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, 2020

OR

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

OR

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)

N/A
(Translation of Registrant's name into English)

Israel
(Jurisdiction of incorporation or organization)

19 Hartum Street, Bynet Building, 3rd Floor, Har HaHotzvim, Jerusalem, 9777518, Israel
(Address of principal executive offices)

Hadar Levy, Senior Vice President, General Manager North America and Interim Chief Financial Officer
300 Knickerbocker Road, Cresskill, New Jersey, 07626
Tel: +1-844-386-7001
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of 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
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None
(Title of Class)

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: 22,250,534 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 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. ☐

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. ☐

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 Financing 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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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 term "NIS" refers to New Israeli Shekels, the lawful currency of the State of Israel, the terms "dollar", "US$", "$" or "U.S." 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 April 16, 2021 ($1 = NIS 3.2810). 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.

The "BrainsWay" name and design logo are our registered trademarks. Solely for convenience, the trademarks, service marks, and trade names referred to in this Annual Report are without the ® and ™ 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.

This Annual Report includes statistics and other data relating to markets, market sizes, and other industry data pertaining to our business that we have 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. 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.

FORWARD-LOOKING STATEMENTS

Some of the statements under the sections entitled "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. In addition, the sections of this Annual Report entitled "Item 4. Information on the Company" contain information obtained from independent industry and other sources that we may not have independently validated. 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:

- the adequacy of our existing capital to meet our future capital requirements;
- market perception and acceptance of Deep Transcranial Magnetic Stimulation ("**Deep TMS**") technology;
- physician and patient satisfaction with the effectiveness, competitive advantages, and benefits of our Deep TMS system;
- availability of reimbursement from third-party payers, including insurance companies and Medicare;
- 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 regulatory approvals of Deep TMS and enhancements to our Deep TMS system on our anticipated time frames, or at all;
- our ability to comply with applicable regulatory approvals and requirements;
- 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 the COVID-19 global pandemic.

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

The following table sets forth our selected financial data, which is derived from our financial statements prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board. We have derived the selected financial data as of December 31, 2020, 2019, and 2018 and for the years ended December 31, 2020, 2019, and 2018 from our audited financial statements included elsewhere in this Annual Report on Form 20-F. You should read this selected financial data and other information provided in this Annual Report in conjunction with, and is qualified in its entirety by, our historical financial information including "Item 5. Operating and Financial Review and Prospects" and our financial statements and related notes appearing elsewhere in this Annual Report.

	Year Ended December 31		
	2020	2019	2018
Statements of Operations Data			
Revenues	$ 22,057	$ 23,101	$ 16,397
Cost of revenues	5,058	5,129	3,589
Gross profit	16,999	17,972	12,808
Research and development expenses, net	5,823	7,876	6,156
Selling and marketing expenses	11,283	13,269	8,345
General and administrative expenses	4,722	5,303	3,421
Total operating expenses	21,828	26,448	17,922
Total operating loss	4,829	8,476	5,114
Financial expenses, net	319	1,430	1,156
Loss before income taxes	5,148	9,906	6,270
Income taxes	237	422	209
Net loss	5,385	10,328	6,479
Basic and diluted net loss per share(1)	(0.24)	(0.50)	(0.39)
Weighted average number of Ordinary Shares outstanding – basic and diluted	22,453,025	20,506,202	16,640,446

(1) Basic loss per ordinary share and diluted loss per ordinary share are the same because outstanding options and warrants would be anti-dilutive due to our net losses in these periods.

	As of December 31 (U.S. Dollars, in thousands)		
	2020	2019	2018
Balance Sheet Data			
Cash, cash equivalents and short-term deposits	$ 17,182	$ 21,895	$ 9,069
Total assets	34,011	38,736	23,602
Total liabilities	14,377	14,516	16,650
Accumulated deficit	(77,294)	(71,909)	(61,581)
Total equity	19,634	24,220	6,952

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, before deciding to invest in our ordinary shares (the "Ordinary Shares") or our American Depositary Shares ("ADSs"). The risks and uncertainties described below in this annual report on Form 20-F for the year ended December 31, 2020 are not the only risks facing us. 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. In such case, you may lose all or part of your investment.

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.

- We have a history of operating losses. We expect to incur additional losses in the future and may never be profitable.
- We cannot ensure that our existing capital will be sufficient to meet our capital requirements.
- Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidate(s).
- Our success depends on Deep TMS as a treatment option for patients, as well as market perception and acceptance of TMS generally, and patient satisfaction with the effectiveness 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.
- 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.
- If we are unable to adequately train physicians and other treatment providers and operators on the safe and appropriate use of our Deep TMS systems, 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-party suppliers for some components used in manufacturing Deep TMS, and we may be unable to immediately transition to alternative parties for these components.
- We rely, and in the future, expect to rely on a network of third-party distributors to market and distribute our products internationally, and if we are unable to maintain and expand this network, we may be unable to generate anticipated revenues.
- 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 rely in part on third parties to conduct our clinical trials. If these third parties fail to perform their duties on time or as expected, we may not be able to obtain regulatory authorization for additional indications that we may seek for Deep TMS.
- Our collaboration arrangements may not be successful, which could adversely affect our ability to develop and commercialize our products.
- If product liability lawsuits are brought against us, our business may be harmed, and we may be required to pay damages that exceed our insurance coverage.
- Our insurance policies protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.
- Our operations could be affected by the COVID-19 global pandemic.
- Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.
- If we experience significant disruptions in our information technology systems, our business may be adversely affected.
- We rely on the use of technology and may become subject to cyber-terrorism or other compromises and shut-downs.
- 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, 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 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 could harm our business.
- We may not receive the necessary regulatory clearances or approvals to market our product for other proposed indications in the future, and failure to timely obtain necessary clearances or approvals for such future indications would adversely affect our ability to grow our business.
- Modifications to our Deep TMS systems may require new 510(k) clearances, de novo classification or PMA, and may require us to cease marketing or recall the modified products until authorizations are obtained.
- Our products must be manufactured in accordance with federal and state 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 authorization 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 recently enacted legislation reforming the U.S. healthcare system, could harm our cash flows, financial condition, and results of operations.
- 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 lives of our patents 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 results from in-license agreements with government agencies and research institutions, the termination of which would prevent us from commercializing Deep TMS.
- Our license agreements for our critical patents and related intellectual property impose significant monetary obligations and other requirements that may adversely affect our ability to successfully execute our business plan.
- 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.
- 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 may require us to spend substantial time and money and could prevent us from developing or commercializing Deep TMS.
- The Israeli government grants that we have received require us to meet several conditions and may restrict our ability to manufacture our Deep TMS systems and transfer relevant know-how outside of Israel and require us to pay royalties and satisfy specified conditions, 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.
- International patent protection is particularly uncertain, and if we are involved in opposition proceedings in foreign countries, we may have to expend substantial sums and management resources.
- Our manufacturing, assembly and other significant functions 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 revenues.
- The price of the ADSs may be volatile and may fluctuate due to factors beyond our control.
- The significant share ownership position of our officers, directors, and entities affiliated with certain of our directors may limit your ability to influence corporate matters.

Risks Related to our Financial Condition and Capital Requirements

We have a history of operating losses. We expect to incur additional losses in the future and may never be profitable.

We have incurred net losses since our inception, largely reflecting research and development, general and administrative expenses, and sales and marketing expenses. We have experienced net losses of $5.4 million and $10.3 million for the years ended December 31, 2020 and 2019, respectively. As a result of ongoing losses, as of December 31, 2020, we had an accumulated deficit of $77.3 million. While we have sold and leased Deep TMS systems in various markets over the last few years, primarily for Major Depressive Disorder (MDD) and recently also for Obsessive-Compulsive Disorder (OCD), we expect to continue to incur significant sales and marketing, product development, regulatory and other expenses as we continue to expand 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 indications, and to develop new enhancements or features to our existing Deep TMS systems. Furthermore, our general and administrative expenses increased following our offering of ADSs on The Nasdaq Global Market, or Nasdaq, in April 2019 due to the increased costs associated with being a public company in the United States. The net losses we incur may fluctuate significantly from period to period. We will need to generate additional revenues to achieve and sustain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. Our failure to achieve or maintain profitability could negatively impact the value of the ADSs.

We cannot ensure that our existing capital will be sufficient to meet our capital requirements.

We believe that our existing capital, other sources of liquidity will be sufficient to meet our capital requirements. To date we have funded our operations primary through offerings of our securities, research and development grants from the Israel Innovation Authority and other sources, a loan under our credit facility which has been repaid, and a Payment Protection Program loan through the Unites States Small Business Administration which has been forgiven. We expect to generate revenues primarily through sales and lease 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 of Deep TMS; our ability to improve or maintain coverage and reimbursement arrangements with third-party and government payers; 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 challenged.

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 ADSs. Additional 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 treatment option for patients, as well as market perception and acceptance of TMS generally.
Our business 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 or to Deep TMS in particular. For example, in June 2018 researchers in medical centers of the U.S. Veterans Affairs reported research findings that showed that approximately 40% of the 81 patients with treatment-resistant major depression achieved remission in a randomized trial of a competitor's TMS device, but the rate was virtually the same with sham treatments versus active stimulation. 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 all TMS solutions generally, which may adversely affect market adoption of 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. Additionally, psychiatrists may find it difficult 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. 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.

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 assure 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, OCD, and smoking addiction, develop and seek regulatory approvals of Deep TMS for new 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 existing treatments (e.g., anti-depressant medications), a growing number of Traditional TMS competitors, rapid technological changes, new product 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 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 or obtain regulatory clearances or approvals to market Deep TMS for new indications, or to develop and obtain regulatory approvals for enhancements or new features for the Deep TMS system. Additionally, Deep TMS for MDD, OCD, smoking addiction, and any future indications, even if cleared, might not be accepted by physicians or the third-party payers who reimburse for the procedures performed with our products. Our risk share pricing model to capture increased market share may also not be successful, and we may be unable to devise new pricing strategies that are attractive to customers. The success of any new indications, enhancements or features for the Deep TMS system will depend on numerous additional factors, including 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 indications, and obtain regulatory approvals of Deep TMS for such indications;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties; and
- develop and obtain the necessary regulatory clearances or approvals for enhancements or features for the Deep TMS system.

If we do not develop and obtain regulatory clearances or approvals for new indications, enhancements or features in time to meet market demand, or if there is insufficient demand for these indications, enhancements or features, 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 offer enhanced enhancements or features or would be 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 transition to indications, and we have limited experience in managing product transitions.

Our success also depends upon patient satisfaction with the effectiveness of Deep TMS.

In order to generate significant revenues from Deep TMS, patients must be satisfied with the effectiveness of Deep TMS. We train our physician customers to properly diagnose patient candidates and select the appropriate patient candidates for treatment using the Deep TMS system, explain to their patients the time-period over which the results from a treatment course can be expected to occur, and measure the success of treatments using medical guidelines. However, our physician customers may not properly diagnose or select appropriate patient candidates for Deep TMS treatment, which may produce results that do not meet patients' expectations. To the extent physicians do not make the proper measurements for a specific patient or use the same procedures at each treatment session, it could result in variability of the treatment efficacy and results for the patient. If patients are not satisfied with the results of Deep TMS, our reputation, and future results of operations may be adversely affected.

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, 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 of Deep TMS for indications that reach the market in a timely manner, to receive adequate coverage and reimbursement from third-party payers, 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, MAG & More, CloudTMS, Magstim, and Nexstim. Competing TMS therapy companies have developed or may develop treatments that can be administered for shorter time periods or may develop treatments that have improved efficacy when compared to our products or that require a less significant investment of resources from physicians. For instance, several Traditional TMS competitors have received FDA clearance for a TMS treatment protocol that can be administered within a shorter time period than the currently cleared protocol for Deep TMS. In addition, psychiatrists and other customers may not be able to easily compare Deep TMS to our focal TMS competitors given the limited data from head-to-head studies.

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 recently approved by the FDA for use in conjunction with an oral antidepressant) and to a lesser degree, ECT, 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.

In addition, our competitors may have more established distribution networks than we do, or may be acquired by enterprises that have more established distribution networks than we do. 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 more rapidly than we can, which could impair our ability to develop and commercialize similar products. 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 other 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.

Moreover, the potential for both TMS competitors or other medical device or pharmaceutical companies to introduce new and disruptive products or forms of therapy can significantly impact our financial performance and ability to compete.

If we are unable to adequately train physicians and other treatment providers and operators on the safe and appropriate use of our Deep TMS systems, 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.

We may be unable to forecast our future growth accurately.

We may be unable to predict future growth related to Deep TMS for MDD, 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. Primary care providers often prescribe anti-depressants without a psychiatric diagnosis of disease. In 73% of visits in which a primary care provider prescribed an anti-depressant, patients did not have a psychiatric diagnosis. Without a psychiatric diagnosis, treatment cannot be tailored to the underlying condition. Accordingly, a significant portion of MDD patients that are considered treatment-resistant may be unresponsive to first-line treatment as a result of incorrect diagnosis, and any such patients may not respond to Deep TMS treatment. In addition, the H-Coils for our Deep TMS systems may prove to be interchangeable 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, 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.

We may be unable to manage our anticipated growth effectively, which could make it difficult to execute our business strategy.

We have been growing rapidly and have a relatively short history of operating as a commercial-stage company. 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. We may be unable to maintain the quality, 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, 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 work force may not be sufficient to handle our expanding growth and we will be required to expand and train these 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.

If we are unable to successfully expand our sales and customer support team and adequately address our customers' needs, it could negatively impact revenues and market acceptance of Deep TMS and we may never generate sufficient revenues to achieve or sustain profitability.

As of December 31, 2020, we had 100 employees, including 26 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, to a lesser extent, on our independent third party distributors outside of the United States. If our employees or our independent distributors 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. We believe it is 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 and features 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 payers 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 payers.

Third-party payers 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, such as Deep TMS for OCD or for smoking addiction, which represent novel approaches to treatment of a disease, addiction, or condition. Even if a third-party payer 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 payer may depend upon a number of factors, including the third-party payer's determination that a treatment is neither experimental nor investigational, 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 payers, including private insurers. Therefore, coverage and reimbursement for treatments can differ significantly from payer to payer. However, many third-party payers 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 one to four 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 most 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: (a) failure of a trial of psychotherapy known to be effective in treating MDD without significant improvement in depressive symptoms and (b) one of the following:

(1) resistance to treatment with psychopharmacologic agents for depression, as evidenced by lack of clinically significant response to four trials of such agents, including at least two different agent classes and two augmentation trials,

(2) Inability to tolerate a therapeutic dose of medications as evidenced by four trials of psychopharmacologic agents with distinct side effects,

(3) History of good response to repetitive TMS in a previous depressive episode (at least three months since the prior episode), or

(4) 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.

Obtaining and maintaining adequate reimbursement of Deep TMS for OCD, for smoking addiction, or for any future indications, as applicable, may be difficult. Currently, there is no third-party coverage of Deep TMS as a treatment for OCD nor for smoking addiction, as payors that have evaluated Deep TMS for OCD coverage have not yet concluded that it is a reasonable and necessary therapy for OCD or for smoking addiction, respectively. We are working to gather and submit additional clinical data in order to sufficiently demonstrate the efficacy of Deep TMS for the treatment of OCD and smoking addiction. These efforts may be expensive and time-consuming. Therefore, it may take significant time to obtain sufficient reimbursement coverage of Deep TMS for OCD and 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 OCD, smoking addiction, or any other future indication for which we obtain authorization, if any.

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 payers 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, including Japan, have government-managed healthcare systems that govern reimbursement for psychiatric treatments and 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 payers outside of the United States, including Japan, 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 payers 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.

We rely on third-party suppliers for some components used in manufacturing Deep TMS, and we may be unable to immediately transition to alternative parties for these components.

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 now assemble our proprietary stimulator in our new-generation Deep TMS systems; however, we remain dependent on a single source third-party supplier for stimulators used in older versions of our Deep TMS system, and accordingly we must still rely on third-party suppliers for those older versions. In addition, we rely on the outsourcing company utilized for the manufacture of certain components in our newer systems, including our proprietary stimulator and 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 regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. While these suppliers have generally met our demand requirements on a timely basis in the past, their ability, and willingness to continue to do so going forward may be limited for several reasons, including our lack of long-term agreements with those suppliers, 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.

Any transition to a new supplier or contract manufacturer could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of Deep TMS or could require that we modify its design. 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 in a timely and cost-effective manner.

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 markets, including Japan, Europe, and various Middle Eastern, Central/South American, and Asian countries.

We are 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.

The sale, lease, and shipment of the Deep TMS system 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, 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:

- 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 payers 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, including export control laws and the U.S. Foreign Corrupt Practices Act of 1977 (FCPA), and anti-money laundering laws;
- 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;
- 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.

We rely and in the future expect to rely on a network of third-party distributors to market and distribute our products internationally, and if we are unable to maintain and expand this network, we may be unable to generate anticipated revenues.

We rely, and expect to rely in the future, on a network of third-party distributors 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. In addition, 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 these third-party distributors and 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 in a timely manner may damage our reputation and could cause us to lose potential customers.

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. 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 trials;
- delays 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 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 do not produce favorable results, our ability to obtain regulatory authorization for such indications may be adversely impacted, which will have a material adverse effect on our business, financial condition, and results of operations.

We rely in part on third parties to conduct our clinical trials. If these third parties fail to perform their duties on time or as expected, we may not be able to obtain regulatory authorization for additional indications that we may seek for Deep TMS.

Our clinical trials are managed by our both own staff and personnel as well as 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 in our clinical trials. 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 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.

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 technology 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. 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 not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results or may change their strategic focus due to the acquisition of competitive products,
- availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- 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;

- collaborators may not properly maintain or defend our intellectual property rights or may use 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;
- 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;
- our collaborators may default on their obligations to us and we may be forced to terminate, litigate, and/or renegotiate such arrangements;
- 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;
- 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.

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.

If product liability lawsuits are brought against us, our business may be harmed, and we may be required to pay damages that exceed our insurance coverage.

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture, and sale of medical devices for the treatment of MDD, OCD, smoking addiction, and other potential indications. Our treatments are designed for patients who suffer from significant psychiatric, 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

Regardless of the merit or eventual outcome, product liability claims may result in:

- decreased demand for Deep TMS;
- injury to our reputation and brand;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients;
- product recalls;
- material defense costs;
- loss of revenues;

- the inability to commercialize new indications, enhancements, or features; and
- diversion of management attention from pursuing our business strategy.

Our existing product liability insurance coverage may be inadequate to protect us from any liabilities we might incur. 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.

Our insurance policies protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include liability, public liability, employer's liability, property, third party liability, umbrella, workers' compensation, products and clinical trial liability, and directors' and officers' insurance. We do not know, however, if these policies will provide us with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

We bear the risk of warranty claims on our products.

We bear the risk of warranty claims on the products we supply, often for the entire contract term for systems which are leased either via the fixed lease or risk share models, and generally for 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 or that any recovery from such vendor or supplier would be adequate. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in 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 as strong a 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 by the COVID-19 global pandemic.

The COVID-19 global pandemic has led governments and authorities around the globe to take various precautionary measures in order to limit the spread of the COVID-19 global pandemic, including government-imposed quarantines, lockdowns, and other public health safety measures, which could have an adverse effect on the global markets and its economy, including on the availability and pricing of materials, manufacturing and delivery efforts, sales to existing and potential customers and leads, collections from accounts, and other aspects of the global economy. Therefore, the COVID-19 global pandemic could disrupt production and cause delays in the supply and delivery of products used in our operations, may further divert the attention and efforts of the medical community to coping with the COVID-19 global pandemic, impact our ability to recruit subjects for ongoing and planned clinical trials, and disrupt the marketplace in which we operate, and may have a material adverse effects on our operations, sales, revenues, collection from accounts and ability to raise funds. In particular, certain of our third-party suppliers may currently source certain components and materials of our Deep TMS systems from Asia and other countries, and the continued spreading of the COVID-19 global pandemic may adversely impact our third-party suppliers' development, manufacture, and supply of our Deep TMS systems. In addition, treatment sessions conducted with our Deep TMS system, which are generally scheduled or non-emergency procedures, may be postponed as hospitals and healthcare centers shift resources to patients affected by the COVID-19 global pandemic. The extent to which the COVID-19 global pandemic impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the COVID-19 global pandemic, and the actions to contain the COVID-19 global pandemic or treat its impact, among others. Moreover, the COVID-19 global pandemic has caused substantial adverse effects on general commercial activity and the world economy, and our business and results of operations could be adversely affected to the extent that this COVID-19 global pandemic or any other epidemic harms the global economy generally.

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

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our 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.

Our operations are vulnerable to interruption or loss due to natural or other disasters, power loss, strikes and other events beyond our control.

A major earthquake, fire, or other disaster, such as a major flood, seasonal storms, military action or terrorist attack affecting our facilities, or those of our third-party manufacturers or suppliers, could significantly disrupt our or their operations, and delay or prevent product shipment or installation during the time required to repair, rebuild or replace our third-party manufacturers or suppliers' damaged manufacturing facilities. These delays could be lengthy and costly. If any of our manufacturers', suppliers' or customers' facilities are negatively impacted by a disaster, shipments of our products could be delayed. Additionally, customers may delay purchases of our products until operations return to normal. Even if we are able to quickly respond to a disaster, the ongoing effects of the disaster could create some uncertainty in the operations of our business. Any shortages may increase our costs for power and energy supplies or could result in blackouts, which could disrupt the operations of our affected facilities and harm our business. In addition, concerns about terrorism, the effects of a terrorist attack, political turmoil or an outbreak of epidemic diseases could have a negative effect on our operations.

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

We depend on our information technology systems for the efficient functioning of our business 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 on the use of technology and may become subject to cyber-terrorism or other compromises and shut-downs.

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.

Security and privacy breaches may expose us to liability and harm our reputation and business.

As part of our business 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 store or contract with third parties to 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, 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 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 the federal and state governments. 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, 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:

- 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 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 the 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, including Dr. David Zacut, the chairman of our board of directors, Christopher R. von Jako, our president and chief executive officer, Hadar Levy, our senior vice president and general manager of North America operations, and Dr. Yiftach Roth, our chief scientist, 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. There is intense competition from numerous medical device, pharmaceutical, and biotechnology companies, universities, governmental entities, and other research institutions, 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 work place, discrimination, wage and hour, 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 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. 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.

We may not receive the necessary regulatory clearances or approvals to market our product for other proposed indications in the future, and failure to timely obtain necessary clearances or approvals for such future indications would adversely affect our ability to grow our business.

An element of our strategy is to continue to upgrade our Deep TMS systems, add new enhancements and features, and expand clearance or approval of the Deep TMS System to include new indications. In the United States, before we can market a new medical device, or claim new or expanded indications for use or introduce a significant modification to an existing product, we must first receive either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, *de novo* classification, or premarket approval application (PMA), from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to 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. 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.

We received marketing authorization of our MDD indication through the 510(k) clearance process and we have made changes to our system for the MDD indication through subsequent 510 (k) clearances. We received marketing authorization of our OCD indication through the *de novo* classification process, but will be permitted to make changes to our system for the OCD indication through subsequent 510(k) clearances. Competitors may seek 510(k) clearance of a TMS device for an OCD indication and use our *de novo* classification as a predicate device in their submission. 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 or PMA approval. 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 the 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 or PMA approvals 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, increase the costs of compliance or restrict our ability to maintain our current clearances. 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 a new administration that may have different policy priorities than the previous one.

In order to sell our products in member countries of the EEA, or in countries that also rely on the CE Mark outside the EEA, our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC), and with the Medical Device Regulation (Regulation 2017/745). 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 essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a Member State of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design, and final inspection of our devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE Mark 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 do 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.

Modifications to our Deep TMS systems may require new 510(k) clearances, de novo classification or PMA, and may require us to cease marketing or recall the modified products until authorizations are obtained.

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 last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials.

Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory 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.

The FDA requires every manufacturer to make this 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 have 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 federal and state 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.

We or our third-party suppliers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA or 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; 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.

Deep TMS system has been authorized for marketing by the FDA only for MDD, 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, 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 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, 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 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, 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 arrange for or recommend 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 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 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 such individuals 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 $11,665 to $23,331 per false or fraudulent claim or statement. 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 substantial settlements 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 health care 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 payers 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;

- HIPAA, which 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 payers, 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 PPACA which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the 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. Beginning in 2022, applicable manufacturers also will be 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, which imposes 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 payer, including commercial insurers or patients; state laws that require 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 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 in the United States (such as the EU, which adopted the General Data Protection Regulation, which became effective in May 2018); 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 have 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 recently have 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 health care fraud statute, and 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 recently enacted 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 Patient Protection and Affordable Care Act (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 have continued to evolve. Since taking office, President Trump has continued to support 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. Substantial uncertainty remains as to the future of the PPACA after the U.S. Supreme Court declined to expedite its review of the Fifth Circuit's holding on January 21, 2020. It is, thus, unlikely that these issues will be resolved before the next presidential election in November 2020. The current administration may seek to pass additional reform measures before the upcoming election. We cannot predict the outcome of the election, nor can we predict the healthcare-reform-related initiatives that the newly elected (or re-elected, as applicable) administration will put forth thereafter. There is no way to know whether, and to what extent, if any, the PPACA will remain in-effect in the future, and it is unclear how judicial decisions, subsequent appeals, election-related measures, or other efforts to repeal and replace or, possibly, to restore the PPACA will impact the U.S. healthcare industry or our business.

We cannot predict the impact that such actions against the PPACA will have on our business, and there is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the United States, or the effect of any future legislation or regulation. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval 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 intend to commercialize in the United States (or our products more specifically, if approved) or reduce medical procedure volumes could adversely affect our business plan to introduce our products in the United States.

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 becomes 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, and the FDA, as agencies of the PHS within the United States Department of Health and Human Services, or 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 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 the proprietary rights of others, and prevent others from infringing such 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 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, have made, use, or sell 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;
- 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 and technologies 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 will only extend to those countries in which we have 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, if any, as a result of our foreign patent applications will have the same scope of coverage as our 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.

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.

However, our business interests may change, or our licensees may disagree with the scope of our license grants. In such cases, such licensing arrangements may result in the development, manufacturing, marketing, and sale by our licensees 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 lives of our patents 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 life 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 is set to expire in 2024. See "Business—Intellectual Property." In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the United States Patent and Trademark Office (USPTO), this increase 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 results 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 or expire 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. 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 enforce our rights under any in-license would materially and adversely affect our ability to commercialize our Deep TMS.

Our license agreements for our critical patents and related intellectual property impose significant monetary obligations and other requirements 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. In addition, 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 provides for in-licensed rights to both a second family of patent applications and a third family of patent applications that covers additional characteristics of Deep TMS (including several Deep TMS coils and stimulators and methods of use), and we have commissioned research at the Weizmann Institute related to the Deep TMS under this agreement.

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, respectively, 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.

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.

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 our exclusive license 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 may require us to spend substantial time and money and could prevent us from developing or commercializing Deep TMS.

The development, manufacture, use, offer for sale, sale or importation of Deep TMS may infringe on the claims of third-party patents or 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. 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. 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 from engaging in normal operations and activities, including developing and 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.

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' 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.

International patent protection is particularly uncertain, and if we are involved in opposition proceedings in foreign countries, we may have to expend substantial sums and management resources.

Patent law outside the United States may be different than in the United States. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, if at all. 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.

Risks Related to Our Functions in Israel

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

Aspects of our business 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 including most recently, central 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 the raising of 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 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 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. These restrictions may materially limit our ability to sell our products 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 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.

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, we incur a significant portion of our expenses in currencies other than U.S. dollars, such as NIS. Likewise, our financial records are maintained in U.S. dollars, while many of our expenses are incurred in 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 Deep TMS 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 our personnel to perform military service.

A significant portion of our senior management and 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. Our operations could be disrupted by the absence for a significant period of time of one or more of these officers or key employees due to military service. Any such disruption could adversely affect our business, results of operations, and financial condition.

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. 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 have received require us to meet several conditions and may restrict our ability to manufacture our Deep TMS systems and transfer relevant know-how outside of Israel and require us to pay royalties and satisfy specified conditions, 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. 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. 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, and restrict 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 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 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 is subject to receipt of 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 IIA's rules and guidelines and the Innovation Law (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, reports on income derived from products developed using grants from the IIA and in certain circumstances, reports regarding change in the holding and change in 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 which it claims incorporate technology funded via IIA programs, and this may lead to additional royalties being payable on additional product candidates. In addition, 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 for IIA Funded Know-how without the approval of the IIA, and we cannot be certain that it 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.

In August 2015, a new amendment to the Innovation Law was enacted, or Amendment No. 7, which came into effect on January 1, 2016. Since Amendment No. 7 has entered into force, the IIA was appointed to act as the entity which is responsible for the activity which was previously under the OCS' responsibility. The IIA was granted wide freedom of action, and among other things, the authority to amend the requirements and restrictions which were specified in the Innovation Law before Amendment No. 7 became effective with respect to the ownership of Funded Know-How (including with respect to the restrictions on transfer of the Funded Know-How and manufacturing activities outside of Israel), as well as with respect to royalty payment obligations which apply to companies that receive grants from the IIA. Although the IIA's published rules which for the most part adopted the principal provisions and restrictions in effect in the Innovation Law prior to the effectiveness of Amendment No. 7, we are unable to assess the effect on our business of any future rules which may be published by the IIA.

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. Members of our current senior management and directors 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. See "Enforceability of Civil Liabilities" for additional information on your ability to enforce civil claim against us and our senior management and directors.

Provisions of our articles of association and 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. 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 for the company 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 for 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 set at 23% in 2018 and thereafter. 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 be continued 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—Tax Benefits Under the 2017 Amendment" 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 our 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, respectively, may fluctuate significantly due to a variety of factors, including:

- 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 our officers, directors, and entities affiliated with certain of our directors 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 18.5% of our outstanding ordinary shares as of April 19, 2021. Accordingly, these persons 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' significant interest in us may discourage third parties from seeking to acquire control of us, which may adversely affect the market price of our ordinary shares.

Holders of ADSs are not treated as holders of our ordinary shares.

Holders of ADSs are not treated as holders of our ordinary shares, unless they withdraw the ordinary shares underlying their ADSs in accordance with the deposit agreement and applicable laws and regulations. The depositary is the holder of the ordinary shares underlying the ADSs. Holders of ADSs therefore do not have any rights as holders of our ordinary shares, other than the rights that they have pursuant to the deposit agreement. See "Description of American Depositary 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 "Description of American Depositary Shares."

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.

ADSs 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.

You 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 your 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 our 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 intend to pay dividends for at least the next several years

We do not anticipate paying any cash dividends for at least the next several years. 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 "Dividend Policy."

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade the ADSs, the price of the ADSs could decline.

The trading market for the ADSs will rely in part 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. 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 $33^1/3\%$ 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 two or more shareholders, having 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. 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) approval of 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) approval of 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. In addition, under the Companies Law, a merger requires approval of the shareholders of each of the merging companies; and

- as permitted by the Israeli Companies Law, our board of directors selects director nominees, and we do not have a written charter or board resolution addressing the nominations process. Directors are not selected, or recommended for board of director selection, by independent directors constituting a majority of the board's independent directors or by a nominations committee comprised solely of independent directors as required by the Nasdaq Listing Rules.

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. See "Management—Foreign Private Issuer and Controlled Company Status."

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 (including disclosures with respect to executive compensation), 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 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 we 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 either directly or indirectly owned of record 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 cost we would 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 after we no longer qualify as an emerging growth company, we may 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 anticipate that we may 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.

Any future changes in the laws and regulations affecting public companies in the United States and Israel, including Section 404 and other provisions of the Sarbanes-Oxley Act, the rules and regulations adopted by the SEC, and the rules of the Nasdaq, will result in increased costs to us as we respond to such changes.

As an "emerging growth company," as defined in the JOBS Act, we take advantage of certain temporary exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act (and the rules and regulations of the SEC thereunder). When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with them. We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs.

Pursuant to Section 404 of the Sarbanes-Oxley Act and the related rules adopted by the SEC and the Public Company Accounting Oversight Board, starting with the next annual report that we file with the SEC, our management will be required to report on the effectiveness of our internal control over financial reporting. In addition, once we no longer qualify as an "emerging growth company" under the JOBS Act and lose the ability to rely on the exemptions related thereto discussed above and depending on our status as per Rule 12b-2 of the Exchange Act, our independent registered public accounting firm may also need to attest to the effectiveness of our internal control over financial reporting under Section 404. We have not yet commenced the process of determining whether our existing internal controls over financial reporting systems are compliant with Section 404 and whether there are any material weaknesses or significant deficiencies in our existing internal controls. This process will require the investment of substantial time and resources, including by our chief financial officer and other members of our senior management. As a result, this process may divert internal resources and take a significant amount of time and effort to complete. In addition, we cannot predict the outcome of this determination and whether we will need to implement remedial actions in order to implement effective controls over financial reporting. The determination and any remedial actions required could result in us incurring additional costs that we did not anticipate, including the hiring of outside consultants. Irrespective of compliance with Section 404 of the Sarbanes-Oxley Act, 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 or are required to do so earlier than anticipated, 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.

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.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies may make the ADSs less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various requirements that are applicable to other public companies that are not "emerging growth companies." Most of such requirements relate to disclosures that we would only be required to make if we also ceased to be a foreign private issuer in the future, for example, the requirement to hold shareholder advisory votes on executive and severance compensation and executive compensation disclosure requirements for U.S. companies. However, as a foreign private issuer, we could still be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. We are exempt from such requirement for as long as we remain an emerging growth company, which may be up to five fiscal years after the date of our initial public offering on Nasdaq in April 2019. We will remain an emerging growth company until the earliest of: (a) the last day of our fiscal year during which we have total annual gross revenues of at least $1.07 billion; (b) December 31, 2024 (the last day of our fiscal year following the fifth anniversary of the closing of our initial public offering on Nasdaq); (c) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act. We may choose to take advantage of some or all of the available exemptions. When we are no longer deemed to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act discussed above. We cannot predict if investors will find the ADSs less attractive as a result of our reliance on exemptions under the JOBS Act. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs, and our share price may be more volatile.

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.

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. 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. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of the ADSs.

Our management will be required to assess the effectiveness of our internal controls and procedures and disclose changes in these controls on an annual basis. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an "emerging growth company" for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

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 do not believe that we are currently a PFIC, and we do not anticipate becoming a PFIC in the foreseeable future. Notwithstanding the foregoing, 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 limited liability company that was incorporated under the laws of the State of Israel in November 2006. We completed our initial public offering on the TASE in January 2007, and in April 2019 we completed the listing of our ADSs on The Nasdaq Global Market. Our ordinary shares are currently listed on the TASE under the symbol "BWAY", and our ADSs are currently listed on The Nasdaq Global Market under the symbol "BWAY". Our Israel-based principal executive offices are located at 19 Hartum Street, Bynet Building, 3rd Floor, Har HaHotzvim, Jerusalem 9777518, Israel, and our telephone number is +972-2-582-4030. We also have U.S. offices located in New Jersey and Boston. Our registered agent in the United States is Brainsway USA, Inc. The address of Brainsway USA, Inc. is 300 Knickerbocker Road, Cresskill, New Jersey, 07626.

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 ordinary shares have been traded on the TASE since January 4, 2007, and our ADSs have been traded on The Nasdaq Global Market since April 16, 2019. On February 25, 2021 we closed a follow-on underwritten public offering of ADSs with gross proceeds of approximately $45.2 million.

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, 2020, 2019, and 2018 were approximately $2.5 million, $3.3 million and $2 million respectively. Our current capital expenditures primarily involve purchase of equipment and system components.

B. Business Overview

We are a commercial stage medical device company focused on advancing neuroscience to improve health and transform lives. We are engaged in the development and commercialization of noninvasive neurostimulation products using our proprietary Deep Transcranial Magnetic Stimulation (Deep TMS) technology for the treatment of major depressive disorder (MDD), obsessive-compulsive disorder (OCD), and smoking addiction, for which we have received marketing authorization from the U.S. Food and Drug Administration (FDA). We have also received CE Mark for these as well as for a variety of other psychiatric and neurological indications. 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. We sell our Deep TMS system for the treatment of MDD and OCD and are currently launching a controlled market release for the treatment of smoking addiction. 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.

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 17.3 million individuals in the United States suffer from a major depressive episode within a given year. Based on 2006-2007 data from the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) study, we estimate that approximately 5.7 million adult MDD patients in the United States are considered treatment-resistant (i.e., do not benefit from anti-depressant medication), of which we estimate that approximately 3.4 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 is the price per treatment session used in our risk share pricing model), we believe our total annual addressable market opportunity for MDD in the United States is approximately $8 billion.

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 2.24 million adults in the United States suffer from OCD annually. Of these people, we estimate approximately 820,000 patients have sought treatment for OCD and approximately 410,000 are considered treatment-resistant. Assuming a course of treatment per patient of 29 treatment sessions and a price paid to us per treatment session of $70 (which is the price per treatment session used in our risk share pricing model), we believe our total annual addressable market opportunity for OCD in the United States is approximately $800 million.

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). Approximately 34 million U.S. adults smoke cigarettes, of which 68% state they want to quit and 55% actually attempted to quit in 2018. Of those attempting to quit, 5.4 million made a serious attempt to quit (i.e. using medication). Only 15-20% of those making serious attempts to quit via mediation were successful, leaving approximately between 4.3 and 4.6 million adults who made serious attempts to quit via medication who were unsuccessful. Assuming a course of treatment per patient of 18 treatment sessions, and even 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 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.

In addition to our FDA clearance of Deep TMS for MDD, 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.

In addition, 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 that provides for an opportunity to develop additional Deep TMS products for a variety of psychiatric, neurological and addiction disorders. We are planning multicenter trials for other indications, including multiple sclerosis (MS), which would be our first neurological indication, and various other addiction disorders beyond smoking addiction.

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. 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, available after one to four failed (inadequate response or intolerable) trials of anti-depressant medications. In addition, our MDD treatment with Deep TMS is eligible for reimbursement from Medicare, and is expected to be available after one to four failed trials of psychopharmacologic agents (such as anti-depressant medications). Reimbursement is not yet generally available for Deep TMS for OCD or smoking addiction. We are actively engaged in efforts to obtain coverage for Deep TMS for OCD treatment based on the novelty of the technology, unmet clinical need and the efficacy and safety profile of the treatment, and plan to seek reimbursement for smoking addiction as our commercialization efforts for that indication progress.

The United States is our primary and most strategic market, representing approximately 88% of our revenues for the year ended December 31, 2020. 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, 2020, we generated revenues of $22.1 million, a decrease of 4.5% compared to the year ended December 31, 2019.

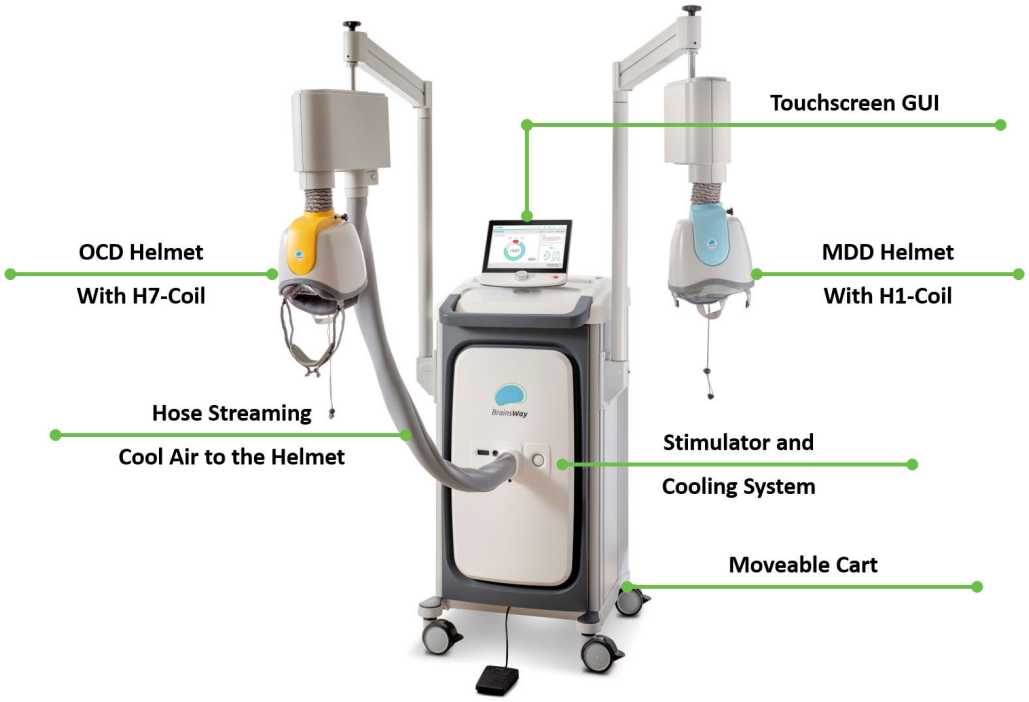
Our Deep TMS Platform

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 one H-Coil that is used in our Deep TMS system for MDD, another H-Coil for that is used for OCD, and another H-Coil used for smoking addiction. Some of our H-Coils are also able to potentially 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 now also include newer systems with our proprietary stimulator. In addition, we are currently developing a next generation multichannel stimulator allowing for simultaneous modulation of different areas of the brain with independent stimulation parameters, thus potentially enabling more flexible and effective treatment of various brain disorders, which we believe would make our Deep TMS systems even more attractive to clinicians, researchers and patients. This innovation is potentially well-positioned for use in neurology indications.

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 (not pictured).

- 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 system has many advantages relative to other TMS products currently on the market. 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. 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 utilize what we refer to as Traditional TMS, which generally utilizes a variation of the 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, some Traditional TMS systems attach the coil 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, and thus failing to achieve 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 comes into contact with the figure 8 coil. Traditional TMS is limited to the narrow area treated, and the manual placing 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 33% 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. The protocol for OCD also requires a short provocation procedure (i.e., triggering of OCD symptoms), 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 1.1 centimeters, Deep TMS creates a magnetic field with a slower and more gradual deterioration that reaches depths from the cortical surface of approximately 1.8 centimeters for BrainsWay's MDD coil, approximately 3.5 centimeters for BrainsWay's OCD coil and approximately 1.5 centimeters for BrainsWay's smoking addiction coil. Studies have also shown that BrainsWay's MDD coil has the capacity for total stimulated brain volume of 17 cm^3 compared to 3 cm^3 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 training protocol also includes instruction on addressing specific obsessions and compulsions.

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, OCD, and smoking addiction.***

  We are the only manufacturer of a TMS device to have been FDA-cleared for three indications based on clinically proven efficacy which was demonstrated in pivotal studies conducted on the device: MDD, which was FDA-cleared in 2013, OCD, which was classified by FDA as a Class II device in a *de novo* classification in August 2018, and smoking addiction, which was cleared for short term treatment in August 2020. For MDD, we are one of only two TMS companies that have performed clinical studies supporting the FDA clearance. For OCD, we are one of only two TMS companies to have devices which are FDA-cleared for this indication, but we are the only company to have received such clearance based on clinical data from a pivotal study on the device. For smoking addiction, we are the first and only TMS company to have received FDA clearance for the treatment of any addiction.

- ***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 that will 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. 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.

- ***We have a commercial track record for MDD, are ramping up commercialization for OCD, and launching a controlled market release for smoking addiction.***

  We have an established commercial footprint in the United States for Deep TMS for MDD, including our own sales, marketing, and support employees at our U.S.-based subsidiary. 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 may be eligible for reimbursement from Medicare. We are also currently selling Deep TMS for MDD in Europe, Mexico, Israel, and certain other countries. We are also increasing our commercialization efforts for Deep TMS for OCD. We believe that our installed base of Deep TMS systems for MDD will facilitate faster expansion into OCD because clinicians who already have a Deep TMS system only need to lease an add-on arm and helmet to the existing system. We are currently working to obtain insurance reimbursement coverage for OCD in the United States. We are currently working on the launch of a controlled market release of our system for the treatment of smoking addiction to be followed by a limited market release to a broader subset of customers. These two phases of the smoking addiction launch will allow the company to properly prepare for full market introduction of the therapy.

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

  We operate commercially utilizing three basic pricing models for our products: (i) a fixed-fee lease model enabling unlimited use; (ii) a leasing risk share model requiring a pay-per-use fee, which often applies beyond a defined minimum fee; and/or (iii) a sales model. Warranty and support are either included (in varying degrees and for varying periods) or may be purchased as part of all pricing models. For Deep TMS for MDD, we offer customers all three pricing models. For Deep TMS for OCD, we generally offer customers either a fixed-fee lease model as part of a combined offering with MDD, or a pay per use fee model. As part of our launch of a controlled market release of Deep TMS for smoking, we plan to offer customers either a fixed-fee lease model or a sales model. We believe these 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.

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

  Deep TMS 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 the targeted brain region. We are planning trials for opioid addiction, and other neurological indications. We were selected to be one of eight participants, out of over 250 applications, in the FDA Innovation Challenge: Devices to Prevent and Treat Opioid Use Disorder. Furthermore, in March 2019, the FDA granted our system a Breakthrough Device Designation for the Treatment of Opioid Use Disorder. The Breakthrough Devices Program is intended by the FDA to help patients have more timely access to medical devices which may provide more effective treatment of life-threatening or irreversibly debilitating diseases or conditions. As a result of these developments, all of our regulatory submissions for the planned opioids addiction study will be subject to priority review by senior FDA officials. Furthermore. In August 2020, we received 510(k) clearance from the FDA for our Deep TMS for its use as an aid in short-term smoking cessation in adults.

Our Strategy

We are currently focused on expanding the commercialization of Deep TMS with respect to the two indications that have FDA marketing authorization, MDD and OCD. Simultaneously, we recently received a 510(k) clearance from the FDA for the Company's Deep TMS system for its use as an aid in short-term smoking cessation in adults, due to our completed pivotal multicenter trial for this indication. 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 a multichannel stimulator allowing for simultaneous modulation of different areas of the brain, as well as pursuing personalized treatment solutions allowing for providers to customize ideal treatment approaches for each patient.

Specific elements of our strategy include the following:

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

  We are continuing to scale up our commercialization of Deep TMS for MDD as we seek to further penetrate the MDD market. 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 commenced full-scale commercialization of Deep TMS for OCD, which is first noninvasive medical device FDA-authorized for the treatment of OCD, pending reimbursement coverage for this indication. In addition, we launched a controlled market release of Deep TMS for smoking addiction, which is currently the only noninvasive medical device FDA-authorized for the treatment of smoking addiction.

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

  We are working to expand the application to other areas as well such as forms of addictions, targeting first opioid addictions, as well as neurological indications such as MS. 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 payer 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 and for smoking addiction, which were granted marketing authorization in the United States, and we are also working to obtain reimbursement in other jurisdictions.

- ***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, we are currently developing a novel multichannel stimulator which is designed to target multiple brain regions simultaneously with independent stimulation parameters, thus potentially enabling more flexible and effective treatment of various brain disorders. These developments include the novel technology of rotational field TMS which involves the operation of two orthogonal coils to induce a rotating field in the brain. This method can stimulate neurons in various orientations, and we believe may potentially increase the efficacy of our technology in various applications. We further believe these enhancements hold the potential to make Deep TMS even more efficient 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, and Israel, and pursue commercialization in additional markets, such as Japan and various Asian countries. We currently have exclusive distribution agreements in Japan, South Korea, Taiwan, Thailand, the Philippines, Ecuador, India, the United Arab Emirates, and Costa Rica.

  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. We are working through our Japanese distributor with the relevant bodies in Japan to update the local society guidelines to include Deep TMS in order to obtain such coverage.

  In Israel, we directly provide operations for our customers.

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 12 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 and the NIMH, an estimated 300 million people worldwide including 17.3 million individuals in the United States develop a major depressive episode within a given year. We estimate that there are 57 million depression patients in India, 55 million in China, 25 million in Europe, and 5 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 and 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). 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. 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.

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. This means that there is still a significant number of patients who could benefit from an alternative treatment such as Deep TMS.

Side effects are one of the most commonly cited reasons for patients terminating the use of anti-depressants. The most troubling side effects resulting from long-term anti-depressant use are insomnia, weight gain, and sexual dysfunction. 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.

TMS has been used as an anti-depressant therapy since 2008. Currently, TMS for MDD is only recommended for treatment-resistant MDD patients, and payers typically require that patients fail three or more anti-depressant medications prior to receiving TMS. However, research has shown that TMS is also effective in treating depressive symptoms in patients who fail one to two anti-depressant medications. 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. 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 reaction 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 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. 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.

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 MDD 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 MDD coil 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:

- Anti-depressant medication-free (following washout period)
- Failure to respond to one to four anti-depressant trials or not tolerant of at least two anti-depressant 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.

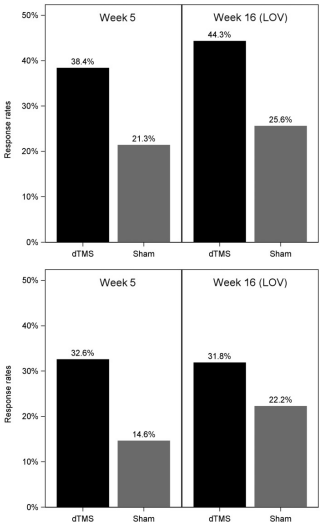
(b) Trial Results

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).

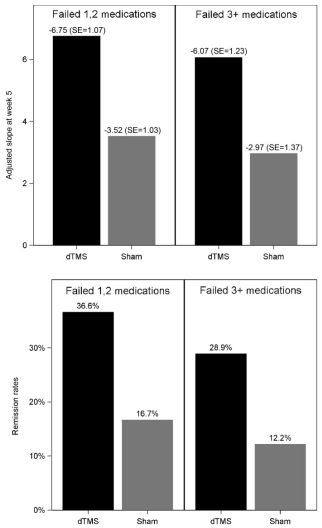
Figure 1. Response and Remission Rates for Deep TMS and Sham Groups at Week 5 and Week 16



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 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.

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 suffer from OCD sometime during their lifetime. According to the National Institute of Mental Health, approximately 1% of the adult population in the United States suffered from OCD in the past year. Based on these data, we estimate that approximately 2.24 million adults in the United States suffer from OCD annually. Of these people, we estimate approximately 820,000 patients have sought treatment for OCD, and approximately 410,000 are treatment resistant. Of that population, 50.6% of cases are characterized had 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 anti-depressant 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 anti-depressant 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 anti-depressant medication. For many patients EX/RP is the add-on treatment of choice when anti-depressant 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 anti-depressant 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 anti-depressant medications, due to their side effects, often lead to cessation of treatment by the patient and as a result, relapse of OCD symptoms.

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 BrainsWay OCD) 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. BrainsWay OCD 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 anti-depressant 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.

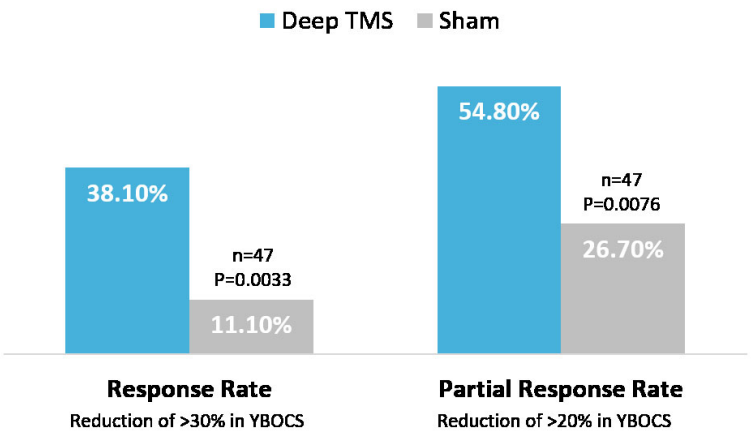
The primary endpoint measure was the Yale-Brown Obsessive Compulsive Scale (YBOCS), which is a score ranging from 0 to 40, with higher scores indicating greater severity of OCD symptoms. The secondary efficacy endpoint measures were response rate at weeks 6 and 10, partial response rate at weeks 6 and 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 ($p = 0.0076$).

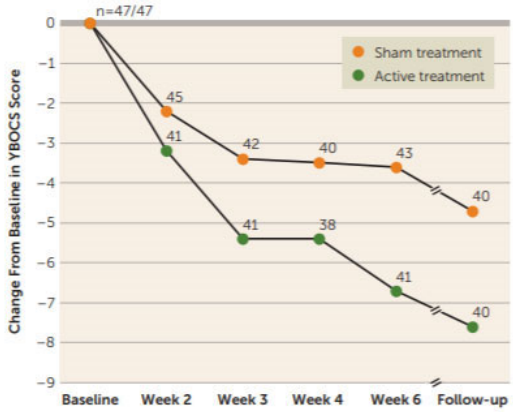
Figure 3. Response and Partial Response Rates for Deep TMS and Sham Treatment Groups



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.

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 us 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.

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 anti-depressant 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.

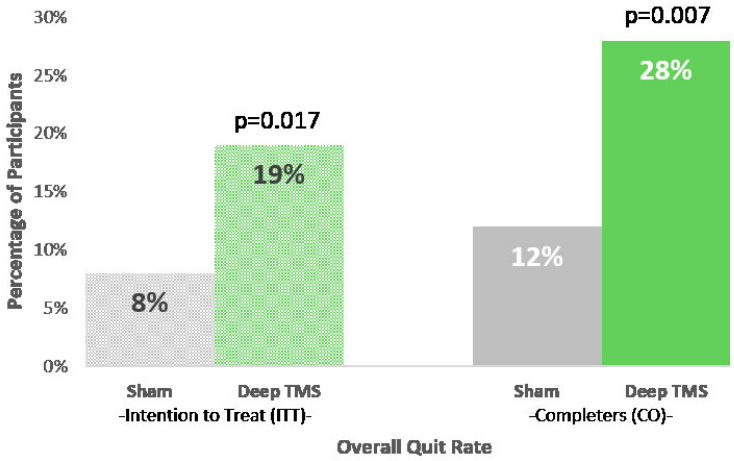
The trial was a randomized, double-blind, multicenter study designed to evaluate the safety and efficacy of Deep TMS treatment as an aid in reducing cigarette smoking in individuals suffering from chronic smoking addiction. It was conducted at 14 sites, primarily in the U.S., and enrolled 262 eligible subjects randomized into two groups: an active treatment group treated with our proprietary H4 coil targeting addiction-related brain circuits, and a sham (placebo) 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 dTMS and sham groups, within the ITT-E and completers (CO) cohorts.

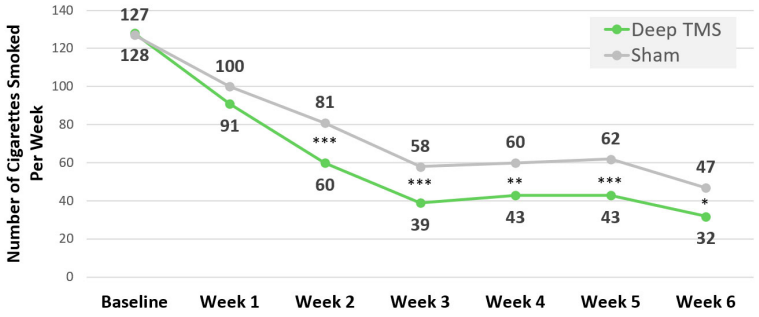
Figure 5. Overall 4-week Continuous Quit Rates for Deep TMS and Sham Treatment Groups



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 dTMS and sham group is significant starting from week 2.

Figure 6. 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 88% of our revenues for the year ended December 31, 2020. 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, sale, support, and logistics independently in the United States. As of December 31, 2020, we had 42 U.S. employees, including 24 sales and marketing employees, and 16 management, administration, and operation employees at our U.S.-based subsidiary.

In the United States, we sell or lease Deep TMS systems by one of the following 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 up to 54 months, for unlimited use; (ii) a risk share model (variable fees) in which the Deep TMS system is leased to a customer which pays fees based on the number of treatments (i.e., usage based fees), often beyond a contractually defined minimum amount; and (iii) a sales model in which the Deep TMS system is sold to the customer for a fixed purchase price, with additional potential revenue from annual warranty paid for the system for each year subsequent to the expiration of the standard warranty for the first year. These three models are designed to facilitate market penetration by addressing the differing clinical needs and risk tolerance among our customer base. While the lease and sales models enable unlimited use of the system by the customer in exchange for higher committed revenues, the risk share model allows for a lower market entry price with higher potential upside to us for customers that exceed the contracted minimum usage amount.

As of December 31, 2020, approximately 47% of our Deep TMS systems installed base for MDD utilized the fixed-fee lease model, approximately 43% utilized the sales model, and approximately 10% utilized our risk share model. We commercialize Deep TMS for OCD based either on the risk share model, which charges per session and per treatment, or based on a fixed lease model as part of a combined offering with our MDD system.

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.

After installation of our system, we offer high quality service, technical support, and repair to customers. Customers leasing the device (whether fixed lease or risk share model lease) 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.

Outside of the United States

Approximately 12% of our revenues for the year ended December 31, 2020 was 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 only via the purchase model, although we lease some of our Deep TMS systems in France and Israel. Our primary focus is on selling to hospitals, medical centers and clinics dealing with the treatment of psychiatric neurological and addiction illnesses and disorders.

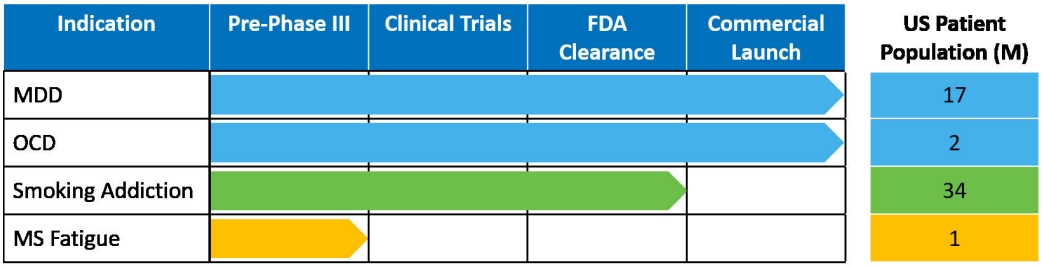
Our non-U.S. sales are managed both by our internal team in Israel and by local agents in various countries. In Israel, we do not use a distributor and our sales team distributes directly to our customers. We have exclusive distribution agreements in Japan, South Korea, Thailand, Taiwan, the Philippines, Ecuador, India, the United Arab Emirates, and Costa Rica, and are seeking new distribution partners for other strategic markets. Under our distribution agreements, the distributor typically receives an exclusive right to commercialize the Deep TMS 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. We are working through our Japanese distributor with the relevant bodies in Japan in an effort to update the local society guidelines to include Deep TMS in order to obtain such coverage.

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 are fatigue in MS, addictions (for example, opioid addiction and/or alcohol addiction) and potentially additional indications in neurology. The U.S. patient population for MS is approximately 1 million.

We have conducted double-blind, placebo-controlled trials evaluating Deep TMS for post stroke rehabilitation Alzheimer's disease (in Israel and Italy), autism spectrum disorders such as Asperger syndrome (in Australia), alcohol addiction (in Israel and Sweden), attention deficit hyperactivity disorder (ADHD) (in Israel), Parkinson's disease (in Israel and Italy), and chronic neuropathic pain (in Japan, Italy, France, and Norway). We believe further clinical study in these and other potential indications could pave the way for marketing authorizations for new indications in the United States and expand the potential for treatment to a wider range of patients. 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.

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 we develop and commercialize will be, subject to intense competition. Our Deep TMS system for MDD competes with existing anti-depressant 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, although faces less direct competition as we are one of only two FDA-cleared TMS products for this indication. 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 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. Our competitors compete with us on the basis of efficacy and safety, regulatory approvals, price and availability of reimbursement from third-party payers, ease of use/administration of the treatment option, reputation, and market trends. Key competitive factors affecting the commercial success 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 reimbursement.

Competitors that sell other forms of TMS therapy for MDD include Neuronetics, Magventure, Magstim, MAG & More, Cloud TMS, and Nexstim, that compete directly with us. Their systems are based on Traditional TMS coils and are generally FDA-cleared for MDD only, although Magventure has a non-clinical trials based FDA clearance for OCD, and there is one other company (eNeura) that is marketing a device that is FDA-cleared for treating pain associated with migraine headaches using single-pulse TMS. By contrast, our unique Deep TMS H-Coils are designed to address a number of different brain disorders. Other than Magventure, none of our competitors in the MDD market is currently FDA-cleared for an OCD indication, and we are the only company currently with marketing authorizations for MDD, OCD, and the treatment of smoking addiction.

We also face competition from pharmaceutical and other companies that develop competitive products, such as anti-depressant medications (including but not limited to a nasal spray utilizing the drug esketamine which was recently 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. In addition, we may face competition from ketamine, which is used as an anesthetic to treat a variety of brain disorders. 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. At any time, these and other potential market entrants may develop treatment alternatives that may render our products uncompetitive or less competitive.

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

In addition, we may face competition in the future from other noninvasive treatments for MDD. 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, 2020, we have received grants from the IIA in an aggregate amount of approximately $12.8 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, 2020, we have paid royalties to the IIA in an aggregate amount of approximately $2.6 million (including amounts in respect of accrued interest), with remaining outstanding royalties of up to $12.5 million.

In addition, we received from MAGNET approvals for grants in an aggregate amount of NIS 8.2 million (approximately $2.5 million based on the NIS to USD exchange rate as of December 31, 2020). 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-based operations team. 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 and at our US warehouses. 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 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. Magstim (UK) has historically supplied us with stimulators, and it is anticipated that they will continue to be used a source for older generation systems which do not include our newer FDA-cleared stimulator.

In order to mitigate against 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. To date, we have not experienced material delays in obtaining any of our components, nor has the ready supply of finished products to our customers or clinicians been adversely affected by 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 requires compliance of said manufacturing process with the ISO 13485 standard, 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 anti-depressant medications. In addition, our MDD treatment with Deep TMS is eligible for reimbursement from Medicare, and is expected to be available after one to four failed trials of psychopharmacologic agents (such as anti-depressant 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. Deep TMS for OCD is not currently eligible for reimbursement. However, there is currently an out-of-pocket market for our Deep TMS systems for OCD, and we are working to broaden the scope of reimbursement coverage for Deep TMS to include OCD treatment, based on a demonstration of the reasonableness and necessity of the treatment through clinical data. 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.

The sales 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 payers, such as government health care programs (e.g., Medicare), private insurance, and managed healthcare organizations. Even if a third-party payer 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 payers 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 payer may depend upon a number of factors, including the third-party payer's determination that a treatment is: neither experimental nor investigational; safe, effective, and medically necessary; appropriate for the specific patient; cost-effective; supported by peer reviewed medical journals; and included in clinical practice guidelines.

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 anti-depressant medications).

In the United States, there is no uniform policy of coverage and reimbursement among private third-party payers. Reimbursement rates from private payers vary depending on the procedure performed, the commercial payer, contract terms, and other factors. Private third-party payers 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 generally requires three to four failures of anti-depressant medications.

Coverage and reimbursement for treatments can differ significantly from payer to payer. 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 payer's determination to provide coverage for a specific treatment does not assure that other payers 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 payers, 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 only treatments using our Deep TMS system for MDD, and do not currently cover our Deep TMS therapy for OCD, smoking addiction, or therapies currently under development for other indications. We are actively working to broaden the scope of reimbursement coverage for Deep TMS therapy to include OCD based on the novelty of the technology, unmet clinical need and the demonstrated efficacy and safety profile of the treatment. We believe that our recent FDA marketing authorizations of Deep TMS for OCD and smoking addiction will help us to obtain reimbursement for those indications. We are actively engaged in efforts to obtain coverage for Deep TMS for OCD treatment based on the novelty of the technology, unmet clinical need and the efficacy and safety profile of the treatment, and plan to seek reimbursement for smoking addiction as our commercialization efforts for that indication progress. However, we can provide no assurance that we can obtain reimbursement coverage for either of those indications, 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 coverages in the United States and in other jurisdictions in which we operate. In regions where we have appointed a local distributor, usually it is an obligation of the distributor under the distribution agreement to obtain reimbursement coverage for Deep TMS in the relevant territory on our behalf. For example, through our Japanese distributor, we recently obtained regulatory approval with the PMDA in Japan, which is a precondition to receiving reimbursement coverage under the Japanese National Health Insurance Plan. We are working through our Japanese distributor with the relevant bodies in Japan to update the local society guidelines to include Deep TMS in order to obtain such coverage.

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.

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.

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, 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. 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 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 our proprietary stimulator.

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 payers play a primary role in the recommendation, prescription, and payment for medical treatments. A medical device manufacturer's arrangements with third-party payers, 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 payers, 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 $11,181 to $22,363 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 health care 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. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payers 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;

- 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 payers, 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 also will be 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 payers, 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 health care 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 have continued to evolve. Since taking office, President Trump has continued to support 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. Substantial uncertainty remains as to the future of the PPACA after the U.S. Supreme Court declined to expedite its review of the Fifth Circuit's holding on January 21, 2020. We cannot predict the healthcare-reform-related initiatives that the newly elected Biden administration will put forth. There is no way to know whether, and to what extent, if any, the PPACA will remain in-effect in the future, and it is unclear how judicial decisions, subsequent appeals, or other efforts to repeal and replace or, possibly, to restore the PPACA will impact the U.S. healthcare industry or our business.

We cannot predict the impact that such actions against the PPACA will have on our business, and there is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the United States, or the effect of any future legislation or regulation. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval 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 intend to commercialize in the United States (or our products more specifically, if approved) or reduce medical procedure volumes could adversely affect our business plan to introduce our products in the United States.

Outside of the United States

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. 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 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, 2020, we had 100 employees, of which 42 are based in the United States and 58 are based outside of the United States (in Israel). This includes 26 employees in sales and marketing (including 24 in the United States) and 26 employees in clinical trials and research and development.

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 not involved in any material legal proceedings.

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

We have offices in the United States and Israel.

In Israel, we have leased offices in Jerusalem, Israel, Since November 2007, pursuant to a lease agreement that expires in September 2022. The facility contains approximately 1,505 square meters of space, and lease payments and management fees are approximately $30,000 plus value added tax, or VAT, per month, in the aggregate, and are paid in NIS. This facility houses various administrative functions, as well as research operations and our central laboratory. Substantially all of our Israeli-based employees are based in this facility We also lease a warehouse and storage area within the same building as our Jerusalem offices pursuant to a lease addendum subject to a term (also expiring in September 2022) comprised of approximately 280 square meters, and subject to monthly fees in the amount of approximately $2,500 plus VAT in the aggregate, paid in NIS.

In the United States, our corporate offices have been located in New Jersey since April 2016. We currently have offices in Cresskill, N.J and Boston, MA. serving as the base for many of our growing U.S. based sales, marketing and logistics workforce. Our Cresskill, NJ offices occupy a space comprised of approximately 2,326 square feet pursuant to a lease with a current term expiring (unless extended) on June 30, 2021, and our Boston offices are located at a shared office space in the Burlington section of the Greater Boston Area.

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

We are a commercial stage medical device company focused on the development and sale of noninvasive neuromodulation products using our proprietary Deep Transcranial Magnetic Stimulation (Deep TMS), technology for the treatment of major depressive disorder (MDD), obsessive-compulsive disorder (OCD), and smoking addiction, for which we have received marketing authorization from the U.S. Food and Drug Administration (FDA). Deep TMS uses magnetic pulses to stimulate neurons and consequently modulates the physiological activity of the brain.

Our 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 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 system received FDA marketing authorization in August 2018 as an adjunct therapy for adult patients suffering from OCD, and we are currently market and sell that indication. In addition, our third Deep TMS system received FDA marketing authorization in August 2020 as a short-term therapy for smoking addiction. Our sales and marketing efforts are currently focused in the United States, where we generated approximately 88% of our revenues in the year ended December 31, 2020.

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 also planning multicenter trials for other indications, including fatigue in multiple sclerosis (MS), which would be the first neurological indication that we plan to advance into multicenter trials, and possibly other addictions such as opioids use disorder, cocaine addiction, and/or alcohol use disorder.

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. A standard MDD, OCD, or smoking addiction session lasts 20, 19, and 18 minutes, respectively. 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 have been reported.

In the United States, we sell or lease Deep TMS systems by one of the following 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 up to 54 months, for unlimited use; (ii) a risk share model (variable fees) in which the Deep TMS system is leased to a customer which pays fees based on the number of treatments (i.e., usage based fees), often beyond a contractually defined minimum amount; and (iii) a sales model in which the Deep TMS system is sold to the customer for a fixed purchase price, with additional potential revenue from annual warranty paid for the system for each year subsequent to the expiration of the standard warranty for the first year. These three models are designed to facilitate market penetration by addressing the differing clinical needs and risk tolerance among our customer base. As of December 31, 2020, approximately 47% of our Deep TMS systems installed base for MDD utilized the fixed-fee lease model, approximately 43% utilized the sales model and approximately 10% utilized our risk share model. We commercialize Deep TMS for OCD based generally on either the risk share model, which charges per session and per treatment, or as part of a fixed-fee lease model together with our MDD system, in an effort to achieve greater market acceptance for that indication. We are in the process of launching a controlled release of Deep TMS for smoking addiction and plan to focus on fixed-fee and sales business models for this indication.

As of December 31, 2020, we had an installed base of approximately 629 Deep TMS systems, whereby 359 systems were leased from us (inclusive of our fixed fee model and our risk share model), and an additional 270 systems were sold by us prior to December 31, 2020. Our installed base increased by 36 systems during the fourth quarter of 2020. In addition, as of December 31, 2020, we had shipped 216 OCD 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, 2020, our revenues were $22.1 million compared to $23.1 million for the year ended December 31, 2019, representing a decrease of 4.5% over the revenues generated in 2019. We incurred net losses of $5.4 million for the year ended December 31, 2020.

As of December 31, 2020, our total committed payments under signed lease contracts was approximately $25.6 million, assuming no exercise of any early termination options, representing an increase of $3.8 million from our total committed payments as of December 31, 2019 of approximately $21.8 million.

As of December 31, 2020, we had an accumulated deficit of $77.3 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, and the lease and sale of our products.

We expect our research, development, and clinical trials expenses to increase in connection with our ongoing activities, particularly as we continue to pursue future FDA clearance for our planned clinical trials for fatigue in MS, various addictions (for example, opioid addiction and/or alcohol addiction) and potentially additional indications in neurology. In addition, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing, and distribution. On February 25, 2021 we closed a follow-on underwritten public offering of ADSs with gross proceeds of approximately $45.2 million before deducting underwriting discount and commissions and offering expenses. We believe that our existing cash resources will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months. However, we may need additional funding to support the continuation of our operating activities.

Components of Our Results of Operations

Revenues

We derive our revenues from the lease and sale of our Deep TMS systems. For Deep TMS for MDD, we offer three different pricing models:

- *Fixed-fee Lease Model:* The customer leases the Deep TMS system and pays a fixed annual fee (which in some cases increases annually) for an unlimited number of treatments for the term of the lease (generally up to 54 months). The pricing of the annual fee generally assumes three (3) to four (4) treatments per day.

- *Risk Share Model:* The customer leases the Deep TMS system and the customer pays a variable fee based on the higher of: fees per treatment (i.e., usage based fees) or any defined contractual minimum fee. As in the fixed-fee lease model, these leases generally have a term of up to 54 months.

- *Sales Model:* The Deep TMS system is sold to the customer for a fixed purchase price. We also offer annual service warranty for the system that may be provided after the expiration of the standard warranty for additional fees.

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 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 include a significant component of depreciation of the Deep TMS systems, due to the fact that we maintain ownership of our systems under our fixed-fee lease and risk share model, in which we lease the system for use by our customers, rather than sell it outright. We expect to continue to own our Deep TMS systems under our fixed-fee lease and risk share model for the foreseeable future, which allows us to maintain our relatively low cost of revenues.

In the case of the Deep TMS systems that we sell under our sales model, the entire cost of the Deep TMS system is recognized upon such sale. 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. 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). Consequently, we believe that our cost of revenues with respect to system components will decrease.

The cost of revenues for systems that we lease or sell also include 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.

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, share-based compensation for employees, and facility costs. Other significant sales and marketing costs include conferences, trade shows, and promotional and marketing activities, including direct and online marketing, practice support programs, media campaigns and travel expenses.

We anticipate an increase in the headcount of our commercial organization as we continue to expand our business in the United States and internationally, and as we receive the relevant regulatory clearances for additional indications for our system. As a result, we expect our sales and marketing expenses to continue to increase.

Research and development expenses, net

Research and development expenses, net, consist primarily of personnel expenses, including salaries and related benefits, share-based compensation for employees, facility costs, laboratory materials, regulatory costs, patents, 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 near future as we advance the development of our Deep TMS technology for the treatment of new indications, which may include fatigue in MS, and other potential psychiatric, neurological, and addiction indications, as well as for various hardware and software development projects related to the Deep TMS system. As a result, we expect our research and development expenses to continue to increase.

A portion of our investment in research and development is funded by participation of the IIA through grants which are presented net of research and development expenses.

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, professional services, including legal and accounting fees as well as administrative costs, including corporate facility costs.

We anticipate that our general and administrative expenses will increase due to planned expansion of our activities. We anticipate higher corporate infrastructure costs including, but 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 increased director and officer insurance premiums, as a result of becoming a public company in the United States.

Finance expenses, net

Our finance expenses, net, consist primarily of expenses related to bank charges, and the amortization of deferred financing costs related to our finance expense with respect to the fair value re-measurement related to our outstanding liability to the IIA on account of grants received for financing our research and development activity, as well as interest income earned on our bank deposits 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 years ended December 31, 2020 and 2019, we did not record an income tax benefit related to our current and carryforward losses for tax purposes as a valuation allowance was established for all deferred tax assets as utilization is not probable due to our cumulative net loss position.

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 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:

Revenue Recognition

We generate revenues from the sale and lease of our systems. We sell products mainly to end users and to a lesser extent, to third-party distributors outside of the United States and do not provide return rights. We typically have post-sale obligations of training and installation of our systems and may provide an annual service warranty for the Deep TMS system after the expiration of the standard warranty. Revenues for such services are deemed distinct performance obligations and are recognized when the services are performed. Revenue recognized from these services has been insignificant for the reported periods.

Revenue from sale of systems are recognized at the point in time when control of the system is transferred to the customer, generally upon delivery of the system to the customer.

We generate lease revenue from (i) a fixed-fee lease model in which the Deep TMS system is leased to a customer for a fixed annual fee, generally for a term of up to 54 months, allowing for unlimited use; and (ii) a risk share model, or a variable fee, in which the Deep TMS system is leased to a customer who pays based on the number of treatments conducted on the system (i.e., usage based fees), often beyond a contractually defined minimum amount. Leases in which substantially all the risks and rewards incidental to ownership of the leased asset are not transferred to the lessee are classified as operating leases. Revenues from operating leases are recognized on a straight-line basis over the lease term. Usage based fees are recognized as revenue when the Company is entitled to receive such revenue.

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.

The Company records an allowance for doubtful accounts based on expected credit losses for trade receivables. The allowance rates are based on days past due for its various customers. The allowance is initially based on the Company's 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.

Royalty Bearing Governmental 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 IIA and repayable to the IIA through royalty-bearing sales are recognized upon receipt as a liability if future economic benefits are expected to be derived through estimated future cash flows from the research project, resulting in royalty bearing sales due to the IIA.

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 recorded as a reduction of the liability.

If no economic benefits are expected from the research activity, the grant 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 each reporting date, the Company evaluates whether there is reasonable assurance that the liability recognized, in whole or in part, will not be repaid 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.

Grants received from the IIA prior to January 1, 2009, which are recognized as a liability, are accounted for as forgivable loans in accordance with IAS 20, based on the original terms of the loan.

Share-based compensation

Share-based compensation reflects the compensation expense of our stock option programs granted to employee and other service providers, in which the compensation expense is measured at the grant date fair value of the options. The grant date fair value of share-based compensation is recognized as an expense over the requisite service period, net of estimated forfeitures. We recognize compensation expense for awards conditioned only on continued service that have a graded vesting schedule using the accelerated method and classify these amounts in our statement of comprehensive loss based on the department to which the related employee/service provider reports.

Options Valuation

We selected the Binomial Lattice option-pricing model as the most appropriate method for determining the estimated fair value of the shared-based compensation. For the purpose of the evaluation of the fair value, and the manner of the recognition of share-based compensation, our management is required to estimate, among others, various subjective parameters that are included in the calculation of the fair value of the option, as well as our results and the number of options that will vest. These parameters include the expected volatility of our share price over the expected term of the options, the risk-free interest rate assumption, forfeitures behaviors and expected dividends.

Fair value of ordinary shares. Since our ordinary shares have traded on the TASE since 2007, and our ADSs have traded on The Nasdaq Global Market since 2019, we have a market price per share of our ordinary shares and ADSs. Until September 30, 2018, the exercise price for the options was determined based on the average price per share over the 30 trading days on TASE prior to the grant date. Subsequent to September 30, 2018, the exercise price for the options was determined based on the average price per share over the 90 trading days on TASE prior to the grant date plus a premium of 10%, and for options granted to U.S. residents, the exercise price for the options was determined based on the greater of (i) average price per share over the 90 trading days on TASE prior to the grant date plus a premium of 10% or (ii) the last closing price per share on TASE prior to the actual grant dates.

Volatility. The expected volatility of the price of our ordinary shares reflects the assumption that the historical volatility of the share prices on the TASE is reasonably indicative of expected future trends.

Risk-free interest rate. The risk-free interest rate is based on observed interest rates appropriate for the expected term of the options granted in dollar terms.

Expected term. The expected term of options granted is derived from the output of the option valuation model and represents the period of time the options are expected to be outstanding.

Expected dividend yield. We have never declared or paid any cash dividends and we do not plan to pay cash dividends in the foreseeable future.

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
	2020				2019				2018			
Statements of operations	U.S. dollars in thousands											
Revenues	4,157	4,820	6,014	7,066	5,182	5,695	5,932	6,292	3,605	3,726	4,294	4,772
Cost of revenues	1,015	992	1,485	1,566	1,158	1,376	1,153	1,442	697	862	925	1,105
Gross profit	3,142	3,828	4,529	5,500	4,024	4,319	4,779	4,850	2,908	2,864	3,369	3,667
Research and development expenses, net	1,795	1,041	1,411	1,576	1,792	2,362	1,913	1,809	1,711	1,270	1,353	1,822
Selling and marketing expenses	3,713	2,178	2,393	2,999	2,838	3,278	3,549	3,604	1,881	1,907	2,028	2,529
General and administrative expenses	1,255	824	1,311	1,332	1,003	1,380	1,492	1,428	733	691	929	1,068
Total operating expenses	6,763	4,043	5,115	5,907	5,633	7,020	6,954	6,841	4,325	3,868	4,310	5,419
Total operating loss	3,621	215	586	407	1,609	2,701	2,175	1,991	1,417	1,004	941	1,752
Finance expenses, net	(309)	179	210	239	236	672	344	178	(415)	741	508	322
Loss before income taxes	3,312	394	796	646	1,845	3,373	2,519	2,169	1,002	1,745	1,449	2,074
Income taxes (tax benefit)	130	177	170	(240)	62	100	113	147	25	81	28	75
Net loss and comprehensive loss	3,442	571	966	406	1,907	3,473	2,632	2,316	1,027	1,826	1,477	2,149

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, 2020 compared to year ended December 31, 2019

Revenues

Our total revenues decreased by $1 million, or 4.5%, from $23.1 million for the year ended December 31, 2019 to $22.1 million for the year ended December 31, 2020. The decrease in revenues was attributed mainly to the effect of COVID-19, despite our ongoing and steady strategic decision to shift our sales and marketing focus to the lease and risk share models, Revenues from leases (inclusive of our fixed-fee model and risk share model) were 62% of the revenues for the year ended December 31, 2020, compared to 57% of the revenues for the year ended December 31, 2019.

Cost of revenues and gross margin

Our cost of revenues was $5.1 million for each of the years ended December 31, 2019 and 2020. There has been no material change in our gross margin for the last three years.

Research and development expenses, net

Our research and development expenses, net, were $5.8 million for the year ended December 31, 2020 compared to $7.9 million for the year ended December 31, 2019. The decrease of $2.1 million, or 26%, was mainly attributed to the Company's efforts to enhance efficiency, given the financial impact of the pandemic.

Selling and marketing expenses

Our selling and marketing expenses were $11.3 million for the year ended December 31, 2020 compared to $13.3 million for the year ended December 31, 2019. The decrease of $2 million, or 15%, is in-line with the Company's efforts to enhance efficiency, as well as to lower operational expenses given the financial impact of the pandemic.

General and administrative expenses

Our general and administrative expenses were $4.7 million for the year ended December 31, 2020 compared to $5.3 million for the year ended December 31, 2019. The decrease in response to the impact of COVID-19 on our business, we initiated a cash preservation program in late March 2020 with the goal of increasing efficiency and managing spend without impeding our growth efforts. This program largely continued throughout 2020.

Finance expenses, net

Our finance expenses, net, were $0.3 million for the year ended December 31, 2020 compared to $1.4 million for the year ended December 31, 2019. The decrease of $1.1 million, or 78%, was mainly attributed to the exchange rate differences and the fair value re-measurement in 2019 related to our outstanding liability to the IIA on account of grants received for financing our research and development activity.

Year ended December 31, 2019 compared to year ended December 31, 2018

For comparison of fiscal year 2019 to fiscal year 2018 please see "Management's Discussion and Analysis of Financial Condition and Results of Operations - Year ended December 31, 2019 compared to year ended December 31, 2018" section in our annual report on form 20-F filed with the SEC on March 23, 2020.

B. Liquidity and Capital Resources

Overview

As of December 31, 2020, we had cash, cash equivalents and short-term deposits of $17.2 million and an accumulated deficit of $77.3 million, compared to cash and short-term deposits of $21.9 million, and an accumulated deficit of $71.9 million as of December 31, 2019. We incurred negative cash flows from operating activities of $7.2 million and $1.4 million for the years ended December 31, 2019 and 2020, respectively. We have incurred operating losses since our inception, and we anticipate that our operating losses will continue in the near term as we seek to expand our sales and marketing initiatives to support our growth in existing and new markets, and invest funds in additional research and development activities. 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, 2020, we raised $84 million from placements of our ordinary shares and exercise of options.

We expect our revenues and expenses to increase in connection with our ongoing activities, particularly as we expand the marketing of our Deep TMS system for MDD and OCD, commence the launch of our controlled market release of our Deep TMS system for smoking addiction, and for other indications for which we may receive regulatory authorizations in the future. Based on our current business plan, we believe that our cash and cash equivalents as of December 31, 2020 and the anticipated revenues from sales of our products will be sufficient to meet our anticipated cash requirements through at least the next 24 months. However, if these sources are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity securities, seek to enter into a new credit facility, or seek financing from third party collaborators. If we raise additional funds by issuing equity securities, our shareholders would experience dilution. Additional debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. We can provide no assurance that additional equity or debt financing will be available on terms favorable to us, or at all. If we raise additional funds through collaborations with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to obtain adequate funds on reasonable terms, we will need to curtail operations significantly, including possibly postponing anticipated clinical trials or entering into financing agreements with unfavorable terms.

Cash flows

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

	Year Ended December 31,	
(in thousands)	**2019**	**2020**
Net cash used in operating activities	$ (7,244)	$ (1,436)
Net cash used in investing activities	(2,446)	(2,465)
Net cash provided by (used in) financing activities	22,474	(1,030)
Exchange rate differences on cash and cash equivalents	(78)	218
Increase (decrease) in cash and cash equivalents	$ 12,706	$ (4,713)

Operating Activities

Net cash used in operating activities was $1.4 million during the year ended December 31, 2020, compared to $7.2 million used during the year ended December 31, 2019. The decrease of $5.8 million was mainly attributed to our efforts to enhance efficiency, as well as to lower operational expenses given the financial impact of the COVID-19 pandemic.

Investing Activities

Net cash used in investing activities was $2.5 million during each of the years ended December 31, 2020 and 2019. The increase of $0.1 million was mainly attributed to the increase in the purchase of equipment and system components offset by a decrease of withdrawal of long-term deposits.

Financing Activities

Net cash used by financing activities was $1.0 million during the year ended December 31, 2020 compared to $22.5 million provided by financing activities during the year ended December 31, 2019. The decrease was mainly attributed to the initial public offering on Nasdaq completed in April 2019.

Government Grants

As of December 31, 2020, our wholly owned subsidiary, Brain Research and Development Services, Ltd., has received grants from the IIA in an aggregate amount of approximately $12.8 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, 2020, Brain Research and Development Services, Ltd. has paid royalties to the IIA in an aggregate amount of approximately $2.6 million (including amounts in respect of accrued interest), with remaining outstanding royalties of up to $12.5 million.

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 grant receipts 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.

Research and development grants received from the European Union 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 $2.5 million based on the NIS to USD exchange rate as of December 31, 2020). There is no requirement to repay the grants or pay royalties thereon. Such non-royalty-bearing grants from 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 attached conditions, on the basis of the costs incurred, and are presented as a deduction from research and development expenses. 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.

In July 2020 the Company received $638,000 as a loan from the Paycheck Protection Program in the United States (the "Program"). The terms of the Program provide that a portion of the loan may be forgiven, to the extent that the amounts spent during the eight-week period on qualifying expenses ("Program Expenses"). The unforgiven part of the loan must be repaid within two years and bears interest at 1% per annum. The Company used the entire proceeds to pay Program Expenses and has since received approval for loan forgiveness of the entire amount.

C. Research and Development, Patents, and Licenses

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, or Yeda, the commercialization arm of the Weizmann Institute for Science (Weizmann Institute) or are owned by us. These include a total of 16 issued U.S. patents, 3 pending U.S. patent applications, 25 issued patents in other jurisdictions (treating Europe as one jurisdiction), and 26 pending patent applications in other jurisdictions.

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 have 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 our 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 seven issued patents in other jurisdictions. The issued patents are set to expire in 2024 in the U.S. and in 2021 in other countries.

Our second group of patents (Patent Family B) relates to additional design features of BrainsWay's MDD coil, BrainsWay's smoking addiction coil, 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, nine issued patents in other jurisdictions, and two pending patent applications in other jurisdictions. The issued patents in this group are set to expire in 2025 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.

Our third group of patents (Patent Family C) relates to a family of central base coils including BrainsWay's OCD coil and also some future products that we are developing. This group of patents is owned by us, and includes three issued U.S. patents, six issued patents in other jurisdictions, and five pending patent applications 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, three issued patents in other jurisdictions, and two pending patent applications 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 which provide coverage of several H-coils, including those used in BrainsWay's MDD and OCD systems. This group of patents (Patent Family E) is owned by us, and includes two issued Chinese Utility Model patent applications: one for BrainsWay's MDD coil, and another one for BrainsWay's OCD coil, one pending patent application in the U.S. and five pending patent applications in other jurisdictions incorporating both BrainsWay's MDD and OCD systems. .

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. This group of patents (Patent Family F) is owned by us, and includes two issued U.S. patents, four issued patents in other jurisdictions and three pending patent applications 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 pending patent application in the U.S. and three pending patent applications in other jurisdictions.

Our eighth group of patents (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 five issued U.S. patents, two pending U.S. patent applications, eight issued patents in other jurisdictions, and seven pending patent applications in other jurisdictions. Patent applications in these families, if issued, 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, an additional group of patents relates to multichannel stimulation and was acquired from TMS Innovations, LLC. More specifically, we recently completed transactions which we believe will enable us to broaden the scope of capabilities in the multichannel stimulator we are developing. Specifically, in February 2019, we acquired all rights previously held by TMS Innovations, LLC in certain specified patents relevant to this area and have completed the process of transferring these patents.

Furthermore, we are currently discussing the possibility of exclusively licensing certain rights held by the Board of Trustees of the Leland Stanford Junior University in various additional patents relating to this area.

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.

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 “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% of our net sales or payments received from sales or leases of our Deep TMS systems using the licensed technology. In addition, we are required to pay a royalty of 8% of 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.

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. Avraham Zangen, the scientific founder and neurobiological advisor of the Company, 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.

We recently exercised our right to add the additional rotational field TMS innovation. To the extent products based on this technology are commercialized we will have to pay Yeda royalties, either at increased rates ranging from an additional 1.6%-2% 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 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 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, the COVID-19 global pandemic has led governments and authorities around the globe, to take various precautionary measures in order to limit the spread of the COVID-19 global pandemic, including government-imposed quarantines, lockdowns, and other public health safety measures, which have had and continues to have an adverse effect on the global markets and its economy, including on the availability and pricing of materials, manufacturing and delivery efforts, sales to existing and potential customers and leads, collections from accounts, and other aspects of the global economy. Therefore, the COVID-19 global pandemic could continue to disrupt production and cause delays in the supply and delivery of products used in our operations, may further divert the attention and efforts of the medical community to coping with the COVID-19 global pandemic, impact our ability to recruit subjects for ongoing and planned clinical trials and disrupt the marketplace in which we operate and may have a material adverse effects on our operations, sales, revenues, collection from accounts and ability to raise funds. In particular, certain of our third-party suppliers may currently source certain components and materials of our Deep TMS systems from Asia and other affected countries, and the continued outbreak and spreading of the COVID-19 global pandemic may adversely impact our third-party suppliers' development, manufacture, and supply of our Deep TMS systems. In addition, treatment sessions conducted with our Deep TMS system, which are generally scheduled or non-emergency procedures, may be postponed as hospitals and healthcare centers shift resources to patients affected by the COVID-19 global pandemic. The extent to which the COVID-19 global pandemic impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the COVID-19 global pandemic and the actions to contain the COVID-19 global pandemic or treat its impact, among others. Moreover, the COVID-19 global pandemic outbreak has begun to have indeterminable adverse effects on general commercial activity and the world economy, and our business and results of operations could be adversely affected to the extent that this COVID-19 global pandemic or any other epidemic harms the global economy generally.

E. Off-Balance Sheet Arrangements

Since inception, we have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2020 based on contractual payments:

(in thousands)	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Lease liability(1)	$ 775	$ 463	$ 312	$ —	$ —
Liability in respect of research and development grants (undiscounted)(2)	13,156	388	1,606	3,054	8,108
Total	$ 13,931	$ 851	$ 1,918	$ 3,054	$ 8,108

(1) Lease liabilities consist of our corporate facilities and motor vehicles. Our total lease payments on all of our facilities and vehicles are approximately $42,000 per month.
(2) Liability in respect of research and developments consists of the projected royalty payments of 3% of revenues derived from research and developments projects for which participation grants were received from the Israeli Government.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

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
Senior Management:		
Christopher R. von Jako	52	President and Chief Executive Officer
Dr. Yiftach Roth	51	Chief Scientist
Hadar Levy	47	Senior Vice President, General Manager of North America, and interim Chief Financial Officer
Moria Ankri	37	Vice President Research and Development
Amit Ginou	40	Vice President Field and Manager of Israel Operations
Christopher Boyer	43	Vice President of Global Marketing
Directors:		
Dr. David Zacut	69	Chairman of the Board
Avner Hagai(2)	65	Vice Chairman of the Board
Eti Mitrany(1)(2)	51	Director
Karen Sarid(1)(2)	70	Director
Prof. Abraham Zangen	51	Director
Yossi Ben Shalom	64	Director
Avner Lushi(1)	54	Director

(1) Member of our audit committee that also serves as our financial statements committee.
(2) Member of our compensation committee.

Executive officers

Christopher R. von Jako serves as our president and chief executive officer since January 1, 2020. Most recently, Dr. von Jako served as CEO of Dynatronics Corporation, a publicly-traded medical device company focusing on high-quality restorative products. Prior to Dynatronics, he served as President and CEO of other companies including NinePoint Medical, Inc. and NeuroTherm, Inc. Earlier in his career, he held increasingly senior roles with other leading medical device companies, including Integra LifeSciences, Covidien, Medtronic, and Radionics. Dr. von Jako holds a Ph.D. in Biomedical Sciences from the University of Pécs, a M.S. degree in Radiological Sciences and Technology from the department of Nuclear Engineering at the Massachusetts Institute of Technology, and a double B.S. degree in Physics and Mathematics from Bates College. He resides in Lynnfield, Massachusetts and continues to serve as an independent director on the boards of NinePoint Medical, Inc., and nView medical Inc.

Dr. Yiftach Roth is one of our scientific founders and key inventors of the Deep TMS technology. Dr. Roth has served as our Research and Development Manager since May 2006 and as a member of the Board of Directors since November 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.

Hadar Levy has served as our Senior Vice President and General Manager North America since May 2020 and is currently also serving as our Interim Chief Financial Officer. Prior to this, Mr. Levy served as our Chief Financial Officer from September 2014 to May 2020. Prior to his service at the Company, 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.

Moria Ankri has served as our Vice President of Research and Development since September 2017. Prior to her service as a Vice President of Research and Development, from 2010 to 2017, Ms. Ankri served as a manager at the Biomedical Development Department of our Company and as a research and development project manager at our Company. Ms. Ankri holds a B.Sc. in Biomedical Engineering from the Jerusalem College of Technology, and a B.Sc. in neurobiology studies at the Hebrew University of Jerusalem.

Amit Ginou has served as our Vice President of Field and Clinical Operations since October 2013. Previously, Mr. Ginou served as the Clinical Trials Manager of our Company from November 2008 to October 2013. Mr. Ginou holds a B.Sc. in Neuroscience from Bar Ilan University and a MA degree in Law from Bar Ilan University.

Christopher Boyer served as Managing Director of Drake Partners LLC, a start-up private equity and management consulting firm, where he led commercial activities for many of the portfolio companies. Prior to Drake Partners, he was Vice President at St. Jude Medical (now part of Abbott), where he managed the commercial integration of NeuroTherm, Inc. He was formerly the Vice President, America Sales, and Global Marketing for NeuroTherm, an international pain management company, where he transformed the sales and marketing organizations to accelerate revenue growth. This effort contributed to the subsequent sale of the company to St. Jude Medical. Earlier in his career, Mr. Boyer held marketing roles of increasing responsibility at Smith & Nephew and Stryker. Prior to his medical device career, he was a field artillery captain in the United States Army, and he received a Bronze Star Medal for his service. Mr. Boyer holds a B.S. in Mathematical Sciences from the United States Military Academy at West Point.

Directors

Dr. David Zacut has served as our Chairman of the Board of Directors since our inception and has been providing consulting services to Brain Research and Development Services 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. Dr. Zacut holds an M.D. degree from the Hebrew University of Jerusalem.

Avner Hagai has served as our Vice Chairman of the Board of Directors since November 2006 and currently serves as a member of our compensation committee. He serves as a director at several companies, including Prisma F.S. Ltd., a building management company, where he has served since 2002. 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 our Director since June 2016, and currently serves as chairperson of our compensation committee and a member of our audit committee. Ms. Mitrany Ms. Mitrany is an executive with over 25 years of global experience in the Life Sciences industry and currently serves as a business and financial consultant to start-up and Israeli-based corporate entities. 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 MBA in Finance, both from Tel-Aviv University.

Prof. Avraham 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 BrainsWay's 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.

Karen Sarid has served as our Director since December 2017 and currently serves as chairperson of our audit committee and a member of our compensation 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.

Yossi Ben Shalom has served as our Director since December 2018. Mr. Ben Shalom is a co-founder of D.B.S.I, a private investment company specializing in investments in mature companies that are positioned globally for high growth or built for vast expansion through M&As. As such, Mr. Ben Shalom serves as the Chairman of Pointer Telocation Ltd. (Nasdaq: PNTR), Rada (Nasdaq: RADA) and Shagrir Group Car Services Ltd. (TASE: SHGR). He also serves as a director at Taldor Computer Systems (1986) Ltd. (TASE: TALD), Eldan Cargo Ltd., The 8 Note Production & Distribution Ltd., Car 2 Go Ltd., Matzman Et Merutz Milenum Ltd. and Kafrit Industries (1993) Ltd. Mr. Ben Shalom was Executive Vice President and Chief Financial Officer of Koor Industries Ltd. from 1998 through to 2000. Before that, Mr. Ben-Shalom served as Chief Financial Officer of Tadiran Ltd. between 1994 and 1998. Mr. Ben Shalom holds a BA in Economics and an MA in Business Administration both from Tel Aviv University.

Mr. Avner Lushi has served as our Director since January 2020 and currently serves as a member of our audit committee. He 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 has served as an independent board member at nine public companies, the two last active ones being Ram-On Investments and Holdings (1999) Ltd and Allmed Solutions Ltd. In addition, he serves as a board member of several private companies as part of his role at GIBF. 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, LLB in Law and a BA in Economics from the Haifa University.

B. Compensation

The aggregate compensation paid, and benefits-in-kind granted to or accrued on behalf of all of our directors and executive officers for their services, in all capacities, to us during the year ended December 31, 2020, was approximately $1.6 million. Out of that amount $1.0 million was paid as salary, $0.25 million was attributed to the value of the equity-based awards granted to senior management during 2020, approximately $0.05 million was attributed to retirement plans and approximately $0.3 million was attributed to all other compensation. 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 comply with our amended Compensation Policy for Executive Officers and Directors recently approved by our shareholders in January 2020 (the "Compensation Policy").

The table and summary below outline the compensation granted to our five highest compensated directors and officers during the year ended December 31, 2020. The compensation detailed in the table below refers to actual compensation granted or paid to the director or officer during the year 2020.

Name and position of director or officer	Base Salary or Other Payments[1]	Value of Social benefits[2]	Value of Equity Based Compensation Granted[3]	All Other Compensation[4]	Total
Christopher von Jako, President and CEO	323,750	-	182,440	140,000	646,190
Hadar Levy, SVP and General Manager North America and interim Chief Financial Officer	280,250	-	148,282	73,750	502,279
Christopher Boyer, VP Global Marketing	121,000	-	28,619	25,667	175,285
Amit Ginou, VP, and Israel Site Manager	115,986	31,811	-	19,820	167,617
Judy Huber, former SVP and CFO	165,038	-	-	-	165,038

(1) "Base Salary or Other Payments" means the aggregate yearly gross monthly salaries or other payments with respect our senior management and members of the board of directors for the year ended December 31, 2020.
(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) Consists of the fair value of the equity-based compensation granted during the year ended December 31, 2020 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 recognized as an expense over the vesting period of the options.
(4) "All Other Compensation" includes, among other things, bonuses, car-related expenses (including tax gross-up) and communication expenses.

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 by us.

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.

For information on exemption and indemnification letters granted to our directors and officers, please see "Item 6C. – Board Practices – Exemption, Insurance and Indemnification of Directors and Officers."

Director Compensation

As of the date of the filing of this annual report, we pay our independent directors an annual cash fee of NIS 47,000 (approximately $14,240) except for Ms. Karen Sarid to whom we pay an annual cash fee of NIS 63,000 (approximately $19,090) for her expertise and special contributions to the work of our Board and its committees. Additionally, as of the date of the filing of this annual report, we pay a cash fee of NIS 2,450 (approximately $740) per meeting of the Board and any committee thereof (or a portion of said amount for meetings which are not attended in person and the payment amount is reduced pursuant to applicable regulations).

Compensation Policy

In general, under the Israeli Companies Law, a public company must have a compensation policy 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 including 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.

The compensation policy must be based on certain considerations, 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 the 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's 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, indemnification and insurance, 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 (except for "special bonuses") are limited to a maximum amount linked to the executive officer's base salary. In addition, the total variable compensation components (cash bonuses and equity-based compensation) may not exceed 60% for office holder which is not the CEO, or 70% for the CEO, of each executive officer's total compensation package 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 other than our chief executive officer will be based on performance objectives and a discretionary evaluation of the executive officer's overall performance by our chief executive officer and subject to minimum thresholds. The annual cash bonus that may be granted to senior management other than our chief executive officer may be based in a rate of up to 20% 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 performance measurable objectives of our chief executive officer will be determined annually by our compensation committee and board of directors, will include the weight to be assigned to each achievement in the overall evaluation. A portion of up to 40% the chief executive officer's annual cash bonus may be based on a discretionary evaluation of the chief executive officer's overall performance by the compensation committee and the board of directors based on quantitative and qualitative criteria.

The equity-based compensation under our compensation policy for our 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 stock options or other equity-based awards, such as restricted shares and restricted share units, 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.

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

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

Our compensation policy was approved by our shareholders on September 6, 2018, and amendments thereto were approved by our shareholders on January 24, 2019 and on January 13, 2020.

C. Board Practices

Appointment of Directors and Terms of Officers

Our board of directors consists of seven (7) directors, including five (5) directors who qualify as "independent" under applicable U.S. securities laws and Nasdaq listing rules: Avner Hagai, Karen Sarid, Eti Mitrany, Yossi Ben Shalom, and Avner Lushi.

Under our articles of association, the number of directors on our board of directors will be not less than four (4) but no more than nine (9) directors, not including any external directors to the extent required to be appointed by the Israeli 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 first annual meeting of shareholders after their appointment, at which they may be re-elected by such general meeting subject to the total number of directors not exceeding nine (9).

Under our articles of association, our board of directors may elect new directors if the number of directors is below the maximum provided in the articles of association, and the term of office of such elected directors shall be until the next general meeting of our shareholders.

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.

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, voting requirements and other provisions would be applicable. We would also be required to include one such external director on each of our board committees.

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, we comply with the requirements of the Nasdaq with respect to the composition of our board and such committees, and therefore we are exempt from the Israeli Companies Law requirements with respect thereto, including the appointment of external directors.

Committees

Israeli Companies Law Requirements

Our board of directors has established two standing committees, the audit committee (which serves also as our financial statements committee) and the compensation 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, will be required to be "independent" (as defined below), and the chairman of the audit committee will be 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 chairman 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 "Management—Our Board of Directors."

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.

Our audit committee consists of Karen Sarid, Eti Mitrany, and Avner Lushi. Karen Sarid serves as Chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq corporate governance 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 SEC rules, and has the requisite financial experience as defined by the Nasdaq listing rules.

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 "Management—Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli Law." 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.

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. 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. 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

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. The chairperson of the compensation committee must be an external director, if any. The remaining members are not required to be external directors, but must be directors who qualify to serve as members of the audit committee (as described above).

The compensation committee, which consists of Eti Mitrany, Avner Hagai, and Karen Sarid, assists the board of directors in determining compensation for our directors and officers. Eti Mitrany serves as Chairperson of the committee. Under SEC and Nasdaq 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 expected compensation committee members meet this heightened standard.

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

(1) 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;

(2) to recommend to the board of directors updates to the compensation policy, from time to time, and examine its implementation;

(3) to decide whether to approve the terms of office, and employment of directors and officers that require approval of the compensation committee; and

(4) 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 outside of Israel. These authorities are intended to allow more flexibility when hiring executives outside Israel, with a view to support our commitment to a strategic transition to US-based leadership.

Pursuant to regulations promulgated under the Israeli Companies Law, we comply with the requirements of the 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 "Management—Our Board of Directors."

Nasdaq Stock Market Requirements

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

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.

As noted above, 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. 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.

Corporate Governance Practices

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. Yisrael Gewirtz of Fahn Kanne Control Management Ltd. (Grant Thornton Israel) serves as our internal auditor.

Duties of Directors and Officers 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 Interests 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 "Management—Disclosure of Compensation of Directors and Senior Management."

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 Personal Interests 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'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 with respect to the terms of the engagement of the company, (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 must be voted in favor of approving the transaction, excluding abstentions; 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 approval 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. In addition, transactions with a controlling shareholder or a controlling shareholder's relative who serves as an officer in a company, directly or indirectly (including through a corporation under his control), involving the receipt of services by a company or their compensation can have a term of five years from the company's initial public offering under certain 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 ballot 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.

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 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 "Description of Share Capital—Acquisitions under Israeli Law") or a private placement which qualifies as a related party transaction (see "Management—Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli Law"), approval at a general meeting of the shareholders of a company is required.

Exculpation, Insurance and Indemnification of Directors and Officers

Under the Israeli Companies Law, a company may not exculpate 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. Our articles of association include such a provision. 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.

Under the Israeli Companies Law and the Israeli Securities Law, 5728-1968 (the "Israeli Securities 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;

- 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; (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;

- 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.

Under the Israeli Companies Law and the Israeli Securities 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.

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 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.

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, 2020, we had 100 employees, of which 42 are based in the United States and 58 are based outside of the United States (in Israel). This includes 26 employees in sales and marketing (including 24 in the United States), and 26 employees in clinical trials and research and development.

	As of December 31,		
	2020	2019	2018
	Company Employees	Company Employees	Company Employees
Management, administration, and operations	48	49	41
Research and development	26	30	30
Sales and Marketing	26	28	25

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 Plan. The Plan is 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, which was approved by our shareholders on January 13, 2020. The Plan supersedes and replaces the original BrainsWay 2014 Share Incentive Plan and provides for the granting of ordinary shares, American Depositary Shares, stock options under various tax regimes in Israel and the U.S., restricted shares, restricted share units, 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 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 Plan, as amended and restated, we may issue options to purchase up to 3,626,200 of our ordinary shares. As of December 31, 2020, options to purchase 1,522,975 ordinary shares, at a weighted average exercise price of $7.4 per share, were outstanding. The option pool under the 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 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 Plan.

On January 26, 2021 our Board of Directors, and on March 4, 2021 our shareholders (with respect to the directors), respectively, approved an exchange offer to all our employees, consultants, and independent directors who are eligible holders for such exchange offer, to incentivize our officers, independent Board members, employees and, consultants to continue to contribute to the Company's success and results of operations. Under the contemplated Exchange Offer, each eligible holder will have the opportunity to exchange the existing options held by such holder with new options with an exercise price of $4.675, being a price equal to the closing price per Ordinary Share on January 25th, 2021 (the closing price of the last trading day prior to our Board's approval) (except for eligible holders that are subject to US tax rules and regulations, for which the exercise price will be the higher of $4.675 ($9.35 per ADS) and the price per ordinary share on the last date before the exchange offer is filed), all other terms of the options, including the number of options, vesting schedule, and term shall remain unchanged. The eligible holders are expected to be those employees, consultants, and independent directors who, on the date the exchange offer commences, are employed by the Company, are providing services to the Company or are independent directors of the Company; and on or prior to the expiration time of such Exchange Offer, continue to be employed by the Company or otherwise provide services to the Company.

The option pool under the 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 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 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 Plan. The exercise price of each stock option granted under the Plan will be determined in accordance with the limitations set forth under the Plan. The exercise price of any stock options granted under the Plan may be paid in cash, through "cashless exercise" mechanism or any other method that may be approved by our compensation committee, which may include procedures for cashless exercise.

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

On January 2020, as part of his employment agreement with the Company, we committed to grant 240,000 restricted stock units ("RSUs") to Mr. von Jako, our President and CEO, of which 60,000 RSUs have been granted on January 1, 2020, and 180,000 RSUs have been committed to be granted in three future grants of 60,000 RSUs upon each anniversary of the employment start date of Mr. von Jako with the Company, subject to certain criteria. At the Annual General Meeting of the Company's Shareholders held on March 4, 2021, our shareholders approved an acceleration of the grant date of the remaining 180,000 RSUs to the date of such approval. The RSUs are subject to a vesting schedule of four years beginning on their respective date of grant, with the first 25% said RSUs vesting 12 months after the date grant, and the remaining 75% of the RSUs vesting in 12 equal portions – each upon the last day of every three month period thereafter until the grant is fully vested. The vesting of the RSUs is subject to Mr. von Jako's continued employment with the Company at the time of each such scheduled vesting, and the RSUs are subject to the terms of our 2019 Award Plan.

Israeli participants in the 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. Our 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 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 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 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 Plan. The compensation committee will, among others, select which eligible persons will receive options or other awards under the 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 Plan. All awards granted under the 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 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 Plan and under applicable law, our board of directors may amend or terminate the Plan, and the compensation committee may amend awards outstanding under the Plan. In addition, an amendment to the Plan that requires shareholder approval under applicable law will not be effective unless approved by the requisite vote of shareholders. In addition, in general, no suspension, termination, modification or amendment of the 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 Plan will continue in effect until all ordinary shares available under the Plan are delivered and all restrictions on those shares have lapsed, unless the Plan is terminated earlier by our board of directors. No awards may be granted under the Plan on or after the tenth anniversary of the date of adoption of the 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 Plan or otherwise, may be subject to further approvals in addition to the approval of the compensation committee as described above. See "Management—Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli Law."

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 April 19, 2021 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 who are among our five highest compensated directors and officers, or our Named Directors and Officers; and
- all of our directors and members of senior management 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 that are currently exercisable or exercisable within 60 days of April 19, 2021, if any, to be outstanding and to be beneficially owned by the person holding the options 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 is based on 32,899,884 ordinary shares outstanding as of April 19, 2021.

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 April 19, 2021, 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 April 19, 2021, there were 68 U.S. persons that were holders of record of our ADSs.

Unless otherwise noted below, the address for each beneficial owner is c/o BrainsWay Ltd., 19 Hartum Street, Bynet Building 3rd Floor, Har HaHotzvim, Jerusalem, 9777518, Israel.

	Shares Beneficially Owned	
	Number	Percentage
Name of Beneficial Owner		
5% or Greater Shareholders		
The Phoenix Provident Funds(1)	3,216,200	9.7%
RTW Funds(2)	3,116,948	9.4%
Dr. David Zacut (3)	1,786,357	5.4%
Avner Hagai(3)	1,741,378	5.3%
Halman Aldubi Provident and Pension Funds Ltd.(4)	1,496,209	4.5%
Dr. Yiftach Roth	1,083,390	3.3%
Prof. Avraham Zangen(5)	940,000	2.8%
Named Directors and Officers		
Christopher von Jako(6)	53,750	*
Hadar Levy(7)	317,467	*
Amit Ginou(8)	87,667	*
Moria Ankri(9)	43,388	*
Karen Sarid (10)	20,625	*
Yossi Ben Shalom (11)	13,750	*
Avner Lushi (12)	6,875	*
Eti Mitrany (13)	4,583	*
All directors and members of senior management as a group	6,099,230	18.5%

* Less than 1.0%

(1) The shares are beneficially owned by various direct or indirect, majority or wholly-owned subsidiaries of the Phoenix Holding Ltd. (the "Phoenix Provident Funds"). The Phoenix Provident Funds manage their own funds and/or the funds of others, including for holders of exchange-traded notes or various insurance policies, members of pension or provident funds, unit holders of mutual funds, and portfolio management clients. Each of the Phoenix Provident Funds operates under independent management and makes its own independent voting and investment decisions. The Phoenix Holding Ltd. is a controlled subsidiary of Delek Group Ltd. The majority of Delek Group Ltd.'s outstanding share capital and voting rights are owned, directly and indirectly, by Itshak Sharon (Tshuva) through private companies wholly-owned by him, and the remainder is held by the public. The address of the Phoenix Provident Funds is HaShalom Road 53 Giv'atayim, 5345433, Israel.
(2) The shares are held by RTW Master Fund, Ltd., one or more private funds (together the "Funds") managed by RTW Investments, LP (the "Adviser"), and Roderick Wong. The Adviser, in its capacity as the investment manager of the Funds, has the power to vote and the power to direct the disposition of all Shares held by the Funds. Roderick Wong is the Managing Partner of the Adviser. The address of RTW Master Fund, Ltd. is 412 West 15th Street Floor 9, New York, New York 10011.
(3) This 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.
(4) The address of Halman Aldubi Provident and Pension Funds Ltd. is 26 Harokmim Street, Holon, Israel.
(5) The address of Prof. Avraham Zangen is Mish'ol HaHadas 23, Jerusalem, Israel.
(6) Consists of 53,750 Ordinary Shares.
(7) Consists of 16,800 Ordinary Shares and options to purchase 300,667 ordinary shares currently exercisable or exercisable within 60 days.
(8) Consists of options to purchase 87,167 ordinary shares currently exercisable or exercisable within 60 days.
(9) Consists of 1,388 Ordinary Shares and options to purchase 42,000 ordinary shares currently exercisable or exercisable within 60 days.
(10) Consists of options to purchase 20,625 ordinary shares currently exercisable or exercisable within 60 days.
(11) Consists of options to purchase 13,750 ordinary shares currently exercisable or exercisable within 60 days.
(12) Consists of options to purchase 6,875 ordinary shares currently exercisable or exercisable within 60 days.
(13) Consists of options to purchase 4,583 ordinary shares currently exercisable or exercisable within 60 days.

B. Related Party Transactions

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."

Consulting Agreement with Prof. Avraham Zangen

We have entered into a consulting agreement with Prof. Avraham Zangen, our scientific founder and greater than 5% shareholder, under which Prof. Zangen provides advisory services to us in the field of neurobiology. 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.

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 "Management—Share Incentive Plan."

Since January 1, 2016, we granted options to purchase 1,426,362 ordinary shares to employees and directors, with a weighted average exercise price of approximately $6.3 per share, or approximately NIS 21.90 per share (based on the exchange rate reported by the Bank of Israel on December 31, 2020).

On January 26, 2021 and on March 4, 2021 our Board of Directors and our shareholders (with respect to the directors), respectively, approved an exchange offer to all our employees, consultants, and independent directors who are eligible holders for such exchange offer, to incentivize our officers, independent Board members, employees and, consultants to continue to contribute to the Company's success and results of operations. Under the contemplated Exchange Offer, each eligible holder will have the opportunity to exchange the existing options held by such holder with new options with an exercise price of $4.675 ($9.35 per ADS), being a price equal to the closing price per Ordinary Share on January 25th, 2021 (the closing price of the last trading day prior to our Board's approval), all other terms of the options, including the number of options, vesting schedule, and term shall remain unchanged. The eligible holders are expected to be those employees, consultants, and independent directors who on the date the Exchange Offer commences, are employed by the Company, are consultants to the Company or are independent directors of the Company; and on or prior to the expiration time of such Exchange Offer, continue to be employed by the Company or otherwise provide services to the Company.

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. We have obtained directors and officers insurance for each of our senior management and directors.

We have provided an undertaking to our directors and senior management to exculpate to the fullest extent permitted by law and to indemnify them for certain liabilities, 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 directors and senior management based on such indemnification undertaking is the greater of (i) 25% of our shareholders' equity pursuant to our most recent audited financial statements at the time the indemnification is actually paid, and (2) $20 million. Such indemnification amounts are in addition to any insurance amounts.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Financial 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 legal proceedings.

Dividend Policy

We have never declared or paid cash dividends to our shareholders. Currently, we do not intend to pay cash dividends. 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, 2020.

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. Our ADSs were traded on The NASDAQ Capital Market under the symbol "BWAY" from April 16, 2019.

B. Plan of Distribution

Not applicable.

C. Markets

Our Ordinary Shares are listed and traded on the TASE, and our ADSs, each representing two Ordinary Share 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

Securities Registers

The transfer agent and registrar for our 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."

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 officer holder may be present at the meeting. 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 the Israeli Companies Law, a contract of a company with its directors, regarding their conditions of service, including the grant to them of exemption from liability from certain actions, insurance, and indemnification as well as the company's contract with its directors on conditions of their employment, in other capacities, require the approval of the compensation committee, the board of directors, and the shareholders by a Special Majority.

Description of Securities

Ordinary Shares

Our authorized share capital currently consists of 60,000,000 ordinary shares, par value NIS 0.04 per share. As of December 31, 2020, there were 22,250,534 ordinary shares issued and outstanding.

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.

As of December 31, 2020, there were outstanding options to purchase an aggregate of 1,522,975 shares of our ordinary shares, with a weighted-average exercise price of $7.4 per ordinary share. In addition, there are options to purchase an additional 2,103,225 ordinary shares reserved for future issuance under our Share Incentive Plan.

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.

Shareholders Meetings. Under Israeli 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 provides 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) 5% or more of our outstanding issued shares and 1% or more of our outstanding voting power or (b) 5% or more of our outstanding voting power. 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.

Under Israeli law, 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 a 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 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 provided to shareholders 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 provided at least 35 days prior to the meeting. Under the Israeli Companies Law, shareholders 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 nine (9) directors, 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. 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 extended by that annual general meeting, or terminated by the 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 election procedures of our directors, see "Item 6. Directors, Senior Management and Employees – C. Board Practices – Appointment of Directors and Terms of Office."

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 among 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.

Our articles of association provide that the following would require approval of at least $66^{2}/_{3}\%$ of the total voting power voted at a general meeting of shareholders: (i) dismissing a director before the end of his or her term in office, and (ii) amending provisions in our articles of association relating to the size of our board of directors, the right of our board of directors to elect new directors provided that the number of directors is less than the maximum number of directors the right of a shareholder to recommend a board nominee for consideration by Company shareholders, the special majority required to dismiss a director before the end of his or her term in office, the conditions under which the term of office of a director is terminated and the ability of the board of directors to function until the next general meeting so long as the number of members of our board of directors is not less than the minimum number of directors required under our articles of association.

Under the Israeli Companies Law, each of (i) the approval of an extraordinary transaction with a controlling shareholder, and (ii) the terms of employment or other engagement of the controlling shareholder of the company or such controlling shareholder's relative (even if not extraordinary) requires the approval described above under "Management—Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli Law—Disclosure of Personal Interests of a Controlling Shareholder and Approval of Transactions." Certain transactions with respect to remuneration of our office holders and directors require further approvals described above under "Management—Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli Law—Compensation of Directors and Senior management." 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 has the power to allot or to issue shares to any person, with restrictions and condition as it deems fit.

Acquisitions under Israeli Law

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 target company's issued and outstanding share capital is required by the Israeli Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company.

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 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. However, a tender offer will 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 a successful 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.

If the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class, 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.

The description above regarding a full tender offer will also apply, with necessary changes, when a full tender offer is accepted, and the offeror has also offered to acquire all of the company's securities.

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 officer in a target company who, in his or her capacity as an officer, 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 officer acted in good faith, and had reasonable grounds to believe he or she was acting for the benefit of the company. However, officers 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.

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, a majority of each party's shareholders, by a majority of each party's shares that are voted on the proposed merger at a shareholders' meeting.

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.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares voting at the shareholders meeting (excluding abstentions) that are held by parties other than the other party to the merger, any person who holds 25% or more of the means of control (See "Management – Audit Committee – Approval of Transactions with Related Parties" for a definition of means of control) of the other party to the merger or anyone on their behalf including their relatives (See "Management – External Directors – Qualifications of External Directors" for a definition of relatives) or corporations controlled by any of them, vote against the merger.

In addition, if the non-surviving entity of the merger has more than one class of shares, the merger must be approved by each class of shareholders. If the transaction would have been approved but for the separate approval of each class of shares or the exclusion of the votes of certain shareholders as provided above, a court may still rule that the company has approved the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the appraisal of the merging companies' value and the consideration offered to the shareholders.

Under the Israeli Companies Law, each merging company must send a copy of the proposed merger plan to its secured creditors. Unsecured creditors are entitled to receive notice of the merger, as provided by the regulations promulgated under the Israeli Companies Law. Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the target company. The court may also give instructions in order to secure the rights of creditors.

In addition, a merger may not be completed unless at least 50 days have passed from the date that a proposal for approval of the merger was filed with the Israeli Registrar of Companies and 30 days from the date that shareholder approval of both merging companies was obtained.

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 our shares represented and voting at a general meeting. Shareholders voting at such a meeting will be subject to the restrictions under the Israeli Companies Law described in "– Voting."

C. Material Contracts

For a description of other material agreements, please see "Item 4. Information on the Company – B. Business Overview.

D. Exchange Controls

Israeli law and regulations do not impose any material foreign exchange restrictions on non-Israeli holders of our Ordinary Shares. 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 American Depositary Shares (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 2021 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 2021), and a marginal tax rate of up to 50% in 2021 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.

Payers 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 647,640 for 2021, 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 acquire ADSs pursuant to this offering and 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 believe we may 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

Although we do not believe that we are currently a PFIC and do not anticipate becoming a PFIC in the foreseeable future, it is possible that we may be treated as a PFIC for U.S. federal income tax purposes for our current taxable year and future taxable years. 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 ADSs, our PFIC status will depend in large part on the market price of the 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 ADSs, we may be a PFIC for the current taxable year and future taxable years.

If we are a PFIC for any year during which you hold the ADSs, we generally will continue to be treated as a PFIC with respect to you for all succeeding years during which you hold the ADSs, unless we cease to be a PFIC and you make a "deemed sale" election with respect to the ADSs you hold. If such election is made, you will be deemed to have sold the 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 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 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 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 ADSs:

- the excess distribution or gain will be allocated ratably over your holding period for the 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 ADSs cannot be treated as capital, even if you hold the 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 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 ADSs as of the close of your taxable year over your adjusted basis in such Ordinary Shares. You are allowed a deduction for the excess, if any, of the adjusted basis of the 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 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 ADSs, are treated as ordinary income. Ordinary loss treatment also applies to the deductible portion of any mark-to-market loss on the ADSs, as well as to any loss realized on the actual sale or disposition of the ADSs to the extent the amount of such loss does not exceed the net mark-to-market gains previously included for the ADSs. Your basis in the 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 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 ADSs are listed on the Nasdaq Global Market and, accordingly, provided the ADSs are regularly traded, if you are a holder of 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 ADSs cease to be marketable stock. If we are a PFIC for any year in which the U.S. Holder owns 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 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. 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, since our Ordinary Shares are traded on the TASE, we have filed Hebrew language periodic, and immediate reports with, and furnish information to, the TASE and the Israeli Securities Authority, as required under Chapter Six of the Israel Securities Law, 1968. Copies of our 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 50% of our expenses in the year ended December 31, 2020, 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. Changes of 5% in the U.S. dollar/NIS exchange rate would have increased/decreased operating expenses by approximately $95 /105 thousand during the year ended December 31, 2020. 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. Since 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 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*:**	***For*:**
$5.00 (or less) per 100 American Depositary Shares (or portion of 100 American Depositary Shares)	● Issuance of American Depositary Shares, including issuances resulting from a distribution 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 to you had been shares and the shares had been deposited for issuance of American Depositary Shares	● Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to American Depositary Shareholders
$.05 (or less) per American Depositary Shares per calendar year	● Depositary services
Registration or transfer fees	● Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	● Cable, telex, and facsimile transmissions (when expressly provided in the deposit agreement) ● Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian have to pay on any American Depositary Share or share underlying an American Depositary Share, for example, stock transfer taxes, stamp duty or withholding taxes	● As necessary
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) - (c) Management's Annual Report on Internal Control over Financial Reporting and Attestation Report of Registered Public Accounting Firm

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

(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, 2020, 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,	
Services Rendered	**2020**	**2019**
	(U.S. dollars in thousands)	
Audit (1)	237	190
Audit-related services (2)	-	27
Tax (3)	63	41
Total	300	258

(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) Audit-related services related to work regarding ongoing consultation.

(3) Tax fees relate to tax compliance, planning, and 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.

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 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. 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 $33^{1}/_{3}$% 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 $33^{1}/_{3}$% 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) approval of 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) approval of 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. In addition, under the Companies Law, a merger requires approval of the shareholders of each of the merging companies; and

- as permitted by the Israeli Companies Law, our board of directors selects director nominees, and we do not have a written charter or board resolution addressing the nominations process. Directors are not selected, or recommended for board of director selection, by independent directors constituting a majority of the board's independent directors or by a nominations committee comprised solely of independent directors as required by the Nasdaq Listing Rules.

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 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 131.

BRAINSWAY LTD

EXHIBIT INDEX

1.1	Articles of Association of the Registrant, as amended (unofficial English translation).
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).
2.2	Form of American Depositary Receipt (incorporated by reference).
2.3	Description of Share Capital (incorporated by reference).
4.1	BrainsWay 2019 Share Incentive Plan.
4.2	Form of Letter of Exculpation and Indemnification (incorporated by reference).
4.3	BrainsWay Compensation Policy (incorporated by reference).
4.4	Employment Agreement, dated April 3, 2006, by and between Brain Research and Development Services Ltd. and Dr. Yiftach Roth, as amended by First Amendment to Employment Agreement, dated May 9, 2006 (incorporated by reference).
4.5	Employment Agreement, dated November 24, 2019, between BrainsWay Ltd. and Christopher Von Jako (incorporated by reference).
4.6	Employment Agreement, dated July 25, 2019, between BrainsWay Inc. and Hadar Levy (incorporated by reference).
4.7	Patent License Agreement, dated July 7, 2003, by and between BrainsWay, Inc. and the United States Public Health Service (incorporated by reference).
4.8	Patent License Amendment, dated August 24, 2005, by and between BrainsWay, Inc. and the United States Public Health Service (incorporated by reference).
4.9	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).
4.10	Research and License Agreement, dated June 2, 2005, by and between BrainsWay, Inc. and Yeda Research and Development Company Ltd. (incorporated by reference).
4.11	First Addendum Agreement, dated August 19, 2007, by and between BrainsWay, Inc. and Yeda Research and Development Company Ltd. (incorporated by reference).
4.12	Second Addendum Agreement, dated January 18, 2009, by and between BrainsWay, Inc. and Yeda Research and Development Company Ltd. (incorporated by reference).
4.13	Third Addendum Agreement, dated March 23, 2010, by and between BrainsWay, Inc. and Yeda Research and Development Company Ltd. (incorporated by reference).
4.14	Fourth Addendum Agreement, dated November 12, 2009, by and between BrainsWay, Inc. and Yeda Research and Development Company Ltd. (incorporated by reference).
4.15	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).
4.16	Fifth Addendum Agreement, dated February 22, 2018, by and between BrainsWay, Inc. and Yeda Research and Development Company Ltd. (incorporated by reference).
8.1	List of Subsidiaries (incorporated by reference).
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.
101	The following financial statements from the Company's 20-F for the fiscal year ended December 31, 2020 formatted in 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.

SIGNATURE

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/ Christopher R. von Jako, Ph.D.
Name: Christopher R. von Jako, Ph.D.
Title: Chief Executive Officer and President

By: /s/ Hadar Levy
Name: Hadar Levy
Title: Senior Vice President and
General Manager North America and Interim Chief Financial Officer

Date: April 19, 2021

BRAINSWAY LTD.
INDEX OF FINANCIAL STATEMENTS

BRAINSWAY LTD.

AUDITED CONSOLIDATED FINANCIAL STATEMENTS AS OF AND FOR THE YEARS ENDED DECEMBER 31, 2020, 2019 AND 2018

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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 the financial position of Brainsway Ltd. and its subsidiaries ("the Company") as of December 31, 2020 and 2019, and the related consolidated statements of comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board.

Basis for Opinion

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

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

Our audits included performing procedures to assess the risks of material misstatement of the 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.

KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

We have served as the Company's auditor since 2003.

Tel-Aviv, Israel
April 19, 2021

BRAINSWAY LTD.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

U.S. dollars in thousands (except share and per share data)

	Note	December 31, 2020	December 31, 2019
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	4	$ 16,961	$ 21,674
Short-term deposits	5	221	221
Trade receivables, net	6	5,582	5,507
Other accounts receivable	7	1,534	1,427
		24,298	28,829
NON-CURRENT ASSETS:			
Long-term deposit		163	168
Leased systems	8	5,198	5,491
System components and other property and equipment	8	$ 4,352	$ 4,248
		9,713	9,907
		$ 34,011	$ 38,736
LIABILITIES AND EQUITY			
CURRENT LIABILITIES:			
Trade payables	10	$ 781	$ 1,320
Other accounts payable	11	3,769	3,379
Deferred revenues	16	1,543	1,305
Liability in respect of research and development grants	12d	707	714
		6,800	6,718
NON-CURRENT LIABILITIES:			
Deferred revenues and other liabilities	16b,e,g	2,015	2,353
Liability in respect of research and development grants	12d	5,524	5,367
Warrants	12c	38	78
		7,577	7,798
EQUITY:	17		
Share capital		233	233
Share premium		95,135	93,649
Share-based payment	18	3,748	4,435
Adjustments arising from translating financial statements from functional currency to presentation currency		(2,188)	(2,188)
Accumulated deficit		(77,294)	(71,909)
		19,634	24,220
		$ 34,011	$ 38,736

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSWAY LTD.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

U.S. dollars in thousands (except share and per share data)

	Note	Year ended December 31, 2020	2019	2018
Revenues	19a	$ 22,057	$ 23,101	$ 16,397
Cost of revenues	19b	5,058	5,129	3,589
Gross profit		16,999	17,972	12,808
Research and development expenses, net	19c	5,823	7,876	6,156
Selling and marketing expenses	19d	11,283	13,269	8,345
General and administrative expenses	19e	4,722	5,303	3,421
Total operating expenses		21,828	26,448	17,922
Operating loss		4,829	8,476	5,114
Finance expense, net	19f	319	1,430	1,156
Loss before income taxes		5,148	9,906	6,270
Income taxes	15b	237	422	209
Net loss and total comprehensive loss		$ 5,385	$ 10,328	$ 6,479
Basic and diluted net loss per share	20	$ (0.24)	$ (0.50)	$ (0.39)

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSWAY LTD.

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 transactions	Adjustments arising from translating financial statements from functional currency to presentation currency	Accumulated deficit	Total equity
Balance at January 1, 2018	$ 171	$ 65,951	$ 3,889	$ (2,188)	$ (55,102)	$ 12,721
Net loss and total comprehensive loss	—	—	—	—	(6,479)	(6,479)
Expiration of share options	—	1,242	(1,242)	—	—	—
Cost of share-based payment	—	—	710	—	—	710
Balance at December 31, 2018	171	67,193	3,357	(2,188)	(61,581)	6,952
Net loss and total comprehensive loss	—	—	—	—	(10,328)	(10,328)
Issuance of shares, net (*)	62	26,271	—	—	—	26,333
Expiration of share options	—	185	(185)	—	—	—
Cost of share-based payment	—	—	1,263	—	—	1,263
Balance at December 31, 2019	233	93,649	4,435	(2,188)	(71,909)	24,220
Net loss and total comprehensive loss	—	—	—	—	(5,385)	(5,385)
Forfeiture of share options	—	—	(187)	—	—	(187)
Exercise of share options	—(**)	466	(466)	—	—	—
Expiration of share options	—	1,020	(1,020)	—	—	—
Cost of share-based payment	—	—	986	—	—	986
Balance at December 31, 2020	$ 233	$ 95,135	$ 3,748	$ (2,188)	$ (77,294)	$ 19,634

(*) Net of issuance expenses of $ 2,290.
(**) Represents amounts less than $ 1.

The accompanying notes are an integral part of the consolidated financial statements.

BRAINSWAY LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands (except share and per share data)

	Year ended December 31,		
	2020	**2019**	**2018**
Cash flows from operating activities:			
Total comprehensive loss	$ (5,385)	$ (10,328)	$ (6,479)
Adjustments to reconcile net loss to net cash used in operating activities:			
Adjustments to profit or loss items:			
Depreciation, amortization and impairment	1,499	1,741	463
Depreciation of leased systems	1,180	1,054	765
Withdrawal of lease due to termination of contract	(5)	-	-
Finance expenses, net	319	1,430	1,157
Cost of share-based payment	799	1,263	710
Income taxes	237	422	209
	4,029	5,910	3,304
Changes in asset and liability items:			
Increase in trade receivables	(7)	(2,634)	(419)
Decrease (increase) in other accounts receivable	(97)	136	(595)
Decrease in long-term prepaid expenses and other assets	—	—	(217)
Increase (decrease) in trade payables	(552)	175	859
Increase (decrease) in other accounts payable	515	(385)	482
Increase (decrease) in deferred revenues and other liabilities	320	555	(314)
	179	(2,153)	(204)
Cash paid and received during the year for:			
Interest paid	(71)	(296)	(239)
Interest received	61	175	37
Income taxes paid	(249)	(552)	(192)
	(259)	(673)	(394)
Net cash used in operating activities	(1,436)	(7,244)	(3,773)
Cash flows from investing activities:			
Purchase of property and equipment and system components	(2,470)	(3,311)	(1,972)
Withdrawal of (investment in) short-term deposits, net	—	(120)	(50)
Withdrawal of long-term deposits, net	5	985	886
Net cash used in investing activities	(2,465)	(2,446)	(1,136)
Cash flows from financing activities:			
Receipt (repayment) of loan from bank, net	—	(3,000)	—
Receipt of government grants	42	176	149
Repayment of liability in respect of research and development grants	(655)	(601)	(414)
Repayment of lease liability	(417)	(434)	—
Proceeds from issuance of shares, net	—	26,333	—
Net cash (used in) provided by financing activities	(1,030)	22,474	(265)
Exchange rate differences on cash and cash equivalents	218	(78)	(367)
Increase (decrease) in cash and cash equivalents	(4,713)	12,706	(5,541)
Cash and cash equivalents at the beginning of the year	21,674	8,968	14,509
Cash and cash equivalents at the end of the year	$ 16,961	$ 21,674	$ 8,968
(a) *Significant non-cash transactions:*			
Purchase of property and equipment on credit	$ 23	$ 183	$ 280
Recognition of new lease liability and right-of-use	$ 48	$ —	$ —
Termination of lease liability and right-of-use	$ (51)	$ —	$ —
long-term prepaid expenses not yet paid	$ —	$ —	$ 1,128

BRAINSWAY LTD.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 1: GENERAL

a. A general description of the Company and its activity:

Brainsway Ltd. ("the Company") incorporated on November 7, 2006, is a commercial stage medical device company focused on the development and sale of non-invasive Deep Transcranial Magnetic Stimulation ("Deep TMS"), technology for the treatment of neurological and addiction disorders. The Deep TMS system ("system") uses magnetic pulses to stimulate neurons and consequently modulates the physiological activity of the brain.

In January 2013, the first commercial Deep TMS system received clearance by the United States Food and Drug Administration ("FDA") for the treatment of major depressive disorder ("MDD") in adults who failed to achieve satisfactory improvement from anti-depressant medication. In August 2019, the Company received clearance of marketing authorization by the FDA for the adjunct therapy for the treatment of obsessive compulsive disorder (OCD) in adults.

In August 24, 2020, Brainsway Ltd. announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the Company's deep transcranial magnetic stimulation ("Deep TMS") system for its use as an aid in short-term smoking cessation in adults.

Brainsway Ltd. ("the Company") and its wholly owned subsidiaries, Brainsway, Inc. ("Inc"), Moach R&D Services Ltd. ("Moach"), Brainsway USA Inc ("USA Inc"), collectively (the "Group") derive revenues from the sale and lease of its systems.

b. In an effort to contain and mitigate the spread of COVID-19 global pandemic, many countries around the world, including the U.S. and Israel, have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus and closed non-essential businesses and offices. As many local jurisdictions continue to have such restrictions in place, the Company's ability to continue to operate its business may also be limited.

To date, the financial impact on the Company's business has been moderate, and the Company has put in place a comprehensive alternative commercial strategy to support growth initiatives while adhering to government and health regulatory guidelines. Additionally, to date, there have been no significant disruptions to the supply chain, and the Company currently has sufficient supply of components to assemble the Company's Deep TMS systems and meet commercial demand. However, the Company has experienced decreased commercial activities which have affected the revenue from leases of the Company's Deep TMS systems due to slower initiation of certain promotional activities associated with a significant decrease in in-clinic patient visits, tests and treatments and the impact on our sales force's ability to engage with healthcare providers in an in-person setting, cancellation of events such as industry conferences and limited local and international travel. The ability to successfully commercialize the Deep TMS system for smoking addiction depends on in-clinic patient visits and the availability of diagnostics, both of which has have been negatively affected by the pandemic. In addition, the COVID-19 pandemic has adversely affected and may continue to adversely affect the Company's clinical and pre-clinical trials, including the ability to initiate and complete clinical and pre-clinical trials within the anticipated timelines, and delays or difficulties in enrolling patients in clinical trials and recruiting clinical site investigators and clinical site staff.

c. The Company has negative cash flows from operating activities and an operating loss of $ 1.4 million and $ 4.8 million for the year ended December 31, 2020, respectively. The Company's management and board of directors believe that the Company has the current funding to finance its business activity according to its plans in the foreseeable future. See also Note 22 (c).

d. The financial statements of the Company as of December 31, 2020 and 2019 and for each of the three years in the period ended December 31, 2020 were authorized for issuance in accordance with a resolution of the board of directors on April 19, 2021.

NOTE 2: SIGNIFICANT 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: SIGNIFICANT ACCOUNTING POLICIES (Continued)

b. Consolidated financial statements:

The consolidated financial statements comprise the financial statements of companies that are controlled by the Company ("subsidiaries"). Control is achieved when the Company has power over the subsidiaries, is exposed or has rights to variable returns from its involvement with the subsidiaries and has the ability to affect those returns through its power over the subsidiaries. In assessing control, the effect of potential voting rights is considered only if they are substantive. The consolidation of the financial statements commences on the date on which control is obtained and ends when such control ceases.

The financial statements of the Company and of the subsidiaries are prepared as of the same dates and periods. The accounting policies in the financial statements of the subsidiaries have been applied consistently and uniformly with those applied in the financial statements of the Company. Significant intragroup balances and transactions and gains or losses resulting from transactions between the Company and the subsidiaries are eliminated in full in the consolidated financial statements.

c. Functional currency, presentation currency and foreign currency:

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 Company's functional and presentation currency is the US Dollar for all reported periods.

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 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 to the functional currency using the exchange rate prevailing at the date when the fair value was determined.

d. 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 and which form part of the Group's cash management.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

e. Short-term deposits:

Short-term 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.

f. Revenue recognition:

IFRS 15 "Revenue from Contracts with Customers" ("Standard") introduces a five-step model that applies to revenue earned from contracts with customers. The accounting policy applied by the Company regarding revenue recognition according to IFRS 15 "Revenue from Contracts with Customers" ("Standard") is as follows:

The Company generates revenues from the sale and lease of its systems. The Company sells its products mainly to end users and to a lesser extent to third-party distributors outside of the United States and does not provide return rights.

Revenues from sale of systems:

Revenue from sale of systems are recognized at the point in time when control of the system is transferred to the customer, generally upon delivery of the system to the customer.

Revenue from rendering of services:

Revenue from rendering of extended warranty services is recognized over time, during the period the customer simultaneously receives and consumes the benefits provided by the Company's performance. The Company charges its customers based on payment terms agreed upon in specific agreements. When payments are made before or after the service is performed, the Company recognizes the resulting contract asset or liability. Revenue from services were insignificant for all reported periods.

NOTE 2: SIGNIFICANT 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. 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. As of December 31, 2020, the Company has no unsatisfied performance obligation with a contract duration of more than one year.

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.

Revenues from lease of systems:

The Company generates revenue from leasing its systems usually for a term of up to four years either for a fixed annual fee, or a variable fee, which is determined based on the higher of: fees per treatment (i.e. usage based fees) or an annual minimum fee as stated in the contract. The classification of a lease as a finance lease or operating lease is determined based on the substance of the lease agreement, and the assessment is made at the inception date of the lease pursuant to the provisions of the Standard. Leases in which substantially all the risks and rewards incidental to ownership of the leased asset are not transferred to the lessee are classified as operating leases. Revenue from operating leases are recognized on a straight-line basis over the lease term. Usage based fees are recognized as revenue when the Company is entitled to receive such revenue.

g. 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") and repayable to the IIA through royalty-bearing sales are recognized upon receipt as a liability if future economic benefits are expected to be derived from the research project, resulting in royalty-bearing sales due to the IIA.

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 recorded as a reduction of the liability.

If no economic benefits are expected from the research activity, the grant 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.

In each reporting date, the Company evaluates whether there is reasonable assurance that the liability recognized, in whole or in part, will not be repaid 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.

Grants received from the IIA prior to January 1, 2009, which are recognized as a liability, are accounted for as forgivable loans in accordance with IAS 20, based on the original terms of the loan.

A forgivable loan from government is treated as government grant when there is reasonable assurance that the grant will be received and that the entity will meet the conditions for forgiveness of the full loan amount. Claims under the government grant relating to eligible expenses are presented as a reduction to the related expense.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

h. Leases:

On January 1, 2019, the Company first applied IFRS 16, "Leases" ("the Standard"). The Company elected to apply the provisions of the Standard using the modified retrospective method (without restatement of comparative data).

The accounting policy for leases applied effective from January 1, 2019, is as follows:

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.

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.

Leases which entitle employees to a company car as part of their employment terms are accounted for as employee benefits in accordance with the provisions of IAS 19 and not as subleases.

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	2	to	3
Motor vehicles		3	

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: SIGNIFICANT ACCOUNTING POLICIES (Continued)

The accounting policy for leases applied until December 31, 2018, is as follows:

The criteria for classifying leases as finance or operating leases depend on the substance of the agreements and is determined at the inception of the lease in accordance with IAS 17.

Leases in which substantially all the risks and rewards of ownership of the leased asset are not transferred are classified as operating leases. Operating lease payments are recognized as an expense in profit or loss on a straight-line basis over the lease term.

i. 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 other comprehensive income or 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.

U.S. dollars in thousands (except share and per share data)

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

j. Leased systems, system components and other property and equipment, net:

The cost of self-constructed systems (leased systems) includes the cost of materials, direct labor and share-based payment, as well as any costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management.

System components are stated at the lower of cost and net realizable value. Cost is determined on a weighted average basis. Net realizable value is based on estimated selling prices less estimated costs to be incurred to completion and disposal. The impairment of leased systems and system components recognized in cost of revenues was $1,061, $1,191 and $340 for the years ended December 31, 2020, 2019 and 2018, respectively.

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	6	-	15
Leasehold improvements		(*)	

(*) Leasehold improvements are depreciated on a straight-line basis over the shorter of the lease term (including the extension option held by the Company and intended to be exercised) and the expected life of the improvement.

The useful life and depreciation method of an asset are reviewed at least each year-end and any changes are accounted for prospectively as a change in accounting estimate.

k. 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.

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.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

l. Financial instruments:

1. 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; or

b. 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.

An impairment loss on debt instruments measured at amortized cost is recognized in profit or loss with a corresponding loss allowance that is offset from the carrying amount of the financial asset, whereas the impairment loss on debt instruments measured at fair value through other comprehensive income is recognized in profit or loss with a corresponding loss allowance that is recorded in other comprehensive income and not as a reduction of the carrying amount of the financial asset in the statement of financial position.

The Company has short-term financial assets such as trade receivables in respect of which the Company applies a simplified approach and measures the loss allowance in an amount equal to the lifetime expected credit losses.

2. Derecognition of financial assets:

A financial asset is derecognized only when the following criteria are met:

a. The contractual rights to the cash flows from the financial asset expire; or

b. The Company has transferred substantially all the risks and rewards deriving from the contractual rights to receive cash flows from the financial asset or has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset; or

c. The Company has retained its contractual rights to receive cash flows from the financial asset but has assumed a contractual obligation to pay the cash flows in full without material delay to a third party.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

3. Financial liabilities:

   Financial liabilities within the scope of the standard are initially recognized at fair value less transaction costs that are directly attributable to the issue of the financial liability, excluding financial liabilities measured at fair value through profit or loss whose transaction costs are carried to profit or loss.

   On the date of initial recognition, the Company classified financial liabilities measured at fair value through profit or loss. Changes in their fair value which can be attributed to changes in the Company's credit risk profile are carried to other comprehensive income.

   After initial recognition, the Company measures all financial liabilities at amortized cost, except for financial liabilities at fair value through profit or loss such as derivatives.

4. Derecognition of financial liabilities:

   A financial liability is derecognized only when it is extinguished, that is when the obligation is discharged, cancelled or expires. A financial liability is extinguished when the debtor discharges the liability by paying in cash, other financial assets, goods or services; or is legally released from the liability.

5. Issue of a unit of securities:

   The issue of a unit of securities involves the allocation of the proceeds received (before issue expenses) to the securities issued in the unit based on the following order: financial derivatives and other financial instruments measured at fair value in each period. Then fair value is determined for financial liabilities that are measured at amortized cost. The proceeds allocated to equity instruments are determined to be the residual amount. Issue costs are allocated to each component pro rata to the amounts determined for each component in the unit.

m. Fair value measurement:

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurement is based on the assumption that the transaction will take place in the asset's or the liability's principal market, or in the absence of a principal market, in the most advantageous market.

The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

Fair value measurement of a non-financial asset takes into account a market participant's ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities measured at fair value or for which fair value is disclosed are categorized into levels within the fair value hierarchy based on the lowest level input that is significant to the entire fair value measurement:

Level 1 — quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 — inputs other than quoted prices included within Level 1 that are observable either directly or indirectly.

Level 3 — inputs that are not based on observable market data (valuation techniques which use inputs that are not based on observable market data).

n. 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.

o. Employee benefit liabilities:

1. Short-term employee benefits:

Short-term employee benefits are benefits that are expected to be settled wholly before twelve months after the end of the annual reporting period in which the employees render the related services. These benefits include salaries, paid annual and sick leave, recreation and social security contributions and are recognized as expenses as the services are rendered. A liability in respect of a cash bonus or a profit-sharing plan is recognized when the Company has a legal or constructive obligation to make such payment as a result of past service rendered by an employee and a reliable estimate of the amount can be made.

2. Post-employment benefits:

The Group has defined contribution plans pursuant to Section 14 of the Severance Pay Law ("Section 14") under which the Group pays fixed contributions and has no legal or constructive obligation to pay further contributions if the fund does not hold sufficient amounts to pay all employee benefits relating to employee service in the current and prior periods.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

The Israeli Severance Pay Law, 1963 ("Severance Pay Law"), specifies that employees are entitled to severance payment following the termination of their employment. Under the Severance Pay Law, the severance payment is calculated as one month salary for each year of employment, or a portion thereof. The majority of the Company's liability for severance pay is covered by the provisions of. Under Section 14, employees are entitled to monthly deposits, at a rate of 8.33% of their monthly salary, made on behalf of the employee with insurance companies. Payments in accordance with Section 14 release the Company from any future severance payments in respect of those employees. As a result, the Company does not recognize any liability for severance pay due to these employees and the deposits under Section 14 are not recorded as an asset in the Company's balance sheet.

Contributions to the defined contribution plan in respect of severance or retirement pay are recognized as an expense when contributed concurrently with performance of the employee's services and no additional provision is required in the financial statements. See also Note 14.

p. Share-based payment transactions:

The Company's employees and other service providers are entitled to remuneration in the form of equity-settled share-based payment.

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.

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 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.

No expense is recognized for awards that do not ultimately vest.

q. Research and development expenses:

Research expenses are recognized in profit or loss when incurred. An intangible asset arising from a development project or from the development phase of an internal project is recognized if the Company can demonstrate all of the following: the technical feasibility of completing the intangible asset so that it will be available for use or sale; the Company's intention to complete the intangible asset and use or sell it; the Company's ability to use or sell the intangible asset; how the intangible asset will generate future economic benefits; the availability of adequate technical, financial and other resources to complete the intangible asset; and the Company's ability to measure reliably the expenditure attributable to the intangible asset during its development. Through December 31, 2020, the Company has not met all the aforementioned criteria and therefore all development costs have been recognized in profit or loss.

r. Net loss per share:

Net loss per share is calculated by dividing the net loss attributable to equity holders of the Company by the weighted number of Ordinary shares outstanding during the period.

Basic net loss per share includes only shares that are outstanding during the period.

Potential Ordinary shares are included in the computation of diluted net loss per share when such shares are dilutive. Potential Ordinary shares that are converted during the period are included in diluted net loss per share only until the conversion date and from that date in basic net loss per share.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

s. Changes in accounting policies – initial adoption of new financial reporting and accounting standards and amendments to existing financial reporting and accounting standards:

1. Amendments to IFRS 10 and IAS 28 regarding sale or transfer of assets between an investor and its associate or joint venture:

   In September 2014, the IASB issued amendments to IFRS 10 and IAS 28 ("the Amendments") regarding the accounting treatment of the sale or transfer of assets (an asset, a group of assets or a subsidiary) between an investor and its associate or joint venture.

   According to the Amendments, when the investor loses control of a subsidiary or a group of assets that are not a business in a transaction with its associate or joint venture, the gain will be partially eliminated such that the gain to be recognized is the gain from the sale to the other investors in the associate or joint venture. According to the Amendments, if the remaining rights held by the investor represent a financial asset as defined in IFRS 9, the gain will be recognized in full.

   If the transaction with an associate or joint venture involves loss of control of a subsidiary or a group of assets that are a business, the gain will be recognized in full.

   The Amendments are to be applied prospectively. A mandatory effective date has not yet been determined by the IASB but early adoption is permitted.

2. Amendment to IAS 16, "Property, Plant and Equipment":

   In May 2020, the IASB issued an amendment to IAS 16, "Property, Plant and Equipment" ("the Amendment"). The Amendment prohibits a company from deducting from the cost of property, plant and equipment ("PP&E") consideration received from the sales of items produced while the company is preparing the asset for its intended use. Instead, the company should recognize such consideration and related costs in profit or loss.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

s. Changes in accounting policies – initial adoption of new financial reporting and accounting standards and amendments to existing financial reporting and accounting standards: (continued)

The Amendment is effective for annual reporting periods beginning on or after January 1, 2022, with earlier application permitted. The Amendment is to be applied retrospectively, but only to items of PP&E made available for use on or after the beginning of the earliest period presented in the financial statements in which the company first applies the Amendment. The company should recognize the cumulative effect of initially applying the Amendment as an adjustment to the opening balance of retained earnings at the beginning of the earliest period presented.

The Company estimates that the application of the Amendment is not expected to have a material impact on the financial statements.

3. Amendment to IAS 37, "Provisions, Contingent Liabilities and Contingent Assets":

In May 2020, the IASB issued an amendment to IAS 37, regarding which costs a company should include when assessing whether a contract is onerous ("the Amendment"). According to the Amendment, costs of fulfilling a contract include both the incremental costs (for example, raw materials and direct labor) and an allocation of other costs that relate directly to fulfilling a contract (for example, depreciation of an item of property, plant and equipment used in fulfilling the contract).

The Amendment is effective for annual periods beginning on or after January 1, 2022 and applies to contracts for which all obligations in respect thereof have not yet been fulfilled as of January 1, 2022. Early application is permitted.

The Company estimates that the application of the Amendment is not expected to have a material impact on the financial statements.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

s. Changes in accounting policies – initial adoption of new financial reporting and accounting standards and amendments to existing financial reporting and accounting standards: (continued)

4. Amendments to IFRS 9, IFRS 7, IFRS 16, IFRS 4 and IAS 39 regarding the IBOR reform:

In September 2019, the IASB published amendments to IFRS 9, "Financial Instruments", IFRS 7, "Financial Instruments: Disclosures" and IAS 39," Financial Instruments: Recognition and Measurement" (collectively - "the Amendment").

The Amendment permits certain temporary reliefs for entities applying hedge accounting for IBOR-based instruments which are affected by the uncertainty involving the expected interest rate benchmark reform. This reform has caused uncertainty relating to the timing and amounts of future cash flows from both hedging instruments and hedged items.

The Amendment is applicable for annual periods beginning on January 1, 2020.

The adoption of the Amendment did not have an effect on the Company's financial statements as of January 1, 2020. See Note 13.

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:

Evaluation of whether to classify a lease as a finance lease or an operating lease in accordance with the criteria stipulated in IFRS 16 requires significant judgment.

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.

- Grants from the IIA:

Government grants received from the IIA are recognized as a liability if future economic benefits are expected from the research and development activity that will result in royalty-bearing sales. There is uncertainty regarding the estimated future cash flows and discount rate used to measure the amount of the liability.

- Provision for allowance for doubtful accounts on trade receivables:

The Group uses a provision matrix to calculate the allowance for doubtful accounts based on expected credit losses (ECL's) for trade receivables. The provision rates are based on days past due for its various customers. The provision matrix is initially based on the Group's 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 ECLs is sensitive to changes in circumstances and forecast economic conditions. The Group's historical credit loss experience and forecast of economic conditions may also not be representative of customers' actual default in the future. The information about the ECLs on the Group's trade receivables is disclosed in Note 6.

- 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.

U.S. dollars in thousands (except share and per share data)

NOTE 4: CASH AND CASH EQUIVALENTS

	December 31,	
	2020	2019
Cash for immediate withdrawal	$ 15,457	$ 11,640
Cash equivalents—short-term deposits (1)	1,504	10,034
	$ 16,961	$ 21,674

(1) The deposits earn annual interest at the respective term of the deposits of approximately 0.5%.

NOTE 5: SHORT-TERM DEPOSITS

	December 31,	
	2020	2019
Bank deposits (1)	$ 221	$ 221

(1) Short-term deposits at banks are for periods of up to one year. The deposits earn annual interest at the respective term of the deposits of approximately 0.5%.

NOTE 6: TRADE RECEIVABLES, NET

a. Trade receivables, net:

	December 31,	
	2020	2019
Open accounts (1)	$ 6,906	$ 6,279
Credit cards	108	158
Less—allowance for doubtful accounts	(1,432)	(930)
Trade receivables, net	$ 5,582	$ 5,507

(1) Trade receivables generally have 90 day credit terms. Certain customers payments are made through monthly credit card transactions.

Impaired debts are accounted for through recording an allowance for doubtful accounts.

b. Movement in allowance for doubtful accounts:

	U.S. dollars in thousands
Balance as of January 1, 2019	$ 335
Provision for the year	835
Derecognition of bad debts	(240)
Balance as of December 31, 2019	930
Provision for the year	1,058
Derecognition of bad debts	(556)
Balance as of December 31, 2020	$ 1,432

Following is information about the credit risk exposure of the Company's trade receivables:

December 31, 2020:

	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	$ 1,757	$ 978	$ 673	$ 670	$ 418	$ 2,518	$ 7,014
Allowance for doubtful accounts	$ 4	$ 5	$ 7	$ 33	$ 159	$ 1,224	$ 1,432
Trade receivables, net	1,753	973	666	637	259	1,294	$ 5,582

December 31, 2019:

	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	$ 2,619	$ 1,133	$ 544	$ 461	$ 247	$ 1,433	$ 6,437
Allowance for doubtful accounts	$ 7	$ 11	$ 8	$ 32	$ 69	$ 803	$ 930
Trade receivables, net	2,612	1,122	536	429	178	630	$ 5,507

U.S. dollars in thousands (except share and per share data)

NOTE 6: TRADE RECEIVABLES, NET (Continued)

As of December 31, 2020, the Company has over 90 days past due trade receivables, net of $ 1,553, of which $ 1,517 were paid between the reporting date and the date of the approval of the financial statements. The Company expects to collect the entire net amount of these debts.

NOTE 7: OTHER ACCOUNTS RECEIVABLE

	December 31,	
	2020	2019
Government authorities	$ 212	$ 378
Accrued income-IIA	208	71
Consumables	442	306
Prepaid expenses and other	672	672
	$ 1,534	$ 1,427

U.S. dollars in thousands (except share and per share data)

NOTE 8: PROPERTY AND EQUIPMENT, NET

December 31, 2020:

	Leased systems	System Components	Laboratory equipment and Computers	Right of use assets	Office furniture and equipment	Leasehold improvements	Total
Cost:							
Balance at January 1, 2020	$ 8,151	3,117	831	1,414	90	52	13,655
Additions	—	3,989	14	48	6	—	4,057
Transfer to Leased systems	1,580	(1,580)	—	—	—	—	—
Reductions	(1,111)(**)	(1,884)(***)	—	(127)	—	—	(3,122)
Balance at December 31, 2020	8,620	3,642	845	1,335	96	52	14,590
Accumulated depreciation:							
Balance at January 1, 2020	2,660	$ —	$ 694	$ 460	$ 50	$ 52	$ 3,916
Additions	1,180	—	81	351	6	—	1,618
Reductions	(418)	—	—	(76)	—	—	(494)
Balance at December 31, 2020	3,422	—	775	735	56	52	5,040
Depreciated cost at December 31, 2020	$ 5,198	$ 3,642	$ 70	$ 600	$ 40	$ —(*)	$ 9,550

December 31, 2019:

	Leased systems	System Components	Laboratory equipment and Computers	Right of use assets	Office furniture and equipment	Leasehold improvements	Total
Cost:							
Balance at January 1, 2019	$ 6,369	$ 2,717	$ 794	$ 1,414	$ 82	$ 52	$ 11,428
Additions	—	5,521	37	—	8	—	5,566
Transfer to Leased systems	2,150	(2,150)	—	—	—	—	—
Reductions	(368)(**)	(2,971)	—	—	—	—	(3,339)
Balance at December 31, 2019	8,151	3,117	831	1,414	90	52	13,655
Accumulated depreciation:							
Balance at January 1, 2019	1,679	—	613	—	44	52	2,388
Additions	1,054	—	81	460	6	—	1,602
Reductions	(73)	—	—	—	—	—	(73)
Balance at December 31, 2019	2,660	—	694	460	50	52	3,916
Depreciated cost at December 31, 2019	$ 5,491	$ 3,117	$ 137	$ 954	$ 40	$ —(*)	$ 9,739

(*) Represents an amount lower than $ 1

(**) Derived mainly from systems leased to customers and sold

(***) Includes impairment charge of $1,061 for the year ended December 31, 2020.

U.S. dollars in thousands (except share and per share data)

NOTE 9: FAIR VALUE MEASUREMENT

The following table presents the fair value measurement hierarchy for the Group's assets and liabilities.

Quantitative disclosures of the fair value measurement hierarchy of the Group's assets and liabilities as of December 31, 2020 and 2019:

	Valuation date	Fair value hierarchy			
		Level 1	Level 2	Level 3	Total
Liabilities measured at fair value:					
Liability in respect of warrants	31.12.2020	$ —	$ 38	$ —	$ 38
Liability in respect of warrants	31.12.2019	$ —	$ 78	$ —	$ 78

The fair value of the warrants for the years ended December 31, 2020 and 2019 was estimated using the Binomial model with the following assumptions:

	Year ended December 31,	
	2020	2019
Dividend yield (%)	0	0
Expected volatility (%)	56.58%	40.24%
Risk-free interest rate (%)	0.12%	1.61%
Expected life (years)	1.75	2.76

U.S. dollars in thousands (except share and per share data)

NOTE 10: TRADE PAYABLES

	December 31,	
	2020	2019
Open debt	$ 781	$ 1,320

Trade payables are non-interest bearing and are normally settled on up to 90 day terms.

NOTE 11: OTHER ACCOUNTS PAYABLE

	December 31,	
	2020	2019
Employee and payroll accruals	$ 972	$ 1,216
Accrued expenses	2,266	1,620
Tax payable	—	1
Liabilities to related parties (1)	102	128
Lease liabilities	429	414
	$ 3,769	$ 3,379

(1) A current non-interest bearing account.

NOTE 12: NON-CURRENT LIABILITIES

a. Composition:

	December 31,	
	2020	2019
Warrants (c)	$ 38	$ 78
Liability in respect of research and development grants(d)	5,524	5,367
Deferred revenues and other liabilities	1,772	1,690
Lease liabilities(b)	243	663
	$ 7,577	$ 7,798

U.S. dollars in thousands (except share and per share data)

NOTE 12: NON-CURRENT LIABILITIES (Continued)

b. Lease liabilities:

	December 31, 2020
Maturity analysis:	
Less than one year	463
One to five years	312
Total lease commitments	775
Impact of discounting remaining lease payments	(103)
Total lease liabilities as of December 31, 2020	672
Lease liabilities as of December 31, 2020:	672
Current	429
Non-current	243
Total	$ 672

	December 31, 2019
Maturity analysis:	
Less than one year	525
One to five years	1,106
Total lease commitments	1,631
Impact of discounting remaining lease payments	(217)
Total lease liabilities as of January 1, 2019	1,414
Lease liabilities as of December 31, 2019:	1,077
Current	414
Non-current	663
Total	$ 1,077

c. Loan from bank:

On August 17, 2017, the Company entered into an agreement for the receipt of a bank credit facility of up to $ 6,000 (the "Bank Credit Facility"). $ 3,000 was withdrawn during 2018 ("the first facility") and bear annual interest of 3-months LIBOR plus 6%. The remaining credit facility ("the second facility") may be withdrawn until March 15, 2018 bearing annual interest 3-months LIBOR plus 6.75%. The interest on the loans is payable on a quarterly basis and the loan principal is repayable in eight equal consecutive quarterly installments, whereby the first installment is due at the end of 18 and 12 months from the date of withdrawal of the loans from the first and second facilities, respectively. Also, according to the agreement, the Company will grant the bank warrants to purchase its ordinary shares for the total exercise price of up to $ 600. The warrants are exercisable for a period of five years from the date of any grant at an exercise price of $ 5.02 per share to be settled in cash or a cashless exercise mechanism.

NOTE 12: NON-CURRENT LIABILITIES (Continued)

On October 3, 2017, the Company granted the bank 59,761 warrants at an aggregate exercise price of $300 as a condition for receiving the first facility.

The fair value of the warrants at the grant date was estimated at $ 150 and the remaining balance of $2,850 was attributed to the loan. Transaction costs of $ 156 were allocated based on to the relative fair value of the warrants and loan. The warrants are classified as a financial liability and measured at fair value through profit or loss.

The remaining warrants will be granted on the date of withdrawal of the loan from the second facility, so that the exercise amount will constitute 10% of the loan actually withdrawn from the second facility. The Company is entitled to make an early repayment of all or part of the loans. In such a case, the Company will pay the bank an early repayment fee as detailed in the agreement.

As part of the agreement, and as a condition for using the first and second facilities, the Group undertook to provide the bank fixed and floating charges on all its assets, including property, cash, goodwill, intellectual property, rights and assets of any kind. In addition, the Group undertook to sign a guarantee letter, unlimited in amount, to secure the loans that will be provided by virtue of the agreement. Also, a senior fixed charge, unlimited in amount, was provided on a specific deposit in which an amount of not less than $ 2,000 was deposited ("the deposited amount"). It was agreed that if by March 16, 2018, the amount of loans actually withdrawn is less than $ 6,000, the deposited amount would be placed at one-third of the actual amount of loans outstanding on that date.

In accordance with the amendments to the agreement signed up to March 14, 2019, loans under the Second facility may be withdrawn until May 30, 2019. The other terms of the first and second facility remain unchanged.

On May 5, 2019, following the Company's initial public offering, the Company repaid the balance of the loan.

d. Government grants:

In July 2020, the Company received $638 as a loan from the Paycheck Protection Program in the United States (the "Program"). The terms of the Program provide that a portion of the loan may be forgiven, to the extent that the amounts spent during the eight-week period were on qualifying expenses ("Program Expenses"). The unforgiven part of the loan must be repaid within two years and bears interest at 1% per annum. The Company used the entire proceeds to pay Program Expenses and received approval for the loan forgiveness. Therefore, the loan has been recorded as a grant against the related Program Expenses.

Moach received from the Israeli Government participation grants in research and development 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, 2020, the maximum royalties payable by the Company in the future in respect of active projects is $12,548, including interest at the LIBOR rate. Through December 31, 2020, royalties paid were $2,624.

NOTE 13: FINANCIAL INSTRUMENTS

a. Classification of financial assets and financial liabilities:

The financial assets and financial liabilities in the statement of financial position are measured at amortized cost, except financial liabilities in respect of warrants at fair value through profit or loss. The balance of financial liabilities in respect of warrants as of December 31, 2020 and 2019 was $ 38 and $78, respectively.

b. Financial risks factors:

The Group's activities expose it to various financial risks such as market risks (foreign currency risk, interest risk), credit risk and liquidity risk. The Group's comprehensive risk management plan focuses on activities that reduce to a minimum any possible adverse effects on the Group's financial performance.

The Company's Chief Financial Officer oversees the management of these risks in accordance with the policies approved by the board of directors.

1. Market risks:

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.

Regulators in many countries are in the process of replacing benchmark Interbank Offered Rates (IBORs), of which one of the most common is the LIBOR, with risk-free interest rate alternatives (RFRs). The replacement of IBORs with RFRs is expected to occur gradually until the end of 2021.

The repayment of grants received by the Company from 2020 have interest rate that reference LIBOR and are expected to be repaid after 2021. As of December 31, 2020, the carrying amount of the financial liabilities is $300. Since an alternative interest rate was not determined by the IIA yet, at this stage the Company is unable to determine the effects, if any, that the discontinuance of IBORs will have on its financial instruments that reference the IBORs.

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 Group monitors its risk of a shortage of cash using a quarterly budget.

U.S. dollars in thousands (except share and per share data)

NOTE 13: FINANCIAL INSTRUMENTS (Continued)

The table below presents the maturity profile of the Group's financial liabilities based on contractual undiscounted payments:

December 31, 2020:

	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	$ 781	$ —	$ —	$ —	$ —	$ —	$ 781
Other accounts payable	3,340	—	—	—	—	—	3,340
Liability in respect of research and development grants	388	713	893	1,261	1,793	8,108	13,156
Lease liability	463	299	13	—	—	—	775
	$ 4,972	$ 1,012	$ 906	$ 1,261	$ 1,793	$ 8,108	$ 18,052

December 31, 2019:

	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	$ 1,320	$ —	$ —	$ —	$ —	$ —	$ 1,320
Other accounts payable	2,965	—	—	—	—	—	2,965
Long-term liabilities	1	1	—	—	—	—	2
Liability in respect of research and development grants	810	1,050	1,335	1,635	1,980	6,792	13,602
Lease liability	572	449	271	—	—	—	1,292
	$ 5,668	$ 1,500	$ 1,606	$ 1,635	$ 1,980	$ 6,792	$ 19,181

c. Fair value:

The carrying amount of cash and cash equivalents, short-term deposits, trade receivables, other accounts receivable, trade payables, other accounts payable, warrants, long-term liabilities approximate their fair value.

Financial liabilities measured at fair value:

December 31, 2020:

	Level 2
Opening balance at January 1, 2020	$ 78
Amounts transferred to the statement of comprehensive loss as finance income	(40)
Closing balance at December 31, 2020	$ 38

U.S. dollars in thousands (except share and per share data)

NOTE 13: FINANCIAL INSTRUMENTS (Continued)

During 2020, 2019 and 2018, there were no transfers between levels of the fair value hierarchy.

d. Sensitivity tests relating to changes in foreign currency:

	December 31,	
	2020	2019
Sensitivity test to changes in the NIS exchange rate:		
Gain (loss) from the change:		
Increase of 5% in exchange rate	(50)	(88)
Decrease of 5% in exchange rate	50	88

As of December 31, 2020, the Company has excess of financial assets over financial liabilities in NIS in relation to US dollar of $ 2,001.

As of December 31, 2020, the Company has excess of financial assets over financial liabilities in Euro and Yen in relation to US dollar of $ 3,198 and $ 437, respectively. An increase or decrease of 5% of the US dollar relative to the Euro or Yen would not have a significant effect on the Company.

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.

NOTE 14: EMPLOYEE BENEFITS AND LIABILITIES

Employee benefits consist of short-term and post-employment benefits.

Defined contribution plans:

Section 14 to the Severance Pay Law, 1963 applies to all of the Company's employees pursuant to which the fixed contributions paid by the Group into pension funds and/or policies of insurance companies release the Group 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 $258 and $325 for the years ended December 31, 2020 and 2019, respectively.

NOTE 15: TAXES ON INCOME

a. Tax rates applicable to the Company and subsidiaries:

1. Tax rate applicable to Company and Moach:

In December 2016, the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2018 and 2019 Budget Years), 2018 was approved, which reduces the corporate income tax rate to 24% (from 25%) effective from January 1, 2018 and to 23% effective from January 1, 2019.

The Israeli corporate income tax rate was 23% for 2018 and thereafter.

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 USA Inc and Inc:

The weighted tax rate for 2018 and thereafter for companies incorporated in the US was 27% and 35%-40% (Federal, State and City tax of the city where the company operates), respectively.

On December 22, 2018, the Tax Cuts and Jobs Act (the "Act") was enacted into law. The income tax effects of changes in tax laws are recognized in the period when enacted. The Act provides for numerous significant tax law changes and modifications with varying effective dates, which include reducing the corporate federal income tax rate from 35% to 21%, creating a semi-territorial tax system (with a one-time mandatory tax on previously deferred foreign earnings), broadening the tax base and allowing for immediate capital expensing of certain qualified property.

The Act also changed to a semi-territorial system. As a result, a one-time transition tax is imposed on the accumulated earnings and profits of the foreign subsidiaries of the US entities. The Company's subsidiaries in the United States do not have any profitable foreign subsidiaries and, therefore, the remaining provisions of the Act have no material impact on the Company's results of operations.

The main differences between the statutory corporate tax rate and the effective tax rate are carryforward losses in Israel in respect of which no deferred taxes were recorded and a current tax expense in respect of income of USA Inc and Inc.

b. Tax benefits under the Israel Law for the Encouragement of Capital Investments, 1959 ("Law") and Amendment to the Law for the Encouragement of Capital Investments, 1959 (Amendment 73):

In December 2016, the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2018 and 2019 Budget Years), 2016 which includes Amendment 73 to the Law for the Encouragement of Capital Investments ("the amendment") was published. According to the amendment, a "beneficiary enterprise" located in development area A will be subject to a tax rate of 7.5% instead of 9% effective from January 1, 2018 and thereafter (the tax rate applicable to preferred enterprises located in other areas remains at 16%).

NOTE 15: TAXES ON INCOME (Continued)

The amendment also prescribes special tax tracks for technological enterprises, which became effective in 2018, as follows:

Technological preferred enterprise—an enterprise for which total consolidated revenues of its parent company and all subsidiaries are less than NIS 10 billion. A technological preferred enterprise, as defined in the amendment, which is located in the center of Israel will be subject to tax at a rate of 12% on profits deriving from intellectual property (in development area A - 7.5%).

Any dividends distributed to a "foreign company", as defined in the amendment, deriving from income from the technological preferred enterprise will be subject to tax at a rate of 4%.

The Law for the Encouragement of Industry (Taxation), 1969:

Moach has the status of an "industrial company", as defined by this law. According to this status and by virtue of regulations published thereunder, the Company is entitled to claim a deduction of accelerated depreciation on equipment used in industrial activities, as determined in the regulations issued under the Inflationary Law. The Company is also entitled to amortize a patent or rights to use a patent or intellectual property that are used in the enterprise's development or advancement, to deduct issuance expenses for shares listed for trading and to file a consolidated report under certain conditions.

Subject to meeting criteria determined in the Law and amendment, at the time Moach becomes profitable for tax purposes, Moach will be entitled to various corporate tax benefits, as implied by the Law and amendment.

c. Tax assessments:

The Company received final tax assessments through the 2015 tax year. The subsidiary, Moach, received final tax assessments through 2015. The subsidiary, Inc, received final tax assessments through the 2017 tax year.

d. Carryforward losses for tax purposes:

Carryforward losses for tax purposes as of December 31, 2020 are approximately $4.0 million in Brainsway Ltd. and approximately $49.3 million in Moach.

e. Deferred taxes:

As it is not probable that taxable income will be derived in the next years, a valuation allowance was established in respect of deferred taxes of the above carryforward losses.

NOTE 16: CONTINGENT LIABILITIES, COMMITMENTS AND CHARGES

a. As for contingent liability in respect of payment of royalties to the IIA, see Note 12d.

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 granted the exclusive right to market, distribute, lease and/or sale, use and promote sales of the systems in the different territories up to a 15 year period. The Company will supply the systems to the distributors and they will install, train and maintain the systems in the territory they operate. The different distributors are committed to minimum quantities as stated in the agreements.

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 major depression 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 years 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 is obligated to pay the Company distribution fees of 190 million Yen (approximately $1.8 million), whereby 100 million Yen (approximately $1 million as of December 31, 2020) paid in September 2013 and 90 million Yen (approximately $0.8 million as of December 31, 2020) paid in 2019.

In each year of the agreement in which the distributor meets the respective annual predetermined revenue target, 10% of the distribution fees are returned to the distributor. The distribution fee which the Company expects to be entitled to is presented in deferred revenues and is recognized as revenue during the estimated exclusivity term. The distributor will pay the Company for any treatment made with the Company's system (pay-per-use), but in no case less than the pre-determined annual amount. The agreement prescribes conditions in which the Company or the distributor can cancel the agreement, including the authorities' demand to require a clinical trial and non-compliance with the requirement to purchase minimum predetermined quantities.

The agreement sets a minimum payment threshold to the Company that is examined every few years throughout the contractual term. If the distributor does not qualify for the minimum payment threshold at the end of each period, the Company will be entitled to terminate the distribution agreement, unless the parties reach another agreement between them. The agreement further determines that the distributor will act on its account to receive the regulatory approvals that are required to market the Company's system for the treatment of depression in patients in Japan and to receive reimbursement coverage at the price range established in the agreement.

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. On January 2019, approval of the PMDA was received.

The Company is currently working through its distributor in Japan with the relevant bodies in Japan to update the local society guidelines to include Deep TMS in order to obtain reimbursement coverage under the Japanese National Health Insurance Plan.

NOTE 16: CONTINGENT LIABILITIES, COMMITMENTS AND CHARGES (Continued)

d. On August 25, 2013, the Company received the approval of the MAGNET committee of the IIA for the development plan of the BSMT tool (brain stimulate and monitor tool). The plan was approved for three years and extended up to five years, in the framework of which the Company was approved work plans with participation rate of up to 66% of a non-royalty bearing grant.

In September 2017 and October 2018, the MAGNET committee approved an annual work plan for the fifth year with the budget of NIS 2,300, of out of which 55% (NIS 1,300) was provided to the Company as non-royalty bearing grants to date. The execution of this plan was completed by December 31, 2018.

e. In March 2014, the Company entered into an exclusive marketing and distribution agreement of the Company's system with a third party in Israel for a maximum period of 15 years, subject to meeting minimum sales targets as set in the agreement. In April 2014, the distributor paid the Company a one-time exclusivity fee of NIS 1 million. Effective July 2019, the Company assumed direct operations for customers in Israel, after terminating its distribution agreement with the third-party distributor, pursuant to which a portion of the exclusivity fee (up to NIS 600) was determined to be refundable depending on future sales.

f. 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 royalties at fixed annual amount of $2 from January 1, 2004 and royalties of 2% of net sales beyond this amount as defined 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 current provision for royalties as of December 31, 2020 is $259.

   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.

The balance of provision for royalties as of December 31, 2019 and 2020 is $ 124 and $ 226, respectively.

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 and 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. While initially valid up to the earlier of December 31, 2018 or 30 days after completion of all the milestones agreed between the parties, in order to provide more time for the defined milestones, the parties extended this date until December 31, 2019. In respect of the performance of the milestones under the fifth addendum, in December 2017, the Company received the approval of the MAGNET committee of the IIA ("Magneton") for a development plan to be performed jointly with Yeda. The Company's approved budget for the development plan is NIS 1.1 million, of which 66% (approximately NIS 0.7 million) which will be provided to the Company as a non-royalty bearing grant over the term of the plan.

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%.

U.S. dollars in thousands (except share and per share data)

NOTE 17: EQUITY

a. Composition of share capital:

	December 31, 2020		December 31, 2019	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
	Number of shares			
Ordinary shares of NIS 0.04 par value each	25,000,000	22,250,534	25,000,000	22,236,368

b. Movement in share capital:

Issued and outstanding capital:

	Number of shares	NIS par value
Balance at January 1, 2020	22,236,368	233,167
Exercise of share options	14,166	164
Balance at December 31, 2020	22,250,534	233,331
Balance at December 31, 2019	22,236,368	233,167

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, Ordinary shareholders have one vote at the shareholders' meeting such that each share confers one vote to its holder.

d. In April 2019, the Company closed its initial public offering in Nasdaq of 2,500,000 American Depositary Shares ("ADSs"), each representing two ordinary shares of Brainsway, at a public offering price of $11.00 per ADS. The gross proceeds to the Company from the offering, before deducting the underwriting discounts and commissions and estimated offering expenses, are approximately $27.5 million.

U.S. dollars in thousands (except share and per share data)

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.

See Note 22, events after the reporting period.

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,		
	2020	2019	2018
Equity-settled share-based payment plans to employees, directors and consultants	$ 799	$ 1,263	$ 710

b. The share-based payment transactions that the Company granted to its employees, directors and consultants are shown in the following table:

Issuance Date	Grantee	Options outstanding as of December 31, 2020	Exercise price NIS	Exercise price $*)	Exercisable as of December 31, 2020	Exercisable Through	Total Fair Value $
December 8, 2015	Employees and Consultant	292,250	25.99	6.70	292,250	December 8, 2025	1,053
December 8, 2015	Employees and Consultant	270,000	31.19	8.04	270,000	December 8, 2025	1,247
April 1, 2017	Chief Executive Officer and Director	566,262	19.97	5.47	566,262	April 1, 2025	1,100
December 3, 2017	Director	27,500	21.37	6.12	9,167	December 3, 2027	54
November 12, 2018	Directors	110,000	23.39	6.36	—	November 12, 2026	298
November 12, 2018	Employees and officers	672,600	23.39 - 24.22	6.36 - 6.59	—	November 12, 2026	2,299
October 1, 2019	Chief Financial and Operating Officer	50,000	19.08	5.48	—	October 1, 2027	100
January 13,2020	Director	55,008	18.52	5.30	---	January 13, 2028	133
May 11, 2020	Chief Financial Officer	100,000		5.58		May 11, 2028	158
June 1, 2020	VP Global Marketing	60,000		5.58		June 1, 2028	177
November 19, 2020	Director of Market Access, Director of Analytics	70,000		3.40		November 19, 2030	228

*) As of grant date.

c. The fair value of the Company's options granted for the years ended December 31, 2020, 2019 and 2018 was estimated using the Binomial model with the following assumptions:

	Year ended December 31,								
	2020			2019			2018		
Dividend yield (%)	0			0			0		
Expected volatility (%)	48.00	-	76.78	40.06	-	48.09	40.51	-	48.25
Risk-free interest rate (%)	0.14	–	0.62	1.61	–	1.73	0.28	-	2.22
Expected exercise factor	2.8			2.8			2.8		
Post-vesting forfeiture rate (%)	5			5			5		

U.S. dollars in thousands (except share and per share data)

NOTE 18: SHARE-BASED PAYMENT (Continued)

d. Movement during the year:

	Year ended December 31,			
	2020		2019	
	Number of options	Weighted average exercise price(*)	Number of options	Weighted average exercise price(*)
		$		$
Outstanding at January 1,	2,213,812	$ 7.1	2,425,192	$ 6.6
Granted	285,008	5.4	50,000	5.5
Exercised	(246,262)	(**)5.8	-	-
Expired	(535,667)	7.4	(59,765)	7.5
Forfeited	(193,916)	6.7	(201,615)	7.0
Outstanding at December 31,	1,522,975	$ 7.5	2,213,812	$ 7.1
Exercisable at December 31,	839,418	$ 9.5	1,362,879	$ 7.38

(*) 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, 2020 and 2019, respectively.

The weighted average remaining contractual life for the options outstanding as of December 31, 2020 and 2019 was approximately six years.

The range of exercise prices for options outstanding as of December 31, 2020 and 2019 was USD 4.0-18.5.

In January 2020, the Company granted the Company's Chief Executive Officer ("CEO") upon his employment, 240,000 restricted stock units ("RSUs") of which 60,000 RSUs were granted through January 26, 2021, and 180,000 RSUs have been committed to be provided in three future grants of 60,000 RSUs upon each anniversary of the employment start date of the CEO with the Company. The terms of the 180,000 committed CEO RSU's were amended subsequent to balance sheet date - See Note 22(b).

(**) The options were exercised by way of a cashless exercise.

NOTE 19: ADDITIONAL INFORMATION TO THE STATEMENTS OF COMPREHENSIVE LOSS

a. Additional information on revenues:

Revenues reported in the financial statements for each group of similar products and services:

	Year ended December 31,		
	2020	2019	2018
Revenues from lease	$ 13,628	$ 13,218	$ 9,569
Revenues from sale	8,429	9,883	6,828
	$ 22,057	$ 23,101	$ 16,397

U.S. dollars in thousands (except share and per share data)

NOTE 19: ADDITIONAL INFORMATION TO THE STATEMENTS OF COMPREHENSIVE LOSS (Continued)

Geographic information:

Revenues reported in the financial statements derived from the Company's country of domicile (Israel) and foreign countries based on the location of the customers, are as follows:

	Year ended December 31,					
	2020	%	2019	%	2018	%
U.S.	$ 19,330	88	$ 20,636	89	$ 14,478	88
Europe	1,847	8	1,353	6	1,102	7
Israel	150	1	845	1	371	2
Other	730	3	267	4	446	3
	$ 22,057	100	$ 23,101	100	$ 16,397	100

The total amounts of future minimum lease payments to be received under non-cancellable operating leases as of December 31, 2020 and 2019 are as follows:

	Year ended December 31,	
	2020	2019
Not later than one year	$ 9,684	$ 8,527
Later than one year and not later than five years	15,875	12,723
Later than five years	32	571
Total future minimum lease payments under non-cancellable operating leases	$ 25,591	$ 21,821

b. Cost of revenues:

	Year ended December 31,		
	2020	2019	2018
Cost of revenues—lease	$ 3,201	$ 2,656	$ 1,923
Cost of revenues—sales	1,857	2,473	1,666
	$ 5,058	$ 5,129	$ 3,589

U.S. dollars in thousands (except share and per share data)

NOTE 19: ADDITIONAL INFORMATION TO THE STATEMENTS OF COMPREHENSIVE LOSS (Continued)

c. Research and development expenses, net:

	Year ended December 31,		
	2020	2019	2018
Salaries and related benefits	$ 3,289	$ 3,338	$ 3,365
Subcontractors	1,530	2,620	2,241
Laboratory materials	275	687	491
Patents	288	334	198
Share-based payment	182	399	31
Travel	2	112	65
Depreciation	87	39	31
Other	383	604	658
Less—Government grants	(213)	(257)	(924)
	$ 5,823	$ 7,876	$ 6,156

d. Selling and marketing expenses:

	Year ended December 31,		
	2020	2019	2018
Salaries and related benefits	$ 6,458	$ 6,419	$ 4,252
Agent commissions	335	221	215
Marketing	3,627	5,239	2,891
Travel	611	1,176	865
Share-based payment	252	214	122
	$ 11,283	$ 13,269	$ 8,345

e. General and administrative expenses:

	Year ended December 31,		
	2020	2019	2018
Salaries and related benefits	$ 1,339	$ 1,774	$ 1,235
Professional fees and office expenses	1,609	1,770	1,176
Depreciation	351	81	30
Travel	17	222	127
Bad debts and allowance for doubtful accounts	1,058	835	296
Share-based payment	348	621	557
	$ 4,722	$ 5,303	$ 3,421

U.S. dollars in thousands (except share and per share data)

NOTE 19: ADDITIONAL INFORMATION TO THE STATEMENTS OF COMPREHENSIVE LOSS (Continued)

f. Finance income and expense:

	Year ended December 31,		
	2020	2019	2018
Finance income:			
Interest-income revaluation of bank deposits	$ 61	$ 175	$ 44
Revaluation of warrants	40	62	—
Exchange rate differences, net	448	—	—
	$ 549	$ 237	$ 44
Finance expense:			
Liability in respect of research and development grants	$ 762	$ 969	$ 519
Interest expense and amortization of deferred costs- loan from bank	—	283	354
Bank commissions	40	108	41
Revaluation of warrants	—	—	28
Exchange rate differences, net	—	192	258
Interest expense of lease liability	66	115	—
	$ 868	$ 1,667	$ 1,200

NOTE 20: NET LOSS PER SHARE

Number of shares and loss used in the computation of net loss per share:

	Year ended December 31,					
	2020		2019		2018	
	Weighted number of shares*)	Loss 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
Used in the computation of basic and diluted net loss	22,453,025	$ 5,385	20,506,202	$ 10,328	16,640,446	$ 6,479

*) 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.

U.S. dollars in thousands (except share and per share data)

NOTE 21: BALANCES AND TRANSACTIONS WITH RELATED PARTIES

a. Balances with interested and related parties:

Composition:

As of December 31, 2020

	Key management personnel	Other interested and related parties
Other accounts payable	$ 64	$ 38

As of December 31, 2019

	Key management personnel	Other interested and related parties
Other accounts payable	$ 102	$ 26

b. Benefits to interested and related parties:

	Year ended December 31,		
	2020	2019	2018
Salary to those employed by the Company or on its behalf	$ 769	$ 945	$ 654
Directors' fees to those not employed by the Company or on its behalf	$ 60	$ 90	$ 100
Number of individuals to whom the salary and benefits relate:			
Related and interested parties employed by the Company or on its behalf	2	3	4
Directors not employed by the Company	6	8	6
	8	11	10

U.S. dollars in thousands (except share and per share data)

NOTE 21: BALANCES AND TRANSACTIONS WITH RELATED PARTIES (Continued)

c. Key management personnel:

	Year ended December 31,		
	2020	2019	2018
Short-term benefits	$ -	$ 3	$ 16
Share-based payment to those employed by the Company or on its behalf	$ 182	$ 190	$ 394
Share-based payment to those not employed by the Company or on its behalf	$ 150	$ 147	$ 41

d. Transactions with interested and related parties:

Year ended December 31, 2020

	Key management personnel*)	Other interested and related parties
Research and development expenses	$ 236	$ -
General and administrative expenses	619	201
Sales and marketing expenses	150	-
	$ 1,005	$ 201

Year ended December 31, 2019

	Key management personnel*)	Other interested and related parties
Research and development expenses	$ 113	$ 81
General and administrative expenses	943	238
	$ 1,056	$ 319

Year ended December 31, 2018

	Key management personnel*)	Other interested and related parties
Research and development expenses	$ 207	$ 81
General and administrative expenses	776	140
	$ 983	$ 221

*) Some of the key management personnel are interested parties by virtue of holdings.

e. Mr. Yaakov Michlin commenced his role as the Company's Chief Executive Officer (CEO) on April 1, 2017. On February 12, 2017, (the general shareholders meeting), his employment terms, including bonuses incremental to his monthly compensation were approved as follows: (1) bonuses of NIS 1 million based on target achievements as outlined in his agreement.; (2) an annual bonus based on the Company's remuneration policy according to the decision of the Company's Board of directors.

NOTE 21: BALANCES AND TRANSACTIONS WITH RELATED PARTIES (Continued)

In addition, upon commencement of his role, Mr. Michlin was granted 566,262 options to purchase Ordinary shares of the Company at an exercise price of NIS 19.97, representing 3.6% and 3.1% of the Company's issued and outstanding capital on a fully diluted basis as of January 5, 2017, the date on which the board of directors approved the employment terms, and December 31, 2018, respectively. The price was determined according to the average closing market price of the Ordinary share 30 days before the date of grant. The options vest over four years from the date of grant as outlined in the agreement. In September 2019, Yaacov Michlin resigned as CEO.

For information regarding the fair value of the options granted to Mr. Michlin, see Note 18b.

Mr. Christopher R. von Jako, PhD commenced his role as the Company's President and Chief Executive Officer (CEO) effective January 1, 2020. Key employment terms include an annual gross base salary and an annual performance-based bonus of up to six months of his base salary and equity grant of RSUs as further detailed in Note 18d.

f. For information regarding the fair value of the options granted to directors, see Note 18b.

NOTE 22: EVENTS AFTER THE REPORTING PERIOD

a. On January 26, 2021, the Board of Directors and on March 4, 2021 the shareholders (with respect to the directors), respectively, approved the repricing, by way of an exchange offer, of approximately 1.474 million Ordinary Shares ("Ordinary Shares") that had previously been granted to officers, independent Board members, employees and consultants of the Company the pursuant to the Brainsway 2014 Share Incentive Plan, and the Brainsway Amended and Restated 2019 Share Incentive Plan (the "2014 Plan" and the "2019 Plan", respectively) to an exercise price of $4.675 ($9.35 per ADS), being a price equal to the closing price per Ordinary Share on January 25, 2021, provided, however, that: (1) with respect to directors' options, the repricing of each option will ,be subject to shareholders approval at an exercise price equal to the higher of (a) $4.675 ($9.35 per ADS) (b) the closing price per Ordinary Share on the last trading date before the date of approval by the shareholders and (2) the exercise price offered to U.S Taxpayers within the proposed exchange offer shall be the higher of (i) the exercise price above and (ii) the fair market value of the Company's ADSs on the last trading date before the filing of the exchange offer.

b. The equity compensation package that the Company granted to the Company's Chief Executive Officer ("CEO") upon his employment, comprised of 240,000 performance-based restricted stock units ("RSUs") of which 60,000 RSUs were granted through to January 26, 2021, and 180,000 RSUs have been committed to be provided in three future grants of 60,000 RSUs upon each anniversary of the employment start date of the CEO with the Company. These future grants, as originally contemplated, would have been subject to satisfaction of certain individual and corporate performance-based criteria as defined in the CEO's employment agreement. The Board of Directors and shareholders approved to grant 180,000 RSUs to the CEO as an amendment to the terms of employment of the CEO, in lieu of future grants of such RSUs per above.

c. The Company announced on March 1, 2021, the closing of its underwritten public offering of 5,315,300 American Depositary Shares ("ADSs"), upsized to include 693,300 ADSs sold pursuant to the underwriters' exercise in full of their option to purchase additional ADSs, at a price to the public of $8.50 per ADS. The gross proceeds from the offering, before deducting underwriting discounts and commissions and offering expenses, were approximately $45.2 million.

Exhibit 1.1

[UNOFFICIAL TRANSLATION INTO ENGLISH]

Amended and Restated Articles of Association

of

Brainsway Limited

Preamble

1.

1.1. In these Articles of Incorporation, save if the context requires otherwise -

"Man", "Person" or "Persons"	Including a corporation
"In Writing"	Handwritten, printed, on a typewriter, on a photocopy, telex, fax or in any other manner which is readable.
"Registered Shareholder"	Shareholder as per the definition of Article 177 (2) of the Law.
"Unregistered Shareholder"	Shareholder as per the definition of Article 177 (1) of the Law.
"The Company"	Brainsway Ltd.
"The Law" or "The Companies Law"	The Companies Law - 1999, as shall be from time to time and the Regulations issued thereunder.
"The Securities Law"	The Securities Law - 1968, as shall be from time to time and the Regulations thereunder, as issued from time to time.
"The Secretary"	The appointed Secretary of the Company.
"The Registry" or "The Registry of Shareholders"	The registry of shareholders of the company which must be maintained according to the Law.
"The Office" or "The Registered Office"	The office of the Company, whose address shall be registered with the Registrar of Companies, as shall be from time to time.
"The Ordinance" or "The Companies Ordinance"	The Companies Ordinance (new version) - 1983, as shall be from time to time, and regulations which shall be issued thereunder.
"Special Majority"	A majority of at least two-thirds of all the votes of the shareholders present at the general meeting or in the class meeting, as the case may be, entitled to vote and voted on their own or by proxy, without taking into account abstentions.
"Ordinary Majority"	Ordinary majority of all of the votes of the shareholders present in the general meeting or in the class meeting, as the case may be,

	entitled to vote and having voted, without taking into account abstentions.
“Year” or “Month”	Of the Gregorian calendar.
“Corporation”	Company, partnership, cooperative association, association and any other incorporated or unincorporated group of persons.
“These Articles” or “The Articles”	The Articles of Incorporation in this document, as shall be amended from time to time.

1.2. For every term in these Articles which has not been defined above, the significance shall be that which is known in The Companies Law, save if this is contradictory to the matter which is written or its contents; the singular shall include the plural and vice versa and the masculine shall include the feminine.

1.3. The headings in these Articles are intended for convenience only and may not be used for interpretation of these Articles.

1.4. In every place where these Articles determine that its provisions shall apply subject to the Ordinance and/or The Companies Law and/or any Law, the intention is the provisions of the Ordinance and/or the provisions of The Companies Law and/or any Law, which may not be stipulated upon, save if the context requires otherwise.

1.5. The provisions which maybe stipulated upon in The Companies Law shall apply to the Company save if determine otherwise in these Articles and to such extent as there is no contradiction between them and the provisions of these Articles.

Name of the Company

2. The name of the Company is Brainsway Ltd.

Limitation of Liability

3. Limited liability

3.1. The liability of a shareholder for the debts of the Company is limited to the discharge of the amount (including premium) at which shares were allotted to him but not less than of nominal value of the shares allotted to him, save if shares were allotted to him at law for a consideration which is lower than their nominal value, in which case his liability is limited to the discharge of the consideration for which the share was allotted to him.

3.2. The Company is not entitled to change the liability of a shareholder or to obligate a shareholder to purchase additional shares without his consents.

Purposes of the Company

4. The purposes for which the Company was established:

4.1. Research, development, marketing and sales of medical devices for the treatment of the human brain.

4.2. To engage in any matter or issue or subject which is legally permissible, at the discretion of the directors and the business managers of the Company.

Contributions

5. The Company is entitled to contribute reasonable amounts to worthy causes, even if the contribution is not in a framework of the business considerations of the Company. The Board of Directors is authorized to determine, at its discretion, the amount of the contribution, the purposes for which it is made, the identity of the recipient and every other condition in this context.

The Registered Office

6. The registered office of the Company shall be at the address determined by the Board of Directors, and shall change from time to time.

The Articles of Incorporation

7. The Company shall be entitled to change these Articles by resolution of the general meeting by ordinary majority.

8. A resolution passed by the general meeting with the majority required for changing of the Articles, as stated in Clause 7 above, which changes any of the provisions of these Articles, shall be deemed a resolution for the alteration of these Articles, even if this was not indicated expressly in the resolution.

9. Subject to provisions of The Companies Law, changes to these Articles shall be valid from the date of a passage of a resolution by the Company or another date determined in the resolution.

Registered Share Capital

10. The registered share capital of the Company is NIS 2,400,000 divided into 60,000,000 ordinary shares of the nominal value of NIS 0.04 each (hereinafter- **the ordinary shares**). The Company is entitled to change the registered share capital subject to the provisions of The Companies Law and these Articles.

The Shares

11. Each ordinary share in the capital of the Company shall have equal rights, for all intents and purposes, to every other ordinary share, including the rights to dividend, bonus shares

and participation in distribution of surplus assets of the Company upon liquidation, proportionally to the nominal value of each share, without taking into account any premium paid thereupon, and all subject to the provisions of these Articles.

12. Each one of the ordinary shares entitles its owner to participate in the general meeting of the Company and to one vote.

13.

13.1. A shareholder in the Company is the party registered as the shareholder in the registry of shareholders or whomever a share is registered in his favor with a stock exchange member, and such share is included in the registered shares in the registry of shareholders of the Company in the name of a company for registration.

A shareholder who is a trustee will report thereupon to the Company, and the Company shall record him in the registry of shareholders, with indication of his trust, and he shall be viewed for purposes of The Companies Law as a shareholder. Without detracting from that stated above, and subject to the provisions of the Articles of the Company, the Company shall recognize a trustee as stated, as a shareholder for all intends and purposes, and shall not recognize some other person, including the beneficiary, as the holder of any rights in the share. Without detracting from that stated above, and subject to the provisions of the Articles of the Company, with the exception of shareholders of the Company as stated, no person shall be recognized by the Company as having any rights in a share and the Company shall not be bound and shall not recognize any benefits under the laws of equity or in the relations of trust or in a proper right, future or partial, in any share or benefit whatsoever in a fractional share or in any other right with regards to a share, rather solely and exclusively the right of the shareholder as stated above, in the share in its entirety, and all save if a competent court has directed otherwise.

13.2. Without detracting from that stated above, and subject to the provisions of these Articles, with the exception of shareholders of the Company as stated in Clause 13.1 above, no person shall be recognized by the Company as having any right in a share and the Company shall not be bound and shall not recognize any benefits under the laws of equity or the relations of trust or a proper right, future or partial, in any share or benefits, in a fractional share or any other right with regard to a share, but rather solely and exclusively the right of the shareholder as stated in Clause 13.1 above, in a share in its entirety and all save if a competent court has directed otherwise.

Share Certificates

14. The certificates testifying to the right of ownership in the shares shall bear the stamp of the Company and the signatures of one director together with the CEO of the Company or together with the Secretary of the Company or the signatures of any two persons who were appointed for this purpose by the Board of Directors.

The Board of Directors is entitled to decide that a signature or stamp as stated shall be carried out mechanically, as shall be determined by the Board of Directors.

15. Unless the terms of the issue of shares determine otherwise:

15.1. Every registered shareholder is entitled to receive from the Company at his request within a period of two months after the allotment, or registration of the transfer, as the case may be, one certificate testifying to his ownership in shares which are registered in his name or, at the consent of the Company, a number of certificates as stated.

15.2. A registration Company is entitled to receive from the Company, at its request, within a period of two months after the allotment, or the registration of the transfer, as the case may be, one certificate testifying to the number of shares and the type of shares registered in its name at the registry of shareholders.

16. Subject to the provisions of The Companies Law, in each certificate shall be specified the number of shares in respect of which it was issued, their serial numbers and their nominal value.

17. A certificate referring to a share registered in the name of two or more persons, shall be delivered to whomever shall appear first in the registry of shareholders with regard to such share, save if all of the shareholders registered upon such share shall direct the Company in writing, to deliver it to some other registered owner.

18. In the event that a share certificate shall be defaced, ruined, lost or harmed, the Board of Directors is entitled to direct its cancellation and the issue of a new certificate in its stead. This, provided that the share certificate was produced to the Company and destroyed by it, or it was proven to the satisfaction of the Board of Directors that the certificate was lost or destroyed and the Company received a guarantee to the satisfaction of the Board of Directors in respect of any possible damage. A reasonable amount as shall be determined by the Board of Directors from time to time shall be paid for every share certificate issued under this clause.

Payment for Shares

19. All of these shares in the issued capital of the Company, shall be shares which were discharged in full.

20. **Canceled.**

Transfer of Shares

21. Every transfer of shares which are registered in the registry of shareholders in the name of the registered shareholder, including a transfer by a company for registration or to it, shall be in writing and provided that the Deed of Transfer shall be signed by hand only, by the transferor and by the transferee, by themselves or by their legal representatives,

and by witnesses to their signature, and shall be delivered to the registered office or to any other place determined by the Board of Directors for this. Subject to the provisions of The Companies Law, the transfer of shares shall not be recorded in the registry of shareholders save after a Deed of Transfer has been delivered to the Company as stated above: The transferor shall continue to be deemed the owner of the transferred shares until the registration of the transferee as the owner of the transferred shares in the registry of shareholders.

The registry of shareholders shall constitute prima facie evidence to the veracity of its content. In an instance of contradiction between that recorded in the registry of shareholders and a share certificate, the evidentiary value of the Registry of Shareholders is superior to the evidentiary value of the share certificate.

22. The Share Transfer Deed will be made in writing, in the form customary in Israel or in any other form approved by the Board of Directors. To such extent as the transferor or the transferee is a corporation, a confirmation by an attorney or an accountant or some other person whose identity is acceptable to the Board of Directors shall be given regarding the authority of the signatories in the name of the corporation to carry out or to receive the transfer, as the case may be.

23. The Company is entitled to close the Registry of Shareholders for a period of time determined by the Board of Directors and provided that it shall not exceed, in total, 30 days each year. When the registry is closed, transfer of shares shall not be recorded in the registry. Without the detracting from that stated above, the Board of Directors is entitled to determine a determining date with regard to the right to vote in a general meeting, or to receive payment of dividend or allotment of rights whatsoever or for any other legal purpose.

24. Subject to the provisions of these Articles or the terms of the issue of shares of any type, shared transfer shall be possible without the need for Board of Directors approval.

25. Every transfer deed shall be submitted to the office or to any other place as shall be determined by the Board of Directors, for registration, together with the certificates of the shares to be transferred, if these were issued, and all other proof required by the Board of Directors regarding the right of ownership of the transferor or his right to transfer the shares. The transfer deeds which shall be recorded shall remain with the Company; however, any transfer deed which the Board of Directors refused to record will be returned to the party who submitted it, at its request.

26. In the event that the Board of Directors refuses to approve the transfer of shares, it shall notify the transferor no later than one month from the date of receiving of the transfer deed.

27. The Company shall be entitled to collect payment for recording of the transfer, in an amount determined by the Board of Directors, from time to time, and which shall be reasonable in the circumstances of the matter.

28.

28.1 Subject to the provisions of The Companies Law and these Articles. If it was proven to the Company to the satisfaction of the Board of Directors in a manner determined by it, that the conditions required at Law were fulfilled for the assignment of the rights in the shares which are registered in the registry in the name of a registered shareholder, the Company shall recognize the assignee, and him alone, as the holder of the rights in the shares as mentioned.

28.2 Notwithstanding that stated above, in an instance of the death of one or more of the registered joint owners of shares registered in their name in the registry, the Company shall recognize the registered owners who remain alive, solely, as the holders of ownership rights in such shares.

29.

29.1 Subject to the provisions of these Articles, the Company shall change the registration of ownership in the shares in the Registry of Shareholders upon receipt of an order of a court to amend the registry or if it was proven to the Company, to the satisfaction of the Board of Directors and in a manner determined by it, that the conditions at Law for the assignment of the rights in the shares were fulfilled, and the Company shall not recognize any right of a person in the shares, prior to the proof of his right, as stated above.

29.2 Without detracting from that stated above, the Board of Directors is entitled to refuse to perform the registration or to delay it, as it shall be entitled to do, in the event that the registered owner himself shall have transferred the shares prior to the assignment of the right.

30. Subject to the provisions of The Companies Law and these Articles, a person who became entitled to a share as stated in Clause 28 above, shall be entitled to carry out a transfer of the shares similar to the right to do so of the registered owner, himself, prior to the assignment of the right.

31. The Company is entitled to destroy a share transfer deed at the expiry of seven years from the date of the recording in the registry, and to destroy Certificate of Shares which were canceled, at the expiry of seven years from the date of their cancellation, and a prima facie presumption shall exist that any deed of transfer and certificates which was destroyed as mentioned, was fully valid and that the transfers, cancellations and registrations as the case may be were carried out at Law.

Changes in the Capital

32. The Company is entitled, in a resolution passed by the general meeting, in an ordinary majority, to increase the registered share capital of the Company and/or to create additional classes of shares in the capital of the Company, and all as it shall determine.

33. Subject to the provisions of The Companies Law, the Company is entitled, in a resolution passed by the general meeting in an ordinary majority:

33.1 To merge its shares, in whole or in part, and to divide them to shares with higher nominal values than the nominal value of the existing shares.

33.2 To divide its shares, in whole or in part, a secondary division, to shares with lower nominal values than the nominal value of the existing shares.

33.3 To reduce the capital of the Company and any principal reserved for redemption of capital.

For purposes of performance of such resolution as stated, the Board of Directors is entitled to resolve, at its discretion, any difficulty which shall arise in connection therewith.

34. Without detracting from the generality of the authorities of the Board of Directors as stated above, if as a result of the merger or division as stated above, there shall remain fractional shares in the hands of shareholders, the Board of Directors is entitled at its discretion to act as follows:

34.1 To determine that fractional shares which shall not accord the owners thereof an entire share, shall be sold by the Company and the proceeds from the sale shall be paid to those entitled under terms and in a manner as determined.

34.2 To allot to each of the owners of the shares whose merger and/or division shall leave them with a fractional share, shares of a class of shares which existed in the capital of the Company prior to the merger and/or division, in such number that the merger thereof with the fraction shall create one whole share, and such allotment shall be deemed valid immediately prior to the merger or division, as the case may be.

34.3 To determine the manner of payment of the amounts which must be paid for the shares which were allotted as stated in Clause 34.2 above, including the manner in which the discharge of the amounts shall be possible on account of bonus shares.

34.4 To determine that the owners of the fractional shares shall not be entitled to receive a whole share in respect of the fraction of a share.

34.5 To determine that the owners of the shares shall not be entitled to receive a whole share in respect of a fraction of a whole share with a certain or lower nominal value and shall be entitled to receive a whole share in respect of the fraction of a whole share with a nominal value which is higher than the stated nominal value.

35. The Company is entitled by resolution of the general meeting by ordinary majority, to cancel registered share capital which has not yet been allotted, and provided that the Company has not undertaken, including a conditional undertaking, to allot the shares.

Change in Rights

36. At any time, when the share capital shall be divided into different classes, the Company shall be entitled by resolution of the general meeting by ordinary majority, save if the conditions of the issue of the shares of such class stipulate otherwise, to cancel, to convert, to expand, to add, to reduce, to amend or to change in some other manner the rights of the class of shares of the Company, and provided that consent for this was received in writing of all of the holders of the shares of such class or the resolution was passed in the general meeting of shareholders of such class by ordinary majority, or in an instance where it was stipulated otherwise in the terms of the issue of the certain class of shares of the Company, as was stipulated in the terms of the issue of such class.

37. The provisions determined in these Articles with regard to the general meeting shall apply mutatis mutandis, to every class meeting and provided that the legal quorum in a class meeting will be present when there shall be present at the opening of the meeting, themselves or by proxy, at least two shareholders who own at least 25% of the number of shares issued of such class. However, if there was not a legal quorum as stated, the class meeting shall be postponed to a later date and in the postponed meeting, a legal quorum shall be fulfilled by any number of participants, regardless of the number of shares they own.

38. The rights accorded to the shareholders or the owners of such class of shares which were issued in respect of ordinary rights and in respect of preferred rights or some other special rights, shall not be deemed for purposes of Clause 36 above as though they were converted, reduced, prejudiced or changed in some other manner by the creation and/or issue of additional shares of any class, whether they are equivalent to them or of a different or preferred class, and shall not be deemed for purposes of the aforementioned clause as though they were converted, reduced, prejudiced or otherwise changed, by a change in the rights attached to shares of any other class, and all save if stipulated otherwise explicitly in the terms of the issue of such shares.

39. **Issue of shares and other securities.**

39.1. The Board of Directors is entitled to issue or allot shares and other securities, which are convertible or may be exercised into shares, up to the limit of the registered share capital of the Company. For this matter, securities which are convertible or may be converted or exercised into shares shall be viewed as though they were exercised or converted at the date of their issue. Without detracting from the generality of that stated above, the Board of Directors shall be entitled to issue the shares and other securities as stated above, to grant rights of choice for their purchase, including options, or to grant them in some other manner, and all to persons who were determined by it and at the time and the prices and terms as determined by it, and to determine any other provision related to this, and

including provisions regarding the manner of distribution of the shares and securities which shall be issued by the Company, between the purchasers thereof, including an instances of oversubscription, and all at the discretion of the Board of Directors.

39.2. The authorities of the Board of Directors as specified in Clause 39.1 above may be delegated as specified in the following paragraphs (1) or (2):

(1) To a Board of Directors committee - in the issue or allotment of securities in the framework of an employee remuneration scheme or agreements of employment or wage between the Company and its employees or between the Company and employees of an associated Company whose Board of Directors has agreed to this in advance, and provided that the issue or allotment shall be in accordance with a program which includes specific covenants which were issued and approved by the Board of Directors.

(2) A Board of Directors committee, the CEO or the holder of such position (in this clause - CEO) or some other person who the CEO has recommended - in the issue of shares subsequent to exercise or conversion of securities of the Company.

40. Without detracting from the generality of that stated above and subject to the provisions of The Companies Law and these Articles, the Board of Directors is entitled to determine that the consideration for the shares shall be paid in cash or in kind and including in securities or any other manner, at its discretion, or that the shares shall be allotted as bonus shares or that the shares shall be allotted for consideration equal to their nominal value or higher than it, whether individually or in series, and all under terms and dates as determined by the Board of Directors at its discretion.

41. In a decision to increase the registered share capital of the Company, the general meeting may determine that the new shares included in the amounts by which the registered share capital was increased as stated (here and after: " **the new shares** ") or any part thereof, will be offered initially at their nominal value or for an added premium, to all of the shareholders holder who hold shares at such times, at a rate proportional to the nominal value of their shares in the Company or to determine other provisions for the manner of the issue and allotment of the new shares. However, in the event that the general meeting has not determined as stated in the decision to increase the registered share capital of the Company, the Board of Directors may offer them as stated in Clause 39 above.

42. The Board of Directors is entitled to resolve to pay commissions or underwriting fees to any person in consideration for subscription or agreement to subscription or the obtaining of subscriptions or the promise of subscriptions upon shares, or bonds or other securities of the Company. The Board of Directors may also, in any event of the issue of securities of the Company, resolve to pay intermediary commissions, in cash, in Company shares or other securities which were issued by the Company or in any other manner or partly in one manner and partly in another, and all subject to the provisions of applicable Law.

Redeemable Securities

43. Subject to the provisions of The Companies Law, the Company is entitled to issue securities which may be redeemed at terms and in a manner determined by the Board of Directors at its discretion.

Registries

44.

44.1 The Company shall conduct a registry of the shareholders and shall record in it the names of the owners of the shares and the additional details required under The Companies Law, immediately after the issue of any shares of the Company. Subject to the provisions of the Law, upon the registration in the registry, a registered shareholder shall be deemed the owner of the shares registered in his name, and even if share certificates were not issued in respect of these shares.

44.2 The Company shall conduct a registry of substantial shareholders as required by The Companies Law.

45. The Company is entitled to conduct an additional registry of shareholders outside of Israel under terms as determined for this matter in The Companies Law.

46. The Company shall conduct a registry of the holders of bonds and securities which may be converted into shares of the Company and all of the provisions of these Articles in connection with shares shall apply also to these convertible securities with regard to the registration in the registry, the issue of certificates, the replacement of certificates, transfer and assignment, mutatis mutandis as the case may be, and all subject to the terms of the issue of the securities.

General Meeting

47. Resolutions of the Company in the following matters shall be passed by the general meeting:

47.1 Changes to the Articles of the Company or its Memorandum.

47.2 Implementation of the authorities of the Board of Directors by the general meeting if the Board of Directors is precluded from implementing its authorities and the implementation of any of its authorities is crucial for the proper conduct of the Company, as stated in Article 52(A) of The Companies Law.

47.3 The appointment of an auditing accountant for the Company and the cessation of his employment.

47.4 The appointment of directors for the Company and their dismissal.

47.5 Approval of actions and transactions requiring the approval of the general meeting under the provisions of Articles 255 and 268 to 275 of The Companies Law.

47.6 Increase of the registered share capital and its decrease in accordance with the provisions of Articles 286 and 287 of The Companies Law and changes in the capital as stated in Clause 33 above.

47.7 Merger as stated in Article 320(A) of The Companies Law.

47.8 Any resolution which must be passed in accordance with these Articles, by the general meeting.

Subject to the provisions of The Companies Law, the general meeting is entitled to undertake authorities given to some other organ, and if the general meeting has undertaken the authorities of the Board of Directors of the Company, the shareholders will be liable and responsible for the liabilities and duties of the directors, as stated in Article 50(b) of The Companies Law.

48. The Company will conduct an annual general meeting every year and not later than the expiry of 15 months from the previous annual meeting, at the date and time as determined by the Board of Directors.

49. The agenda of the annual general meeting shall include the following items:

49.1 Discussion of the financial reports of the Company and the Board of Directors report on the state of affairs of the Company which are submitted to the general meeting.

49.2 Appointment of directors and determination of their wages.

49.3 Appointment of an auditing accountant.

49.4 Reporting by the Board of Directors upon the wage of the auditing accountant for the auditing activity and for the additional services, if any.

49.5 In addition to that stated above, the agenda of the annual meeting may include any other matter which was determined in the agenda as stated in Clause 52 below.

The general meeting as stated above shall be called **"an annual meeting"** and any other general meeting shall be called **"a special meeting".**

50. The Board of Directors of the Company will convene a special meeting in accordance with its resolution and in accordance with the demand of any of the following:

50.1 Two directors or one-quarter of the serving directors.

50.2 A shareholder, one or more, with at least 5% of the issued share capital and 1% of the voting rights in the Company, or one or more shareholder with at least 5% of the voting rights in the Company.

In the event that the Board of Directors was required to convene a special meeting as stated above, it shall be convened within 21 days from the date upon which the demand was submitted to it, at a date determined in the notice upon the special meeting as stated in Clause 54.1 below and provided that the date of the meeting shall be not later than 35 days from the date of the publishing of the notice and all subject to the provisions of The Companies Law and Clause 53.1 below.

51. In the event that the Board of Directors fails to summon a special meeting as requested under Clause 50 above, the requesting party is entitled, and when one is speaking of shareholders-also part of them who have more than half of their voting rights, to convene the meeting itself, and provided that it shall not take place more than three months from the date of submission of the request as stated, and shall be convened, to such extent as possible, in the same manner as assemblies are convened by the Board of Directors.

52.

52.1 The agenda of the general meeting shall be determined by the Board of Directors and shall include the matters for which the convening of the special meeting under Clause 50 above was requested as well as a subject requested as stated in Clause 52.2 below. The Board of Directors may include election of directors in an agenda of a special meeting.

52.2 One or more shareholders with at least 1% of the voting rights in the general meeting may request the Board of Directors to include a subject in the agenda of the general meeting which shall be convened in the future, and provided that the subject is appropriate for deliberation in the general meeting.

52.3 A request as stated in Clause 52.2 above will be submitted to the Company in writing not less than 10 days from the date of notice of the convening of the general meeting and a text of the resolution which is proposed by the shareholder shall be attached to it as well as the details of his holdings in the Company (including indirect or derivative holdings), relationships and/or agreements between him and other shareholders in the Company and insofar as such request is in connection with the appointment of a director - also details regarding the director nominee (including all details required by law and reporting rules) and regarding relationships or agreements that the director nominee has with the shareholders of the Company, and if the Company is listed for trading on the Nasdaq, whether he or she is eligible to be appointed as an independent director in accordance with Nasdaq Listing Rules.

53.

53.1 Notice of the general meeting will be published in accordance with the requirements of the Law at least 14 days prior to the convening of

the meeting with the exception of notice of a general meeting with an agenda which includes the items specified in Article 87 of The Companies Law, which shall be published 35 days at least prior to its convening.

53.2 In addition to the notice upon the general meeting as stated in Clause 53.1 above, the Company will deliver notice upon the general meeting only to shareholders who are registered in the registry whose address is in Israel.

54.

54.1 In the notice upon the general meeting there shall be specified the place, the date and the time at which the general meeting shall be convened and it shall include the agenda, a synopsis of the proposed resolutions, the required majority for the resolutions, the date of determination of the rights of all of the shareholders to vote in the general meeting and any other detail required at law. In the event that the Company shall determine that a postponed meeting shall be held at a date which is later than that determined in Article 78 (b) of the Law, it shall indicate the date as mentioned in the notice.

54.2 In a decision regarding the convening of an meeting, the Board of Directors is entitled to determine the manner of the detailing of these issues on the agenda for the meeting, which will be delivered to such shareholders entitled to participate in the meeting, and all at the discretion of the Board of Directors and subject to the provisions of The Companies Law.

54.3 Without detracting from the authorities of the Board of Directors as stated in this Clause 54 above, and without detracting from a generality of the provisions of these Articles with regard to the transfer of the authorities by the Board of Directors, the Board of Directors will be entitled to transfer its authorities as stated in this Clause 54 above, 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.

55. A good faith defect in the convening of a general meeting or its conduct, including a defect arising from non-fulfillment of a provision or condition determined in the Law or in these Articles, including with regard to the manner of the convening of the general meeting or its conduct, shall not invalidate any resolution passed in the general meeting and shall not prejudice the deliberations conducted therein, subject to the provisions of any Law.

Deliberations in the General Meeting

56. No deliberations may be commenced at the general meeting unless a legal quorum is present at the opening of the meeting. A legal quorum will be constituted when there are present, themselves or by proxy, a shareholder or shareholders who have at least one-third of the voting rights, within one-half of an hour from the time determined for the opening of the meeting, save if determined otherwise in these Articles.

57. In the absence of a legal quorum at the general meeting at the expiry of half of an hour from a time determined for commencement of the meeting (or the expiry of some other time as determined by the Chairman of the meeting, but in any event no more than one hour), the meeting shall be postponed for seven days, for the same date at the same hour and in the same place, without the requirement to notify the shareholders thereupon and subject to the provisions of The Companies Law, the Securities Law and the Regulations promulgated under these laws, or some later date if indicated in the notice upon the meeting, or a date, hour and place which are different, as determined by the Board of Directors in the notice to the shareholders.

58. A legal quorum for a postponed meeting shall be constituted when there are present, themselves or by proxy, one or more shareholders who have at least one-third of the voting rights, within half of an hour from the time determined for the opening of the meeting. In the absence of a legal quorum at the postponed meeting at the expiry of half of an hour from the time determined for commencement of the postponed meeting, any two shareholders present at the postponed meeting, themselves or by proxy, shall constitute legal quorum at the postponed meeting.

59. The Chairman of the Board of Directors or, in his absence, any director appointed by the Board of Directors, will chair every general meeting of the Company. In the absence of a chairman as stated or if at some meeting none of these are present after the passage of 15 minutes from the time determined for commencement of the meeting or if they refuse to serve as Chairman of the meeting, the directors which are present may, by majority between them, elect a chairman from amongst them or from any of the officers in the Company present at the meeting, and if they fail to do so-the shareholders present will elect themselves or by proxy one of the directors or one of the officers present to chair the meeting. In the absence of directors or officers or if all of the directors or officers refuse to chair the meeting, one of the shareholders or their proxy as stated shall be elected to chair the meeting.

60. The Company shall maintain minutes of the proceedings in the general meeting which shall include the following details:

60.1 The names of the shareholders participating in the general meeting and the number of shares held by them.

60.2 The matters discussed at the general meeting and the resolution is passed.

61. Minutes which are signed by the chairman of the general meeting constitute prima facie evidence to their content.

Voting and the Passage of Resolutions at the General Meeting

62. A shareholder wishing to vote at the general meeting shall prove to the company his ownership in a share as required by The Companies Law and the Companies Ordinance (proof of ownership of share for a purpose of voting at general meeting) — 2000. Without

the detracting from the generality of that stated above, the Board of Directors is entitled to determine provisions and procedures regarding the proof of ownership of shares in the company.

63. A shareholder is entitled to vote in the general meeting or in a class meeting, himself or by proxy, all in accordance with the provisions of these Articles and subject to the provisions of The Companies Law. A proxy for a vote is not required to be a shareholder in the company. Voting in the general meeting of the Company by means of a voting deed, in accordance with the provisions of The Companies Law and the regulations there under, will be possible solely and exclusively on issues specified in Articles 87A(1) — 87A (3) and 87A(5), of The Companies Law.

64. Subject to the provisions of applicable Law, in an instance of joint ownership in a share, any one of them may vote at any meeting, whether himself or by proxy, in relation to such share, as though he was the sole party entitled to it. If more than one joint owner of a share participates in an meeting, himself or by proxy, the vote will be made by the party whose name appears first in the registry of shareholders with regard to the share or in the confirmation of the stock exchange member with regard to the ownership in the share **("confirmation of ownership"),** or some other document determined by the Board of Directors for such matter, as the case maybe. Individual legal guardians or individual executors of estate over a registered shareholder who is deceased, shall be considered for purposes of this clause as joint owners in these shares. Without the detracting from that stated above, in an instance where more than one shareholder is registered in the registry of shareholders of the Company as the holder of a share, the Company shall view the first person registered in the registry of shareholders as the legal representative of the remaining parties registered as holding the share, save if a document was delivered to the company, signed by the majority of the registered owners of the share, or a court order, indicating the name of some other registered owner as the representative of the holders of the share.

65. Every party entitled to a share under clause 28 above, is entitled to vote by virtue thereof in any general meeting in the same manner as though he was the registered owner of such shares and provided that he shall prove to the satisfaction of the Board of Directors his entitlement to the share at least 48 hours prior to the date of the general meeting or the postponed meeting, as the case maybe, in which he intends to vote, save if the Company has previously recognized his right to vote by virtue of the shares at such meeting.

66. A document appointing a proxy for a vote **("deed of appointment")** shall be made in writing and shall be signed by the appointing party, and if the appointing party is a corporation, the deed of an appointment shall be made in writing and shall be signed in a manner binding the corporation. The Board of Directors is entitled to require delivery to the Company prior to the convening of the meeting, of a confirmation in writing, to the satisfaction of the Board of Directors, regarding the authority of the signatories to bind the corporation. The Board of Directors is further entitled to determine provisions and procedures in everything related thereto.

66. A deed of appointment or a suitable copy thereof, to the satisfaction of the Board of Directors, will be deposited at the registered office or some other place or places, in Israel or outside of Israel - as shall be determined by the Board of Directors from time to time, generally or for a specific instance - at least 48 hours prior to commencement of the meeting or the postponed meeting, as the case maybe, in which the proxy intends to vote in reliance upon such deed of appointment. Notwithstanding, that stated above, the chairman of the meeting may, at his discretion, accept such deed of appointment also after the time as stated, if he deems this appropriate, at his discretion. If a deed of appointment shall not be received as stated in this clause above, it shall not be valid in such meeting.

67. A proxy for a vote is entitled to participate in deliberations of the general meeting and to be elected as a chairman as was the shareholder appointing him, and provided that it was not indicated otherwise in the deed of appointment.

67.1. A deed of appointment appointing a proxy for vote shall be in the format customary in Israel or in any other format approved by the Board of Directors.

67.2. The deed of appointment will indicate the class and the number of shares in respect of which it was issued. In the absence of indication in the deed of appointment of the number of shares in respect of which it was issued or an indication therein of a number of shares which is higher than the number of shares registered in the name of the shareholder or which are indicated in the confirmation of ownership, as the case maybe, the deed of appointment will be deemed to have been issued in respect of all of the shares of the shareholder.

67.3. In the event that the deed of appointment was issued in respect of a number of shares which is lower than the number of shares registered in the name of the shareholder or indicated in the confirmation of ownership, as the case maybe, the shareholder will be deemed as refraining from appearing at the vote in respect of the balance of the shares and the deed of appointment will be valid in respect of number of shares indicated therein.

68. Without detracting from the provisions of these Articles with regard to the appointment of a proxy for a vote, a shareholder holding more than one share will be entitled to appoint more than one proxy subject to the following provisions:

68.1. Each deed of appointment will indicate the class and the number of shares in respect of which it was issued.

68.2. In the event that the total number of shares of any class indicated in deeds of appointment issued by one shareholder shall exceed the number of shares of such class registered in his name or indicated in the confirmation of ownership, as the case maybe, all the deeds of appointment issued by such shareholder shall be invalidated.

69. A shareholder or a proxy is entitled to vote a part of the shares which are owned by him or for which he is a proxy, and is entitled to vote part of the shares in one manner and part of the shares in another manner.

70. A vote made by virtue of a deed of appointment shall be valid even if prior to the vote the appointing party passed away or was declared incompetent or the deed of appointment was canceled or the share was transferred in respect of which the deed of appointment was granted, save if notice was received at the office prior to the meeting, in writing, with regard to the death, incapacity, cancellation or transfer, as the case may be. Notwithstanding that stated above, the chairman of the meeting is entitled, at his discretion, to receive such notice as stated also during the course of the meeting, if he deems this appropriate at his discretion.

71. A deed of appointment shall be valid also with regard to any postponed meeting or an meeting to which the deed of appointment relates, and provided that it was not indicated otherwise in the deed of appointment.

72. Every ordinary share entitles its owner to participate in the general meeting of the Company and to one vote.

73. A resolution proposed for a vote in the general meeting shall be decided by a count of the participating votes. The manner of the counting of the votes will be determined by the chairman of the Board of Directors, unless prior to the vote, a secret ballot was requested by a shareholder or holders with at least 10% of the issued share capital of the Company. In a case of a dispute whether to accept or reject any individual vote in the vote, the chairman of the meeting shall determine the matter and his good faith decision shall be final and decisive.

74. A declaration made by the chairman that a resolution was passed or rejected at the general meeting, unanimously or by some majority, and the declaration was recorded in this matter in the minutes of the meeting, shall be prima facie evidence to that stated, and it shall not be necessary to prove the number of votes (or their proportional share) which were made in favor or against such resolution.

75. Subject to the provisions of the Companies Law or the provisions of these Articles with regard to some other majority, decisions of the general meeting shall be passed by an ordinary majority. The chairman of the meeting shall not have an additional vote or a decisive vote.

76. The chairman of the general meeting is entitled, at the consent of an meeting in which a legal quorum is present, to postpone it or to postpone the deliberation or the passage of a resolution in some specific matter on the agenda, to a later time or a place which shall be determined, and he is required to do so in accordance with the demand of the meeting. At such, postponed meeting as stated, no matter will be deliberated which was not on the agenda and for which a resolution was not passed in the meeting at which the postponement was resolved upon. If the general meeting was postponed for more than

21 days, notice will be issued upon the postponed meeting, as stated in Clauses 53 and 54 above. If the general meeting was postponed without changing its agenda, for a date not exceeding 21 days, the notices and summons with regard to the new date will be issued as early as possible, and not later than 72 hours prior to the general meeting. The notices and the summons as stated will be issued in accordance with Clauses 53 and 54 above, mutatis mutandis.

The Board of Directors

77. The number of directors shall not be less than four and shall not exceed nine (not including external directors, to the extent there is an obligation to appoint them, and not including up to two additional directors appointed by the Board of Directors as described in Article 80.

78. The annual general meeting of the Company shall appoint, by ordinary majority, the members of the Board of Directors. Each appointed director 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 extended by that annual general meeting, or terminated by the general meeting in accordance with Article 82. A director is not required to be a shareholder in the Company. The provisions of this clause with regard to the appointment of directors shall not apply to external directors who will be appointed in the accordance with the provisions of the Companies Law, to the extent there is an obligation to appoint them.

79. With the exception of directors who served in the Company up until the date of the annual meeting and/or parties upon whom the Board of Directors of the Company recommended their appointment as director before the general meeting, no director will be appointed at the annual meeting, unless a shareholder in the Company who holds at least 1% of the Company's share capital, who is seeking to propose him as a candidate, shall submit to the office at least 45 (forty-five) days prior to the convening of the annual meeting, a document in writing signed by the shareholder notifying of the intent of the shareholder to propose the candidate for appointment as director, with the consent in writing of the candidate attached to this document to serve as a director together with his resume, as stated in Article 52.3 above.

80. The Board of Directors shall appoint up to two (2) directors whose term of office will expire on the date of the next following annual meeting, provided that they may be reappointed by the Board of Directors according to this Article for one additional term of office, provided that they may be reappointed by the annual meeting (subject to Article 78 above).

81. The general meeting or the Board of Directors is entitled to determine that the service of a director appointed by them, as the case may be, shall commence at a later date from the date of the resolution upon his appointment.

82. Notwithstanding that stated above, the general meeting is entitled at any time to remove a director from his position, with the exception of an external director (regarding which there shall apply the provisions of the Companies Law) prior to the end of his period of service, and provided that the director is granted a reasonable opportunity to present his position before the general meeting. Any general meeting may, by ordinary majority, appoint in the stead of a director who was removed from his position as stated above, some other party as director, and provided that the recommendation of a shareholder was given as stated in Clause 79 above.

The position of a director shall be vacated automatically in any one of the following instances:

82.1. Resignation.

82.2. Declaration of bankruptcy.

82.3. Conviction of a crime as stated in Article 232 of the Law.

82.4. If the director is a corporation which has resolved voluntary liquidation, or an order for liquidation has been issued against it.

82.5. Per a decision of the court as stated in Article 233 of the Law.

82.6. Declaration of legal incompetency.

82.7. If his term was automatically terminated in accordance with the law.

82.8. Death.

83. If the position of the director is vacated, the Board of Directors may continue to operate in every matter so long as the number of directors is not less than the minimum number of directors determined in Clause 77 above.

For so long as the general meeting was not convened, the Board of Directors shall not be entitled to act upon manners which may be postponed, up to the date of the convening of the general meeting for the appointment of the directors.

84. A director may resign by submission of notice to the Board of Directors, to the chairman of the Board of Directors or the Company, as required in the Companies Law. The resignation shall be valid on the date of the delivery of the notice. Unless the notice determines a later date. A director will provide the reasons for his resignation.

85. Subject to the provisions of the Companies Law, the Company is entitled to pay directors remuneration for fulfillment of their position as directors.

86.

86.1. A director may appoint an alternate (hereinafter: **"Alternate director"**). Notwithstanding that stated above, a party not eligible to be appointed as a director will not be appointed nor serve as an alternate director, nor shall a serving director in the Company or a serving alternate director.

A serving director may be appointed as an alternate director for a membership in a Board of Directors committee, and provided that at the date of appointment as an alternate director to a member of a committee, he does not serve as a member of such Board of Directors committee and if he is an alternate director to an external director, the candidate will be an external director with accounting and financial expertise or professional competency, in accordance with the competency of the director being replaced.

86.2. An alternate director shall be equivalent to the director whom he replaces, and shall be entitled to be present at members of the Board of Directors and/or committees of the Board of Directors, to participate and to vote therein as it was entitled to be director who appointed him. Notwithstanding that stated, the Company shall not pay remuneration to an alternate director.

86.3. A director who appointed an alternate director may, subject to the provisions of the law, cancel the appointment at any time. Additionally, the position of the alternate directors shall be vacated at any time when the position of the director who appointed the alternate director shall be vacated in any manner.

86.4. Any appointment or cancellation of an alternate director as stated above, will be by notice in writing delivered to the alternate director and to the Company, and will be valid after delivery of the deed of appointment, or deed of cancellation as stated or at the time

determined in the deed of appointment or deed of cancellation, the later of these, and if a period was not determined in the deed of appointment, the period shall be congruent with the period of service of the appointing director.

External Directors

87. At least two external directors shall serve in the Company, to the extent there is an obligation to appoint them, and the provisions determined in the Companies Law shall apply in this matter.

Authorities of the Directors and their Duties

88. The directors shall have all of the authorities and the powers granted to them in accordance with these Articles, in accordance with the Companies Law and applicable law.

89. Without detracting from the provisions of these Articles, the Board of Directors shall direct the policies of the Company and shall oversee performance of the positions of the CEO and his activities, and including:

89.1. Shall determine the action plans of the Company, principles for the financing thereof and priorities among them.

89.2. Shall examine the financial state of the Company, determine the credit framework which the Company may take.

89.3. Shall determine the organizational structure and the wage policy.

89.4. May decide upon the issue of a series of bonds.

89.5. Is responsible for preparation and approval of financial reports as stated in Article 171 of the Companies Law.

89.6. Will report to the annual meeting upon the state of affairs of the Company and its business results as stated in Article 173 of the Companies Law.

89.7. Will appoint and dismiss the CEO.

89.8. Will decide upon actions and transactions requiring its approval under these Articles or the provisions of Articles 255 and 268 through 275 of the Companies Law.

89.9. May allot shares and securities convertible into shares up to the limit of the registered share capital of the Company.

89.10. May resolve upon distribution of dividend, interim dividend or distribution of bonus shares as the case may be.

89.11. May resolve upon a significant acquisition as per the definition of this term in Article 1 of the Companies Law, from all of the shareholders of the Company or part thereof or any of them, at its discretion.

89.12. Will express its opinion upon a special purchase offer as stated in Article 328 of the Companies Law.

89.13. Will determine the minimum number of directors required in the Board of Directors, who must have financing and accounting expertise, as per the definition thereof under Article 240 of the Companies Law. The Board of Directors will determine the minimum number as stated taking into account, inter alia, the type of Company, its size, the scope of activity and complexity of operations, subject to the number of directors determined under Clause 77 above.

The authorities of the Board of Directors under this clause may not be delegated to the CEO, save as specified in Clause 39.2(2).

90. The Board of Directors may exercise any authority of the Company not accorded by law or in these Articles to some other organ.

91.

91.1. The Board of Directors may resolve that authorities granted to the CEO will be transferred to its own authority, and all for a certain purpose or certain period of time.

91.2. Without detracting from that stated above, the Board of Directors may direct the CEO how to operate with regard to a certain matter. If the CEO shall fail to fulfill the instructions, the Board of Directors may exercise the authorities required for performance of the instruction in his stead.

91.3. If the CEO was precluded from exercising his authorities, the Board of Directors may do so in his stead.

92. Subject to the provisions of the Companies Law, the Board of Directors may delegate any of the authorities of the CEO to an officer in the Company or some other person. Delegation of authorities of the Board of Directors may be for a certain matter or a certain period of time, and all at the discretion of the Board of Directors.

Receiving of Credit and Granting of Guarantees and Collateral

93. Without detracting from any of the authorities accorded to the Board of Directors under these Articles, the Board of Directors may from time to time at its discretion resolve upon:

93.1 Receiving of credit by the Company in any amount and the securing of its discharge in the manner it shall deem proper:

93.2. The granting of a guarantee, collateral and any type of security.

93.3. The issue of a series of bonds, including capital notes or deeds of undertaking, including debentures, capital notes or deeds of undertaking which are convertible or maybe exercised into shares, and to determine the terms thereof, to pledge its property, in whole or in part, in the present or in the future, whether by floating charge or fixed charge. Bonds, capital notes, deeds of undertaking or other securities as stated above may be issued at a discount or at a premium and in any other manner, with deferred rights or special rights and/or preferred rights and/or other rights and all as determined by the Board of Directors at its discretion.

94. That stated in Clause 93 above does not negate the authorities of the CEO or any party appointed therefore to resolve upon the receiving of credit by the Company and/or the issue of collateral by the Company within the limits of the credits and the collateral determined by the Board of Directors.

Committees of the Board of Directors

95. Subject to the provisions of the Companies Law, the Board of Directors may as it deems proper, establish committees of two or more members, appoint members from out of the members of the Board of Directors (hereinafter: " **Board of Directors committee"),** and to delegate to the Board of Directors committee its authorities, in whole or in part.

In a Board of Directors committee to which the Board of Directors has delegated any of its authorities, only members of the Board of Directors may serve. In a Board of Directors committee whose function is to advise the Board of Directors or recommend only, parties who are not members of the Board of Directors may serve.

Notwithstanding that stated above, in the following matters, the Board of Directors may not delegate any of its authorities to a Board of Directors committee, but rather shall be entitled to establish committees for recommendation only:

95.1. Determination of general policies of the Company.

95.2. Distribution, save for the purchase of shares of the Company in accordance with a framework determined in advance by the Board of Directors.

95.3. Determination of the position of the Board of Directors on a matter requiring approval of the general meeting or the issue of an opinion on the profitability of a special purchase offer, as stated in Article 329 of the Companies Law.

95.4. Appointment of directors.

95.5. Issue or allotment of shares or of securities convertible into shares or which may be exercised into shares, or a series of bonds, save as specified in Clause 39.2 above.

95.6. Approval of financial reports.

95.7. Approval of transactions and actions requiring approval of the Board of Directors under the provisions of Articles 255 and 268 through 275 of the Companies Law.

96. A resolution passed or an action carried out by a Board of Directors committee, is deemed a resolution passed or an action carried out by the Board of Directors save if determined explicitly otherwise by the Board of Directors, for a certain matter or for a certain committee. The Board of Directors may from time to time expand, reduce or cancel the delegation of authorities to a Board of Directors committee, but the reduction or cancellation as stated shall not prejudice the validity of a resolution of the committee according to which the Company has acted as towards some other person who was unaware of the cancellation.

97.

97.1. The legal quorum for the opening of a Board of Directors committee shall be two committee members who are serving at the time of the meeting, or their alternates, unless determined otherwise by the Board of Directors.

97.2. The general provisions of these Articles with regard to the operation of the Board of Directors shall apply, mutatis mutandis, also upon the Board of Directors committees so long as they have not been replaced by directives issued by the Board of Directors for such matter, and all subject to the provisions of the Companies Law.

97.3. The Board of Directors committee shall report to the Board of Directors continuously upon its resolutions or recommendations.

98.

98.1. The Board of Directors will appoint an audit committee from amongst its members. The number of members of the audit committee shall not be less than three and all of the external directors (to the extent there is an obligation to appoint them) shall be members therein. The following shall not be members of the audit committee: The chairman of the Board of Directors, any director employed by the Company or routinely providing services to it, and a controlling interest in the Company or his relation.

98.2. The functions of the audit committee shall be as determined in the Companies Law including any other function imposed upon it by the Board of Directors.

Actions of the Board of Directors

99. Subject to the provisions of these Articles, the Board of Directors may convene for purposes of performance of its functions and postpone its meetings and regulate its activities and deliberations as it shall deem fit.

100. The Board of Directors will appoint one of its members as chairman of the Board of Directors (hereinafter **"Chairman of the Board of Directors"**). The Board of Directors may appoint one or more of its members as deputy chairman of the Board of Directors who shall serve as replacement chairman in his absence. The Board of Directors may determine the period for which the chairman and his deputies shall serve. In the absence of such determination, the chairman of the Board of Directors and his deputies shall serve for so long as they serve as directors and no resolution has been passed by the Board of Directors of the Company upon their replacement.

101. The chairman of the Board of Directors shall chair meetings of the Board of Directors and shall conduct them. If the chairman of the Board of Directors is absent from a meeting of the Board of Directors, in accordance with a notice delivered in advance, or has failed to appear to a meeting of the Board of Directors within 15 minutes from the date determined for the meeting (hereinafter: **"absence"**), then the deputy chairman of the Board of Directors shall chair the meeting (if one was appointed). In the absence of both the chairman of the Board of Directors and his deputy from the meeting, members of the Board of Directors who are present will elect one of their members as chairman of the meeting.

102. The Board of Directors will convene as per the requirements of the Company, and at least once every three months.

103. The chairman of the Board of Directors may convene the Board of Directors at any time, and determine the place and the date for the meeting of the Board of Directors.

104. Without detracting from that stated above, the chairman of the Board of Directors shall be required to convene the Board of Directors upon the occurrence of one of the following:

104.1. Receiving a demand for convening of the Board of Directors from at least two directors, for deliberation upon a matter which shall be specified in their demand, and if there are five directors in the Company (or less), a demand for convening of the Board of Directors from at least one director shall suffice for conducting of a discussion on the matter specified in his demand.

104.2. Receiving notice or report of the CEO which requires an action of the Board of Directors.

104.3. Receiving notice from the auditing accountant of material defects in the accounting auditing of the Company.

105. Upon receipt of the notice or report as stated, the chairman of the Board of Directors shall convene the Board of Directors, without delay, not later than the passage of 14 days from the date of the demand, report or notice, as the case may be.

105.1. Notice in advance of the convening of the Board of Directors shall be provided to each of the members of the Board of Directors three days prior to the date of the meeting.

105.2. Notwithstanding that stated above, the Board of Directors may, at the consent of all of the directors, convene for a meeting without notice.

106. The agenda of meetings of the Board of Directors will be determined by the chairman of the Board of Directors and shall include:

106.1. Matters determined by the chairman of the Board of Directors.

106.2. Matters determined as stated in Clause 104 above.

106.3. Any matter which a director or the CEO has requested of the chairman of the Board of Directors, a reasonable time prior to the convening of the meeting of the Board of Directors, to be included in the agenda (hereinafter: " **the agenda** ").

107. The notice of the convening of the Board of Directors shall indicate the date of the meeting, its location and reasonable details of the matters to be discussed at the meeting, in accordance with the agenda. The notice may be in writing and it may be oral.

108. Notice of a meeting of the Board of Directors, if the notice is delivered in writing, shall be delivered to the address which the director provided to the Company in advance save if the director has requested that the notice be delivered to him at some other location or if he has consented to its delivery at some other location.

109. The legal quorum for the opening of a meeting of the Board of Directors shall be a majority of the members of the Board of Directors serving at the time of the meeting and entitled to participate therein, themselves or their alternates.

In the absence of a legal quorum upon the passage of half of an hour from the time determined for the meeting of the Board of Directors, the meeting shall be postponed for 48 hours. At a postponed meeting as stated in the absence of a legal quorum within half of an hour from the convening, the directors who are present and entitled to vote shall constitute the legal quorum.

110.

110.1. In a vote in the Board of Directors, each director shall have one vote. Resolutions of the Board of Directors shall be passed by a majority of the votes of the directors present at the meeting and voting therein, without taking into account abstentions. The chairman of the Board of Directors shall not have a decisive vote in the event of a tie.

110.2. In the event of tied votes, the proposed resolution upon which the members of the Board of Directors have voted shall be deemed rejected.

111. The Board of Directors may conduct meetings by any means of communication and provided that all of the directors participating can hear each other simultaneously. The Board of Directors may regulate the manner and the methods for the conduct of its meetings by means of communication.

112. The Board of Directors may pass resolution even without actually convening, and provided that all of the directors entitled to participate in the deliberation and to vote upon the matter presented for resolution, have consented to the resolution and have signed thereupon (or on separate copies thereof, including by means of facsimile). A resolution passed in such manner shall be valid for all intents and purposes as though it was passed at a meeting of the Board of Directors, which was convened and conducted lawfully.

Minutes

113. The Board of Directors shall ensure that minutes shall be held of the proceedings and the meetings of the Board of Directors. The minutes shall be recorded in books prepared for such purpose and shall include, inter alia, the following details:

113.1. The names of the participating directors and other parties present of every meeting of the Board of Directors.

113.2. The matters discussed at the meeting of the Board of Directors and the resolutions passed.

Each minutes shall be signed by the chairman of the Board of Directors or by the chairman of the meeting, as the case may be. Minutes which are signed and approved as stated shall serve as prima facie evidence to the content thereof.

114. The provisions of Clause 113 above shall apply also to the meetings of the Board of Directors committees and the passage of resolutions of the Board of Directors without convening, as stated in Clause 112 above.

The CEO

115. The Board of Directors shall appoint from time to time a CEO for the Company, and is entitled to appoint more than one CEO (each one of these shall hereinafter be called: **CEO**). The Board of Directors is also entitled to dismiss the CEO or to replace him at any time it deems proper.

116. The CEO is not required to be a shareholder in the Company nor must he be a director.

117. The CEO is responsible for the continuous management of the affairs of the Company, in the framework of the policy determined by the Board of Directors and subject to its directives.

118. The CEO shall have all of the authorities of management and execution not granted at law or in these Articles or by virtue thereof to some other organ of the Company with the exception of authorities as stated which shall be transferred from him to the Board of Directors in accordance with the provisions of Clause 91.1 above, if they shall be transferred. The CEO shall be subordinate to the Board of Directors.

119. Subject to the provisions of the Companies Law and these Articles, the Board of Directors may from time to time deliver and grant to the CEO authorities belonging to the Board of Directors under these Articles, as it shall deem fit, and it is entitled to grant any of these authorities for such period, such purpose and under such terms and limitations as the Board of Directors shall deem appropriate, and the Board of Directors is entitled to grant these authorities, both without relinquishing its authority in the matter or in their stead or subordinates to them, in whole or in part, and is entitled from time to time to cancel, suspend and change these authorities, in whole or in part.

120. Without detracting from that stated in Article 127 and 129 below, the CEO is entitled, with the approval of the Board of Directors, to delegate any of his authorities to other/s, subordinate to him. Approval of the Board of Directors as mentioned may be granted generally or for a specific matter.

121. Without detracting from the provisions of the Companies Law and applicable law, the CEO will submit to the Board of Directors reports on matters, at times and at a scope as determined by the Board of Directors, whether in a specific resolution or in the framework of the procedures of the Board of Directors.

122. The wage of the CEO may be paid as a salary, or commission or participation in the profit or the granting of securities or the rights to purchase these, or in any other manner.

Validity of Actions and Approval of Transactions

123. Subject to the provisions of applicable law, all of the actions taken by the Board of Directors or by a Board of Directors committee or by any person acting as director or member of a Board of Directors committee or by an officer, as the case may be - shall be valid even if it evolves thereafter that there was some defect in the appointment of the director, Board of Directors committee, director who is a member of the committee or officer, as the case may be, or that any of the officers mentioned was prohibited from serving in such position.

124.

124.1 Subject to the provisions of the Companies Law, the holding of shares in the Company and the service as an officer in the Company whilst being a party at interest or an officer

in any other corporation, including a corporation in which the Company is a party at interest or a shareholder in the Company, shall not preclude an officer from being an officer in the Company. Additionally, an officer shall not be precluded from being an officer in the Company due to his engagement or subsequent to the engagement of any corporation as stated above, in a contract with the Company in any matter or manner whatsoever.

124.2 Subject to the provisions of the Companies Law, the service of a person as an officer in the Company shall not preclude him and/or his relations and/or some other corporation in which he is a party at interest, from engaging with the Company in transactions in which the officer has a personal interest in any manner whatsoever.

124.3 Subject to the provisions of the Companies Law, an officer shall be entitled to participate and to vote in deliberations with regard to approval of transactions or actions in which he has a personal interest.

125. Subject to the provisions of the Companies Law, a transaction of the Company with some other person in whom the officer in the Company has a personal interest, and which are not extraordinary transactions, will be approved as follows:

125.1 Engagement as stated above in a transaction which is not extraordinary shall be approved by the Board of Directors or by some other party (including the audit committee of the Company) authorized therefor by the Board of Directors, whether in a specific resolution or in the framework of the procedures of the Board of Directors, whether by general agreement or by agreement to a certain type of transactions or a specific transaction.

125.2 Approval of transactions which are not extraordinary as stated above may be made by general approval for a certain type of transaction or approval for a specific transaction.

126. Subject to the provisions of the Companies Law, general notice issued to the Board of Directors by an officer or a controlling interest in the Company with regard to his personal interest in a certain body, with details of his personal interest, shall constitute disclosure by the officer or the controlling interest, to the Company, with regard to his personal interest as stated for purposes of any engagement with the aforementioned body, or an engagement in which the aforementioned body has a personal interest.

Signature on behalf of the Company

127. Subject to the provisions of the Companies Law and these Articles, the Board of Directors may authorize any party to act and to sign on behalf of the Company, whether himself or some other person, generally or on certain matters.

128. The Company shall have a stamp bearing the name of the Company. A signature upon a document shall not bind the Company save if it was signed by those authorized to sign on behalf of the Company together with the stamp of the Company or its printed name.

Appointment of Legal Representatives

129. Subject to the provisions of the 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.

Exemption, Indemnification and Insurance

130. Subject to the provisions of the Companies Law, the Company is entitled to exempt an officer from liability, in whole or in part, due to damage for breach of the duty of caution towards it. However, a Company may not exempt a director in advance from his liability towards it due to breach of the duty of caution upon distribution.

131. Subject to the provisions of the Companies Law and the Securities Law, the Company may engage in a contract to insure the liability of its officer, for liability imposed upon him due to an act carried out by virtue of his position as an officer, in any one of the following:

131.1. Breach of the duty of caution towards the Company or towards some other person.

131.2. Breach of the fiduciary duty towards the Company and provided that the officer acted in good faith and had reasonable cause to assume that the actions shall not harm the welfare of the Company.

131.3. Monetary liabilities imposed upon him in favor of some other person including payments to the victim of the breach as stated in Article 52nd (a)(1)(a) of this security's law.

131.4. Any other event for which it is permitted and/or shall be permitted to insure the liability of an officer including for expenses made in connection with proceedings conducted against him (as defined in Article 56h (a)(1) of the Securities Law) including reasonable litigation expenses and including lawyers professional fees.

132. Subject to the provisions of the Companies Law and the Securities Law -

132.1. The Company is entitled to provide an undertaking in advance to indemnify its officers for liability or expense as stated in Clause 133 below, in any of the following (hereinafter: " **undertaking for indemnification** "):

(a) As specified in Clause 133.1 below and provided that the undertaking for indemnification will be limited to events which in the opinion of the Board of Directors are anticipated in light of the activity of the Company in practice at the time of the issue

of the undertaking for indemnification and to an amount or a criteria which the Board of Directors has determined are reasonable in the circumstances and that in the undertaking for indemnification, there shall be indicated the events which in the opinion of the Board of Directors are anticipated in light of the activity of the Company in practice at the time of the issue of the undertaking and the amount or criteria which the Board of Directors has determined are reasonable in the circumstances.

(b) As specified in Clause 133.2 or 133.3 below.

132.2. Without detracting from that stated in Clause 132.1 above, the Company is entitled to indemnify an officer therein retroactively, due to a liability or an expense as stated in Clause 133 below which was imposed upon him due to an action taken as an officer in the Company.

133. An undertaking for indemnification or indemnification as stated in Clause 132 above, may be granted due to liability or expense as specified in sub Clauses 133.1 to 133.4 below, which were imposed upon the officer or which he expended due to an action taken by virtue of being an officer in the Company, as follows:

133.1. A monetary liability imposed upon him in favor of some other party by a judgment, including a judgment issued in a settlement or an arbitrator's judgment approved by a court, for payment to the injured party of a breach as stated in article 52ns (a)(1)(a) of the Security's law.

133.2. Reasonable litigation expenses including attorney's professional fees which the officer expended due to investigation or proceedings conducted against him by an authority entitled to conduct an investigation or proceedings and which ended without submission of an indictment against him and without monetary liabilities imposed upon him as an alternative to a criminal proceeding or which ended without submission of an indictment against him or the imposition of monetary liability as an alternative to criminal proceedings for a crime which does not require the proof of *mens rea* ; in this paragraph -

Termination of proceedings without submission of an indictment in the matter in which a criminal investigation was commenced - means the closing of the case as per Article 62 of the Criminal Procedural Law (combined version) - 1982 (in this sub-clause - the Criminal Procedural Law) or a stay of proceedings by the Attorney General under Article 231 of the Criminal Procedural Regulations.

"Monetary liability as an alternative to criminal proceedings" - monetary liability imposed at law as an alternative to a criminal proceeding, including an administrative fine under the Administrative Crimes Law - 1985, a fine for a crime determined as a fine-crime under the provisions of the Criminal Procedural Regulations, and administrative fine or ransom.

133.3. Reasonable litigation expenses, including lawyers professional fees, which the officer expended or was obligated by the court, in proceedings commenced against him by the

Company or in its name or by some other person, or a criminal indictment from which he was acquitted or a criminal indictment in which he was convicted of a crime which does not require the proof of mens rea.

133.4. Any other liability or expense for which indemnification of an officer is and/or shall be permitted.

133.5. An expense made in connection with proceedings under Section H3, H4 or I1 of the Securities Law, including reasonable litigation expenses and lawyer's professional fees.

134. Subject to the provisions of the Companies Law, nothing in the provisions of these Articles shall limit the Company in any manner in connection with its engagement in an insurance contract or in connection with the granting of an exemption or indemnification:

134.1. In connection with an officer in the Company or a director in another Company, to such extent as the insurance, exemption or indemnification are not prohibited under any law.

134.2. In connection with parties who are not officers in the Company or directors in another Company, including but without detracting from the generality of that stated above, employees, contractors or advisers.

134A. The maximum amount of indemnification that the Company will pay to all officers who receive a letter of indemnity from the Company (in addition to the amounts received from an insurance company, if received, under directors and officers liability insurance purchased by the Company, if purchased), in the aggregate for one event or more, shall not exceed the greater of the following: (i) an amount that constitutes 25% of the Company's shareholders' equity after excluding the minority interest, on the actual payment date of the indemnification; and (ii) US $10 million, and if the Company lists for trade on a stock exchange outside of Israel - US $20 million.

Dividends, Funds, and Amortization of Funds and Profits

135. The Board of Directors may, prior to resolving upon distribution of dividend, as stated in clause 137 above, allocate from the within the profits, certain amounts as they shall deem fit and subject to any law, to a general fund or to a fund reserved for distribution of dividend, for distribution of bonus shares or some other purpose, as shall be determined by the Board of Directors at its discretion. The Board of Directors of the Company may, prior to resolving upon distribution of dividend, allot from within the profits certain amounts, as which shall be in fit, to a general fund or to a fund reserved for any purpose, as the Board of Directors shall determine at its discretion. In accordance with the discretion of the Board of Directors, profits of the Company which the Board of Directors has not resolved to distribute as dividend shall be transferred to the following year.

136. Until use is made of the aforementioned funds, the Board of Directors may invest the amounts allotted as stated above and the funds, in any investment, as it shall deem fit, and to handle such investments, to change them or to make any other use thereof, and is

entitled to distribute the reserved fund into special funds and to use each fund or part thereof for purposes of the business of the Company, without maintaining it separate from the remainder of the assets of the Company, all according to the discretion of the Board of Directors and the terms it shall determine.

137. Subject to the provisions of the Companies Law, the Board of Directors may resolve upon distribution of dividend. The Board of Directors resolving upon distribution of dividend may resolve that the dividend shall be paid, in whole and in part, in cash or in kind, and including this in securities or any other manner, at its discretion.

138.

138.1.

(A) Subject to the provisions of the Companies Law, the Board of Directors may resolve upon the allotment of bonus shares, and to convert into share capital as per the definition thereof in Article 302(b) of the Companies Law, some of the profits of the Company derived from shares or from a premium on shares or from any other source included in the shareholders capital, indicated in its last financial reports, in an amount determined by the Board of Directors and which shall not be less than the nominal value of the bonus shares.

(B) A Board of Directors resolving upon the allotment of bonus shares, shall determine whether they shall be of one class only for all shareholders without taking into account the class of shares held by them or for each shareholder as stated there shall be distributed bonus shares of the same class in respect of each class of shares held by him.

(C) Bonus shares which shall be allotted under this clause shall be deemed as fully paid up.

138.2 A Board of Directors resolving upon allotment of bonus shares may resolve that the Company shall transfer to a special fund designated for distribution of bonus shares in the future, such amounts that the conversion thereof into share capital shall suffice to allot to whomever shall, at such time for any reason, be entitled to purchase shares in the Company (including rights which may be implemented only at a later date), bonus shares which shall be due to him, had he exercised the right to purchase shares on the eve of the determining date for the right to receive the bonus shares (in this clause - " **the determining date** "). In the event that after the determining date a holder of a right as stated shall exercise his right to purchase shares or part thereof, the Company shall allot bonus shares to him with a nominal value and which are due to him had he exercised the right to purchase shares which he actually purchased, on the eve of the determining date, and this by the conversion into share capital of the special fund as mentioned. Bonus shares shall accord the owners thereof participation and distribution of dividends in cash or bonus shares starting on the date determined by the Board of Directors. With regard to determination of the amount which shall be transferred to the special fund as stated, any amounts transferred to such fund in respect of previous distributions of bonus shares shall

be viewed as already amortized and that shares have already allotted from it, which grant bonus shares to the holders of the right to purchase shares.

139. Subject to the rights ancillary to the classes of shares issued by the Company and the provisions of these Articles, a dividend or a bonus share shall be distributed to the shareholders proportionally to the nominal value of each share, without taking into account any premium which was paid thereupon.

140. In order to execute a resolution regarding distribution of dividend or allotment of bonus shares, the Board of Directors is entitled:

140.1 To resolve at its discretion any difficulty which shall arise in connection therewith and to adopt all of the steps it deems proper to overcome such difficulty.

140.2 To resolve that fractions lower than a certain amount determined by the Board of Directors shall not be taken into account for adjustment of the right of the shareholders or to sell fractions of shares and to pay the consideration for them (net) to those entitled to them.

140.3 To authorize to sign on behalf of the shareholders upon any contract or other documents required for the validity of the allotment and or distribution, and particularly to authorize to sign and submit for registration a document in writing as stated in Article 291 of the Companies Law.

140.4 To determine the value of certain assets which shall be distributed and to decide that payments in cash will be paid to shareholders on the basis of the value which was determined.

140.5 To grant cash or certain assets to trustees in favor of parties entitled thereto, as shall seem practical in view of the Board of Directors.

140.6 To make any arrangement or other arrangement which shall be required in the opinion of the Board of Directors to enable the allotment or distribution, as the case may be.

141. Dividend or other benefit in respective shares shall not bear interest or linkage differences.

142. The Board of Directors may delay any dividend or bonus shares or other benefits in respect of a share for which the consideration determined therefor, in whole or in part, was not paid to the Company, and to collect any amount as stated or consideration which shall be received from the sale of any bonus shares or other benefits, on account of the debt or liability in respect of the aforementioned share, this, whether the aforementioned share is owned exclusively by the shareholder in debt or jointly with other shareholders.

143. The Board of Directors may delay any dividend or bonus share or other benefit in respect of a share to which a person is entitled to be registered as its owner in the registry or is

entitled to transfer it, under clauses 28 or 30 above, as the case may be, until such person shall be registered as the owner of the share or until he shall transfer it at law, as the case may be.

144. The Board of Directors may determine from time to time the manner of the payment of the dividend or allotment of bonus shares or their transfer to those entitled and instructions, procedures and arrangements in connection therewith, both with regard to the registered shareholders and non-registered shareholders. Without detracting from the generality of that stated above, the Board of Directors is entitled to determine as follows:

144.1.

(A) Subject to that stated in sub-clause (B) below, a dividend or funds which shall be distributed to registered shareholders shall be paid to the registered shareholder by the dispatch of a check by post to his address as shall be registered in registry of shareholders, or in the instance of jointly registered owners of the share, to the party whose name appears first in the registry of shareholders regarding such share. Every dispatch of a check as stated shall be made at the risk of the registered shareholder. Without detracting from that stated above, the Board of Directors may determine that a dividend amount less than a certain amounts determined by the Board of Directors shall not be sent by check as stated, and there shall apply to it the provisions of sub-clause (B) below.

(B) The Board of Directors may determine that the payment of dividend or funds which are distributed to the registered shareholders, may be made at the office or any other place determined by the Board of Directors.

144.2. Dividends distributed to non-registered shareholders shall be transferred to such shareholders by means of a company for registration or any other means determined by the Board of Directors.

145. If two or more persons are jointly registered for a share in the registry of shareholders, each of them is entitled to issue a valid receipt for any dividend, share or other security, or other funds or benefits due in respect of the share.

Documents of the Company

146.

146.1. Shareholders shall have a right to view documents of the Company specified in Articles 184 of the Companies Law, upon fulfillment of the conditions determined therefor.

146.2. Shareholders shall not have a right to view documents of the Company or any part of them save if they were granted a right as stated, under statute or under these Articles or if they were permitted so to do by the Board of Directors as stated in Clause 146.1 above.

147. Subject to the provisions of applicable law, any book, record or registry which the Company must maintain in accordance with the law or these Articles, will be maintained using technical or other means as decided by the Board of Directors.

Financial Reports

148. The financial reports of the Company shall be signed by the party authorized therefor by the Board of Directors, as required at law.

Auditing Accountant

149. The auditing accountant or the auditing accountants shall be appointed at every annual meeting and shall serve in their position until the end of the following annual meeting.

150.

150.1. The Board of Directors shall determine the wage for the audit activity of the auditing accountant appointed by the Company, at the discretion of the Board of Directors.

150.2. The wage of the auditing accountant for additional services to the Company which are not auditing service, shall be determined by the Board of Directors at its discretion.

Notices

151. The provision of notices or delivery of documents to shareholders and a company for registration, in accordance with the provisions of the law or these Articles, shall be in such manners indicated below in this section.

152. Notice of a general meeting shall be delivered in accordance with Clause 53 above.

153.

153.1. Without detracting from that stated above, the Company is entitled to deliver notice or document to a shareholder by personal delivery or by facsimile or by post or by electronic mail. Postal delivery shall be made to the address of the shareholder registered in the registry or in the absence of such registered address, at the address delivered by him to the Company for the dispatch of notices to him. Notice delivered by means of facsimile shall be sent to the shareholder in accordance with the facsimile number delivered by him to the Company. Notice delivered by email shall be sent to the shareholder at the email address delivered by him to the Company.

153.2.

(A) Notice or documents delivered to the shareholder shall be deemed delivered upon their time of their delivery to his possession.

(B) Notice or documents sent by post shall be deemed properly delivered if delivered for postal dispatch when they bear the proper address and are lawfully postaged. Delivery shall be deemed to have been performed at the time at which the letter was to be delivered in the ordinary manner by the post, and not more than three days from the date in which the letter including the notice was delivered as stated at the post office.

(C) Notice sent by facsimile or email shall be deemed delivered 24 hours after the dispatch.

154. Without detracting from that stated above, the Company is entitled to deliver notice to shareholders by publication of the notice once, in two daily papers published in Israel in the Hebrew language, both in addition to and in the stead of notice as stated in clause 153 above. The date of publication in the paper shall be deemed the date of receipt of the notice by the shareholders.

155. The Company is entitled to notify upon the delivery of a document at the office or in any other place determined by the Board of Directors or in any other manner, including by means of the internet.

156. The Company is entitled to deliver to joint shareholders a notice or a document by dispatched to the shareholder whose name appears first in the registry of shareholders for such share.

157. Every person to whom a right to any share was lawfully transferred, by transfer or any other manner, shall be bound by such notice with regard to such share which was lawfully delivered to the person from whom his right derives to such share, prior to the recording of his details in the registry.

158. Any document or notice delivered to a shareholder in the Company in accordance with the provisions of these Articles shall be deemed as properly delivered notwithstanding his death, bankruptcy or the liquidation of such shareholder or the assignment of the right in the shares, in accordance with the law (whether the Company knew thereof or not) for so long as some other party was not registered in his stead as a shareholder, and the dispatch or delivery as stated shall be deemed for all purposes as sufficient with regard to any party interested in such shares and/or entitled to them by virtue of assignment of the right, in accordance with the law, whether together with such shareholder or by virtue thereof or in his stead.

159. Subject to the provisions of applicable law, a shareholder, director or any other party, who is entitled to receive notice in accordance with these Articles or at law, may waive its receipt, whether an advance or in retrospect, whether in a special circumstance or in general, and having done so, the notice will be deemed to have been lawfully provided and any proceedings or action in respect of which notice was to have been given, shall be deemed valid and in force.

160. Confirmation in writing signed by a director or by the Secretary of the Company with regard to the dispatch of a document or a notice in any one of the manners specified in these Articles, shall be deemed decisive proof of any detail included therein.

161. For so long as advance notice of a number of days must be granted or a notice is valid for a certain period, the date of delivery shall be included in the count of the number of days or the period, save as indicated otherwise. If notice was given in more than one of the manners specified above, it shall be deemed to have been received at the earliest dates at which it was considered received, as stated above.

Merger

162. Approval of a merger in accordance with the first chapter of the eighth section of the Companies Law, requires an ordinary majority in the general meeting or a class meeting, as the case maybe, and all subject to the provisions of applicable law.

Liquidation

163. Subject to the provisions of applicable law, the liquidator is entitled, whether in voluntary or other liquidation, in accordance with the resolution of the general meeting passed by ordinary majority, to distribute in kind between the shareholders, the surplus assets, in whole or in part, and the liquidator is further entitled in accordance with a resolution of the general meeting passed by an ordinary majority to deposit any part of the surplus assets in trust which shall be held in favor of the shareholders, as the liquidator shall deem appropriate. For the purpose of distribution of surplus assets in kind, the liquidator may determine the proper value of the property available for distribution and to decide how to carry out the distribution between the shareholders taking into account the ancillary rights from the different classes of shares in the Company which they own.

Bearer Shares

164. Subject to the provisions of applicable law, the Company is entitled to issue for a share which was paid up in full, a share certificate in accordance with the provisions which shall be determined for this matter by the Board of Directors of the Company, and in such instance, the share shall be registered as stated in Article 130(a)(2) of the Companies Law, and the name of the shareholder shall be erased from the registry of shareholders.

Internal Auditor

165. The organizational supervisor of the internal auditor shall be the chairman of the Board of Directors, or if the Board of Directors shall determine - the CEO of the Company.

166. Proposals for the annual work plan shall be submitted by the internal auditor for approval of the Board of Directors of the Company, or if the Board of Directors has determined, for approval of the audit committee.

Exhibit 4.1

BRAINSWAY LTD.
AMENDED AND RESTATED 2019 SHARE INCENTIVE PLAN

Unless otherwise defined, terms used herein shall have the meaning ascribed to them in Section 2 hereof.

1. PURPOSE; TYPES OF AWARDS; CONSTRUCTION.

1.1 Purpose. The purpose of this Amended and Restated 2019 Share Incentive Plan (as amended, this "Plan") is to afford an incentive to Service Providers of Brainsway Ltd., an Israeli company (together with any successor corporation thereto, the "Company"), or any Affiliate of the Company, which now exists or hereafter is organized or acquired by the Company, to continue as Service Providers, to increase their efforts on behalf of the Company or its Affiliates and to promote the success of the Company's business, by providing such Service Providers with opportunities to acquire a proprietary interest in the Company by the issuance of Shares or restricted Shares ("Restricted Shares") of the Company, and by the grant of options to purchase Shares ("Options"), Restricted Share Units ("RSUs") and other Share-based Awards pursuant to Sections 11 through 13 of this Plan.

1.2 Types of Awards. This Plan is intended to enable the Company to issue Awards under various tax regimes, including:

(i) pursuant and subject to the provisions of Section 102 of the Ordinance (or the corresponding provision of any subsequently enacted statute, as amended from time to time), and all regulations and interpretations adopted by any competent authority, including the Israeli Income Tax Authority (the "ITA"), including the Income Tax Rules (Tax Benefits in Stock Issuance to Employees) 5763-2003 or such other rules so adopted from time to time (the "Rules") (such Awards that are intended to be (as set forth in the Award Agreement) and which qualify as such under Section 102 of the Ordinance and the Rules, "102 Awards");

(ii) pursuant to Section 3(9) of the Ordinance or the corresponding provision of any subsequently enacted statute, as amended from time to time (such Awards, "3(9) Awards");

(iii) Incentive Stock Options within the meaning of Section 422 of the Code, or the corresponding provision of any subsequently enacted United States federal tax statute, as amended from time to time, to be granted to Employees who are deemed to be residents of the United States, for purposes of taxation (such Awards that are intended to be (as set forth in the Award Agreement) and which qualify as an incentive stock option within the meaning of Section 422(b) of the Code, "Incentive Stock Options"); and

(iv) Awards not intended to be (as set forth in the Award Agreement) or which do not qualify as an Incentive Stock Option to be granted to Service Providers who are deemed to be residents of the United States for purposes of taxation ("Nonqualified Stock Options").

In addition to the issuance of Awards under the relevant tax regimes in the United States of America and the State of Israel, and without derogating from the generality of Section 25, this Plan contemplates issuances to Grantees in other jurisdictions or under other tax regimes with respect to which the Committee is empowered to make the requisite adjustments in this Plan and set forth the relevant conditions in an appendix to this Plan or in the Company's agreement with the Grantee in order to comply with the requirements of such other tax regimes.

1.3 Company Status. This Plan contemplates the issuance of Awards by the Company, both as a private and public company.

1.4 Construction. To the extent any provision herein conflicts with the conditions of any relevant tax law, rule or regulation which are relied upon for tax relief in respect of a particular Award to a Grantee, the Committee is empowered, but is not required, hereunder to determine that the provisions of such law, rule or regulation shall prevail over those of this Plan and to interpret and enforce such prevailing provisions.

2. DEFINITIONS.

2.1 Terms Generally. Except when otherwise indicated by the context, (i) the singular shall include the plural and the plural shall include the singular; (ii) any pronoun shall include the corresponding masculine, feminine and neuter forms; (iii) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, restated, supplemented or otherwise modified (subject to any restrictions on such amendments, restatements, supplements or modifications set forth therein or herein), (iv) references to any law, constitution, statute, treaty, regulation, rule or ordinance, including any section or other part thereof shall refer to it as amended from time to time and shall include any successor thereof, (v) reference to a "company" or "entity" shall include a, partnership, corporation, limited liability company, association, trust, unincorporated organization, or a government or agency or political subdivision thereof, and reference to a "person" shall mean any of the foregoing or an individual, (vi) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Plan in its entirety, and not to any particular provision hereof, (vii) all references herein to Sections shall be construed to refer to Sections to this Plan; (viii) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation"; and (ix) use of the term "or" is not intended to be exclusive.

2.2 Defined Terms. The following terms shall have the meanings ascribed to them in this Section 2:

2.2.1 "Affiliate" shall mean, (i) with respect to any person, any other person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such person (with the term "control" or "controlled by" within the meaning of Rule 405 of Regulation C under the Securities Act), including, without limitation, any Parent or Subsidiary, or (ii) for the purpose of 102 Awards, "Affiliate" shall only mean an "employing company" within the meaning and subject to the conditions of Section 102(a) of the Ordinance.

2.2.2 "Applicable Law" shall mean any applicable law, rule, regulation, statute, pronouncement, policy, interpretation, judgment, order or decree of any federal, provincial, state or local governmental, regulatory or adjudicative authority or agency, of any jurisdiction, and the rules and regulations of any stock exchange, over-the-counter market or trading system on which the Company's shares are then traded or listed.

2.2.3 "Award" shall mean any Option, Restricted Share, RSUs or any other Share-based award granted under this Plan.

2.2.4 "Board" shall mean the Board of Directors of the Company.

2.2.5 "Code" shall mean the United States Internal Revenue Code of 1986, and any applicable regulations promulgated thereunder, all as amended.

2.2.6 "Committee" shall mean a committee established or appointed by the Board to administer this Plan, subject to Section 3.1.

2.2.7 "Companies Law" shall mean the Israel Companies Law, 5759-1999, and the regulations promulgated thereunder, all as amended from time to time.

2.2.8 "Controlling Shareholder" shall have the meaning set forth in Section 32(9) of the Ordinance.

2.2.9 "Disability" shall mean (i) the inability of a Grantee to engage in any substantial gainful activity or to perform the major duties of the Grantee's position with the Company or its Affiliates by reason of any medically determinable physical or mental impairment, as determined by a qualified doctor acceptable to the Company, (ii) if applicable, a "permanent and total disability" as defined in Section 22(e)(3) of the Code or Section 409A(a)(2)(c)(i) of the Code, as amended from time to time, or (iii) as defined in a policy of the Company that the Committee deems applicable to this Plan, or that makes reference to this Plan, for purposes of this definition.

2.2.10 "Employee" shall mean any person treated as an employee (including an officer or a director who is also treated as an employee) in the records of the Company or any of its Affiliates (and in the case of 102 Awards, subject to Section 9.3 or in the case of Incentive Stock Options, who is an employee for purposes of Section 422 of the Code); provided, however, that neither service as a director nor payment of a director's fee shall be sufficient to constitute employment for purposes of this Plan. The Company shall determine in good faith and in the exercise of its discretion whether an individual has become or has ceased to be an Employee and the effective date of such individual's employment or termination of employment, as the case may be. For purposes of a person's rights, if any, under this Plan as of the time of the Company's determination, all such determinations by the Company shall be final, binding and conclusive, notwithstanding that the Company or any court of law or governmental agency subsequently makes a contrary determination.

2.2.11 "employment", "employed" and words of similar import shall be deemed to refer to the employment of Employees or to the services of any other Service Provider, as the case may be.

2.2.12 "exercise" "exercised" and words of similar import, when referring to an Award that does not require exercise or that is settled upon vesting (such as may be the case with RSUs or Restricted Shares, if so determined in their terms), shall be deemed to refer to the vesting of such an Award (regardless of whether or not the wording included reference to vesting of such an Awards explicitly).

2.2.13 "Exercise Period" shall mean the period, commencing on the date of grant of an Award, during which an Award shall be exercisable, subject to any vesting provisions thereof (including any acceleration thereof, if any) and subject to the termination provisions hereof.

2.2.14 "Exercise Price" shall mean the exercise price for each Share covered by an Option or the purchase price for each Share covered by any other Award.

2.2.15 "Fair Market Value" shall mean, as of any date, the value of a Share or other property as determined by the Board, in its discretion, subject to the following: (i) if, on such date, the Shares are listed on any securities exchange, the average closing sales price per Share on which the Shares are principally traded over the thirty (30) day calendar period preceding the subject date (utilizing all trading days during such 30 calendar day period), as reported in The Wall Street Journal or such other source as the Company deems reliable; (ii) if, on such date, the Shares are then quoted in an over-the-counter market, the average of the closing bid and asked prices for the Shares in that market during the thirty (30) day calendar period preceding the subject date (utilizing all trading days during such 30 calendar day period), as reported in The Wall Street Journal or such other source as the Company deems reliable; (iii) if, on such date, the Shares are not then listed on a securities exchange or quoted in an over-the-counter market, or in case of any other property, such value as the Committee, in its sole discretion, shall determine, with full authority to determine the method for making such determination and which determination shall be conclusive and binding on all parties, and shall be made after such consultations with outside legal, accounting and other experts as the Committee may deem advisable; provided, however, that, if applicable, the Fair Market Value of the Shares shall be determined in a manner that satisfies the applicable requirements of and subject to Section 409A of the Code, and with respect to Incentive Stock Options, in a manner that satisfies the applicable requirements of and subject to Section 422 of the Code, subject to Section 422(c)(7) of the Code. The Committee shall maintain a written record of its method of determining such value. If the Shares are listed or quoted on more than one established stock exchange or over-the-counter market, the Committee shall determine the principal such exchange or market and utilize the price of the Shares on that exchange or market (determined as per the method described in clauses (i) or (ii) above, as applicable) for the purpose of determining Fair Market Value.

2.2.16 "Grantee" shall mean a person who has been granted an Award(s) under this Plan.

2.2.17 "Ordinance" shall mean the Israeli Income Tax Ordinance (New Version) 1961, and the regulations and rules (including the Rules) promulgated thereunder, all as amended from time to time.

2.2.18 "Parent" shall mean any company (other than the Company), which now exists or is hereafter organized, (i) in an unbroken chain of companies ending with the Company if, at the time of granting an Award, each of the companies (other than the Company) owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other companies in such chain, or (ii) if applicable and for purposes of Incentive Stock Options, as defined in Section 424(e) of the Code.

2.2.19 "Prior Plan" shall mean the Brainsway LTD. 2014 Share Incentive Plan.

2.2.20 "Prior Plan Awards" shall mean (i) awards that were granted under the Prior Plan and were outstanding on the Effective Date and that, on or after the Effective Date, are forfeited, expire, or are canceled in accordance with the terms of the Prior Plan and the applicable award agreement or (ii) any shares subject to awards relating to our ordinary shares under the Prior Plan that, on or after the Effective Date, are settled in cash.

2.2.21 "Retirement" shall mean a Grantee's retirement pursuant to Applicable Law or in accordance with the terms of any tax-qualified retirement plan maintained by the Company or any of its Affiliates in which the Grantee participates or is subject to.

2.2.22 "Securities Act" shall mean the U.S. Securities Act of 1933, and the rules and regulations promulgated thereunder, all as amended from time to time.

2.2.23 "Service Provider" shall mean an Employee, director, officer, consultant, advisor and any other person or entity who provides services to the Company or any Parent, Subsidiary or Affiliate thereof. Service Providers shall include prospective Service Providers to whom Awards are granted in connection with written offers of an employment or other service relationship with the Company or any Parent, Subsidiary or any Affiliates thereof, provided however that such employment or service shall have actually commenced.

2.2.24 "Shares" shall mean Ordinary Shares, par value NIS 0.04, of the Company (as adjusted for stock split, reverse stock split, bonus shares, combination or other recapitalization events), or shares of such other class of shares of the Company as shall be designated by the Board in respect of the relevant Award(s). "Shares" include any securities or property issued or distributed with respect thereto.

2.2.25 "Subsidiary" shall mean any company (other than the Company), which now exists or is hereafter organized or acquired by the Company, (i) in an unbroken chain of companies beginning with the Company if, at the time of granting an Award, each of the companies other than the last company in the unbroken chain owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other companies in such chain, or (ii) if applicable and for purposes of Incentive Stock Options, as defined in Section 424(f) of the Code.

2.2.26 "Ten Percent Shareholder" shall mean a Grantee who, at the time an Award is granted to the Grantee, owns shares possessing more than ten percent (10%) of the total combined voting power of all classes of shares of the Company or any Parent or Subsidiary, within the meaning of Section 422(b)(6) of the Code.

2.2.27 "Trustee" shall mean the trustee appointed by the Committee to hold the Awards (and, in relation with 102 Awards, approved by the ITA), if so appointed.

2.3 Other Defined Terms. The following terms shall have the meanings ascribed to them in the Sections set forth below:

Term	Section
102 Awards	1.2(i)
102 Capital Gains Track Awards	9.1
102 Non-Trustee Awards	9.2
102 Ordinary Income Track Awards	9.1
102 Trustee Awards	9.1
3(9) Awards	1.2(ii)
Award Agreement	6
Cause	6.6.4.4
Company	1.1
Effective Date	24.1
Election	9.2
Eligible 102 Grantees	9.3.1

Incentive Stock Options	1.2(iii)
ISO Share Issuance Limit	5
ITA	1.1(i)
Market Stand-Off	17.1
Market Stand-Off Period	17.1
Merger/Sale	14.2
Nonqualified Stock Options	1.2(iv)
Plan	1.1
Recapitalization	14.1
Required Holding Period	9.5
Restricted Period	11.2
Restricted Share Agreement	11
Restricted Share Unit Agreement	12
Restricted Shares	1.1
RSUs	1.1
Rules	1.1(i)
Securities	17.1
Successor Corporation	14.2.1
Withholding Obligations	18.5

3. ADMINISTRATION.

3.1 To the extent permitted under Applicable Law, the Articles of Association and any other governing document of the Company, this Plan shall be administered by the Committee. In the event that the Board does not appoint or establish a committee to administer this Plan, this Plan shall be administered by the Board. In the event that an action necessary for the administration of this Plan is required under Applicable Law to be taken by the Board without the right of delegation, or if such action or power was explicitly reserved by the Board in appointing, establishing and empowering the Committee, then such action shall be so taken by the Board. In any such event, all references herein to the Committee shall be construed as references to the Board. Even if such a Committee was appointed or established, the Board may take any action that are stated to be vested in the Committee, and shall not be restricted or limited from exercising all rights, powers and authorities under this Plan or Applicable Law.

3.2 The Board shall appoint the members of the Committee, may from time to time remove members from, or add members to, the Committee, and shall fill vacancies in the Committee, however caused, provided that the composition of the Committee shall at all times be in compliance with any mandatory requirements of Applicable Law, the Articles of Association and any other governing document of the Company. The Committee may select one of its members as its Chairman and shall hold its meetings at such times and places as it shall determine. The Committee may appoint a Secretary, who shall keep records of its meetings, and shall make such rules and regulations for the conduct of its business as it shall deem advisable and subject to mandatory requirements of Applicable Law.

3.3 Subject to the terms and conditions of this Plan, any mandatory provisions of Applicable Law and any provisions of any Company policy required under mandatory provisions of Applicable Law, and in addition to the Committee's powers contained elsewhere in this Plan, the Committee shall have full authority, in its discretion, from time to time and at any time, to determine any of the following, or to recommend to the Board any of the following if it is not authorized to take such action according to Applicable Law:

(i) eligible Grantees,

(ii) grants of Awards and setting the terms and provisions of Award Agreements (which need not be identical) and any other agreements or instruments under which Awards are made, including, but not limited to, the number of Shares underlying each Award,

(iii) the time or times at which Awards shall be granted,

(iv) the terms, conditions and restrictions applicable to each Award (which need not be identical) and any Shares acquired upon the exercise or (if applicable) vesting thereof, including, without limitation, (1) designating Awards under Section 1.2; (2) the vesting schedule, the acceleration thereof and terms and conditions upon which Awards may be exercised or become vested, (3) the Exercise Price, (4) the method of payment for Shares purchased upon the exercise or (if applicable) vesting of the Awards, (5) the method for satisfaction of any tax withholding obligation arising in connection with the Awards or such Shares, including by the withholding or delivery of Shares, (6) the time of the expiration of the Awards, (7) the effect of the Grantee's termination of employment with the Company or any of its Affiliates, and (8) all other terms, conditions and restrictions applicable to the Award or the Shares not inconsistent with the terms of this Plan,

(v) to accelerate, continue, extend or defer the exercisability of any Award or the vesting thereof, including with respect to the period following a Grantee's termination of employment,

(vi) the interpretation of this Plan and the meaning, interpretation and applicability of terms referred to in Applicable Laws,

(vii) policies, guidelines, rules and regulations relating to and for carrying out this Plan, and any amendment, supplement or rescission thereof, as it may deem appropriate,

(viii) to adopt supplements to, or alternative versions of, this Plan, including, without limitation, as it deems necessary or desirable to comply with the laws of, or to accommodate the tax regime or custom of, foreign jurisdictions whose citizens or residents may be granted Awards,

(ix) the Fair Market Value of the Shares or other property,

(x) the tax track (capital gains, ordinary income track or any other track available under the Section 102 of the Ordinance) for the purpose of 102 Awards,

(xi) the authorization and approval of conversion, substitution, cancellation or suspension under and in accordance with this Plan of any or all Awards or Shares,

(xii) the amendment, modification, waiver or supplement of the terms of each outstanding Award (with the consent of the applicable Grantee, if such amendments refers to the increase of the Exercise Price of Awards or reduction of the number of Shared underlying an Award (but, in each case, other than as a result of an adjustment or exercise of rights in accordance with Section 14)) unless otherwise provided under the terms of this Plan,

(xiii) without limiting the generality of the foregoing, and subject to the provisions of Applicable Law, to grant to a Grantee the holder of an outstanding Award, in exchange for the cancellation of such Award, a new Award having an Exercise Price lower than that provided in the Award so canceled and containing such other terms and conditions as the Committee may prescribe in accordance with the provisions of this Plan or to set a new Exercise Price for the same Award lower than that previously provided in the Award,

(xiv) to correct any defect, supply any omission or reconcile any inconsistency in this Plan or any Award Agreement and all other determinations and take such other actions with respect to this Plan or any Award as it may deem advisable to the extent not inconsistent with the provisions of this Plan or Applicable Law, and

(xv) any other matter which is necessary or desirable for, or incidental to, the administration of this Plan and any Award thereunder.

3.4 The authority granted hereunder includes the authority to modify Awards to eligible individuals who are foreign nationals or are individuals who are employed outside Israel to recognize differences in local law, tax policy or custom, in order to effectuate the purposes of this Plan but without amending this Plan.

3.5 The Board and the Committee shall be free at all times to make such determination and take such actions as they deem fit. The Board and the Committee need not take the same action or determination with respect to all Awards, with respect to certain types of Awards, with respect to all Service Providers or any certain type of Service Providers and actions and determinations may differ as among the Grantees, and as between the Grantees and any other holders of securities of the Company.

3.6 All decisions, determinations, and interpretations of the Committee, the Board and the Company under this Plan shall be final and binding on all Grantees (whether before or after the issuance of Shares pursuant to Awards), unless otherwise determined by the Committee, the Board or the Company, respectively. The Committee shall have the authority (but not the obligation) to determine the interpretation and applicability of Applicable Laws to any Grantee or any Awards. No member of the Committee or the Board shall be liable to any Grantee for any action taken or determination made in good faith with respect to this Plan or any Award granted hereunder.

3.7 Any officer of the Company shall have the authority to act on behalf of the Company with respect to any matter, right, obligation, determination or election which is the responsibility of or which is allocated to the Company herein, provided the officer has apparent authority with respect to such matter, right, obligation, determination or election.

4. ELIGIBILITY.

4.1 Awards may be granted to Service Providers of the Company or any Affiliate thereof, taking into account the qualification under each tax regime pursuant to which such Awards are granted. A person who has been granted an Award hereunder may be granted additional Awards, if the Committee shall so determine, subject to the limitations herein. However, eligibility in accordance with this Section 4 shall not entitle any person to be granted an Award, or, having been granted an Award, to be granted an additional Award.

4.2 Awards may differ in number of Shares covered thereby, the terms and conditions applying to them or on the Grantees or in any other respect (including, that there should not be any expectation (and it is hereby disclaimed) that a certain treatment, interpretation or position granted to one shall be applied to the other, regardless of whether or not the facts or circumstances are the same or similar).

5. SHARES.

5.1 The maximum aggregate number of Shares that may be issued under this Plan shall initially be 3,626,200 authorized but unissued Shares (the "Pool") (except and as adjusted pursuant to Section 14.1 of this Plan and for Prior Plan Awards eligible for reuse pursuant to the following paragraph), or such other number as the Board may determine from time to time (without the need to amend the Plan in case of such determination). However, except as adjusted pursuant to Section 14.1, in no event shall more than such number of Shares included in the Pool be available for issuance pursuant to the exercise of Incentive Stock Options (the "ISO Share Issuance Limit").

5.2 Any Share underlying an Award granted hereunder or any Prior Plan Award that has expired or was cancelled, terminated, forfeited or repurchased, for any reason, without having been exercised, shall, automatically and without any further action on the part of the Company or any Grantee, again be available for grant of Awards and Shares issued upon exercise or (if applicable) vesting thereof for the purposes of this Plan (unless this Plan shall have been terminated) or unless the Board determines otherwise. Such Shares may, in whole or in part, be authorized but unissued Shares, treasury shares (dormant shares) or Shares otherwise that shall have been or may be repurchased by the Company (to the extent permitted pursuant to the Companies Law). Any Shares under the Pool that are not subject to outstanding or exercised Awards at the termination of this Plan shall cease to be reserved for the purpose of this Plan.

6. TERMS AND CONDITIONS OF AWARDS.

Each Award granted pursuant to this Plan shall be evidenced by a written agreement between the Company and the Grantee or a written notice delivered by the Company (the "Award Agreement"), in substantially such form or forms and containing such terms and conditions, as the Committee shall from time to time approve. The Award Agreement shall comply with and be subject to the following general terms and conditions and the provisions of this Plan (except for any provisions applying to Awards under different tax regimes), unless otherwise specifically provided in such Award Agreement, or the terms referred to in other Sections of this Plan applying to Awards under such applicable tax regimes, or terms prescribed by Applicable Law. Award Agreements need not be in the same form and may differ in the terms and conditions included therein.

6.1 Number of Shares. Each Award Agreement shall state the number of Shares covered by the Award.

6.2 Type of Award. Each Award Agreement may state the type of Award granted thereunder, provided that the tax treatment of any Award, whether or not stated in the Award Agreement, shall be as determined in accordance with Applicable Laws.

6.3 Exercise Price. Each Award Agreement shall state the Exercise Price, which shall not be less than NIS 0.1. Unless otherwise set forth in this Plan, an Exercise Price of an Award of less than the par value of the Shares shall comply with Section 304 of the Companies Law, 1999, as amended. Subject to Section 3 and to the foregoing, the Committee may reduce the Exercise Price of any outstanding Award, on terms and subject to such conditions as it deems advisable. The Exercise Price shall also be subject to adjustment as provided in Section 14 hereof.

6.4 Manner of Exercise. An Award may be exercised, as to any or all Shares as to which the Award has become exercisable, by written notice delivered in person or by mail (or such other methods of delivery prescribed by the Company) to the Chief Financial Officer of the Company or to such other person as determined by the Committee, or in any other manner as the Committee shall prescribe from time to time, specifying the number of Shares with respect to which the Award is being exercised (which may be equal to or lower than the aggregate number of Shares that have become exercisable at such time, subject to the last sentence of this Section), accompanied by payment of the aggregate Exercise Price for such Shares in the manner specified in the following sentence. The Exercise Price shall be paid in full with respect to each Share, at the time of exercise, either in (i) cash, (ii) if the Company's shares are listed for trading on any securities exchange or over-the-counter market, all or part of the Exercise Price and any withholding taxes may be paid by the delivery (on a form prescribed by the Company) of an irrevocable direction to a securities broker approved by the Company to sell Shares and to deliver all or part of the sales proceeds to the Company or the Trustee, (iii) if the Company's shares are listed for trading on any securities exchange or over-the-counter market, and if the Committee so determines, all or part of the Exercise Price and any withholding taxes may be paid by the delivery (on a form prescribed by the Company) of an irrevocable direction to pledge Shares to a securities broker or lender approved by the Company, as security for a loan, and to deliver all or part of the loan proceeds to the Company or the Trustee, or (iv) in such other manner as the Committee shall determine, which may include procedures for cashless exercise. A Grantee may not exercise Awards unless the aggregate Exercise Price thereof is equal to or in excess of the lower of: (a) the aggregate Exercise Price for all Shares as to which the Award has become exercisable at such time; or (b) US$2,000.

Notwithstanding the above, as long as the Company's Shares are listed for trading on Tel-Aviv Stock Exchange Ltd. conversion shall not be executed on the record date for the distribution of bonus shares, offer by way of rights, distribution of a dividend, consolidation of capital, splitting of capital or reduction of capital (each of the aforesaid hereinafter referred to as "company event").

6.5 Term and Vesting of Awards.

6.5.1 Each Award Agreement shall provide the vesting schedule for the Award as determined by the Committee. The Committee shall have the authority to determine the vesting schedule and accelerate the vesting of any outstanding Award at such time and under such circumstances as it, in its sole discretion, deems appropriate. Unless otherwise resolved by the Committee and stated in the Award Agreement, and subject to Sections 6.6 and 6.7 hereof, Awards shall vest and become exercisable under the following schedule: twenty-five percent (25%) of the Shares covered by the Award, on the first anniversary of the vesting commencement date determine by the Committee (and in the absence of such determination, of date on which such Award was granted), and six and one-quarter percent (6.25%) of the Shares covered by the Award at the end of each subsequent three-month period thereafter over the course of the following three (3) years; provided that the Grantee remains continuously as a Service Provider of the Company or its Affiliates throughout such vesting dates.

6.5.2 The Award Agreement may contain performance goals and measurements (which, in case of 102 Awards, shall, if then required, be subject to obtaining a specific tax ruling or determination from the ITA), and the provisions with respect to any Award need not be the same as the provisions with respect to any other Award. Such performance goals may include, but are not limited to, sales, earnings before interest and taxes, return on investment, earnings per share, any combination of the foregoing or rate of growth of any of the foregoing, as determined by the Committee. The Committee may adjust performance goals pursuant to Awards previously granted to take into account changes in law and accounting and tax rules and to make such adjustments as the Committee deems necessary or appropriate to reflect the inclusion or the exclusion of the impact of extraordinary or unusual items, events or circumstances.

6.5.3 The Exercise Period of an Award will be 10 years from the date of grant of the Award, unless otherwise determined by the Committee, but subject to the vesting provisions described above and the early termination provisions set forth in Sections 6.6 and 6.7 hereof. At the expiration of the Exercise Period, any Award, or any part thereof, that has not been exercised within the term of the Award and the Shares covered thereby not paid for in accordance with this Plan and the Award Agreement shall terminate and become null and void, and all interests and rights of the Grantee in and to the same shall expire.

6.6 Termination.

6.6.1 Unless otherwise determined by the Committee, and subject to Section 6.7 hereof, an Award may not be exercised unless the Grantee is then a Service Provider of the Company or an Affiliate thereof or, in the case of an Incentive Stock Option, a company or a parent or subsidiary company of such company issuing or assuming the Option in a transaction to which Section 424(a) of the Code applies, and unless the Grantee has remained continuously so employed since the date of grant of the Award and throughout the vesting dates.

6.6.2 In the event that the employment or service of a Grantee shall terminate (other than by reason of death, Disability or Retirement), all Awards of such Grantee that are unvested at the time of such termination shall terminate on the date of such termination, and all Awards of such Grantee that are vested and exercisable at the time of such termination may be exercised within up to three (3) months after the date of such termination (or such different period as the Committee shall prescribe), but in any event no later than the date of expiration of the Award's term as set forth in the Award Agreement or pursuant to this Plan; provided, however, that if the Company (or the Subsidiary or Affiliate, when applicable) shall terminate the Grantee's employment or service for Cause (as defined below) or if at any time during the Exercise Period (whether prior to and after termination of employment or service, and whether or not the Grantee's employment or service is terminated by either party as a result thereof), facts or circumstances arise or are discovered with respect to the Grantee that would have constituted Cause, all Awards theretofore granted to such Grantee (whether vested or not) shall, to the extent not theretofore exercised, terminate on the date of such termination (or on such subsequent date on which such facts or circumstances arise or are discovered, as the case may be) unless otherwise determined by the Committee.

6.6.3 Notwithstanding anything to the contrary, the Committee, in its absolute discretion, may, on such terms and conditions as it may determine appropriate, extend the periods for which Awards held by any Grantee may continue to vest and be exercisable; it being clarified that such Awards may lose their entitlement to certain tax benefits under Applicable Law as a result of the modification of such Awards and/or in the event that the Award is exercised beyond the later of: (i) three (3) months after the date of termination of the employment or service relationship; or (ii) the applicable period under Section 6.7 below with respect to a termination of the employment or service relationship because of the death, Disability or Retirement of Grantee.

6.6.4 For purposes of this Plan:

6.6.4.1 a termination of employment or service of a Grantee shall not be deemed to occur in case of (i) a transition or transfer of a Grantee among the Company and its Affiliates, (ii) a change in the capacity in which the Grantee is employed or renders service to the Company or any of its Affiliates or a change in the identity of the employing or engagement entity among the Company and its Affiliates, provided, in case of (i) and (ii) above, that the Grantee has remained continuously employed by and/or in the service of the Company and its Affiliates since the date of grant of the Award and throughout the vesting period; (iii) if the Grantee takes any unpaid leave as set forth in Section 6.8(i) below.

6.6.4.2 An entity or an Affiliate thereof assuming an Award or issuing in substitution thereof in a transaction to which Section 424(a) of the Code applies or in a Merger/Sale in accordance with Section 14 shall be deemed as an Affiliate of the Company for purposes of this Section 6.6, unless the Committee determines otherwise.

6.6.4.3 In the case of a Grantee whose principal employer or service recipient is a Subsidiary or Affiliate, the Grantee's employment shall also be deemed terminated for purposes of this Section 6.6 as of the date on which such principal employer or service recipient ceases to be a Subsidiary or Affiliate.

6.6.4.4 The term "Cause" shall mean (irrespective of, and in addition to, any definition included in any other agreement or instrument applicable to the Grantee, and unless otherwise determined by the Committee) any of the following: (i) any theft, fraud, embezzlement, dishonesty, willful misconduct, breach of fiduciary duty for personal profit, falsification of any documents or records of the Company or any of its Affiliates, felony or similar act by the Grantee (whether or not related to the Grantee's relationship with the Company); (ii) an act of moral turpitude by the Grantee, or any act that causes significant injury to, or is otherwise adversely affecting, the reputation, business, assets, operations or business relationship of the Company (or a Subsidiary or Affiliate, when applicable); (iii) any breach by the Grantee of any material agreement with or of any material duty of the Grantee to the Company or any Subsidiary or Affiliate thereof (including breach of confidentiality, non-disclosure, non-use non-competition or non-solicitation covenants towards the Company or any of its Affiliates) or failure to abide by code of conduct or other policies (including, without limitation, policies relating to confidentiality and reasonable workplace conduct); or (iv) any act which constitutes a breach of a Grantee's fiduciary duty towards the Company or an Affiliate or Subsidiary, including disclosure of confidential or proprietary information thereof or acceptance or solicitation to receive unauthorized or undisclosed benefits, irrespective of their nature, or funds, or promises to receive either, from individuals, consultants or corporate entities that the Company or a Subsidiary does business with; (v) the Grantee's unauthorized use, misappropriation, destruction, or diversion of any tangible or intangible asset or corporate opportunity of a Company or any of its Affiliates (including, without limitation, the improper use or disclosure of confidential or proprietary information); or (vi) any circumstances that constitute grounds for termination for cause under the Grantee's employment or service agreement with the Company or Affiliate, to the extent applicable. For the avoidance of doubt, the determination as to whether a termination is for Cause for purposes of this Plan, shall be made in good faith by the Committee and shall be final and binding on the Grantee.

6.7 Death, Disability or Retirement of Grantee.

6.7.1 If a Grantee shall die while employed by, or performing service for, the Company or its Affiliates, or within the three (3) month period (or such longer period of time as determined by the Board, in its discretion) after the date of termination of such Grantee's employment or service (or within such different period as the Committee may have provided pursuant to Section 6.6 hereof), or if the Grantee's employment or service shall terminate by reason of Disability, all Awards theretofore granted to such Grantee may (to the extent otherwise vested and exercisable and unless earlier terminated in accordance with their terms) be exercised by the Grantee or by the Grantee's estate or by a person who acquired the legal right to exercise such Awards by bequest or inheritance, or by a person who acquired the legal right to exercise such Awards in accordance with Applicable Law in the case of Disability of the Grantee, as the case may be, at any time within one (1) year (or such longer period of time as determined by the Board, in its discretion) after the death or Disability of the Grantee (or such different period as the Committee shall prescribe), but in any event no later than the date of expiration of the Award's term as set forth in the Award Agreement or pursuant to this Plan. In the event that an Award granted hereunder shall be exercised as set forth above by any person other than the Grantee, written notice of such exercise shall be accompanied by a certified copy of letters testamentary or proof satisfactory to the Committee of the right of such person to exercise such Award.

6.7.2 In the event that the employment or service of a Grantee shall terminate on account of such Grantee's Retirement, all Awards of such Grantee that are exercisable at the time of such Retirement may, unless earlier terminated in accordance with their terms, be exercised at any time within the three (3) month period after the date of such Retirement (or such different period as the Committee shall prescribe).

6.8 Suspension of Vesting. Unless the Committee provides otherwise, vesting of Awards granted hereunder shall be suspended during any unpaid leave of absence, other than in the case of any (i) leave of absence which was pre-approved by the Company explicitly for purposes of continuing the vesting of Awards, or (ii) transfers between locations of the Company or any of its Affiliates, or between the Company and any of its Affiliates, or any respective successor thereof. For clarify, for purposes of this Plan, military leave, statutory maternity or paternity leave or sick leave are not deemed unpaid leave of absence.

6.9 Securities Law Restrictions. Except as otherwise provided in the applicable Award Agreement or other agreement between the Service Provider and the Company, if the exercise of an Award following the termination of the Service Provider's employment or service (other than for Cause) would be prohibited at any time solely because the issuance of Shares would violate the registration requirements under the Securities Act or equivalent requirements under equivalent laws of other applicable jurisdictions, then the Award shall remain exercisable and terminate on the earlier of (i) the expiration of a period of three (3) months (or such longer period of time as determined by the Board, in its discretion) after the termination of the Service Provider's employment or service during which the exercise of the Award would not be in such violation, or (ii) the expiration of the term of the Award as set forth in the Award Agreement or pursuant to this Plan. In addition, unless otherwise provided in a Grantee's Award Agreement, if the sale of any Shares received upon exercise or (if applicable) vesting of an Award following the termination of the Grantee's employment or service (other than for Cause) would violate the Company's insider trading policy, then the Award shall terminate on the earlier of (i) the expiration of a period equal to the applicable post-termination exercise period after the termination of the Grantee's employment or service during which the exercise of the Award would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Award as set forth in the applicable Award Agreement or pursuant to this Plan.

6.10 Voting Proxy. Until immediately after the listing for trading on a stock exchange or market or trading system of the Company's (or the Successor Corporation's) shares, the Shares subject to an Award or to be issued pursuant to an Award or any other Securities, shall, unless otherwise determined by the Committee, be subject to an irrevocable proxy and power of attorney by the Grantee or the Trustee (if so requested from the Trustee), as the case may be, to the Company, which shall designate such person or persons (with a right of substitution) from time to time as determined by the Committee (and in the absence of such determination, the CEO or Chairman of the Board, ex officio). The Trustee is deemed to be instructed by the Grantee to sign such proxy, as requested by the Company. The proxy shall entitle the holder thereof to receive notices, vote and take such other actions in respect of the Shares or other Securities. Any person holding or exercising such voting proxies shall do so solely in his capacity as the proxy holder and not individually. All Awards granted hereunder shall be conditioned upon the execution of such irrevocable proxy in substantially the form prescribed by the Committee from time to time. So long as any such Shares are subject to such irrevocable proxy and power of attorney or held by a Trustee (and unless a proxy was given by the Trustee as aforesaid), (i) in any shareholders meeting or written consent in lieu thereof, such Shares shall be voted by the proxy holder, unless directed otherwise by the Board, in the same proportion as the result of the vote at the shareholders' meeting (or written consent in lieu thereof) in respect of which the Shares are being voted (whether an extraordinary or annual meeting), and (ii) or in any act or consent of shareholders under the Company's Articles of Association or otherwise, such Shares shall be cast by the proxy holder, unless directed otherwise by the Board, in the same proportion as the result of the shareholders' act or consent. The provisions of this Section shall apply to the Grantee and to any purchaser, assignee or transferee of any Shares.

6.11 Other Provisions. The Award Agreement evidencing Awards under this Plan shall contain such other terms and conditions not inconsistent with this Plan as the Committee may determine, at or after the date of grant, including provisions in connection with the restrictions on transferring the Awards or Shares covered by such Awards, which shall be binding upon the Grantees and any purchaser, assignee or transferee of any Awards, and other terms and conditions as the Committee shall deem appropriate.

7. NONQUALIFIED STOCK OPTIONS.

Awards granted pursuant to this Section 7 are intended to constitute Nonqualified Stock Options and shall be subject to the general terms and conditions specified in Section 6 hereof and other provisions of this Plan, except for any provisions of this Plan applying to Awards under different tax laws or regulations. In the event of any inconsistency or contradictions between the provisions of this Section 7 and the other terms of this Plan, this Section 7 shall prevail.

7.1 Eligibility for Awards. Nonqualified Stock Options may not be granted to Service Providers who is deemed to be a resident of the United States for purposes of taxation and who are providing services only to a "parent" of the Company, as such term is defined in Rule 405 of Regulation C under the Securities Act, unless the Shares underlying such Awards are treated as "service recipient stock" under Section 409A of the Code because the Awards are granted pursuant to a corporate transaction (such as a spin off transaction) or unless such Awards comply with the distribution requirements of Section 409A of the Code.

7.2 Exercise Price. The Exercise Price of a Nonqualified Stock Option shall not be less than 100% of the Fair Market Value of the Shares on the date of grant unless the Committee specifically indicates that the Awards will have a lower Exercise Price and the Award complies with Section 409A of the Code. Notwithstanding the foregoing, Nonqualified Stock Option may be granted with an exercise price lower than the minimum exercise price set forth above if such Award is granted pursuant to an assumption or substitution for another option in a manner qualifying under the provisions of Section 424(a) of the Code.

8. INCENTIVE STOCK OPTIONS.

Awards granted pursuant to this Section 8 are intended to constitute Incentive Stock Options and shall be granted subject to the following special terms and conditions, the general terms and conditions specified in Section 6 hereof and other provisions of this Plan, except for any provisions of this Plan applying to Awards under different tax laws or regulations. In the event of any inconsistency or contradictions between the provisions of this Section 8 and the other terms of this Plan, this Section 8 shall prevail.

8.1 Eligibility for Awards. Incentive Stock Options may be granted only to Employees of the Company, or to Employees of a Parent or Subsidiary corporation thereof (as such terms are defined in Sections 424(e) and 424(f) of the Code). Any person who is not an Employee on the effective date of the grant of an Award to such person may be granted only a Nonqualifed Stock Option. An Incentive Stock Option granted to a prospective Employee upon the condition that such person become an Employee shall be deemed granted effective on the date such person commences employment, with an exercise price determined as of such date in accordance with Section 8.2.

8.2 Exercise Price. The Exercise Price of Incentive Stock Option shall not be less than one hundred percent (100%) of the Fair Market Value of the Shares covered by the Awards on the date of grant or such other price as may be determined pursuant to the Code. No Incentive Stock Option granted to any Ten-Percent Shareholder shall have an Exercise Price less than 110% of the Fair Market Value of a Share covered by the Awards on the effective date of grant. Notwithstanding the foregoing, Incentive Stock Option may be granted with an exercise price lower than the minimum exercise price set forth above if such Award is granted pursuant to an assumption or substitution for another option in a manner qualifying under the provisions of Section 424(a) of the Code.

8.3 Date of Grant. Incentive Stock Option shall be granted within 10 years from the date this Plan is adopted, or the date this Plan is approved by the shareholders, whichever is earlier.

8.4 Exercise Period. No Incentive Stock Option shall be exercisable after the expiration of ten (10) years after the effective date of grant of such Award, subject to Section 8.6. No Incentive Stock Option granted to a prospective Employee may become exercisable prior to the date on which such person commences employment.

8.5 Value of Shares. The aggregate Fair Market Value (determined as of the date the Incentive Stock Option is granted) of the Shares with respect to which all Incentive Stock Options granted under this Plan and all other option plans of any Parent or Subsidiary or Affiliate become exercisable for the first time by each Grantee during any calendar year shall not exceed one hundred thousand United States dollars ($100,000) with respect to such Grantee. To the extent that the aggregate Fair Market Value of Shares with respect to which the Incentive Stock Options are exercisable for the first time by any Grantee during any calendar years as mentioned above exceeds one hundred thousand United States dollars ($100,000), such Awards shall be treated as Nonqualified Stock Options. The foregoing shall be applied by taking Awards into account in the order in which they were granted, and the Fair Market Value of any Share to be determined at the time of the grant of the Awards. If the Code is amended to provide for a different limitation from that set forth in this Section 8.5, such different limitation shall be deemed incorporated herein effective as of the date and with respect to such Awards as required or permitted by such amendment to the Code. If an Award is treated as an Incentive Stock Option in part and as a Nonqualifed Stock Option in part by reason of the limitation set forth in this Section 8.5, the Grantee may designate which portion of such Award the Grantee is exercising. In the absence of such designation, the Grantee shall be deemed to have exercised the Incentive Stock Option portion of the Award first. Separate certificates representing each such portion may be issued upon the exercise of the Award.

8.6 Ten Percent Shareholder. In the case of an Incentive Stock Option granted to a Ten Percent Shareholder, (i) the Exercise Price shall not be less than one hundred and ten percent (110%) of the Fair Market Value of the Shares on the date of grant of such Incentive Stock Option, and (ii) the Exercise Period shall not exceed five (5) years from the effective date of grant of such Incentive Stock Option.

8.7 Incentive Stock Option Lock-Up Period. No disposition of Shares received pursuant to the exercise of Incentive Stock Options, shall be made by the Grantee within 2 years from the date of grant, nor within 1 year after the transfer of such Shares to him. To the extent that the Grantee violates the aforementioned limitations, the Incentive Stock Options shall be deemed to be Nonqualified Stock Options.

8.8 Approval. To the extent required by Applicable Law, the status of any Shares issued upon exercise of Incentive Stock Options shall be subject to approval of this Plan and any amendment thereto by the Company's shareholders, such approval to be provided 12 months before or after the date of adoption of this Plan or its amendment (if applicable), as the case may be, by the Board.

8.9 Leave of Absence. Notwithstanding Section 6.8, a Grantee's employment shall not be deemed to have terminated if the Grantee takes any leave as set forth in Section 6.8(i); provided, however, that if any such leave exceeds ninety (90) days, on the one hundred eighty-first (181st) day following the commencement of such leave any Incentive Stock Option held by the Grantee shall cease to be treated as an Incentive Stock Option and instead shall be treated thereafter as a Nonqualifed Stock Option, unless the Grantee's right to return to employment is guaranteed by statute or contract.

8.10 Exercise Following Termination for Disability. Notwithstanding anything else in this Plan to the contrary, Incentive Stock Options that are not exercised within three (3) months following termination of Grantee's employment with the Company or its Parent or Subsidiary or a corporation or a Parent or Subsidiary of such corporation issuing or assuming a Award in a transaction to which Section 424(a) of the Code applies, or within one year in case of termination of Grantee's employment with the Company or its Parent or Subsidiary due to a disability (within the meaning of Section 22(e)(3) of the Code), shall be deemed to be Nonqualified Stock Options.

8.11 Adjustments to Incentive Stock Options. Any Awards Agreement providing for the grant of Incentive Stock Options shall indicate that adjustments made pursuant to this Plan with respect to Incentive Stock Options could constitute a "modification" of such Incentive Stock Options (as that term is defined in Section 424(h) of the Code) or could cause adverse tax consequences for the holder of such Incentive Stock Options and that the holder should consult with his or her tax advisor regarding the consequences of such "modification" on his or her income tax treatment with respect to the Incentive Stock Option.

8.12 Notice to Company of Disqualifying Disposition. Each Grantee who receives an Incentive Stock Option must agree to notify the Company in writing immediately after the Grantee makes a Disqualifying Disposition of any Shares received pursuant to the exercise of Incentive Stock Options. A "Disqualifying Disposition" is any disposition (including any sale) of such Shares before the later of (i) two years after the date the Grantee was granted the Incentive Stock Option, or (ii) one year after the date the Grantee acquired Shares by exercising the Incentive Stock Option. If the Grantee dies before such Shares are sold, these holding period requirements do not apply and no disposition of the Shares will be deemed a Disqualifying Disposition.

9. 102 AWARDS.

Awards granted pursuant to this Section 9 are intended to constitute 102 Awards and shall be granted subject to the following special terms and conditions, the general terms and conditions specified in Section 6 hereof and other provisions of this Plan, except for any provisions of this Plan applying to Awards under different tax laws or regulations. In the event of any inconsistency or contradictions between the provisions of this Section 9 and the other terms of this Plan, this Section 9 shall prevail.

9.1 Tracks. Awards granted pursuant to this Section 9 are intended to be granted pursuant to Section 102 of the Ordinance pursuant to either (i) Section 102(b)(2) thereof, under the capital gain track ("102 Capital Gain Track Awards"), or (ii) Section 102(b)(1) thereof under the ordinary income track ("102 Ordinary Income Track Awards", and together with 102 Capital Gain Track Awards, "102 Trustee Awards"). 102 Trustee Awards shall be granted subject to the special terms and conditions contained in this Section 9, the general terms and conditions specified in Section 6 hereof and other provisions of this Plan, except for any provisions of this Plan applying to Options under different tax laws or regulations.

9.2 Election of Track. Subject to Applicable Law, the Company may grant only one type of 102 Trustee Awards at any given time to all Grantees who are to be granted 102 Trustee Awards pursuant to this Plan, and shall file an election with the ITA regarding the type of 102 Trustee Awards it elects to grant before the date of grant of any 102 Trustee Awards (the "Election"). Such Election shall also apply to any other securities, including bonus shares, received by any Grantee as a result of holding the 102 Trustee Awards. The Company may change the type of 102 Trustee Awards that it elects to grant only after the expiration of at least 12 months from the end of the year in which the first grant was made in accordance with the previous Election, or as otherwise provided by Applicable Law. Any Election shall not prevent the Company from granting Awards, pursuant to Section 102(c) of the Ordinance without a Trustee ("102 Non-Trustee Awards").

9.3 Eligibility for Awards.

Subject to Applicable Law, 102 Awards may only be granted to an "employee" within the meaning of Section 102(a) of the Ordinance (which as of the date of the adoption of this Plan means (i) individuals employed by an Israeli company being the Company or any of its Affiliates, and (ii) individuals who are serving and are engaged personally (and not through an entity) as "office holders" by such an Israeli company), but may not be granted to a Controlling Shareholder ("Eligible 102 Grantees"). Eligible 102 Grantees may receive only 102 Awards, which may either be granted to a Trustee or granted under Section 102 of the Ordinance without a Trustee.

9.4 102 Award Grant Date.

9.4.1 Each 102 Award will be deemed granted on the date determined by the Committee, subject to Section 9.4.2, provided that (i) the Grantee has signed all documents required by the Company or pursuant to Applicable Law, and (ii) with respect to 102 Trustee Award, the Company has provided all applicable documents to the Trustee in accordance with the guidelines published by the ITA.

9.4.2 Unless otherwise permitted by the Ordinance, any grants of 102 Trustee Awards that are made on or after the date of the adoption of this Plan or an amendment to this Plan, as the case may be, that may become effective only at the expiration of thirty (30) days after the filing of this Plan or any amendment thereof (as the case may be) with the ITA in accordance with the Ordinance shall be conditional upon the expiration of such 30-day period, such condition shall be read and is incorporated by reference into any corporate resolutions approving such grants and into any Award Agreement evidencing such grants (whether or not explicitly referring to such condition), and the date of grant shall be at the expiration of such 30-day period, whether or not the date of grant indicated therein corresponds with this Section. In the case of any contradiction, this provision and the date of grant determined pursuant hereto shall supersede and be deemed to amend any date of grant indicating in any corporate resolution or Award Agreement.

9.5 102 Trustee Awards.

9.5.1 Each 102 Trustee Award, each Share issued pursuant to the exercise of any 102 Trustee Award, and any rights granted thereunder, including bonus shares, shall be issued to and registered in the name of the Trustee and shall be held in trust for the benefit of the Grantee for the requisite period prescribed by the Ordinance or such longer period as set by the Committee (the "Required Holding Period"). In the event that the requirements under Section 102 of the Ordinance to qualify an Award as a 102 Trustee Award are not met, then the Award may be treated as a 102 Non-Trustee Award or 3(9) Award, all in accordance with the provisions of the Ordinance. After termination of the Required Holding Period, the Trustee may release such 102 Trustee Awards and any such Shares, provided that (i) the Trustee has received an acknowledgment from the ITA that the Grantee has paid any applicable taxes due pursuant to the Ordinance, or (ii) the Trustee and/or the Company and/or its Affiliate withholds all applicable taxes and compulsory payments due pursuant to the Ordinance arising from the 102 Trustee Awards and/or any Shares issued upon exercise or (if applicable) vesting of such 102 Trustee Awards. The Trustee shall not release any 102 Trustee Awards or Shares issued upon exercise or (if applicable) vesting thereof prior to the payment in full of the Grantee's tax and compulsory payments arising from such 102 Trustee Awards and/or Shares or the withholding referred to in (ii) above.

9.5.2 Each 102 Trustee Award shall be subject to the relevant terms of the Ordinance, the Rules and any determinations, rulings or approvals issued by the ITA, which shall be deemed an integral part of the 102 Trustee Awards and shall prevail over any term contained in this Plan or Award Agreement that is not consistent therewith. Any provision of the Ordinance, the Rules and any determinations, rulings or approvals by the ITA not expressly specified in this Plan or Award Agreement that are necessary to receive or maintain any tax benefit pursuant to Section 102 of the Ordinance shall be binding on the Grantee. The Grantee granted a 102 Trustee Awards shall comply with the Ordinance and the terms and conditions of the Trust Agreement entered into between the Company and the Trustee. The Grantee shall execute any and all documents that the Company and/or its Affiliates and/or the Trustee determine from time to time to be necessary in order to comply with the Ordinance and the Rules.

9.5.3 During the Required Holding Period, the Grantee shall not release from trust or sell, assign, transfer or give as collateral, the Shares issuable upon the exercise or (if applicable) vesting of a 102 Trustee Awards and/or any securities issued or distributed with respect thereto, until the expiration of the Required Holding Period. Notwithstanding the above, if any such sale, release or other action occurs during the Required Holding Period it may result in adverse tax consequences to the Grantee under Section 102 of the Ordinance and the Rules, which shall apply to and shall be borne solely by such Grantee. Subject to the foregoing, the Trustee may, pursuant to a written request from the Grantee, but subject to the terms of this Plan, release and transfer such Shares to a designated third party, provided that both of the following conditions have been fulfilled prior to such release or transfer: (i) payment has been made to the ITA of all taxes and compulsory payments required to be paid upon the release and transfer of the Shares, and confirmation of such payment has been received by the Trustee and the Company, and (ii) the Trustee has received written confirmation from the Company that all requirements for such release and transfer have been fulfilled according to the terms of the Company's corporate documents, any agreement governing the Shares, this Plan, the Award Agreement and any Applicable Law.

9.5.4 If a 102 Trustee Award is exercised or (if applicable) vested, the Shares issued upon such exercise or (if applicable) vesting shall be issued in the name of the Trustee for the benefit of the Grantee.

9.5.5 Upon or after receipt of a 102 Trustee Award, if required, the Grantee may be required to sign an undertaking to release the Trustee from any liability with respect to any action or decision duly taken and executed in good faith by the Trustee in relation to this Plan, or any 102 Trustee Awards or Share granted to such Grantee thereunder.

9.6 102 Non-Trustee Awards. The foregoing provisions of this Section 9 relating to 102 Trustee Awards shall not apply with respect to 102 Non-Trustee Awards, which shall, however, be subject to the relevant provisions of Section 102 of the Ordinance and the applicable Rules. The Committee may determine that 102 Non-Trustee Awards, the Shares issuable upon the exercise or (if applicable) vesting of a 102 Non-Trustee Awards and/or any securities issued or distributed with respect thereto, shall be allocated or issued to the Trustee, who shall hold such 102 Non-Trustee Awards and all accrued rights thereon (if any), in trust for the benefit of the Grantee and/or the Company, as the case may be, until the full payment of tax arising from the 102 Non-Trustee Awards, the Shares issuable upon the exercise or (if applicable) vesting of a 102 Non-Trustee Awards and/or any securities issued or distributed with respect thereto. The Company may choose, alternatively, to force the Grantee to provide it with a guarantee or other security, to the satisfaction of each of the Trustee and the Company, until the full payment of the applicable taxes.

9.7 Israeli Index Base for 102 Awards. Each 102 Award will be subject to the Israeli index base of the Value of Benefit, as defined in Section 102(a) of the Ordinance, as determined by the Committee in its discretion, pursuant to the Rules, from time to time. The Committee may amend (which may have a retroactive effect) the Israeli index base, pursuant to the Ordinance, without the Grantee's consent.

9.8 Written Grantee Undertaking. To the extent and with respect to any 102 Trustee Award, and as required by Section 102 of the Ordinance and the Rules, by virtue of the receipt of such Award, the Grantee is deemed to have undertaken and confirm in writing the following (and such undertaking is deemed incorporated into any documents signed by the Grantee in connection with the employment or service of the Grantee and/or the grant of such Award). The following written undertaking shall be deemed to apply and relate to all Awards granted to the Grantee, whether under this Plan or other plans maintained by the Company, and whether prior to or after the date hereof.

9.8.1 The Grantee shall comply with all terms and conditions set forth in Section 102 of the Ordinance with regard to the "Capital Gain Track" or the "Ordinary Income Track", as applicable, and the applicable rules and regulations promulgated thereunder, as amended from time to time;

9.8.2 The Grantee is familiar with, and understand the provisions of, Section 102 of the Ordinance in general, and the tax arrangement under the "Capital Gain Track" or the "Ordinary Income Track" in particular, and its tax consequences; the Grantee agrees that the Awards and Shares that may be issued upon exercise or (if applicable) vesting of the Awards (or otherwise in relation to the Awards), will be held by a trustee appointed pursuant to Section 102 of the Ordinance for at least the duration of the "Holding Period" (as such term is defined in Section 102) under the "Capital Gain Track" or the "Ordinary Income Track", as applicable. The Grantee understands that any release of such Awards or Shares from trust, or any sale of the Share prior to the termination of the Holding Period, as defined above, will result in taxation at marginal tax rate, in addition to deductions of appropriate social security, health tax contributions or other compulsory payments; and

9.8.3 The Grantee agrees to the trust deed signed between the Company, his employing company and the trustee appointed pursuant to Section 102 of the Ordinance.

10. 3(9) AWARDS.

Awards granted pursuant to this Section 10 are intended to constitute 3(9) Awards and shall be granted subject to the general terms and conditions specified in Section 6 hereof and other provisions of this Plan, except for any provisions of this Plan applying to Awards under different tax laws or regulations. In the event of any inconsistency or contradictions between the provisions of this Section 10 and the other terms of this Plan, this Section 10 shall prevail.

10.1 To the extent required by the Ordinance or the ITA or otherwise deemed by the Committee to be advisable, the 3(9) Awards and/or any shares or other securities issued or distributed with respect thereto granted pursuant to this Plan shall be issued to a Trustee nominated by the Committee in accordance with the provisions of the Ordinance. In such event, the Trustee shall hold such Awards and/or any shares or other securities issued or distributed with respect thereto in trust, until exercised or (if applicable) vested by the Grantee and the full payment of tax arising therefrom, pursuant to the Company's instructions from time to time as set forth in a trust agreement, which will have been entered into between the Company and the Trustee. If determined by the Board or the Committee, and subject to such trust agreement, the Trustee shall be responsible for withholding any taxes to which a Grantee may become liable upon issuance of Shares, whether due to the exercise or (if applicable) vesting of Awards.

10.2 Shares pursuant to a 3(9) Award shall not be issued, unless the Grantee delivers to the Company payment in cash or by bank check or such other form acceptable to the Committee of all withholding taxes due, if any, on account of the Grantee acquired Shares under the Award or gives other assurance satisfactory to the Committee of the payment of those withholding taxes.

11. RESTRICTED SHARES.

The Committee may award Restricted Shares to any eligible Grantee, including under Section 102 of the Ordinance. Each Award of Restricted Shares under this Plan shall be evidenced by a written agreement between the Company and the Grantee (the "Restricted Share Agreement"), in such form as the Committee shall from time to time approve. The Restricted Shares shall be subject to all applicable terms of this Plan, which in the case of Restricted Shares granted under Section 102 of the Ordinance shall include Section 9 hereof, and may be subject to any other terms that are not inconsistent with this Plan. The provisions of the various Restricted Shares Agreements entered into under this Plan need not be identical. The Restricted Share Agreement shall comply with and be subject to Section 6 and the following terms and conditions, unless otherwise specifically provided in such Agreement and not inconsistent with this Plan, or Applicable Law:

11.1 Purchase Price. Section 6.4 shall not apply. Each Restricted Share Agreement shall state an amount of Exercise Price to be paid by the Grantee, if any, in consideration for the issuance of the Restricted Shares and the terms of payment thereof, which may include, payment in cash or by issuance of promissory notes or other evidence of indebtedness on such terms and conditions as determined by the Committee.

11.2 Restrictions. Restricted Shares may not be sold, assigned, transferred, pledged, hypothecated or otherwise disposed of, except by will or the laws of descent and distribution (in which case they shall be transferred subject to all restrictions then or thereafter applicable thereto), until such Restricted Shares shall have vested (the period from the date on which the Award is granted until the date of vesting of the Restricted Share thereunder being referred to herein as the "Restricted Period"). The Committee may also impose such additional or alternative restrictions and conditions on the Restricted Shares, as it deems appropriate, including the satisfaction of performance criteria. Such performance criteria may include, but are not limited to, sales, earnings before interest and taxes, return on investment, earnings per share, any combination of the foregoing or rate of growth of any of the foregoing, as determined by the Committee or pursuant to the provisions of any Company policy required under mandatory provisions of Applicable Law. Certificates for shares issued pursuant to Restricted Share Awards shall bear an appropriate legend referring to such restrictions, and any attempt to dispose of any such shares in contravention of such restrictions shall be null and void and without effect. Such certificates may, if so determined by the Committee, be held in escrow by an escrow agent appointed by the Committee, or, if a Restricted Share Award is made pursuant to Section 102 of the Ordinance, by the Trustee. In determining the Restricted Period of an Award the Committee may provide that the foregoing restrictions shall lapse with respect to specified percentages of the awarded Restricted Shares on successive anniversaries of the date of such Award. To the extent required by the Ordinance or the ITA, the Restricted Shares issued pursuant to Section 102 of the Ordinance shall be issued to the Trustee in accordance with the provisions of the Ordinance and the Restricted Shares shall be held for the benefit of the Grantee for such period as may be required by the Ordinance.

11.3 Forfeiture; Repurchase. Subject to such exceptions as may be determined by the Committee, if the Grantee's continuous employment with or service to the Company or any Affiliate thereof shall terminate for any reason prior to the expiration of the Restricted Period of an Award or prior to the timely payment in full of the Exercise Price of any Restricted Shares, any Shares remaining subject to vesting or with respect to which the purchase price has not been paid in full, shall thereupon be forfeited, transferred to, and redeemed, repurchased or cancelled by, as the case may be, in any manner as set forth in Section 6.6.2(i) thought (v), subject to Applicable Laws and the Grantee shall have no further rights with respect to such Restricted Shares.

11.4 Ownership. During the Restricted Period the Grantee shall possess all incidents of ownership of such Restricted Shares, subject to Section 6.10 and Section 11.2, including the right to vote and receive dividends with respect to such Shares. All securities, if any, received by a Grantee with respect to Restricted Shares as a result of any stock split, stock dividend, combination of shares, or other similar transaction shall be subject to the restrictions applicable to the original Award.

12. RESTRICTED SHARE UNITS.

An RSU is an Award covering a number of Shares that is settled, if vested and (if applicable) exercised, by issuance of those Shares. An RSU may be awarded to any eligible Grantee, including under Section 102 of the Ordinance, provided that, to the extent required by Applicable Laws, a specific ruling is obtained from the ITA to grant RSUs as 102 Trustee Awards. The Award Agreement relating to the grant of RSUs under this Plan (the "Restricted Share Unit Agreement"), shall be in such form as the Committee shall from time to time approve. The RSUs shall be subject to all applicable terms of this Plan, which in the case of RSUs granted under Section 102 of the Ordinance shall include Section 9 hereof, and may be subject to any other terms that are not inconsistent with this Plan. The provisions of the various Restricted Share Unit Agreements entered into under this Plan need not be identical. RSUs may be granted in consideration of a reduction in the recipient's other compensation.

12.1 Exercise Price. No payment of Exercise Price shall be required as consideration for RSUs, unless included in the Award Agreement or as required by Applicable Law (including, Section 304 of the Companies Law, 1999, as amended), and Section 6.4 shall apply, if applicable.

12.2 Shareholders' Rights. The Grantee shall not possess or own any ownership rights in the Shares underlying the RSUs and no rights as a shareholder shall exist prior to the actual issuance of Shares in the name of the Grantee.

12.3 Settlements of Awards. Settlement of vested RSUs shall be made in the form of Shares. Distribution to a Grantee of an amount (or amounts) from settlement of vested RSUs can be deferred to a date after settlement as determined by the Committee. The amount of a deferred distribution may be increased by an interest factor or by dividend equivalents. Until the grant of RSUs is settled, the number of Shares underlying such RSUs shall be subject to adjustment pursuant hereto.

12.4 Section 409A Restrictions. Notwithstanding anything to the contrary set forth herein, any RSUs granted under this Plan that are not exempt from the requirements of Section 409A of the Code shall contain such restrictions or other provisions so that such RSUs will comply with the requirements of Section 409A of the Code, if applicable to the Company. Such restrictions, if any, shall be determined by the Committee and contained in the Restricted Share Unit Agreement evidencing such RSU. For example, such restrictions may include a requirement that any Shares that are to be issued in a year following the year in which the RSU vests must be issued in accordance with a fixed, pre-determined schedule.

13. OTHER SHARE OR SHARE-BASED AWARDS.

13.1 The Committee may grant other Awards under this Plan pursuant to which Shares (which may, but need not, be Restricted Shares pursuant to Section 11 hereof), cash (in settlement of Share-based Awards) or a combination thereof, are or may in the future be acquired or received, or Awards denominated in stock units, including units valued on the basis of measures other than market value.

13.2 The Committee may also grant stock appreciation rights without the grant of an accompanying option, which rights shall permit the Grantees to receive, at the time of any exercise of such rights, cash equal to the amount by which the Fair Market Value of all Shares in respect to which the right was granted exceed the exercise price thereof.

13.3 Such other Share-based Awards as set forth above may be granted alone, in addition to, or in tandem with any Award of any type granted under this Plan.

14. EFFECT OF CERTAIN CHANGES.

14.1 General. In the event of a divisions or subdivision of the outstanding share capital of the Company, any distribution of bonus shares (stock split), consolidation or combination of share capital of the Company (reverse stock split), reclassification with respect to the Shares or any similar recapitalization events (each, a "Recapitalization"), reorganization (which may include a combination or exchange of shares, spin-off or other corporate divestiture or division, or other similar occurrences) then (i) the number of Shares reserved and available for grants of Awards and (ii) the number of Shares covered by outstanding Awards, , will be proportionately adjusted. Any fractional shares resulting from such adjustment shall be treated as determined by the Committee, and in the absence of such determination shall be rounded to the nearest whole share, and the Company shall have no obligation to make any cash or other payment with respect to such fractional shares. No adjustment shall be made by reason of the distribution of subscription rights or rights offering to outstanding shares or distribution of dividends to outstanding shareholders or other issuance of shares by the Company, unless the Committee determines otherwise. The adjustments determined pursuant to this Section 14.1 (including a determination that no adjustment is to be made) shall be final, binding and conclusive.

14.2 Merger/Sale of Company. In the event of (i) a sale of all or substantially all of the assets of the Company, or a sale (including an exchange) of all or substantially all of the shares of the Company, to any person, or a purchase by a shareholder of the Company or by an Affiliate of such shareholder, of all the shares of the Company held by all or substantially all other shareholders or by other shareholders who are not Affiliated with such acquiring party; (ii) a merger (including, a reverse merger and a reverse triangular merger), consolidation, amalgamation or like transaction of the Company with or into another corporation; (iii) a scheme of arrangement for the purpose of effecting such sale, merger, consolidation, amalgamation or other transaction; or (iv) such other transaction or set of circumstances that is determined by the Board, in its discretion, to be a transaction subject to the provisions of this Section 14.2; excluding any of the above transactions in clauses (i) through (iii) if the Committee determines that such transaction should be excluded from the definition hereof and the applicability of this Section 14.2 (such transaction, a "Merger/Sale"), then, without derogating from the Committee's general authority and power under this Plan, without the Grantee's consent and action and without any prior notice requirement:

14.2.1 Unless otherwise determined by the Committee in its sole and absolute discretion, any Award then outstanding shall be assumed or be substituted by the Company, or by the successor corporation in such Merger/Sale or by any parent or Affiliate thereof, as determined by the Committee in its discretion (the "Successor Corporation"), under terms as determined by the Committee or the terms of this Plan applied by the Successor Corporation to such assumed or substituted Awards;

For the purposes of this Section 14.2.1, the Award shall be considered assumed or substituted if, following a Merger/Sale, the Award confers on the holder thereof the right to purchase or receive, for each Share underlying an Award immediately prior to the Merger/Sale, either (i) the consideration (whether stock, cash, or other securities or property, or any combination thereof) distributed to or received by holders of Shares in the Merger/Sale for each Share held on the effective date of the Merger/Sale (and if holders were offered a choice or several types of consideration, the type of consideration as determined by the Committee), or (ii) regardless of the consideration received by the holders of Shares in the Merger/Sale, solely shares or any type of Awards (or their equivalent) of the Successor Corporation at a value to be determined by the Committee in its discretion, or a certain type of consideration (whether stock, cash, or other securities or property, or any combination thereof) as determined by the Committee. Any of the above consideration referred to clauses (i) and (ii) shall be subject to the same vesting and expiration terms of the Awards applying immediately prior to the Merger/Sale, unless the Committee determines in its discretion that the consideration shall be subject to different vesting and expiration terms, or other terms. The foregoing shall not limit the Committee's authority to determine, in its sole discretion, that in lieu of such assumption or substitution of Awards for Awards of the Successor Corporation, such Award will be substituted for any other type of asset or property, including as set forth in Section 14.2.2 hereunder.

14.2.2 Regardless of whether or not Awards are assumed or substituted, the Committee may (but shall not be obligated to), in its sole discretion:

14.2.2.1 provide for the Grantee to have the right to exercise the Award in respect of Shares covered by the Award which would otherwise be exercisable or vested, under such terms and conditions as the Committee shall determine, and the cancellation of all unexercised and unvested Awards upon or immediately prior to the closing of the Merger/Sale, unless the Committee provides for the Grantee to have the right to exercise the Award, or otherwise for the acceleration of vesting of such Award, as to all or part of the Shares covered by the Award which would not otherwise be exercisable or vested, under such terms and conditions as the Committee shall determine; and/or

14.2.2.2 provide for the cancellation of each outstanding Award at or immediately prior to the closing of such Merger/Sale, and payment to the Grantee of an amount in cash, shares of the Company, the acquiror or of a corporation or other business entity which is a party to the Merger/Sale or other property, as determined by the Committee to be fair in the circumstances, and subject to such terms and conditions as determined by the Committee. The Committee shall have full authority to select the method for determining the payment (being the Black-Scholes model or any other method). The Committee's determination may further provide that payment shall be set to zero if the value of the Shares is determined to be less than the Exercise Price or in respect of Shares covered by the Award which would not otherwise be exercisable or vested, or that payment may be made only in excess of the Exercise Price.

14.2.3 The Committee may determine that any payments made in respect of Awards shall be made or delayed to the same extent that payment of consideration to the holders of the Shares in connection with the Merger/Sale is made or delayed as a result of escrows, indemnification, earn outs, holdbacks or any other contingencies; and the terms and conditions applying to the payment made to the Grantees, including participation in escrow, indemnification, releases, earn-outs, holdbacks or any other contingencies.

14.2.4 Notwithstanding the foregoing, in the event of a Merger/Sale, the Committee may determine, in its sole discretion that upon completion of such Merger/Sale the terms of any Award be otherwise amended, modified or terminated, as the Committee shall deem in good faith to be appropriate and without any liability to the Company or its Affiliates and to their respective its officers, directors, employees and representatives and the respective successors and assigns of any of the foregoing in connection with the method of treatment or chosen course of action permitted hereunder.

14.2.5 Neither the authorities and powers of the Committee under this Section 14.2, nor the exercise or implementation thereof, shall (i) be restricted or limited in any way by any adverse consequences (tax or otherwise) that may result to any holder of an Award, and (ii) as, inter alia, being a feature of the Award upon its grant, be deemed to constitute a change or an amendment of the rights of such holder under this Plan, nor shall any such adverse consequences (as well as any adverse tax consequences that may result from any tax ruling or other approval or determination of any relevant tax authority) be deemed to constitute a change or an amendment of the rights of such holder under this Plan, and may be effected without consent of any Grantee and without any liability to the Company or its Affiliates and to their respective its officers, directors, employees and representatives and the respective successors and assigns of any of the foregoing. The Committee need not take the same action with respect to all Awards or with respect to all Service Providers. The Committee may take different actions with respect to the vested and unvested portions of an Award. The Committee may determine an amount or type of consideration to be received or distributed in a Merger/Sale which may differ as among the Grantees, and as between the Grantees and any other holders of shares of the Company.

14.2.6 The Committee's determinations pursuant to this Section 14 shall be conclusive and binding on all Grantees.

14.2.7 If determined by the Committee, the Grantees shall be subject to the definitive agreement(s) in connection with the Merger/Sale as applying to holders of Shares including, such terms, conditions, representations, undertakings, liabilities, limitations, releases, indemnities, participating in transaction expenses and escrow arrangement, in each case as determined by the Committee. Each Grantee shall execute such separate agreement(s) or instruments as may be requested by the Company, the Successor Corporation or the acquiror in connection with such in such Merger/Sale and in the form required by them. The execution of such separate agreement(s) may be a condition to the receipt of assumed or substituted Awards, payment in lieu of the Award or the exercise of any Award.

14.3 Reservation of Rights. Except as expressly provided in this Section 14 (if any), the Grantee of an Award hereunder shall have no rights by reason of any Recapitalization of shares of any class, any increase or decrease in the number of shares of any class, any dissolution, liquidation, reorganization (which may include a combination or exchange of shares, spin-off or other corporate divestiture or division, or other similar occurrences), Merger/Sale. Any issue by the Company of shares of any class, or securities convertible into shares of stock of any class, shall not affect, and no adjustment by reason thereof shall be made with respect to, the number, type or price of shares subject to an Award. The grant of an Award pursuant to this Plan shall not affect in any way the right or power of the Company to make adjustments, reclassifications, reorganizations or changes of its capital or business structures or to merge or to consolidate or to dissolve, liquidate or sell, or transfer all or part of its business or assets or engage in any similar transactions.

15. NON-TRANSFERABILITY OF AWARDS; SURVIVING BENEFICIARY.

15.1 All Awards granted under this Plan by their terms shall not be transferable otherwise than by will or by the laws of descent and distribution, unless otherwise determined by the Committee or under this Plan, provided that with respect to Shares issued upon exercise or (if applicable) the vesting of Awards the restrictions on transfer shall be the restrictions referred to in Section 16 (Conditions upon Issuance of Shares) hereof. Subject to the above provisions, the terms of such Award, this Plan and any applicable Award Agreement shall be binding upon the beneficiaries, executors, administrators, heirs and successors of such Grantee. Awards may be exercised or otherwise realized, during the lifetime of the Grantee, only by the Grantee or by his guardian or legal representative, to the extent provided for herein. Any transfer of an Award not permitted hereunder (including transfers pursuant to any decree of divorce, dissolution or separate maintenance, any property settlement, any separation agreement or any other agreement with a spouse) and any grant of any interest in any Award to, or creation in any way of any direct or indirect interest in any Award by, any party other than the Grantee shall be null and void and shall not confer upon any party or person, other than the Grantee, any rights. Notwithstanding the foregoing, upon the request of the Grantee and subject to Applicable Law the Committee, at its sole discretion, may permit the Grantee to transfer the Award to a trust whose beneficiaries are the Grantee and/or the Grantee's immediate family members (all or several of them).

15.2 As long as the Shares are held by the Trustee in favor of the Grantee, all rights possessed by the Grantee over the Shares are personal, and may not be transferred, assigned, pledged or mortgaged, other than by will or laws of descent and distribution.

15.3 The provisions of this Section 15 shall apply to the Grantee and to any purchaser, assignee or transferee of any Shares.

16. CONDITIONS UPON ISSUANCE OF SHARES; GOVERNING PROVISIONS.

16.1 Legal Compliance. The grant of Awards and the issuance or Shares upon exercise or settlement of Awards shall be subject to compliance with all Applicable Laws as determined by the Company, including, applicable requirements of federal, state and foreign law with respect to such securities. The Company shall have no obligations to issue Shares pursuant to the exercise or settlement of an Award and Awards may not be exercised or settled, if the issuance of Shares upon exercise or settlement would constitute a violation of any Applicable Laws as determined by the Company, including, applicable federal, state or foreign securities laws or other law or regulations or the requirements of any stock exchange or market system upon which the Shares may then be listed. In addition, no Award may be exercised unless (i) a registration statement under the Securities Act shall at the time of exercise or settlement of the Award be in effect with respect to the shares issuable upon exercise of the Award, or (ii) in the opinion of legal counsel to the Company, the shares issuable upon exercise of the Award may be issued in accordance with the terms of an applicable exemption from the registration requirements of the Securities Act. The inability of the Company to obtain authority from any regulatory body having jurisdiction, if any, deemed by the Company to be necessary to the lawful issuance and sale of any Shares hereunder, and the inability to issue Shares hereunder due to non-compliance with any Company policies with respect to the sale of Shares, shall relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority or compliance shall not have been obtained or achieved. As a condition to the exercise of an Award, the Company may require the person exercising such Award to satisfy any qualifications that may be necessary or appropriate, to evidence compliance with any Applicable Law or regulation and to make any representation or warranty with respect thereto as may be requested by the Company, including to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares, all in form and content specified by the Company.

16.2 Provisions Governing Shares. Shares issued pursuant to an Award shall be subject to the Articles of Association of the Company, any limitation, restriction or obligation included in any shareholders agreement applicable to all or substantially all of the holders of shares (regardless of whether or not the Grantee is a formal party to such shareholders agreement), any other governing documents of the Company, all policies, manuals and internal regulations adopted by the Company from time to time, in each case, as may be amended from time to time, including any provisions included therein concerning restrictions or limitations on disposition of Shares (such as, but not limited to, right of first refusal and lock up/market stand-off) or grant of any rights with respect thereto, forced sale and bring along provisions, any provisions concerning restrictions on the use of inside information and other provisions deemed by the Company to be appropriate in order to ensure compliance with Applicable Laws. Each Grantee shall execute such separate agreement(s) as may be requested by the Company relating to matters set forth in this Section 16.2. The execution of such separate agreement(s) may be a condition by the Company to the exercise of any Award.

16.3 Forced Sale. In the event the that Board approves a Merger/Sale effected by way of a forced or compulsory sale (whether pursuant to the Company's Articles of Association or pursuant to Section 341 of the Companies Law), then, without derogating from such provisions and in addition thereto, the Grantee shall be obligated, and shall be deemed to have agreed to the offer to effect the Merger/Sale on the terms approved by the Board (and the Shares held by or for the benefit of the Grantee shall be included in the shares of the Company approving the terms of such Merger/Sale for the purpose of satisfying the required majority), and shall sell all of the Shares held by or for the benefit of the Grantee on the terms and conditions applying to the holders of Shares, in accordance with the instructions then issued by the Board, whose determination shall be final. No Grantee shall contest, bring any claims or demands, or exercise any appraisal rights related to any of the foregoing. The proxy pursuant to Section 6.10 includes an authorization of the holder of such proxy to sign, by and on behalf of any Grantee, such documents and agreements as are required to affect the sale of Shares in connection with such Merger/Sale.

17. MARKET STAND-OFF

17.1 In connection with any underwritten public offering of equity securities of the Company pursuant to an effective registration statement filed under the Securities Act or equivalent law in another jurisdiction, the Grantee shall not directly or indirectly, without the prior written consent of the Company or its underwriters, (i) lend, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any Shares or other Awards, any securities of the Company (whether or not such Shares were acquired under this Plan), or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Shares or securities of the Company and any other shares or securities issued or distributed in respect thereto or in substitution thereof (collectively, "Securities"), or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Securities, whether any such transaction described in clauses (i) or (ii) is to be settled by delivery of Securities, in cash or otherwise. The foregoing provisions of this Section 17.1 shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement. Such restrictions (the "Market Stand-Off") shall be in effect for such period of time (the "Market Stand-Off Period"): (A) following the first public filing of the registration statement relating to the underwritten public offering until the extirpation of 180 days following the effective date of such registration statement relating to the Company's initial public offering or 90 days following the effective date of such registration statement relating to any other public offering, in each case, provided, however, that if (1) during the last 17 days of the initial Market Stand-Off Period, the Company releases earnings results or announces material news or a material event or (2) prior to the expiration of the initial Market Stand-Off Period, the Company announces that it will release earnings results during the 15-day period following the last day of the initial Market Stand-Off Period, then in each case the Market Stand-Off Period will be automatically extended until the expiration of the 18-day period beginning on the date of release of the earnings results or the announcement of the material news or material event; or (B) such other period as shall be requested by the Company or the underwriters. Notwithstanding anything herein to the contrary, if the underwriter(s) and the Company agree on a termination date of the Market Stand-Off Period in the event of failure to consummation a certain public offering, then such termination shall apply also to the Market Stand-Off Period hereunder with respect to that particular public offering.

17.2 In the event of a subdivision of the outstanding share capital of the Company, the distribution of any securities (whether or not of the Company), whether as bonus shares or otherwise, and whether as dividend or otherwise, a recapitalization, a reorganization (which may include a combination or exchange of shares or a similar transaction affecting the Company's outstanding securities without receipt of consideration), a consolidation, a spin-off or other corporate divestiture or division, a reclassification or other similar occurrence, any new, substituted or additional securities which are by reason of such transaction distributed with respect to any Shares subject to the Market Stand-Off, or into which such Shares thereby become convertible, shall immediately be subject to the Market Stand-Off.

17.3 In order to enforce the Market Stand-Off, the Company may impose stop-transfer instructions with respect to the Shares acquired under this Plan until the end of the applicable Market Stand-Off period.

17.4 The underwriters in connection with a registration statement so filed are intended third party beneficiaries of this Section 17 and shall have the right, power and authority to enforce the provisions hereof as though they were a party hereto. Each Grantee shall execute such separate agreement(s) as may be requested by the Company or the underwriters in connection with such registration statement and in the form required by them, relating to Market Stand-Off (which need not be identical to the provisions of this Section 17, and may include such additional provisions and restrictions as the underwriters deem advisable) or that are necessary to give further effect thereto. The execution of such separate agreement (s) may be a condition by the Company to the exercise of any Award.

17.5 Without derogating from the above provisions of this Section 17 or elsewhere in this Plan, the provisions of this Section 17 shall apply to the Grantee and the Grantee's heirs, legal representatives, successors, assigns, and to any purchaser, assignee or transferee of any Awards or Shares.

18. AGREEMENT REGARDING TAXES; DISCLAIMER.

18.1 If the Committee shall so require, as a condition of exercise of an Award, the release of Shares by the Trustee or the expiration of the Restricted Period, a Grantee shall agree that, no later than the date of such occurrence, the Grantee will pay to the Company (or the Trustee, as applicable) or make arrangements satisfactory to the Committee and the Trustee (if applicable) regarding payment of any applicable taxes and compulsory payments of any kind required by Applicable Law to be withheld or paid.

18.2 TAX LIABILITY. ALL TAX CONSEQUENCES UNDER ANY APPLICABLE LAW WHICH MAY ARISE FROM THE GRANT OF ANY AWARDS OR THE EXERCISE THEREOF, THE SALE OR DISPOSITION OF ANY SHARES GRANTED HEREUNDER OR ISSUED UPON EXERCISE OR (IF APPLICABLE) THE VESTING OF ANY AWARD, THE ASSUMPTION, SUBSTITUTION, CANCELLATION OR PAYMENT IN LIEU OF AWARDS OR FROM ANY OTHER ACTION IN CONNECTION WITH THE FOREGOING (INCLUDING WITHOUT LIMITATION ANY TAXES AND COMPULSORY PAYMENTS, SUCH AS SOCIAL SECURITY OR HEALTH TAX PAYABLE BY THE GRANTEE OR THE COMPANY IN CONNECTION THEREWITH) SHALL BE BORNE AND PAID SOLELY BY THE GRANTEE, AND THE GRANTEE SHALL INDEMNIFY THE COMPANY, ITS SUBSIDIARIES AND AFFILIATES AND THE TRUSTEE, AND SHALL HOLD THEM HARMLESS AGAINST AND FROM ANY LIABILITY FOR ANY SUCH TAX OR PAYMENT OR ANY PENALTY, INTEREST OR INDEXATION THEREON. EACH GRANTEE AGREES TO, AND UNDERTAKES TO COMPLY WITH, ANY RULING, SETTLEMENT, CLOSING AGREEMENT OR OTHER SIMILAR AGREEMENT OR ARRANGEMENT WITH ANY TAX AUTHORITY IN CONNECTION WITH THE FOREGOING WHICH IS APPROVED BY THE COMPANY.

18.3 NO TAX ADVISE. THE GRANTEE IS ADVISED TO CONSULT WITH A TAX ADVISOR WITH RESPECT TO THE TAX CONSEQUENCES OF RECEIVING, EXERCISING OR DISPOSING OF AWARDS HEREUNDER. THE COMPANY DOES NOT ASSUME ANY RESPONSIBILITY TO ADVISE THE GRANTEE ON SUCH MATTERS, WHICH SHALL REMAIN SOLELY THE RESPONSIBILITY OF THE GRANTEE.

18.4 TAX TREATMENT. THE COMPANY DOES NOT UNDERTAKE OR ASSUME ANY LIABILITY OR RESPONSIBILITY TO THE EFFECT THAT ANY AWARD SHALL QUALIFY WITH ANY PARTICULAR TAX REGIME OR RULES APPLYING TO PARTICULAR TAX TREATMENT, OR BENEFIT FROM ANY PARTICULAR TAX TREATMENT OR TAX ADVANTAGE OF ANY TYPE AND THE COMPANY SHALL BEAR NO LIABILITY IN CONNECTION WITH THE MANNER IN WHICH ANY AWARD IS EVENTUALLY TREATED FOR TAX PURPOSES, REGARDLESS OF WHETHER THE AWARD WAS GRANTED OR WAS INTENDED TO QUALIFY UNDER ANY PARTICULAR TAX REGIME OR TREATMENT. THIS PROVISION SHALL SUPERSEDE ANY TYPE OF AWARDS OR TAX QUALIFICATION INDICATED IN ANY CORPORATE RESOLUTION OR AWARD AGREEMENT, WHICH SHALL AT ALL TIMES BE SUBJECT TO THE REQUIREMENTS OF APPLICABLE LAW. THE COMPANY DOES NOT UNDERTAKE AND SHALL NOT BE REQUIRED TO TAKE ANY ACTION IN ORDER TO QUALIFY THE AWARD WITH THE REQUIREMENT OF ANY PARTICULAR TAX TREATMENT AND NO INDICATION IN ANY DOCUMENT TO THE EFFECT THE ANY AWARD IS INTENDED TO QUALIFY FOR ANY TAX TREATMENT SHALL IMPLY SUCH AN UNDERTAKING. NO ASSURANCE IS MADE BY THE COMPANY OR ANY OF ITS AFFILIATES THAT ANY PARTICULAR TAX TREATMENT ON THE DATE OF GRANT WILL CONTINUE TO EXIST OR THAT THE AWARD WOULD QUALIFY AT THE TIME OF EXERCISE OR DISPOSITION THEREOF WITH ANY PARTICULAR TAX TREATMENT. THE COMPANY AND ITS AFFILIATES SHALL NOT HAVE ANY LIABILITY OR OBLIGATION OF ANY NATURE IN THE EVENT THAT AN AWARD DOES NOT QUALIFY FOR ANY PARTICULAR TAX TREATMENT, REGARDLESS WHETHER THE COMPANY COULD HAVE OR SHOULD HAVE TAKEN ANY ACTION TO CAUSE SUCH QUALIFICATION TO BE MET AND SUCH QUALIFICATION REMAINS AT ALL TIMES AND UNDER ALL CIRCUMSTANCES AT THE RISK OF THE GRANTEE. THE COMPANY DOES NOT UNDERTAKE OR ASSUME ANY LIABILITY TO CONTEST A DETERMINATION OR INTERPRETATION (WHETHER WRITTEN OR UNWRITTEN) OF ANY TAX AUTHORITIES, INCLUDING IN RESPECT OF THE QUALIFICATION UNDER ANY PARTICULAR TAX REGIME OR RULES APPLYING TO PARTICULAR TAX TREATMENT. IF THE AWARDS DO NOT QUALIFY UNDER ANY PARTICULAR TAX TREATMENT IT COULD RESULT IN ADVERSE TAX CONSEQUENCES TO THE GRANTEE.

18.5 The Company or any Subsidiary or Affiliate may take such action as it may deem necessary or appropriate, in its discretion, for the purpose of or in connection with withholding of any taxes and compulsory payments which the Trustee, the Company or any Subsidiary or Affiliate is required by any Applicable Law to withhold in connection with any Awards (collectively, "Withholding Obligations"). Such actions may include (i) requiring a Grantees to remit to the Company in cash an amount sufficient to satisfy such Withholding Obligations and any other taxes and compulsory payments, payable by the Company in connection with the Award or the exercise or (if applicable) the vesting thereof; (ii) subject to Applicable Law, allowing the Grantees to provide Shares to the Company, in an amount that at such time, reflects a value that the Committee determines to be sufficient to satisfy such Withholding Obligations; (iii) withholding Shares otherwise issuable upon the exercise of an Award at a value which is determined by the Committee to be sufficient to satisfy such Withholding Obligations; or (iv) any combination of the foregoing. The Company shall not be obligated to allow the exercise of any Award by or on behalf of a Grantee until all tax consequences arising from the exercise of such Award are resolved in a manner acceptable to the Company.

18.6 Each Grantee shall notify the Company in writing promptly and in any event within ten (10) days after the date on which such Grantee first obtains knowledge of any tax bureau inquiry, audit, assertion, determination, investigation, or question relating in any manner to the Awards granted or received hereunder or Shares issued thereunder and shall continuously inform the Company of any developments, proceedings, discussions and negotiations relating to such matter, and shall allow the Company and its representatives to participate in any proceedings and discussions concerning such matters. Upon request, a Grantee shall provide to the Company any information or document relating to any matter described in the preceding sentence, which the Company, in its discretion, requires.

18.7 With respect to 102 Non-Trustee Options, if the Grantee ceases to be employed by the Company or any Affiliate, the Grantee shall extend to the Company and/or its Affiliate with whom the Grantee is employed a security or guarantee for the payment of taxes due at the time of sale of Shares, all in accordance with the provisions of Section 102 of the Ordinance and the Rules.

18.8 For the purpose hereof "tax(es)" means (a) all federal, state, local or foreign taxes, charges, fees, imposts, levies or other assessments, including all income, capital gains, transfer, withholding, payroll, employment, social security, national security, health tax, wealth surtax, stamp, registration and estimated taxes, customs duties, fees, assessments and charges of any similar kind whatsoever (including under Section 280G of the Code), (b) all interest, indexation differentials, penalties, fines, additions to tax or additional amounts imposed by any taxing authority in connection with any item described in clause (a), (c) any transferee or successor liability in respect of any items described in clauses (a) or (b) payable by reason of contract, assumption, transferee liability, successor liability, operation of Applicable Law, or as a result of any express or implied obligation to assume Taxes or to indemnify any other person, and (d) any liability for the payment of any amounts of the type described in clause (a) or (b) payable as a result of being a member of an affiliated, consolidated, combined, unitary or aggregate group for any taxable period, including under U.S. Treasury Regulations Section 1.1502-6(a) (or any predecessor or successor thereof of any analogous or similar provision under Law) or otherwise.

19. RIGHTS AS A SHAREHOLDER; VOTING AND DIVIDENDS.

19.1 Subject to Section 11.4, a Grantee shall have no rights as a shareholder of the Company with respect to any Shares covered by an Award until the Grantee shall have exercised the Award, paid the Exercise Price therefor and becomes the record holder of the subject Shares. In the case of 102 Awards or 3(9) Awards (if such Awards are being held by a Trustee), the Trustee shall have no rights as a shareholder of the Company with respect to the Shares covered by such Award until the Trustee becomes the record holder for such Shares for the Grantee's benefit, and the Grantee shall not be deemed to be a shareholder and shall have no rights as a shareholder of the Company with respect to the Shares covered by the Award until the date of the release of such Shares from the Trustee to the Grantee and the transfer of record ownership of such Shares to the Grantee (provided however that the Grantee shall be entitled to receive from the Trustee any cash dividend or distribution made on account of the Shares held by the Trustee for such Grantee's benefit, subject to any tax withholding and compulsory payment). No adjustment shall be made for dividends (ordinary or extraordinary, whether in cash, securities or other property) or distribution of other rights for which the record date is prior to the date on which the Grantee or Trustee (as applicable) becomes the record holder of the Shares covered by an Award, except as provided in Section 14 hereof.

19.2 With respect to all Awards issued in the form of Shares hereunder or upon the exercise or (if applicable) the vesting of Awards hereunder, any and all voting rights attached to such Shares shall be subject to Section 6.9, and the Grantee shall be entitled to receive dividends distributed with respect to such Shares, subject to the provisions of the Company's Articles of Association, as amended from time to time, and subject to any Applicable Law.

19.3 The Company may, but shall not be obligated to, register or qualify the sale of Shares under any applicable securities law or any other Applicable Law.

20. NO REPRESENTATION BY COMPANY.

By granting the Awards, the Company is not, and shall not be deemed as, making any representation or warranties to the Grantee regarding the Company, its business affairs, its prospects or the future value of its Shares. The Company shall not be required to provide to any Grantee any information, documents or material in connection with the Grantee's considering an exercise of an Award. To the extent that any information, documents or materials are provided, the Company shall have no liability with respect thereto. Any decision by a Grantee to exercise an Award shall solely be at the risk of the Grantee.

21. NO RETENTION RIGHTS.

Nothing in this Plan, any Award Agreement or in any Award granted or agreement entered into pursuant hereto shall confer upon any Grantee the right to continue in the employ of, or be in the service of the Company or any Subsidiary or Affiliate thereof as a Service Provider or to be entitled to any remuneration or benefits not set forth in this Plan or such agreement, or to interfere with or limit in any way the right of the Company or any such Subsidiary or Affiliate to terminate such Grantee's employment or service (including, any right of the Company or any of its Affiliates to immediately cease the Grantee's employment or service or to shorten all or part of the notice period, regardless of whether notice of termination was given by the Company or its Affiliates or by the Grantee). Awards granted under this Plan shall not be affected by any change in duties or position of a Grantee, subject to Sections 6.6 through 6.8. No Grantee shall be entitled to claim and the Grantee hereby waives any claim against the Company or any Subsidiary or Affiliate that he or she was prevented from continuing to vest Awards as of the date of termination of his or her employment with, or services to, the Company or any Subsidiary or Affiliate. No Grantee shall be entitled to any compensation in respect of the Awards which would have vested had such Grantee's employment or engagement with the Company (or any Subsidiary or Affiliate) not been terminated.

22. PERIOD DURING WHICH AWARDS MAY BE GRANTED.

Awards may be granted pursuant to this Plan from time to time within a period of ten (10) years from the Effective Date, which period may be extended from time to time by the Board. From and after such date (as extended) no grants of Awards may be made and this Plan shall continue to be in full force and effect with respect to Awards or Shares issued thereunder that remain outstanding.

23. AMENDMENT OF THIS PLAN.

23.1 The Board at any time and from time to time may suspend, terminate, modify or amend this Plan, whether retroactively or prospectively. Any amendment effected in accordance with this Section shall be binding upon all Grantees and all Awards, whether granted prior to or after the date of such amendment, and without the need to obtain the consent of any Grantee. No termination or amendment of this Plan shall affect any then outstanding Award unless expressly provided by the Board.

23.2 Subject to changes in Applicable Law that would permit otherwise, without the approval of the Company's shareholders, there shall be (i) no increase in the maximum aggregate number of Shares that may be issued under this Plan as Incentive Stock Options (except by operation of the provisions of Section 14.1), (ii) no change in the class of persons eligible to receive Incentive Stock Options, and (iii) no other amendment of this Plan that would require approval of the Company's shareholders under any Applicable Law. Unless not permitted by Applicable Law, if the grant of an Award is subject to approval by shareholders, the date of grant of the Award shall be determined as if the Award had not been subject to such approval. Failure to obtain approval by the shareholders shall not in any way derogate from the valid and binding effect of any grant of an Award, which is not an Incentive Stock Option. Upon approval of an amendment to this Plan by the shareholders of the Company as set forth above, all Incentive Stock Options granted under this Plan on or after such amendment shall be fully effective as if the shareholders of the Company had approved the amendment on the same date.

24. APPROVAL.

24.1 This Plan shall take effect upon its adoption by the Board (the "Effective Date").

24.2 Solely with respect to grants of Incentive Stock Options, this Plan shall also be subject to shareholders' approval, within one year of the Effective Date, by the required majority (however, if the grant of an Award is subject to approval by shareholders, the date of grant of the Award shall be determined as if the Award had not been subject to such approval). Failure to obtain approval by the shareholders shall not in any way derogate from the valid and binding effect of any grant of an Award, which is not an Incentive Stock Option. Upon approval of this Plan by the shareholders of the Company as set forth above, all Incentive Stock Options granted under this Plan on or after the Effective Date shall be fully effective as if the shareholders of the Company had approved this Plan on the Effective Date.

24.3 102 Awards are conditional upon the filing with or approval by the ITA, if required, as set forth in Section 9.49. Failure to so file or obtain such approval shall not in any way derogate from the valid and binding effect of any grant of an Award, which is not an 102 Award.

25. RULES PARTICULAR TO SPECIFIC COUNTRIES; SECTION 409A.

25.1 Notwithstanding anything herein to the contrary, the terms and conditions of this Plan may be supplemented or amended with respect to a particular country or tax regime by means of an appendix to this Plan, and to the extent that the terms and conditions set forth in any appendix conflict with any provisions of this Plan, the provisions of such appendix shall govern. Terms and conditions set forth in such appendix shall apply only to Awards granted to Grantees under the jurisdiction of the specific country or such other tax regime that is the subject of such appendix and shall not apply to Awards issued to a Grantee not under the jurisdiction of such country or such other tax regime. The adoption of any such appendix shall be subject to the approval of the Board or the Committee, and if determined by the Committee to be required in connection with the application of certain tax treatment, pursuant to applicable stock exchange rules or regulations or otherwise, then also the approval of the shareholders of the Company at the required majority.

25.2 The Company intends that this Plan comply with Section 409A of the Code, including any amendments or replacements of such section, and this Plan shall be so construed. To the extent applicable, this Plan and any agreement hereunder shall be interpreted in accordance with Section 409A of the Code. Notwithstanding any provision of this Plan to the contrary, in the event that, following the Effective Date, the Board determines that any Award may be subject to Section 409A of the Code, the Board may adopt such amendments to this Plan and such agreement or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Board determines are necessary or appropriate to (a) exempt the Award from Section 409A of the Code and/or preserve the intended tax treatment of the benefits provided with respect to the Award or (b) comply with the requirements of Section 409A of the Code.

26. GOVERNING LAW; JURISDICTION.

This Plan and all determinations made and actions taken pursuant hereto shall be governed by the laws of the State of Israel, except with respect to matters that are subject to tax laws, regulations and rules of any specific jurisdiction, which shall be governed by the respective laws, regulations and rules of such jurisdiction. Certain definitions, which refer to laws other than the laws of such jurisdiction, shall be construed in accordance with such other laws. The competent courts located in Tel-Aviv-Jaffa, Israel shall have exclusive jurisdiction over any dispute arising out of or in connection with this Plan and any Award granted hereunder. By signing any Award Agreement or any other agreement relating to an Award, each Grantee irrevocably submits to such exclusive jurisdiction.

27. NON-EXCLUSIVITY OF THIS PLAN.

The adoption of this Plan shall not be construed as creating any limitations on the power or authority of the Company to adopt such other or additional incentive or other compensation arrangements of whatever nature as the Company may deem necessary or desirable or preclude or limit the continuation of any other plan, practice or arrangement for the payment of compensation or fringe benefits to employees generally, or to any class or group of employees, which the Company or any Affiliate now has lawfully put into effect, including any retirement, pension, savings and stock purchase plan, insurance, death and disability benefits and executive short-term or long-term incentive plans.

28. MISCELLANEOUS.

28.1 Survival. The Grantee shall be bound by and the Shares issued upon exercise or (if applicable) the vesting of any Awards granted hereunder shall remain subject to this Plan after the exercise or (if applicable) the vesting of Awards, in accordance with the terms of this Plan, whether or not the Grantee is then or at any time thereafter employed or engaged by the Company or any of its Affiliates.

28.2 Additional Terms. Each Award awarded under this Plan may contain such other terms and conditions not inconsistent with this Plan as may be determined by the Committee, in its sole discretion.

28.3 Fractional Shares. No fractional Share shall be issuable upon exercise or vesting of any Award and the number of Shares to be issued shall be rounded down to the nearest whole Share, with in any Share remaining at the last vesting date due to such rounding to be issued upon exercise at such last vesting date.

28.4 Severability. If any provision of this Plan, any Award Agreement or any other agreement entered into in connection with an Award shall be determined to be illegal or unenforceable by any court of law in any jurisdiction, the remaining provisions hereof and thereof shall be severable and enforceable in accordance with their terms, and all provisions shall remain enforceable in any other jurisdiction. In addition, if any particular provision contained in this Plan, any Award Agreement or any other agreement entered into in connection with an Award shall for any reason be held to be excessively broad as to duration, geographic scope, activity or subject, it shall be construed by limiting and reducing such provision as to such characteristic so that the provision is enforceable to fullest extent compatible with Applicable Law as it shall then appear.

28.5 Captions and Titles. The use of captions and titles in this Plan or any Award Agreement or any other agreement entered into in connection with an Award is for the convenience of reference only and shall not affect the meaning or interpretation of any provision of this Plan or such agreement.

* * *

Exhibit 12.1

CERTIFICATION BY CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Christopher von Jako, 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)) 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) 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

c) 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 19, 2021

/s/ Christopher von Jako
Christopher von Jako
Chief Executive Officer

Exhibit 12.2

CERTIFICATION BY CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Hadar Levy, certify that:

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)) 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) 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

c) 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 19, 2021

/s/ Hadar Levy
Hadar Levy
Interim Chief Financial Officer

Exhibit 13

CERTIFICATION BY CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUAN 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 period ended December 31, 2020 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 19, 2021

/s/ Christopher von Jako
Christopher von Jako
Chief Executive Officer

/s/ Hadar Levy
Hadar Levy
Interim Chief Financial Officer

Exhibit 15.1

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CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-230979) of Brainsway Ltd. of our report dated April 19, 2021 with respect to the consolidated financial statements of Brainsway Ltd., included in this Annual Report (Form 20-F) of Brainsway Ltd. for the year ended December 31, 2020.

Kost Forer Gabbay & Kasierer
A member of Ernst & Young Global

Tel-Aviv, Israel
April 19, 2021