the articles of association;
- an increase in the company's authorized share capital;
- a 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 discriminating against other shareholders.

The remedies generally available upon a breach of contract will also apply to a breach of the shareholder duties mentioned above, and in the event of discrimination against other shareholders, additional remedies may be 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 (including in a class meeting), 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 any other power with respect to a company, is under a duty to act with fairness towards the company. The Israeli 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.

Approval of Terms of Office and Employment of Office Holders

The Israeli Companies Law provides that the process for approval of Terms of Office and Employment of office holders, that are required to be for the benefit of the company, is as follows:

a. With respect to a chief executive officer, a controlling shareholder or a relative of a controlling shareholder, approval is required by the (i) compensation committee, (ii) board of directors and (iii) company's shareholders with the "special majority" described above (in that order). Subject to certain conditions, the Israeli Companies Law provides an exemption from the shareholder approval requirement in connection with the approval of the Terms of Office and Employment of a CEO candidate.

b. With respect to a director, approval is required by the (i) compensation committee, (ii) board of directors and (iii) company's shareholders with a regular majority (in that order).

c. With respect to any other office holder, approval is required by the compensation committee and the board of directors (in that order); however, in the event of an update of existing Terms of Office and Employment, which the compensation committee confirms is not material, the approval of the compensation committee is sufficient.

In the event the transaction with any office holder is not in accordance with the compensation policy, the approval of the company's shareholders, by "special majority," is also required. In the event the company's shareholders do not approve the compensation of the CEO or other office holders (who are not directors, controlling shareholders or relatives of the controlling shareholders), the compensation committee and board of directors may, in special situations, approve the transaction, subject to their providing detailed reasons and after discussion and examination of the rejection by the company's shareholders. The Companies Regulations (Relief in Related Party Transactions), 2000, promulgated under the Israeli Companies Law provide additional temporary or permanent relief from the shareholder approval requirement under certain circumstances.

Approval of Private Placements

Under the Israeli Companies Law and the regulations promulgated thereunder, a private placement of securities does not require approval at a general meeting of the shareholders of a company; provided however, that in special circumstances, such as a private placement which is intended to obviate the need to conduct a special tender offer (see the section titled "Acquisitions under Israeli Law" in Exhibit 2.3 attached to this Annual Report) or a private placement which qualifies as a related party transaction (see "*Item 6. Directors, Senior Management and Employees—C. Board Practices—Duties of Directors and Officers and Approval of Specified Related Party Transactions under the Israeli Companies Law*"), approval at a general meeting of the shareholders of a company is required.

Exculpation, Insurance and Indemnification of Directors and Officers

Exculpation

Under the Israeli Companies Law, a company may not exculpate (or exempt) an office holder from liability for a breach of the fiduciary duty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of the office holder's duty of care but only if a provision authorizing such exculpation is included in its articles of association. A company may not exculpate in advance a director from liability arising due to the breach of his or her duty of care in connection with dividend or distribution to shareholders.

Indemnification

Under the Israeli Companies Law, the Israeli Securities Law, 5728-1968 (the "Israeli Securities Law") and the Israeli Economic Competition Law, 5748-1988 (the "Israeli Competition Law") a company may indemnify an office holder in respect of the following liabilities, payments, and expenses incurred for acts performed by him or her as an office holder, either in advance of an event or following an event, provided its articles of association include a provision authorizing such indemnification:

- a monetary liability incurred by or imposed on the office holder in favor of another person pursuant to a court judgment, including pursuant to a settlement confirmed as judgment or arbitrator's decision approved by a competent court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events and amount or criteria; (ii) concluded without the filing of an indictment against the office holder but with the imposition of a monetary obligation on the office holder in lieu of criminal proceedings for an offense that does not require proof of criminal intent; or (iii) in connection with a monetary sanction;

- reasonable litigation expenses, including reasonable attorneys' fees, which were incurred by the office holder as a result of an investigation or proceeding filed against the office holder by an authority authorized to conduct such investigation or proceeding, provided that such investigation or proceeding was either (i) concluded without the filing of an indictment against such office holder and without the imposition on him of any monetary obligation in lieu of a criminal proceeding;

- a monetary liability imposed on the office holder in favor of a payment for a breach offended at an Administrative Procedure (as defined below) as set forth in Section 52(54)(a)(1)(a) to the Israeli Securities Law;

- expenses expended by the office holder with respect to an Administrative Procedure under the Israeli Securities Law, including reasonable litigation expenses and reasonable attorneys' fees;

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or which were imposed on the office holder by a court (i) in a proceeding instituted against him or her by the company, on its behalf, or by a third party, (ii) in connection with criminal indictment of which the office holder was acquitted, or (iii) in a criminal indictment which the office holder was convicted of an offense that does not require proof of criminal intent; and

- any other obligation or expense in respect of which it is permitted or will be permitted under applicable law to indemnify an office holder, including, without limitation, matters referenced in Section 56H(b)(1) of the Israeli Securities Law.

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 Israeli Securities Law.

Insurance

Under the Israeli Companies Law, the Israeli Securities Law and the Israeli Competition Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder if and to the extent provided in the company's articles of association:

- a breach of the fiduciary duty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder;
- a monetary liability imposed on the office holder in favor of a third party;
- a monetary liability imposed on the office holder in favor of an injured party at an Administrative Procedure pursuant to Section 52(54)(a) (1)(a) of the Israeli Securities Law; and
- expenses incurred by an office holder in connection with an Administrative Procedure, including reasonable litigation expenses and reasonable attorneys' fees.

Limitations on, and Approval Process of, Exculpation, Indemnification and Insurance

Under the Israeli Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of the fiduciary duty, except for indemnification and insurance for a breach of the fiduciary duty to the company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- a breach of duty of care committed intentionally or recklessly, excluding a breach solely arising out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine, civil fine, financial sanction or forfeit levied against the office holder.

Under the Israeli Companies Law, exculpation, indemnification, and insurance of office holders must be approved by the compensation committee and the board of directors, and, with respect to directors or controlling shareholders, their relatives and third parties in which controlling shareholders have a personal interest, also by the shareholders.

Our articles of association and compensation policy permit us to exculpate, indemnify, and insure our office holders to the fullest extent permitted or to be permitted by law. Our office holders are currently covered by a directors' and officers' liability insurance policy. As of the date of this report, no claims for directors' and officers' liability insurance have been filed under this policy, and we are not aware of any pending or threatened litigation or proceeding involving any of our office holders, including our directors, in which indemnification is sought.

We have entered into agreements with each of our current office holders exculpating them from a breach of their duty of care to us to the fullest extent permitted by law, subject to limited exceptions, and undertaking to indemnify them to the fullest extent permitted by law, subject to limited exceptions, to the extent that these liabilities are not covered by insurance. This indemnification is limited, with respect to any monetary liability imposed in favor of a third party, to events determined as foreseeable by the board of directors based on our activities. The maximum aggregate amount of indemnification that we may pay to our office holders based on such indemnification agreement with respect to any monetary liability imposed in favor of a third party is the greater of (1) 25% of our shareholders' equity less the minority rights pursuant to our audited or reviewed consolidated financial statements at the time the indemnification is actually paid, and (2) $20 million. Such indemnification is in addition to any insurance amounts. However, in the opinion of the SEC, indemnification of office holders for liabilities arising under the Securities Act is against public policy and therefore unenforceable.

D. Employees

Our employees include professionals with extensive experience in medical device development and applications, neurology and psychopathology, pre-clinical experimentation, clinical development, and business development.

As of December 31, 2024, we had 120 employees, of which 49 are based in the United States and 71 are based outside of the United States (in Israel).

The following table includes information concerning our employees as of December 31, 2024, 2023 and 2022:

	As of December 31,		
	2024	**2023**	**2022**
Management, administration, and operations	35	31	58
Research and development	32	29	35
Sales and Marketing	53	46	41

While none of our employees are party to any collective bargaining agreements, certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists' Associations) are applicable to our employees by order of the Israel Ministry of Labor. Such orders are part of the employment related laws and regulations which apply to our employees and set certain mandatory terms of employment. Such mandatory terms of employment primarily concern the length of the workday, minimum daily wages, pension plan benefits for all employees, insurance for work-related accidents, procedures for dismissal of employees, severance pay and other conditions of employment. We generally provide our employees with benefits and working conditions beyond the required minimums.

We have never experienced any employment-related work stoppages and believe our relationship with our employees is good.

E. Share Ownership

For information regarding the share ownership of our directors and executive officers, please see "*Item 7.A. Major Shareholders*."

Award Plans

On May 29, 2014, we adopted the Share Incentive Plan, as amended from time to time, or the 2014 Plan. The 2014 Plan was intended to afford an incentive to our and any of our affiliate's employees, directors, officers, consultants, advisors, and any other person or entity who provides services to the Company, its subsidiaries and affiliates, to continue as service providers, to increase their efforts on our and our affiliates' behalf and to promote our success, by providing such persons with opportunities to acquire a proprietary interest in us.

On September 26, 2019 we adopted the BrainsWay Ltd. Amended and Restated 2019 Share Incentive Plan, or the 2019 Plan, which was approved by our shareholders on January 13, 2020. The 2019 Plan provides for the granting of Ordinary Shares, ADSs, stock options under various tax regimes in Israel and the U.S., restricted shares, RSUs, and other share-based awards to employees, officers, directors, and/or other service providers, including advisors of the Company, and/or of its subsidiaries, and/or affiliated companies of the Company. The same number of our Ordinary Shares are available for issuance as awards under the 2019 Plan as were available under the 2014 Plan as of the effective date of the 2019 Plan, and the 2014 Plan continues to govern the terms of awards issued thereunder prior to the effective date of the 2019 Plan.

Under the 2019 Plan, we may issue up to 3,626,200 of our Ordinary Shares, including in the form of options or RSUs. As of December 31, 2024, options to purchase 2,626,113 Ordinary Shares, at a weighted average exercise price of $2.67 per share and 428,452 unvested RSUs were outstanding.

The equity pool under the 2019 Plan is subject to adjustment if particular capital changes affect our share capital or such other number as our Board of Directors may determine from time to time. Ordinary shares subject to outstanding awards under the 2019 Plan that subsequently expire, are cancelled, forfeited, repurchased or terminated for any reason before being exercised, will be automatically, and without any further action, returned to the "pool" of reserved shares and will again be available for grant under the 2019 Plan.

A stock option is the right to purchase a specified number of Ordinary Shares in the future at a specified exercise price and subject to the other terms and conditions specified in the option agreement and the 2019 Plan. The exercise price of each stock option granted under the 2019 Plan will be determined in accordance with the limitations set forth under the 2019 Plan. The exercise price of any stock options granted under the 2019 Plan may be paid in cash, through "cashless exercise" mechanism or any other method that may be approved by our compensation committee.

Our compensation committee may also grant, or recommend that our Board of Directors' grant, other forms of equity incentive awards under the 2019 Plan, such as restricted shares, RSUs, and other forms of share-based compensation.

Israeli participants in the 2019 Plan may be granted options subject to Section 102 of the Israeli Income Tax Ordinance (New Version), 1961, or the Israeli Tax Ordinance. Section 102 of the Israeli Tax Ordinance allows employees, directors and officers who are not controlling shareholders (as defined for those purposes under the Israeli Tax Ordinance) and are considered Israeli residents (and in certain cases also non-Israeli residents for the time they worked in Israel) to receive favorable tax treatment for compensation in the form of shares or options. Non-employee service providers and controlling shareholders may only be granted options under another section of the Israeli Tax Ordinance, which does not provide for similar tax benefits. Section 102 includes two alternatives for tax treatment involving the issuance of options or shares to a trustee for the benefit of the grantees and also includes an additional alternative for the issuance of options or shares directly to the grantee. Commonly, the most favorable tax treatment for the grantees is under Section 102(b)(2) of the Israeli Tax Ordinance, the issuance to a trustee under the "capital gain track." However, under this track we are not allowed to deduct an expense with respect to the issuance of the options or shares. Any options granted under the 2019 Plan to participants in the United States will be either "incentive stock options," which may be eligible for special tax treatment under the Internal Revenue Code of 1986, or options other than incentive stock options (referred to as "nonqualified stock options"), as determined by our compensation committee or our Board of Directors and stated in the option agreement.

Our compensation committee administers the 2019 Plan, or if determined otherwise by our Board of Directors, the Plan will be administered by our Board of Directors or other designated committee on its behalf. Even if the compensation committee or any other committee was appointed by our Board of Directors in order to administrate the 2019 Plan, our Board of Directors may, subject to any legal limitations, exercise any powers or duties of the compensation committee or any other committee concerning the 2019 Plan. The compensation committee will, among others, select which eligible persons will receive options or other awards under the 2019 Plan and will determine, or recommend to our Board of Directors, the number of Ordinary Shares covered by those options or other awards, the terms under which such options or other awards may be exercised (however, vested options generally may not be exercised later than ten years from the grant date of an option and a lesser period if the grantee ceased to be employed by, or provide services to, the company) or may be settled or paid, and the other terms and conditions of such options and other awards under the 2019 Plan. All awards granted under the 2019 Plan shall not be transferable other than by will or by the laws of descent and distribution, unless otherwise determined by our compensation committee.

To the extent permitted under applicable law, our compensation committee will have the authority to accelerate the vesting of any outstanding awards at such time and under such circumstances as it, in its sole discretion, deems appropriate. In the event of a change of control, as defined in the 2019 Plan, any award then outstanding shall be assumed or an equivalent award shall be substituted by the successor corporation of the merger or sale or any parent or affiliate thereof as determined by our Board of Directors. In the event that the awards are not assumed or substituted, our compensation committee may, in its discretion, accelerate the vesting, exercisability of the outstanding award, or provide for the cancellation of such award and payment of cash, as determined to be fair in the circumstances.

Subject to particular limitations specified in the 2019 Plan and under applicable law, our Board of Directors may amend or terminate the 2019 Plan, and the compensation committee may amend awards outstanding under the 2019 Plan. In addition, an amendment to the 2019 Plan that requires shareholder approval under applicable law will not be effective unless approved by the requisite vote of shareholders. Moreover, in general, no suspension, termination, modification or amendment of the 2019 Plan may adversely affect any award previously granted without the written consent of grantees holding a majority in interest of the awards so affected. The 2019 Plan will continue in effect until all Ordinary Shares available under the 2019 Plan are delivered and all restrictions on those shares have lapsed, unless the 2019 Plan is terminated earlier by our Board of Directors. No awards may be granted under the 2019 Plan on or after the tenth anniversary of the date of adoption of the 2019 Plan unless our Board of Directors chooses to extend the term.

Any equity award to an office holder, director or controlling shareholder, whether under the 2019 Plan or otherwise, may be subject to further approvals in addition to the approval of the compensation committee as described above. See "*Item 6. Directors, Senior Management and Employees—C. Board Practices—Duties of Directors and Officers and Approval of Specified Related Party Transactions under the Israeli Companies Law*."

F. Disclosure of 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 with respect to the beneficial ownership of our Ordinary Shares as of March 31, 2025 by:

- each person or entity known by us to own beneficially 5% or more of our outstanding Ordinary Shares;
- our directors and members of senior management, or our Named Directors and Officers; and
- all of our Named Directors and Officers as a group.

The beneficial ownership of our Ordinary Shares is determined in accordance with the rules of the SEC. Under these rules, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. For purposes of the table below, we deem Ordinary Shares issuable pursuant to options or warrants that are currently exercisable or exercisable within 60 days of March 31, 2025, if any, to be outstanding and to be beneficially owned by the person holding them for the purposes of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. The percentage of Ordinary Shares beneficially owned set forth below is based on 37,738,456 Ordinary Shares outstanding as of March 31, 2025.

Except where otherwise indicated, we believe, based on information furnished to us by such owners, that the beneficial owners of the Ordinary Shares listed below have sole investment and voting power with respect to such shares.

None of our shareholders have different voting rights from other shareholders. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our Company.

As of March 31, 2025, there was one shareholder of record of our Ordinary Shares. The number of record holders is not representative of the number of beneficial holders of our Ordinary Shares, as the shares of all our shareholders who hold Ordinary Shares that are traded on the TASE are recorded in the name of our Israeli share registrar, Registration Co. of United Mizrahi Bank Ltd. As of March 31, 2025, there were 13 persons that were holders of record in the United States of ADSs representing our Ordinary Shares, representing approximately 40.6% of our outstanding Ordinary Shares. The number of record holders is not representative of the number of beneficial holders of the ADSs, as the ADSs of certain of our shareholders who hold ADSs that are traded on Nasdaq are recorded in the name of their respective brokers.

Unless otherwise noted below, the address for each beneficial owner is c/o BrainsWay Ltd., 16 Hartum Street, RAD Tower, 14th Floor, Har HaHotzvim, Jerusalem, 9777516, Israel.

	Shares Beneficially Owned	
	Number	**Percentage**
5% or Greater Shareholders		
Valor BrainsWay Holdings, LLC[1]	7,207,490	17.69%
Dr. David Zacut[2]	2,167,043	5.74%
Masters Capital Management, LLC[3]	2,000,000	5.30%
Named Directors and Officers		
Ami Boehm, *Chairman of the Board*[4]	196,875	*
Dr. David Zacut, *Vice Chairman of the Board* [2]	2,167,043	5.74%
Avner Hagai, *director*[5]	1,781,726	4.72%
Eti Mitrany, *director* [6]	36,875	*
Karen Sarid, *director*[7]	36,875	*
Prof. Abraham Zangen, *director* [8]	934,375	2.48%
Avner Lushi, *director* [9]	36,875	*
Jonathan Shulkin, *director*[1]	7,743,984	19.01%
Hadar Levy, *Chief Executive Officer*[10]	67,880	1.75%
Ido Marom, *Chief Financial Officer*[11]	88,125	*
Gilead Moiseyev, *Chief Technology Officer*[12]	11,250	*
Dr. Yiftach Roth, *Chief Scientist*[13]	1,097,562	2.91%
Colleen Hanlon, *Vice President of Medical Affairs*[14]	23,750	*
All Named Directors and Officers as a group (13 persons)	14,826,195	35.46%

*** Less than 1.0%**

(1) The number of Ordinary Shares beneficially owned by Valor BrainsWay Hopldings, LLC consists of: (i) 2,103,745 ADSs (representing 4,207,490 Ordinary Shares) and (ii) 1,500,000 ADSs (representing 3,000,000 Ordinary Shares) issuable upon exercise of the Valor Warrant, which is currently exercisable. Valor Siren Ventures II L.P., Valor Siren Ventures II-A L.P. and Valor Siren Ventures II-B L.P., together, the Valor Funds, collectively hold a majority of the interests in Valor and Valor Management LLC, serves as the manager of Valor. Valor SV Associates II L.P., or Valor SV Associates, is the general partner of the Valor Funds, Valor SV Capital II LLC, or Valor SV Capital, is the general partner of Valor SV Associates, Valor Management LP is the managing member of Valor SV Capital, and Valor Funds Group LLC is the general partner of Valor Management LP and the managing member of Valor Management LLC. Jonathan Shulkin, a member of our Board of Directors, is a principal at Valor and an authorized officer of Valor BrainsWay and Antonio Gracias is the managing member of Valor Funds Group LLC, the majority owner of Valor Management LP and of Valor Funds Group LLC, and an authorized officer of Valor. By virtue of their positions and relationships with certain of the foregoing Valor entities, and with respect to Mr. Shulkin his service on our Board of Directors, Messrs. Shulkin and Gracias may be deemed to share beneficial ownership over the shares held of record by Valor; however, each disclaims beneficial ownership of such shares for purposes of Sections 13(d) or 13(g) of the Exchange Act. In addition to the aforementioned ADSs and Warrant directly held by Valor BrainsWay Holdings, LLC, Mr. Shulkin has sole voting and dispositive power over 268,247 ADSs (representing 536,494 Ordinary Shares or 1.5% of our outstanding Ordinary Shares) held through an entity of which he is the sole owner and Mr. Gracias has sole voting and dispositive power over 243,500 ADSs (representing 487,000 Ordinary Shares or 1.29% of our outstanding Ordinary Shares). The principal business address of each of the Valor entities and Messrs. Shulkin and Garcias is 320 N. Sangamon Street, Suite 1200, Chicago, IL 60607.

(2) Consists of shares held directly by the named beneficial owner as well as shares held by family members or affiliates of the named beneficial owner and options to purchase 6,250 Ordinary Shares with an exercise price per share of NIS 11.17 expiring on March 5, 2034.

(3) The shares are held by Masters Capital Management, LLC and Michael Masters has beneficial ownership by virtue of his role as a control person of Masters Capital Management, LLC. The address of Masters Capital Management, LLC is 3060 Peachtree Road, Suite 1425, Atlanta, Georgia 30305, United States of America.

(4) Consists of shares held directly by the named beneficial owner as well as shares held by family members or affiliates of the named beneficial owner and options to purchase 168,750 and 18,750 Ordinary Shares with an exercise price per share of NIS 4.56 and NIS 11.17, respectively, expiring on February 9, 2033 and March 5, 2034, respectively.

(5) Consists of shares held directly by the named beneficial owner as well as shares held by family members or affiliates of the named beneficial owner and options to purchase 6,250 Ordinary Shares with an exercise price per share of NIS 11.17 expiring on March 5, 2034.

(6) Consists of shares held directly by the named beneficial owner as well as shares held by family members or affiliates of the named beneficial owner and options to purchase 27,500 and 6,250 Ordinary Shares with an exercise price per share of NIS 15.26 and NIS 11.17, respectively, expiring on January 13, 2028 and March 5, 2034, respectively.

(7) Consists of shares held directly by the named beneficial owner as well as shares held by family members or affiliates of the named beneficial owner and options to purchase 27,500 and 6,250 Ordinary Shares with an exercise price per share of NIS 15.26 and NIS 11.17, respectively, expiring on December 2, 2027 and March 5, 2034, respectively.

(8) Consists of shares held directly by the named beneficial owner as well as shares held by family members or affiliates of the named beneficial owner and options to purchase 6,250 Ordinary Shares with an exercise price per share of NIS 11.17 expiring on March 5, 2034.

(9) Consists of shares held directly by the named beneficial owner as well as shares held by family members or affiliates of the named beneficial owner and options to purchase 27,500 and 6,250 Ordinary Shares with an exercise price per share of NIS 15.26 and NIS 11.17, respectively, expiring on January 13, 2028 and March 5, 2034, respectively.

(10) Consists 61,630 Ordinary Shares and options to purchase 609,250 Ordinary Shares as follows: (i) options to purchase 398,000 Ordinary Shares with an exercise price per share of $4.68 expiring on December 8, 2025 (220,000 options), November 12, 2026 (128,000 options) and October 1, 2027 (50,000 options), (ii) options to purchase 180,000 Ordinary Shares with an exercise price per share of $1.3 expiring on February 9, 2033, and (iii) options to purchase 31,250 Ordinary Shares with an exercise price per share of NIS 11.17 expiring on March 5, 2034.

(11) Consists of shares held directly by the named beneficial owner as well as shares held by family members or affiliates of the named beneficial owner and options to purchase 75,000 and 8,750 Ordinary Shares with an exercise price per share of NIS 4.28 and NIS 11.17, respectively, expiring on August 8, 2033 and March 5, 2034, respectively.

(12) Consists of shares held directly by the named beneficial owner as well as shares held by family members or affiliates of the named beneficial owner and options to purchase 7,500 Ordinary Shares with an exercise price per share of NIS 11.17 expiring on March 5, 2034.
(13) Consists of shares held directly by the named beneficial owner as well as shares held by family members or affiliates of the named beneficial owner.
(14) Consists of shares held directly by the named beneficial owner as well as shares held by family members or affiliates of the named beneficial owner and options to purchase 2,500 Ordinary Shares with an exercise price per share of NIS 11.17 expiring on March 5, 2034.

The voting rights of our major shareholders do not differ from the voting rights of holders of our Ordinary Shares who are not major shareholders. Each of our Ordinary Shares entitles the holder to one vote at our Company's shareholder meetings.

Changes in Percentage Ownership by Major Shareholders

Since April 12, 2022, which was the date we filed our Annual Report for the fiscal year ended December 31, 2021, we are not aware of significant changes in the reported percentage ownership held by any of our 5% or greater shareholders other than: (i) The Phoenix Provident Funds which decreased from 13.04% to below 5%, (ii) Dr. David Zacut which increased from 5.4% to 5.89%, (iii) Mr. Avner Hagai which decreased from 5.3% to below 5%, (iv) Cowen Financial Products, LLC which decreased from 5.03% to below 5%, (v) RTW Funds which decreased from 9.4% to below 5%, (vi) Wasatch Advisors Inc. and AIGH Capital Management, LLC each became 5% or greater shareholders but have since decreased their respective holdings to below 5% as of the date of this report and (vii) as a result of the private placement to Valor in November 2024, Valor's beneficial ownership increased to 17.73% (with each of the individuals holding shared voting and dispositive powers over its holdings beneficially owning additional shares as set forth above).

Control by Another Corporation, Foreign Government or Other Persons

To the best of our knowledge, the Company is not directly or indirectly owned or controlled by another corporation(s), by any foreign government or by any other natural or legal person(s) severally or jointly.

B. Related Party Transactions

Valor Private Placement

On September 29, 2024, we entered into a securities purchase agreement with Valor for a private placement offering, or the Valor Private Placement. In the Valor Private Placement, we agreed to issue to Valor (i) an aggregate of 2,103,745 ADSs (representing 4,207,490 Ordinary Shares), at a purchase price of US$9.50686 per ADS, a 20% premium above the 30-day volume-weighted average price (VWAP) of the ADSs for an aggregate consideration of $20 million, and (ii) a warrant to purchase up to an additional 1,500,000 ADSs (representing up to 3,000,000 Ordinary Shares) at an exercise price of US$9.50686 per ADS, which may further increase the gross proceeds from the Valor Private Placement to up to a total of approximately $34.3 million if the Valor Warrant is fully exercised in cash. The Valor Warrant became exercisable immediately upon issuance thereof at the closing of the Valor Private Placement on November 5, 2024 and is exercisable for 18 months following its initial issuance date, provided, however, that during such 18-month period, if the ADS closing price for any thirty (30) consecutive trading days exceeds the Valor Warrant exercise price by 40% or more, Valor shall be required to fully exercise the Valor Warrant within five (5) trading days.

In connection with the Valor Private Placement we granted Valor the right to nominate (i) at least one member to our Board of Directors so long as Valor holds, directly or indirectly, or together with any Valor Affiliates at least 10% of our issued and outstanding share capital and (ii) two members to our Board of Directors so long as Valor holds, directly or indirectly, or together with the Valor Affiliates at least 20% of our issued and outstanding share capital.

Concurrently with the execution of the securities purchase agreement, we and Valor entered into a registration rights agreement pursuant to which we agreed to file within 10 days following receipt of the shareholder approval of the Valor Private Placement a registration statement with the SEC to register the resale of the ADSs sold in the Valor Private Placement, as well as the securities underlying the Valor Warrant. On November 5, 2024, we entered into an amendment to the Valor registration rights agreement providing that such registration statement will be filed within three business days after the filing of our Annual Report on Form 20-F for the fiscal year ended December 31, 2024.

The Valor Private Placement was consummated on November 5, 2024 after our shareholders approved its terms, the appointment of Jonathan Shulkin as a member of our Board of Directors and amendments to our articles of association. For more information see "*Item 6.C. Board Practices"* above.

Employment Agreements

We have entered into written employment agreements with each member of our senior management. These agreements provide for notice periods of varying duration for termination of the agreement by us or by the relevant executive officer, during which time the executive officer will continue to receive base salary and benefits. These agreements also 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. See "Risk Factors—Risks Related to Employee Matters—*Under applicable employment laws, we may not be able to enforce covenants not to compete*."

Employment Agreement with Hadar Levy our Chief Executive Officer

In March 2023 we entered into an employment agreement with Hadar Levy reflecting his compensation package and other terms as our new CEO. The terms were approved by our shareholders in the annual general meeting held on March 20, 2023. The following is a description of Mr. Levy's compensation package, effective as of the date that Mr. Levy was appointed as the CEO, namely February 13, 2023: Annualized gross base salary of NIS 1,020,000 (calculated on the basis of NIS 85,000 monthly); Performance-based bonus in a gross amount not exceeding six (6) months of then current base salary based on achievement of the milestones, goals and targets to be set each year by the Board; 320,000 options to purchase Ordinary Sharers of the Company, at an exercise price based on the closing price of the Company on the last trading day prior to the date of the shareholders meeting, namely March 19, 2023, subject to standard terms our 2019 Plan and compliance with all applicable laws. The options are subject to our standard 4 year vesting period, with acceleration in the event of a change of control; If Mr. Levy's employment is terminated by the company without cause (1) where such termination occurs during the first two years of employment as CEO, Mr. Levy shall be entitled to a 6 month prior notice, and (2) where such termination occurs after the first two year of employment as CEO, Mr. Levy shall be entitled to a 4 month prior notice; Mr. Levy undertook not to compete with the products and services offered by the Company and not to do any interfering activities during the term of his employment and for 12 months of the date of termination of his employment for any reason.

At our 2024 AGM, our shareholders approved a grant to Mr. Levy of equity consisting of (i) 125,000 options to purchase Ordinary Shares of the Company (at an exercise price equal to NIS 11.17 per share, being the closing price of our Ordinary Shares on the TASE on March 4, 2024 which was the last trading day before our Board of Directors approved such grant); and (ii) 62,500 restricted share units. The grants are subject to a four-year vesting period, with the first 25% vesting on the date falling 12 months following the March 5, 2024 vesting commencement date, and the remaining 75% vesting in 12 equal quarterly portions until the end of the four-year period, provided, in each case that Mr. Levy continues to be employed by us at the time of each such scheduled vesting date. The grants shall otherwise be in accordance with our 2019 Plan.

Employment Agreement with Ido Marom our Chief Financial Officer

In September 2023 we entered into an employment agreement with Ido Marom reflecting his compensation and other terms as our new CFO. The following is a description of Mr. Marom's compensation package, effective as of September 1, 2023: Monthly base salary of NIS 50,000 and beginning from November 16, 2023 a monthly base salary of NIS 55,000 (approximately an annual amount of NIS 647,500); Target Annual Bonus up to three (3) months of then current base salary based on achievements of the milestones, goals and targets to be set each year by the CEO and the Board and subject to Compensation Policy; 150,000 options to purchase Ordinary Sharers of the Company, at an exercise price based on the closing price of the Company on the last trading day prior to the date of the Board approval, namely August 7, 2023, subject to standard terms in the company's Amended and Restated 2019 Share Incentive Plan and compliance with all applicable laws. The options are subject to our standard 4 year vesting period, with acceleration in the event of a change of control; Mr. Marom undertook not to compete with the products and services offered by the Company and not to do any interfering activities during the term of his employment and for 12 months of the date of termination of his employment for any reason.

Engagement with executive directors

We have engaged with each of our executive directors for compensation paid to them with respect to the services provided to the Company, for more information please see "*Item 6.B.—Compensation—Director Compensation*."

Consulting Agreement with Prof. Abraham Zangen

In April 2009, we entered into a consulting agreement, which was last amended in May 2014, with Prof. Abraham Zangen, our scientific founder and a member of our Board, under which Prof. Zangen provides advisory services to us in the field of neurobiology. Prof. Zangen's monthly consulting fee is NIS 19,375. This agreement provides for a notice period of 180 days for termination of the agreement by Prof. Zangen and 30 days for termination of the agreement by us.

Sponsorship of an Obesity Study at BGU

In 2021, we entered into an addendum to a July 2012 agreement with Ben Gurion Negev Technology and Applications Ltd. which operates a lab associated with Prof. Zangen, a director of the Company. Under the terms of the addendum, we agreed to sponsor a 40-patient obesity study involving Deep TMS.

Option Grants

Each of our directors and members of senior management are participants in our Share Incentive Plan, pursuant to which they receive from time to time grants of options to purchase our Ordinary Shares. For more information, see "*Item 6. Directors, Senior Management and Employees—Share Ownership—Award Plans*."

Since January 1, 2022, we granted options to purchase 1,768,000 Ordinary Shares to employees and directors, with a weighted average exercise price of approximately $1.7 per share, or approximately NIS 5.97 per share (based on the exchange rate reported by the Bank of Israel on December 31, 2024), and 818,400 restricted share units (RSUs).

Directors and Officers Insurance Policy and Indemnification Agreements

Our articles of association permit us to exculpate, indemnify, and insure each of our directors and officers to the fullest extent permitted by the Israeli Companies Law. For information, please see "*Item 6.C.—Board Practices—Exculpation, Insurance and Indemnification of Directors and Officers*."

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

The financial statements required by this item are found at the end of this Annual Report, beginning on page F-1.

Legal Proceedings

From time to time, we may become a party to legal proceedings and claims in the ordinary course of business. We are not currently a party to any significant active legal proceedings, subject to any disclosure set forth under "*Item 4. Information on the Company—Business Overview—Legal Proceedings*" which is incorporated herein by reference.

Export Sales

For geographical breakdown of the Company's sales, see Note 17 to the financial statements included at the end of this Annual Report.

Dividend Policy

We have never declared or paid cash dividends to our shareholders. We do not have current plans to pay cash dividends in the near term. We currently intend to reinvest any future earnings, if any, in developing and expanding our business. Any future determination relating to our dividend policy will be at the discretion of our Board of Directors and will depend on a number of factors, including future earnings, if any, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, applicable Israeli law and other factors our Board of Directors may deem relevant.

B. Significant Changes

Except as otherwise disclosed in this Annual Report, no significant change has occurred since December 31, 2024.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our Ordinary Shares have been trading on the TASE under the symbol "BWAY" since January 2007. The ADSs representing our Ordinary Shares have been trading on The Nasdaq Global Market under the symbol "BWAY" since April 16, 2019.

There were no suspensions in the trading of our shares in 2024, 2023 and 2022.

B. Plan of Distribution

Not applicable.

C. Markets

Our Ordinary Shares are listed and traded on the TASE, and ADSs, each representing two Ordinary Shares and evidenced by an American depositary receipt, or ADR, are traded on The Nasdaq Global Market under the symbol "BWAY." The ADRs were issued pursuant to a Depositary Agreement entered into with The Bank of New York.

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

For a description of provisions of our articles of association relating to the power of directors; rights, preferences and restrictions attaching to each class of the shares; changes in control of the company; and other information required under Item 10.B, please see Exhibit 2.3 "Description of Share Capital," which is incorporated herein by reference.

C. Material Contracts

For a description of our material agreements, please see "*Item 5.C—Research and Development, Patents, and Licenses*" and "*Item 7.B.—Related Party Transactions*."

D. Exchange Controls

Israeli law and regulations do not impose any material foreign exchange restrictions on non-Israeli holders of our Ordinary Shares or on the Company with respect to the import or export of capital. Dividends, if any, paid to holders of our Ordinary Shares, and any amounts payable upon our dissolution, liquidation or winding up, as well as the proceeds of any sale in Israel of our Ordinary Shares to an Israeli resident, may be paid in non-Israeli currency or, if paid in Israeli currency, may be converted into U.S. dollars at the rate of exchange prevailing at the time of conversion.

E. Taxation

Israeli Tax

Considerations General

The following is a summary of the material tax consequences under Israeli law concerning the purchase, ownership, and disposition of our Ordinary Shares or ADSs (Shares).

This discussion does not purport to constitute a complete analysis of all potential tax consequences applicable to investors upon purchasing, owning or disposing of our Shares. In particular, this discussion does not take into account the specific circumstances of any particular investor (such as tax-exempt entities, financial institutions, certain financial companies, broker-dealers, investors that own, directly or indirectly, 10% or more of our outstanding voting rights, all of whom are subject to special tax regimes not covered under this discussion). To the extent that issues discussed herein are based on legislation which has yet to be subject to judicial or administrative interpretation, there can be no assurance that the views expressed herein will accord with any such interpretation in the future.

Potential investors are urged to consult their own tax advisors as to the Israeli or other tax consequences of the purchase, ownership, and disposition of the Shares, including, in particular, the effect of any foreign, state or local taxes.

General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax on their taxable income at the rate of 23% for the 2024 tax year.

Taxation of Shareholders Capital Gains

Capital gains tax is imposed on the disposition of capital assets by an Israeli resident, and on the disposition of such assets by a non-Israeli resident if those assets are either (i) located in Israel; (ii) are shares or a right to a share in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel, unless an exemption is available or unless an applicable double tax treaty between Israel and the seller's country of residence provides otherwise. The Israeli Income Tax Ordinance distinguishes between "Real Gain" and the "Inflationary Surplus." Real Gain is the excess of the total capital gain over Inflationary Surplus generally computed on the basis of the increase in the Israeli Consumer Price Index between the date of purchase and the date of disposition. Inflationary Surplus is not subject to tax.

Real Gain accrued by individuals on the sale of the Shares will be taxed at the rate of 25%. However, if the individual shareholder is a "Controlling Shareholder" (i.e., a person who holds, directly or indirectly, alone or together with another, 10% or more of one of the Israeli resident company's means of control) at the time of sale or at any time during the preceding 12-month period, such gain will be taxed at the rate of 30%.

Corporate and individual shareholders dealing in securities in Israel are taxed at the tax rates applicable to business income (23% in 2024), and a marginal tax rate of up to 50% in 2024 for individuals, including an excess tax (as discussed below).

Notwithstanding the foregoing, capital gains generated from the sale of our Shares by a non-Israeli shareholder may be exempt from Israeli tax under the Israeli Income Tax Ordinance provided that the following cumulative conditions are met: (i) the Shares were purchased upon or after the registration of the Shares on the stock exchange (this condition will not apply to shares purchased on or after January 1, 2009), and (ii) the seller does not have a permanent establishment in Israel to which the generated capital gain is attributed. However, non-Israeli resident corporations will not be entitled to the foregoing exemption if Israeli residents: (i) have a 25% or more interest in such non-Israeli corporation or (ii) are the beneficiaries of, or are entitled to, 25% or more of the income or profits of such non-Israeli corporation, whether directly or indirectly. In addition, such exemption would not be available to a person whose gains from selling or otherwise disposing of the securities are deemed to be business income.

In addition, the sale of the Shares may be exempt from Israeli capital gains tax under the provisions of an applicable double tax treaty. For example, the Convention between the Government of the U.S. and the Government of the State of Israel with respect to Taxes on Income (U.S.-Israel Double Tax Treaty) exempts a U.S. resident (for purposes of the treaty) from Israeli capital gain tax in connection with the sale of the Shares, provided that: (i) the U.S. resident owned, directly or indirectly, less than 10% of the voting power of the company at any time within the 12-month period preceding such sale; (ii) the U.S. resident, being an individual, is present in Israel for a period or periods of less than 183 days during the taxable year; and (iii) the capital gain from the sale was not derived through a permanent establishment of the U.S. resident in Israel; however, under the U.S-Israel Double Tax Treaty, the taxpayer would be permitted to claim a credit for such taxes against the U.S. federal income tax imposed with respect to such sale, exchange or disposition, subject to the limitations under U.S. law applicable to foreign tax credits. The U.S-Israel Double Tax Treaty does not relate to U.S. state or local taxes.

Payors of consideration for the Shares, including the purchaser, the Israeli stockbroker or the financial institution through which the Shares are held, are obligated, subject to certain exemptions, to withhold tax upon the sale of Shares at a rate of 25% of the consideration for individuals and corporations.

Upon the sale of traded securities, a detailed return, including a computation of the tax due, must be filed and an advanced payment must be paid to the Israeli Tax Authority on January 31 and July 31 of every tax year in respect of sales of traded securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Israeli Income Tax Ordinance and regulations promulgated thereunder, such return need not be filed, and no advance payment must be paid. Capital gains are also reportable on annual income tax returns.

Dividends

Dividends distributed by a company to a shareholder who is an Israeli resident individual will generally be subject to income tax at a rate of 25%. However, a 30% tax rate will apply if the dividend recipient is a Controlling Shareholder, as defined above, at the time of distribution or at any time during the preceding 12-month period. If the recipient of the dividend is an Israeli resident corporation, such dividend will generally be exempt from Israeli income tax provided that the income from which such dividend is distributed, derived or accrued within Israel.

Dividends distributed by an Israeli resident company to a non-Israeli resident (either an individual or a corporation) are generally subject to Israeli withholding tax on the receipt of such dividends at the rate of 25% (30% if the dividend recipient is a Controlling Shareholder at the time of distribution or at any time during the preceding 12-month period). These rates may be reduced under the provisions of an applicable double tax treaty. For example, under the U.S.-Israel Double Tax Treaty, the following tax rates will apply in respect of dividends distributed by an Israeli resident company to a U.S. resident: (i) if the U.S. resident is a corporation which holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding shares of the voting stock of the Israeli resident paying corporation, and not more than 25% of the gross income of the Israeli resident paying corporation for such prior taxable year (if any) consists of certain types of interest or dividends the tax rate is 12.5%; (ii) if both the conditions mentioned in clause (i) above are met and the dividend is paid from an Israeli resident company's income which was entitled to a reduced tax rate under The Law for the Encouragement of Capital Investments, 1959, the tax rate is 15%; and (iii) in all other cases, the tax rate is 25%. The aforementioned rates under the U.S.-Israel Double Tax Treaty will not apply if the dividend income is attributed to a permanent establishment of the U.S. resident in Israel.

Excess Tax

Individual holders who are subject to tax in Israel (whether any such individual is an Israeli resident or non-Israeli resident), and who have taxable income that exceeds a certain threshold in a tax year (NIS 721,560 for 2024, linked to the Israeli Consumer Price Index) will be subject to an additional tax at the rate of 3% on his or her taxable income for such tax year that is in excess of such amount. For this purpose, taxable income includes taxable capital gains from the sale of securities and taxable income from interest and dividends, subject to the provisions of an applicable double tax treaty.

Estate and Gift Tax

Israel does not currently impose estate or gift taxes.

Foreign Exchange Regulations

Non-residents of Israel who hold our Shares are able to receive any dividends, and any amounts payable upon the dissolution, liquidation, and winding up of our affairs, repayable in non-Israeli currency at the rate of exchange prevailing at the time of conversion. However, Israeli income tax is generally required to have been paid or withheld on these amounts. In addition, the statutory framework for the potential imposition of currency exchange control has not been eliminated and may be restored at any time by administrative action.

U.S. Federal Income Tax Considerations

The following is a summary of the material U.S. federal income tax consequences relating to the ownership and disposition of our Ordinary Shares and ADSs by U.S. Holders, as defined below. This summary addresses solely U.S. Holders who hold Ordinary Shares or ADSs, as applicable, as capital assets for tax purposes. This summary is based on current provisions of the Internal Revenue Code of 1986, as amended (Code), current and proposed Treasury regulations promulgated thereunder, and administrative and judicial decisions as of the date hereof, all of which are subject to change, possibly on a retroactive basis. In addition, this section is based in part upon representations of the depositary and the assumption that each obligation in the deposit agreement and any related agreement will be performed in accordance with its terms. This summary does not address all U.S. federal income tax matters that may be relevant to a particular holder or all tax considerations that may be relevant with respect to an investment in our Ordinary Shares or ADSs.

This summary does not address tax considerations applicable to a holder of our Ordinary Shares or ADSs that may be subject to special tax rules including, without limitation, the following:

- dealers or traders in securities, currencies or notional principal contracts;
- financial institutions;
- insurance companies;
- real estate investment trusts;
- banks;
- persons subject to the alternative minimum tax;
- tax-exempt organizations;
- traders that have elected mark-to-market accounting;
- investors that hold Ordinary Shares or ADSs as part of a "straddle", "hedge", or "conversion transaction" with other investments;
- regulated investment companies;
- persons that actually or constructively own 10 percent or more of our voting shares;
- persons that are treated as partnerships or other pass-through entities for U.S. federal income purposes and persons who hold the Shares through partnerships or other pass-through entities; and
- persons whose functional currency is not the U.S. dollars.

This summary does not address the effect of any U.S. federal taxation other than U.S. federal income taxation. In addition, this summary does not include any discussion of state, local, or foreign tax consequences to a holder of our Ordinary Shares or ADSs.

You are urged to consult your own tax advisor regarding the foreign and U.S. federal, state, local, and other tax consequences of an investment in Ordinary Shares or ADSs.

For purposes of this summary, a "U.S. Holder" means a beneficial owner of an Ordinary Share or ADS that is for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the U.S.;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in the U.S. or under the laws of the U.S. or any political subdivision thereof;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (1) if (a) a court within the U.S. is able to exercise primary supervision over the administration of the trust and (b) one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

If an entity that is classified as a partnership for U.S. federal tax purposes holds Ordinary Shares or ADSs, the U.S. federal tax treatment of its partners will generally depend upon the status of the partners and the activities of the partnership. Entities that are classified as partnerships for U.S. federal tax purposes and persons holding Ordinary Shares or ADSs through such entities should consult their own tax advisors.

In general, if you hold ADSs, you will be treated as the holder of the underlying Ordinary Shares represented by those ADSs for U.S. federal income tax purposes. Accordingly, gain or loss generally will not be recognized if you exchange ADSs for the underlying Ordinary Shares represented by those ADSs.

Distributions

Subject to the discussion under "*Item 10. Additional Information—E. Taxation—U.S. Federal Income Tax Considerations—Passive Foreign Investment Companies*" below, the gross amount of any distribution, including the amount of any Israeli taxes withheld from such distribution, see "*Item 10. Additional Information—E. Taxation—Israeli Tax Considerations*", actually or constructively received by a U.S. Holder with respect to our Ordinary Shares (or, in the case of ADSs, received by the depositary) will be taxable to the U.S. Holder as foreign source dividend income to the extent of our current and accumulated earnings and profits as determined under U.S. federal income tax principles.

The U.S. Holder will not be eligible for any dividends received deduction in respect of the dividends paid by us. Distributions in excess of earnings and profits will be non-taxable to the U.S. Holder to the extent of the U.S. Holder's adjusted tax basis in its Ordinary Shares or ADSs. Distributions in excess of such adjusted tax basis will generally be taxable to the U.S. Holder as capital gain from the sale or exchange of property as described below under "Sale or Other Disposition of Ordinary Shares or ADSs." If we do not report to a U.S. Holder the portion of a distribution that exceeds earnings and profits, then the distribution will generally be taxable as a dividend. The amount of any distribution of property other than cash will be the fair market value of that property on the date of distribution.

Under the Code, certain dividends received by non-corporate U.S. Holders will be subject to a maximum federal income tax rate of 20%. This reduced income tax rate is only applicable to dividends paid by a "qualified foreign corporation" that is not a PFIC for the year in which the dividend is paid or for the preceding taxable year, and only with respect to Ordinary Shares or ADSs held by a qualified U.S. Holder (i.e., a non-corporate holder) for a minimum holding period (generally 61 days during the 121-day period beginning 60 days before the ex-dividend date). As discussed below, however, we will likely be a "passive foreign investment company" (see "*Item 10. Additional Information—E. Taxation—U.S. Federal Income Tax Considerations—Passive Foreign Investment Companies*" below) for our current taxable year and future taxable years. Accordingly, dividends paid by us to individual U.S. Holders may not be eligible for the reduced income tax rate applicable to qualified dividends. You should consult your own tax advisor regarding the availability of this preferential tax rate under your particular circumstances.

The amount of any distribution paid in a currency other than U.S. dollars (a "foreign currency"), including the amount of any withholding tax thereon, will be included in the gross income of a U.S. Holder in an amount equal to the U.S. dollar value of the foreign currency calculated by reference to the exchange rate in effect on the date of the U.S. Holder's (or, in the case of ADSs, the depositary's) receipt of the dividend, regardless of whether the foreign currency is converted into U.S. dollars. If the foreign currency is converted into U.S. dollars on the date of receipt, a U.S. Holder generally should not be required to recognize a foreign currency gain or loss in respect of the dividend. If the foreign currency received in the distribution is not converted into U.S. dollars on the date of receipt, a U.S. Holder will have a basis in the foreign currency equal to its U.S. dollar value on the date of receipt. Any gain or loss on a subsequent conversion or other disposition of the foreign currency will be treated as U.S. source ordinary income or loss.

Subject to certain conditions and limitations, any Israeli taxes withheld on dividends may be creditable against a U.S. Holder's U.S. federal income tax liability, subject to generally applicable limitations. The rules relating to foreign tax credits and the timing thereof are complex. U.S. Holders should consult their own tax advisors regarding the availability of a foreign tax credit in their particular situation.

Sale or Other Disposition of Ordinary Shares or ADSs

Subject to the discussion under "*Item 10. Additional Information—Taxation—U.S. Federal Income Tax Considerations—Passive Foreign Investment Companies*" below, if a U.S. Holder sells or otherwise disposes of its Ordinary Shares or ADSs, gain or loss will be recognized for U.S. federal income tax purposes in an amount equal to the difference between the amount realized on the sale or other disposition and such holder's adjusted basis in the Ordinary Shares or ADSs. Such gain or loss generally will be a capital gain or loss, and will be a long-term capital gain or loss if the holder had held the Ordinary Shares or ADSs for more than one year at the time of the sale or other disposition. Long-term capital gains realized by non-corporate U.S. Holders are generally subject to a preferential U.S. federal income tax rate. In general, gain or loss recognized by a U.S. Holder on the sale or other disposition or our Ordinary Shares or ADSs will be U.S. source gain or loss for purposes of the foreign tax credit limitation. As discussed below in "Item 10. Additional Information – Taxation — U.S. Federal Income Tax Considerations – Passive Foreign Investment Companies," however, we may be a PFIC for our current taxable year and future taxable years. If we are a PFIC, any such gain will be subject to the PFIC rules, as discussed below, rather than being taxed as a capital gain.

If a U.S. Holder receives foreign currency upon a sale or exchange of Ordinary Shares or ADSs, gain or loss will be recognized in the manner described above under "Distributions." However, if such foreign currency is converted into U.S. dollars on the date received by the U.S. Holder, the U.S. Holder generally should not be required to recognize any foreign currency gain or loss on such conversion.

As discussed above under the heading "*Item 10. Additional Information—E. Taxation—Israeli Tax Considerations—Taxation of Shareholders*," a U.S. Holder who holds Ordinary Shares or ADSs through an Israeli broker or other Israeli intermediary may be subject to Israeli withholding tax on any capital gains recognized on a sale or other disposition of the Ordinary Shares or ADSs if the U.S. Holder does not obtain approval of an exemption from the Israeli Tax Authorities or claim any allowable refunds or reductions. U.S. Holders are advised that any Israeli tax paid under circumstances in which an exemption from (or a refund of or a reduction in) such tax was available will not be creditable for U.S. federal income tax purposes. U.S. Holders are advised to consult their Israeli broker or intermediary regarding the procedures for obtaining an exemption or reduction.

Medicare Tax on Unearned Income

Certain U.S. Holders that are individuals, estates or trusts are required to pay an additional 3.8% tax on their net investment income, which would include dividends paid on the Ordinary Shares or ADSs and capital gains from the sale or other disposition of the Ordinary Shares or ADSs.

Passive Foreign Investment Companies

We have not made a formal determination as to whether we would be classified as a PFIC and it is possible that we will be treated as a PFIC for U.S. federal income tax purposes for our current taxable year. A non-U.S. corporation is considered a PFIC for any taxable year if either:

- at least 75% of its gross income for such taxable year is passive income; or
- at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income.

For purposes of the above calculations, if a non-U.S. corporation owns, directly or indirectly, 25% or more of the total value of the outstanding shares of another corporation, it will be treated as if it (a) held a proportionate share of the assets of such other corporation, and (b) received a proportionate share of the income of such other corporation directly. Passive income generally includes dividends, interest, rents, royalties, and capital gains, but generally excludes rents and royalties which are derived in the active conduct of a trade or business, and which are received from a person other than a related person.

A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). Because the value of our assets for purposes of the asset test will generally be determined by reference to the market price of the Ordinary Shares or ADSs, our PFIC status will depend in large part on the market price of the Ordinary Shares or ADSs, which may fluctuate significantly. Based on our retention of a significant amount of cash and cash equivalents, and depending on the market price of the Ordinary Shares or ADSs, we may be treated as a PFIC for the 2024 taxable year and may be treated as a PFIC in future taxable years.

If we are a PFIC for any year during which you hold the Ordinary Shares or ADSs, we generally will continue to be treated as a PFIC with respect to you for all succeeding years during which you hold the Ordinary Shares or ADSs, unless we cease to be a PFIC and you make a "deemed sale" election with respect to the Ordinary Shares or ADSs you hold. If such election is made, you will be deemed to have sold the Ordinary Shares or ADSs you hold at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain from such deemed sale would be subject to the consequences described below. After the deemed sale election, the Ordinary Shares or ADSs with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

For each taxable year we are treated as a PFIC with respect to you, you will be subject to special tax rules with respect to any "excess distribution" you receive and any gain you realize from a sale or other disposition (including a pledge) of the Ordinary Shares or ADSs, unless you make a "mark-to-market" election as discussed below. Distributions you receive in a taxable year that are greater than 125% of the average annual distributions you received during the shorter of the three preceding taxable years or your holding period for the Ordinary Shares or ADSs will be treated as an excess distribution. Under these special tax rules, if you receive any excess distribution or realize any gain from a sale or other disposition of the Ordinary Shares or ADSs:

- the excess distribution or gain will be allocated ratably over your holding period for the Ordinary Shares or ADSs;
- the amount of excess distribution or gain allocated to the current taxable year, and any taxable year before the first taxable year in which we were a PFIC, must be included in gross income (as ordinary income) for the current tax year; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year, and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to.

The tax liability for amounts allocated to years before the year of disposition or "excess distribution" cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the Ordinary Shares or ADSs cannot be treated as capital, even if you hold the Ordinary Shares or ADSs as capital assets.

If we are treated as a PFIC with respect to you for any taxable year, to the extent any of our subsidiaries are also PFICs, you will be deemed to own your proportionate share of any such lower-tier PFIC, and you may be subject to the rules described in the preceding two paragraphs with respect to the shares of such lower-tier PFICs you would be deemed to own. As a result, you may incur liability for any "excess distribution" described above if we receive a distribution from such lower-tier PFICs or if any shares in such lower-tier PFICs are disposed of (or deemed disposed of). You should consult your own tax advisor regarding the application of the PFIC rules to any of our subsidiaries.

Alternatively, a U.S. Holder of "marketable stock" (as defined below) in a PFIC may make a mark-to-market election for such stock to elect out of the general tax treatment for PFICs discussed above. If you make a mark-to-market election for the Ordinary Shares or ADSs, you will include in income for each year we are a PFIC an amount equal to the excess, if any, of the fair market value of the Ordinary Shares or ADSs as of the close of your taxable year over your adjusted basis in such Ordinary Shares or ADSs. You are allowed a deduction for the excess, if any, of the adjusted basis of the Ordinary Shares or ADSs over their fair market value as of the close of the taxable year. However, deductions are allowable only to the extent of any net mark-to-market gains on the Ordinary Shares or ADSs included in your income for prior taxable years. Amounts included in your income under a mark-to-market election, as well as gain on the actual sale or other disposition of the Ordinary Shares or ADSs, are treated as ordinary income. Ordinary loss treatment also applies to the deductible portion of any mark-to-market loss on the Ordinary Shares or ADSs, as well as to any loss realized on the actual sale or disposition of the Ordinary Shares or ADSs to the extent the amount of such loss does not exceed the net mark-to-market gains previously included for the Ordinary Shares or ADSs. Your basis in the Ordinary Shares or ADSs will be adjusted to reflect any such income or loss amounts. If you make a valid mark-to-market election, the tax rules that apply to distributions by corporations which are not PFICs would apply to distributions by us, except the lower applicable tax rate for qualified dividend income would not apply. If we cease to be a PFIC when you have a mark-to-market election in effect, gain or loss realized by you on the sale of the Ordinary Shares or ADSs will be a capital gain or loss and taxed in the manner described above under "Sale or Other Disposition of Ordinary Shares or ADSs."

The mark-to-market election is available only for "marketable stock," which is a stock that is traded in other than de minimis quantities on at least 15 days during each calendar quarter, or regularly traded, on a qualified exchange or another market, as defined in applicable U.S. Treasury regulations. Any trades that have as their principal purpose meeting this requirement will be disregarded. The Ordinary Shares or ADSs are listed on the Nasdaq Global Market and, accordingly, provided the Ordinary Shares or ADSs are regularly traded, if you are a holder of Ordinary Shares or ADSs, the mark-to-market election would be available to you if we are a PFIC. Once made, the election cannot be revoked without the consent of the IRS unless the Ordinary Shares or ADSs cease to be marketable stock. If we are a PFIC for any year in which the U.S. Holder owns Ordinary Shares or ADSs but before a mark-to-market election is made, the interest charge rules described above will apply to any mark-to-market gain recognized in the year the election is made. If any of our subsidiaries are or become PFICs, the mark-to-market election will not be available with respect to the shares of such subsidiaries that are treated as owned by you. Consequently, you could be subject to the PFIC rules with respect to income of the lower-tier PFICs the value of which already had been taken into account indirectly via mark-to-market adjustments. A U.S. Holder should consult its own tax advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

In certain circumstances, a U.S. Holder of stock in a PFIC can make a "qualified electing fund election" to mitigate some of the adverse tax consequences of holding stock in a PFIC by including in income its share of the corporation's income on a current basis. However, we do not currently intend to prepare or provide the information that would enable you to make a qualified electing fund election.

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an annual report containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file the annual report will cause the statute of limitations for such U.S. Holder's U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. Holder files the annual report, and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder's entire
U.S. federal income tax return will remain open during such period. U.S. Holders should consult their own tax advisors regarding the requirements of filing such information returns under these rules, taking into account the uncertainty as to whether we are currently treated as or may become a PFIC.

YOU ARE STRONGLY URGED TO CONSULT YOUR OWN TAX ADVISOR REGARDING THE IMPACT OF OUR POTENTIAL PFIC STATUS ON YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs AS WELL AS THE APPLICATION OF THE PFIC RULES TO YOUR INVESTMENT IN THE ADSs.

Backup Withholding and Information Reporting

Payments of dividends with respect to Ordinary Shares or ADSs and the proceeds from the sale, retirement, or other disposition of Ordinary Shares or ADSs made by a U.S. paying agent or other U.S. intermediary will be reported to the IRS and to the U.S. Holder as may be required under applicable U.S. Treasury regulations. We, or an agent, a broker, or any paying agent, as the case may be, may be required to withhold tax (backup withholding), currently at the rate of 24%, if a non-corporate U.S. Holder that is not otherwise exempt fails to provide an accurate taxpayer identification number and comply with other IRS requirements concerning information reporting. Certain U.S. Holders (including, among others, corporations and tax-exempt organizations) are not subject to backup withholding. Any amount of backup withholding withheld may be used as a credit against your U.S. federal income tax liability provided that the required information is furnished to the IRS. U.S. Holders should consult their own tax advisors as to their qualification for exemption from backup withholding and the procedure for obtaining an exemption.

U.S. Holders may be required to file certain U.S. information reporting returns with the IRS with respect to an investment in our Ordinary Shares or ADSs, including, among others, IRS Form 8938 (Statement of Specified Foreign Financial Assets). As described above under "*Item 10. Additional Information—Taxation—U.S. Federal Income Tax Considerations—Passive Foreign Investment Companies*," each U.S. Holder who is a shareholder of a PFIC must file an annual report containing certain information. Substantial penalties may be imposed upon a U.S. Holder that fails to comply with the required information reporting.

U.S. Holders should consult their own tax advisors regarding the backup withholding tax and information reporting rules.

EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF AN INVESTMENT IN OUR ORDINARY SHARES OR ADSs IN LIGHT OF SUCH INVESTOR'S PARTICULAR CIRCUMSTANCES.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the information reporting requirements of the Exchange Act, applicable to foreign private issuers, and under those requirements, we file reports with the SEC. Those other reports or other information are available to the public through the SEC's website at *http://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 are 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. companies whose securities are registered under the Exchange Act or, in some cases, at all. However, we are required to comply with the informational requirements of the Exchange Act, and, accordingly, file current reports on Form 6-K, annual reports on Form 20-F and other information with the SEC.

In addition, prior to the listing of the ADSs on the Nasdaq, our Ordinary Shares were only traded on the TASE and therefore we filed Hebrew language periodic and immediate reports with, and furnished information to, the TASE and the Israeli Securities Authority, as required under Chapter Six of the Israel Securities Law. Copies of our past filings with the Israeli Securities Authority can be retrieved electronically through the MAGNA distribution site of the Israeli Securities Authority (*www.magna.isa.gov.il*) and the TASE website (*www.maya.tase.co.il*).

We maintain a corporate website at *www.brainsway.com.* Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report.

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk is the risk of loss related to changes in market prices, including interest rates and foreign exchange rates, of financial instruments that may adversely impact our financial position, results of operations or cash flows. Our overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on our financial performance.

Risk of Interest Rate Fluctuation and Credit Exposure Risk

At present, our credit and interest risk arise from cash and cash equivalents, deposits with banks as well as accounts receivable. A substantial portion of our liquid instruments is invested in short-term deposits.

We estimate that because the liquid instruments are invested mainly for the short-term, the credit, and interest risk associated with these balances is low. The primary objective of our investment activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing risk and loss. Our investments are exposed to market risk due to fluctuations in interest rates, which may affect our interest income and the fair market value of our investments. We manage this exposure by performing ongoing evaluations of our investments.

Foreign Currency Exchange Risk

The U.S. dollar is our functional and reporting currency. Although a substantial portion of our expenses (mainly salaries and related costs) are denominated in NIS, accounting for approximately 35.5% of our expenses in the year ended December 31, 2024, all of our financing has been in U.S. dollars, and the substantial majority of our liquid assets are held in U.S. dollars. Furthermore, while we anticipate that a portion of our expenses, principally salaries and related personnel expenses in Israel will continue to be denominated in NIS, we expect to incur an increasing amount of expenses in U.S. dollars as we increase our marketing and sales personnel and enhance our clinical studies in the United States. Changes of 5% in the U.S. dollar/NIS exchange rate would have increased/decreased operating expenses by approximately $906 thousand during the year ended December 31, 2024. We also have expenses, although to a much lesser extent, in other non-U.S. dollar currencies, in particular the Euro.

Moreover, for the next few years we expect that the substantial majority of our revenues from the sale or lease of our systems in the United States, if any, will be denominated in U.S. dollars. As a portion of our expenses is denominated in NIS and other non-U.S. currencies, we are exposed to risk associated with exchange rate fluctuations vis-à-vis the non-U.S. currencies.

We do not hedge our foreign currency exchange risk. In the future, we may enter into formal currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

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

Each of the American Depositary Shares, or ADSs, represents two (2) Ordinary Shares. The ADSs trade on The Nasdaq Global Market.

The form of the deposit agreement for the ADSs and the form of American Depositary Receipt (ADR) that represents an ADS have been incorporated by reference as exhibits to this Annual Report on Form 20-F. Copies of the deposit agreement are available for inspection at the principal office of The Bank of New York Mellon, located at 101 Barclay Street, New York, New York 10286, and at the principal office of our custodians in Israel, Bank Leumi Le-Israel, 34 Yehuda Halevi St., Tel Aviv 65546, Israel.

Fees and Expenses

Persons depositing or withdrawing shares or American Depositary Shareholders must pay:

$5.00 (or less) per 100 American Depositary Shares (or portion of 100 American Depositary Shares, including issuances resulting from a distribution Depositary Shares)	● Issuance of shares or rights or other property ● Cancellation of American Depositary Shares for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per American Depositary Share	● Any cash distribution to American Depositary Shareholders
A fee equivalent to the fee that would be payable if securities distributed	● Distribution of securities distributed to holders of deposited securities to you which are distributed had been shares and the shares had been deposited for issuance of American Shareholders by the depositary to American Depositary Shares
$.05 (or less) per American Depositary Shares per calendar year	● Depositary services
Taxes and other governmental charges the depositary or the custodian have to	● As necessary pay on any American Depositary Share or share underlying an American Depositary Share, for example, stock transfer taxes, stamp duty or withholding taxes
Any charges incurred by the depositary or its agents for servicing the deposited securities	● As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

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

We performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that information required to be disclosed on Form 20-F and filed with the SEC is recorded, processed, summarized, and reported timely within the time period specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act, is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. There can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within the company to disclose information otherwise required to be set forth in our reports. Nevertheless, our disclosure controls and procedures are designed to provide reasonable assurance of achieving the desired control objectives. Based on our evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this report are effective at such reasonable assurance level.

(b) Management's Annual Report on Internal Control over Financial Reporting

Our management, under the supervision of our Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. The Company's internal control over financial reporting is a process designed 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. Internal control over financial reporting includes policies and procedures that:

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

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we assessed the effectiveness of our internal control over financial reporting as of December 31, 2024, based on the framework for Internal Control-Integrated Framework set forth by The Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013). Based on our assessment and this framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2024.

(c) Attestation Report of Registered Public Accounting Firm

Our independent registered public accounting firm, Kost Forer Gabbay & Kasierer, a member firm of Ernst & Young Global, has issued an audit report on the effectiveness of our internal control over financial reporting. The report is included in our audited consolidated financial statements set forth in "*Item 18 - Financial Statements*."

(d) Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2024, 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

Our Board of Directors has determined that Ms. Karen Sarid and Ms. Eti Mitrany are audit committee financial experts. Ms. Karen Sarid and Ms. Eti Mitrany are independent directors for the purposes of The Nasdaq Listing Rules.

ITEM 16B. CODE OF ETHICS

As of the date of this Annual Report, we have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. This code of ethics is posted on our website, https://investors.brainsway.com/static-files/4f9e73f4-18d6-409a-b198-74984439a2e0.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Independent Registered Public Accounting Firm

The following table sets forth, for each of the years indicated, the aggregate fees billed by our independent registered public accounting firm for professional services.

	Year Ended December 31,	
	2024	2023
Services Rendered	**In U.S dollars thousands**	
Audit (1)	310	235
Tax fees (2)	46	44
Total	356	279

(1) Audit fees consist of services that would normally be provided in connection with statutory and regulatory filings or engagements, including services that generally only the independent accountant can reasonably provide.

(2) Tax fees relate to tax compliance, tax planning, and tax advice.

Audit Committee Pre-Approval Policies and Procedures

Our audit committee's specific responsibilities in carrying out its oversight of the quality and integrity of the accounting, auditing, and reporting practices of the Company include the approval of audit and non-audit services to be provided by the external auditor. The audit committee approves in advance the particular services or categories of services to be provided to the Company during the following yearly period and also sets forth a specific budget for such audit and non-audit services. Additional non-audit services may be pre-approved by the audit committee.

During 2024, all services provided to us by Ernst & Young were approved by our Audit Committee pursuant to paragraph (c)(7)(i) of Rule 2-01 of Regulation S-X.

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

Nasdaq Stock Listing Rules and Home Country Practices

As a foreign private issuer whose ADSs are listed on The Nasdaq Global Market, we are permitted to follow certain home country corporate governance practices instead of certain requirements of the rules of The Nasdaq Global Market. Pursuant to the "foreign private issuer exemption":

- we established a quorum requirement such that the quorum for any meeting of shareholders is two or more shareholders holding at least 33 and 1/3% of our voting rights, which complies with Nasdaq requirements; however, if the meeting is adjourned for lack of quorum, the quorum for such adjourned meeting will be any number of shareholders, instead of 33 and 1/3% of our voting rights;

- we also follow Israeli corporate governance practice in lieu of Nasdaq Marketplace Rule 5635(c), which requires shareholder approval for certain dilutive events (such as issuances that will result in a change of control, certain transactions other than a public offering involving issuances of a 20% or greater interest in us and certain acquisitions of the shares or assets of another company) and prior to an issuance of securities when a stock option or purchase plan is to be established or materially amended or other equity compensation arrangement made or materially amended, pursuant to which stock may be acquired by officers, directors, employees or consultants. By contrast, under the Israeli Companies Law, shareholder approval is required (subject to certain limited exceptions) for, among other things: (a) transactions with directors concerning the terms of their service (including indemnification, exemption, and insurance for their service or for any other position that they may hold at a company); (b) extraordinary transactions with controlling shareholders of publicly held companies; (c) terms of office, and employment or other engagement of our controlling shareholder, if any, or such controlling shareholder's relative; (d) transactions with the company's Chief Executive Officer with respect to his or her compensation, whether in accordance with the approved compensation policy of the company or not, or transactions with officers of the company not in accordance with the approved compensation policy; (e) the compensation policy of the company for office holders; and (f) certain private placements involving the issuance of 20% or more of our total voting rights, or private placements as a result of which a person will become a controlling shareholder of the company, subject to certain exemptions and exceptions. In addition, under the Israeli Companies Law, a merger generally requires approval of the shareholders of each of the merging companies; and

Otherwise, we comply with the rules generally applicable to U.S. domestic companies listed on The Nasdaq Global Market. However, we may in the future decide to use the foreign private issuer exemption with respect to some or all of the other Nasdaq corporate governance rules.

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 Compliance Policy, which, among other things, governs the purchase, sale and other dispositions of our securities by our directors, executive officers and employees. Our Insider Trading Compliance Policy aims to promote compliance with applicable insider trading laws, rules and regulations, and Nasdaq listing standards. A copy of our Insider Trading Compliance Policy is filed as Exhibit 11.1 to this Annual Report.

ITEM 16K. CYBERSECURITY

We operate in the medical device sector, which is subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees or customers; violation of privacy laws and other litigation and legal risk; and reputational risk. We recognize the critical importance of developing, implementing, and maintaining cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data. We currently have security measures in place to protect information we may have on our employees, vendors, and in some cases (for example, in our clinical trial data sets) patients, as well as to prevent data loss and other security breaches.

Our current cybersecurity risk assessment and protection program consists of various cybersecurity software features and capabilities designed to protect our systems and alert us of any cybersecurity incidents, such as software to strengthen protection against targeted attacks and previously unknown exploits, a network intrusion detection system, firewall and router features enabling unified threat management, load balancing, multi Wide Area Network (WAN) and various measures which limit the ability of different sectors within our organization to access certain types of information.

In the event of a cybersecurity incident or threat, our Information Technology (IT) personnel and/or other personnel alert our Quality Assurance (QA) team and/or appropriate members of our Research and Development (R&D) team such as our Head of Software Development. Our QA manager previously served as a Medical Devices lead auditor for the Israel Standards Institute and has over 20 years of overall QA and project management experience including with respect to managing QA systems, regulatory affairs, supporting engineering and production processes, and involvement in corrective and preventive actions (CAPA).

Our Head of Software Development previously served as a conditional access engineer (a key function in cybersecurity compliance) and a technical program manager for large cyber-focused programs, and periodically attends cybersecurity workshops.

These departments/individuals and/or their teams are responsible for the day-to-day assessment and management of risks arising from cybersecurity threats, including the prevention, mitigation, detection, and remediation of cybersecurity incidents.

In the event of a material incident or threat, our CEO is notified as well. The CEO would then be expected to report the threat to the audit committee of the Board of Directors, which is responsible for oversight of strategic, financial and other major risks to the Company, which could include those posed by cybersecurity threats. This would include reviewing any cybersecurity measures taken by the IT team and any reports of cybersecurity incidents or threats. The audit committee could also be notified of this type of threat to the extent deemed appropriate by our internal auditor, which conducts various risk assessments on our company and issues periodic reports where appropriate.

We maintain business continuity, contingency, and recovery plans which may be used in the event of a cybersecurity incident.

We leverage the advice of third-party auditors and consultants as needed to help us assess and identify risks from cybersecurity threats and to help manage our risk assessment program. We rely on, and plan to increase our collaboration with, a leading provider of cybersecurity services having operations in the U.S., Israel and the Philippines for various projects and initiatives relating to our company and technology (including with respect to the integration of certain cloud-based capabilities within our proprietary Deep TMS device). This provider offers a wide variety of CISO training, compliance, strategy, governance and other resources and tools which we believe will help us address any future cybersecurity threats that may arise in our dynamic and evolving field.

We also have policies and procedures to oversee and identify the risks from cybersecurity threats associated with our use of third-party service providers and vendors. Cybersecurity considerations are taken into account by our Company in its selection of outside vendors, particularly those involved with R&D initiatives such as our efforts to integrate cloud-based capabilities within our proprietary Deep TMS device and our plans with respect to our next generation devices incorporating rotational field technology. Any code relating to the operating systems on our devices, and any off-the-shelf software we wish to integrate into our devices, is vetted to ensure that it meets certain cybersecurity requirements relating, for example, to access limitations and encryption capabilities. Our Head of Software Development requires that subcontractors involved in code writing/development be licensed by or partnered with the world's leading cloud operator, and personally reviews all code inputs and functional configuration inputs to ensure that it meets various cybersecurity protections such as those relating to access limitations, encryption capabilities and password protection.

Furthermore, as part of our routine contracting with customers, our legal department routinely considers whether and to what extent specialized contractual agreements (including, for example, Business Associates Agreements) are warranted or prudent, and/or whether to include specific contractual provisions (including for example, requirements to restrict collection, transmission and storage of and/or to anonymize confidential Patient Health Information pursuant to the Health Insurance Portability and Accountability Act (HIPAA) and/or other similar patient privacy statutes). Inclusion of these contracts and/or clauses, where appropriate, is intended to limit any negative impact that may result from a cybersecurity breach of our IT systems and our customer-facing devices.

To date, no cybersecurity incident (or aggregation of incidents) or cybersecurity threat has materially affected our results of operations or financial condition. However, an actual or perceived breach of our security could damage our reputation, cause existing clients to discontinue using our Deep TMS systems, prevent us from attracting new clients, interfere with the progress of our clinical trials, interfere with our efforts to pursue regulatory approvals for our product candidates, or subject us to third-party lawsuits, regulatory fines or other actions or liabilities, any of which could adversely affect our business, operating results or financial condition. During the year ended December 31, 2024 we purchased a cyber liability insurance policy. For further information, see also "*Item 3D. Risk Factors - Risks Related to our Business and Industry*."

ITEM 17. FINANCIAL STATEMENTS

Not applicable.

ITEM 18. FINANCIAL STATEMENTS

The financial statements required by this item are found at the end of this Annual Report, beginning on page F-1.

ITEM 19. EXHIBITS

See Exhibit Index on page 153.

EXHIBIT INDEX

1.1	Articles of Association of the Registrant, as amended (incorporated by reference to Exhibit A of Exhibit 99.1 to the Form 6-K filed by the Company with the SEC on October 1, 2024).
2.1	Form of Deposit Agreement between BrainsWay Ltd., The Bank of New York Mellon as Depositary, and owners and holders from time to time of ADSs issued thereunder (incorporated by reference to Exhibit 1 to the Registration Statement on Form F-6 filed by The Bank of New York Mellon with the SEC on February 1, 2019).
2.2	Form of American Depositary Receipt (incorporated by reference to Exhibit 1 to the Registration Statement on Form F-6 filed by The Bank of New York Mellon with the SEC on February 1, 2019).
2.3**	Description of Share Capital.
4.1	Amended and Restated BrainsWay 2019 Share Incentive Plan (incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 20-F filed by the Company with the SEC on April 19, 2021).
4.2	Form of Letter of Exculpation and Indemnification (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form F-1 filed by the Company with the SEC on January 14, 2019).
4.3	Compensation Policy for Executive Officers and Directors, dated June 17, 2024 (incorporated by reference to Appendix B of Exhibit 99.1 to the Company's Form 6-K, filed by the Company with the SEC on May 9, 2024).
4.4	Employment Agreement, dated March 22, 2023, between BrainsWay Ltd. and Hadar Levy as Chief Executive Officer (incorporated by reference to Exhibit 4.6 to the Company's Annual Report on Form 20-F filed by the Company with the SEC on March 27, 2023).
4.6	Patent License Agreement, dated July 7, 2003, by and between BrainsWay, Inc. and the United States Public Health Service (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form F-1 filed by the Company with the SEC on January 14, 2019).

4.7	Patent License Amendment, dated August 24, 2005, by and between BrainsWay, Inc. and the United States Public Health Service (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form F-1 filed by the Company with the SEC on January 14, 2019).
4.8	Second Amendment to Patent License Agreement, dated April 17, 2008, by and between BrainsWay, Inc. and the United States Public Health Service (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form F-1 filed by the Company with the SEC on January 14, 2019).
4.9	Research and License Agreement, dated June 2, 2005, by and between BrainsWay, Inc. and Yeda Research and Development Company Ltd. (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form F-1 filed by the Company with the SEC on January 14, 2019).
4.10	First Addendum Agreement, dated August 19, 2007, by and between BrainsWay, Inc. and Yeda Research and Development Company Ltd. (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form F-1 filed by the Company with the SEC on January 14, 2019).
4.11	Second Addendum Agreement, dated January 18, 2009, by and between BrainsWay, Inc. and Yeda Research and Development Company Ltd. (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form F-1 filed by the Company with the SEC on January 14, 2019).
4.12	Third Addendum Agreement, dated March 23, 2010, by and between BrainsWay, Inc. and Yeda Research and Development Company Ltd. (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form F-1 filed by the Company with the SEC on January 14, 2019).
4.13	Fourth Addendum Agreement, dated November 12, 2009, by and between BrainsWay, Inc. and Yeda Research and Development Company Ltd. (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form F-1 filed by the Company with the SEC on January 14, 2019).
4.14	First Amendment to Fourth Addendum Agreement, dated May 11, 2010, by and between BrainsWay, Inc. and Yeda Research and Development Company Ltd. (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form F-1 filed by the Company with the SEC on January 14, 2019).
4.15	Fifth Addendum Agreement, dated February 22, 2018, by and between BrainsWay, Inc. and Yeda Research and Development Company Ltd. (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form F-1 filed by the Company with the SEC on January 14, 2019).
4.16	Underwriting Agreement, dated February 23, 2021, between the Company and Oppenheimer & Co. Inc. (incorporated by reference to Exhibit 1.1 to the Form 6-K filed by the Company with the SEC on February 25, 2021).
4.17	Securities Purchase Agreement, dated as of September 29, 2024, by and between BrainsWay Ltd. and Valor BrainsWay Holdings, LLC (incorporated by reference to Exhibit 99.2 to the Form 6-K filed by the Company with the SEC on September 30, 2024).
4.18	Warrant to Purchase American Depositary Shares issued to Valor BrainsWay Holdings, LLC (incorporated by reference to Exhibit 99.3 to the Form 6-K filed by the Company with the SEC on September 30, 2024).
4.19	Registration Rights Agreement, dated as of September 29, 2024, by and between BrainsWay Ltd. and Valor BrainsWay Holdings, LLC (incorporated by reference to Exhibit 99.4 to the Form 6-K filed by the Company with the SEC on September 30, 2024).

4.20	First Amendment, dated as of November 5, 2024, to Registration Rights Agreement, dated as of September 29, 2024, by and between BrainsWay Ltd. and Valor BrainsWay Holdings, LLC (incorporated by reference to Exhibit 99.2 to the Form 6-K filed by the Company with the SEC on November 5, 2024)
8.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Registration Statement on Form F-1 filed by the Company with the SEC on January 14, 2019).
11.1**	BrainsWay Ltd. Insider Trading Compliance Policy.
12.1**	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
12.2**	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
13**	Certification by Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1**	Consent of Kost Forer Gabbay & Kasierer, Member Firm of Ernst & Young Global.
97.1	BrainsWay Ltd. Policy for Recovery of Erroneously Awarded Compensation (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 20-F, filed with the SEC on March 28, 2024).
101	The following financial statements from the Company's 20-F for the fiscal year ended December 31, 2024 formatted in Inline XBRL: (i) Consolidated Statements of Comprehensive Loss, (ii) Consolidated Statements of Financial Position, (iii) Consolidated Statements of Changes in Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to the Consolidated Financial Statements.
104	Cover Page Interactive Data File.

** Filed herewith.

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 its behalf.

BRAINSWAY LTD.

By: /s/ Hadar Levy
Name: Hadar Levy
Title: Chief Executive Officer

By: /s/ Ido Marom
Name: Ido Marom
Title: Chief Financial Officer

Date: April 21, 2025

BRAINSWAY LTD. AND ITS SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2024

U.S. DOLLARS IN THOUSANDS

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BRAINSWAY LTD. AND ITS SUBSIDIARIES

AUDITED CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2024 AND 2023 AND FOR THE YEARS ENDED DECEMBER 31, 2024, 2023 AND 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the Shareholders and the Board of Directors
of

BRAINSWAY LTD.

Opinion on the financial statements

We have audited the accompanying consolidated statements of financial position of Brainsway Ltd. and subsidiaries (the Company) as of December 31, 2024 and 2023, the related consolidated statements of comprehensive profit (loss), changes in 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 "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at 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 International Financial Reporting Standards as issued by the International Accounting Standard Board.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated April 21, 2025, expressed an unqualified opinion thereon.

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 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. 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.

Critical Audit Matter

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

Inventory Valuation

Description of the Matter	The Company's inventory totaled $4,426 thousand as of December 31, 2024. As explained in Note 2 to the consolidated financial statements, the Company assesses the value of all inventories, including raw materials, work in progress and finished goods, in each reporting period. The Company values inventories at the lower of cost and estimated net realizable value in each reporting period. Excess and obsolete inventory is written down to its estimated net realizable value if less than cost. Auditing management's estimates for excess and obsolete inventory involved subjective auditor judgment because management's assessment of whether a write down is required and the measurement of any excess of cost over net realizable value is judgmental and considers several qualitative factors that are affected by market and economic conditions outside the Company's control. In particular, the obsolete and excess inventory calculations are sensitive to significant assumptions.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design, and tested the operating effectiveness of internal controls over the Company's excess and obsolete inventory reserve process. This included management's assessment of the assumptions and data underlying the excess and obsolete inventory valuation. Our substantive audit procedures included, evaluating the significant assumptions stated above and testing the completeness and accuracy of the underlying data used in management's excess and obsolete inventory valuation assessment. We performed sensitivity analyses over the significant assumptions to evaluate the changes in the excess and obsolete inventory estimates that would result from changes in the underlying assumptions. In addition, we performed inquiries of the Company's management and obtained documentation to evaluate the Company's estimate.

/s/ KOST FORER GABBAY & KASIERER
KOST FORER GABBAY & KASIERER
A Member of EY Global

We have served as the Company's auditor since 2003.

Tel-Aviv, Israel
April 21, 2025

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the shareholders and the board of directors of
BRAINSWAY LTD.

Opinion on Internal Control Over Financial Reporting

We have audited Brainsway Ltd. and subsidiaries' internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (the COSO criteria). In our opinion, Brainsway Ltd. Company and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated statements of financial position of the Company as of December 31, 2024 and 2023, the related consolidated statements of comprehensive profit (loss), changes in equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes and our report dated April 21, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ KOST FORER GABBAY & KASIERER
KOST FORER GABBAY & KASIERER
A Member of EY Global
Tel-Aviv, Israel
April 21, 2025

BRAINSWAY LTD. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

U.S. dollars in thousands (except share and per share data)

	Note	December 31, 2024	December 31, 2023
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	4	$ 69,345	$ 10,520
Restricted cash	4	271	271
Short-term deposits	5	-	35,465
Trade receivables, net	6	4,596	3,780
Inventory	7	4,426	3,717
Other current assets	8	1,032	1,712
Total current assets		79,670	55,465
NON-CURRENT ASSETS:			
System components	9	1,707	1,273
Leased systems, net	9	3,959	3,700
Other property and equipment, net	9	752	389
Right-of-use assets	12	5,530	428
Other long-term assets	10	2,698	1,717
Total non-current assets		14,646	7,507
Total assets		$ 94,316	$ 62,972
LIABILITIES AND EQUITY			
CURRENT LIABILITIES:			
Trade payables		$ 2,868	$ 758
Deferred revenues		4,434	2,504
Liability in respect of government grants	16a	1,293	1,008
Current maturities of lease liabilities	12	824	232
Other accounts payable	11	5,927	5,259
Total current liabilities		15,346	9,761
NON-CURRENT LIABILITIES:			
Deferred revenues		3,625	5,314
Liability in respect of government grants	16a	5,803	6,077
Lease liabilities	12	4,800	239
Warrants liability	13c	2,429	-
Total non-current liabilities		16,657	11,630
EQUITY:	17		
Share capital Ordinary shares of NIS 0.4 par value: Authorized- 120,000,000 ordinary shares; Issued and outstanding- 37,626,427 ordinary shares on December 31, 2024 and 33,242,189 ordinary shares on December 31, 2023		413	367
Share premium		157,597	140,344
Reserve for share-based payment	18	4,872	4,360
Currency translation adjustments		(2,188)	(2,188)
Accumulated deficit		(98,381)	(101,302)
Total equity		62,313	41,581
Total equity and liabilities		$ 94,316	$ 62,972

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSWAY LTD. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE PROFIT (LOSS)

U.S. dollars in thousands (except share and per share data)

	Note	Year ended December 31, 2024	2023	2022
Revenues	19a	$ 41,016	$ 31,785	$ 27,177
Cost of revenues	19b	10,435	8,308	7,129
Gross profit		30,581	23,477	20,048
Research and development expenses, net	19c	7,190	6,665	7,678
Selling and marketing expenses	19d	16,203	16,456	18,199
General and administrative expenses	19e	5,797	5,315	6,854
Total operating expenses		29,190	28,436	32,731
Operating profit (loss)		1,391	(4,959)	(12,683)
Finance income	19f	3,584	2,171	1,117
Finance expense	19f	1,516	1,158	1,468
Profit (loss) before income taxes		3,459	(3,946)	(13,034)
Income taxes	15	538	251	315
Net profit (loss) and total comprehensive profit (loss)		$ 2,921	$ (4,197)	$ (13,349)
Basic net income (loss) per share	20	0.09	(0.13)	(0.40)
Diluted net income (loss) per share	20	$ 0.05	$ (0.13)	$ (0.40)

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSWAY LTD. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

U.S. dollars in thousands (except share and per share data)

	Share capital	Share premium	Reserve for share-based payment	Currency translation adjustments	Accumulated deficit	Total equity
Balance as of January 1, 2022	$ 363	137,566	5,340	(2,188)	(83,756)	57,325
Net loss and total comprehensive loss	-	-	-	-	(13,349)	(13,349)
Exercise of share options	1	436	(437)	-	-	-
Expiration of share options	-	197	(197)	-	-	-
Issuance of shares, net	-(*)	(53)	-	-	-	(53)
Cost of share-based payment	-	-	1,474	-	-	1,474
Balance as of December 31, 2022	364	138,146	6,180	(2,188)	(97,105)	45,397
Net loss and total comprehensive loss	-	-	-	-	(4,197)	(4,197)
Exercise of share options	3	798	(801)	-	-	-
Expiration of share options	-	1,400	(1,400)	-	-	-
Cost of share-based payment	-	-	381	-	-	381
Balance as of December 31, 2023	367	140,344	4,360	(2,188)	(101,302)	41,581
Net income and total comprehensive income	-	-	-	-	2,921	2,921
Exercise of share-based payment info shares	1	805	(789)	-	-	17
Forfeiture of share options	-	140	(140)	-	-	-
Issuance of shares, net (**)	45	16,308	-	-	-	16,353
Cost of share-based payment	-	-	1,441	-	-	1,441
Balance as of December 31, 2024	$ 413	157,597	4,872	(2,188)	(98,381)	62,313

(*) Less than $1

(**) Net of issuance expenses of $222 thousand

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSWAY LTD. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands (except share and per share data)

	Year ended December 31,		
	2024	**2023**	**2022**
Cash flows from operating activities:			
Total comprehensive profit (loss)	$ 2,921	$ (4,197)	$ (13,349)
Adjustments to reconcile net profit (loss) to net cash used in operating activities:			
Adjustments to profit or loss items:			
Depreciation and amortization	660	362	558
Depreciation of leased systems	1,111	975	976
Impairment and disposal of inventory and system components	1,519	1,447	816
Finance expenses (income), net	(2,068)	(1,013)	351
Cost of share-based payment	1,441	381	1,474
Income taxes	538	251	315
Total adjustments to reconcile loss	3,201	2,403	4,490
Changes in asset and liability items:			
Increase in inventory	(920)	(506)	(3,595)
Decrease (increase) in trade receivables	(867)	1,089	1,456
Decrease (increase) in other current assets	1,649	(312)	(403)
Increase (decrease) in trade payables	2,119	(327)	-
Increase in other accounts payable	129	62	298
Increase in deferred revenues	277	1,629	790
Total changes in asset and liability	2,387	(1,635)	(1,454)
Cash (paid) received during the year for:			
Interest paid	(124)	(253)	(46)
Interest received	2,922	1,707	1,042
Income taxes paid	(1,009)	(11)	(443)
Total cash received during the year	1,789	1,443	553
Net cash provided by (used in) operating activities	10,298	1,284	(9,760)
Cash flows from investing activities:			
Proceeds from disposal (purchase) of property and equipment and system components, net	(3,794)	(2,387)	1,936
Proceeds from lease assets	76	-	-
Proceeds from short-term bank deposits	35,000	-	40,254
Investment in short-term bank deposits	-	(35,000)	-
Investment in long-term deposits, net	(971)	(22)	(21)
Net cash provided by (used in) investing activities	30,311	(37,409)	42,169
Cash flows from financing activities:			
Proceeds from government grants	-	32	15
Repayment of liability in respect of research and development grants	(1,108)	(787)	(977)
Repayment of lease liabilities	(424)	(271)	(533)
Issuance of share capital, net	-	-	(52)
Exercise of share options	17	-	-
Issuance of warrants liability	3,425	-	
Proceeds from issuance of shares, net	16,353	-	-
Net cash provided by (used in) financing activities	18,263	(1,026)	(1,547)
Exchange rate differences on balance of cash and cash equivalents	(47)	90	(202)
Increase (decrease) in cash and cash equivalents	58,825	(37,061)	30,660
Cash and cash equivalents at the beginning of the year	10,520	47,581	16,921
Cash and cash equivalents at the end of the year	$ 69,345	$ 10,520	$ 47,581
(a) Significant non-cash transactions:			
Right-of-use asset recognized with corresponding lease liability	$ 5,548	$ 308	$ 301

NOTE 1: GENERAL

a. A general description of the Company and its activity:

BrainsWay Ltd. (the "Company") is a leader in advanced non-invasive neurostimulation treatments for mental health disorders. The Company is advancing neuroscience with its proprietary Deep Transcranial Magnetic Stimulation (Deep TMS™) platform technology to improve health and transform lives. The Company has obtained from the U.S. Food and Drug Administration (FDA) three cleared indications backed by pivotal studies demonstrating clinically proven efficacy. Current indications include MDD (Major Depressive Disorder), obsessive-compulsive disorder (OCD), and smoking addiction.

The Company received its first commercial Deep TMS product received clearance from the FDA in 2013, for the treatment of MDD in adult patients who have failed to achieve satisfactory improvement from anti-depressant medication. In April 2021, the Company received FDA clearance for a shorter innovative MDD treatment and in August 2021, the Company received an additional clearance from the FDA for expansion of the existing MDD clearance to include the non-invasive treatment of anxiety symptoms. In 2022, the Company extended its FDA clearance for MDD (including anxious depression) to our H7 Coil, also via the 510(k) process. In May 2024, the FDA cleared an expansion of the Company's MDD clearance allowing for the treatment of patients with late life depression. The expanded clearance covers MDD patients ages 22 to 86, changing the previous upper age limit of 68.

The Company received *de novo* clearance from the FDA in August 2018 for use of its Deep TMS an adjunct therapy for adult patients suffering from OCD, and a clearance from the FDA in August 2020 for use of its Deep TMS system as an aid in short-term smoking cessation in adults.

The Company and its wholly owned subsidiaries, BrainsWay, Inc. ("Inc"), Brain R&D Services Ltd. ("Brain R&D"), BrainsWay USA Inc ("USA Inc"), (collectively the "Group") derive revenues from the sale and lease of its systems and from related services.

NOTE 1: GENERAL (Continued)

b. The Company has an operating income of $2,921 for the year ended December 31, 2024. The company's management and board of directors believe that the Company has the sufficient funding to finance its business activity according to its plans in the foreseeable future.

NOTE 2: ACCOUNTING POLICIES

The following accounting policies have been applied consistently in the financial statements for all periods presented, unless otherwise stated.

a. Basis of presentation of the financial statements:

These financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board.

The Company's financial statements have been prepared on a cost basis, except for certain financial instruments which are presented at fair value through profit or loss. The Company has elected to present the profit or loss items using the function of expense method.

NOTE 2: ACCOUNTING POLICIES (Continued)

b. Functional currency, presentation currency, foreign currency and Cash equivalents:

1. Functional currency and presentation currency:

The functional currency is the currency that best reflects the economic environment in which the Company operates and conducts its transactions, is separately determined for each Group entity and is used to measure its financial position and operating results. The Group determines the functional currency of each Group entity. The Group's functional and presentation currency is the US Dollar for all reported periods and subsidiaries.

2. Transactions, assets and liabilities in foreign currency:

Transactions denominated in foreign currency are recorded upon initial recognition at the exchange rate at the date of the transaction. After initial recognition, monetary assets and liabilities denominated in foreign currency are translated at each reporting date into the functional currency at the exchange rate at that date. Exchange rate differences, other than those capitalized to qualifying assets or accounted for as hedging transactions in equity, are recognized in profit or loss. Non-monetary assets and liabilities denominated in foreign currency and measured at cost are translated at the exchange rate at the date of the transaction. Non-monetary assets and liabilities denominated in foreign currency and measured at fair value are translated into the functional currency using the exchange rate prevailing at the date when the fair value was determined.

3. Cash equivalents

Cash equivalents are considered as highly liquid investments, including unrestricted short-term bank deposits with an original maturity of three months or less from the date of investment or with a maturity of more than three months, but which are redeemable on demand without penalty.

4. Short-term deposits

Short-term bank deposits are deposits with an original maturity of more than three months from the date of investment and which do not meet the definition of cash equivalents. The deposits are presented according to their terms of deposit. The deposits earn annual interest at the respective term of the deposits of approximately 6%.

c. Inventories

Inventories are measured at the lower of cost and net realizable value. The cost of inventories comprises costs of purchase and costs incurred in bringing the inventories to their present location and condition. Net realizable value is the estimated selling price in the ordinary course of business less estimated costs of completion and estimated costs necessary to make the sale. The Company periodically evaluates the condition and age of inventories and makes provisions for slow moving inventories accordingly. Furthermore, inventory classified as short-term for sale or consumption, while inventory to be converted into fixed assets in the future for internal use or leasing to customers, is classified as system component as a long-term asset. These classifications are determined according to management's estimates for the use of inventory in the foreseen future. Inventory provisions have been recorded to cover risks arising from slow-moving items, technological obsolescence and excess inventories according to revenue forecasts.

Cost of inventories is determined as follows:

Raw materials - at cost of purchase using the weighted average cost method

Work in progress and finished goods - on the basis of average costs including materials, labor and other direct and indirect manufacturing costs based on normal capacity.

NOTE 2: ACCOUNTING POLICIES (Continued)

d. Revenue recognition:

Revenue from contracts with customers is recognized when the control over the goods or services is transferred to the customer. The transaction price is the amount of the consideration that is expected to be received based on the contract terms, excluding amounts collected on behalf of third parties (such as taxes). The Company does not offer a right of refund in its contracts.

In determining the amount of revenue from contracts with customers, the Company evaluates whether it is a principal or an agent in the arrangement. The Company is a principal when the Company controls the promised goods or services before transferring them to the customer. In these circumstances, the Company recognizes revenue for the gross amount of the consideration. When the Company is an agent, it recognizes revenue for the net amount of the consideration, after deducting the amount due to the principal.

The Company primarily generates revenue from two major streams: (a) sale of systems and related services and (b) lease of systems.

Revenues from sale of systems and related services:

Revenue from sale of systems is recognized at the point in time when control of the system is transferred to the customer, generally upon shipment of the system to the customer.

Revenue from rendering of extended warranty services are recognized ratably over the contract period as the services have a consistent continuous pattern of transfer to a customer during the contract period. Payment terms between the Company and its customers are typically up to twelve months, and vary by the type of customer, country of sale and the products or services offered. When payments are made before or after the service is performed, the Company recognizes the resulting contract asset or liability.

Revenue from operating leases:

A lease in which substantially all the risks and rewards incidental to ownership of the leased asset have not been transferred to the lessee is classified as an operating lease. Lease payments are recognized as income in profit or loss on a straight-line basis over the lease term. Payment terms between the Company and its customers for lease contracts are typically spread over the term of the lease.

Costs of obtaining a contract:

In order to obtain certain contracts with customers, the Company incurs incremental costs in obtaining the contract (such as sales commissions which are contingent on making binding sales). The Company applies judgment in estimating the amortization period by taking into consideration customer contract terms, history of renewals, expected length of customer relationship, as well as the useful life of the products. Sales commission expenses are amortized over the expected period of benefits and included in Selling and Marketing expenses in the accompanying consolidated statements of income. For costs that the Company would have capitalized and amortized over one year or less, the Company has elected to apply the practical expedient and expense these contract costs as incurred. Costs to obtain contracts amortization expense for the years 2024, 2023 and 2022 were $2,600, $3,400 and $1,767, respectively.

NOTE 2: ACCOUNTING POLICIES (Continued)

Contract liabilities:

A contract liability, presented as deferred revenues, is the obligation to transfer goods or services to a customer for which the Company has received consideration (or an amount of consideration is due) from the customer. Deferred revenue will be recognized as revenue in profit and loss when the work is performed. The Company elected to apply the practical expedient in IFRS 15 and does not provide disclosure of the remaining unsatisfied performance obligations with respect to contracts that have a term of up to one year.

The Company's remaining performance obligations represent contracted revenue that has not yet been recognized. As of December 31, 2024, the aggregate amount of the transaction price allocated to remaining performance obligations that the Company expects to recognize as revenue was $6,964. As of December 31, 2024, the Company expects to recognize 41% of its remaining performance obligations as revenue over the next 12 months, and the remainder through 2030.

Allocating the transaction price:

For contracts that consist of more than one performance obligation at contract inception, the Company allocates the contract transaction price to each performance obligation identified in the contract on a relative stand-alone selling price basis. The stand-alone selling price is the price at which the Company would sell the promised goods or services separately to a customer.

e. Government grants:

Government grants are recognized when there is reasonable assurance that the grants will be received and the Company will comply with all attached conditions.

Government grants received from the Israel Innovation Authority ("IIA") are recognized upon receipt as a liability if future economic benefits are expected from the research project, that will result in royalty-bearing sales.

A liability for the grant is first measured at fair value using a discount rate that reflects a market rate of interest. The difference between the amount of the grant received and the fair value of the liability is accounted for as a government grant and recognized as a reduction of research and development expenses. After initial recognition, the liability is measured at amortized cost using the effective interest method. Royalty payments are treated as a reduction of the liability.

If no economic benefits are expected from the research activity, the grant received is recognized as a reduction of the related research and development expenses. In that event, the royalty obligation is treated as a contingent liability in accordance with IAS 37.

At each reporting date, the Company evaluates whether there is reasonable assurance that the liability recognized, in whole or in part, will not be repaid (as the Company will not be required to pay royalties) based on the best estimate of future sales and using the original effective interest method, and if so, the appropriate amount of the liability is derecognized against a corresponding reduction in research and development expenses.

Amounts paid as royalties are recognized as settlement of the liability.

NOTE 2: ACCOUNTING POLICIES (Continued)

f. Taxes on income:

Current or deferred taxes are recognized in profit or loss, except to the extent that they relate to items which are recognized in equity.

1. Current taxes:

The current tax liability is measured using the tax rates and tax laws that have been enacted or substantively enacted at the reporting date, as well as adjustments required in connection with the tax liability in respect of previous years.

2. Deferred taxes:

Deferred taxes are computed in respect of temporary differences between the carrying amounts in the financial statements and the amounts attributed for tax purposes.

Deferred taxes are measured at the tax rate that is expected to apply when the asset is realized or the liability is settled, based on tax laws that have been enacted or substantively enacted by the reporting date.

Deferred tax assets are reviewed at each reporting date and reduced to the extent that it is not probable that they will be utilized. Temporary differences that can be deducted for which deferred tax assets had not been recognized are reviewed at each reporting date and a respective deferred tax asset is recognized to the extent that utilization is probable.

Taxes that would apply in the event of the disposal of investments in subsidiaries have not been taken into account in computing deferred taxes, as long as the disposal of the investments in subsidiaries is not probable in the foreseeable future. Also, deferred taxes that would apply in the event of distribution of earnings by subsidiaries as dividends have not been taken into account in computing deferred taxes, since the distribution of dividends does not involve an additional tax liability or since it is the Company's policy not to initiate distribution of dividends from a subsidiary that would trigger an additional tax liability.

Deferred taxes are offset if there is a legally enforceable right to offset a current tax asset against a current tax liability and the deferred taxes relate to the same taxpayer and the same taxation authority.

NOTE 2: ACCOUNTING POLICIES (Continued)

g. Leases:

The Company accounts for a contract as a lease when the contract terms convey the right to control the use of an identified asset for a period of time in exchange for consideration.

1. The Company as lessee:

For leases in which the Company is the lessee, the Company recognizes on the commencement date of the lease a right-of-use asset and a lease liability, excluding leases whose term is up to 12 months and leases for which the underlying asset is of low value. For these excluded leases, the Company has elected to recognize the lease payments as an expense in profit or loss on a straight-line basis over the lease term. In measuring the lease liability, the Company has elected to apply the practical expedient in the Standard and does not separate the lease components from the non-lease components (such as management and maintenance services, etc.) included in a single contract.

On the commencement date, the lease liability includes all unpaid lease payments discounted at the interest rate implicit in the lease, if that rate can be readily determined, or otherwise using the Company's incremental borrowing rate. After the commencement date, the Company measures the lease liability using the effective interest rate method.

On the commencement date, the right-of-use asset is recognized in an amount equal to the lease liability plus lease payments already made on or before the commencement date and initial direct costs incurred. The right-of-use asset is measured applying the cost model and depreciated over the shorter of its useful life and the lease term.

Following are the amortization periods of the right-of-use assets by class of underlying asset:

	Years
Lease facilities	10
Motor vehicles	3 - 4

The Company tests for impairment of the right-of-use asset whenever there are indications of impairment pursuant to the provisions of IAS 36.

NOTE 2: ACCOUNTING POLICIES (Continued)

2. The Company as lessor:

In order to determine whether to classify a lease as a finance lease or an operating lease, the Company evaluates whether the lease transfers substantially all the risks and rewards incidental to ownership of the asset.

h. System components, leased systems and other property and equipment, net::

Other property and equipment are measured at cost, including directly attributable costs, less accumulated depreciation, accumulated impairment losses and any related investment grants and excluding day-to-day servicing expenses. Cost includes spare parts and auxiliary equipment that are used in connection with plant and equipment.

Depreciation is calculated on a straight-line basis over the useful life of the assets at annual rates as follows:

	%		
Leased systems		15	
Laboratory equipment		15	
Computers		33	
Office furniture and equipment	3	-	15
Leasehold improvements	10	-	33

The useful life, depreciation method and residual value of an asset are reviewed at least each year-end and any changes are accounted for prospectively as a change in accounting estimate. Depreciation of an asset ceases at the earlier of the date that the asset is classified as held for sale and the date that the asset is derecognized.

System components include raw materials to be converted into fixed assets in the future for internal use or leasing to customers, and depreciated over the useful life once converted to fixed assets.

NOTE 2: ACCOUNTING POLICIES (Continued)

i. Impairment of non-financial assets:

The Company evaluates the need to record an impairment of non-financial assets whenever events or changes in circumstances indicate that the carrying amount is not recoverable. If the carrying amount of non-financial assets exceeds their recoverable amount, the assets are reduced to their recoverable amount. The recoverable amount is the higher of fair value less costs of sale and value in use. In measuring value in use, the expected cash flows are discounted using a pre-tax discount rate that reflects the risks specific to the asset and the time value of money. The recoverable amount of an asset that does not generate independent cash flows is determined for the cash-generating unit to which the asset belongs. Impairment losses are recognized in profit or loss.

An impairment loss of an asset is reversed only if there have been changes in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized. Reversal of an impairment loss, as above, shall not be increased above the lower of the carrying amount that would have been determined (net of depreciation or amortization) had no impairment loss been recognized for the asset in prior years and its recoverable amount. The reversal of impairment loss of an asset presented at cost is recognized in profit or loss.

j. Impairment of financial assets:

The Company evaluates at the end of each reporting period the loss allowance for financial debt instruments which are not measured at fair value through profit or loss. The Company distinguishes between two types of loss allowances:

a) Debt instruments whose credit risk has not increased significantly since initial recognition, or whose credit risk is low - the loss allowance recognized in respect of this debt instrument is measured at an amount equal to the expected credit losses within 12 months from the reporting date (12-month ECLs); or

b) Debt instruments whose credit risk has increased significantly since initial recognition, and whose credit risk is not low - the loss allowance recognized is measured at an amount equal to the expected credit losses over the instrument's remaining term (lifetime ECLs).

The Company has short-term financial assets such as trade receivables in respect of which the Company applies the simplified approach in IFRS 9 and measures the loss allowance in an amount equal to the lifetime expected credit losses.

k. Provisions:

A provision in accordance with IAS 37 is recognized when the Group has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation.

NOTE 2: ACCOUNTING POLICIES (Continued)

1. Share-based payment transactions:

The Company's employees and other service providers are granted remuneration in the form of equity-settled share-based payment (options and restricted shares).

The cost of equity-settled transactions with employees is measured at the fair value of the equity instruments granted at grant date. The fair value of an option granted is determined using the Binomial Lattice option-pricing model ("Binomial model"). The Binomial model takes into account variables such as volatility, dividend yield rate, and risk-free interest rate and also allows for the use of dynamic assumptions and considers the contractual term of the option, the probability that the option will be exercised prior to the end of its contractual life, and the probability of termination or retirement of the option holder in computing the value of the option.

As for other service providers, the cost of the transactions is measured at the fair value of the goods or services received as consideration for equity instruments granted.

The fair value of the restricted shares granted is determined using the closing price of the Company's share, as quoted in the Tel-Aviv Stock Exchange (TASE) on the day of the grant.

The cost of equity-settled transactions is recognized in profit or loss together with a corresponding increase in equity during the period which the performance and/or service conditions are to be satisfied ending on the date on which the relevant employees become entitled to the award ("the vesting period"). The cumulative expense recognized for equity-settled transactions at the end of each reporting date includes the Group's best estimate of the number of equity instruments that will ultimately vest.

No expense is recognized for awards that do not ultimately vest.

If the Company modifies the conditions on which equity-instruments were granted, an additional expense is recognized for any modification that increases the total fair value of the share-based payment arrangement or is otherwise beneficial to the employee/other service provider at the modification date.

m. Reclassification:

Certain amounts in prior periods in the Consolidated Statements of Financial Position have been reclassified to conform with current period presentation.

NOTE 2: ACCOUNTING POLICIES (Continued)

n. New currently Effective Requirements.

- Amendment to IAS 1, "Disclosure of Accounting Policies":

  The amendment, together with the subsequent amendment to IAS 1 (see hereunder) replaces certain requirements for classifying liabilities as current or non-current. According to the amendment, a liability is classified as non-current when the entity has the right to defer settlement for at least 12 months after the reporting period, and it "has substance" and is in existence at the end of the reporting period. According to the subsequent amendment, as published in October 2022, covenants with which the entity must comply after the reporting date do not affect classification of the liability as current or non-current. Additionally, the subsequent amendment adds disclosure requirements for liabilities subject to covenants within 12 months after the reporting date, such as disclosure regarding the nature of the covenants, the date they need to be complied with and facts and circumstances that indicate the entity may have difficulty complying with the covenants. Furthermore, the amendment clarifies that the conversion option of a liability will affect its classification as current or non-current, other than when the conversion option is recognized as equity.

  The amendment and subsequent amendment are effective for reporting periods beginning on or after January 1, 2024, with earlier application being permitted. The amendment and subsequent amendment are applicable retrospectively, including an amendment to comparative data.

  The Amendment did not have a material impact on the Company's consolidated financial statements.

- Forthcoming requirements

  Presentation and Disclosure in Financial Statements - IFRS 18

  In April 2024, the IASB issued IFRS 18 Presentation and Disclosure in Financial Statements ("IFRS 18") which replaces IAS 1 Presentation of Financial Statements. IFRS 18 requires an entity to classify all income and expenses within its statement of profit or loss into one of five categories: operating; investing; financing; income taxes; and discontinued operations. The first three categories are new. These categories are complemented by the requirement to present subtotals and totals for "operating profit or loss," "profit or loss before financing income and taxes," and "profit or loss." IFRS 18, and the amendments to the other standards, is effective for reporting periods beginning on or after January 1, 2027, but earlier application is permitted.

  The Company is currently assessing the impact of the Standard on its financial statements.

NOTE 3: SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS

In the process of applying the significant accounting policies in the financial statements, the Group has made the following judgments, estimates and assumptions, which have the most significant effect on the amounts recognized in the financial statements:

a. Judgments:

- Classification of leases – the Company as a lessor:

  In order to determine whether to classify a lease as a finance lease or an operating lease, the Company evaluates whether the lease transfers substantially all the risks and rewards incidental to ownership of the asset.

- Determining the fair value of share-based payment transactions:

  The fair value of share-based payment transactions is determined upon initial recognition by the Binomial model. The Binomial model is based on share price and exercise price and assumptions regarding expected volatility, term of share option, dividend yield and risk-free interest rate.

b. Estimates and assumptions:

The preparation of the financial statements requires management to make estimates and assumptions that have an effect on the application of the accounting policies and on the reported amounts of assets, liabilities, revenues and expenses. Changes in accounting estimates are reported in the period of the change in estimate.

The key assumptions made in the financial statements concerning uncertainties at the reporting date and the critical estimates computed by the Group that may result in a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

- Allowance for Doubtful Accounts based on Expected Credit Losses on Trade Receivables

  The Company applies a simplified approach and measure the loss allowance in respect of our short-term financial assets, trade receivables, in an amount equal to the lifetime expected credit losses.

  Allowance for doubtful accounts is recorded based on expected credit losses for trade receivables. The allowance rates are based on days past due for various customers. The allowance is initially based on the Company's historically observed default rates as well as forward-looking information. At each reporting date, the historical observed default rates are updated and changes in the forward-looking estimates are analyzed. The amount of the allowance is sensitive to changes in circumstances and forecasted economic conditions.

- Impairment of Inventory

  The net realizable value is determined based on management's evaluation including forecasts and estimates as to the amounts expected to be realized from the sale or use of inventory. The possible effects on the financial statements are the recognition of impairment loss or the reversal of impairment loss.

NOTE 3: SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS

- Determining the Fair Value of an Unquoted Financial Asset or Liability - for the Warrants Liability

  The fair value of unquoted financial assets or liability in Level 3 of the fair value hierarchy is determined using valuation techniques, generally using future cash flows discounted at current rates applicable for items with similar terms and risk characteristics. Changes in estimated future cash flows and estimated discount rates, after consideration of risks such as liquidity risk, credit risk and volatility, are liable to affect the fair value of these assets of liability.

NOTE 4: CASH AND CASH EQUIVALENTS AND RESTRICTED CASH

1. Cash and cash equivalents:

	December 31,	
	2024	**2023**
Cash for immediate withdrawal	$ 14,068	$ 10,520
Cash equivalents - bank deposits less than three months	55,277	-
	$ 69,345	$ 10,520

2. Restricted cash:

	December 31,	
	2024	**2023**
Restricted cash - bank deposits	$ 271	$ 271

NOTE 5: SHORT-TERM DEPOSITS

	December 31,	
	2024	**2023**
Bank deposits	$ -	35,465(*)

NOTE 6: TRADE RECEIVABLES, NET

a. Trade receivables, net:

	December 31,	
	2024	2023
Open accounts (1)	$ 5,758	$ 4,684
Less-allowance for credit losses	(1,162)	(904)
Trade receivables, net	$ 4,596	$ 3,780

(1) Trade receivables generally have 90-day credit terms. Certain customers payments are made through monthly credit card transactions.

b. Movement in allowance credit losses:

	U.S. dollars in thousands
Balance as of January 1, 2023	$ 1,101
Change in provision for the year	(131)
Derecognition of bad debts	(66)
Balance as of December 31, 2023	904
Change in provision for the year	432
Derecognition of bad debts	(174)
Balance as of December 31, 2024	$ 1,162

NOTE 6: TRADE RECEIVABLES, NET (Continued)

Following is information about the credit risk exposure of the Company's trade receivables: December 31, 2024:

	U.S. dollars in thousands						
	Not past due	<30 days	30 - 60 days	61 - 90 days	91 - 120 days	>120 days	Total
	U.S. dollars in thousands						
Gross carrying amount	$ 2,962	$ 658	$ 777	$ 200	$ 372	$ 789	$ 5,758
Allowance for doubtful accounts	$ 126	$ 104	$ 120	$ 99	$ 103	$ 610	$ 1,162
Trade receivables, net	$ 2,836	$ 554	$ 657	$ 101	$ 269	$ 179	$ 4,596

Following is information about the credit risk exposure of the Company's trade receivables: December 31, 2023:

	U.S. dollars in thousands						
	Not past due	<30 days	30 - 60 days	61 - 90 days	91 - 120 days	>120 days	Total
	U.S. dollars in thousands						
Gross carrying amount	$ 2,817	$ 167	$ 271	$ 314	$ 253	$ 862	$ 4,684
Allowance for doubtful accounts	$ 7	$ 12	$ 19	$ 44	$ 235	$ 587	$ 904
Trade receivables, net	$ 2,810	$ 155	$ 252	$ 270	$ 18	$ 275	$ 3,780

NOTE 7: INVENTORY

	December 31,	
	2024	2023
Raw materials	$ 2,795	$ 1,791
Work in progress	208	1,211
Finished goods	2,573	1,833
	5,576	4,835
Provision for Inventory	(1,150)	(1,118)
Inventory, net	$ 4,426	$ 3,717

NOTE 8: OTHER CURRENT ASSETS

	December 31,	
	2024	2023
Government authorities	$ 454	$ 420
Prepaid expenses and other	578	1,292
	$ 1,032	$ 1,712

NOTE 9: SYSTEM COMPONENTS, OTHER PROPERTY AND EQUIPMENT, NET

December 31, 2024:

	System Components	Leased systems	Laboratory equipment and Computers	Office furniture and equipment	Leasehold improvements	Total
Cost:						
Balance as of January 1, 2024	$ 1,273	$ 8,494	$ 1,217	$ 225	$ 102	$ 11,311
Purchases	3,112	2,092	80	223	307	5,814
Transfer to Leased systems	(2,092)	-	-	-	-	(2,092)
Reductions	(586)	(2,405)(**)	-	-	(15)	(3,006)
Balance as of December 31, 2024	1,707(*)	8,181	1,297	448	394	12,027
Accumulated depreciation:						
Balance as of January 1, 2024	-	4,794	1,006	90	59	5,949
Additions	-	1,111	83	132	32	1,358
Reductions	-	(1,683)	-	-	(15)	(1,698)
Balance as of December 31, 2024	-	4,222	1,089	222	76	5,609
Depreciated cost as of December 31, 2024	$ 1,707	$ 3,959	$ 208	$ 226	$ 318	$ 6,418

(*) Includes impairment provision of $464
(**) Derived mainly from returned systems as well as sale of leased systems.

December 31, 2023

	System Components	Leased systems	Laboratory equipment and Computers	Office furniture and equipment	Leasehold improvements	Total
Cost						
Balance as of January 1, 2023	$ 1,220	$ 7,227	$ 1,276	$ 225	$ 81	$ 10,029
Purchases	2,336	-	30	-	21	2,387
Transfer to Leased systems	(1,905)	1,994	(89)	-	-	-
Reductions	(378)	(727)(**)	-	-	-	(1,105)
Balance as of December 31, 2023	1,273(*)	8,494	1,217	225	102	11,311
Accumulated depreciation:						
Balance as of January 1, 2023	-	4,109	926	76	55	5,166
Additions	-	975	80	14	4	1,073
Reductions	-	(290)	-	-	-	(290)
Balance as of December 31, 2023	-	4,794	1,006	90	59	5,949
Depreciated cost as of December 31, 2023	$ 1,273	$ 3,700	$ 211	$ 135	$ 43	$ 5,362

(*) Includes impairment provision of $607
(**) Derived mainly from returned systems as well as sale of leased systems.

NOTE 10: OTHER LONG-TERM ASSETS

	December 31,	
	2024	2023
Prepaid expenses and deposits	$ 1,635	$ 889
Deferred tax assets, net (see note 15(d))	1,063	828
	$ 2,698	$ 1,717

NOTE 11: OTHER ACCOUNTS PAYABLE

	December 31,	
	2024	2023
Employee and payroll accruals	$ 2,724	$ 2,065
Accrued expenses	2,576	2,480
Institutions	250	153
Income tax payable	268	504
Other (1)	109	57
	$ 5,927	$ 5,259

(1) current non-interest-bearing accounts.

NOTE 12: LEASES

A. Information regarding material lease agreements

a. The Company leases offices in Jerusalem for a base period of five years under a contract for offices, labs and manufacturing facilities starting July 2024. The Jerusalem office lease agreement contains a five year extension option that the Company is reasonably certain to exercise.
The contractual periods of the aforesaid lease agreement and extension ends July 2035.

b. The Company leases vehicles for approximately four-year periods from a leasing company. The agreements with the leasing company do not contain extension and/or termination options that the Company is reasonably certain to exercise..

The Company leases vehicles for approximately four-year periods from a leasing company. The agreements with the leasing company do not contain extension and/or termination options that the Company is reasonably certain to exercise.

The vehicles and office lease payments are linked to the local consumer price indexes known on the lease's date of inception.

B. Information on leases in which the Company is a lessee:

	Year ended December 31,	
	2024	2023
Interest expense on lease liabilities	$ 127	$ 48
Exchange rate differences	64	3
Adjustments for indexation	74	-
Depreciation expenses on right-of-use assets	483	264

C. Right-of-use assets

Composition:

December 31, 2024:

	Buildings	Vehicles	Total
Cost:			
Balance as of January 1, 2024	296	478	774
Additions to right-of-use assets for new leases	5,215	407	5,622
Adjustments for indexation	74	-	74
Disposals	(296)	(118)	(414)
Balance as of December 31, 2024	5,289	767	6,056
Accumulated depreciation:			
Balance as of January 1, 2024	216	130	346
Depreciation	325	158	483
Disposals	(216)	(87)	(303)
Balance as of December 31, 2024	325	201	526
Depreciated cost as of December 31, 2024	4,964	566	5,530

December 31, 2023:

	Buildings	Vehicles	Total
Cost:			
Balance as of January 1, 2023	408	406	814
Additions to right-of-use assets for new leases	3	305	308
Disposals	(115)	(233)	(348)
Balance as of December 31, 2023	296	478	774
Accumulated depreciation:			
Balance as of January 1, 2023	207	124	331
Depreciation	124	140	264
Disposals	(115)	(134)	(249)
Balance as of December 31, 2023	216	130	346

Depreciated cost as of December 31, 2023	80	348	428

NOTE 12: LEASES

C. Lease liabilities:

December 31, 2024:

	U.S. dollars in thousands
Maturity analysis:	
Less than one year	$ 834
One to five years	3,920
More then five years	2,868
Total lease commitments	7,622
Impact of discounting remaining lease payments	(1,998)
Lease liabilities as of December 31, 2024:	5,624
Current	824
Non-current	4,800
Total	$ 5,624

December 31, 2023:

	U.S. dollars in thousands
Maturity analysis:	
Less than one year	$ 234
One to five years	284
Total lease commitments	518
Impact of discounting remaining lease payments	(47)
Lease liabilities as of December 31, 2023:	471
Current	232
Non-current	239
Total	$ 471

D. Information on leases in which the Company is a lessor:

Maturity analysis of undiscounted future lease payments receivable for operating leases:

	December 31,	
	2024	2023
First year	$ 12,031	$ 8,954
Second year	10,650	6,866
Third year	8,926	5,288
Fourth year	5,630	3,424
Fifth year	1,260	1,232
Sixth year and thereafter	24	159
	$ 38,521	$ 25,923

NOTE 13: FINANCIAL INSTRUMENTS

a. Financial risks factors:

The Company is exposed to foreign currency risk, interest risk, credit risk and liquidity risk. The Company's senior management oversees the management of these risks in accordance with the policies approved by the board of directors.

1. Foreign currency risk:

The currency exposure arises from current accounts and deposits that are mainly managed in NIS and from liability in respect of employee payroll accruals that are paid in NIS.

2. Interest rate risk:

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates.

The Company's exposure to the risk of changes in market interest rates relates primarily to the Company's long-term liabilities in respect of government grants received from IIA. The repayment of grants received by the Company from 2018 bear an interest rate that reference LIBOR and are expected to be repaid after 2024.

3. Credit risk:

Credit risk is the risk that a counterparty will not meet its obligations as a customer or under a financial instrument leading to a loss to the Group. The Group is exposed to credit risk from its operating activity (primarily trade receivables).

4. Liquidity risk:

The Company monitors its risk of a shortage of cash using a quarterly budget.

NOTE 13: FINANCIAL INSTRUMENTS (Continued)

1. The table below presents the maturity profile of the Group's financial liabilities based on contractual undiscounted payments including interest payments:

December 31, 2024:

	Less than one year	1 to 2 years	2 to 3 years	3 to 4 years	4 to 5 years	>5 years	Total
Trade payables	$ 2,868	$ -	$ -	$ -	$ -	$ -	$ 2,868
Other accounts payable	5,927	-	-	-	-	-	5,927
Liability in respect of research and development grants	1,419	2,040	2,685	2,850	1,609	169	10,772
	$ 10,214	$ 2,040	$ 3,685	$ 2,850	$ 1,609	$ 169	$ 19,567

December 31, 2023:

	Less than one year	1 to 2 years	2 to 3 years	3 to 4 years	4 to 5 years	>5 years	Total
Trade payables	$ 758	$ -	$ -	$ -	$ -	$ -	$ 758
Other accounts payable	5,259	-	-	-	-	-	5,259
Liability in respect of research and development grants	1,119	1,575	2,250	2,685	2,850	529	11,008
	$ 7,136	$ 1,575	$ 2,250	$ 2,685	$ 2,850	$ 529	$ 17,025

b. Sensitivity tests relating to changes in foreign currency:

December 31, 2024	USD	NIS	Other	Total
Cash and Cash equivalents	67,791	630	924	69,345
Restricted cash	271	-	-	271
Short-term deposits	-	-	-	-
Trade receivables, net	2,938	560	1,098	4,596
Other current assets	135	897	-	1,032
Other long-term Assets	2,611	82	5	2,698
	73,746	2,169	2,027	77,942
Financial liabilities at amortized cost	(11,170)	(10,343)	(2)	(21,515)
Total net financial assets	62,576	(8,174)	2,025	56,427
December 31, 2023				
Cash and Cash equivalents	8,594	579	1,347	10,520
Restricted cash	271	-	-	271
Short-term deposits	35,465	-	-	35,465
Trade receivables, net	2,640	63	1,077	3,780
Other current assets	229	1,483	-	1,712
Other long-term Assets	1,542	169	6	1,717
	48,741	2,294	2,430	53,465
Financial liabilities at amortized cost	(10,752)	(2,870)	49	(13,573)
Total net financial assets	37,979	(576)	2,479	39,892

NOTE 13: FINANCIAL INSTRUMENTS (Continued)

The following is a sensitivity analysis of changes to profit (loss) and equity in the exchange rate of the NIS as of December 31:

	December 31,	
	2024	2023
Sensitivity test to changes in the NIS exchange rate:		
Gain (loss) from the change:		
Increase of 5% in exchange rate	$ (307)	$ 95
Increase of 10% in exchange rate	$ (615)	$ 190
Decrease of 5% in exchange rate	$ 307	$ (95)
Decrease of 10% in exchange rate	$ 615	$ (190)

As of December 31, 2024, the Company has a deficit of financial liabilities over financial assets in NIS in relation to US dollar of $8,099

As of December 31, 2024, the Company has an excess of financial assets over financial liabilities in Euro and CAD in relation to US dollar of $1,598 and $431, respectively. An increase or decrease of 5% of the US dollar relative to the Euro and CAD would have an effect of $80 and $22, respectively.

Sensitivity tests and principal work assumptions:

The selected changes in the relevant risk variables were determined based on management's estimate as to reasonable possible changes in these risk variables.

The Company has performed sensitivity tests of principal market risk factors that are liable to affect its reported operating results or financial position. The sensitivity tests present the profit or loss in respect of each financial instrument for the relevant risk variables chosen for that instrument as of each reporting date. The test of risk factors was determined based on the materiality of the exposure of the operating results or financial condition of each risk with reference to the functional currency and assuming that all the other variables are constant.

c. Warrants liability:

	2024	2023
Balance as of January 1,	$ -	$ -
Warrants value at the date of issuance	3,425	-
Gain from remeasurement to fair value through profit or loss	(996)	-
Balance as of December 31	$ 2,429	$ -

On November 5, 2024, the Company consummated a private placement of 2,103,745 ADSs and warrants to purchase 1,500,000 ADSs at an exercise price of $9.50686 per ADS (the "Warrant") to Valor BrainsWay Holdings, LLC ("Valor"), for aggregate immediate gross proceeds of approximately $20 million.

The Warrant became exercisable upon issuance thereof at the closing of the investment and will remain exercisable for 18 months after the initial issuance date (the "Exercise Period"). Under the Warrant, if at any time during the Exercise Period, the ADS closing price of any thirty (30) consecutive trading day period exceeds the exercise price of the Warrant by 40% or more, Valor shall be required to fully exercise the Warrant within five (5) trading days. Valor may also exercise the Warrant, in whole or in part, at any time during the Exercise Period, by means of a "cashless exercise" according to the formula set forth in the Warrant.

The Company has classified the Warrant as a financial liability (see Note 3b).

NOTE 14: EMPLOYEE BENEFITS AND LIABILITIES

Employee benefits consist of short-term and post-employment benefits.

Post-employment benefits:

According to the Israeli labor laws and the Severance Pay Law, 1963 (the "Severance Pay Law"), the Company is required to pay compensation to an employee upon dismissal or retirement or to make current contributions in defined contribution plans pursuant to Section 14 of the Severance Pay Law, as specified below. The Company's liability is accounted for as a post-employment benefit. The computation of the Company's employee benefit liability is made according to the current employment contract based on the employee's salary and employment term which establish the entitlement to receive the compensation.

The post-employment employee benefits are normally financed by contributions classified as defined benefit plan or as defined contribution plan, as detailed below.

Defined contribution plans:

Section 14 of the Severance Pay Law applies to all of the Company's employees and provides that the fixed contributions paid by the Company into pension funds and/or insurance policies release the Company from any additional liability to employees for whom said contributions were made. These contributions benefits represent defined contribution plans.

Expense in respect of defined contribution plans was $390, $343 and $345 for the years ended December 31, 2024, 2023 and 2022, respectively.

NOTE 15: TAXES ON INCOME

a. Tax rates applicable to the Company and subsidiaries:

1. Tax rate applicable to the Company and Brain R&D:

The Israeli corporate income tax rate was 23% in 2024, 2023 and 2022.

A company is taxable on its real capital gains at the corporate income tax rate in the year of sale.

2. Tax rate applicable to US subsidiaries:

The subsidiaries are subject to U.S federal tax at the rate of 21%.

On December 22, 2017, the Tax Cuts and Jobs Act (the "Tax Act") was signed into law making significant changes to U.S. income tax law. These changes include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years 2018 onwards and created new taxes on certain foreign-sourced earnings and certain related-party payments.

The Tax Act required the Company to pay U.S. income taxes on accumulated foreign subsidiaries earnings not previously subject to U.S. income tax at a rate of 15.5% to the extent of foreign cash and certain other net current assets and 8% on the remaining earnings.

b. Tax assessments:

The Company and the Israeli subsidiary received final tax assessments through tax year 2017 as for the statute of limitation. The subsidiary, Inc, received final tax assessments through the 2019 tax year.

c. Carryforward losses for tax purposes:

Carryforward losses for tax purposes as of December 31, 2024 amount to approximately $82 million in Brain R&D and BrainsWay Ltd. (on an Israeli consolidated basis).

d. Deferred taxes:

Deferred taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax liabilities and assets are as follows:

1. Composition:

	Year ended December 31,	
	2024	2023
Gross deferred tax assets:		
Employee benefits	$ 115	$ 78
Lease liabilities	-	6
Deferred revenue	959	759
Other temporary differences	-	28
Gross deferred tax assets	1,074	871
Gross deferred tax liabilities:		
Property, plant and equipment	(11)	(36)
Right-of-use assets	-	(7)
Gross deferred tax liabilities	(11)	(43)
Deferred tax assets, net	$ 1,063	$ 828

2. The Company did not record deferred tax assets with respect to net operating losses incurred by the Company and the Israeli subsidiary since it is not probable that they will generate a taxable income in future years.

NOTE 15: TAXES ON INCOME (Continued)

e. Theoretical tax:

The reconciliation between the tax expense, assuming that all the income, expenses, gains and losses in profit or loss were taxed at the statutory tax rate and the taxes on income recorded in profit or loss is as follows:

	Year ended December 31,		
	2024	2023	2022
Profit (loss) before taxes on income	$ 3,459	$ (3,946)	$ (13,034)
Statutory federal income tax rate	21%	21%	21%
Tax (tax benefit) computed at the statutory tax rate	$ 726	$ (829)	$ (2,737)
Unrecognized temporary differences	(59)	(47)	140
Decrease (increase) in unrecognized tax losses in the year	(351)	1,070	2,889
Tax adjustment in respect of different tax rates	107	44	21
Taxes in respect of previous years	90	5	-
Non-deductible expenses and other differences	25	8	2
	$ 538	$ 251	$ 315

1. Statutory income tax rate according to US federal tax rate in respect of income generated by the US subsidiaries, for which income tax was recorded for the years ended December 31, 2024 2023 and 2022.

f. Taxes on income (tax benefits) included in the consolidated statements of comprehensive loss:

	Year ended December 31,		
	2024	2023	2022
Current taxes	$ 683	$ 798	$ 133
Deferred taxes	(235)	(552)	182
Taxes in respect of previous years	90	5	-
	$ 538	$ 251	$ 315

NOTE 16: CONTINGENT LIABILITIES, COMMITMENTS AND CHARGES

a. Brain R&D received from the Israeli Government participation grants in research and development in an aggregate amount of approximately $13,400 and, in return, it is currently obligated to pay royalties amounting to 3% of sales of products from such grants up to 100% of total grants received.

As of December 31, 2024, the maximum royalties payable by the Company in the future in respect of active projects is $10,063, including interest at the LIBOR rate. Through December 31, 2024, royalties paid were $6,243.

	2024	2023
Balance as of January 1,	$ 7,085	$ 7,073
Grants received during the year	—	32
Royalties paid during the year	(1,108)	(819)
Amounts carried to profit and loss	1,119	799
Balance as of December 31,	$ 7,096	$ 7,085
Current maturities in respect of government grants	$ 1,293	$ 1,008
Non-current liability in respect of government grants	$ 5,803	$ 6,077

b. The Company entered into a few distribution agreements with third parties regarding different territories around the world. According to these distribution agreements, the third parties are generally granted the exclusive right to market, distribute, lease and/or sale, use and promote sales of the systems in the relevant territories for a period defined in the agreement, generally ranging from 3 to 10 years. The Company supplies the

systems to the distributors, and they promote and provide various services (such as installation, training and maintenance) to local customers. These distributors are typically contractually committed to meet minimum order quantities, absent which may serve as grounds for termination.

NOTE 16: CONTINGENT LIABILITIES, COMMITMENTS AND CHARGES (Continued)

c. In September 2013, the Company entered into a distribution agreement in Japan with Century Medical Inc., a member of the Itochu concern, which specializes in the import and distribution of medical systems and equipment in Japan. According to the agreement, the distributor was granted the exclusive right to market the Company's system for the treatment of MDD in patients in Japan for a ten-year period which begins after the required regulatory approvals for marketing the system in Japan and after either obtaining reimbursement or deployment of a commercial product to a clinical site. If the distributor meets the minimum quantities which it has committed during the contractual term, the agreement will be extended for an additional five year period. The distributor is granted a right of first offer to distribute the Company's system in Japan without further codification.

In consideration for the above, the distributor was obligated to pay the Company distribution fees of 190 million Yen (approximately $1.8 million), whereby 100 million Yen was paid in September 2013 and 90 million Yen was paid in 2019.

On January 22, 2018, the distributor in Japan applied to the Pharmaceutical and Medical Devices Agency ("PMDA"), which is responsible for all import and export licenses of pharmaceuticals and medical equipment to Japan, for approval of marketing and selling the Company's systems in Japan. In January 2019, approval of the PMDA was received, and in 2024, our distributor succeeded in updating the guidelines issued by the Japanese Society of Psychology and Neurology to include coverage for Deep TMS.

In September 2024, the parties executed an amendment to the agreement which finally launched commercial sales in the Territory – through a new pricing model established in the amendment (which changed from a pay-per-use model contemplated under the original agreement to a purchase model, and which set revised annual revenue minimum achievement levels and targets). Under the terms of the revised agreement, at the end of each year, provided the annual revenue targets have been met, for every $500 in revenues received (i.e. cash collected), the Company pays the distributor a fee of 9.5 million Yen, up to an aggregate cap of 190 million Yen. Failure to meet the minimum payment threshold to the Company at the end of any year during the contractual term causes the deficiency to "roll over" into the next year, which, if not met, entitles the Company to terminate the distribution agreement within 60 days without any penalty.

The Company will unwind the upfront payment it received for exclusivity as it recognizes revenues during the term of the agreement.

NOTE 16: CONTINGENT LIABILITIES, COMMITMENTS AND CHARGES (Continued)

d. License agreements:

1. In July 2003, Inc signed a license agreement with the agencies of the U.S. Public Health Service within the U.S. Department of Health and Human Services ("PHS"), according to which the Company was granted an exclusive license to develop, manufacture, make use of, market, sell and import products and processes to be developed in the framework of the license agreement with respect to TMS and a right to enter into sublicense agreements, subject to approval of the PHS. In return, Inc is committed to pay PHS earned royalties of 2% (beyond the first $10,000 in cumulative sales, a milestone which has passed), with a minimum annual royalty of $2 subject to the terms in the agreement.

   In addition, if Inc enters into a sub-license agreement, it is committed to pay royalties of 8% of the net consideration received for the grant of the sub-license.

   The agreement is valid until the expiration of the last to expire of the licensed patent rights under the agreement. PHS is entitled to cancel the agreement if Inc does not comply with the conditions detailed in the agreement.

2. In June 2005 and March 2010, Inc signed a research and licensing agreement and addendum with Yeda Research and Development Company Ltd. ("Yeda"), according to which Inc was granted an exclusive license to intellectual property that can be used for research, development, marketing and manufacturing of products in the field of TMS treatment and may have the right to grant sublicenses subject to conditions specified in the agreement in consideration of royalty payment as follows:

   a) 1% of net sales systems based upon certain patents (which include technology licensed from PHS);

   b) 3% for the first $10,000 of net sales, and 2% for net sales over $10,000, for all other Deep TMS products solely based on certain patents licensed exclusively from Yeda provided however in the event that the products are sold to a sublicensee and are thereafter sold by such sublicensee, the royalties paid to Yeda will be based on the higher of the net sales by the licensee or the net sales of the sale by the sublicensee.

NOTE 16: CONTINGENT LIABILITIES, COMMITMENTS AND CHARGES (Continued)

c) 4%-8% of the net cash proceeds that the Company receives in respect of granting sublicenses or options for sublicenses dependent on the patents licensed.

Royalties are payable at the later of 15 years after the first commercial sale or the patent life (20 years through October 2021). The agreement expires at the later of: the expiration of the last patent, 15 years after Inc starts to sell products integrating the patent or after a period of 20 years during which no sales are made.

The license agreement with Yeda may be subject to modifications in the event that the license agreement with PHS is modified (see 1, above) and may be cancelled based on various conditions, including the cancellation of the PHS agreement.

On February 22, 2018, Inc and Yeda signed an additional addendum to the agreement (the "fifth addendum"), according to which Inc received the right to examine an additional invention based upon the patent issued in connection with research in the field of rotational electrical fields owned by Yeda. Under the fifth addendum, the Company has the right to include the aforementioned invention and the intellectual property accompanying it under the Yeda license agreement.

In January 2020, the Company exercised the right granted to it under the fifth addendum, and accordingly royalties on net sales of products which are based on the use of the invention and know-how subject to the fifth addendum will be paid to Yeda at increased rates of 1.6%-2% in addition to the royalties described above and, in certain cases, at a flat rate of 2%. In respect of products under the fifth addendum that are not based on patents or research results for which the license was granted according to the original agreement (excluding the fifth addendum), royalties on net sales will be at the fixed rate of 5%.

NOTE 17: EQUITY

a. Composition of share capital:

	December 31, 2024		December 31, 2023	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
	Number of shares			
Ordinary shares of NIS 0.04 par value each	120,000,000	37,626,427	120,000,000	33,242,189

b. Movement in share capital:

	Number of shares	NIS par value
Balance as of January 1, 2024	33,242,189	1,329,687
Vesting of RSU	134,357	5,374
Exercise of share options	42,391	1,696
Issue of shares	4,207,490	168,300
Balance of December 31, 2024	37,626,427	1,505,057

c. Rights attached to shares:

Ordinary shares confer their holders' rights to receive dividends in cash and in Company's shares, right to nominate the Company's directors and rights to participate in distribution of dividends upon liquidation in proportion to their holdings. Also, holders of ordinary shares have one vote at the shareholders' meeting such that each share confers one vote to its holder.

NOTE 17: EQUITY (Continued)

d. Capital management in the Company:

The Company's capital management objectives are to preserve the Group's ability to ensure business continuity thereby creating a return for the shareholders, investors and other interested parties.

The Company is not under any minimal equity requirements, nor is it required to attain a certain level of capital return.

NOTE 18: SHARE-BASED PAYMENT

a. The expense recognized in the financial statements for services received is shown in the following table:

	Year ended December 31,		
	2024	2023	2022
Equity-settled share-based payment plans to employees, directors and consultants.	$ 1,441	$ 381	$ 1,475

b. The share-based payment transactions that the Company granted to its employees, directors and consultants are shown in the following table:

Range of exercise prices	Options outstanding as of December 31, 2024(*)	Weighted Average remaining contractual Term	Weighted Average exercise price ($)	Options exercisable December 31, 2024(*)
0.76-4.71	2,626,113	6.24	2.67	1,358,925

(*) Options and restricted shares.

c. The fair value of the Company's options granted for the years ended December 31, 2024, 2023 and 2022 was estimated using the following assumptions:

	Year ended December 31,		
	2024	2023	2022
Expected volatility (%)	38.86-38.95	48.9 - 71.61	33.00 - 64.44
Risk-free interest rate (%)	4.40-4.43	3.39 - 4.58	0.06 - 2.90

NOTE 18: SHARE-BASED PAYMENT (Continued)

d. The following table presents the changes in the number of share options and the weighted average exercise prices of share options:

	Year ended December 31,			
	2024		2023	
	Number of options	Weighted average exercise price (*)	Number of options	Weighted average exercise price (*)
Outstanding at January 1,	2,072,100	$ 2.94	1,549,600	$ 4.6
Granted	765,000	3.12	913,000	0.9
Exercised	(42,391)	2.35	-	-
Expired	(144,846)	4.24	(90,200)	4.3
Forfeited	(23,750)	3.32	(300,300)	3.8
Outstanding at December 31,	2,626,113	$ 2.93	2,072,100	$ 2.9
Exercisable at December 31,	1,358,925	$ 3.55	1,127,537	$ 4.6

(*) The exercise price of all options denominated in NIS and was translated to USD in the table above using the exchange rate as of December 31, 2024 and 2023, respectively.

The contractual life of the options is ten years from the grant date. The weighted average remaining contractual life for the options outstanding as of December 31, 2024 and 2023 was approximately six years and five years, respectively.
The weighted average share price on the date of exercise of the share options was $4.9 in 2024 (no exercises during 2023).
The weighted average fair value of options granted during 2024 was $1.74 (for options granted during 2023, the weighted average fair value was $0.54)

During 2021, the Company completed a repricing of outstanding options via an exchange offer pursuant to which the Company exchanged previously granted options with new options. For those that chose to participate in the exchange, the repricing resulted in an updated exercise price of $4.675 or NIS 15.26 per ordinary share, and is otherwise subject to the same expiration date, vesting schedule and other terms as previously existed prior to the exchange offer. Several employees chose not to participate in the exchange because their options were subject to a lower exercise price than that offered in the repricing. Accordingly, the exercise price range for options outstanding as of December 31, 2023 and 2024 was NIS 2.78-15.26.

NOTE 18: SHARE-BASED PAYMENT (Continued)

e. The following table presents the changes in the number of restricted shares and the weighted average exercise prices of restricted shares:

	2024	2023
	Number of Restricted shares	Number of Restricted shares
Outstanding at January 1,	269,638	769,040
Granted	320,000	-
Vested	(134,357)	(193,347)
Forfeited	(26,829)	(306,055)
Outstanding at December 31,	428,452	269,638

The weighted average fair value of restricted shares granted during 2024 was $3.26.

NOTE 19: ADDITIONAL INFORMATION TO THE STATEMENTS OF COMPREHENSIVE LOSS

a. Additional information on revenues:

1. Revenues reported in the financial statements for each group of similar products and services:

	Year ended December 31,		
	2024	2023	2022
Revenues from sale	$ 22,413	$ 20,372	$ 16,182
Revenues from lease	14,501	8,523	9,244
Revenues from sale related service	3,412	2,311	1,276
Revenues from other service	690	579	475
	$ 41,016	$ 31,785	$ 27,177

2. Revenues from major customers, each accounting for 10% or more of total revenues reported in the financial statements:

	Year ended December 31,		
	2024	2023	2022
Customer A	19%	15%	*)
Customer B	11%	*)	16%

*) Less than 10 %

Geographic information:

Revenues reported in the financial statements based on the location of the customers, are as follows:

	Year ended December 31,					
	2024	%	2023	%	2022	%
U.S.	$ 33,227	81	$ 23,979	75	$ 20,300	75
Other	7,789	19	7,806	25	6,877	25
	$ 41,016	100	$ 31,785	100	$ 27,177	100

b. Cost of revenues:

	Year ended December 31,		
	2024	2023	2022
Cost of revenues from sale	$ 5,997	$ 5,792	$ 4,917
Cost of revenues from lease	3,562	1,670	1,790
Cost of revenues from sale related service	648	678	324
Cost of revenues from other service	228	168	98
	$ 10,435	$ 8,308	$ 7,129

NOTE 19: ADDITIONAL INFORMATION TO THE STATEMENTS OF COMPREHENSIVE PROFIT (LOSS) (Continued)

c. Research and development expenses, net:

	Year ended December 31,		
	2024	2023	2022
Salaries and related benefits	$ 4,413	$ 4,012	$ 4,516
Subcontractors	1,420	1,564	1,318
Laboratory materials	346	333	494
Patents	287	133	200
Share-based payment	318	264	357
Travel	43	48	14
Depreciation	201	108	99
Other	162	235	690
Less: Government grants	-	(32)	(10)
	$ 7,190	$ 6,665	$ 7,678

d. Selling and marketing expenses:

	Year ended December 31,		
	2024	2023	2022
Salaries and related benefits	$ 9,019	$ 10,273	$ 10,268
Agent commissions	222	489	425
Marketing, advertising and events	3,083	2,729	3,835
Travel	1,547	1,542	1,915
Share-based payment	180	126	486
Depreciation	214	137	143
Collection costs and other	1,938	1,160	1,127
	$ 16,203	$ 16,456	$ 18,199

NOTE 19: ADDITIONAL INFORMATION TO THE STATEMENTS OF COMPREHENSIVE PROFIT (LOSS) (Continued)

e. General and administrative expenses:

	Year ended December 31,		
	2024	2023	2022
Salaries and related benefits	$ 2,073	$ 2,689	$ 2,324
Professional fees and office expenses	2,023	2,638	3,310
Depreciation	185	141	312
Travel	27	16	11
Allowance for doubtful accounts	570	(145)	281
Share-based payment	919	(24)	616
	$ 5,797	$ 5,315	$ 6,854

NOTE 19: ADDITIONAL INFORMATION TO THE STATEMENTS OF COMPREHENSIVE LOSS (Continued)

f. Finance income and expense:

	Year ended December 31,		
	2024	2023	2022
Finance income:			
Interest-income revaluation of bank deposits	$ 2,477	$ 2,171	$ 1,109
Remeasurement of warrants	996	-	8
Hedging	111	-	-
	3,584	2,171	1,117
Finance expense:			
Liability in respect of government grants	1,119	799	1,148
Bank commissions	36	27	22
Exchange rate differences	160	61	252
Interest expense of lease liability	127	48	46
Hedging	-	223	-
Other	74	-	-
	1,516	115	1,468
Finance income (expense), net	$ 2,068	$ 1,013	$ (351)

NOTE 20: NET INCOME (LOSS) PER SHARE

Number of shares and income (loss) used in the computation of net income (loss) per share:

	Year ended December 31,					
	2024		2023		2022	
	Weighted number of shares	Income attributable to equity holders of the Company	Weighted number of shares*)	Loss attributable to equity holders of the Company	Weighted number of shares*)	Loss attributable to equity holders of the Company
For the computation of basic net income (loss)	33,969,077	$ 2,921	33,155,669	$ (4,197)	32,980,997	$ (13,349)
Effect of potential dilutive ordinary shares	799,882	(996)	-	-	-	-
For the computation of diluted net profit (loss)	34,768,959	$ 1,925	33,155,669	$ (4,197)	32,980,997	$ (13,349)

*) Computation of diluted loss per share did not include potential ordinary shares that would result from conversion of outstanding options and warrants, since their conversion has anti-dilutive effect.

NOTE 21: BALANCES AND TRANSACTIONS WITH RELATED PARTIES

a. Balances with interested and related parties

As of December 31, 2024

	Key management personnel	Other interested and related parties
Vendors	$ -	$ 7
Other accounts payable	$ 331	$ 110

As of December 31, 2023

	Key management personnel	Other interested and related parties
Vendors	$ -	$ 45
Other accounts payable	$ 335	$ 57

b. Benefits to interested and related parties:

	Year ended December 31,		
	2024	2023	2022
Salary to those employed by the Company or on its behalf	$ -	$ -	$ 762
Directors' fees to those not employed by the Company or on its behalf	$ 453	$ 411	$ 280
Number of individuals to whom the salary and benefits relate:			
Related and interested parties employed by the Company or on its behalf	-	-	3
Directors not employed by the Company	9	8	5
	9	8	8

NOTE 21: BALANCES AND TRANSACTIONS WITH RELATED PARTIES (Continued)

c. Share-based payment:

	Year ended December 31,		
	2024	**2023**	**2022**
Share-based payment to those employed by the Company or on its behalf	$ 354	$ 207	$ 287
Share-based payment to those not employed by the Company or on its behalf	$ 429	$ 102	$ 28

d. Transactions with interested and related parties:

Year ended December 31, 2024

	Key management personnel (*)	**Other interested and related parties**
Research and development expenses	$ -	$ 70
General and administrative expenses	846	383
	$ 846	$ 453

Year ended December 31, 2023

	Key management personnel (*)	**Other interested and related parties**
Research and development expenses	$ -	$ 70
General and administrative expenses	801	298
	$ 801	$ 368

Year ended December 31, 2022

	Key management personnel (*)	**Other interested and related parties**
Research and development expenses	$ 107	$ 81
General and administrative expenses	861	308
	$ 968	$ 389

NOTE 21: BALANCES AND TRANSACTIONS WITH RELATED PARTIES (Continued)

*) Some of the key management personnel are interested parties by virtue of holdings.

e. For transactions including the issuance of shares and warrants to related parties, see Note 13C.

f. For information regarding the fair value of the options granted to directors, see Note 18b.

Exhibit 2.3

DESCRIPTION OF SHARE CAPITAL

The following description of our share capital is a summary of the rights of our ordinary shares and certain provisions of our articles of association currently in effect. This summary does not purport to be complete and is qualified in its entirety by the provisions of our articles of association previously filed with the Securities and Exchange Commission and incorporated by reference as an exhibit to the Annual Report on Form 20-F, as well as to the applicable provisions of the Israeli Companies Law. We encourage you to read our articles of associations and applicable portions of the Israeli Companies Law carefully.

American Depositary Shares

Each of the American Depositary Shares, or ADSs, represents 2 Ordinary Shares. The ADSs trade on the NASDAQ Global Market.

The principal office of The Bank of New York Mellon is located at 240 Greenwich Street, New York, New York 10286.

You may hold American Depositary Shares either (A) directly (i) by having an American Depositary Receipt, which is a certificate evidencing a specific number of American Depositary Shares, registered in your name, or (ii) by having American Depositary Shares registered in your name in the Direct Registration System, or (B) indirectly by holding a security entitlement in American Depositary Shares through your broker or other financial institution. If you hold American Depositary Shares directly, you are a registered American Depositary Share holder. This description assumes you are an American Depositary Share holder. If you hold the American Depositary Shares indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of American Depositary Share holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

The Direct Registration System, or DRS, is a system administered by The Depository Trust Company, also referred to as DTC, pursuant to which the depositary may register the ownership of uncertificated American Depositary Shares, which ownership is confirmed by periodic statements sent by the depositary to the registered holders of uncertificated American Depositary Shares.

As an American Depositary Share holder, we will not treat you as one of our shareholders and you will not have shareholder rights. Israeli law governs shareholder rights. The depositary will be the holder of the ordinary shares underlying your American Depositary Shares. As a registered holder of American Depositary Shares, you will have American Depositary Share holder rights. A deposit agreement among us, the depositary and you, as an American Depositary Share holder, and all other persons indirectly holding American Depositary Shares sets out American Depositary Share holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the American Depositary Shares.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of American Depositary Receipt, each of which has been filed as an exhibit to our Registration Statement on Form F-1 filed with the Securities and Exchange Commission.

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The depositary has agreed to pay to American Depositary Share holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. You will receive these distributions in proportion to the number of shares your American Depositary Shares represent.

- Cash. The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the U.S. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those American Depositary Share holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the American Depositary Share holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

  Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. It will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.

- Shares. The depositary may, and will if we so request, distribute additional American Depositary Shares representing any shares we distribute as a dividend or free distribution. The depositary will only distribute whole American Depositary Shares. It will sell shares which would require it to deliver a fractional American Depositary Share and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional American Depositary Shares, the outstanding American Depositary Shares will also represent the new shares. The depositary may sell a portion of the distributed shares sufficient to pay its fees and expenses in connection with that distribution.

- Rights to purchase additional shares. If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may make these rights available to American Depositary Share holders. If the depositary decides it is not legal and practical to make the rights available but that it is practical to sell the rights, the depositary will use reasonable efforts to sell the rights and distribute the proceeds in the same way as it does with cash. The depositary will allow rights that are not distributed or sold to lapse. In that case, you will receive no value for them.

  If the depositary makes rights available to American Depositary Share holders, it will exercise the rights and purchase the shares on your behalf. The depositary will then deposit the shares and deliver American Depositary Shares to the persons entitled to them. It will only exercise rights if you pay it the exercise price and any other charges the rights require you to pay.

  U.S. securities laws may restrict transfers and cancellation of the American Depositary Shares represented by shares purchased upon exercise of rights. For example, you may not be able to trade these American Depositary Shares freely in the U.S. In this case, the depositary may deliver restricted depositary shares that have the same terms as the American Depositary Shares described in this section except for changes needed to put the necessary restrictions in place.

- Other Distributions. The depositary will send to American Depositary Share holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. After consultation with us to the extent practicable, it may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case American Depositary Shares will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than American Depositary Shares) to American Depositary Share holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution.

  The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any American Depositary Share holders. We have no obligation to register American Depositary Shares, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of American Depositary Shares, shares, rights or anything else to American Depositary Share holders. This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.

Deposit, Withdrawal and Cancellation

How are American Depositary Shares issued?

The depositary will deliver American Depositary Shares if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of American Depositary Shares in the names you request and will deliver the American Depositary Shares to or upon the order of the person or persons that made the deposit.

How can American Depositary Share holders withdraw the deposited securities?

You may surrender your American Depositary Shares at the depositary's corporate trust office. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the American Depositary Shares to the American Depositary Share holder or a person the American Depositary Share holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its corporate trust office, if feasible.

How do American Depositary Share holders interchange between certificated American Depositary Shares and uncertificated American Depositary Shares?

You may surrender your American Depositary Receipt to the depositary for the purpose of exchanging your American Depositary Receipt for uncertificated American Depositary Shares. The depositary will cancel that American Depositary Receipt and will send to the American Depositary Share holder a statement confirming that the American Depositary Share holder is the registered holder of uncertificated American Depositary Shares. Alternatively, upon receipt by the depositary of a proper instruction from a registered holder of uncertificated American Depositary Shares requesting the exchange of uncertificated American Depositary Shares for certificated American Depositary Shares, the depositary will execute and deliver to the American Depositary Share holder an American Depositary Receipt evidencing those American Depositary Shares.

Voting Rights

How do you vote?

American Depositary Share holders may instruct the depositary to vote the number of deposited shares their American Depositary Shares represent. The depositary will notify American Depositary Share holders of shareholders' meetings and arrange to deliver our proxy and voting materials to them if we ask it to. Those materials will describe the matters to be voted on and explain how American Depositary Share holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. *Otherwise, you won't be able to exercise your right to vote unless you withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares.*

The depositary will try, as far as practical, subject to the laws of Israel and of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by American Depositary Share holders. The depositary will only vote or attempt to vote as instructed.

If the depositary solicited your voting instructions but does not receive instructions by the date specified, the depositary will consider you to have instructed it to give a proxy to a person designated by us to vote the deposited shares, unless we notify the depositary that:

- we do not wish to receive a proxy;
- substantial opposition exists;
- the matter would materially and adversely affect the rights of holders of our ordinary shares.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise your right to vote and there may be nothing you can do if your shares are not voted as you requested.*

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the American Depositary Receipts without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of American Depositary Share holders, it will not become effective for outstanding American Depositary Shares until 30 days after the depositary notifies American Depositary Share holders of the amendment. At the time an amendment becomes effective, you are considered, by continuing to hold your American Depositary Shares, to agree to the amendment and to be bound by the American Depositary Receipts and the deposit agreement as amended.

How may the deposit agreement be terminated?

The depositary will terminate the deposit agreement at our direction by mailing notice of termination to the American Depositary Share holders then outstanding at least 30 days prior to the date fixed in such notice for such termination. The depositary may also terminate the deposit agreement by mailing notice of termination to us and the American Depositary Share holders if 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment.

After termination, the depositary and its agents will do the following under the deposit agreement but nothing else: collect distributions on the deposited securities, sell rights and other property, and deliver shares and other deposited securities upon cancellation of American Depositary Shares. Four months after termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement for the pro rata benefit of the American Depositary Share holders that have not surrendered their American Depositary Shares. It will not invest the money and has no liability for interest. The depositary's only obligations will be to account for the money and other cash. After termination our only obligations will be to indemnify the depositary and to pay fees and expenses of the depositary that we agreed to pay.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of American Depositary Shares

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith;
- are not liable if we are or it is prevented or delayed by law or circumstances beyond our control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of American Depositary Shares to benefit from any distribution on deposited securities that is not made available to holders of American Depositary Shares under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the American Depositary Shares or the deposit agreement on your behalf or on behalf of any other person; and

- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of an American Depositary Share, make a distribution on an American Depositary Share, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;

- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver American Depositary Shares or register transfers of American Depositary Shares generally when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Your Right to Receive the Shares Underlying your American Depositary Shares

American Depositary Share holders have the right to cancel their American Depositary Shares and withdraw the underlying shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our shares;

- when you owe money to pay fees, taxes and similar charges; or

- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to American Depositary Shares or to the withdrawal of shares or other deposited securities.

Rights of American Depositary Share Holders

Our articles of association provide that holders of American Depositary Shares shall be deemed as our shareholders with respect to our Ordinary Shares represented by such American Depositary Shares for all intents and purposes, including with respect to (i) each Ordinary Share represented by such American Depositary Shares, which shall have all rights, privileges and obligations attached to the Ordinary Shares for all intents and purposes, and (ii) any and all reference to shareholder(s) in our articles of association, which shall include holders of American Depositary Shares and any authorized bank, broker, depository or other nominee with respect to American Depositary Shares, as the case may be.

Securities Registers

The transfer agent and registrar for the ADSs is The Bank of New York Mellon, and its address is 101 Barclay Street, New York, NY.

Objects and Purposes

According to Section 4 of our articles of association, we shall engage in any legal business. Our number with the Israeli Registrar of Companies is 51-389076-4.

Private Placements

Under the Israeli Companies Law, if (i) as a result of a private placement a person would become a controlling shareholder or (ii) a private placement will entitle investors to receive 20% or more of the voting rights of a company as calculated before the private placement, and all or part of the private placement consideration is not in cash or in public traded securities or is not in market terms and if as a result of the private placement the holdings of a substantial shareholder will increase or as a result of it a person will become a substantial shareholder, then, in either case, the allotment must be approved by the board of directors and by the shareholders of the company. A "substantial shareholder" is defined as a shareholder who holds five percent or more of the company's outstanding share capital, assuming the exercise of all of the securities convertible into shares held by that person. In order for the private placement to be on "market terms" the board of directors has to determine, on the basis of detailed explanation, that the private placement is on market terms, unless proven otherwise.

Board of Directors

Under our articles of association, resolutions by the board of directors are decided by a majority of votes of the directors present, or participating, in the case of voting by media, and voting, each director having one vote.

In addition, the Israeli Companies Law requires that certain transactions, actions, and arrangements be approved as provided for in a company's articles of association and in certain circumstances by the compensation or audit committee and by the board of directors itself. Those transactions that require such approval pursuant to a company's articles of association must be approved by its board of directors. In certain circumstances, compensation or audit committee and shareholder approval are also required. See "Item 6. Directors, Senior Management and Employees – C. Board Practices" in our annual report on Form 20-F.

The Israeli Companies Law requires that a member of the board of directors or senior management of the company promptly and, in any event, not later than the first board meeting at which the transaction is discussed, disclose any personal interest that he or she may have, either directly or by way of any corporation in which he or she is, directly or indirectly, a 5% or greater shareholder, director or general manager or in which he or she has the right to appoint at least one director or the general manager, as well as all related material information known to him or her, in connection with any existing or proposed transaction by the company. In addition, if the transaction is an extraordinary transaction, (that is, a transaction other than in the ordinary course of business, otherwise than on market terms, or is likely to have a material impact on the company's profitability, assets or liabilities), the member of the board of directors or senior management must also disclose any personal interest held by his or her spouse, siblings, parents, grandparents, descendants, spouse's descendants, siblings, and parents, and the spouses of any of the foregoing.

Once the member of the board of directors or senior management complies with the above disclosure requirement, a company may approve the transaction in accordance with the provisions of its articles of association. Under the provisions of the Israeli Companies Law, whoever 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 this meeting or vote on this matter, unless it is not an extraordinary transaction as defined in the Israeli Companies Law. However, if the chairman of the board of directors or the chairman of the audit committee has determined that the presence of a director or an officer with a personal interest is required for the presentation of a matter, such office holder may be present at the meeting for the presentation of the matter. Notwithstanding the foregoing, if the majority of the directors have a personal interest in a matter, they will be allowed to participate and vote on this matter, but an approval of the transaction by the shareholders in the general meeting will be required.
Our articles of association provide that, subject to the Israeli Companies Law, all actions executed in good faith by the board of directors or by a committee thereof or by any person acting as a director or a member of a committee of the board of directors, will be deemed to be valid even if, after their execution, it is discovered that there was a flaw in the appointment of these persons or that any one of these persons was disqualified from serving in his or her office.

Our articles of association provide that, subject to the provisions of the Israeli Companies Law, the board of directors may appoint board of directors' committees. The committees of the board of directors report to the board of directors their resolutions or recommendations on a regular basis, as prescribed by the board of directors. The board of directors may cancel the resolution of a committee that has been appointed by it; however, such cancellation will not affect the validity of any resolution of a committee, pursuant to which we acted, vis-à-vis another person, who was not aware of the cancellation thereof. Decisions or recommendations of the committee of the board which require the approval of the board of directors will be brought to the directors' attention a reasonable time prior to the discussion at the board of directors.

According to Israeli Companies Law, the board of directors may direct the chief executive officer how to act in a specific matter, and if the chief executive officer does not so act, the board of directors is authorized to act in his/her stead.

According to our articles of association, subject to the provisions of the Israeli Companies Law, the board of directors is entitled at any time to grant a power of attorney to any person to legally represent the Company for such purposes and with such authorities and discretion and for such period of time and subject to such terms and all as the board of directors shall deem fit. The board of directors will be entitled to grant to such person, inter alia, authorities to transfer to some other, fully or partially, the authorities and powers and discretion granted to him.

According to the Israeli Companies Law and our articles of association, the board of directors is entitled to transfer its authorities, to a board of directors committee and/or an officer in the Company, whether for the purpose of a certain general meeting or for a period of time.

According to the Israeli Companies Law, an authority not granted under the law or the articles of association of a company to another, may be operated by its board of directors.

Ordinary Shares

Authorized and Outstanding Share Capital. Our authorized share capital currently consists of 120,000,000 Ordinary Shares, par value NIS 0.04 per share.

All of our outstanding Ordinary Shares are and will be validly issued, fully paid and non-assessable. Our Ordinary Shares are not redeemable and do not have any preemptive rights.

Transfer of Shares. Fully paid Ordinary Shares are issued in registered form and may be freely transferred pursuant to our articles of association unless that transfer is restricted or prohibited by another instrument. There are no Israeli law and regulations that impose limitations on the rights to own securities, including the rights of non-resident or foreign shareholders to hold or exercise voting rights on the securities imposed by foreign law or by the charter or other constituent document of the Company.

Shareholders Meetings. Under the Israeli Companies Law, we are required to hold an annual general meeting of our shareholders once every calendar year that must be held no later than 15 months after the date of the previous annual general meeting. All general meetings other than the annual meeting of shareholders are referred to in our articles of association as special meetings. In accordance with our articles of association and the Israeli Companies Law, our board of directors may call special meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Israeli Companies Law and regulations promulgated thereunder provide that our board of directors is required to convene a special meeting upon the written request of (i) any two of our directors or one-quarter of the members of our board of directors or (ii) one or more shareholders holding, in the aggregate, either (a) 10% or more of our outstanding issued shares and 1% or more of our outstanding voting power or (b) 10% or more of our outstanding voting power. This is different from the Delaware General Corporation Law, or the DGCL, which allows such right of shareholders to be denied by a provision in a company's certificate of incorporation. Our articles of association provide that a special meeting will be convened in accordance with the resolution of our board of directors and in accordance with the demand, among others, of one or more shareholders with at least 5% of the issued share capital and 1% of the voting rights in our company or one or more shareholders with at least 5% of the voting rights in our company.

Under Israeli law, one or more shareholders holding at least 5% of the voting rights at a general meeting of shareholders may request that our board of directors include a proposal that relates to the election or removal of a director in the agenda of a general meeting of shareholders to be convened in the future. One or more shareholders holding at least 1% of the voting rights at the general meeting 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 any other matter at the general meeting.

Subject to the provisions of the Israeli 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 may generally be between four and forty days prior to the date of the meeting. Furthermore, the Israeli Companies Law requires, inter alia, that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

- amendments to our articles of association;

- appointment or termination of our auditors;
- appointment of external directors (if applicable);
- approval of certain related party transactions;
- increases or reductions of our authorized share capital;
- mergers; and
- the exercise of our board of director's powers by a general meeting, if our board of directors is unable to exercise its powers and the exercise of any of its powers is required for our proper management.

The Company shall give notice of a general meeting only to the shareholders registered in the registry, whose address is in Israel. Our articles of association, in accordance with the provisions of the Israeli Companies Law requires that a notice of any annual general meeting or special general meeting be published at least 14 days prior to the meeting and, if the agenda of the meeting includes the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, or as otherwise required under applicable law, notice must be published at least 35 days prior to the meeting. Under the Israeli Companies Law, shareholders of a public company are not permitted to take action by written consent in lieu of a meeting.

Election of Directors. Our Ordinary Shares do not have cumulative voting rights for the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors. Under our articles of association, our board of directors must consist of not less than four (4) but no more than eight (8 directors, including the Valor Designee (as such term is defined in our articles of association) and not including any external directors required to be appointed by the Israel Companies Law and not including up to two (2) additional directors who may be appointed by our board of directors whose term of office would expire on the next following annual meeting of shareholders after their appointment, provided that they may be reappointed by the Board of Directors for one additional term of office, provided that they may be reappointed by the annual meeting. Each appointed director, other than external directors, if any, shall serve as a member of the Board of Directors until the next annual general meeting. The term of a director shall terminate at the next annual general meeting, unless he or she are reelected at the annual general meeting. Pursuant to our articles of association, 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. For a more detailed description on the composition of our board of directors and the election procedures of our directors, including rights granted to Valor (as such term is defined in our annual report on Form 20-F, see "Item 6. Directors, Senior Management and Employees – C. Board Practices – Appointment of Directors and Terms of Office" in our annual report on Form 20-F.

Dividend and Liquidation Rights. Our profits, in respect of which a resolution was passed to distribute them as a dividend or bonus shares, are to be paid pro rata to the amount paid or credited as paid on account of the nominal value of shares held by the shareholders. In the event of our liquidation, the liquidator may, with the general meeting's approval, distribute parts of our property in specie pro rata to the amount paid or credited as paid on account of the nominal value of shares held by the shareholders and he may, with similar approval, deposit any part of our property with trustees in favor of the shareholders as the liquidator, with the approval mentioned above deems fit.

Voting, Shareholders' Meetings, and Resolutions. Our articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by the Israeli Companies Law. The Ordinary Shares all have equal voting rights. Under the Israeli Companies Law, certain transactions with controlling shareholders and approvals in connection with compensation terms of the directors and certain officers require, among other approvals, the approval of the shareholders by a special majority. For more information see "Item 6. Directors, Senior Management and Employees – C. Board Practices" in our annual report on Form 20-F.

Under our articles of association, any change to the rights and privileges of the holders of any class of our shares requires a simple majority of the class so affected. Another exception to the simple majority vote requirement is a resolution for the voluntary winding up, or an approval of a scheme of arrangement or reorganization, of the company pursuant to Section 350 of the Israeli Companies Law, which requires the approval of holders of 75% of the voting rights represented at the meeting, in person, by proxy or by voting deed and voting on the resolution.

Allotment of Shares. Our board of directors generally has the power to allot or to issue shares to any person, with restrictions and conditions as it deems fit.

Acquisitions under Israeli Law

Special Tender Offer

The Israeli Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of at least 25% of the voting rights in the company. This rule does not apply if there is already another holder of at least 25% of the voting rights in the company.

Similarly, the Israeli Companies Law provides that an acquisition of shares of a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company.

These requirements do not apply if the acquisition (i) occurs in the context of a private offering, on the condition that the shareholders meeting approved the acquisition as a private offering whose purpose is to give the acquirer at least 25% of the voting rights in the company if there is no person who holds at least 25% of the voting rights in the company, or as a private offering whose purpose is to give the acquirer 45% of the voting rights in the company, if there is no person who holds 45% of the voting rights in the company; (ii) was from a shareholder holding at least 25% of the voting rights in the company, and resulted in the acquirer becoming a holder of at least 25% of the voting rights in the company; or (iii) was from a holder of more than 45% of the voting rights in the company and resulted in the acquirer becoming a holder of more than 45% of the voting rights in the company.

The special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror, and (ii) the special tender offer is accepted by a majority of the votes of those offerees who gave notice of their position in respect of the offer; in counting the votes of offerees, the votes of a holder in control of the offeror, a person who has personal interest in acceptance of the special tender offer, a holder of at least 25% of the voting rights in the company, or any person acting on their or on the offeror's behalf, including their relatives or companies under their control, are not taken into account.

In the event that a special tender offer is made, a company's board of directors is required to express its opinion on the advisability of the offer or must abstain from expressing any opinion if it is unable to do so, provided that it gives the reasons for its abstention.

An office holder in a target company who, in his or her capacity as an office holder, performs an action the purpose of which is to cause the failure of an existing or foreseeable special tender offer or is to impair the chances of its acceptance, is liable to the potential purchaser and shareholders for damages resulting from his acts, unless such office holder acted in good faith, and had reasonable grounds to believe he or she was acting for the benefit of the company. However, office holders of the target company may negotiate with the potential purchaser in order to improve the terms of the special tender offer, and may further negotiate with third parties in order to obtain a competing offer.

If a special tender offer was accepted by a majority of the shareholders who announced their stand on such offer, then shareholders who did not respond to the special offer or had objected to the special tender offer may accept the offer within four days of the last day set for the acceptance of the offer. In the event that a special tender offer is accepted, then the purchaser or any person or entity controlling it and any corporation controlled by them must refrain from making a subsequent tender offer for the purchase of shares of the target company and may not execute 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.

Full Tender Offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the issued and outstanding share capital of the company or of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the same class for the purchase of all of the issued and outstanding shares of the same class.

If the shareholders who do not respond to or accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class of the shares, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. A tender offer will also be deemed to be accepted if the shareholders who do not accept it hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of the shares.

Upon completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition the Israeli court to determine whether the tender offer was for less than fair value, and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may determine in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above, as long as, among other things, the offeror and the company disclosed the information required by law in connection with the full tender offer.

If the full tender offer was not accepted in accordance with any of the above alternatives, the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

Shares purchased in contradiction to the special or full tender offer rules under the Israeli Companies Law will have no rights and will become dormant shares.

Merger

The Israeli Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Israeli Companies Law are met, by simple majority of the outstanding shares of each party to the merger that are represented and voting on the merger.

The board of directors of a merging company is required pursuant to the Israeli Companies Law to discuss and determine whether in its opinion there exists a reasonable concern that, as a result of a proposed merger, the surviving company will not be able to satisfy its obligations towards its creditors, taking into account the financial condition of the merging companies. If the board of directors has determined that such a concern exists, it may not approve a proposed merger. Following the approval of the board of directors of each of the merging companies, the boards of directors must jointly prepare a merger proposal for submission to the Israeli Registrar of Companies.

In the event that shares of the target company are held by the acquiring company or by a person holding 25% or more of any type of controlling means of the acquiring company, the merger will not be approved if a majority of the shareholders of the target company attending and voting at the meeting at which the merger is considered (without taking into account, for that purpose, the shares held by the acquiring company or by a person holding 25% or more of any type of controlling means of the acquiring company) object to and do not vote in favor of the merger. If a person holds 25% or more of any type of controlling means of more than one merging company, the same provisions shall apply with regard to the shareholders' vote with respect to each such company. Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if the court concludes that there exists a reasonable concern that as a result of the merger the surviving company will be unable to satisfy the target company's obligations. Furthermore, a merger may not close unless at least 30 days have passed from the time that the general meeting of each of the merging companies was held and at least 50 days have passed from the date on which the merger proposal was sent to the Israeli Registrar of Companies.

Anti-takeover Measures

The Israeli Companies Law allows us to create and issue shares having rights different from those attached to our Ordinary Shares, including shares providing certain preferred or additional rights to voting, distributions or other matters and shares having preemptive rights. We do not have any authorized or issued shares other than Ordinary Shares. In the future, if we do create and issue a class of shares other than Ordinary Shares, such class of shares, depending on the specific rights that may be attached to them, may delay or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their Ordinary Shares. The authorization of a new class of shares will require an amendment to our articles of association which requires the prior approval of a majority of the shares represented and voting at a general meeting.

Exhibit 11.1

BRAINSWAY LTD.

INSIDER TRADING COMPLIANCE POLICY

This Insider Trading Compliance Policy (this "***Policy***") consists of five sections:

- Section I provides an overview;
- Section II sets forth the policies of the Company prohibiting insider trading;
- Section III explains insider trading;
- Section IV consists of procedures that have been put in place by the Company to prevent insider trading;
- Section V sets forth additional transactions that are prohibited by this Policy.

I. SUMMARY

Preventing insider trading is necessary to comply with securities laws and to preserve the reputation and integrity of Brainsway Ltd. (the "***Company***") as well as that of all persons affiliated with the Company. "Insider trading" occurs when any person purchases or sells a security while in possession of inside information relating to the security. As explained in Section III below, "inside information" is information that is both "material" and "non-public." Insider trading is a crime both under Israeli law and under U.S. federal laws. The penalties for violating insider trading laws include imprisonment, disgorgement of profits, civil fines, and significant criminal fines of up to $5 million for individuals and $25 million for corporations. Insider trading is also prohibited by this Policy, and violation of this Policy may result in Company-imposed sanctions, including termination of employment for cause.

This Policy applies to all officers, directors and employees of the Company, members of the Company's advisory board as well as any other person designated by the Chief Financial Officer who have access to material non-public information of the Company ("***Service Providers***"). Individuals subject to this Policy are responsible for ensuring that members of their households also comply with this Policy. This Policy also applies to any entities controlled by individuals subject to the Policy, including any corporations, partnerships or trusts (such entities, together with all officers, directors, employees and Service Providers of the Company, are referred to as the "***Covered Persons***"), and transactions by these entities should be treated for the purposes of this Policy and applicable securities laws as if they were for the individual's own account. This Policy extends to all activities within and outside an individual's Company duties. Every officer, director, employee and Service Provider must review this Policy. Questions regarding the Policy should be directed to the Company's Chief Financial Officer.

II. Statement of Policies Prohibiting Insider Trading

No officer, director, employee or Service Provider shall purchase or sell any type of security while in possession of material, non-public information relating to the security, whether the issuer of such security is the Company or any other company.

Additionally, no officer, director, employee or Service Provider shall purchase or sell any security of the Company during the period beginning on the 14th calendar day before the end of any fiscal quarter of the Company and ending upon the completion of the second full trading day in the U.S. (and the lapse of at least one trading day in Israel) after the public release of earnings data for such fiscal quarter or during any other trading suspension period declared by the Company. For the purposes of this Policy, a "trading day" is a day on which national stock exchanges are open for trading.

These prohibitions do not apply to:

- purchases of the Company's securities by a Covered Person from the Company or sales of the Company's securities by a Covered Person to the Company;
- exercises of stock options or other equity awards or the surrender of shares to the Company in payment of the exercise price or in satisfaction of any tax withholding obligations in a manner permitted by the applicable equity award agreement, or vesting of equity-based awards, that in each case do not involve a market sale of the Company's securities (the "cashless exercise" of a Company stock option through a broker does involve a market sale of the Company's securities, and therefore would not qualify under this exception);
- *bona fide* gifts of the Company's securities; or
- purchases or sales of the Company's securities made pursuant to any binding contract, specific instruction or written plan entered into outside of a black-out period and while the purchaser or seller, as applicable, was unaware of any material, non-public information and which contract, instruction or plan (i) meets all of the requirements of the affirmative defense provided by Rule 10b5-1 ("***Rule 10b5-1***") promulgated under the U.S. Securities Exchange Act of 1934, as amended (the "***1934 Act***") (with respect to trades on the U.S. public markets)("**U.S. Trading Plan**") or of a blind trust as defined under the Israeli Securities Law, 1968 (with respect to trades on the Tel-Aviv Stock Exchange)("**Israeli Trading Plan**" and together with the U.S. Trading Plan, the "**Trading Plan**"), (ii) was pre-cleared in advance by the Company's Chief Financial Officer (and in the case of a plan adopted by the Chief Financial Officer, by the Chief Executive Officer) and (iii) has not been amended or modified in any respect after such initial pre-clearance without such amendment or modification being pre-cleared in advance pursuant to this Policy.

No officer, director, employee or Service Provider shall directly or indirectly communicate (or "***tip***") material, non-public information to anyone outside of the Company (except in accordance with the Company's policies regarding the protection or authorized external disclosure of Company information) or to anyone within the Company other than on a need-to-know basis.

III. Explanation of Insider Trading

*"**Insider trading**"* refers to the purchase or sale of a security while in possession of "material," "non-public" information relating to the security or its issuer.

*"**Securities**"* includes stocks, bonds, notes, debentures, options, warrants and other convertible securities, as well as derivative instruments.

*"**Purchase**"* and *"**sale**"* are defined broadly under both the Israeli and the U.S. federal securities law. *"Purchase"* includes not only the actual purchase of a security, but any contract to purchase or otherwise acquire a security. *"Sale"* includes not only the actual sale of a security, but any contract to sell or otherwise dispose of a security. These definitions extend to a broad range of transactions, including conventional cash-for-stock transactions, conversions, the exercise of stock options, and acquisitions and exercises of warrants or puts, calls or other derivative securities.

It is generally understood that insider trading includes the following:

- trading by insiders while in possession of material, non-public information;
- trading by persons other than insiders while in possession of material, non-public information, if the information either was given in breach of an insider's fiduciary duty to keep it confidential or was misappropriated; and
- communicating or tipping material, non-public information to others, including recommending the purchase or sale of a security while in possession of such information.

Additionally, under Israeli regulations, when a Key Insider sells a company's securities within three months following the purchase of such securities, or alternatively, when a Key Insider purchases securities within three months following the sale of such securities, a rebuttable presumption arises that the Key Insider engaged in Insider Trading. A "Key Insider" is an officer or anyone who fills the position of an officer, a family member of an officer, a shareholder who holds 5% or more of the Company's securities or voting rights or can appoint at least one director, or a corporation controlled by any of them.

A. What Facts are Material?

The materiality of a fact depends upon the circumstances. A fact is considered "material" if there is a substantial likelihood that a reasonable investor would consider it important in making a decision to buy, sell or hold a security, or if the fact is likely to have a significant effect on the market price of the security. Material information can be positive or negative and can relate to virtually any aspect of a company's business or to any type of security, debt or equity.

Examples of material information include (but are not limited to) information about:

- corporate earnings or earnings forecasts;
- possible mergers, acquisitions, tender offers or dispositions;
- major new products or product developments;

- important business developments such as trial results, developments regarding strategic collaborators or the status of regulatory submissions;
- management or control changes;
- significant financing developments including pending public sales or offerings of debt or equity securities;
- defaults on borrowings;
- bankruptcies; and
- significant litigation or regulatory actions.

Moreover, material information does not have to be related to a company's business. For example, the contents of a forthcoming newspaper column that is expected to affect the market price of a security can be material.

A good general rule of thumb: **When in doubt, do not trade.**

B. What is Non-Public?

Information is "non-public" if it is not available to the general public. In order for information to be considered public, it must be widely disseminated in a manner making it generally available to investors through such media as Dow Jones, Business Wire, Reuters, The Wall Street Journal, Associated Press, or United Press International, a broadcast on widely available radio or television programs, publication in a widely available newspaper, magazine or news web site, or public disclosure documents filed with the SEC that are available on the SEC's web site.

The circulation of rumors, even if accurate and reported in the media, does not constitute effective public dissemination. In addition, even after a public announcement, a reasonable period of time must lapse in order for the market to react to the information. Generally, one should allow two full trading days following publication as a reasonable waiting period before such information is deemed to be public.

C. Who is an Insider?

"Insiders" include officers, directors, employees and certain third-party service providers of a company and anyone else who has access to material inside information about a company on or within six months prior to trading in the Company's securities. Insiders have independent fiduciary duties to their company and its stockholders not to trade on material, non-public information relating to the company's securities. All officers, directors, employees and Service Providers of the Company should consider themselves insiders with respect to material, non-public information about the Company's business, activities and securities. Officers, directors, employees and Service Providers may not trade in the Company's securities while in possession of material, non-public information relating to the Company, nor may they tip such information to anyone outside the Company (except in accordance with the Company's policies regarding the protection or authorized external disclosure of Company information) or to anyone within the Company other than on a need-to-know basis.

Individuals subject to this Policy are responsible for ensuring that members of their households also comply with this Policy. This Policy also applies to any entities controlled by individuals subject to the Policy, including any corporations, partnerships or trusts, and transactions by these entities should be treated for the purposes of this Policy and applicable securities laws as if they were for the individual's own account.

D. Trading by Persons Other than Insiders

Insiders may be liable for communicating or tipping material, non-public information to a third party ("***tippee***"), and insider trading violations are not limited to trading or tipping by insiders. Persons other than insiders also can be liable for insider trading, including tippees who trade on material, non-public information tipped to them or individuals who trade on material, non-public information that has been misappropriated.

Tippees inherit an insider's duties and are liable for trading on material, non-public information illegally tipped to them by an insider. Similarly, just as insiders are liable for the insider trading of their tippees, so are tippees who pass the information along to others who trade. In other words, a tippee's liability for insider trading is no different from that of an insider. Tippees can obtain material, non-public information by receiving overt tips from others or through, among other things, conversations at social, business, or other gatherings.

E. Penalties for Engaging in Insider Trading

Penalties for trading on or tipping material, non-public information can extend significantly beyond any profits made or losses avoided, both for individuals engaging in such unlawful conduct and their employers. The United States Securities and Exchange Commission ("***SEC***") and United States Department of Justice have made the civil and criminal prosecution of insider trading violations a top priority. Enforcement remedies available to the government or private plaintiffs under the U.S. federal securities laws include:

- SEC administrative sanctions;
- securities industry self-regulatory organization sanctions;
- civil injunctions;
- damage awards to private plaintiffs;
- disgorgement of all profits;
- civil fines for the violator of up to three times the amount of profit gained or loss avoided;
- civil fines for the employer or other controlling person of a violator (i.e., where the violator is an employee or other controlled person) of up to the greater of $1,525,000 (subject to adjustment for inflation) or three times the amount of profit gained or loss avoided by the violator;
- criminal fines for individual violators of up to $5,000,000 ($25,000,000 for an entity); and
- jail sentences of up to 20 years.

In Israel, the use of inside information may be a criminal offense and Israeli courts sentence violators of inside trading rules to jail sentences and to heavy fines.

In addition, insider trading could result in serious sanctions by the Company, including dismissal. Insider trading violations are not limited to violations of the Israeli or U.S. federal securities laws. Other U.S. federal, state and Israeli civil or criminal laws, such as the laws prohibiting mail and wire fraud and the Racketeer Influenced and Corrupt Organizations Act (RICO), also may be violated in connection with insider trading.

F. Size of Transaction and Reason for Transaction Do Not Matter

The size of the transaction or the amount of profit received does not have to be significant to result in prosecution. The SEC has the ability to monitor even the smallest trades, and the SEC performs routine market surveillance. Brokers and dealers are required by law to inform the SEC of any possible violations by people who may have material, non-public information. The SEC aggressively investigates even small insider trading violations.

G. Examples of Insider Trading

Examples of insider trading cases include:

- actions brought against corporate officers, directors, employees and third-party service providers who traded in a company's securities after learning of significant confidential corporate developments;
- friends, business associates, family members and other tippees of such officers, directors, employees and third-party service providers who traded in the securities after receiving such information;
- government employees who learned of such information in the course of their employment; and
- other persons who misappropriated, and took advantage of, confidential information from their employers.

The following are illustrations of insider trading violations. These illustrations are hypothetical and, consequently, not intended to reflect on the actual activities or business of the Company or any other entity.

Trading by Insider

An officer of X Corporation learns that earnings to be reported by X Corporation will increase dramatically. Prior to the public announcement of such earnings, the officer purchases X Corporation's stock. The officer, an insider, is liable for all profits as well as penalties of up to three times the amount of all profits. The officer also is subject to, among other things, criminal prosecution, including up to $5,000,000 in additional fines and 20 years in jail. Depending upon the circumstances, X Corporation and the individual to whom the officer reports also could be liable as controlling persons.

Trading by Tippee

An officer of X Corporation tells a friend that X Corporation is about to publicly announce that it has concluded an agreement for a major acquisition. This tip causes the friend to purchase X Corporation's stock in advance of the announcement. The officer is jointly liable with his friend for all of the friend's profits, and each is liable for all civil penalties of up to three times the amount of the friend's profits. The officer and his friend are also subject to criminal prosecution and other remedies and sanctions, as described above.

H. Prohibition of Records Falsification and False Statements

Section 13(b)(2) of the 1934 Act requires companies subject to the Act to maintain proper internal books and records and to devise and maintain an adequate system of internal accounting controls. The SEC has supplemented the statutory requirements by adopting rules that prohibit (1) any person from falsifying records or accounts subject to the above requirements and (2) officers or directors from making any materially false, misleading, or incomplete statement to any accountant in connection with any audit or filing with the SEC. These provisions reflect the SEC's intent to discourage officers, directors and other persons with access to the Company's books and records from taking action that might result in the communication of materially misleading financial information to the investing public.

IV. Statement of Procedures Preventing Insider Trading

The following procedures have been established, and will be maintained and enforced, by the Company to prevent insider trading. Every officer, director, employee and Service Provider is required to follow these procedures.

A. Pre-Clearance of All Trades by All Officers and Directors, and Certain Employees and Service Providers

To provide assistance in preventing inadvertent violations of applicable securities laws and to avoid the appearance of impropriety in connection with the purchase and sale of the Company's securities, **all transactions in the Company's securities (including without limitation, acquisitions and dispositions of Company stock, the exercise of stock options and the sale of Company stock issued upon exercise of stock options) by officers, directors and such other employees and Service Providers as are designated from time to time by the Board of Directors, the Chief Executive Officer or the Chief Financial Officer as being subject to this pre-clearance process (a "*Pre-Clearance Person*") must be pre-cleared** by the Company's Chief Financial Officer. Pre-clearance does not relieve anyone of his or her responsibility under SEC rules.

A request for pre-clearance may be oral or in writing (including without limitation by e-mail), should be made at least two business days in advance of the proposed transaction and should include the identity of the Pre-Clearance Person, the type of proposed transaction (for example, an open market purchase, a privately negotiated sale, an option exercise, etc.), the proposed date of the transaction and the number of shares or options to be involved. In addition, unless otherwise determined by the Chief Financial Officer, the Pre-Clearance Person must execute a certification (in the form approved by the Chief Financial Officer) that he, she or it is not aware of material, nonpublic information about the Company. The Chief Financial Officer shall have sole discretion to decide whether to clear any contemplated transaction (The Chief Executive Officer shall have sole discretion to decide whether to clear transactions by the Chief Financial Officer or persons or entities subject to this policy as a result of their relationship with the Chief Financial Officer). All trades that are pre-cleared must be effected within five business days of receipt of the pre-clearance unless a specific exception has been granted by the Chief Financial Officer (or the Chief Executive Officer, in the case of the Chief Financial Officer or persons or entities subject to this policy as a result of their relationship with the Chief Financial Officer). A pre-cleared trade (or any portion of a pre-cleared trade) that has not been effected during the five business day period must be pre-cleared again prior to execution. Notwithstanding receipt of pre-clearance, if the Pre-Clearance Person becomes aware of material, non-public information or becomes subject to a black-out period before the transaction is effected, the transaction may not be completed.

B. Black-Out Periods

Additionally, no officer, director, employee or Service Provider shall purchase or sell any security of the Company during the period beginning on the 14th calendar day before the end of any fiscal quarter of the Company and ending upon the completion of the second full trading day in the U.S. (and the lapse of at least one trading day in Israel) after the public release of earnings data for such fiscal quarter or during any other trading suspension period declared by the Company, except for purchases and sales made pursuant to the permitted transactions described in Section II.

Exceptions to the black-out period policy may be approved only by the Company's Chief Financial Officer (or, in the case of an exception for the Chief Financial Officer or persons or entities subject to this policy as a result of their relationship with the Chief Financial Officer, the Chief Executive Officer or, in the case of exceptions for directors or persons or entities subject to this policy as a result of their relationship with a director, the Board of Directors).

From time to time, the Company, through the Board of Directors, the Company's disclosure committee or the Chief Financial Officer, may recommend that officers, directors, employees, Service Providers or others suspend trading in the Company's securities because of developments that have not yet been disclosed to the public. Subject to the exceptions noted above, all of those affected should not trade in the Company's securities while the suspension is in effect, and should not disclose to others that the Company has suspended trading.

If the Company is required to impose a "pension fund black-out period" under Regulation BTR, each director and executive officer shall not, directly or indirectly sell, purchase or otherwise transfer during such black-out period any equity securities of the Company acquired in connection with his or her service as a director or officer of the Company, except as permitted by Regulation BTR.

C. Post-Termination Transactions

With the exception of the pre-clearance requirement, this Policy continues to apply to transactions in the Company's securities even after termination of service to the Company. If an individual is in possession of material, non-public information when his or her service terminates, that individual may not trade in the Company's securities until that information has become public or is no longer material.

D. Information Relating to the Company

1. *Access to Information*

Access to material, non-public information about the Company, including the Company's business, earnings or prospects, should be limited to officers, directors, employees and Service Providers of the Company on a need-to-know basis. In addition, such information should not be communicated to anyone outside the Company under any circumstances (except in accordance with the Company's policies regarding the protection or authorized external disclosure of Company information) or to anyone within the Company on an other than need-to-know basis.

In communicating material, non-public information to employees and Service Providers of the Company, all officers, directors, employees and Service Providers must take care to emphasize the need for confidential treatment of such information and adherence to the Company's policies with regard to confidential information.

2. *Inquiries From Third Parties*

Inquiries from third parties, such as industry analysts or members of the media, about the Company should be directed to the Chief Financial Officer.

E. Limitations on Access to Company Information

The following procedures are designed to maintain confidentiality with respect to the Company's business operations and activities.

All officers, directors, employees and Service Providers should take all steps and precautions necessary to restrict access to, and secure, material, non-public information by, among other things:

- maintaining the confidentiality of Company-related transactions;
- conducting their business and social activities so as not to risk inadvertent disclosure of confidential information. Review of confidential documents in public places should be conducted so as to prevent access by unauthorized persons;
- restricting access to documents and files (including computer files) containing material, non-public information to individuals on a need-to-know basis (including maintaining control over the distribution of documents and drafts of documents);
- promptly removing and cleaning up all confidential documents and other materials from conference rooms following the conclusion of any meetings;
- disposing of all confidential documents and other papers, after there is no longer any business or other legally required need, through shredders when appropriate;
- restricting access to areas likely to contain confidential documents or material, non-public information;
- safeguarding laptop computers, mobile devices, tablets, memory sticks, CDs and other items that contain confidential information; and

- avoiding the discussion of material, non-public information in places where the information could be overheard by others such as in elevators, restrooms, hallways, restaurants, airplanes or taxicabs.

Personnel involved with material, non-public information, to the extent feasible, should conduct their business and activities in areas separate from other Company activities.

3. *Limitation on Liability*

None of the Company, the Chief Financial Officer, the Authorizing Officer, the Company's other employees, the Company's other Service Providers or any other person will have any liability for any delay in reviewing, or refusal of, a request for pre-clearance submitted pursuant to Section IV of this Policy or a Trading Plan submitted pursuant to this Policy. Notwithstanding any review of pre-clearance of a transaction pursuant to Section IV of this Policy or a Trading Plan submitted pursuant to this Policy, none of the Company, the Chief Financial Officer, the Authorizing Officer, the Company's other employees, the Company's other Service Providers or any other person assumes any liability for the legality or consequences of such Trading Plan or transaction to the person engaging in or adopting such Trading Plan or transaction.

V. Additional Prohibited Transactions

The Company has determined that there is a heightened legal risk and/or the appearance of improper or inappropriate conduct if the persons subject to this Policy engage in certain types of transactions. Therefore, officers, directors, employees and Service Providers shall comply with the following policies with respect to certain transactions in the Company securities:

A. Short Sales

Short sales of the Company's securities evidence an expectation on the part of the seller that the securities will decline in value, and therefore signal to the market that the seller has no confidence in the Company or its short-term prospects. In addition, short sales may reduce the seller's incentive to improve the Company's performance. For these reasons, short sales of the Company's securities are prohibited by this Policy.

B. Publicly Traded Options

A transaction in options is, in effect, a bet on the short-term movement of the Company's stock and therefore creates the appearance that an officer, director, employee or Service Provider is trading based on inside information. Transactions in options also may focus an officer's, director's, employee's or Service Provider's attention on short-term performance at the expense of the Company's long-term objectives. Accordingly, transactions in puts, calls or other derivative securities involving the Company's equity securities, on an exchange or in any other organized market, are prohibited by this Policy.

C. Hedging Transactions

Certain forms of hedging or monetization transactions, such as zero-cost collars and forward sale contracts, allow an officer, director, employee or Service Provider to lock in much of the value of his or her stock holdings, often in exchange for all or part of the potential for upside appreciation in the stock. These transactions allow the officer, director, employee or Service Provider to continue to own the covered securities, but without the full risks and rewards of ownership. When that occurs, the officer, director, employee or Service Provider may no longer have the same objectives as the Company's other stockholders. Therefore, all hedging transactions involving the Company's equity securities are prohibited by this Policy.

D. Purchases of the Company's Securities on Margin; Pledging the Company's Securities to Secure Margin or Other Loans

Purchasing on margin means borrowing from a brokerage firm, bank or other entity in order to purchase the Company's securities (other than in connection with a cashless exercise of stock options through a broker under the Company's equity plans). Margin purchases of the Company's securities are prohibited by this Policy. Pledging the Company's securities as collateral to secure loans is prohibited. This prohibition means, among other things, that you cannot hold the Company's securities in a "margin account" (which would allow you to borrow against your holdings to buy securities).

E. Director and Executive Officer Cashless Exercises

The Company will not arrange with brokers to administer cashless exercises on behalf of directors and executive officers of the Company. Directors and executive officers of the Company may use the cashless exercise feature of their equity awards only if (i) the director or officer retains a broker independently of the Company, (ii) the Company's involvement is limited to confirming that it will deliver the stock promptly upon payment of the exercise price, (iii) the director or officer uses a cashless exercise arrangement, in which the Company agrees to deliver stock against the payment of the purchase price on the same day the sale of the stock underlying the equity award settles and (iv) the director or officer otherwise complies with this Policy. Under a cashless exercise, a broker, the issuer, and the issuer's transfer agent work together to make all transactions settle simultaneously. This approach is to avoid any inference that the Company has "extended credit" in the form of a personal loan to the director or executive officer. Questions about cashless exercises should be directed to the Chief Financial Officer.

F. Partnership Distributions

Nothing in this Policy is intended to limit the ability of a venture capital partnership or other similar entity with which a director is affiliated to distribute Company securities to its partners, members or other similar persons. It is the responsibility of each affected director and the affiliated entity, in consultation with their own counsel (as appropriate), to determine the timing of any distributions, based on all relevant facts and circumstances and applicable securities laws.

Exhibit 12.1

CERTIFICATION BY CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Hadar Levy, certify that:

1. I have reviewed this annual report on Form 20-F of BrainsWay Ltd.;

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; and

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 functions):

    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: April 21, 2025

/s/ Hadar Levy
Hadar Levy
Chief Executive Officer

Exhibit 12.2

CERTIFICATION BY CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ido Marom, certify that:

1. I have reviewed this annual report on Form 20-F of BrainsWay Ltd.;

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; and

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 functions):

    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: April 21, 2025

/s/ Ido Marom
Ido Marom
Chief Financial Officer

Exhibit 13

CERTIFICATION BY CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of BrainsWay Ltd. (the "Company") on Form 20-F for the year ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 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.

Dated: April 21, 2025

/s/ Hadar Levy
Hadar Levy
Chief Executive Officer

/s/ Ido Marom
Ido Marom
Chief Financial Officer

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements:

(1) Registration Statement (Form F-3 No. 333-280934) of Brainsway Ltd. and in the related Prospectus,

(2) Registration Statement (Form S-8 No. 333-230979) pertaining to the 2014 Share Incentive Plan of Brainsway Ltd.

of our reports dated April 21, 2025, with respect to the consolidated financial statements of Brainsway Ltd., and the effectiveness of internal control over financial reporting of Brainsway Ltd., included in this Annual Report (Form 20-F) of Brainsway Ltd. for the year ended December 31, 2024.

Tel Aviv, Israel
April 21, 2025

/s/ Kost Forer Gabbay & Kasierer
KOST FORER GABBAY AND KASIERER
A member of EY Global