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Filed pursuant to Rule 424(b)(4)  
Registration No. 333-229233

PROSPECTUS

**2,500,000 American Depositary Shares**  
**Representing 5,000,000 Ordinary Shares**



We are offering 2,500,000 American Depositary Shares, or the ADSs. Each ADS represents 2 of our ordinary shares. This is our initial public offering in the United States, and no public market currently exists in the United States for the ADSs. The ADSs have been approved for listing on the Nasdaq Global Market, or Nasdaq, under the symbol "BWAY."

Our ordinary shares are listed on the Tel Aviv Stock Exchange, or the TASE, under the symbol "BRIN." On April 15, 2019, the last reported sale price of our ordinary shares on the TASE was NIS 19.65, or \$5.52 per share (based on the exchange rate reported by the Bank of Israel on such date, which was NIS 3.561 = US\$1.00).

We are an "emerging growth company," under the federal securities laws and, as such, will be subject to reduced public company reporting requirements. See "Prospectus Summary — Implications of Being an Emerging Growth Company and a Foreign Private Issuer."

**Investing in the ADSs involves a high degree of risk. See "Risk Factors" beginning on page 13 of this prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

	<b>Per ADS</b>	<b>Totals</b>
Public Offering Price (1)	\$ 11.00	\$ 27,500,000
Underwriting Discounts and Commission (2)	\$ 0.77	\$ 1,925,000
Proceeds to Brainsway Ltd. (before expenses)	\$ 10.23	\$ 25,575,000

(1) Based on the last reported sale price of our ordinary shares on the TASE on April 15, 2019.

(2) See "Underwriting" beginning on page 172 of this prospectus for a description of compensation payable to the underwriters.

Delivery of the ADSs is expected to be made on or about April 22, 2019. We have granted the underwriters an option for a period of 30 days to purchase up to an additional 375,000 ADSs. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$2,213,750, and the total proceeds to us, before expenses, will be \$29,411,250.

**Cantor**

**Raymond James**

**Oppenheimer & Co.**

**Ladenburg Thalmann**

Prospectus dated April 16, 2019

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## ABOUT THIS PROSPECTUS

Neither we nor any of the underwriters have authorized anyone to provide information different from that contained in this prospectus, any amendment or supplement to this prospectus or in any free writing prospectus prepared by us or on our behalf. When you make a decision about whether to invest in the ADSs, you should not rely upon any information other than the information in this prospectus, any amendment or supplement to this prospectus and any free writing prospectus prepared by us or on our behalf. Neither the delivery of this prospectus nor the sale of the ADSs means that information contained in this prospectus is correct after the date of this prospectus. This prospectus is not an offer to sell or solicitation of an offer to buy these ADSs in any circumstances under which the offer or solicitation is unlawful.

We report under International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or the IASB. None of our financial statements were prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP.

All references to "Brainsway," "we," "us," "our," "the Company" and similar designations refer to Brainsway Ltd. and its consolidated subsidiaries. The terms "shekels," "Israeli shekels" and "NIS" refer to New Israeli Shekels, the lawful currency of the State of Israel, the terms "dollar," "US\$" or "\$" refer to U.S. dollars, the lawful currency of the United States.

The "Brainsway" name and design logo are our registered trademarks. Solely for convenience, the trademarks, service marks, and trade names referred to in this prospectus 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 prospectus 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 prospectus 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 prospectus 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 and 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 and 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 prospectus should be viewed with caution. We believe that information from these industry publications included in this prospectus is reliable.

No action is being taken in any jurisdiction outside the United States to permit a public offering of the ADSs or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of the prospectus applicable to that jurisdiction.

## PROSPECTUS SUMMARY

*This summary does not contain all of the information you should consider before investing in the ADSs. You should read this summary together with the more detailed information appearing in this prospectus, including "Risk Factors," "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business" and our financial statements and the related notes included at the end of this prospectus, before making an investment in the ADSs.*

### Overview

We are a commercial stage medical device company focused on the development and sale of non-invasive neuromodulation products using our proprietary Deep Transcranial Magnetic Stimulation (Deep TMS) technology for the treatment of major depressive disorder (MDD) and obsessive-compulsive disorder (OCD), 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 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 Focal TMS, that generally use a "figure 8" design. We believe that our Deep TMS technology has the potential to be safe and effective for the treatment of a wide range of psychiatric, neurological and addiction disorders beyond MDD and OCD.

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 2015 study by the World Health Organization (WHO), MDD 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 16.2 million individuals in the United States suffer from a major depressive episode in any given year. Based on 2006-2007 data from the Sequenced Treatment Alternatives to Relieve Depression (STAR\*D) study, we estimate that approximately 4.9 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 our expected revenues for a course of treatment under one of our pricing models (the pay-per-use 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 our expected revenues for a course of treatment under our existing pricing models, we believe our total annual addressable market opportunity for OCD in the United States is approximately \$800 million.

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 are the first and only medical device company to offer an FDA-authorized non-invasive treatment for OCD, the marketing authorization for which we received in August 2018 as an adjunct therapy for adult patients suffering from OCD. Our pivotal trial for OCD demonstrated statistically significant response and partial response rates of 38.1% and 54.8%, respectively, after six weeks of daily active Deep TMS treatment of 19 minutes per session, compared to 11.1% and 26.7%, respectively, after sham treatment. We believe that our Deep TMS product for OCD presents a significant additional market opportunity, and we have recently commenced sales and marketing efforts of Deep TMS for OCD.

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 currently conducting multicenter clinical trials to support FDA clearance of Deep TMS for smoking cessation and post-traumatic stress disorder (PTSD). We are also planning multicenter trials for other indications, including opioid addiction, fatigue in multiple sclerosis (MS), and post-stroke rehabilitation, the latter of which are the first neurological indications that we plan to advance into multicenter trials.

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. 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 standard MDD or OCD session lasts 20 and 19 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.

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 three to four failures of anti-depressant medications. In addition, our MDD treatment with Deep TMS may be eligible for reimbursement from Medicare, and is expected to be available after four failures of anti-depressant medications. Deep TMS for OCD is not currently eligible for reimbursement. However, we believe that 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 novelty of the technology, unmet clinical need and the efficacy and safety profile of the treatment.

The United States is our primary and most strategic market, representing approximately 88% of our revenues for the year ended December 31, 2018. 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 are currently ramping up our commercialization efforts of Deep TMS for OCD. We generate revenue from various flexible pricing models that are designed to maximize market penetration. For the year ended December 31, 2018, we generated revenues of \$16.4 million, an increase of 47% compared to the year ended December 31, 2017.

### **Our Deep TMS Platform**

Our proprietary Deep TMS technology is intended for non-invasive 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 for different regions of the brain which are known to be associated with specific brain disorders to influence the neurological networks of those regions. For example, we have one H-Coil (BrainsWay D) that is used in our Deep TMS system for MDD, and we have another H-Coil (BrainsWay OCD) that is used for OCD and is in clinical development for PTSD (and future clinical development is planned for opioid addiction). The H-Coils transmit pulses which are generated by a power supply, known as a stimulator. We recently 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 obtained FDA 510(k) clearance for our proprietary stimulator as a modification to the FDA clearance for the MDD indication. 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 and is potentially well-positioned for use in neurology indications.

Our Deep TMS system is comprised of the various key components, as illustrated below:

- 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 Focal 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 Focal 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 or actually fasten the coil next to the patient's head. Focal TMS is limited to the narrow area treated, and the manual placing of the figure 8 coil in Focal TMS may cause inaccuracies in the region treated. Studies suggest that the figure 8 coil misses the target in 33% of patients.

We believe that Deep TMS has additional advantages over Focal TMS because it is capable of stimulating deeper and broader areas of the brain. Studies have shown that while Focal TMS devices create an electromagnetic field estimated to penetrate the cortical surface of the brain up to depths in the range of 0.7 to 1.1 centimeters, Deep TMS reaches depths from the cortical surface of approximately 1.8 centimeters for BrainsWay D and approximately 3.5 centimeters for BrainsWay OCD. Studies have also shown that BrainsWay D has the capacity for total stimulated brain volume of 17 cm<sup>3</sup> compared to 3 cm<sup>3</sup> for the figure 8 coil used in Focal TMS. We believe this deeper and broader penetration of Deep TMS provides an advantage over Focal TMS because of its potential to address a wider variety of brain disorders, and for a given disorder, to stimulate more relevant brain structures.

### **Our Strengths**

We are focused on improving the quality of life for patients who suffer from psychiatric, neurological and addiction disorders. We believe that the following strengths will allow us to build our business and potentially expand our market opportunity.

- ***Deep TMS technology has advantages over Focal 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 Focal 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 Focal TMS.
- ***We have obtained FDA marketing authorizations of Deep TMS for MDD and OCD.*** We are the only company to have obtained FDA marketing authorizations for TMS products in more than one psychiatric indication: MDD, which was FDA-cleared in 2013, and OCD, which was classified by FDA as a Class II device in a *de novo* classification in August 2018. For MDD, we are one of only two TMS companies that have performed clinical studies supporting the FDA clearance. We are the first and only TMS company to have developed a non-invasive medical device that has received FDA marketing authorization for OCD.
- ***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. Overall, Deep TMS treatment was safe and well-tolerated by patients in these trials.

- ***We have a commercial track record for MDD, and are ramping up commercialization for OCD.*** 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 the 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 subject to certain limitations. We are also currently selling Deep TMS for MDD in Europe, Mexico, Israel and certain other countries. We are currently ramping up 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.
- ***Our flexible pricing models are designed to achieve market penetration.*** For Deep TMS for MDD, we offer a fixed-fee lease model enabling unlimited use, including warranty and support, or provide an option to purchase, including a one-year warranty. In addition, we offer a risk share model, a pay-per-use pricing model with a minimum annual fee, for MDD, and for OCD, we offer only our risk share model. We believe these pricing models will increase market acceptance among clinics and psychiatric professionals at reduced up-front costs compared to our sales or fixed-lease models. Based on our commercial data and depending on insurer reimbursement rates, we believe our psychiatrist customers can generate approximately \$10,000 of revenues per patient 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 in advanced stages of several pivotal multicenter clinical trials for smoking cessation and PTSD, and we are also planning trials for fatigue in MS, post-stroke rehabilitation and opioid addiction. In November 2018, 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. We are currently working directly with the FDA to accelerate the performance of our clinical trial for opioid addiction, and subject to the successful outcome of this trial, expedite the marketing approval of Deep TMS for treatment of this disorder. As a result of these developments, all of our regulatory submissions in this process will be subject to priority review by senior FDA officials.

## **Our Strategy**

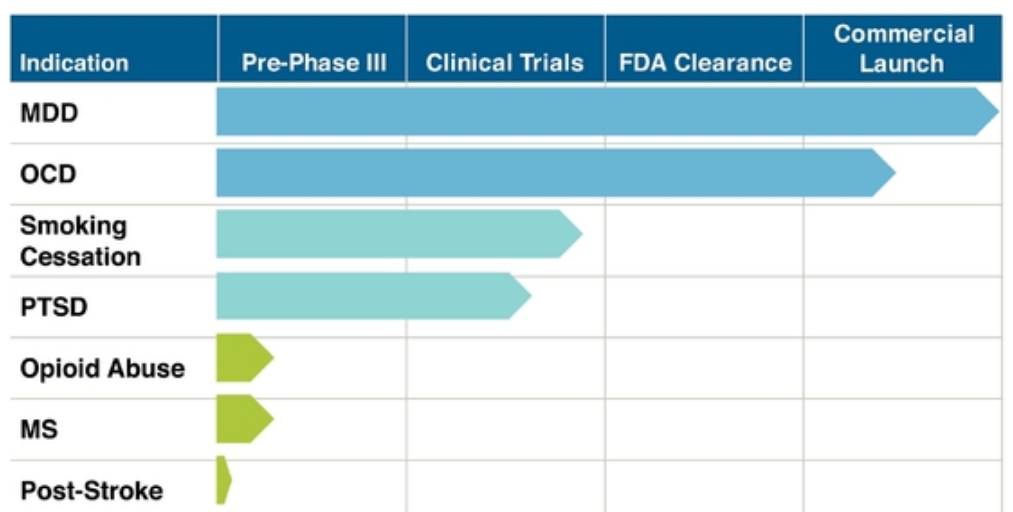
Our goal is to maintain and extend our leadership position in Deep TMS therapy for patients with psychiatric disorders. The key elements of our strategy include:

- Increase the full-scale commercialization of Deep TMS for MDD and accelerate commercialization of Deep TMS for OCD;
- Advance clinical trials for additional indications for Deep TMS;
- Expand reimbursement coverage for Deep TMS for OCD and other approved indications in the future;
- Develop innovative enhancements and features for our Deep TMS systems; and
- Increase our international commercial footprint.



## Our Clinical Pipeline

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



## Recent Developments

### *Preliminary Results for First Quarter of 2019*

Our financial results for the three months ended March 31, 2019 are not yet finalized. The following information reflects our preliminary results for this period:

**Revenues.** Revenues for the three months ended March 31, 2019 are expected to be in the range of \$4.9 million to \$5.2 million, compared to \$3.6 million for the first quarter of 2018.

**Net Losses.** Net losses for the three months ended March 31, 2019 are expected to be in the range of \$1.6 million to \$2.1 million, compared to \$1.0 million for the first quarter of 2018.

### *Cautionary Statement Regarding Preliminary Results*

The preliminary results for the three months ended March 31, 2019 are unaudited and subject to completion, reflect management's current views and may change as a result of our review of our results and other factors, including economic and competitive risks and uncertainties. Such preliminary results are subject to the finalization and closing of our accounting books and records (which have yet to be performed), and should not be viewed as a substitute for full financial statements prepared in accordance with IFRS. We caution you that these preliminary results are not guarantees of future performance or outcomes and that actual results may differ materially from those described above. You should read this information together with the sections of this prospectus entitled "Selected Financial Data", "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Risk Factors," and our audited financial statements included elsewhere in this prospectus.

These preliminary results have been prepared by and are the sole responsibility of our management. Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global ("KFGK"), our independent auditors, have not audited, reviewed, compiled or performed any procedures with respect to the foregoing preliminary financial information. Accordingly, KFGK does not express an opinion or any other form of assurance with respect thereto.

## **Risks Associated with Our Business**

Investing in the ADSs involves risks. You should carefully consider the risks described in "Risk Factors" beginning on page 13 before making a decision to invest in the ADSs. The following is a summary of some of the principal risks we face:

- we have incurred losses in the past and may be unable to achieve or sustain profitability in the future;
- our success depends on market perception and acceptance of Deep TMS;
- our success depends upon physician and patient satisfaction with the effectiveness and competitive advantages and benefits of Deep TMS;
- we face competition from other TMS companies that are or may be in the future FDA-cleared to market TMS products for the indications we are pursuing;
- if coverage for reimbursement is reduced for MDD or is unavailable for OCD or other future indications, physicians and patients may be less likely to adopt Deep TMS;
- our long-term growth depends on our ability to increase market penetration, commercialize Deep TMS for current indications and develop and commercialize additional indications and expand enhancements and features through our research and development efforts;
- 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 sales;
- we rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, which could delay our product development activities;
- 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 required to comply with the terms of our license agreements, and any violation or breach of these terms could result in termination of our licenses;
- our ability to obtain and maintain adequate protection of our intellectual property, including intellectual property that is licensed to us; and
- the possibility that we may face third-party claims of intellectual property infringement.

## **Corporate Information**

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 our ordinary shares are currently listed on the TASE under the symbol "BRIN." Our principal executive offices are located at 19 Hartum Street, Bynet Building, 3rd Floor, Har HaHotzvim, Jerusalem 91451, Israel, and our telephone number is +972-2-581-3140. Our address on the internet is [www.brainsway.com](http://www.brainsway.com). We do not incorporate the information on, or accessible through, our website into this prospectus, and you should not consider it part of this prospectus, nor should you rely on any such information in making your decision whether to purchase the ADSs.

## **Implications of Being an Emerging Growth Company and a Foreign Private Issuer**

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or JOBS Act. As such, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other publicly traded entities that are not emerging growth companies. These exemptions provide that:

- we may present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- we are not required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board (PCAOB), regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; and
- we are not required to submit certain executive compensation matters to shareholder advisory votes, such as "say-on-pay," "say-on-frequency" and "say-on-golden parachutes;" and we are not required to disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the closing of this offering or such earlier time that we no longer qualify as an emerging growth company. As a result, the information we provide to our shareholders may be different than you might receive from other public reporting companies in which you hold equity interests.

Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 13(a) of the Exchange Act, for complying with new or revised accounting standards. Accordingly, as an emerging growth company, we have elected to utilize this exemption and delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

Upon the closing of this offering, we will report under the Exchange Act as a non-U.S. company with foreign private issuer status. For as long as we qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specific information, or current reports on Form 8-K, upon the occurrence of specified significant events.

Both foreign private issuers and emerging growth companies are also exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer.

### The Offering

ADSs offered by us	2,500,000 ADSs representing 5,000,000 ordinary shares (or 2,875,000 ADSs representing 5,750,000 ordinary shares if the underwriters exercise their option to purchase additional ADSs in full).
Ordinary shares to be outstanding after this offering	21,640,446 ordinary shares (or 22,390,446 ordinary shares if the underwriters exercise their option to purchase additional ADSs in full).
Option to purchase additional ADSs	We have granted the underwriters an option to purchase up to 375,000 additional ADSs representing 750,000 ordinary shares from us within 30 days of the date of this prospectus.
American Depositary Shares	<p>Each ADS represents 2 ordinary shares.</p> <p>The depositary will hold the ordinary shares underlying the ADSs. You will have the rights of an ADS holder or beneficial owner (as applicable) as provided in the deposit agreement among us, the depositary and holders and beneficial owners of ADSs from time to time.</p> <p>To better understand the terms of the ADSs, see "Description of American Depositary Shares." We also encourage you to read the deposit agreement, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part.</p>
ADSs depositary	The Bank of New York Mellon
Use of proceeds	<p>We estimate that we will receive net proceeds from this offering of approximately \$24.2 million, or approximately \$28.1 million if the underwriters exercise their option to purchase additional ADSs in full, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We intend to use the net proceeds from this offering for working capital and general corporate purposes, including for our sales and marketing, to fund our clinical trials and research and development and to repay the outstanding balance of the borrowings under our credit facility.</p> <p>See "Use of Proceeds" for additional information.</p>
Risk factors	See "Risk Factors" and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in the ADSs.
Nasdaq Global Market symbol	"BWAY"

Unless otherwise stated, the number of ordinary shares to be outstanding after this offering is based on 16,640,446 ordinary shares outstanding as of December 31, 2018, and excludes the following:

- 2,308,192 ordinary shares issuable upon the exercise of options outstanding as of December 31, 2018, at a weighted average exercise price of \$6.94 per ordinary share;
- an additional 1,332,008 ordinary shares reserved for future issuance pursuant to the exercise of options under our Share Incentive Plan; and
- 59,761 ordinary shares issuable upon the exercise of a warrant to purchase our ordinary shares, with an exercise price of \$5.02 per share, held by Mizrahi Tefahot Bank Ltd., which we refer to as Mizrahi Tefahot Bank.

Unless otherwise indicated, all information in this prospectus assumes or gives effect to:

- an initial public offering price of \$11.00 per ADS; and
- no exercise by the underwriters of their option to purchase up to 375,000 additional ADSs from us.

**SUMMARY FINANCIAL DATA**

The following tables present our summary statement of operations for the years ended December 31, 2017 and 2018, and our summary balance sheet data as of December 31, 2018. Our summary statement of operations for the years ended December 31, 2017 and 2018, and our summary balance sheet as of December 31, 2018 has been derived from our audited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected in the future, and results for the year ended December 31, 2018 are not necessarily indicative of the results to be expected for any future period. We prepare our financial statements in accordance with the International Financial Reporting Standard (IFRS), as issued by the International Accounting Standards Board (IASB). You should read this summary financial data together with "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

<u>(In thousands, other than share and per share data)</u>	<u>Year Ended</u> <u>December 31,</u>	
	<u>2017</u>	<u>2018</u>
<b>Statement of Operations Data:</b>		
Revenues	\$ 11,145	\$ 16,397
Cost of revenues	2,595	3,589
Gross profit	8,550	12,808
Research and development expenses, net	5,343	6,156
Selling and marketing expenses	6,331	8,345
General and administrative expenses	3,487	3,421
Total operating expenses	15,161	17,922
Total operating loss	6,611	5,114
Financial expenses, net	274	1,156
Loss before income taxes	6,885	6,270
Income taxes	169	209
Net loss and total comprehensive loss	7,054	6,479
Basic and diluted net loss per share(1)	(0.48)	(0.39)
Weighted average number of ordinary shares outstanding—basic and diluted	14,768,514	16,640,446

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

<u>(In thousands)</u>	<u>As of December 31, 2018</u>	
	<u>Actual</u>	<u>Pro Forma As Adjusted(2)(3)</u>
<b>Balance Sheet Data:</b>		
Cash, cash equivalents and short-term deposits	\$ 9,069	\$ 33,303
Total assets	23,602	47,836
Total liabilities	16,650	16,650
Accumulated deficit	(61,581)	(61,581)
Total equity	<u>6,952</u>	<u>31,186</u>

- (2) These pro forma adjusted balance sheet data give further effect to the issuance and sale of 2,500,000 ADSs by us in this offering at an initial public offering price of \$11.00 per ADS, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) Excludes (i) 2,308,192 ordinary shares issuable upon the exercise of options outstanding as of December 31, 2018, at a weighted average exercise price of \$6.94 per ordinary share; (ii) an additional 1,332,008 ordinary shares reserved for future issuance pursuant to the exercise of options under our Share Incentive Plan; and (iii) an additional 59,761 ordinary shares for future issuance pursuant to the exercise of a warrant to purchase our ordinary shares, with an exercise price of \$5.02 per share, held by Mizrahi Tefahot Bank.

## RISK FACTORS

*Investing in the ADSs involves a high degree of risk. You should carefully consider the risks described below and all other information contained in this prospectus before you decide to buy the ADSs. If any of the following risks actually occur, our business, financial condition and results of operations could be materially and adversely affected. In that event, the trading price of the ADSs would likely decline and you might lose all or part of your investment. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, cash flows and results of operations.*

### **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 \$7.1 million and \$6.5 million for the years ended December 31, 2017 and 2018, respectively. As a result of ongoing losses, as of December 31, 2018, we had an accumulated deficit of \$61.6 million. While we have sold and leased Deep TMS systems in various markets over the last few years, primarily for MDD, 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 will increase following this offering 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 and the net proceeds of this offering will be sufficient to meet our capital requirements.***

We believe that our existing capital, other sources of liquidity and the net proceeds from this offering 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, and a loan under our credit facility. 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 and OCD, 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 and competitive pressures and technologies. Our industry is characterized by intense competition, including from existing treatments (e.g., anti-depressant medications), a growing number of focal 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 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 currently marketed Deep TMS systems for MDD, OCD 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 focal 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, one of our focal TMS competitors has received FDA clearance for a TMS treatment protocol that can be administered within a shorter time period than Deep TMS. In addition, psychiatrists and other customers may not be able to easily compare Deep TMS to our focal TMS competitors given the absence of 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, if FDA-cleared, 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.

***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 and other psychiatric indications because 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. In one study in a managed care environment, 89% of patients did not receive an adequate medication dosage or duration of treatment from their clinicians. 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. As a result of the foregoing factors, the addressable market for Deep TMS for MDD and OCD 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, 2018, we had 96 employees, including 25 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.

***If coverage for reimbursement is reduced for MDD or is unavailable for OCD or other future indications, physicians may be reluctant to use Deep TMS.***

In the United States, sales of Deep TMS will depend, in part, on the extent to which the treatment sessions using Deep TMS are covered and reimbursed by third-party payers, including private insurers and government healthcare programs. 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. Medicare coverage for Deep TMS as a treatment for MDD generally requires four failures of anti-depressant medications and private insurance coverage for Deep TMS generally requires three to four failures of anti-depressant medications. Reimbursement of Deep TMS as a treatment for MDD is also generally limited to 36 treatment sessions. Currently, there is no third party coverage of Deep TMS as a treatment for OCD, and it may take significant time to obtain sufficient reimbursement coverage before we can fully commercialize Deep TMS for OCD. Further, 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, or due to large annual deductibles associated with certain health insurance plans.

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. Third-party payers often rely upon Medicare coverage policies 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. Therefore, 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 is 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. 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 recently began assembling our proprietary stimulator in our Deep TMS systems for MDD and OCD; 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. 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 such as Mexico and Israel. Additionally, we intend to market and expand the commercialization of Deep TMS in other markets, including Japan, Europe and various 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 and 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 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 undertaking clinical trials of Deep TMS for new indications, including smoking cessation and PTSD. 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 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 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 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 and other potential indications. Our treatments are designed for patients who suffer from significant psychiatric and neurological disorders and addictions, and these patients are more likely to experience significant adverse health outcomes, which could increase the risk of product liability lawsuits. Furthermore, if physicians and other operators are not sufficiently trained in the use of our Deep TMS systems, they may misuse or ineffectively use our system, which may result in unsatisfactory patient outcomes. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients.

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 the result of 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, employers 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, generally 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.

***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 regulated at 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), and by various laws at the state level, 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 liable for compliance with HIPAA.

While we implemented security measures relating to our operations, generally, those measures may not prevent security breaches that could harm our business. Advances in computer capabilities, inadequate technology or facility security measures or other factors may result in a compromise or

breach of our systems and the data and PHI we store and process. Our security measures may be breached as a result of actions by third parties or employee error or malfeasance. 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 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 and 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 the chairman of our board of directors, Dr. David Zacut, our chief executive officer, Mr. Yaacov Michlin, and our chief scientist, Dr. Yiftach Roth, 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 have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. 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 clearances or approvals for our future indications, and failure to timely obtain necessary clearances or approvals for our 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.

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, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens

on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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, by 2020 comply 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. We will need to submit a request for 510(k) clearance of our proprietary stimulator as a modification to the recent

marketing authorization for the OCD indication prior to incorporating the proprietary stimulator into Deep TMS systems commercialized for the OCD indication.

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 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. 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 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 and OCD 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." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use Deep TMS off-label. Furthermore, the use of Deep TMS for MDD or OCD other than as stated on the FDA label, or for indications other than those authorized by the FDA, may not effectively 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.

If the FDA or any foreign regulatory body 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.

***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 \$11,181 to \$22,363 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 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:

- imposes an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions (described in more detail below), although the effective rate paid may be lower. Under the Consolidated Appropriations Act of 2016 and due to subsequent legislative amendment, the excise tax has been suspended through December 31, 2019;
- 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 certain aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has 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. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes 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." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including delaying imposition of the medical device excise tax on non-exempt medical devices through December 31, 2019. As a result, there is significant uncertainty regarding future healthcare reform and its impact on our operations.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will stay in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several types of

providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Recently there has been heightened governmental scrutiny over the manner in which drug and medical device manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to product pricing, reduce the cost of certain products under Medicare, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies. At the state level, individual states in the United States are also increasingly passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures.

Moreover, the policies of the Trump Administration and their impact on the regulation of our products in the United States remain uncertain. The outcome of the 2016 election and the 2018 Congressional mid-term elections resulting in a split in majority control between the House of Representatives and the Senate could result in significant legislative and regulatory reforms impacting the FDA's regulation of our products. Any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business. We also expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

***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 Operations in Israel**

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

Our business and operations 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 operations 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.***

In the future, we expect that a substantial portion of our revenues will be generated in U.S. dollars, although we currently incur a significant portion of our expenses in currencies other than U.S. dollars, such as NIS. Our financial records are maintained, and will be maintained, in U.S. dollars, although many of our expenses are incurred in NIS. As a result, our financial results may be affected by fluctuations in the exchange rates of currencies in the 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, this offering and, 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 recently 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, as of the date of this prospectus, 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 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 waiver, 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 the Offering and the ADSs**

### ***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 Nasdaq or the 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 31% of our outstanding ordinary shares as of April 2, 2019 and, after giving effect to this offering (assuming no exercise by the underwriters to purchase additional ADSs), 24% of our ordinary shares. 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.

***You will experience immediate and substantial dilution in the net tangible book value of the ADSs you purchase in this offering.***

As of December 31, 2018, we had 16,640,446 ordinary shares issued and outstanding, and after this offering, there will be 21,640,446 ordinary shares issued and outstanding (assuming no exercise by the underwriters to purchase additional ADSs). The initial public offering price of the ADSs will substantially exceed the net tangible book value per share of the ADSs immediately after this offering. As a result, you will experience immediate and substantial dilution of approximately \$8.34 per ADS (assuming no exercise by the underwriters of the option to purchase additional ADSs), representing the difference between our net tangible book value per share as of December 31, 2018 after giving effect to this offering and after deducting the underwriting discounts, commissions and estimated offering expenses payable by us. As a result of this dilution, as of December 31, 2018, investors purchasing ADSs from us in this offering will have contributed approximately 32% of the total amount of our total gross funding to date but will own only approximately 23% of our equity.

As of December 31, 2018, we had outstanding 2,308,192 ordinary shares issuable upon the exercise of options. We have reserved for future issuance under the Share Incentive Plan options to purchase an additional 1,332,008 ordinary shares. In addition, our credit facility lender, Mizrahi Tefahot Bank, has an outstanding warrant to purchase 59,761 shares of our ordinary shares, with an exercise price of \$5.02 per share and expiry date of October 8, 2022. If outstanding options to purchase our ordinary shares are exercised in the future, additional options are granted under our Share Incentive Plan, or Mizrahi Tefahot Bank exercises its warrant, you will experience additional dilution. See "Dilution" for a more complete description of how the value of your investment in the ADSs will be diluted upon the consummation of this offering and may be diluted in the future.

***There has been no prior public market in the United States for the ADSs, and an active trading market in the United States may not develop.***

Prior to this offering, there has been no public market in the United States for the ADSs. An active trading market in the United States may not develop following completion of this offering or, if developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other companies by using our shares as consideration.

***The market price of the ADSs could be negatively affected by future sales of the ADSs or ordinary shares on either Nasdaq or the TASE, respectively.***

Future sales by us or our shareholders of a substantial number of the ADSs or ordinary shares in the public market following this offering, or the perception that these sales might occur, could cause the market price of the ADSs to decline or could impair our ability to raise capital through a future sale of, or pay for acquisitions using, our equity securities. Of our issued and outstanding shares, all of the ADSs sold in this offering will be freely transferable, except for any shares held by our "affiliates," as that term is defined in Rule 144 under the Securities Act.

Upon the closing of this offering, approximately 24% of our outstanding ordinary shares (assuming no exercise by the underwriters to purchase additional ADSs) will be beneficially owned by shareholders that have agreed with the underwriters that, subject to limited exceptions, for a period of 180 days after the date of this prospectus, they will not directly or indirectly offer, pledge, sell, contract to sell, sell any option or contract to purchase or otherwise dispose of any ordinary shares, ADSs or

any securities convertible into or exercisable or exchangeable for ordinary shares or ADSs, or in any manner transfer all or a portion of the economic consequences associated with the ownership of ordinary shares or ADSs, or cause a registration statement covering any ordinary shares or ADSs to be filed, without the prior written consent of the lead underwriters, which may, at any time without notice, release all or any portion of the shares subject to the corresponding lock-up agreements. After the expiration of the lock-up period, these shares can be resold into the public markets in accordance with the requirements of Rule 144, subject to certain volume limitations.

In addition, we intend to file one or more registration statements on Form S-8 with the Securities and Exchange Commission, or the SEC, covering all of the ordinary shares issuable under our Share Incentive Plan or any other equity incentive plans that we may adopt, and such shares will be freely transferable, except for any shares held by "affiliates," as such term is defined in Rule 144 under the Securities Act. The market price of the ADSs may drop significantly when the restrictions on resale by our existing shareholders lapse and these shareholders are able to sell our ordinary shares into the market.

Upon the filing of the registration statements and following the expiration of the lock-up restrictions described above, the number of ordinary shares and ADSs that are potentially available for sale in the open market will increase materially, which could make it harder for the value of our ordinary shares and ADSs to appreciate unless there is a corresponding increase in demand for our ordinary shares or ADSs. This increase in available shares could result in the value of your investment in the ADSs decreasing.

In addition, the exercise of outstanding or future options or warrants, or a sale by us of additional ordinary shares or ADSs or similar securities in order to raise capital, might have a similar negative impact on the share price of the ADSs. A decline in the price of the ADSs might impede our ability to raise capital through the issuance of additional ordinary shares or ADSs or other equity securities, and may cause you to lose part or all of your investment in the ADSs.

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

By participating in this offering you will become a holder of ADSs with underlying ordinary shares in a company incorporated under Israeli law. 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 depository 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 depository. However, the depository 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 depository may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depository are closed, or at any time if we or the depository 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 depository 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 depository. If a lawsuit is brought against us and/or the depository 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 depository 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.***

Except as described in this prospectus and the deposit agreement, 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 depository 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 depository, 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 depository 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 depository 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 depository'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 depository 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 will be 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 in conjunction with this offering, the ADSs have been approved for listing on the Nasdaq Global Market. 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 have broad discretion as to the use of the net proceeds from this offering and may not use them effectively.***

We intend to use the net proceeds from this offering for working capital and general corporate purposes, including for our sales and marketing, to fund our clinical trials and to repay the outstanding balance of the borrowings under our credit facility. For more information, see "Use of Proceeds." However, our management will have broad discretion in the application of the net proceeds. Our shareholders may not agree with the manner in which our management chooses to allocate the net proceeds from this offering. The failure by our management to apply these funds effectively could have

a material adverse effect on our business, financial condition and results of operation. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income.

***We do not intend to pay dividends for at least the next several years following this offering.***

We do not anticipate paying any cash dividends for at least the next several years following this offering. 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 intend to follow certain home country corporate governance practices instead of certain Nasdaq requirements.***

As a foreign private issuer whose shares will be 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 intend to establish a quorum requirement such that the quorum for any meeting of shareholders is two or more shareholders holding at least 33<sup>1</sup>/<sub>3</sub>% 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 intend to 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 intend to 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 will be 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 will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be 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 will incur increased costs as a result of operating as a public company in the United States, and our management will 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 will 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 will 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. We expect that these rules and regulations will increase our legal and financial compliance costs, introduce new costs such as investor relations, increased insurance premiums and stock exchange listing fees, and will make some activities more time-consuming and costly. Our board and other personnel will need to devote a substantial amount of time to these initiatives. We are currently 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 may 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 second annual report that we file with the SEC after the closing of this offering, 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 this offering. 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) the last day of our fiscal year following the fifth anniversary of the closing of this offering; (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 and certain gains, and cash (including cash raised in this offering) 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 also may 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, including this offering. 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."

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

We make forward-looking statements in this prospectus that are subject to risks and uncertainties. These forward-looking statements include information about possible or assumed future results of our business, financial condition, results of operations, liquidity, plans and objectives. In some cases, you can identify forward-looking statements by terminology such as "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "potential," or the negative of these terms or other similar expressions. Forward-looking statements are based on information we have when those statements are made or our management's good faith belief as of that time with respect to future events and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- the adequacy of our existing capital and the net proceeds of this offering to meet our future capital requirements;
- market perception and acceptance of Deep TMS technology;
- physician and patient satisfaction with the effectiveness and 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; and
- our ability to obtain and maintain adequate protection of our intellectual property, including intellectual property licensed to us.

You should review carefully the risks and uncertainties described under the heading "Risk Factors" in this prospectus for a discussion of these and other risks that relate to our business and investing in the ADSs. The forward-looking statements contained in this prospectus are expressly qualified in their entirety by this cautionary statement. Except as required by law, we undertake no obligation to update publicly any forward-looking statements after the date of this prospectus to conform these statements to actual results or to changes in our expectations.



## USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$24.2 million, or approximately \$28.1 million if the underwriters exercise in full their option to purchase additional ADSs, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering for working capital and general corporate purposes, including for our sales and marketing, to fund our clinical trials and research and development and to repay the outstanding balance of the borrowings under our credit facility. Specifically, we intend to use net proceeds as follows:

- up to \$10 million for sales and marketing;
- \$5 million for our clinical trial of Deep TMS for opioid addiction; \$5 million for our clinical trial of Deep TMS for fatigue in MS; and \$5 million for our clinical trial of Deep TMS for post-stroke rehabilitation;
- \$3 million to repay the outstanding balance of our borrowings under our credit facility with Mizrahi Tefahot Bank, which bears interest equal to quarterly LIBOR + 6%, and is repayable in eight equal quarterly installments commencing April 2019 and ending January 2021; and
- the remainder for working capital and general corporate purposes.

We believe that the net proceeds of this offering, together with 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.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition, which could change in the future as our plans and business conditions evolve. We believe that the proceeds dedicated to finance our clinical trials for the indications noted above will be sufficient to complete those trials. However, we cannot predict with certainty any or all of the particular uses for the net proceeds to be received upon the closing of this offering, or the amounts, if any, that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to successfully commercialize Deep TMS, our ability to continue development of our clinical trials, and timing of FDA clearance for additional indications for Deep TMS. As a result, our management will have broad discretion in the application of the net proceeds, which may include uses not set forth above, and investors will be relying on our judgment regarding the application of the net proceeds from this offering. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business.

Pending their use, we plan to invest the net proceeds from this offering in short and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government or to hold such proceeds as cash. We cannot predict whether these investments will yield a favorable return.

## **DIVIDEND POLICY**

We have never declared or paid any cash dividends, and we anticipate that, for the foreseeable future, we intend to retain any future earnings to support operations and to finance the growth and development of our business. Accordingly, we do not expect to pay cash dividends in the foreseeable future.

The distribution of dividends may also be limited by the Israeli Companies Law, which permits the distribution of dividends only out of retained earnings or earnings derived over the two most recent fiscal years, whichever is higher, provided that there is no reasonable concern that payment of a dividend will prevent us from satisfying our existing and foreseeable obligations as they become due. Our articles of association provide that dividends will be paid at the discretion of, and upon resolution by, our board of directors, subject to the provisions of the Israeli Companies Law.

**CAPITALIZATION**

The following table sets forth our cash and cash equivalents and short-term deposits and capitalization as of December 31, 2018, on:

- an actual basis;
- a pro forma as adjusted basis, to give further effect to (1) the amendment to our articles of association to increase our authorized share capital (see "Description of Share Capital") and (2) the issuance and sale of 2,500,000 ADSs in this offering at the initial public offering price of \$11.00 per ADS, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us (and assuming no exercise of the underwriters' option to purchase up to an additional 375,000 ADSs at the initial public offering price).

You should read this table in conjunction with our financial statements and related notes included elsewhere in this prospectus and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

(In thousands, except share data)	As of December 31, 2018	
	Actual	Pro Forma As Adjusted
Cash and cash equivalents and short term deposits	\$ 9,069	\$ 33,303
Loan from bank—long-term	2,083	2,083
Equity:		
Ordinary shares—share capital of NIS 0.04 par value per share; 25,000,000 shares authorized and 16,640,446 shares issued and outstanding, actual; 35,000,000 shares authorized and 21,640,446 issued and outstanding, pro forma as adjusted	171	226
Share premium	67,193	91,372
Share-based payment	3,357	3,357
Adjustments arising from translating financial statements from functional currency to presentation currency	(2,188)	(2,188)
Accumulated deficit	(61,581)	(61,581)
Total equity	6,952	31,186
Total capitalization	\$ 9,035	\$ 33,269

The preceding table excludes (i) 2,308,192 ordinary shares issuable upon the exercise of options outstanding as of December 31, 2018, at a weighted average exercise price of \$6.94 per ordinary share; (ii) an additional 1,332,008 ordinary shares reserved for future issuance pursuant to the exercise of options under our Share Incentive Plan; and (iii) an additional 59,761 ordinary shares for future issuance pursuant to the exercise of a warrant to purchase our ordinary shares, with an exercise price of \$5.02 per share, held by Mizrahi Tefahot Bank.

## DILUTION

If you invest in the ADSs in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per ADS and the net tangible book value per ADS after this offering. Our net tangible book value as of December 31, 2018, was approximately \$4.5 million, or \$0.54 per ADS. Net tangible book value per ADS was calculated by:

- subtracting our liabilities from our tangible assets;
- dividing the difference by the number of ordinary shares outstanding; and
- multiplying such amount by 2 (one ADS represents 2 ordinary shares).

After giving further effect to the issuance and sale of 2,500,000 ADSs in this offering at the initial public offering price of \$11.00 per ADS, after deducting underwriting discounts and commissions and estimated offering expenses payable by us (and assuming no exercise of the underwriters' option to purchase up to an additional 375,000 ADSs at the initial public offering price), our as adjusted net tangible book value on December 31, 2018 would have been approximately \$28.7 million, or \$2.66 per ADS. This represents an immediate dilution in the as adjusted net tangible book value of \$8.34 per ADS to investors purchasing the ADSs in this offering.

The following table illustrates the immediate dilution to new investors:

Initial public offering price per ADS	\$ 11.00
Historical net tangible book value per ADS as of December 31, 2018	0.54
Increase in as adjusted net tangible book value per ADS attributable to the offering	2.12
As adjusted net tangible book value per ADS after this offering	2.66
Dilution per ADS to new investors	<u>\$ 8.34</u>
Percentage of dilution per ADS to new investors	<u>76%</u>

If the underwriters' option to purchase additional shares from us is exercised in full, the as adjusted net tangible book value would be \$2.90 per ADS and the dilution per ADS to new investors in this offering would be \$8.10, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The table below summarizes, on a pro forma basis as of December 31, 2018, the differences for our existing shareholders and new investors in this offering, with respect to the number of ordinary shares (treating each ADS as 2 ordinary shares) purchased from us, the total consideration paid and the average price per ordinary share paid before deducting fees and offering expenses.

	Shares purchased		Total consideration		Average price per ADS
	Number	%	Amount in Thousands	%	
Existing shareholders	16,640,446	77%	\$ 57,961	68%	\$ 6.97
New investors	5,000,000	23%	27,500	32%	11.00
Total	21,640,446	100%	\$ 85,461	100%	\$ 7.90

The table and discussion above excludes (i) 2,308,192 ordinary shares issuable upon the exercise of options outstanding as of December 31, 2018, at a weighted average exercise price of \$6.94 per ordinary share; (ii) an additional 1,332,008 ordinary shares reserved for future issuance pursuant to the exercise of options under our Share Incentive Plan; and (iii) an additional 59,761 ordinary shares for future issuance pursuant to the exercise of a warrant to purchase our ordinary shares, with an exercise price of \$5.02 per share, held by Mizrahi Tefahot Bank. If all of our outstanding options and warrants as of December 31, 2018 were exercised (treating each ADS as 2 ordinary shares), (1) existing investors

would represent 80% of ADSs, representing a total consideration of 73% of ADSs and an average price per ADS of \$7.30; (2) new investors would represent 20% of ADSs, representing a total consideration of 27% of ADSs and an average price per ADS of \$11.00; and (3) the average price per ADS for all investors would be \$8.03.

To the extent any additional options are issued under our Share Incentive Plan, or we issue additional ADSs or ordinary shares in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our shareholders.

**SELECTED FINANCIAL DATA**

The following table sets forth our selected historical financial data, which is derived from our audited financial statements, which have been prepared in accordance with the IFRS. The selected balance sheet data as of December 31, 2017 and 2018 and our selected statements of comprehensive loss data for the years ended December 31, 2017 and 2018 were derived from our audited financial statements included elsewhere in this prospectus. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the financial information in those statements. Our historical results are not necessarily indicative of the results that should be expected in the future, and results for the year ended December 31, 2018 are not necessarily indicative of the results to be expected for any future period. You should read this selected financial data in conjunction with, and it is qualified in its entirety by, reference to our historical financial information and other information provided in this prospectus including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

<b>(In thousands, other than share and share data)</b>	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2018</b>
<b>Statement of Operations Data:</b>		
Revenues	\$ 11,145	\$ 16,397
Cost of revenues	2,595	3,589
Gross profit	8,550	12,808
Research and development expenses, net	5,343	6,156
Selling and marketing expenses	6,331	8,345
General and administrative expenses	3,487	3,421
Total operating expenses	15,161	17,922
Total operating loss	6,611	5,114
Financial expenses, net	274	1,156
Loss before income taxes	6,885	6,270
Income taxes	169	209
Net loss	7,054	6,479
Basic and diluted net loss per share(1)	(0.48)	(0.39)
Weighted average number of ordinary shares outstanding—basic and diluted	14,768,514	16,640,446

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

<b>(In thousands)</b>	<b>As of</b>	
	<b>December 31, 2017</b>	<b>December 31, 2018</b>
<b>Balance Sheet Data:</b>		
Cash, cash equivalents and short-term deposits	\$ 14,559	\$ 9,069
Total assets	27,030	23,602
Total liabilities	14,309	16,650
Accumulated deficit	(55,102)	(61,581)
Total equity	12,721	6,952

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis should be read in conjunction with our financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of the prospectus contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. See "Special Note Regarding Forward-Looking Statements."*

### Overview

We are a commercial stage medical device company focused on the development and sale of non-invasive neuromodulation products using our proprietary Deep Transcranial Magnetic Stimulation (Deep TMS), technology for the treatment of major depressive disorder (MDD) and obsessive-compulsive disorder (OCD), 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 have commenced sales and marketing efforts for that indication. 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, 2018.

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 currently conducting multicenter clinical trials to support FDA clearance of Deep TMS for smoking cessation and PTSD. We are also planning multicenter trials for other indications, including opioid addiction, fatigue in multiple sclerosis (MS), and post-stroke rehabilitation, the latter of which are the first neurological indications that we plan to advance into multicenter trials.

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 standard MDD or OCD session lasts 20 and 19 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 four years, 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 higher of: fees per treatment (i.e., usage based fees) or an annual minimum fee as stated in the contract, 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, 2018, approximately 50% of our Deep TMS systems installed base for MDD utilized the fixed-fee lease model, approximately 40% utilized the sales model and approximately 10% utilized our risk share model. We have started, and expect to continue, to commercialize Deep TMS for OCD based solely on the risk share model, which charges per session and per treatment, in an effort to achieve greater market acceptance for that indication.

As of December 31, 2018, we had an installed base of approximately 383 Deep TMS systems, whereby 237 systems were leased from us (inclusive of our fixed fee model and our risk share model) and an additional 146 systems were sold by us prior to December 31, 2018. Our installed base increased by 33 systems during the fourth quarter of 2018. In addition, as of December 31, 2018, we had shipped 58 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, 2018, our revenues were \$16.4 million compared to \$11.1 million for the year ended December 31, 2017, representing an increase of 47% over the revenues generated in 2017. We incurred net losses of \$6.5 million for the year ended December 31, 2018.

As of December 31, 2018, our total committed payments under signed lease contracts was approximately \$29.4 million, assuming no exercise of any early termination options, representing an increase of \$9.1 million from our total committed payments as of December 31, 2017 of approximately \$20.3 million. See "Key Business Metrics—Committed Payments."

As of December 31, 2018, we had an accumulated deficit of \$61.6 million. Our primary sources of capital to date have been from public offerings in Israel 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 clinical trials of Deep TMS to support future FDA clearance for smoking cessation and PTSD and our planned clinical trials for opioid addiction, fatigue in MS and post-stroke rehabilitation. In addition, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We believe that the net proceeds of this offering, together with 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 four years). 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 an annual minimum fee (determined based on a minimum number of monthly or annual treatments). As in the fixed-fee



lease model, these leases generally have a term of up to four years. The pricing of the minimal annual fee generally assumes approximately 400 sessions per year.

- **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 recently developed and have received FDA clearance for our own proprietary stimulator for MDD (in May 2018) and OCD (in March 2019). 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 smoking cessation and PTSD 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 and investor relations and 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, interest expense payable under our credit facility and the amortization of deferred financing costs related to our bank loan and 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, 2017 and 2018, 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.

## **Key Business Metrics**

### ***Committed Payments***

Committed payments is a non-IFRS financial metric that we define as an aggregate amount of minimum lease payments under signed contracts pursuant to our fixed-fee lease and risk share pricing models (variable fees). We consider committed payments to be a useful metric for management and investors because it is an important indicator of our expected revenues to be recognized over the respective lease terms. Committed payments assume no exercise of the customer's early termination option under the relevant contract.

We believe that this non-IFRS financial measure is useful in evaluating our business as a way of assisting an investor in evaluating future cash flows of our business.

Below is a table showing a breakdown of our committed payments, by year in which such payments are expected to be made, for (1) leases signed in the three months ended December 31, 2018, (2) all signed leases as of December 31, 2018 and (3) signed leases as of December 31, 2018 with early termination options:

(in thousands)	Total	2018 <sup>(1)</sup>	2019	2020	2021	2022 and thereafter
Leases signed in the three months ended December 31, 2018 <sup>(2)(3)</sup>	\$ 4,892	\$ 419	\$ 712	\$ 1,210	\$ 1,383	\$ 1,168
All signed leases as of December 31, 2018 <sup>(2)(4)</sup>	38,607	9,783	10,746	8,802	6,083	3,193
Signed leases as of December 31, 2018 with early termination options <sup>(5)</sup>	9,192	1,802	2,862	2,502	1,558	468

- (1) Includes revenues recognized during the year ended December 31, 2018.
- (2) Assumes no exercise of early termination options.
- (3) Increases in our committed payments from leases signed in preceding quarters were \$4.4 million for the three months ended September 30, 2018, \$4.5 million for the three months ended June 30, 2018, \$3.8 million for the three months ended March 31, 2018, \$4.2 million for the three months ended December 31, 2017, \$4.0 million for the three months ended September 30, 2017, \$4.1 million for the three months ended June 30, 2017 and \$3.8 million for the three months ended March 31, 2017.
- (4) Included in these amounts are the leases signed in the three months ended December 31, 2018.
- (5) Included within all signed leases as of December 31, 2018.

With regard to the leases using the risk share model (variable fees), 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 an annual minimum fee (determined based on a minimum number of monthly or annual treatments). To the extent the customer uses the TMS System beyond the minimum number of treatments in the lease, the customer would pay additional fees to us. Since we cannot predict the actual usage by our customers under such leases, any such additional fees are not estimable at this time and are not included in the table above.

### 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 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 prospectus. 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 four years, 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 higher of: fees per treatment (i.e., usage based fees) or an annual minimum fee as stated in the contract. 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.

### ***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, we have a market price per share of our ordinary shares. Until September 30, 2018, the exercise price for the options was determined based on the average price per share over the 30 trading days 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 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 prior to the grant date plus a premium of 10% and (ii) the last closing price per share 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.

**Results of operations**

The following table summarizes our results of operations for the indicated periods:

(in thousands)	For the Year Ended	
	December 31,	
	2017	2018
Revenues	\$ 11,145	\$ 16,397
Cost of revenues	2,595	3,589
Gross profit	\$ 8,550	\$ 12,808
Research and development expenses, net	\$ 5,343	\$ 6,156
Selling and marketing expenses	6,331	8,345
General and administrative expenses	3,487	3,421
Total operating expenses	15,161	17,922
Total operating loss	6,611	5,114
Finance expenses, net	274	1,156
Loss before income taxes	6,885	6,270
Income taxes	169	209
Net loss and comprehensive loss	\$ 7,054	\$ 6,479

**Year ended December 31, 2018 compared to year ended December 31, 2017****Revenues**

Our total revenues increased by \$5.3 million, or 47%, from \$11.1 million for the year ended December 31, 2017 to \$16.4 million for the year ended December 31, 2018. The increase in revenues was attributed mainly to the ongoing and steady increase in our revenues from the lease of Deep TMS systems in accordance with our strategic decision to shift our sales and marketing focus to the lease and risk share models, which was further supported by an increase in direct sales. Revenues from leases (inclusive of our fixed-fee model and risk share model) were 58% of the revenues for the year ended December 31, 2018, compared to 60% of the revenues for the year ended December 31, 2017.

**Cost of revenues and gross margin**

Our cost of revenues increased by \$1.0 million, or 38%, from \$2.6 million for the year ended December 31, 2017 to \$3.6 million for the year ended December 31, 2018. The increase in cost of revenues is in line with our increase in revenues. There was no material change in the gross margin, which was 78% for the year ended December 31, 2018 compared to 77% for the year ended December 31, 2017.

**Research and development expenses, net**

Our research and development expenses, net, were \$6.2 million for the year ended December 31, 2018 compared to \$5.3 million for the year ended December 31, 2017. The increase of \$0.9 million, or 15%, was mainly attributed to the acceleration and growth of our research and development activity, both in clinical trials and in hardware and software development, offset by an increase in the participation of the IIA in projects under development.

**Selling and marketing expenses**

Our selling and marketing expenses were \$8.3 million for the year ended December 31, 2018 compared to \$6.3 million for the year ended December 31, 2017. The increase of \$2.0 million, or 32%,

was mainly attributed to the continued growth in our U.S. marketing activity and in our target markets, including recruitment of sales, marketing and support personnel in the United States.

### **General and administrative expenses**

Our general and administrative expenses were \$3.4 million for the year ended December 31, 2018 compared to \$3.5 million for the year ended December 31, 2017. The change was immaterial.

### **Finance expenses, net**

Our finance expenses, net, were \$1.2 million for the year ended December 31, 2018 compared to \$0.3 million for the year ended December 31, 2017. The increase of \$0.9 million, or 322%, was mainly attributed to fluctuations in foreign currency exchange rates, interest expense and amortization of deferred costs of a bank loan and fair value re-measurement related to our outstanding liability to the IIA on account of grants received for financing our research and development activity.

## **Liquidity and Capital Resources**

### **Overview**

As of December 31, 2018, we had cash, cash equivalents and short-term deposits of \$9.1 million and an accumulated deficit of \$61.6 million, compared to cash and short-term deposits of \$10.6 million and an accumulated deficit of \$59.1 million as of December 31, 2017. We incurred negative cash flows from operating activities of \$3.5 million and \$3.8 million for the years ended December 31, 2017 and 2018, 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 Israel and private placements of our securities, grants from the IIA, borrowings under our credit facility and leases and sales of our Deep TMS systems. From inception through December 31, 2018, we raised \$58 million from placements of our ordinary shares and exercise of options, and as of December 31, 2018, we had \$3 million of borrowings outstanding under our credit facility, which matures in April 2021 and has \$3 million of additional borrowing capacity. We intend to repay the outstanding balance of the loan with the proceeds of this offering and terminate the credit facility following the closing of this offering.

We expect our revenues and expenses to increase in connection with our on-going activities, particularly as we expand the marketing of our Deep TMS system for MDD and OCD, and for other indications for which we receive regulatory authorizations in the future. Furthermore, following the completion of this offering, we expect to incur additional costs as a U.S. public company. Based on our current business plan, we believe that our cash and cash equivalents as of December 31, 2018, anticipated revenues from sales of our products and net proceeds from this offering 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, expand our existing credit facility or 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.

## Indebtedness

### *Credit facility agreement with Mizrahi Tefahot Bank*

On August 17, 2017, our wholly owned subsidiary, Brain Research and Development Services Ltd., entered into a credit facility agreement with Mizrahi Tefahot Bank Ltd., which we refer to as Mizrahi Tefahot Bank, for the provision of two (2) lines of credit in the amount of \$3 million each and \$6 million in the aggregate. The first line of credit was drawn in its entirety on October 8, 2017, and the second line was extended in March 2019, and may be drawn and utilized through May 30, 2019. As of December 31, 2018, the outstanding principal balance under the credit facility was \$3 million.

The first line of credit is repayable over a period of 42 months and bears quarterly interest in the amount of LIBOR + 6%, which was 8.47% in the quarter ended December 31, 2018. The principal of the first line of credit is repayable in eight (8) consecutive equal payments with the first payment due 18 months after the date that the loan was drawn. If the second line of credit is withdrawn, such second line of credit will be repayable over a period of 36 months and will bear quarterly interest in the amount of LIBOR + 6%.

As part of the credit terms, Mizrahi Tefahot Bank was granted a warrant to purchase 59,761 of our ordinary shares at an exercise price of \$5.02 per share. In the event that we use the second line of credit described above, the number of ordinary shares issuable upon the exercise of the warrant may be increased by up to an additional 59,761 ordinary shares. We do not intend to use the second line of credit.

We are entitled at any time to make early repayment of the loan, in whole or in part, subject to the payment of an early repayment fee. We intend to repay the outstanding balance of the loan and terminate the credit facility following the closing of this offering.

As security interest for the loan, we granted to Mizrahi Tefahot Bank a first fixed and floating charge over all our assets and the assets of our subsidiaries, including accounts receivables and including a fixed charge on a specific cash deposit in an amount of not less than 33.3% of the unpaid outstanding loan at any time. In addition, we and each of our subsidiaries guaranteed the bank loan.

Under our credit facility agreement, we also undertook certain financial covenants. In addition, we undertook not to make any distribution to our shareholders until repayment, which we expect to do with the proceeds of this offering. All covenants are currently met.

## Cash flows

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

(in thousands)	Year Ended	
	December 31,	
	2017	2018
Net cash used in operating activities	\$ (3,467)	\$ (3,773)
Net cash used in investing activities	(2,451)	(1,136)
Net cash provided by (used in) financing activities	11,108	(265)
Exchange rate differences on cash and cash equivalents	145	(367)
Increase (decrease) in cash and cash equivalents	\$ 5,335	\$ (5,541)



### *Operating Activities*

Net cash used in operating activities was \$3.8 million during the year ended December 31, 2018, compared to \$3.5 million used during the year ended December 31, 2017. The increase of \$0.3 million was immaterial.

### *Investing Activities*

Net cash used in investing activities was \$1.1 million during the year ended December 31, 2018 compared to net cash provided by investing activities of \$2.5 million during the year ended December 31, 2017. The decrease of \$1.4 million was mainly attributed to the release of a restricted deposit in 2018.

### *Financing Activities*

Net cash used in financing activities was \$0.3 million during the year ended December 31, 2018 compared to \$11.1 million produced by financing activities during the year ended December 31, 2017. The change was mainly attributed to a receipt of a loan from a bank of \$2.7 million and net proceeds from the issuance of ordinary shares of \$8.5 million in 2017.

### **Government Grants**

As of December 31, 2018, we have received grants from the IIA in an aggregate amount of approximately \$12.2 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, 2018, we have paid royalties to the IIA in an aggregate amount of approximately \$1.4 million (including amounts in respect of accrued interest), with remaining outstanding royalties of up to \$12.8 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, we received from MAGNET approvals for grants in an aggregate amount of NIS 8.6 million (approximately \$2.3 million based on the NIS to USD exchange rate as of December 31, 2018). 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.

### Private Placement

On December 11, 2017, we completed a private placement of our ordinary shares to a group of shareholders led by the Phoenix Provident Fund, pursuant to which the investors invested an aggregate gross amount of \$8.6 million in consideration for 1,924,662 of our ordinary shares.

### Research and Development Expenses, Net

The following table describes our research and development expenses, net, for the indicated periods:

(in thousands)	Year Ended December 31,	
	2017	2018
Salaries and related benefits	\$ 2,954	\$ 3,365
Subcontractors	1,584	2,241
Laboratory materials	453	491
Patents	134	198
Share-based payment	180	31
Travel	35	65
Depreciation	35	31
Other	362	658
Less—Government grants	(394)	(924)
Total research and development expenses, net	<u>\$ 5,343</u>	<u>\$ 6,156</u>

While we are currently focused on developing future indications and enhancements to our system, our future research and development expenses will depend on the clinical success of each indication and the rate of patient recruitment, among other factors. We expect our research and development expenses to increase from current levels as we advance our clinical trials. The lengthy process of completing clinical trials and seeking regulatory approvals for new indications for our system requires substantial expenditures. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause our research and development expenses to increase and adversely affect our results of operations.

### Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2018 based on contractual payments:

(in thousands)	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating lease obligations(1)	\$ 1,414	\$ 404	\$ 770	\$ 239	\$ —
Principal under credit facility(2)	3,000	750	2,250	—	—
Interest under credit facility(2)	398	238	160	—	—
Liability in respect of research and development grants (undiscounted)(3)	13,484	631	2,040	3,435	7,378
Others	3	2	1	—	—
Total	<u>\$ 18,299</u>	<u>\$ 2,025</u>	<u>\$ 5,221</u>	<u>\$ 3,673</u>	<u>\$ 7,378</u>

- (1) Operating lease obligations consist of our corporate facilities. Our total lease payments on all of our facilities are approximately (without vehicles) \$36,000 per month.
- (2) We intend to repay the outstanding balance of the amounts due under the credit facility with the proceeds of this offering and terminate the credit facility promptly following the closing of this offering.

- (3) 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.

### **Off-Balance Sheet Arrangements**

We do not have any, and during the periods presented we did not have any, off-balance sheet arrangements.

### **Quantitative and Qualitative Disclosure about Market Risk**

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of foreign currency exchange rates, which is discussed in detail below.

#### ***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 45% of our expenses in the year ended December 31, 2018, 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 9% during the year ended December 31, 2018. 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. See "Risk Factors—Exchange rate fluctuations between the U.S. dollar, the NIS and other foreign currencies, may negatively affect our future revenues." If the NIS fluctuates significantly against the U.S. dollar it may have a negative impact on our results of operations. As of the date of this prospectus, and for the periods under review, fluctuations in the currency exchange rates have not materially affected our results of operations or financial condition.

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.

#### ***Inflation-related risks***

We do not believe that the rate of inflation in Israel has had a material impact on our business to date, however, our costs in Israel will increase if the inflation rate in Israel exceeds the devaluation of the NIS against the U.S. dollar or if the timing of such devaluation lags behind inflation in Israel.

### **Recent Accounting Pronouncements**

For a description of our recently issued accounting pronouncements, see Note 2(d) to our interim consolidated financial statements appearing elsewhere in this prospectus.

## **JOBS Act**

Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2) (B) of the Securities Act for complying with new or revised accounting standards. This means that an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to utilize this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. In addition, as a result of this election, our future financial statements may not be comparable to those of public companies that are not emerging growth companies and are required to comply with public company effective dates for new or revised accounting standards.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we also elected or may elect to rely on other exemptions, including without limitation, not (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). These exemptions will apply until the earliest of (a) the last day of our fiscal year in which we have total annual gross revenues of at least \$1.07 billion; (b) the last day of our fiscal year following the fifth anniversary of the closing of this offering; (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.

## BUSINESS

### Overview

We are a commercial stage medical device company focused on the development and sale of non-invasive neuromodulation products using our proprietary Deep Transcranial Magnetic Stimulation (Deep TMS) technology for the treatment of major depressive disorder (MDD) and obsessive-compulsive disorder (OCD), 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 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 Focal TMS, that generally use a "figure 8" design. We believe that our Deep TMS technology has the potential to be safe and effective for the treatment of a wide range of psychiatric, neurological and addiction disorders beyond MDD and OCD.

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 2015 study by the World Health Organization (WHO), MDD 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 16.2 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 4.9 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.

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 are the first and only medical device company to offer an FDA-authorized non-invasive treatment for OCD, the marketing authorization for which we received in August 2018 as an adjunct therapy for adult patients suffering from OCD. Our pivotal trial for OCD demonstrated statistically significant response and partial response rates of 38.1% and 54.8%, respectively, after six weeks of daily active Deep TMS treatment of 19 minutes per session, compared to 11.1% and 26.7%, respectively, after sham treatment.

We 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 currently conducting multicenter clinical trials to support FDA clearance of Deep TMS for smoking cessation and PTSD. We are also planning multicenter trials for other indications, including opioid addiction, multiple sclerosis (MS), and post-stroke rehabilitation, the latter of which are the first neurological indications that we plan to advance into multicenter trials.

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 standard MDD or OCD session lasts 20 minutes and 19 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.

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 three to four failures of anti-depressant medications. In addition, our MDD treatment with Deep TMS may be eligible for reimbursement from Medicare, and is expected to be available after four failures of anti-depressant medications. Deep TMS for OCD is not currently eligible for reimbursement. However, we believe that 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 novelty of the technology, unmet clinical need and the efficacy and safety profile of the treatment.

The United States is our primary and most strategic market, representing approximately 88% of our revenues for the year ended December 31, 2018. 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 are currently ramping up our commercialization efforts of Deep TMS for OCD. We generate revenue from various flexible pricing models that are designed to maximize market penetration. For the year ended December 31, 2018, we generated revenues of \$16.4 million, an increase of 47% compared to the year ended December 31, 2017.

### **Our Deep TMS Platform**

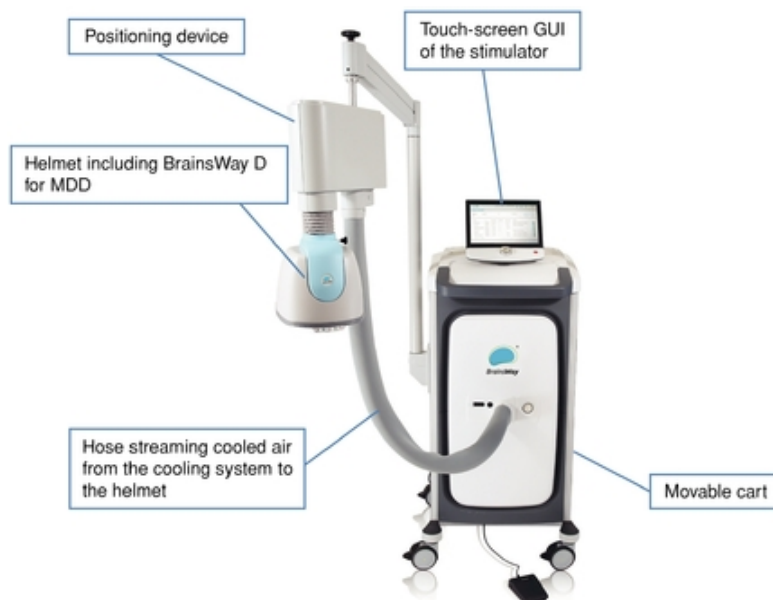
Our proprietary Deep TMS technology is intended for non-invasive treatment of psychiatric, neurological and addiction disorders. The system includes an H-Coil uniquely designed to transmit electric current flows at varying rates, creating an electromagnetic field that serves to depolarize cortical neurons 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 (BrainsWay D) that is used in our Deep TMS system for MDD, and we have another H-Coil for OCD (BrainsWay OCD) that is used for OCD and is in clinical development for PTSD (and future clinical development is planned for opioid addiction). The H-Coils transmit pulses which are generated by a power supply, known as a stimulator. We recently 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 obtained FDA 510(k) clearance for our proprietary stimulator as a modification to the FDA clearance for the MDD indication. 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:

- 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 Focal 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 Focal 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. Focal TMS is limited to the narrow area treated, and the manual placing of the figure 8 coil in Focal 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. A standard MDD or OCD session lasts 20 and 19 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 Focal 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 Focal TMS because it is capable of stimulating deeper and broader areas of the brain. Studies have shown that while Focal 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 D and approximately 3.5 centimeters for BrainsWay OCD. Studies have also shown that BrainsWay D has the capacity for total stimulated brain volume of 17 cm<sup>3</sup> compared to 3 cm<sup>3</sup> for the figure 8 coil used in Focal TMS. We believe this deeper and broader penetration of Deep TMS provides an advantage over Focal 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 Focal 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 Focal 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 Focal TMS.



- ***We have obtained FDA marketing authorizations of Deep TMS for MDD and OCD.***

We are the only company to have obtained FDA marketing authorizations for TMS products in more than one psychiatric indication: MDD, which was FDA-cleared in 2013, and OCD, which was classified by FDA as a Class II device in a *de novo* classification in August 2018. For MDD, we are one of only two TMS companies that have performed clinical studies supporting the FDA clearance. We are the first and only TMS company to have developed a non-invasive medical device that has received FDA marketing authorization for OCD.

- ***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. Overall, Deep TMS treatment was safe and well-tolerated by patients in these trials.

- ***We have a commercial track record for MDD, and are ramping up commercialization for OCD.***

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 the 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 currently ramping up 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.

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

For Deep TMS for MDD, we offer a fixed-fee lease model enabling unlimited use, including warranty and support, or provide an option to purchase, including a one-year warranty. In addition, we offer a risk share model, a pay-per-use pricing model with a minimum annual fee, for MDD, and for OCD, we offer only our risk share model. We believe these pricing models will increase market acceptance among clinics and psychiatric professionals at reduced up-front costs compared to our sales or fixed-lease models. Based on our commercial data, and depending on insurer reimbursement rates, we believe our psychiatrist customers can generate approximately \$10,000 of revenues per patient 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 in advanced stages of several pivotal multicenter clinical trials for smoking cessation and PTSD, and we are also planning trials for fatigue in MS, post-stroke rehabilitation and opioid addiction. In November 2018, 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. We are currently working directly with the FDA to accelerate the performance of our clinical trial for opioid addiction, and subject to the successful outcome of this trial, expedite the marketing approval of Deep TMS for treatment of this disorder. As a result of these developments, all of our regulatory submissions in this process will be subject to priority review by senior FDA officials.

## **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 are continuing to pursue the potential application of Deep TMS for smoking cessation and PTSD through our ongoing pivotal multicenter trials for these indications. 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 and accelerate commercialization of Deep TMS for OCD.***

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 plan to commence full-scale commercialization of our Deep TMS for OCD, which is currently the only non-invasive medical device FDA-authorized for the treatment of OCD, pending reimbursement coverage for this indication.

- ***Advance clinical trials for additional indications for Deep TMS.***

The majority of our research and development efforts are currently focused on completing our multi-center clinical trials for treatment of smoking cessation and PTSD and pursuing other technological innovations. We are also 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 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. We aim to achieve similar levels of reimbursement for Deep TMS for OCD, which was recently granted marketing authorization in the United States, and we are also working to obtain reimbursement for MDD and OCD 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. We believe this design enhancement would make Deep TMS even more efficient to clinicians, researchers and patients, and is potentially well-positioned for use in neurology.

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

We are working to expand our existing commercial footprint in Europe, Latin America and Israel, and pursue commercialization in additional markets, such as Japan and various Asian countries. We have exclusive distribution agreements in Japan, Mexico, Brazil and Israel, and are currently seeking additional distribution partners in other strategic markets. We recently 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 still working through our Japanese distributor with the relevant bodies in Japan to obtain such coverage.

## **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 16.2 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 non-invasive 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 D) for MDD. 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 D 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.

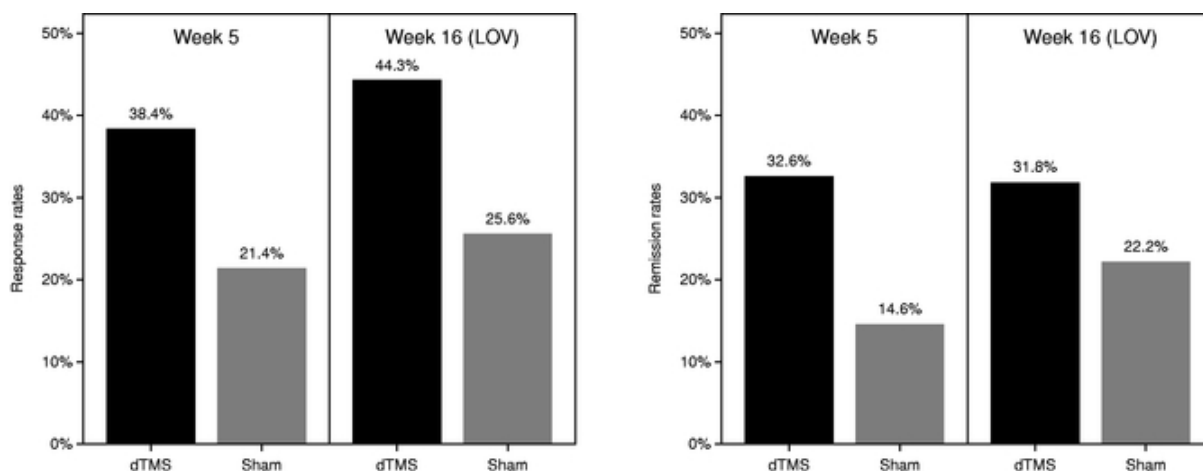
*(b) Trial Results*

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

We and Yeda have agreed to cooperate in order to seek patent protection with regard to the licensed technology, to defend any patents licensed under the agreement against any infringement claims and to bring claims against third parties who are infringing the patents licensed under the agreement. The patents are to be registered in the name of Yeda, and where possible, at our request, we shall be registered as the holder of the exclusive license for use of the patent. We have agreed to pay all expenses related to registration and defense of the patents under the Yeda license agreement, and in the event that we are not interested in registration of a patent with regard to the licensed technology, Yeda is permitted to register such patent at its expense.

In addition, under a recent amendment to the Yeda agreement, we received an exclusive option to in-license certain intellectual property rights owned by Yeda relating to an innovation known as "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 may increase the efficacy of TMS for numerous applications.

Under the Yeda license agreement, we have agreed to pay to Yeda royalties as follows:

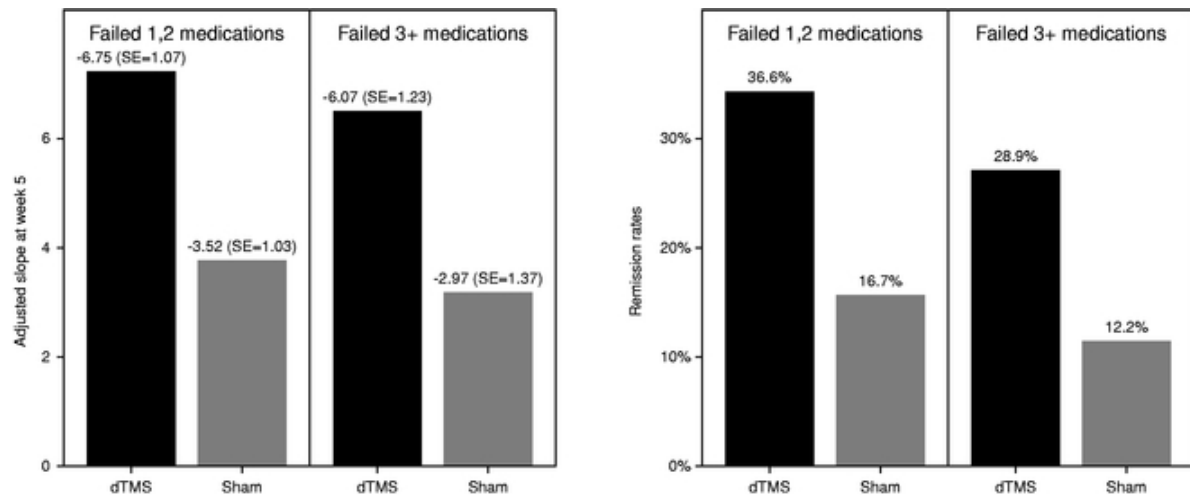
- (i) 1% of net sales/leases of Deep TMS systems based upon Patent Family A and Patent Family B (which include technology licensed from PHS);
- (ii) 3% for the first \$10 million of net sales/leases, and 2% for net sales/leases over \$10 million, for all other Deep TMS products based solely on Patent Family C (which is licensed exclusively from Yeda); provided, however, in the event the products are sold to a sub-licensee and are thereafter sold by such sub-licensee, the royalties paid to Yeda will be based on the higher of the net sales/leases of the product by the licensee or the net sales/leases of the sale by the sub-licensee; and
- (iii) 4% of the net cash proceeds that we receive in respect of granting sublicenses or options for sublicenses (8% for Patent Family C).

Investigators then performed a subset analysis to understand whether there were statistically significant differences in response to treatment between patients who had failed one to two anti-depressant medications compared to three or more medications. The data for this is shown in Figure 2. For the group of patients who failed one to two medications, the slope was  $-6.75$  for the Deep TMS group compared to  $-3.52$  for the sham group. This difference was statistically significant ( $p = 0.0327$ ). For the group of patients who failed three or more medications, the slope of HDRS score change was  $-6.07$  for the Deep TMS group compared to  $-2.97$  for the sham group. However, this difference did not reach statistical significance ( $p = 0.0958$ ).

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). We believe that our Deep TMS system is the only non-invasive medical device that has obtained FDA marketing authorization to treat OCD.

## 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.

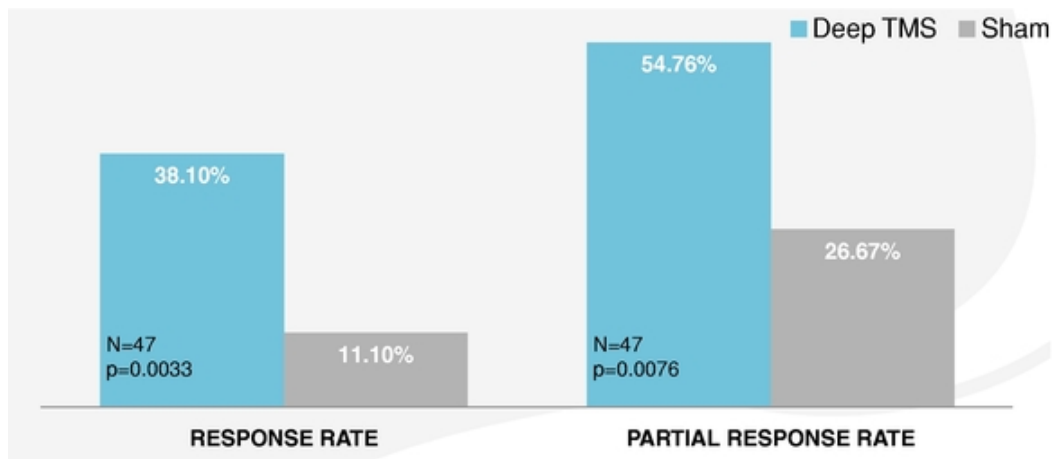
The primary endpoint measure was the Yale-Brown Obsessive Compulsive Scale (YBOCS), which is a score ranging from 0 to 40, with higher scores indicating greater severity of OCD symptoms. The secondary efficacy endpoint measures were response rate at weeks 6 and 10, partial response rate at weeks 6 and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

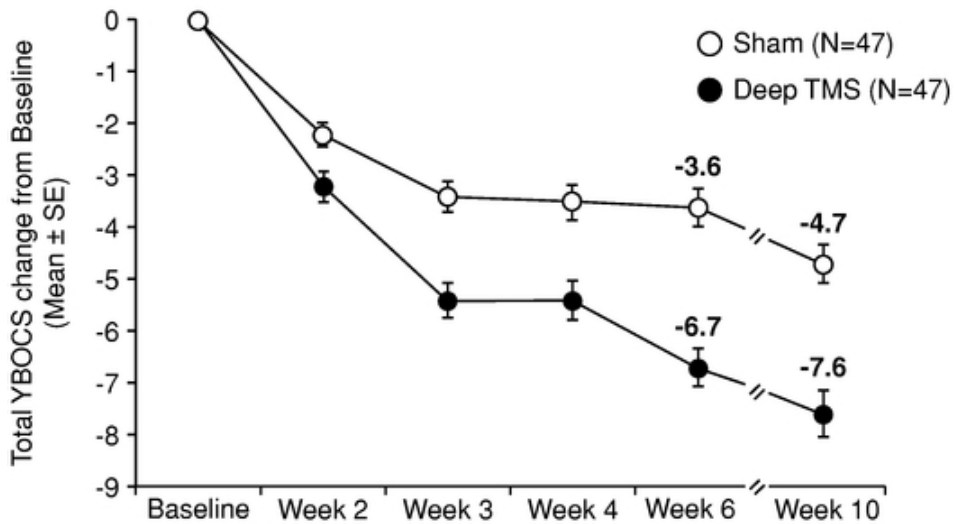
**Figure 3. Response and Partial Response Rates for Deep TMS and Sham Treatment Groups**



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**



## 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, 2018. 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 and support and logistics independently in the United States. As of December 31, 2018, we had 26 U.S. employees, including 18 sales and marketing employees and six field services 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 four years, for unlimited use and including warranty and support; (ii) a risk share model in which the Deep TMS system is leased to a customer which pays based on the usage of the system, subject to an annual 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 warranties paid for the system for each year beginning the second year from purchase. These three models are designed to facilitate market penetration by addressing the different needs and risk tolerance among our customer base. In the beginning of 2017, we shifted our sales and marketing focus in the United States from the sales model to the fixed-fee lease model and the risk share model, which we anticipate will increase market acceptance of our Deep TMS systems. 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, 2018, approximately 50% of our Deep TMS systems installed base for MDD utilized the fixed-fee lease model, approximately 40% utilized the sales model and approximately 10% utilized our risk share model. We have started, and expect to continue, to commercialize Deep TMS for OCD based solely on the risk share model, which charges per session and per treatment, in an effort to achieve greater market acceptance for that indication.

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.

### *Outside of the United States*

Approximately 12% of our revenues for the year ended December 31, 2018 were generated outside of the United States. A significant part of our sales outside the United States are made indirectly with local distributors and agents. Most of our sales outside the United States are made only via the purchase model, although we lease some of our Deep TMS systems in France, Mexico 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.

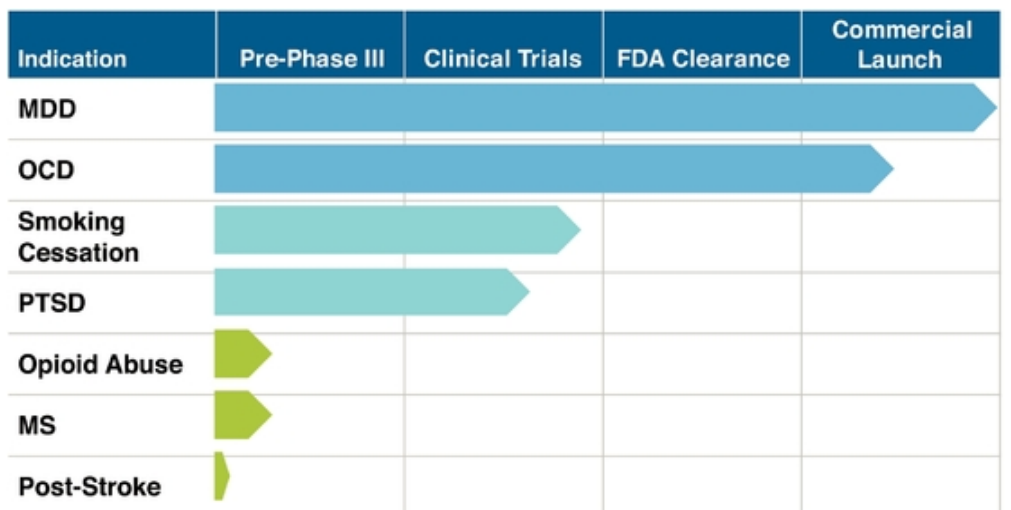
Our non-U.S. sales are managed both by our internal team in Israel and by local agents in various countries. We have exclusive distribution agreements in Japan, South Korea, Thailand, Mexico, Brazil and Israel. In these agreements, the distributor receives an exclusive right to distribute the systems of our Deep TMS systems 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. In some instances, we reserve the right to engage directly with the customer in which case it pays the distributor a commission derived from the transaction with the customer.

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 addition to the regulatory approval requirements, the distributor is also required to implement efforts to obtain reimbursement and or coverage, as well as to market Deep TMS systems in the territory, including, in some cases, holding the marketing authorization in their name. For example, 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 still working through our Japanese distributor with the relevant bodies in Japan to obtain such coverage.

We aim to increase our marketing and sales outside the United States by means of distributors in other countries, and we are currently seeking additional distribution agreements. Marketing and the success of penetration in each country is contingent on a variety of factors, including, among others, the existence of regulatory approvals, the availability of reimbursement, the support of key opinion leaders and the ease and ultimate success of market participants in adopting our technology.

### Our Clinical Pipeline

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



## ***Smoking Cessation***

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. Approximately 38 million U.S. adults smoke cigarettes, and 480,000 die from smoking each year. The global smoking cessation market is estimated at \$3 billion per annum, and this market value is anticipated to increase. The most common smoking cessation option is nicotine replacement therapy, 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.

We currently have a double-blind, randomized, multicenter study in smoking cessation ongoing, with subject enrollment almost completed. In this study we are seeking to enroll at least 260 subjects, assuming 164 individuals complete the study across 10 sites in the United States and Israel. To date, we have enrolled 257 subjects, and plan to enroll additional subjects so as to ensure we will have a sufficient number of completers). Individuals in the study receive either Deep TMS or sham treatment over the course of six weeks (with five daily sessions during the first three weeks and one weekly session during the subsequent three weeks), and a follow-up visit in four months (at week 16 from baseline) thereafter. The primary endpoint is a comparison of the four-week continuous quit rate, as a measure of abstinence from smoking, between active and sham treatment groups during the six week treatment phase. The secondary endpoint is the number of cigarettes smoked per day. We expect to receive the results of this trial in the second quarter of 2019.

## ***PTSD***

PTSD is psychiatric disorder in the field of trauma and stress related disorders, which develops subsequent to exposure to an actual or threatened death, serious injury or sexual violation. PTSD may impair patients' quality of life for years, as well as their ability to function normally in daily life. The incidence of PTSD is higher among war veterans. We estimate that the U.S. patient population for PTSD is approximately 13 million. Existing treatments include CBT and anti-depressant medications.

In 2014, we commenced a double—blind, randomized, multicenter clinical study of Deep TMS for PTSD (using the same coil design as that utilized in BrainsWay OCD) in our clinical study at 12 leading institutions, including, among others, MUSC, Stanford, University of Florida, and the CAMH in Toronto. To date, we have enrolled 77 patients out of 176 targeted patients. Individuals in the study receive either Deep TMS or sham treatment over four weeks (three sessions per week), with two booster sessions at week five and nine. The primary endpoint is a comparison between active and sham treatment groups of the change in CAPS-5 score (a standard score used to measure PTSD) from baseline to week five. We expect to receive the interim results of this trial in the second half of 2019. Additionally, together with Cohen Veterans Bioscience and in collaboration with Stanford University, we launched a project involving the collection and analysis of electroencephalogram (EEG) data from PTSD patients in order to identify potential biomarkers and potentially enable a personalized medicine approach designed to guide patients toward treatment options that are best suited for them, potentially including Deep TMS.

## ***Additional Potential Deep TMS Applications***

Our primary focus for additional potential applications for Deep TMS are opioid addiction, and indications in neurology, including fatigue in MS and post-stroke rehabilitation. The U.S. patient population for opioid addiction, MS and post-stroke rehabilitation is approximately 2 million, 1 million and 795,000, respectively.



We have previously recruited patients as part of a Phase III clinical trial of Deep TMS for bipolar disorder. We have recently ceased actively recruiting patients for this trial in order to focus our strategy on our proposed clinical trials for opioid addiction, fatigue in MS and post-stroke rehabilitation. We have also conducted double-blind, placebo-controlled trials evaluating Deep TMS for Alzheimer's disease, autism spectrum disorders such as Asperger syndrome, alcohol addiction, attention deficit hyperactivity disorder (ADHD), Parkinson's disease and chronic neuropathic pain. Further clinical study in these 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.

## **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 the only FDA-approved TMS product 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, and 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 focal TMS coils and are FDA-cleared for MDD only, although 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. None of our competitors in the MDD market is currently FDA-cleared for an OCD indication, and thus we are the only company currently with marketing authorizations for MDD and OCD.

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 non-invasive treatments for MDD. Examples of non-invasive 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**

Our success depends in part on our ability to obtain and maintain protection for our proprietary Deep TMS technology, its therapeutic applications, and related trade secrets and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. 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: H-Coil for MDD (BrainsWay D), the H-Coil for OCD (BrainsWay OCD) and to future products we are developing, including one that is the subject of pivotal multicenter clinical trials expected to be

completed soon: H-Coil for smoking cessation. 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 the BrainsWay D 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, seven issued patents in other jurisdictions, and four pending patent applications in other jurisdictions. The issued patents related to BrainsWay D 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 OCD and also some future products that we are developing. This group of patents is owned by us, and includes two issued U.S. patents, one pending U.S. patent application, two issued patents in other jurisdictions, and seven 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 BrainsWay D and also some future products we are developing. Patent Family D is owned by us, and includes one issued U.S. patent, two 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 fifth group of patents (Patent Family E) consists of utility model patent applications for BrainsWay D and BrainsWay OCD. This group of patents (Patent Family E) is owned by us, and includes two pending Chinese Utility Model patent applications: one for BrainsWay D and another one for BrainsWay OCD and a PCT patent application incorporating both.

Our sixth group of patents (Patent Family F) relates to a family of circular coils including the H-Coil for smoking, the subject of pivotal multicenter clinical trials, 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, one issued patent in another jurisdiction and four 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 U.S. provisional application.

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 three issued U.S. patents, two pending U.S. patent applications, six issued patents in other jurisdictions, and five pending patent applications in other jurisdictions. Patent applications in these families, if issued, are set to expire in 2028, 2029, 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 recently 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 are currently in the process of transferring these patents.

Furthermore, in February 2019, we obtained an option, exercisable for up to one year, to exclusively license the rights held by the Board of Trustees of the Leland Stanford Junior University in certain specified patents relating to this area.

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" in this prospectus.

### ***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.

If we exercise our right to add the additional rotational field TMS innovation, then 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.

### **Government Grants**

As of December 31, 2018, we have received grants from the IIA in an aggregate amount of approximately \$12.2 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, 2018, we have paid royalties to the IIA in an aggregate amount of approximately \$1.4 million (including amounts in respect of accrued interest), with remaining outstanding royalties of up to \$12.8 million.

In addition, we received from MAGNET approvals for grants in an aggregate amount of NIS 8.6 million (approximately \$2.3 million based on the NIS to USD exchange rate as of December 31, 2018). 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 Hackensack, New Jersey. We recently completed the development of, and received FDA clearance for, our own integral stimulator to our Deep TMS system for MDD, and

have commenced commercially incorporating it into our systems. We are working to obtain FDA approval of our stimulator for OCD, and currently rely on third-party suppliers for that indication. 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 as a source for older generation systems which do not include our recently FDA-cleared stimulator for MDD, as well as for other indications, including OCD, for which our proprietary stimulator is not currently FDA approved.

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 three to four failures of anti-depressant medications. In addition, our MDD treatment with Deep TMS may be eligible for reimbursement from Medicare, and is expected to be available after four failures of anti-depressant medications. Typically, these insurers will provide reimbursement for up to 36 treatment sessions of Deep TMS for MDD, although the maximum number of covered sessions varies by insurer. Deep TMS for OCD is not currently eligible for reimbursement. However, we believe that 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 novelty of the technology, unmet clinical need and the efficacy and safety profile of the treatment.

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 four failures of 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 covers only treatments using our Deep TMS system for MDD, and does not currently cover our Deep TMS therapy for OCD 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 authorization of Deep TMS for OCD will help us to obtain reimbursement for that indication, but we can provide no assurance that we can obtain the same level of reimbursement coverage for OCD 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 still working through our Japanese distributor with the relevant bodies in Japan 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, postmarket 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 and 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.

### *Postmarket 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
- postmarket 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 postmarketing 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:

- imposes an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, although the effective rate paid may be lower. Under the Consolidated Appropriations Act of 2016, the excise tax was suspended through December 31, 2017, and under the continuing resolution on appropriations for fiscal year 2018, or 2018 Appropriations Resolution, signed by President Trump on January 22, 2018, was further suspended through December 31, 2019;

- 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 certain aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. President Trump has signed Executive Orders and other directives designed to delay the implementation of any certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes 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." Additionally, the 2018 Appropriations Resolution delayed the implementation of certain PPACA-mandated fees, including, without limitation, the medical device excise tax. As a result, there is significant uncertainty regarding future healthcare reform and its impact on a medical device manufacturer's operations.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will stay in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, the Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015, or MACRA, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

Recently there has been heightened governmental scrutiny over the manner in which drug and medical device manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to product pricing, reduce the cost of certain products under Medicare, review the relationship between pricing and manufacturer patient assistance programs, and reform government healthcare program reimbursement methodologies. At the state level, individual states in the United States are also increasingly passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures.



It is likely that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for a medical device manufacturer's products or additional pricing pressure.

### **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 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, 2018, we had 96 employees, of which 70 are based in Israel and 26 are based in the United States. This includes 25 employees in sales and marketing (including 18 in the United States) and 30 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.

### **Property**

We are headquartered in Jerusalem, Israel. Since November 2007, we have leased our corporate headquarters 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. The monthly payments owed are adjusted based on movements in Israel's Consumer Price Index since October 2007. This facility houses our administrative and research operations and our central laboratory. Substantially all of our Israeli-based employees are based in this facility.

In the United States, we lease corporate offices in Hackensack, New Jersey pursuant to a lease agreement that expires in April 2021. The facility contains approximately 2,380 square feet of space, and lease payments and management fees are approximately \$5,000 per month. This facility houses our U.S.-based sales and marketing workforce.

### **Legal Proceedings**

We are not involved in any material legal proceedings.

**MANAGEMENT****Senior Management and Directors**

The following table sets forth information concerning our senior management and directors, including their ages, as of the date of this prospectus:

<u>Name</u>	<u>Age</u>	<u>Position</u>
<b>Senior Management:</b>		
Yaacov Michlin	49	Chief Executive Officer
Dr. Yiftach Roth	49	Chief Scientist
Hadar Levy	45	Chief Financial Officer
Moria Ankri	35	Vice President Research and Development
Amit Ginou	38	Vice President Field and Clinical Operations
Joseph Perekupka	46	Vice President Sales Operations North America
Joshua Hexter	48	Chief Business Officer
<b>Directors:</b>		
Dr. David Zacut	67	Chairman of the Board
Avner Hagai(2)	63	Vice Chairman of the Board
Daniel Azriel(1)	68	Director
Gavriel Magen	59	Director
Eti Mitrany(1)(2)	49	Director
Karen Sarid	68	Director
Eynat Tsafir(1)(2)	53	Director
Yossi Ben Shalom	62	Director
Orly Uri	60	Director

(1) Member of our audit committee.

(2) Member of our compensation committee.

**Senior Management**

*Yaacov Michlin* has served as our President and Chief Executive Officer since April 2017. Mr. Michlin has served as a co-chairman of Israeli Advanced Technology Industries Organization since October 2018. Prior to his service at the Company, from 2009 to 2017, Mr. Michlin served as President and Chief Executive Officer of Yisum Research Development Company of the Hebrew University of Jerusalem; from 2012 to 2014, served as Chairman of Israel Tech Transfer Organization; from 2012 to 2015, served as Chairman of Qlight Nanotech Ltd.; and from 2012 to 2017, served as Chairman of Integra Ltd. Mr. Michlin holds an LLB and BA in Economics and LLM from Bar Ilan University and an MBA from the Technion Israel Institute of Technology.

*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 Chief Financial Officer since September 2014. 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.

*Joseph Perekupka* has served as Vice President of North American Sales and Operations since 2015. From 2004 to 2014, Mr. Perekupka worked in the cardiovascular medical device market at St. Jude Medical. Mr. Perekupka holds a B.S. in Marketing from Pennsylvania State University and an MBA in Management and Finance (graduate with honors) from Fordham University.

*Joshua Hexter* has served as Chief Business Officer since November 2018. Previously, Mr. Hexter served as Chief Operating Officer and Vice President of Business Development at Oramed Pharmaceuticals Inc. from 2013 through 2018. Prior to joining Oramed, he served as Executive Director of Corporate Licensing at BioLineRx from 2007 to 2013. Mr. Hexter holds a bachelor's degree from the University of Wisconsin and a master's degree in management from Boston University.

## **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. He serves as a director at several companies, including at Hofit Kibbutz Kinneret Ltd., a plastics manufacturer, where he has served since 2010, and at 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.

*Daniel Azriel* has served as our Director since December 2006, and current serves as a member of our audit committee. Mr. Azriel served as the General Manager of the National Insurance Institute of Israel (NII) from 1982 to 1985, was a partner in Glass, Feinstein and Azriel law firm from 1977 to 1997, was the head of the municipality of Mevaseret Zion from 1999 to 2004, and established his own law firm in 1997 where he maintains his law practice today. Mr. Azriel earned an LLB degree from the Hebrew University in Jerusalem.

*Gavriel Magen* has served as our Director since December 2006. Mr. Magen has been the Chief Executive Officer of Polybid Ltd., the largest Expandable Polystyrene (EPS) producer in Israel, since January 1, 2009. From 2007 to 2009 Mr. Magen served as the Chief Executive Officer of Plassim Ltd., an Israeli company that manufactures pipes for numerous applications and from 2000 to 2007 he served as the Chief Executive Officer of Oran Palmach Subba Agricultural Cooperative Society Ltd., an Israeli producer of safety, strengthened and reinforced glass. Mr. Magen holds a BA in Business Administration from the Ruppin Academic Center in Hefer Valley, Israel. He resides in Har Adar.

*Eti Mitrany* has served as our Director since June 2016, and until the closing of this offering, serves as an external director for purposes of compliance with Israeli corporate governance rules. Ms. Mitrany has served as Senior Vice President, Head of the Corporate Economic Department at Teva

Pharmaceuticals since 2012, with global responsibility for Teva's business planning and analysis. Prior to that, Ms. Mitrany held various positions in Teva, including CFO of specialty R&D, and CFO and Director of Financial Planning & Analysis of the global branded business. Ms. Mitrany joined Teva in 1995 as a financial analyst of Copaxone—the first innovative product of Teva for the treatment of multiple sclerosis. Ms. Mitrany received her BA in Economics and MBA in Finance, both from Tel-Aviv University.

*Eynat Tsafir* has served as our Director and chairperson of our audit committee and our financial statements committee since June 2016, and until the closing of this offering, serves as an external director for purposes of compliance with Israeli corporate governance rules. Ms. Tsafir is an independent consultant providing financial consulting to organizations and individuals. Ms. Tsafir is an external director (with accounting and financial expertise) at Altshuler Shaham Portfolio Management Ltd. and Mediterranean Sea Towers Ltd. and an Independent Director at Shapir Engineering and Industry Ltd. Ms. Tsafir worked at Discount Bank from 2006 to 2009 as a Business Development Manager and at Bank Leumi from 1990 to 2005 establishing and managing the activity for institutional investors and strategic players in the capital markets, and serving in a variety of other positions, including as a middle market business manager in the commercial banking sector, credit officer and macro economist. Ms. Tsafir earned a BA (cum laude) in Finance and an MA in Finance, both from Tel Aviv University.

*Karen Sarid* has served as our Director since December 2017. 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 Hairstetics Ltd. and Eva Visual Ltd. and 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.

*Orly Uri* has served as our Director since December 2018. She previously served as our external director, member of our finance committee and chairperson of our audit committee and our compensation committee from 2007 until April 2016. Ms. Uri is a financial, strategic and organizational advisor to institutions, organizations and corporations in the healthcare sector in Israel and abroad. Prior to that she served as head of planning, budgeting and economics department in Leumit HMO between 1996 and 2003. She started her career in Klalit HMO in various financial and audit positions between 1986 and 1999. Ms. Uri was a guest lecturer in Ben Gurion University and in Ashkelon University between 2000 and 2004. Ms. Uri earned a BA in Economics and Business Administration and a M.Sc. in Industrial and Management Engineering—Medical Management, both from Ben Gurion University.

### **Compensation of Senior Management and Directors**

The table and summary below outline the compensation granted to our five highest compensated directors and officers during the year ended December 31, 2018. The compensation detailed in the

table below refers to actual compensation granted or paid to the director or officer during the year ended December 31, 2018.

<u>Name and position of director or officer</u>	<u>Base Salary or Other Payments<sup>(1)</sup></u>	<u>Value of Social benefits<sup>(2)</sup></u>	<u>Value of Equity Based Compensation Granted<sup>(3)</sup></u>	<u>All Other Compensation<sup>(4)</sup></u>	<u>Total</u>
Amounts in U.S.\$ dollars are based on 2018 monthly average representative U.S. dollar—NIS rate of exchange					
Yaacov Michlin, CEO	262,000	63,000	394,000	17,000	736,000
Hadar Levy, CFO	155,000	44,000	110,000	16,000	325,000
Joseph Perekupka, VP Sales, North America	211,000	—	41,000	—	252,000
Amit Ginou, VP Field and Clinical Operations	121,000	33,000	28,000	13,000	195,000
Moria Ankri, VP Research and Development	114,000	32,000	12,000	11,000	169,000

- (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, 2018.
- (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, 2018 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, car-related expenses (including tax gross-up) and communication expenses.

The aggregate compensation paid by us to our senior management and directors for the year ended December 31, 2018 was approximately \$2.0 million. This amount includes approximately \$0.2 million set aside or accrued to provide pension, severance, retirement or similar benefits or expenses, but does not include business travel, relocation, professional and business association dues and expenses reimbursed to officers, and other benefits commonly reimbursed or paid by companies in Israel.

**Disclosure of Compensation of Senior Management**

For so long as we qualify as a foreign private issuer under U.S. securities laws, we are not required to comply with the proxy rules applicable to U.S. domestic companies, including the requirement applicable to emerging growth companies to disclose the compensation of our chief executive officer and other two most highly compensated senior management on an individual, rather than an aggregate, basis. Nevertheless, regulations promulgated under the Israeli Companies Law require us, as a public company listed on the TASE, and after we become a U.S. public company, to disclose the annual compensation of our five most highly compensated directors and officers on an individual basis, rather than on an aggregate basis. This disclosure will not be as extensive as that required of a U.S. domestic issuer.

**Compensation of Directors and Senior Management**

*Directors.* Under the Israeli Companies Law, the compensation of our directors requires the approval of our compensation committee, the subsequent approval of the board of directors and, unless exempted under regulations promulgated under the Israeli Companies Law, the approval of the

shareholders at a general meeting. The approval of each of the compensation committee and the board of directors should be in accordance with the company's stated compensation policy; however, in special circumstances, they may approve compensation terms of directors that are inconsistent with such policy provided that they have considered those provisions that must be included in the compensation policy according to the Israeli Companies Law, and shareholder approval will also be required, provided that:

- at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in such matter, present and voting at such meeting, are voted in favor of the compensation package, excluding abstentions; or
- the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in such matter voting against the compensation package does not exceed two percent (2%) of the aggregate voting rights in the company.

*Members of senior management other than the chief executive officer.* The Israeli Companies Law requires the approval of the compensation of a public company's senior management (other than the chief executive officer) in the following order: (i) the compensation committee and (ii) the company's board of directors. The approval of each of the compensation committee and the board of directors should be in accordance with the company's stated compensation policy; however, in special circumstances, they may approve compensation terms of the company's executive officers that are inconsistent with such policy provided that they have considered those provisions that must be included in the compensation policy according to the Israeli Companies Law and the company's shareholders approve the transaction (by a special majority vote as discussed above with respect to the approval of director compensation). However, if the shareholders of the company do not approve a compensation arrangement with an executive officer that is inconsistent with the company's stated compensation policy, the compensation committee and board of directors may override the shareholders' decision if each of the compensation committee and the board of directors provide detailed reasons for their decision, after having discussed, among others, the transaction and considered the shareholders' opposition.

*Chief executive officer.* Under the Israeli Companies Law, the compensation of a public company's chief executive officer is required to be approved by: (i) the company's compensation committee; (ii) the company's board of directors, and (iii) the company's shareholders (by a special majority vote as discussed above with respect to the approval of director compensation), in that order. However, if the shareholders of the company do not approve the compensation arrangement with the chief executive officer, the compensation committee and board of directors may override the shareholders' decision if each of the compensation committee and the board of directors provide a detailed report for their decision after having discussed among others the transaction and considered the shareholders' opposition. The approval of each of the compensation committee and the board of directors should be in accordance with the company's stated compensation policy; however, in special circumstances, they may approve compensation terms of a chief executive officer that are inconsistent with such policy provided that they have considered those provisions that must be included in the compensation policy according to the Israeli Companies Law and that shareholder approval was obtained (by a special majority vote as discussed above with respect to the approval of director compensation). In addition, the compensation committee may waive the shareholder approval requirement with regards to the approval of the engagement terms of a candidate for the chief executive officer position, if they determine that the compensation arrangement is consistent with the company's stated compensation policy, and that the chief executive officer did not have a prior business relationship with the company or a controlling shareholder of the company and that subjecting the approval of the engagement to a shareholder vote would impede the company's ability to employ the chief executive officer candidate.

## Foreign Private Issuer Status

### *Foreign Private Issuer*

After the consummation of this offering, we will be a "foreign private issuer" under U.S. securities laws and Nasdaq corporate governance rules. As a foreign private issuer, we will be exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

As a foreign private issuer, we are permitted to follow certain Israeli corporate governance practices instead of the Nasdaq corporate governance rules, provided that we disclose which requirements we are not following and the equivalent Israeli requirement. Pursuant to the "foreign private issuer exemption":

- we intend to establish a quorum requirement such that the quorum for any meeting of shareholders is two or more shareholders holding at least 33<sup>1</sup>/<sub>3</sub>% 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 of our shareholders, holding any percentage of our voting rights;
- we also intend to 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 intend to comply with the rules generally applicable to U.S. domestic companies listed on the Nasdaq Global Market. 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 the closing of this offering, we also intend to comply with Israeli corporate governance requirements under the Israeli Companies Law applicable to public companies.



## Our Board of Directors

Our board of directors consists of nine (9) directors, including eight (8) directors who qualify as "independent" under applicable U.S. securities laws and Nasdaq listing rules: Avner Hagai, Daniel Azriel, Gavriel Magen, Karen Sarid, Eti Mitrany, Eynat Tsafir, Yossi Ben Shalom and Orly Uri.

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

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 general 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).

Our directors are divided into three classes with staggered three-year terms (other than any external directors that may be required under the Companies Law). Each class of directors consists, as nearly as possible, of one-third of the total number of directors constituting the entire board of directors (other than external directors, if any). At each annual general meeting of our shareholders, the election or re-election of directors following the expiration of the term of office of the directors of that class of directors will be for a term of office that expires on the third annual general meeting following such election or re-election, such that from 2019 and after, at each annual general meeting the term of office of only one class of directors will expire. Each director holds office until the third annual general meeting of our shareholders and until his or her successor is duly appointed, unless the tenure of such director expires earlier pursuant to the Israeli Companies Law or if, he or she is not an external director, unless removed from office by the general meeting of shareholders by a majority of at least 66<sup>2</sup>/<sub>3</sub>% of the total voting power voted at such general meeting of shareholders, after he or she is given a reasonable opportunity to bring his or her position before the general meeting as described below.

Our current directors, other than external directors, are divided among the three classes as follows:

- Class I directors consist of Dr. David Zcut, Avner Hagai and Daniel Azriel, and their term will expire at our annual general meeting of our shareholders to be held in 2019;
- Class II directors consist of Gavriel Magen and Karen Sarid, and their term will expire at our annual general meeting of our shareholders to be held in 2020; and
- Class III directors consist of Orly Uri and Yossi Ben-Shalom, and their term will expire at our annual general meeting of our shareholders to be held in 2021.

Eti Mitrany and Eynat Tsafrir will serve as our external directors until the closing of this offering and shall serve as independent directors after this offering, and each has a term of three years which will expire in 2019.

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 skill, 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 have at least two directors with the requisite financial and accounting expertise.

### ***Family Relationships***

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

### ***Arrangements for Election of Directors and Senior Management***

We are not a party to, and there are no arrangements or voting agreements that we are aware of for the election of our directors and senior management.

### ***Alternate Directors***

Our articles of association provide, as allowed by the Israeli Companies Law, that any director may, by written notice to us, appoint another person who is qualified to serve as a director to serve as an alternate director. The alternate director will be regarded as a director. Under the Israeli Companies Law, a person who is not qualified to be appointed as a director, a person who is already serving as a director or a person who is already serving as an alternate director for another director, may not be appointed as an alternate director. Nevertheless, a director who is already serving as a director may be appointed as an alternate director for a member of a committee of the board of directors as long as he or she is not already serving as a member of such committee. The term of appointment of an alternate director may be for one meeting of the board of directors or until notice is given of the cancellation of the appointment.

### ***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 intend to comply with the requirements of Nasdaq with respect to the composition of our audit committee and compensation committee and 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 Daniel Azriel, Eti Mitrany and Eynat Tsafrir. Eynat Tsafrir 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 Daniel Azriel, Eti Mitrany and Eynat Tsafrir 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 will adopt an audit committee charter effective immediately after the pricing of this offering 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 chairman of the compensation committee must be an external director. 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 Avner Hagai, Eti Mitrany and Eynat Tsafirir, assists the board of directors in determining compensation for our directors and officers. Eti Mitrani 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.

Pursuant to regulations promulgated under the Israeli Companies Law, we intend to comply with the requirements of the Nasdaq with respect to the composition of our audit committee and compensation committee and 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."

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 and 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 and 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 an amendment was approved by our shareholders on January 24, 2019.

### **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. Recently and through the end of March 2019, Mr. Rami Itselev has served as our internal auditor. As of April 1, 2019, we plan to retain Mr. Yisrael Gewirtz of Fahn Kanne Control Management Ltd. (Grant Thornton Israel) to serve in this capacity.

### **Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli 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 prospectus, 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.

#### **Employment and Consulting Agreements with Senior Management**

We have entered into written employment or service agreements with each member of our senior management. See "Certain Relationships and Related Party Transactions—Employment Agreements" for additional information.

#### **Directors' Service Contracts**

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.

#### **Share Incentive Plan**

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.

Under the Plan, as amended and restated, we may issue options to purchase up to 3,500,000 of our ordinary shares. As of December 31, 2018, options to purchase 2,308,192 ordinary shares, at a weighted average exercise price of \$6.94 per share, were outstanding, including options to purchase 1,209,859 ordinary shares previously issued under our Plan. In addition, there are options to purchase an

additional 1,332,008 ordinary shares reserved for future issuance under our Plan. 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.

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."

### **Code of Business Conduct and Ethics**

Effective upon the closing of this offering, we will adopt a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, senior management and directors. Following the closing of this offering, the Code of Conduct will be available on our website at [www.brainsway.com](http://www.brainsway.com). The nominating and corporate governance committee of our board of directors will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, senior management and directors. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of the applicable stock exchange concerning any amendments to, or waivers from, any provision of the Code of Conduct.

## PRINCIPAL SHAREHOLDERS

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of March 4, 2019 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 March 4, 2019, 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 prior to the offering is based on 16,640,446 ordinary shares outstanding as of March 4, 2019. The percentage of ordinary shares beneficially owned after the offering is based on the number of shares outstanding prior to the offering, plus the ADSs that we are selling in this offering.

The percentages of ordinary shares beneficially owned after the offering assume that the underwriters will not exercise their option to purchase additional ADSs in the offering. 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.

Upon the closing of this offering, none of our shareholders will have different voting rights from other shareholders. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our Company.

As of March 4, 2019, there was one shareholder of record of our ordinary shares. The number of record holders is not representative of the number of beneficial holders of our ordinary shares, as the shares of all our shareholders who hold ordinary shares that are traded on the TASE are recorded in the name of our Israeli share registrar, Registration Co. of United Mizrahi Bank Ltd. As of March 4, 2019, there were no U.S. persons that were holders of record of our ordinary shares.



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.

Name of Beneficial Owner	Shares Beneficially Owned Prior to the Offering		Percentage Beneficially Owned After the Offering
	Number	Percentage	
<b>5% or Greater Shareholders</b>			
The Phoenix Provident Funds(1)	1,841,698	11.07%	8.51%
Dr. David Zacut	1,769,297	10.63%	8.18%
Avner Hagai(2)	1,739,138	10.45%	8.04%
Dr. Yiftach Roth	1,083,390	6.51%	5.01%
Prof. Avraham Zangen(3)	940,000	5.65%	4.34%
IBI Mutual Fund Management Ltd.(4)	907,970	5.46%	4.20%
<b>Named Directors and Officers</b>			
Yaacov Michlin(5)	336,962	1.99%	1.54%
Joseph Perekupka(6)	56,250	*	*
Hadar Levy(7)	165,000	*	*
Amit Ginou(8)	52,000	*	*
Moria Ankri(9)	19,888	*	*
<b>All directors and members of senior management as a group</b>	5,221,925	31.33%	24.10%

\* Denotes less than 1% beneficial ownership

- (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) This consists of shares held directly by Mr. Hagai as well as shares held by family members or affiliates of Mr. Hagai.
- (3) The address of Prof. Avraham Zangen is Mish'ol HaHadas 23, Jerusalem, Israel.
- (4) The shares are beneficially owned by IBI Investment House Ltd. through a subsidiary of IBI Investment House Ltd., IBI Mutual Fund Management Ltd. IBI Investment House Ltd. is publicly traded in Israel and Mr. Zvi Lubetzky, Mr. David Weisberg and Mr. Emanuel Kook are the controlling shareholders, holding approximately 60% of the issued and outstanding capital of IBI Investment House Ltd. as of the date of this prospectus. The address of IBI Mutual Fund Management Ltd. is 9 Ahad Ha'am Street, Tel-Aviv, 61291, Israel.
- (5) Consists of 22,500 ordinary shares and options to purchase 314,462 ordinary shares currently exercisable or exercisable within 60 days.

- (6) Consists of options to purchase 56,250 ordinary shares currently exercisable or exercisable within 60 days.
- (7) Consists of options to purchase 165,000 ordinary shares currently exercisable or exercisable within 60 days.
- (8) Consists of options to purchase 51,500 ordinary shares currently exercisable or exercisable within 60 days.
- (9) Consists of options to purchase 18,500 ordinary shares currently exercisable or exercisable within 60 days.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

### Related Party Transaction Procedures

The Israeli Companies Law provides for special approval processes for transactions with controlling shareholders, directors and officers. See "Management—Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli Law."

### Employment Agreements

We have entered into written employment agreements with each member of our senior management, which are filed as exhibits to the registration statement of which this prospectus forms a part. 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 1,556,062 ordinary shares to employees and directors, with a weighted average exercise price of approximately \$5.94 per share, or approximately NIS 22.25 per share (based on the exchange rate reported by the Bank of Israel on December 31, 2018).

### 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 \$10 million (as may be increased from time to time by shareholders' approval), or, subject to and upon completion of this offering to 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.

## DESCRIPTION OF SHARE CAPITAL

### General

Our authorized share capital currently consists of 25,000,000 ordinary shares, par value NIS 0.04 per share, and we have received shareholder approval to increase our authorized share capital to 35,000,000 ordinary shares effective subject to and upon the pricing of this offering. As of December 31, 2018, there were 16,640,446 ordinary shares issued and outstanding and, upon the closing of this offering, 21,640,446 ordinary shares will be issued and outstanding (assuming that the underwriters do not exercise their option to purchase additional ADSs).

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, 2018, there were outstanding options to purchase an aggregate of 2,308,192 shares of our ordinary shares, with a weighted-average exercise price of \$6.94 per ordinary share. In addition, there are options to purchase an additional 1,332,008 ordinary shares reserved for future issuance under our Share Incentive Plan.

As of December 31, 2018, there was an outstanding warrant to purchase 59,761 shares of our ordinary shares, with an exercise price of \$5.02 per share and expiry date of October 8, 2022, held by Mizrahi Tefahot Bank.

### Establishment

We were incorporated under the laws of the State of Israel on November 7, 2006. We are registered with the Israeli Registrar of Companies.

### Registration Number and Purposes of the Company

Our registration number with the Israeli Registrar of Companies is 51-389076-4. Our purpose as set forth in our articles of association is to (1) research, develop, market and sell medical equipment for the treatment of the human brain; and (2) engage in any lawful activity, at the discretion of the directors and officers.

### Voting Rights and Conversion

All ordinary shares will have identical voting and other rights in all respects.

### Transfer of Shares

Our fully paid ordinary shares are issued in registered form and may be freely transferred under our articles of association, unless the transfer is restricted or prohibited by another instrument, applicable law or the rules of a stock exchange on which the shares are listed for trade. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our articles of association or the laws of the State of Israel, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

### 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 first general 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).

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. Furthermore, under our articles of association our directors (other than external directors, if any) are divided into three classes with staggered three-year terms. For a more detailed description on the composition of our board of election procedures of our directors, see "Management—Corporate Government Practices—Board of Directors."

Our articles of association provide that approval of at least  $66\frac{2}{3}\%$  of the total voting power voted at a general meeting of shareholders would be required to amend the provisions of our articles of association relating to our staggered board.

### **Dividend and Liquidation Rights**

We may declare a dividend to be paid to our shareholders in proportion to their respective shareholdings. Under the Israeli Companies Law, dividend distributions are determined by the board of directors and do not require the approval of the shareholders of a company unless the company's articles of association provide otherwise. Our articles of association do not require shareholder approval of a dividend distribution and provide that dividend distributions may be determined by our board of directors.

Pursuant to the Israeli Companies Law, the distribution amount is limited to the greater of retained earnings or earnings generated over the previous two years, according to our then last reviewed or audited financial statements, provided that the date of the financial statements is not more than six months prior to the date of the distribution, or we may distribute dividends that do not meet such criteria only with court approval. In each case, we are only permitted to distribute a dividend if our board of directors (and the court, if applicable), determines that there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to our shareholders in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

### **Exchange Controls**

There are currently no Israeli currency control restrictions on remittances of dividends, proceeds from the sale of the shares or interest or other payments to non-residents of Israel, except for shareholders who are subjects of certain countries that are considered to be in a state of war with Israel at such time.

### **Shareholder 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, following the closing of this offering, 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.

Under our articles of association and the Israeli Companies Law, notice of a general meeting shall be published in at least two daily widely circulated newspapers in Hebrew; 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.

## **Voting Rights**

### **Quorum Requirements**

Pursuant to our articles of association, holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote before the shareholders at a general meeting. Under our articles of association, the quorum required for general meetings of shareholders must consist of two or more shareholders present in person or by proxy holding  $33\frac{1}{3}\%$  or more of the voting rights in the Company, which complies with the quorum requirements for general meetings under Nasdaq listing rules. A meeting adjourned for lack of a quorum will generally be adjourned to the same day of the following week at the same time and place, or to such other day, time or place as indicated by our board of directors if so specified in the notice of the meeting. At the reconvened meeting, two or more shareholders present in person or by proxy holding any percentage of voting rights in the Company shall constitute a lawful quorum, instead of  $33\frac{1}{3}\%$  of the issued share capital as required under Nasdaq listing rules.

### **Vote Requirements**

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<sup>2</sup>/<sub>3</sub>% 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, our staggered board, 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.

### **Access to Corporate Records**

Under the Israeli Companies Law, shareholders are provided access to minutes of our general meetings, our shareholders register and principal shareholders register, our articles of association, our financial statements and any document that we are required by law to file publicly with the Israeli Companies Registrar or the Israel Securities Authority. In addition, shareholders may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Israeli Companies Law. We may deny this request if we believe it has not been made in good faith or if such denial is necessary to protect our interest or protect a trade secret or patent.

### **Modification of Class Rights**

Under the Israeli Companies Law and our articles of association, the rights attached to any class of share, such as voting, liquidation and dividend rights, may be amended by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting, or otherwise in accordance with the rights attached to such class of shares, in addition to the ordinary majority vote of all classes of shares voting together as a single class at a shareholder meeting, as set forth in our articles of association.

## 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 a public Israeli 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 relevant class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, 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 also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of 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 an 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 include 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 (a) 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 or the shareholders who accept the offer constitute less than a majority of the offerees that do not have a personal interest in the acceptance of the tender offer, or (b) the shareholders who did not accept the tender offer hold 2% or more 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.

### **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 25% or more of the voting rights in the company. This requirement 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 in 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, subject to certain exceptions.

A special tender offer must be extended to all shareholders of a company but the offeror is not required to purchase shares representing more than 5% of the voting power attached to the company's outstanding shares, regardless of how many shares are tendered by shareholders. A 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 number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer (excluding the purchaser and its controlling shareholder, holders of 25% or more of the voting rights in the company or any person having a personal interest in the acceptance of the tender offer or any other person acting on their behalf, including relatives and entities under such person's control). If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or



such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Under the DGCL there are no provisions relating to mandatory tender offers.

### **Merger**

The Israeli Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Israeli Companies Law are met, by a majority vote of each party's shares, and, in the case of the target company, a majority vote of each class of its shares voted on the proposed merger at a shareholders meeting.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the votes of the shares represented at the shareholders meeting that are held by parties other than the other party to the merger, or by any person (or group of persons acting in concert) who holds (or hold, as the case may be) 25% or more of the voting rights or the right to appoint 25% or more of the directors of the other party, vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same special majority approval that governs all extraordinary transactions with controlling shareholders (as described 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").

If the transaction would have been approved by the shareholders of a merging company but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the 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 value to the parties to the merger and the consideration offered to the shareholders of the company.

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 merging entities, and may further give instructions to secure the rights of creditors.

In addition, a merger may not be consummated unless at least 50 days have passed from the date on which a proposal for approval of the merger was filed by each party with the Israeli Registrar of Companies and at least 30 days have passed from the date on which the merger was approved by the shareholders of each party.

### ***Anti-Takeover Measures under Israeli Law***

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 rights with respect to voting, distributions or other matters and shares having preemptive rights. Under the provisions of the Israeli Securities Law we are not allowed to create and issue any class of shares providing different voting rights other than preferred shares which have preferred dividend rights and no voting rights. As of the closing of this offering, no preferred shares will be authorized under our articles of association. In the future, if we do authorize, create and issue a specific class of preferred shares, such class of shares, depending on the specific rights that may be attached to it, may have the ability to frustrate or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their shares. The authorization and designation of a class of preferred shares will require an amendment to our articles of association, which requires the prior approval of the holders of a majority of the voting power attaching to our issued and outstanding shares at a general meeting.

The convening of the meeting, the shareholders entitled to participate and the majority vote required to be obtained at such a meeting will be subject to the requirements set forth in the Israeli Companies Law as described above in "—Voting Rights."

As an Israeli company we are not subject to the provisions of Section 203 of the DGCL, which in general prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested shareholder" for a period of three years after the date of the transaction in which the person became an interested shareholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a "business combination" includes a merger, asset sale or other transaction resulting in a financial benefit to the interested shareholder, and an "interested shareholder" is a person who, together with affiliates and associates, owns, or within three years prior did own, 15% or more of the voting shares of a corporation.

### **Borrowing Powers**

Pursuant to the Israeli Companies Law and our articles of association, our board of directors may exercise all powers and take all actions that are not required under law or under our articles of association to be exercised or taken by our shareholders, including the power to borrow money for company purposes.

### **Changes in Capital**

Our articles of association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Israeli Companies Law and must be approved by a resolution duly adopted by our shareholders at a general meeting. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings or profits, require the approval of both our board of directors and an Israeli court (if applicable).

### **Transfer Agent and Registrar**

Our share register will be maintained by The Bank of New York Mellon upon the closing of this offering. The share register reflects only record owners of our ordinary shares. Holders of the ADSs will not be treated as our shareholders and their names will therefore not be entered in our share register. The depositary, the custodian or their nominees will be the holder of the ordinary shares underlying the ADSs. Holders of the ADSs have a right to receive the ordinary shares underlying their ADSs. For discussion on the ADSs and ADS holder rights, see "Description of American Depositary Shares" in this prospectus.

### **Listing**

The ADSs have been approved for listing on The Nasdaq Global Market under the symbol "BWAY."

### **Home Country Practices**

As a foreign private issuer whose shares will be 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 intend to establish a quorum requirement such that the quorum for any meeting of shareholders is two or more shareholders holding at least 33<sup>1</sup>/<sub>3</sub>% 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<sup>1</sup>/<sub>3</sub>% of our voting rights;

- we also intend to 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 intend to 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.

## DESCRIPTION OF AMERICAN DEPOSITARY SHARES

The Bank of New York Mellon, as depositary, will register and deliver American Depositary Shares, also referred to as ADSs. Each ADS will represent 2 ordinary shares (or a right to receive 2 ordinary shares) deposited with Bank Leumi, as custodian for the depositary in Israel. Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The deposited shares together with any other securities, cash or other property held by the depositary are referred to as the deposited securities. The depositary's office at which the ADSs will be administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

You may hold ADSs either (A) directly (i) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (ii) by having uncertificated ADSs registered in your name, or (B) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC. If you hold ADSs directly, you are a registered ADS holder, also referred to as an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. Israeli law governs shareholder rights. The depositary will be the holder of the shares underlying the ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR, which are exhibits to the registration statement of which this prospectus forms a part.

### Dividends and Other Distributions

#### *How will you receive dividends and other distributions on the shares?*

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of shares the ADSs represent.

**Cash.** The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. See Material Tax Considerations—Taxation of Our Shareholders—Dividends. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the

nearest whole cent. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some of the value of the distribution.

**Shares.** The depositary may distribute additional ADSs representing any shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

**Rights to purchase additional shares.** If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. In that case, you will receive no value for them. The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

**Other Distributions.** The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.

## **Deposit, Withdrawal and Cancellation**

### ***How are ADSs issued?***

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

***How can ADS holders withdraw the deposited securities?***

You may surrender the ADSs to the depository for the purpose of withdrawal. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depository will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depository will deliver the deposited securities at its office, if feasible. However, the depository is not required to accept surrender of ADSs to the extent it would require delivery of a fraction of a deposited share or other security. The depository may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

***How do ADS holders interchange between certificated ADSs and uncertificated ADSs?***

You may surrender your ADR to the depository for the purpose of exchanging your ADR for uncertificated ADSs. The depository will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depository of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depository will execute and deliver to the ADS holder an ADR evidencing those ADSs.

**Voting Rights**

***How do you vote?***

ADS holders may instruct the depository how to vote the number of deposited shares their ADSs represent. If we request the depository to solicit your voting instructions (and we are not required to do so), the depository will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depository how to vote. For instructions to be valid, they must reach the depository by a date set by the depository. The depository will try, as far as practical, subject to the laws of Israel and the provisions of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depository to solicit your voting instructions, you can still send voting instructions, and, in that case, the depository may try to vote as you instruct, but it is not required to do so.

Except by instructing the depository as described above, you won't be able to exercise voting rights unless you surrender the ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares. In any event, the depository will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depository to vote your shares. In addition, the depository and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested.

In order to give you a reasonable opportunity to instruct the depository as to the exercise of voting rights relating to Deposited Securities, if we request the Depository to act, we agree to give the depository notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

## Fees and Expenses

***Persons depositing or withdrawing shares or ADS holders must pay:***

\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)

\$.05 (or less) per ADS

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 ADSs

\$.05 (or less) per ADS per calendar year

Registration or transfer fees

Expenses of the depositary

Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes

Any charges incurred by the depositary or its agents for servicing the deposited securities

***For:***

- Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
- Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
- Any cash distribution to ADS holders
- Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
- Depositary services
- 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
- Cable and facsimile transmissions (when expressly provided in the deposit agreement)
- Converting foreign currency to U.S. dollars
- As necessary
- 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 depository and that may earn or share fees, spreads or commissions.

The depository 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 depository or its affiliate receives when buying or selling foreign currency for its own account. The depository 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 depository's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

#### **Payment of Taxes**

You will be responsible for any taxes or other governmental charges payable on the ADSs or on the deposited securities represented by any of the ADSs. The depository may refuse to register any transfer of the ADSs or allow you to withdraw the deposited securities represented by the ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your American Depositary Shares to pay any taxes owed and you will remain liable for any deficiency. If the depository sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

#### **Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities**

The depository will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do by an ADS holder surrendering ADSs and subject to any conditions or procedures the depository may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depository as a holder of deposited securities, the depository will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depository receives new securities in exchange for or in lieu of the old deposited securities, the depository will hold those replacement securities as deposited securities under the deposit agreement. However, if the depository decides it would not be lawful and practical to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depository may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depository will continue to hold the replacement securities, the depository may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the



depository may call for surrender or of those ADSs or cancel those ADSs upon notice to the ADS holders.

## **Amendment and Termination**

### ***How may the deposit agreement be amended?***

We may agree with the depository to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depository for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depository notifies ADS holders of the amendment. At the time an amendment becomes effective, you are considered, by continuing to hold the ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.

### ***How may the deposit agreement be terminated?***

The depository will initiate termination of the deposit agreement if we instruct it to do so. The depository may initiate termination of the deposit agreement if

- 60 days have passed since the depository told us it wants to resign but a successor depository has not been appointed and accepted its appointment;
- we delist the ADSs from an exchange on which they were listed and do not list the ADSs on another exchange;
- we appear to be insolvent or enter insolvency proceedings
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depository will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depository may sell the deposited securities. After that, the depository will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depository will sell as soon as practicable after the termination date.

After the termination date and before the depository sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depository may refuse to accept a surrender for the purpose of withdrawing deposited securities or reverse previously accepted surrenders of that kind if it would interfere with the selling process. The depository may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depository will continue to collect distributions on deposited securities, but, after the termination date, the depository is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

## Limitations on Obligations and Liability

### *Limits on our Obligations and the Obligations of the Depository; Limits on Liability to Holders of ADSs*

The deposit agreement expressly limits our obligations and the obligations of the depository. It also limits our liability and the liability of the depository. We and the depository:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depository will not be a fiduciary or have any fiduciary duty to holders of ADSs;
- are not liable if we are or it is prevented or delayed by law or by events or circumstances beyond our or its ability to prevent or counteract with reasonable care or effort from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement, or for any;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- the depository has no duty to make any determination or provide any information as to our tax status, or any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs or be liable for the inability or failure of an ADS holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit.

In the deposit agreement, we and the depository agree to indemnify each other under certain circumstances.

## Requirements for Depository Actions

Before the depository will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depository may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depository may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depository or our transfer books are closed or at any time if the depository or we think it advisable to do so.

## **Your Right to Receive the Shares Underlying the ADSs**

ADS holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our shares;
- when you owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

## **Direct Registration System**

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

## **Shareholder communications; inspection of register of holders of ADSs**

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depositary will send you copies of those communications or otherwise make those communications available to you if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

## **Jury Trial Waiver**

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law.

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, our ordinary shares have been traded only on the TASE and have not been listed in the United States. Sales of substantial amounts of our ordinary shares or ADSs following this offering, or the perception that these sales could occur, could adversely affect prevailing market prices of our ordinary shares and ADSs and could impair our future ability to obtain capital, especially through an offering of equity securities. Assuming that the underwriters do not exercise their option to purchase additional ADSs in this offering and assuming no exercise of options outstanding following this offering we will have an aggregate of 21,640,446 ordinary shares outstanding upon the closing of this offering. Of these shares, all the ADSs sold in this offering will be freely tradable without restriction or further registration under the Securities Act, unless purchased by "affiliates" (as that term is defined under Rule 144 of the Securities Act), who may sell only the volume of shares described below and whose sales would be subject to additional restrictions described below. In addition, all of our ordinary shares outstanding before this offering will be freely tradable without restriction or further registration under the Securities Act other than shares held by our affiliates and those of our shareholders who have signed lock-up agreements. Under Rule 144 of the Securities Act, an "affiliate" of a company is a person that directly or indirectly controls, is controlled by or is under common control with that company. Affiliates may sell only the volume of shares described below and their sales are subject to additional restrictions described below.

### Eligibility of Restricted Shares for Sale in the Public Market

As a result of contractual restrictions described below and the provisions of Rules 144 and 701, the ADSs sold in this offering and the restricted securities will be available for sale in the public market as follows:

- all the ADSs sold in this offering will be eligible for immediate sale upon the closing of this offering; and
- 6,161,195 ordinary shares will be eligible for sale in the public market upon expiration of lock-up agreements 180 days after the date of this prospectus, subject in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701.

### Lock-up Agreements

All of our directors, senior management and certain shareholders have signed lock-up agreements pursuant to which, subject to certain exceptions, such persons have agreed not to sell or otherwise dispose of ordinary shares or any securities convertible into or exchangeable for ordinary shares or ADSs for a period of 180 days after the date of this prospectus without the prior written consent of the representative of the underwriters, who may, at any time upon requisite notice, release all or any portion of the ordinary shares or ADSs from the restrictions in any such agreement.

### Rule 144

#### *Shares Held For Six Months*

In general, under Rule 144 as currently in effect, and subject to the terms of any lock-up agreement, commencing 90 days following the closing of this offering, a person, including an affiliate, who has beneficially owned our ordinary shares or ADSs for six months or more, including the holding period of any prior owner other than one of our affiliates (i.e., commencing when the shares were acquired from us or from an affiliate of us as restricted securities), is entitled to sell our ordinary shares or ADSs, subject to the availability of current public information about us (which information will be deemed to be available as long as we continue to file required reports with the SEC). In the case of an affiliate shareholder, the right to sell is also subject to the fulfillment of certain additional

conditions, including manner of sale provisions, notice requirements, and a volume limitation that limits the number of shares that may be sold thereby, within any three-month period, to the greater of:

- 1% of the number of ordinary shares and ADSs (each ADS representing 2 ordinary shares) then outstanding; or
- the average weekly trading volume of the ADSs on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Rule 144 also provides that affiliates that sell our ordinary shares or ADSs that are not restricted securities must nonetheless comply with the same restrictions applicable to restricted securities, other than the holding period requirement.

#### ***Shares Held by Non-Affiliates for One Year***

Under Rule 144 as currently in effect, a person who is not considered to have been one of our affiliates at any time during the three months preceding a sale and who has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than one of our affiliates, is entitled to sell his, her or its shares under Rule 144 without complying with the provisions relating to the availability of current public information or with any other conditions under Rule 144. Therefore, unless subject to a lock-up agreement or otherwise restricted, such shares may be sold immediately upon the closing of this offering.

#### **Rule 701**

In general, under Rule 701 as currently in effect, each of our employees, consultants or advisors who purchases our ordinary shares or ADSs from us in connection with a compensatory stock plan or other written agreement executed prior to the closing of this offering is eligible to resell such ordinary shares or ADSs in reliance on Rule 144, but without compliance with some of the restrictions, as described below.

Rule 701 will apply to the options granted under our Share Incentive Plan prior to the closing of this offering, along with the shares acquired upon exercise of these options, including exercises following the closing of this offering. Securities issued in reliance on Rule 701 are restricted securities and may be sold beginning 90 days following the closing of this offering in reliance on Rule 144 by:

- persons other than affiliates, without restriction; and
- affiliates, subject to the manner-of-sale, current public information and filing requirements of Rule 144,

in each case, without compliance with the six-month holding period requirement of Rule 144.

#### **Form S-8 Registration Statements**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register, in the aggregate, ordinary shares, issued or reserved for issuance under our Share Incentive Plan. The registration statement on Form S-8 will become effective automatically upon filing. Ordinary shares issued upon exercise of a stock option or other award and registered pursuant to the Form S-8 registration statement will, subject to vesting provisions and Rule 144 volume limitations applicable to our affiliates, be available for sale in the open market immediately unless they are subject to the 180-day lock-up or, if subject to the lock-up, immediately after the 180-day lock-up period expires.

## MATERIAL TAX CONSIDERATIONS

The following description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our ordinary shares or ADSs. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign or other taxing jurisdiction.

### Israeli Tax Considerations and Government Programs

The following is a summary of the material Israeli tax laws applicable to us, and some Israeli Government programs benefiting us. This section also contains a discussion of some Israeli tax consequences to persons owning our ordinary shares or ADSs. This summary does not discuss all the aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of this kind of investor include traders in securities or persons that own, directly or indirectly, 10% or more of our outstanding voting capital, all of whom are subject to special tax regimes not covered in this discussion. Some parts of this discussion are based on new tax legislation which has not yet been subject to judicial or administrative interpretation. The discussion should not be construed as legal or professional tax advice and does not cover all possible tax considerations.

SHAREHOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS AS TO THE ISRAELI OR OTHER TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES OR ADSs, INCLUDING, IN PARTICULAR, THE EFFECT OF ANY FOREIGN, STATE OR LOCAL TAXES.

#### *General Corporate Tax Structure in Israel*

Israeli resident companies are generally subject to corporate tax at the rate of 24% and 23% of a company's taxable income in 2017 and 2018, respectively. However, the effective tax rate payable by a company that derives income from entitled for benefits in accordance with the Industry Encouragement Law (as defined below) may be considerably less. Capital gains derived by an Israeli resident company are subject to tax at the prevailing corporate tax rate.

Under Israeli tax legislation, a corporation will be considered as an "Israeli resident company" if it meets one of the following: (i) it was incorporated in Israel; or (ii) the control and management of its business are exercised in Israel.

#### *Law for the Encouragement of Industry (Taxes), 5729-1969*

The Law for the Encouragement of Industry (Taxes), 5729-1969, generally referred to as the Industry Encouragement Law, provides several tax benefits for "Industrial Companies."

The Industry Encouragement Law defines an "Industrial Company" as a company resident in Israel and which was incorporated in Israel of which 90% or more of its income in any tax year, other than income from defense loans, is derived from an "Industrial Enterprise" owned by it and which is located in Israel. An "Industrial Enterprise" is defined as an enterprise whose principal activity in a given tax year is industrial production.

The following corporate tax benefits, among others, are available to Industrial Companies:

- amortization over an eight-year period of the cost of purchased know-how and patents and rights to use a patent and know-how which are used for the development or advancement of the Industrial Enterprise;

- under limited conditions, an election to file consolidated tax returns with related Israeli Industrial Companies; and
- expenses related to a public offering are deductible in equal amounts over three years.

Brainsway Ltd. qualifies as an Industrial Parent Company and its Israeli subsidiary, Brain Research and Development Services Ltd. ("Moach") qualifies as an Industrial Company and is eligible for various corporate tax benefits, as described above.

#### *Tax Benefits and Grants for Research and Development*

Israeli tax law allows, under certain conditions, a tax deduction for expenditures, including capital expenditures, for the year in which they are incurred. Expenditures are deemed related to scientific research and development projects, if:

- The expenditures are approved by the relevant Israeli government ministry, determined by the field of research;
- The research and development must be for the promotion of the company; and
- The research and development is carried out by or on behalf of the company seeking such tax deduction.

The amount of such deductible expenses is reduced by the sum of any funds received through government grants for the financing of such scientific research and development projects. No deduction under these research and development deduction rules is allowed if such deduction is related to an expense invested in an asset depreciable under the general depreciation rules of the Israeli Tax Ordinance, 1961. Expenditures not so approved are deductible in equal amounts over three years.

From time to time we may apply to the Israeli Innovation Authority for approval to allow a tax deduction for all research and development expenses during the year incurred. There can be no assurance that such application will be accepted.

#### *Law for the Encouragement of Capital Investments, 5719-1959*

The Law for the Encouragement of Capital Investments, 5719-1959, generally referred to as the Investment Law, provides certain incentives for capital investments in production facilities (or other eligible assets) by "Industrial Enterprises", including Benefited Enterprise, Preferred Enterprise or Technological Enterprise Preferred Enterprise or Special Preferred Technology Enterprise (as defined under the Investment Law).

#### ***New Tax Benefits under the 2017 Amendment.***

The 2017 Amendment was enacted as part of the Economic Efficiency Law that was published on December 29, 2016, and is effective as of January 1, 2017. The 2017 Amendment provides new tax benefits for two types of "Technology Enterprises", as described below, and is in addition to the other existing tax beneficial programs under the Investment Law.

The 2017 Amendment provides that a technology company satisfying certain conditions will qualify as a "Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 12% on income that qualifies as "Preferred Technology Income", as defined in the Investment Law. The tax rate is further reduced to 7.5% for a Preferred Technology Enterprise located in development zone A. In addition, a Preferred Technology Enterprise will enjoy a reduced corporate tax rate of 12% on capital gain derived from the sale of certain "Benefitted Intangible Assets" (as defined in the Investment Law) to a related foreign company if the Benefitted Intangible Assets were acquired from a

foreign company on or after January 1, 2017 for at least NIS 200 million, and the sale receives prior approval from the National Authority for Technological Innovation, or NATI.

The 2017 Amendment further provides that a technology company satisfying certain conditions will qualify as a "Special Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 6% on "Preferred Technology Income" regardless of the company's geographic location within Israel. In addition, a Special Preferred Technology Enterprise will enjoy a reduced corporate tax rate of 6% on capital gain derived from the sale of certain "Benefitted Intangible Assets" to a related foreign company if the Benefitted Intangible Assets were either developed by an Israeli company or acquired from a foreign company on or after January 1, 2017, and the sale received prior approval from NATI. A Special Preferred Technology Enterprise that acquires Benefitted Intangible Assets from a foreign company for more than NIS 500 million will be eligible for these benefits for at least ten years, subject to certain approvals as specified in the Investment Law.

Dividends distributed by a Preferred Technology Enterprise or a Special Preferred Technology Enterprise, paid out of Preferred Technology Income, are subject to withholding tax at source at the rate of 20%, and if distributed to a foreign company and other conditions are met, the withholding tax rate will be 4%.

The termination or substantial reduction of any of the benefits available under the Investment Law could materially increase our tax liabilities once we are profitable.

Moach is currently located in development zone A, which as described above, may entitle it to a reduced tax rate of 7.5% for Preferred Technology Enterprise. 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 described above.

#### *Taxation of Our Shareholders*

##### Capital Gains

Capital gain 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. The Israeli Tax Ordinance distinguishes between "Real Gain" and the "Inflationary Surplus." Real Gain is the excess of the total capital gain over Inflationary Surplus computed generally 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 currently subject to tax in Israel.

Real Gain accrued by individuals on the sale of our ordinary shares or ADSs 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%. Real Gain derived by corporations will be generally subject to the corporate tax rate of 23%.

Individual and corporate shareholder dealing in securities in Israel are taxed at the tax rates applicable to business income—23% for corporations, and a marginal tax rate of up to 50% for individuals, including an excess tax.

Notwithstanding the foregoing, capital gain derived from the sale of our ordinary shares or ADSs by a non-Israeli shareholder may be exempt under the Israeli Tax Ordinance from Israeli capital gain tax provided that the seller does not have a permanent establishment in Israel to which the derived capital gain is attributed. However, non-Israeli corporations will not be entitled to the foregoing exemption if more than 25% of its means of control are held, directly and indirectly, by Israeli



residents, and Israeli residents are entitled to 25% or more of the revenues or profits of the corporation, 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 shares may be exempt from Israeli capital gain tax under the provisions of an applicable tax treaty. For example, the U.S.-Israel Double Tax Treaty exempts U.S. residents from Israeli capital gain tax in connection with such sale, provided (i) the U.S. resident owned, directly or indirectly, less than 10% of an Israeli resident company's voting power at any time within the 12-month period preceding such sale; (ii) the seller, 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.

In some instances where our shareholders may be liable for Israeli tax on the sale of their ordinary shares or ADSs, the payment of the consideration may be subject to the withholding of Israeli tax at source at a rate of 25% if the seller is an individual and at the corporate tax rate (23%) if the seller is a corporation. Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale.

At the sale of securities traded on a stock exchange a detailed return, including a computation of the tax due, must be filed and an advanced payment must be paid on January 31 and June 30 of every tax year in respect of sales of securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Israeli Tax Ordinance and regulations promulgated thereunder, the aforementioned return need not be filed and no advance payment must be paid. Capital gain is also reportable on the annual income tax return.

## Dividends

We have never paid cash dividends. A distribution of a dividend by our company from income attributed to a Benefited Enterprise will generally be subject to withholding tax in Israel at a rate of 15% unless a reduced tax rate is provided under an applicable tax treaty. A distribution of a dividend by our company from income attributed to a Preferred Enterprise or Preferred Technology Technological Enterprise will generally be subject to withholding tax in Israel at the following tax rates: Israeli resident individuals—up to 20% in Zone A; Israeli resident companies—0% ; Non-Israeli residents—20% (4% in respect of Preferred Technology Enterprise if certain conditions are met), subject to a reduced rate under the provisions of any applicable double tax treaty. A distribution of dividends from income, which is not attributed to a Preferred Enterprise or Preferred Technology Enterprise to an Israeli resident individual, will generally be subject to withholding tax at a rate of 25%, or 30% 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 not be subject to Israeli tax provided the income from which such dividend is distributed was derived or accrued within Israel. The Israeli Tax Ordinance provides that a non-Israeli resident (either individual or corporation) is generally subject to Israeli withholding tax on the receipt of dividends at the rate of 25% (30% if the dividends recipient is a "Controlling Shareholder" (as defined above), at the time of distribution or at any time during the preceding 12-month period); those rates may be subject to a reduced rate under the provisions of an applicable double tax treaty. Under the U.S.-Israel Double Tax Treaty, the following withholding 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 share capital 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 type of interest or dividends—the 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 applicable to an Approved Enterprise—the rate is 15% and (iii) in all other cases, the rate is 25%. The aforementioned rates under the Israel U.S. Double Tax Treaty will not apply if the dividend income was derived through a permanent establishment of the U.S. resident in Israel.

A non-Israeli resident who receives dividends from which tax was withheld is generally exempt from the obligation to file tax returns in Israel with respect to such income, provided that (i) such income was not generated from a business conducted in Israel by the taxpayer, and (ii) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed.

Dividends are generally subject to Israeli withholding tax at a rate of 25% so long as the shares are registered with a nominee company (whether or not the recipient is a "Controlling Shareholder" (as defined above), unless relief is provided in a treaty between Israel and the shareholder's country of residence and provided that a certificate from the Israel Tax Authority allowing for a reduced withholding tax rate is obtained in advance.

#### Excess Tax

Individuals who are subject to tax in Israel are also subject to an additional tax at a rate of 3% on annual income exceeding NIS 649,560 for 2019, linked to the annual change in the Israeli consumer price index, including, but not limited to income derived from, dividends, interest and capital gains.

#### Foreign Exchange Regulations

Non-residents of Israel who hold our ordinary shares or ADSs 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.

#### Estate and Gift Tax

Israeli law presently does not impose estate or gift taxes.

#### **Certain U.S. Federal Income Tax Consequences**

The following is a summary of the U.S. federal income tax considerations generally applicable to a U.S. Holder (as defined below) of the acquisition, ownership, and disposition of the ADSs. This summary does not purport to address all U.S. federal income tax matters that may be relevant to a particular U.S. Holder of the ADSs, nor is it a complete analysis of all potential U.S. federal income tax consequences. This summary does not address any tax consequences arising under any state, local or non-U.S. tax laws or U.S. federal estate or gift tax laws. This summary is based on the provisions of the Internal Revenue Code of 1986, as amended (the "Code"), the Treasury regulations thereunder, and administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect. This summary applies only to a U.S. Holder that acquires the ADSs in this offering and holds the ADSs as capital assets for U.S. federal income tax purposes (generally, property held for investment). This summary does not address all U.S. federal income tax considerations that may be relevant to shareholders that are subject to special tax rules, including, without limitation, expatriates and certain former citizens of the United States, partnerships and other pass-through entities, financial institutions, insurance companies, brokers, dealers or traders in securities, commodities or currencies, tax-exempt organizations, tax qualified retirement plans and individual retirement accounts, regulated investment companies, real estate

investment trusts, persons subject to the alternative minimum tax, persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar, persons holding the ADSs as part of a hedge, straddle or other risk reduction strategy or as part of a hedging or conversion transaction or other integrated investment, persons that own or have owned (directly, indirectly, or by attribution) 10% or more of the total combined voting power or value of the outstanding shares (including ADSs) of Brainsway, and persons who acquired the ADSs through stock option or shares purchase plan programs or in other compensatory arrangements.

If a partnership (or other entity taxed as a partnership for U.S. federal income tax purposes) holds the ADSs, the tax treatment of a partner in the partnership generally will depend upon the status of the partner and the activities of the partnership. Partnerships and partners in such a partnership are urged to consult their tax advisers regarding the tax consequences of acquiring, owning, and disposing of the ADSs.

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of the ADSs acquired in this offering that is: (i) a citizen or an individual who is a resident of the United States as determined for U.S. federal income tax purposes; (ii) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any State or political subdivision thereof or the District of Columbia; (iii) an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or (iv) a trust (1) if a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons has the authority to control all of the substantial decisions of the trust; or (2) that has a valid election in effect under applicable Treasury regulations to be treated as a U.S. person.

This summary is of a general nature only and is not intended to be tax advice to any prospective investor, and no representation with respect to the tax consequences to any particular investor is made. Prospective investors are urged to consult their tax advisers with respect to the U.S. federal, state, local and non-U.S. income and other tax considerations relevant to them, having regard to their particular circumstances.

In general, a U.S. Holder who owns ADSs is treated as the beneficial owner of the underlying shares represented by those ADSs for U.S. federal income tax purposes. The remainder of this discussion assumes that a U.S. Holder of the ADSs will be treated in this manner. Accordingly, gain or loss generally will not be recognized if a U.S. Holder exchanges ADSs for the underlying ordinary shares represented by those ADSs.

#### *Distributions*

Subject to the discussion under "— Passive Foreign Investment Company Considerations" below, the gross amount of a distribution paid to a U.S. Holder with respect to the ADSs (including amounts withheld to pay Israeli withholding taxes) will be included in such holder's gross income as dividend income to the extent that the distribution is paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent that the amount of a distribution exceeds our current and accumulated earnings and profits, it will be treated first as a tax-free return of a U.S. Holder's tax basis in the ADSs, and to the extent the amount of the distribution exceeds such U.S. Holder's tax basis, the excess will be taxed as capital gain. Because we do not expect to calculate our earnings and profits in accordance with U.S. federal income tax principles, U.S. Holders should expect that a distribution generally will be treated as a dividend for U.S. federal income tax purposes.

Dividends received by individuals and other non-corporate U.S. Holders of the ADSs generally will be subject to tax at preferential rates applicable to long-term capital gains, provided that such holders meet certain holding period and other requirements and that Brainsway is not treated as a PFIC (as defined below) for the taxable year in which the dividend is paid or for the preceding taxable year. Dividends on the ADSs generally will not be eligible for the dividends-received deduction allowed to corporations. U.S. Holders are urged to consult their tax advisers regarding the application of the relevant rules to their particular circumstances.

Dividends paid on the ADSs generally will constitute foreign-source income classified as "passive category" income for foreign tax credit limitation purposes. A U.S. Holder may be entitled to deduct or credit any Israeli withholding taxes on dividends in determining its U.S. income tax liability, subject to certain limitations (including that the election to deduct or credit foreign taxes applies to all of such U.S. Holder's foreign taxes for a particular taxable year). The rules governing the foreign tax credit are complex. U.S. Holders are urged to consult their tax advisers regarding the availability of the foreign tax credit under their particular circumstances.

#### *Receipt of Foreign Currency*

The U.S. dollar value of any distribution on the ADSs made in NIS generally will be calculated by reference to the exchange rate between U.S. dollars and NIS in effect on the date of actual or constructive receipt of such distribution by the U.S. Holder, regardless of whether the NIS so received are in fact converted into U.S. dollars. If the NIS so received are converted into U.S. dollars on the date of receipt, then a U.S. Holder generally will not recognize foreign currency gain or loss on such conversion. If the NIS so received are not converted into U.S. dollars on the date of receipt, then a U.S. Holder generally will have a tax basis in the NIS equal to the U.S. dollar value of such NIS on the date of receipt. Any gain or loss on a subsequent conversion or other disposition of the NIS generally will be treated as ordinary income or loss to a U.S. Holder and generally will be U.S.-source income or loss for U.S. foreign tax credit purposes. U.S. Holders are urged to consult their tax advisers regarding the U.S. federal income tax consequences of receiving distributions on the ADSs in NIS.

#### *Sale or Other Disposition of ADSs*

Subject to the discussion under "— Passive Foreign Investment Company Considerations" below, a U.S. Holder will recognize taxable gain or loss upon the sale, exchange, or other taxable disposition of the ADSs equal to the difference, if any, between the amount realized for the ADSs and the U.S. Holder's tax basis in such ADSs. The gain or loss will be capital gain or loss. Non-corporate U.S. Holders, including individual U.S. Holders that have held the ADSs for more than one year, currently are eligible for reduced tax rates. The deductibility of capital losses is subject to limitations. Any such gain or loss recognized by a U.S. Holder generally will be treated as U.S.-source gain or loss for foreign tax credit limitation purposes.

#### *Passive Foreign Investment Company Considerations*

Certain adverse tax consequences could apply to a U.S. Holder if we are treated as a "passive foreign investment company" (a "PFIC") for any taxable year during which the U.S. Holder holds the ADSs. In general, a non-U.S. corporation is 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 and certain gains, and cash (including cash raised in this offering) is a passive asset for PFIC purposes. For purposes of the asset test and income test, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share

of the assets of the other corporation and received directly its proportionate share of the income of the other corporation.

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, including this offering. Moreover, our PFIC status is determined on an annual basis after the end of each taxable year. 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.

In general, if we were a PFIC for any taxable year during which a U.S. Holder held the ADSs, gain recognized upon a disposition (including, under certain circumstances, a pledge) of ADSs by the U.S. Holder would be allocated ratably over the U.S. Holder's holding period for such ADSs. The amounts allocated to the taxable year of disposition and to taxable years prior to the first taxable year in which we were a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest tax rate in effect for that taxable year for individuals or corporations, as appropriate, and an interest charge would be imposed on the resulting tax liability for each such year. Further, to the extent that any distribution received by a U.S. Holder on ADSs exceeded 125% of the average of the annual distributions received on such ADSs during the preceding three years or the U.S. Holder's holding period, whichever is shorter, that distribution would be subject to taxation in the same manner.

Alternatively, if we were a PFIC and if the ADSs were "regularly traded" on a "qualified exchange," a U.S. Holder might be able to make a mark-to-market election with respect to the ADSs that would result in tax treatment different from the general tax treatment for PFICs described above. The ADSs would be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of the ADSs were traded on a qualified exchange on at least 15 days during each calendar quarter. The Nasdaq Global Market, where the ADSs are expected to be listed, is a qualified exchange for this purpose. If a U.S. Holder makes the mark-to-market election, in each year that we are a PFIC the U.S. Holder generally will recognize as ordinary income any excess of the fair market value of the ADSs at the end of the taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ADSs over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder's tax basis in the ADSs will be adjusted to reflect these income or loss amounts. In addition, if a U.S. Holder makes the mark-to-market election, any gain that the U.S. Holder recognizes on the sale or other disposition of ADSs in a year in which we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). U.S. Holders should consult their tax advisers regarding the availability and advisability of making a mark-to-market election in their particular circumstances.

We do not intend to provide information necessary for U.S. Holders to make qualified electing fund elections, which, if available, would result in a further alternative tax treatment.

If we were a PFIC for any year during which a U.S. Holder owned the ADSs, we generally would continue to be treated as a PFIC with respect to such U.S. Holder's ADSs unless (i) we ceased to be a PFIC and (ii) the U.S. Holder had made a "deemed sale" election under the PFIC rules to recognize gain (but not loss) under the PFIC rules described above, without the receipt of corresponding cash.

If we were a PFIC or, with respect to a particular U.S. Holder, we were treated as a PFIC for the taxable year in which we pay a dividend or for the prior taxable year, the preferential rates discussed above with respect to dividends paid to certain non-corporate U.S. Holders would not apply. In addition, if we were a PFIC for any taxable year during which a U.S. Holder owns ADSs, the U.S. Holder would be required to file annual reports with the Internal Revenue Service, subject to certain exceptions.

U.S. Holders are urged to consult their tax advisers regarding the potential application of the PFIC rules to an investment in the ADSs.

#### *Additional Tax on Net Investment Income*

Certain U.S. Holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may include all or a portion of their dividend income and net gains from the disposition of the ADSs. Each U.S. Holder that is an individual, estate or trust is urged to consult its tax advisers regarding the applicability of this tax to its income and gains in respect of the ADSs.

#### *Foreign Financial Asset Reporting*

Citizens or individual residents of the United States holding "specified foreign financial assets" (which generally include shares and other securities issued by a foreign person unless held in an account maintained by a financial institution) that exceed certain U.S. dollar thresholds are required to report information relating to such assets, which could include the ADSs, by filing a completed Internal Revenue Service Form 8938 (Statement of Specified Foreign Financial Assets) with their tax returns. Significant penalties may apply for the failure to satisfy this reporting obligation. U.S. Holders are urged to consult their tax advisers regarding the foregoing reporting obligation with regard to their ownership of the ADSs.

#### *Information Reporting and Backup Withholding*

Distributions with respect to the ADSs and proceeds from the sale, exchange, or redemption of the ADSs may be subject to information reporting to the Internal Revenue Service and U.S. backup withholding. Backup withholding will not apply, however, to a U.S. Holder who furnishes a correct taxpayer identification number and makes other required certifications, or who is otherwise exempt from backup withholding and properly establishes such exempt status. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a U.S. Holder's U.S. federal income tax liability, and a U.S. Holder generally may obtain a refund of any excess amounts withheld under the backup withholding rules by timely filing the appropriate claim for refund with the Internal Revenue Service and furnishing any required information.

## UNDERWRITING

Subject to the terms and conditions set forth in an underwriting agreement, dated April 16, 2019, between us and Cantor Fitzgerald & Co., 499 Park Avenue, New York, New York 10022, as the representative of the underwriters named below (the "Representative") and the book-running manager of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the ADSs shown opposite its name below:

<u>Underwriter</u>	<u>Number of ADSs</u>
Cantor Fitzgerald & Co.	1,300,000
Raymond James & Associates, Inc.	475,000
Oppenheimer & Co. Inc.	475,000
Ladenburg Thalmann & Co. Inc.	250,000
Total	<u>2,500,000</u>

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the ADSs if any of them are purchased. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

### Option to Purchase Additional ADSs

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of 375,000 ADSs from us at the initial public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional ADSs proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more ADSs than the total number set forth on the cover page of this prospectus.

### Commission and Expenses

The underwriters have advised us that they propose to offer the ADSs to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of \$0.4620 per ADS. After the offering, the Representative may change the initial public offering price and other selling terms.

The following table shows the initial public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection

with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional ADSs.

	Per ADS		Total	
	Without Option to Purchase Additional Ordinary Shares	With Option to Purchase Additional Ordinary Shares	Without Option to Purchase Additional Ordinary Shares	With Option to Purchase Additional Ordinary Shares
Initial public offering price	\$ 11.00	\$ 11.00	\$ 27,500,000	\$ 31,625,000
Underwriting discounts and commissions paid by us	\$ 0.77	\$ 0.77	\$ 1,925,000	\$ 2,213,750
Proceeds to us, before expenses	\$ 10.23	\$ 10.23	\$ 25,575,000	\$ 29,411,250

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$1.3 million. We also have agreed to reimburse the underwriters for up to \$25,000 of certain of their counsel's fees and expenses, which reimbursed fee is deemed underwriting compensation for this offering by FINRA. In addition, we have agreed to pay Raymond James & Associates, Inc. a one-time fee of approximately \$50,000 for certain advisory services.

### Determination of Offering Price

Prior to this offering, there has been no public market for the ADSs in the United States. The initial public offering price was determined by negotiations between us and the Representative. Among the factors considered in determining the initial public offering price were the trading price of our ordinary shares on the TASE, our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

### Listing

The ADSs have been approved for listing on the Nasdaq Global Market under the trading symbol "BWAY."

### No Sales of Similar Securities

We, our senior management and directors and certain shareholders have agreed, subject to specified exceptions, not to directly or indirectly, for a period of 180 days after the date of the underwriting agreement:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Securities Exchange Act of 1934, as amended,
- otherwise dispose of any ordinary shares or ADSs, options or warrants to acquire ordinary shares or ADSs, or securities exchangeable or exercisable for or convertible into ordinary shares or ADSs currently or hereafter owned either of record or beneficially,
- enter into any swap, hedge or other agreement or transaction that transfers, in whole or in part, the economic consequence of ownership of ordinary shares or ADSs, or securities exchangeable or exercisable for or convertible into ordinary shares or ADSs, or
- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of Cantor Fitzgerald & Co.



In addition, we and each such person agrees that, without the prior written consent of Cantor Fitzgerald & Co., we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any ordinary share or ADS or any security convertible into or exercisable or exchangeable for ordinary shares or ADSs.

The restrictions above will not apply in certain circumstances, including:

- transfers by gift, will or operation of law;
- transfers to certain related entities;
- the exercise or conversion of options;
- the establishment of 10b5-1 trading plans, provided no sales can occur during the 180-day lock-up period;
- the transfer of ordinary shares or ADSs acquired on the open market following this offering;
- the transfer of ordinary shares or ADSs to the Company to satisfy tax withholding obligations in connection with the vesting or exercise of equity awards;
- transfers pursuant to a bona fide third-party tender offer for all outstanding shares of the Company, merger, consolidation or other similar transaction made to all holders of the Company's securities involving a change of control of the Company;
- transfers to the Company pursuant to contractual arrangements that provide for the repurchase of shares by the Company in connection with the termination of employment with the Company; and
- certain sales of ordinary shares or ADSs by officers in the event of termination of their employment with the Company.

Cantor Fitzgerald & Co. may, in its sole discretion and at any time or from time to time before the termination of the 180-day lock-up period, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of ordinary shares or ADSs prior to the expiration of the lock-up period.

#### **Market Making, Stabilization and Other Transactions**

Cantor Fitzgerald & Co. may make a market in the ADSs as permitted by applicable laws and regulations. However, Cantor Fitzgerald & Co. is not obligated to do so, and Cantor Fitzgerald & Co. may discontinue any market-making activities at any time without notice in its sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the ADSs, that you will be able to sell any of the ADSs held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters have advised us that, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the ADSs at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of the ADSs in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional ADSs or purchasing ADSs in the open market. In determining the source of ADSs to close out the covered short position, the

underwriters will consider, among other things, the price of ADSs available for purchase in the open market as compared to the price at which they may purchase ADSs through the option to purchase additional ADSs.

"Naked" short sales are sales in excess of the option to purchase additional ADSs. The underwriters must close out any naked short position by purchasing ADSs in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ADSs in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of ADSs on behalf of the underwriters for the purpose of fixing or maintaining the price of the ADSs. A syndicate covering transaction is the bid for or the purchase of ADSs on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of the ADSs or preventing or retarding a decline in the market price of the ADSs. As a result, the price of the ADSs may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the ADSs originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we, nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the ADSs. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

### **Passive Market Making**

The underwriters may also engage in passive market making transactions in the ADSs on The Nasdaq Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of the ADSs in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded. Passive market making may cause the price of the ADSs to be higher than the price that otherwise would exist in the open market in the absence of those transactions. The underwriters are not required to engage in passive market making and, if commenced, may end passive market making activities at any time.

### **Electronic Distribution**

A prospectus in electronic format may be made available by e-mail (or on the web sites) or through online services maintained by one or more of the underwriters or their affiliates. The underwriters may agree with us to allocate a specific number of ADSs for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

### **Other Activities and Relationships**

The underwriters and certain of their respective affiliates are full service financial institutions engaged in a wide range of activities for their own accounts and the accounts of customers, which may

include corporate finance, mergers and acquisitions, merchant banking, equity and fixed income sales, trading and research, derivatives, foreign exchange, futures, asset management, custody, clearance and securities lending. The underwriters and certain of their affiliates, from time to time, may in the future perform various investment banking and financial advisory services for us and our affiliates, for which they would receive customary fees and expenses.

In addition, in the ordinary course of their business, the underwriters and certain of their affiliates may, directly or indirectly, hold long or short positions, trade and otherwise conduct such activities in or with respect to debt or equity securities and/or bank debt of, and/or derivative products. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

## **Notice to Investors**

### ***Canada***

This prospectus constitutes an "exempt offering document" as defined in and for the purposes of applicable Canadian securities laws. No prospectus has been filed with any securities commission or similar regulatory authority in Canada in connection with the offer and sale of the ADSs. No securities commission or similar regulatory authority in Canada has reviewed or in any way passed upon this prospectus or on the merits of the ADSs and any representation to the contrary is an offence.

**Canadian investors are advised that this prospectus has been prepared in reliance on section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* ("NI 33-105"). Pursuant to section 3A.3 of NI 33-105, this prospectus is exempt from the requirement that the Company and the underwriter(s) provide investors with certain conflicts of interest disclosure pertaining to "connected issuer" and/or "related issuer" relationships that may exist between the Company and the underwriter(s) as would otherwise be required pursuant to subsection 2.1(1) of NI 33-105.**

#### *Resale Restrictions*

The offer and sale of the ADSs in Canada is being made on a private placement basis only and is exempt from the requirement that the Company prepares and files a prospectus under applicable Canadian securities laws. Any resale of the ADSs acquired by a Canadian investor in this offering must be made in accordance with applicable Canadian securities laws, which may vary depending on the relevant jurisdiction, and which may require resales to be made in accordance with Canadian prospectus requirements, pursuant to a statutory exemption from the prospectus requirements, in a transaction exempt from the prospectus requirements or otherwise under a discretionary exemption from the prospectus requirements granted by the applicable local Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the ADSs outside of Canada.

#### *Representations of Purchasers*

Each Canadian investor who purchases the ADSs will be deemed to have represented to the Company and the underwriter(s) that the investor (i) is purchasing the ADSs as principal, or is deemed to be purchasing as principal in accordance with applicable Canadian securities laws, for investment only and not with a view to resale or redistribution; (ii) is an "accredited investor" as such term is defined in section 1.1 of National Instrument 45-106 *Prospectus Exemptions* ("NI 45-106") or, in Ontario, as such term is defined in section 73.3(1) of the *Securities Act* (Ontario); and (iii) is a "permitted client" as such term is defined in section 1.1 of National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*.

### *Taxation and Eligibility for Investment*

Any discussion of taxation and related matters contained in this prospectus does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a Canadian investor when deciding to purchase the ADSs and, in particular, does not address any Canadian tax considerations. No representation or warranty is hereby made as to the tax consequences to a resident, or deemed resident, of Canada of an investment in the ADSs or with respect to the eligibility of the ADSs for investment by such investor under relevant Canadian federal and provincial legislation and regulations.

### *Rights of Action for Damages or Rescission*

Securities legislation in certain of the Canadian jurisdictions provides certain purchasers of securities pursuant to an offering memorandum (such as this prospectus), including where the distribution involves an "eligible foreign security" as such term is defined in Ontario Securities Commission Rule 45-501 *Ontario Prospectus and Registration Exemptions* and in Multilateral Instrument 45-107 *Listing Representation and Statutory Rights of Action Disclosure Exemptions*, as applicable, with a remedy for damages or rescission, or both, in addition to any other rights they may have at law, where the offering memorandum, or other offering document that constitutes an offering memorandum, and any amendment thereto, contains a "misrepresentation" as defined under applicable Canadian securities laws. These remedies, or notice with respect to these remedies, must be exercised or delivered, as the case may be, by the purchaser within the time limits prescribed under, and are subject to limitations and defences under, applicable Canadian securities legislation. In addition, these remedies are in addition to and without derogation from any other right or remedy available at law to the investor.

### *Language of Documents*

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur Canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.*

### **Australia**

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

### ***European Economic Area***

In relation to each Member State of the European Economic Area, no offer of any securities which are the subject of the offering contemplated by this prospectus has been or will be made to the public in that Member State other than any offer where a prospectus has been or will be published in relation to such securities that has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the relevant competent authority in that Member State in accordance with the Prospectus Directive, except that an offer of such securities may be made to the public in that Member State:

- to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;
- to fewer than 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of securities shall require the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any securities in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive), and includes any relevant implementing measure in the Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

### ***Hong Kong***

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32) of Hong Kong. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to

"professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

### ***Japan***

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

### ***Singapore***

This prospectus has not been and will not be lodged or registered with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase of the securities may not be issued, circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to the public or any member of the public in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person as defined under Section 275(2), or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor as defined under Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the Offer Shares under Section 275 of the SFA except:

- to an institutional investor under Section 274 of the SFA or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in

cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions, specified in Section 275 of the SFA;

- where no consideration is given for the transfer; or
- where the transfer is by operation of law.

### **Switzerland**

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, or FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

### **Israel**

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the shares is directed only at, investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals", each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

### **United Kingdom**

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors (as defined in the Prospectus Directive) that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, referred to herein as the "Order", and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated or caused to be communicated. Each such person is referred to herein as a "Relevant Person."

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United

Kingdom. Any person in the United Kingdom that is not a Relevant Person should not act or rely on this document or any of its contents.

Any invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (the "FSMA") may only be communicated or caused to be communicated in connection with the issue or sale of the securities in circumstances in which Section 21(1) of the FSMA does not apply. All applicable provisions of the FSMA must be complied with in respect of anything done by any person in relation to the securities in, from or otherwise involving the United Kingdom.



**EXPENSES RELATED TO OFFERING**

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the offer and sale of ADSs in this offering. All amounts listed below are estimates except the SEC registration fee, Nasdaq listing fee and the FINRA filing fee.

<u>Expense</u>	<u>Amount</u>
SEC registration fee	\$ 4,160.49
FINRA filing fee	5,649.13
Nasdaq Global Market listing fee	125,000
Printing and engraving expenses	50,000
Legal fees and expenses	800,000
Depository, transfer agent and registrar fees	14,000
Accounting fees and expenses	300,000
Miscellaneous	41,792.38
<b>Total</b>	<b>\$ 1,340,602</b>

## LEGAL MATTERS

The validity of the ordinary shares underlying the ADSs being offered by this prospectus and other legal matters concerning this offering relating to Israeli law will be passed upon for us by Gross, Kleinhendler, Hodak, Halevy, Greenberg, Shenhav & Co., Tel-Aviv, Israel. Certain legal matters in connection with this offering relating to U.S. law will be passed upon for us by Torys LLP, New York, New York. Legal counsel to the underwriters are Agmon & Co., Rosenberg Hacoen & Co., Tel Aviv, Israel, with respect to Israeli law, and Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., Boston, Massachusetts, with respect to U.S. law.

## EXPERTS

The consolidated financial statements of our Company as of December 31, 2018 and 2017 and for each of the two years in the period ended December 31, 2018 appearing in this prospectus and the registration statement have been audited by Kost Forer Gabbay & Kasierer, an independent registered public accounting firm and a member firm of Ernst & Young Global, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing. The offices of Kost Forer Gabbay & Kasierer are located at 144A Menachem Begin Road, Tel-Aviv, 6492102, Israel.

## ENFORCEABILITY OF CIVIL LIABILITIES

We are incorporated under the laws of the State of Israel. Service of process upon us and upon our directors and officers and the Israeli experts named in this prospectus, substantially all of whom reside outside the United States, may be difficult to obtain within the United States. Furthermore, because substantially all of our assets and substantially all of our directors and senior management are located outside the United States, any judgment obtained in the United States against us or any of our directors and officers may not be collectible within the United States.

We have irrevocably appointed Brainsway USA Inc as our agent to receive service of process in any action against us in any U.S. federal or state court arising out of this offering or any purchase or sale of securities in connection with this offering. The address of our agent is 3 University Plaza Drive, Hackensack, New Jersey, 07601.

We have been informed by our legal counsel in Israel, Gross, Kleinhendler, Hodak, Halevy, Greenberg, Shenhav & Co., that it may be difficult to initiate an action with respect to U.S. securities law in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum to hear such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact by expert witnesses which can be a time-consuming and costly process. Certain matters of procedure may also be governed by Israeli law.

Subject to certain time limitations and legal procedures, Israeli courts may enforce a U.S. judgment in a civil matter which, subject to certain exceptions, is non-appealable, including judgments based upon the civil liability provisions of the Securities Act and the Exchange Act and including a monetary or compensatory judgment in a non-civil matter, provided that:

- the judgment was rendered by a court which was, according to the laws of the state of the court, competent to render the judgment;
- the obligation imposed by the judgment is enforceable according to the rules relating to the enforceability of judgments in Israel and the substance of the judgment is not contrary to public policy; and
- the judgment is executory in the state in which it was given.

Even if these conditions are met, an Israeli court will not declare a foreign civil judgment enforceable if:

- the judgment was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases);
- the enforcement of the judgment is likely to prejudice the sovereignty or security of the State of Israel;
- the judgment was obtained by fraud;
- the opportunity given to the defendant to bring its arguments and evidence before the court was not reasonable in the opinion of the Israeli court;
- the judgment was rendered by a court not competent to render it according to the laws of private international law as they apply in Israel;
- the judgment is contradictory to another judgment that was given in the same matter between the same parties and that is still valid; or

- at the time the action was brought in the foreign court, a lawsuit in the same matter and between the same parties was pending before a court or tribunal in Israel.

If a foreign judgment is enforced by an Israeli court, it generally will be payable in Israeli currency, which can then be converted into non-Israeli currency and transferred out of Israel. The usual practice in an action before an Israeli court to recover an amount in a non-Israeli currency is for the Israeli court to issue a judgment for the equivalent amount in Israeli currency at the rate of exchange in force on the date of the judgment, but the judgment debtor may make payment in foreign currency. Pending collection, the amount of the judgment of an Israeli court stated in Israeli currency ordinarily will be linked to the Israeli consumer price index plus interest at the annual statutory rate set by Israeli regulations prevailing at the time. Judgment creditors must bear the risk of unfavorable exchange rates.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form F-1 under the Securities Act relating to this offering of the ADSs. This prospectus does not contain all of the information contained in the registration statement. The rules and regulations of the SEC allow us to omit certain information from this prospectus that is included in the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we filed any of these documents as an exhibit to the registration statement, you may read the document itself for a complete description of its terms.

The SEC maintains an Internet site that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are also available to the public through this web site at <http://www.sec.gov>.

We are not currently subject to the informational requirements of the Exchange Act. As a result of this offering, we will become subject to the informational requirements of the Exchange Act applicable to foreign private issuers and will fulfill the obligations of these requirements by filing reports with the SEC. As a foreign private issuer, we will be exempt from the rules under the Exchange Act relating to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic 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 intend to file with the SEC, within 120 days after the end of our 2019 fiscal year, an annual report on Form 20-F containing financial statements which will be audited and reported on, with an opinion expressed, by an independent registered public accounting firm. We also intend to file with the SEC reports on Form 6-K containing unaudited financial information for the first three quarters of each fiscal year.

We maintain a corporate website at [www.brainsway.com](http://www.brainsway.com). Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

**BRAINSWAY LTD.  
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**BRAINSWAY LTD.**

**AUDITED FINANCIAL STATEMENTS AS OF AND FOR THE YEARS ENDED  
DECEMBER 31, 2018 AND 2017**





**Kost Forer Gabbay & Kasierer**  
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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, 2018 and 2017, and the related consolidated statements of comprehensive loss, changes in equity and cash flows for each of the two years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, 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.

/s/ KOST FORER GABBAY & KASIERER  
A Member of Ernst & Young Global  
We have served as the Company's auditor since 2003.

Tel-Aviv, Israel  
March 26, 2019

**BRAINSWAY LTD.**
**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**
**U.S. dollars in thousands (except share and per share data)**

	Note	December 31,	
		2018	2017
<b>ASSETS</b>			
<b>CURRENT ASSETS:</b>			
Cash and cash equivalents	5	\$ 8,968	\$ 14,509
Short-term deposits	6	101	50
Trade receivables, net	7	2,904	2,419
Other accounts receivable	8	1,505	909
		<u>13,478</u>	<u>17,887</u>
<b>NON-CURRENT ASSETS:</b>			
Restricted deposit	13b, 17h	1,007	2,009
Long-term prepaid expenses	1c	1,345	—
Long-term deposit		146	25
Property and equipment, net	9	7,626	7,109
		<u>10,124</u>	<u>9,143</u>
		<u>\$ 23,602</u>	<u>\$ 27,030</u>
<b>LIABILITIES AND EQUITY</b>			
<b>CURRENT LIABILITIES:</b>			
Trade payables	11	\$ 2,243	\$ 1,631
Other accounts payable	12	3,459	1,803
Deferred revenues	17c	1,333	2,448
Loan from bank	13b	750	—
Liability in respect of research and development grants	13c	554	251
		<u>8,339</u>	<u>6,133</u>
<b>NON-CURRENT LIABILITIES:</b>			
Loan from bank	13b	2,083	2,727
Deferred revenues and other liabilities	17e, 17g	1,108	309
Liability in respect of research and development grants	13c	4,980	5,028
Warrants	13b	140	112
		<u>8,311</u>	<u>8,176</u>
<b>EQUITY:</b>			
	18		
Share capital		171	171
Share premium		67,193	65,951
Share-based payment	19	3,357	3,889
Adjustments arising from translating financial statements from functional currency to presentation currency		(2,188)	(2,188)
Accumulated deficit		(61,581)	(55,102)
		<u>6,952</u>	<u>12,721</u>
		<u>\$ 23,602</u>	<u>\$ 27,030</u>

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)

		Year ended December 31,	
	Note	2018	2017
Revenues	20a	\$ 16,397	\$ 11,145
Cost of revenues	20b	3,589	2,595
Gross profit		12,808	8,550
Research and development expenses, net	20c	6,156	5,343
Selling and marketing expenses	20d	8,345	6,331
General and administrative expenses	20e	3,421	3,487
Total operating expenses		17,922	15,161
Operating loss		5,114	6,611
Finance income	20f	(44)	(133)
Finance expense	20f	1,200	407
Loss before income taxes		6,270	6,885
Income taxes	16b	209	169
Net loss and total comprehensive loss		\$ 6,479	\$ 7,054
Basic and diluted net loss per share	21	\$ (0.39)	\$ (0.48)

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, 2017	\$ 149	57,502	\$ 2,872	\$ (2,188)	\$ (48,048)	\$ 10,287
Net loss and total comprehensive loss	—	—	—	—	(7,054)	(7,054)
Issuance of shares, net(*)	22	8,423	—	—	—	8,445
Expiration of share options	—	26	(26)	—	—	—
Cost of share-based payment	—	—	1,043	—	—	1,043
Balance at December 31, 2017	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 of issuance expenses of \$ 133.

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,	
	2018	2017
<i>Cash flows from operating activities:</i>		
Total comprehensive loss	\$ (6,479)	\$ (7,054)
Adjustments to reconcile net loss to net cash used in operating activities:		
Adjustments to profit or loss items:		
Depreciation and amortization	1,228	1,072
Finance expenses, net	1,157	274
Cost of share-based payment	710	1,028
Income taxes	209	169
	<u>3,304</u>	<u>2,543</u>
Changes in asset and liability items:		
Increase in trade receivables	(419)	(21)
Decrease (increase) in other accounts receivable	(595)	113
Increase in long-term prepaid expenses	(217)	—
Increase in trade payables	859	310
Increase in other accounts payable	482	163
Increase (decrease) in deferred revenues and other liabilities	(314)	523
	<u>(204)</u>	<u>1,088</u>
Cash paid and received during the year for:		
Interest paid	(239)	—
Interest received	37	12
Taxes	(192)	(56)
	<u>(394)</u>	<u>(44)</u>
Net cash used in operating activities	<u>(3,773)</u>	<u>(3,467)</u>
<i>Cash flows from investing activities:</i>		
Purchase of property and equipment(*)	(1,972)	(985)
Withdrawal of (Investment in) restricted deposit	1,007	(2,000)
Withdrawal of (Investment in) short-term deposits, net	(50)	535
Withdrawal of (Investment in) long-term deposits, net	(121)	(1)
Net cash used in investing activities	<u>(1,136)</u>	<u>(2,451)</u>
<i>Cash flows from financing activities:</i>		
Receipt of loan from bank, net	—	2,702
Receipt of government grants	149	186
Repayment of liability in respect of research and development grants	(414)	(375)
Issuance of warrants	—	150
Proceeds from issuance of shares, net	—	8,445
Net cash used in/provided by financing activities	<u>(265)</u>	<u>11,108</u>
Exchange rate differences on cash and cash equivalents	(367)	145
Increase (decrease) in cash and cash equivalents	(5,541)	5,335
Cash and cash equivalents at the beginning of the year	14,509	9,174
Cash and cash equivalents at the end of the year	<u>\$ 8,968</u>	<u>\$ 14,509</u>
(a) <i>Significant non-cash transactions:</i>		
Purchase of property and equipment on credit	\$ 280	\$ 469
long-term prepaid expenses not yet paid	<u>\$ 1,128</u>	<u>\$ —</u>

(\*) Derives mainly from purchase of system components

**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 2018, the Company received clearance of marketing authorization by the FDA for the adjunct therapy for the treatment of obsessive-compulsive disorder (OCD) 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. The Group had negative cash flows from operating activities and an operating loss of \$ 3.8 million and \$ 5.1 million for the year ended December 31, 2018, respectively. In August 2017, the Company entered into an agreement for the receipt of a bank credit facility of up to \$ 6,000. In October 2017, the Company withdrew \$ 3,000 from the said credit facility (see Note 13b and 13d). The Company's management and board of directors believe that the Company will have the required funding to finance its business activity according to its plans in the foreseeable future.
- c. On January 14, 2019, the Company filed with the SEC a registration statement on Form F-1 for an initial public offering of the Company's securities in the United States through ADSs (American Depositary Shares, each representing a number of shares to be determined in connection with the offering process). In 2018, the Company incurred expenses of \$ 1.3 million relating to the process of submitting the registration statement, which were recognized as long-term prepaid expenses.

**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.

**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**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.

**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**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. Allowance for doubtful accounts (accounting policy applied until December 31, 2017):

The allowance for doubtful accounts is determined in respect of specific trade receivables whose collection in the opinion of the Company's management, is doubtful. The Company did not recognize an allowance in respect of groups of customers that are collectively assessed for impairment since it did not identify any groups of customers which bear similar credit risks. Impaired receivables are derecognized when they are assessed as uncollectible.

See Note 2m with respect to accounting applied commencing January 1, 2018.

g. Revenue recognition:

IFRS 15, "Revenue from Contracts with Customers" ("IFRS 15") has been adopted for the first time in these financial statements using the modified retrospective method.

The new standard has been applied for the first time in these financial statements. The Company elected to adopt the provisions of the new standard using the modified retrospective method with the application of certain practical expedients and without restatement of comparative data. There was no effect of the initial adoption of the new standard on the opening balance of retained earnings as at January 1, 2018.

IFRS 15 introduces a five-step model that applies to revenue earned from contracts with customers.

The accounting policy applied from January 1, 2018 regarding revenue recognition according to IFRS 15 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, in the reporting periods in which the services are rendered. When payments are made before the service is performed, the Company recognizes the resulting contract liability as deferred revenue. Revenue from services were insignificant for all reported periods.



**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**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, 2018 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. 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.

h. 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

**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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.

i. Leases:

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.

j. 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.

**BRAINSWAY LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****U.S. dollars in thousands (except share and per share data)****NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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.

**k. Property and equipment, net:**

Property and equipment are measured at cost less accumulated depreciation and excluding day-to-day servicing expenses.

The cost of self-constructed 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.

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
Motor vehicles	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 Group 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.

**l. 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

**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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.

Impairment of leased equipment is recognized in cost of revenues. For the years ended December 31, 2018 and 2017, impairment of nil and \$ 225 was recorded, respectively.

m. Financial instruments:

IFRS 9, "Financial Instruments" ("IFRS 9") has been adopted for the first time in these financial statements. The Company chose to adopt the provisions of IFRS 9 retrospectively with certain reliefs and not to restate comparative figures. The first time adoption of IFRS 9 had no impact on accumulated deficit as of January 1, 2018.

1. Impairment of financial assets:

The Company reviews at the end of each reporting period the provision for loss of financial debt instruments which are not measured at fair value through profit or loss. The Company distinguishes between two types of provision for losses:

- a. Debt instruments whose credit quality has not significantly deteriorated since their initial recognition date or whose credit risk is low—the provision for loss that will be recognized in respect of this debt instrument will take into account expected credit losses within 12 months from the reporting date; or
- b. Debt instruments whose credit quality has significantly deteriorated since their initial recognition date or whose credit risk is not low—the provision for loss that will be recognized will take into account expected credit losses over the instrument's remaining term.

An impairment loss of debt instruments measured at amortized cost is carried to profit or loss against a provision whereas an impairment loss of debt instruments measured at fair value through other comprehensive income will be carried against a capital reserve and will not reduce the carrying amount of the financial asset in the statement of financial position.

The Company has financial assets bearing short-term credit such as trade receivables in respect of which it is required to adopt the relief prescribed in the model i.e., the Company will measure the provision for loss in an amount which is equivalent to the 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

**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)**

nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

- 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.

3. 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.

4. 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.

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.

n. 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.

**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**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).

o. 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.

p. 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.

**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**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 15.

q. 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.

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.

**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**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 IAS 17 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.

- 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.

**NOTE 4: DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION**

a. IFRS 16, "Leases":

In January 2016, the IASB issued IFRS 16, "Leases" ("IFRS 16"), which replaces IAS 17, "Leases", IFRIC 4, "Determining whether an Arrangement contains a Lease", SIC-15, "Operating Leases-Incentives" and SIC-27, "Evaluating the Substance of Transactions Involving the Legal Form of a Lease." IFRS 16 sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for all leases under a single on-balance sheet model similar to the accounting for finance leases under IAS 17. The standard includes two recognition exemptions for lessees—leases of 'low-value' assets (e.g., personal computers) and



**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**NOTE 4: DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION (Continued)**

short-term leases (i.e., leases with a lease term of 12 months or less). At the commencement date of a lease, a lessee will recognize a liability to make lease payments (i.e., the lease liability) and an asset representing the right to use the underlying asset during the lease term (i.e., the right-of-use asset). Lessees will be required to separately recognize the interest expense on the lease liability and the depreciation expense on the right-of-use asset.

Lessees will be also required to remeasure the lease liability upon the occurrence of certain events (e.g., a change in the lease term, a change in future lease payments resulting from a change in an index or rate used to determine those payments). The lessee will generally recognize the amount of the remeasurement of the lease liability as an adjustment to the right-of-use asset.

Lessor accounting under IFRS 16 is substantially unchanged from today's accounting under IAS 17. Lessors will continue to classify all leases using the same classification principle as in IAS 17 and distinguish between two types of leases: operating and finance leases.

IFRS 16, which is effective for annual periods beginning on or after 1 January 2019, requires lessees and lessors to make more extensive disclosures than under IAS 17.

The Company expects to adopt the modified retrospective approach and that the effect of the first-time adoption of IFRS 16 as of January 1, 2019 will result in an increase of approximately \$1,400 of the Company's total assets and corresponding liabilities.

Also, the effect of the first-time adoption of IFRS 16 in 2019 is expected to result in a decrease of approximately \$500 in the Company's operating lease expense, an increase of approximately \$500 and an increase of approximately \$100 in the Company's depreciation and amortization expense and finance expense, respectively. The total effect of the first-time adoption of IFRS 16 in 2019 on operating loss and loss before taxes is immaterial.

In addition, the effect of the first-time adoption of IFRS 16 in 2019 is expected to result in an increase of approximately \$400 in cash flows from operating activities and a corresponding decrease in cash flows from financing activities.

The above quantitative disclosures refer to the impact known to the Company as of today based on the existing lease contracts as of January 1, 2019. The accounting treatment of transactions in which the Company is the lessor will remain without any material change. The Company has a bank credit facility that contains certain financial covenants. The first-time adoption of IFRS 16 is not expected to have an effect on these covenants. The Company's forecast of the effects of IFRS 16 on the financial statements depends on additional contracts that will be signed during the period up to the first-time adoption of IFRS 16 and changes in various economic variables that may affect the discount rates used for the calculation of the liabilities during the period up to the first-time adoption of IFRS 16.

**BRAINSWAY LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****U.S. dollars in thousands (except share and per share data)****NOTE 4: DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION (Continued)****b. IFRIC 23, "Uncertainty over Income Tax Treatments":**

In June 2017, the IASB issued IFRIC 23, "Uncertainty over Income Tax Treatments" ("the Interpretation"). The Interpretation clarifies the rules of recognition and measurement of assets or liabilities in accordance with the provisions of IAS 12, "Income Taxes", in situations of uncertainty involving income taxes. The Interpretation provides guidance on considering whether some tax treatments should be considered collectively, examination by the tax authorities, measurement to reflect uncertainty involving income taxes in the financial statements and accounting for changes in facts and circumstances underlying the uncertainty.

The Interpretation is to be applied in financial statements for annual periods beginning on January 1, 2019. Early adoption is permitted. Upon initial adoption, the Company will apply the Interpretation using one of two approaches: 1. Full retrospective adoption, without restating comparative data, by recording the cumulative effect through the date of initial adoption in the opening balance of retained earnings, or 2. Full retrospective adoption including restatement of comparative data.

The Company does not expect the Interpretation to have any material impact on its financial statements.

**NOTE 5: CASH AND CASH EQUIVALENTS**

	<u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
Cash for immediate withdrawal	\$ 5,965	\$ 7,386
Cash equivalents—short-term deposits(1)	3,003	7,123
	<u>\$ 8,968</u>	<u>\$ 14,509</u>

(1) The deposits earn annual interest at the respective term of the deposits (U.S. dollar—0.5%).

As of December 31, 2018, the Group had a \$ 3,000 unused credit facility, see Note 13b.

**NOTE 6: SHORT-TERM DEPOSITS**

	<u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
Bank deposits(1)	<u>\$ 101</u>	<u>\$ 50</u>

(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 (U.S. dollar—1.38%).

**BRAINSWAY LTD.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**
**U.S. dollars in thousands (except share and per share data)**
**NOTE 7: TRADE RECEIVABLES, NET**

a. Trade receivables, net:

	<u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
Open accounts(1)	\$ 3,165	\$ 2,707
Credit cards	74	—
Less—allowance for doubtful accounts	(335)	(288)
Trade receivables, net	<u>\$ 2,904</u>	<u>\$ 2,419</u>

(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>U.S. dollars in thousands</u>
Balance as of January 1, 2017	\$ —
Charge for the year	420
Derecognition of bad debts	(132)
Balance as of December 31, 2017	288
Provision for the year	335
Derecognition of bad debts	(249)
Reversal in respect of collected doubtful accounts	(39)
Balance as of December 31, 2018	<u>\$ 335</u>

(1) Following is information about the credit risk exposure of the Company's trade receivables as of December 31, 2018:

	<u>U.S. dollars in thousands</u>						
	<u>Not past due</u>	<u>&lt; 30 days</u>	<u>30 - 60 days</u>	<u>61 - 90 days</u>	<u>91 - 120 days</u>	<u>&gt;120 days</u>	<u>Total</u>
	<u>U.S. dollars in thousands</u>						
Gross carrying amount	\$ 1,210	\$ 953	\$ 207	\$ 305	\$ 266	\$ 298	\$ 3,239
Allowance for doubtful accounts	\$ 148	\$ 39	\$ 12	\$ 23	\$ 23	\$ 90	\$ 335
Trade receivable, net							<u>\$ 2,904</u>

## BRAINSWAY LTD.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## NOTE 7: TRADE RECEIVABLES, NET (Continued)

(2) Following is an analysis of past due but not impaired trade receivables (allowance for doubtful accounts) as of December 31, 2018 and 2017:

	Neither past due nor impaired	Past due trade receivables with aging of					Total
		< 30 days	30 - 60 days	60 - 90 days	90 - 120 days	> 120 days	
December 31, 2018	\$ 1,062	\$ 914	\$ 195	\$ 282	\$ 243	\$ 208	\$ 2,904
December 31, 2017	\$ 1,198	\$ 323	\$ 258	\$ 77	\$ 153	\$ 410	\$ 2,419

As of December 31, 2018, the Company has over 90 days past due trade receivables of \$ 451, of which \$ 258 were paid between the reporting date and the date of the approval of the financial statements. The Company expects to collect the entire amount of these debts.

## NOTE 8: OTHER ACCOUNTS RECEIVABLE

	December 31,	
	2018	2017
Government authorities	\$ 738	\$ 394
Accrued income-IIA	332	113
Consumables	91	271
Prepaid expenses and other	344	131
	\$ 1,505	\$ 909

**BRAINSWAY LTD.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**
**U.S. dollars in thousands (except share and per share data)**
**NOTE 9: PROPERTY AND EQUIPMENT, NET**
**December 31, 2018:**

	Leased systems	System Components	Laboratory equipment	Motor vehicles	Computers	Office furniture and equipment	Leasehold improvements	Total
<i>Cost:</i>								
Balance at								
January 1, 2018	\$ 4,627	\$ 3,553	\$ 160	\$ 1	\$ 472	\$ 75	\$ 52	\$ 8,940
Additions	—	2,645	6	—	155	7	—	2,813
Transfer to Leased								
systems	2,458	(2,458)	—	—	—	—	—	—
Reductions	(716)**	(1,023)	—	—	—	—	—	(1,739)
Balance at								
December 31, 2018	<u>6,369</u>	<u>2,717</u>	<u>166</u>	<u>1</u>	<u>627</u>	<u>82</u>	<u>52</u>	<u>10,014</u>
<i>Accumulated depreciation:</i>								
Balance at								
January 1, 2018	1,187	—	145	1	408	38	52	1,831
Additions	817	—	8	—	51	6	—	882
Reductions	(325)	—	—	—	—	—	—	(325)
Balance at								
December 31, 2018	<u>1,679</u>	<u>—</u>	<u>153</u>	<u>1</u>	<u>459</u>	<u>44</u>	<u>52</u>	<u>2,388</u>
Depreciated cost at								
December 31, 2018	<u>\$ 4,690</u>	<u>\$ 2,717</u>	<u>\$ 13</u>	<u>\$ —(*)</u>	<u>\$ 168</u>	<u>\$ 38</u>	<u>\$ —(*)</u>	<u>\$ 7,626</u>

(\*) Represents an amount lower than \$ 1

(\*\*) Derives mainly from systems leased to customers and sold

**BRAINSWAY LTD.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**
**U.S. dollars in thousands (except share and per share data)**
**NOTE 9: PROPERTY AND EQUIPMENT, NET (Continued)**
**December 31, 2017:**

	Leased systems	System Components	Laboratory equipment	Motor vehicles	Computers	Office furniture and equipment	Leasehold improvements	Total
<i>Cost:</i>								
Balance at								
January 1, 2017	\$ 4,093	\$ 3,750	\$ 160	\$ 1	\$ 438	\$ 75	\$ 52	\$ 8,585
Additions	—	2,721	—	—	34	—	—	2,739
Transfer to Leased systems								
	1,957	(1,957)	—	—	—	—	—	—
Reductions	(1,423)(**)	(961)	—	—	—	—	—	(2,384)
Balance at								
December 31, 2017	4,627	3,553	160	1	472	75	52	8,940
<i>Accumulated depreciation:</i>								
Balance at								
January 1, 2017	1,179	—	122	1	352	33	52	1,603
Additions	680	—	23	—	56	5	—	900
Reductions	(672)	—	—	—	—	—	—	(672)
Balance at								
December 31, 2017	1,187	—	145	1	408	38	52	1,831
Depreciated cost								
at December 31, 2017	<u>\$ 3,440</u>	<u>\$ 3,553</u>	<u>\$ 15</u>	<u>\$ —(*)</u>	<u>\$ 64</u>	<u>\$ 37</u>	<u>\$ —(*)</u>	<u>\$ 7,109</u>

(\*) Represents an amount lower than \$ 1.

(\*\*) Derives mainly from systems leased to customers and sold

**NOTE 10: 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, 2018 and 2017:

	Valuation date	Fair value hierarchy			Total
		Level 1	Level 2	Level 3	
<i>Liabilities measured at fair value:</i>					
Liability in respect of warrants	31.12.2018	\$ —	\$ 140	\$ —	\$ 140
Liability in respect of warrants	31.12.2017	\$ —	\$ 112	\$ —	\$ 112

## BRAINSWAY LTD.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## NOTE 11: TRADE PAYABLES

	December 31,	
	2018	2017
Open debt	\$ 2,243	\$ 1,631

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

## NOTE 12: OTHER ACCOUNTS PAYABLE

	December 31,	
	2018	2017
Employee and payroll accruals	\$ 1,067	\$ 955
Accrued expenses	2,161	665
Tax payable	130	128
Liabilities to related parties(1)	101	55
	<u>\$ 3,459</u>	<u>\$ 1,803</u>

(1) A current non-interest bearing account.

## NOTE 13: NON-CURRENT LIABILITIES

a. Composition:

	December 31,	
	2018	2017
Loan from bank(b)	\$ 2,083	\$ 2,727
Warrants(b)	140	112
Liability in respect of research and development grants(c)	4,980	5,028
Deferred revenues and other liabilities	1,108	309
	<u>\$ 8,311</u>	<u>\$ 8,176</u>

b. 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 2017 ("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

**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**NOTE 13: NON-CURRENT LIABILITIES (Continued)**

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.

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.

c. Government grants:

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, 2018, the maximum royalties payable by the Company in the future in respect of active projects is \$ 12,820, including interest at the Libor rate. Through December 31, 2018, royalties paid were \$ 1,386.

d. Financial covenants:

According to the Bank Credit Facility agreement (see: b above), the withdrawal of the credit facility is subject to meeting the following financial covenants: (1) total trade receivables and the cash balance will not be less than \$ 4,000 provided that the total cash, including the restricted deposit, is not less than \$ 2,000; (2) minimum lease fees expected to be received from all signed lease contracts of the Company during a period of four years shall be no less than \$ 15,000 (cumulative); (3) minimum lease fees expected to be received from all signed lease contracts of the



**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**NOTE 13: NON-CURRENT LIABILITIES (Continued)**

Company during a period of four years offset by amounts that may not be received from customers due to early termination of the lease contract, shall be no less than \$ 7,500 and (4) total short and long-term financial credit shall not exceed \$ 6,000.

As of December 31, 2018, the Company met the abovementioned financial covenants.

**NOTE 14: 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, 2018 and 2017 was \$ 140 and \$112, 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. 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).

3. Liquidity risk:

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

**BRAINSWAY LTD.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**
**U.S. dollars in thousands (except share and per share data)**
**NOTE 14: FINANCIAL INSTRUMENTS (Continued)**

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

**December 31, 2018**

	Less than one year	1 to 2 years	2 to 3 years	3 to 4 years	4 to 5 years	> 5 years	Total
Trade payables	\$ 2,243	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 2,243
Other accounts payable	3,394	—	—	—	—	—	3,394
Loan from bank	988	1,637	773	—	—	—	3,398
Long-term liabilities	2	1	—	—	—	—	3
Liability in respect of research and development grants	631	855	1,185	1,545	1,890	7,378	13,484
	<u>\$ 7,258</u>	<u>\$ 2,493</u>	<u>\$ 1,958</u>	<u>\$ 1,545</u>	<u>\$ 1,890</u>	<u>\$ 7,378</u>	<u>\$ 22,521</u>

**December 31, 2017**

	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	\$ 1,631	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 1,631
Other accounts payable	1,803	—	—	—	—	—	1,803
Loan from bank	219	963	1,624	771	—	—	3,577
Long-term liabilities	2	2	2	—	—	—	6
Liability in respect of research and development grants	504	782	1,470	1,855	2,380	6,207	13,198
	<u>\$ 4,159</u>	<u>\$ 1,747</u>	<u>\$ 3,096</u>	<u>\$ 2,626</u>	<u>\$ 2,380</u>	<u>\$ 6,207</u>	<u>\$ 20,215</u>

**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, 2018**

	Level 2
Opening balance at January 1, 2018	\$ 112
Amounts transferred to the statement of comprehensive loss as finance income	28
Closing balance at December 31, 2018	<u>\$ 140</u>

**BRAINSWAY LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****U.S. dollars in thousands (except share and per share data)****NOTE 14: FINANCIAL INSTRUMENTS (Continued)**

During 2017, there were no transfers between Level 1 to Level 3 for fair value measurements of financial instruments, however there were transfers into Level 2 for fair value measurements of financial instruments.

## d. Sensitivity tests relating to changes in foreign currency:

	<u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
<b>Sensitivity test to changes in the NIS exchange rate:</b>		
Gain (loss) from the change:		
Increase of 5% in exchange rate	3	405
Decrease of 5% in exchange rate	(3)	(405)

As of December 31, 2018, the Company has excess of financial assets over financial liabilities in NIS in relation to US dollar of \$ 52.

As of December 31, 2018, the Company has excess of financial assets over financial liabilities in Euro and Yen in relation to US dollar of \$ 621 and \$910, 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 15: 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 \$299 and \$263 for the years ended December 31, 2018 and 2017, respectively.

**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**NOTE 16: 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 2017 and 2018 Budget Years), 2017 was approved, which reduces the corporate income tax rate to 24% (from 25%) effective from January 1, 2017 and to 23% effective from January 1, 2018.

The Israeli corporate income tax rate was 23% and 24% in 2018 and 2017, respectively.

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 in 2018 and 2017 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, 2017, 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 2017 and 2018 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, 2017 and thereafter (the tax rate applicable to preferred enterprises located in other areas remains at 16%).

**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**NOTE 16: TAXES ON INCOME (Continued)**

The amendment also prescribes special tax tracks for technological enterprises, which became effective in 2017, 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 2011 tax year. The subsidiary, Moach, received final tax assessments through 2012. The subsidiary, Inc, received final tax assessments through the 2014 tax year.

d. Carryforward losses for tax purposes:

Carryforward losses for tax purposes as of December 31, 2018 are approximately \$3 million in Brainsway Ltd. and approximately \$42 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 17: CONTINGENT LIABILITIES, COMMITMENTS AND CHARGES**

a. As for contingent liability in respect of payment of royalties to the IIA, see Note 13c.

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

**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**NOTE 17: CONTINGENT LIABILITIES, COMMITMENTS AND CHARGES (Continued)**

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.

- 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 after the required regulatory approvals for marketing the system in Japan are obtained. 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. 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 \$1.7 million) in two payments: 100 million Yen (approximately \$0.9 million as of December 31, 2018) paid in September 2013 and 90 million Yen (approximately \$0.8 million as of December 31, 2018) is payable upon receipt of regulatory approval to market the Company's system in Japan.

In each year of the agreement in which the distributor meets the predetermined revenue target, 10% of the distribution fees are returned to the distributor. The \$0.9 million distribution fee advance is presented in deferred revenues as of December 31, 2018 and 2017. 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 in 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 Pharmaceutical and Medical Devices Agency ("PMDA") was received, and as a result, half of the balance of the payment was received by the Company. The remaining payment of 45 million Yen will be paid to the Company on the earlier of inclusion of the treatment of the company's Deep TMS system under coverage of Japan's National Health Insurance Plan, and December 2019.

**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**NOTE 17: 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 the first four years of the plan, the Company received grants of NIS 7,300.

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, and the receipt of the rest of the balance from the grant is subjected to the approval of the MAGNET Committee.

- 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. Also, it was agreed with the distributor on a minimum monthly payment for any leased system and an additional payment based on the number of treatments made with the system beyond the minimum monthly payment.

In September 2017, an amendment to the agreement was signed, extending the term of the agreement to 15 years from the date of the amendment, setting a minimum annual payment subject to its compliance with certain conditions detailed in the amendment to the agreement. As part of the amendment, the distributor must meet the order and installation target of 12 new systems each year, up to a cumulative total of 50 systems. In addition, if its income from a single system exceeds the predetermined amount, the Company will be entitled to 10%-20% of its revenues from that system based on the lease year of the system. In accordance with the terms of the amendment to the agreement, the distributor made a first order of five systems, which were delivered in 2018.

- f. Commitments:

*Operating lease commitments:*

The Group has entered into operating leases on vehicles. These leases have an average life of three years, with no renewal option included in the contract.

1. Moach has a lease agreement until September 30, 2022, at monthly rentals of NIS 99, linked to the Israeli CPI of May 2017. The agreement gives an early termination option on September 30, 2020 in consideration for a predetermined compensation with a six-months notice.

In addition, Moach has a lease agreement from July 2015 according to which Moach rents a warehouse in consideration for monthly rentals of NIS 8. The rent is binding until July 31, 2019 with a renewal option until July 31, 2021. The options may be automatically exercised unless Moach notifies of its intent not to exercise the options until six months before the end of the last lease period. In 2019, Moach exercised the second option.

**BRAINSWAY LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****U.S. dollars in thousands (except share and per share data)****NOTE 17: CONTINGENT LIABILITIES, COMMITMENTS AND CHARGES (Continued)**

2. USA Inc has a lease agreement for its offices in the US until July 31, 2021 in consideration for monthly rentals of \$4. The rent increases every year by 2%.

Future minimum commitments under non-cancellable lease agreements as of December 31 are as follows:

2019	\$ 525
2020	492
2021	375
2022	239
	<u>\$ 1,631</u>

g. 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, 2018 is \$179.

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.



**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**NOTE 17: 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, 2018 is \$ 90.

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.

If the Company exercises the right granted to it under the fifth addendum, 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%.

- h. Charges—loan from bank—see note 13

## BRAINSWAY LTD.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## NOTE 18: EQUITY

## a. Composition of share capital:

	December 31, 2018		December 31, 2017	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
	Number of shares			
Ordinary shares of NIS 0.04 par value each	25,000,000	16,640,446	25,000,000	16,640,446

## b. Movement in share capital:

Issued and outstanding capital:

	Number of shares	NIS par value
Balance at January 1, 2017	14,715,784	148,832
Exercise of options	1,924,662	22,065
Balance at December 31, 2017	16,640,446	170,897
Balance at December 31, 2018	16,640,446	170,897

## 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 December, 2017, the Company entered into a private placement agreement with a group of investors according to which the Company issued 1,924,662 Ordinary in consideration for NIS 29,928 (\$8,578). Issuance expenses amounted to \$133.

It should be noted that if the Company wishes to raise capital during the twelve months after the closing date, by way of a public offering or private placement of shares and/or securities convertible into shares ("the additional offering") and if the effective price per share in the additional offering is less than the share price according to this private placement then, the investors will be entitled to receive additional Ordinary shares in respect of the shares issues as part of this private placement which are still held by such investor in consideration for NIS 0.3 per Ordinary share such that the price per share in respect of the total shares issued in this private placement equal to the effective price in the additional offering. For the purpose of calculating the adjustment, the effective price according to this private placement will be adjusted for distribution (as defined in the Companies Law), rights issuance, split or consolidation of capital and issuance of bonus shares. All changes are taken into account in the computation of the effective price in the additional offering.

**BRAINSWAY LTD.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**
**U.S. dollars in thousands (except share and per share data)**
**NOTE 18: EQUITY (Continued)**

## e. Capital management in the Company:

The Company's capital management objectives are to preserve the Group's ability to ensure business continuity thereby creating a return for the shareholders, investors and other interested parties.

The Company is not under any minimal equity requirements nor is it required to attain a certain level of capital return.

**NOTE 19: SHARE-BASED PAYMENT**

## a. The expense recognized in the financial statements for services received is shown in the following table:

	Year ended December 31,	
	2018	2017
Equity-settled share-based payment plans to employees, directors and consultants	\$ 710	\$ 1,028

## 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, 2018	Exercise price NIS	Exercise price (\$*)	Exercisable as of December 31, 2018	Exercisable Through	Total Fair Value \$
November 23, 2015	Director	37,597	27.97	7.18	25,065	November 23, 2025	117
December 8, 2015	Employees and Consultant	304,333	25.99	6.70	202,889	December 8, 2025	1,053
December 8, 2015	Employees and Consultant Chief Executive Officer and	270,000	31.19	8.04	180,000	December 8, 2025	1,247
April 1, 2017	Director	566,262	19.97	5.47	247,740	April 1, 2025	1,100
December 3, 2017	Director	27,500	21.37	6.12	—	December 3, 2027	54
November 12, 2018	Directors	110,000	23.39	6.36	—	November 12, 2026	298
November 12, 2018	Employees and officers	852,300	23.39 - 24.22	6.36 - 6.59	—	November 12, 2026	2,299

\*) As of grant date.

## c. The fair value of the Company's options granted for the years ended December 31, 2018 and 2017 was estimated using the Binomial model with the following assumptions:

	Year ended December 31,	
	2018	2017
Dividend yield (%)	0	0
Expected volatility (%)	40.51 - 48.25	40.58 - 56.77
Risk-free interest rate (%)	0.28 - 2.22	0.11 - 2.00
Expected exercise factor	2.8	2.8
Post-vesting forfeiture rate (%)	5	5 - 10

**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**NOTE 19: SHARE-BASED PAYMENT (Continued)**

d. Movement during the year:

	Year ended December 31,			
	2018		2017	
	Number of options	Weighted average exercise price(*) \$	Number of options	Weighted average exercise price(*) \$
Outstanding at January 1,	1,721,059	\$ 7.9	1,148,297	\$ 8.11
Granted	962,300	6.3	593,762	5.77
Expired	(199,499)	10.8	(8,017)	8.11
Forfeited	(58,668)	7.9	(12,983)	7.5
Outstanding at December 31,	<u>2,425,192</u>	<u>\$ 6.6</u>	<u>1,721,059</u>	<u>\$ 7.9</u>
Exercisable at December 31,	<u>912,893</u>	<u>\$ 7.17</u>	<u>599,357</u>	<u>\$ 9.69</u>

(\*) 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, 2018 and 2017, respectively.

The weighted average remaining contractual life for the options outstanding as of December 31, 2018 and 2017 was approximately six years.

The range of exercise prices for options outstanding as of December 31, 2018 and 2017 was NIS 19.97-59.13.

**NOTE 20: 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,	
	2018	2017
Revenues from lease	\$ 9,569	\$ 6,654
Revenues from sale	6,828	4,491
	<u>\$ 16,397</u>	<u>\$ 11,145</u>

## BRAINSWAY LTD.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## NOTE 20: 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,			
	2018	%	2017	%
U.S.	\$ 14,478	88	\$ 9,957	89
Europe	1,102	7	871	8
Israel	371	2	180	2
Other	446	3	137	1
	<u>\$ 16,397</u>	<u>100</u>	<u>\$ 11,145</u>	<u>100</u>

The total amounts of future minimum lease payments to be received under non-cancellable operating leases as of December 31, 2018 and 2017 are as follows:

	Year ended December 31,	
	2018	2017
Not later than one year	\$ 7,884	\$ 6,103
Later than one year and not later than five years	13,402	7,779
Later than five years	148	293
Total future minimum lease payments under non cancellable operating leases	<u>\$ 21,434</u>	<u>\$ 14,175</u>

The total amounts of usage based fees recognized as revenues for the years ended on December 31, 2018 and 2017 were \$697 and \$516, respectively.

## b. Cost of revenues:

	Year ended December 31,	
	2018	2017
Cost of revenues—lease	\$ 1,923	\$ 1,483
Cost of revenues—sales	1,666	1,112
	<u>\$ 3,589</u>	<u>\$ 2,595</u>

## BRAINSWAY LTD.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## NOTE 20: ADDITIONAL INFORMATION TO THE STATEMENTS OF COMPREHENSIVE LOSS (Continued)

## c. Research and development expenses, net:

Salaries and related benefits	\$ 3,365	\$ 2,954
Subcontractors	2,241	1,584
Laboratory materials	491	453
Patents	198	134
Share-based payment	31	180
Travel	65	35
Depreciation	31	35
Other	658	362
Less—Government grants	(924)	(394)
	<u>\$ 6,156</u>	<u>\$ 5,343</u>

## d. Selling and marketing expenses:

	Year ended December 31,	
	2018	2017
Salaries and related benefits	\$ 4,252	\$ 3,597
Agent commissions	215	138
Marketing	2,891	1,690
Travel	865	777
Share-based payment	122	129
	<u>\$ 8,345</u>	<u>\$ 6,331</u>

## e. General and administrative expenses:

Salaries and related benefits	\$ 1,235	\$ 1,179
Professional fees and office expenses	1,075	1,002
Depreciation	30	20
Travel	127	64
Allowance for doubtful accounts	397	503
Share-based payment	557	719
	<u>\$ 3,421</u>	<u>\$ 3,487</u>

## BRAINSWAY LTD.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## NOTE 20: ADDITIONAL INFORMATION TO THE STATEMENTS OF COMPREHENSIVE LOSS (Continued)

f. Finance income and expense:

Finance income:			
Interest-income revaluation of bank deposits	\$	44	\$ 22
Revaluation of warrants		—	38
Exchange rate differences		—	73
	\$	44	\$ 133
Finance expense:			
Liability in respect of research and development grants	\$	519	\$ 273
Interest expense and amortization of deferred costs- loan from bank		354	87
Bank commissions		41	47
Revaluation of warrants		28	—
Exchange rate differences		258	—
	\$	1,200	\$ 407

## NOTE 21: NET LOSS PER SHARE

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

	Year ended December 31,			
	2018		2017	
	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	16,640,446	\$ 6,479	14,768,514	\$ 7,054

\*) 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.

## BRAINSWAY LTD.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## NOTE 22: BALANCES AND TRANSACTIONS WITH RELATED PARTIES

## a. Balances with interested and related parties:

Composition:

As of December 31, 2018

	Key management personnel	Other interested and related parties
Other accounts payable	\$ 95	\$ 6

As of December 31, 2017

	Key management personnel	Other interested and related parties
Other accounts payable	\$ 48	\$ 7

## b. Benefits to interested and related parties:

	Year ended December 31,	
	2018	2017
Salary to those employed by the Company or on its behalf	\$ 654	\$ 593
Directors' fees to those not employed by the Company or on its behalf	\$ 100	\$ 98
Number of individuals to whom the salary and benefits relate:		
Related and interested parties employed by the Company or on its behalf	4	4
Directors not employed by the Company	6	7
	<u>10</u>	<u>11</u>



## BRAINSWAY LTD.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## NOTE 22: BALANCES AND TRANSACTIONS WITH RELATED PARTIES (Continued)

c. Key management personnel:

	Year ended December 31,	
	2018	2017
Short-term benefits	\$ 16	\$ 11
Share-based payment to those employed by the Company or on its behalf	\$ 394	\$ 501
Share-based payment to those not employed by the Company or on its behalf	\$ 41	\$ 2

d. Transactions with interested and related parties:

## 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

## Year ended December 31, 2017

	Key management personnel*)	Other interested and related parties
Research and development expenses	\$ 200	\$ 81
General and administrative expenses	821	99
	\$ 1,021	\$ 180

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

e. Mr. Yaakov Michlin commenced his role as the Company's 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. No expense recorded during the years ended December 31, 2017 and 2018 with respect to these bonuses; (2) an annual bonus based on the Company's remuneration policy according to the decision of the Company's Board of directors.

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

**BRAINSWAY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**NOTE 22: BALANCES AND TRANSACTIONS WITH RELATED PARTIES (Continued)**

date on which the board of directors approved the employment terms, and December 31, 2017, 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.

For information regarding the fair value of the options granted to Mr. Michlin, see Note 19.

- f. On December 3, 2017, at the general shareholders meeting, the Company granted a director of the Company, Ms. Karen Sarid, 27,500 options to purchase Ordinary shares at an exercise price of NIS 21.37 per share.

For information regarding the fair value of the options granted to Ms. Sarid, see Note 19b.

**NOTE 23: EVENTS AFTER THE REPORTING PERIOD**

During 2019 and until the date of the approval of these financial statements, 19,833 of options granted to officers who terminated employment at the Company in 2018 were expired.

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**2,500,000 American Depositary Shares**  
**Representing 5,000,000 Ordinary Shares**



**Brainsway**

**Brainsway Ltd.**

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**PROSPECTUS**

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**Cantor**

**Raymond James  
Ladenburg Thalmann**

**Oppenheimer & Co.**

**April 16, 2019**

Until and including May 11, 2019, 25 days after the date of this prospectus, all dealers that buy, sell or trade the ADSs, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as underwriters and with respect to unsold allotments or subscriptions.

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