ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

The following table sets forth our selected financial data, which is derived from our financial statements prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board. We have derived the selected financial data as of December 31, 2019, 2018, and 2017 and for the years ended December 31, 2019, 2018, and 2017 from our audited financial statements included elsewhere in this Annual Report on Form 20-F. You should read this selected financial data and other information provided in this Annual Report in conjunction with, and is qualified in its entirety by, our historical financial information including "Item 5. Operating and Financial Review and Prospects" and our financial statements and related notes appearing elsewhere in this Annual Report.

	Year Ended December 31		
	2019	2018	2017
Statements of Operations Data			
Revenues	$ 23,101	$ 16,397	$ 11,145
Cost of revenues	5,129	3,589	2,595
Gross profit	17,972	12,808	8,550
Research and development expenses, net	7,876	6,156	5,343
Selling and marketing expenses	13,269	8,345	6,331
General and administrative expenses	5,303	3,421	3,487
Total operating expenses	26,448	17,922	15,161
Total operating loss	8,476	5,114	6,611
Financial expenses, net	1,430	1,156	274
Loss before income taxes	9,906	6,270	6,885
Income taxes	422	209	169
Net loss	10,328	6,479	7,054
Basic and diluted net loss per share(1)	(0.50)	(0.39)	(0.48)
Weighted average number of Ordinary Shares outstanding – basic and diluted	23,236,368	16,640,446	14,768,514

	As of December 31 (U.S. Dollars, in thousands)		
	2019	2018	2017
Balance Sheet Data			
Cash, cash equivalents and short-term deposits	$ 21,895	$ 9,069	$ 14,559
Total assets	38,736	23,602	27,030
Total liabilities	14,516	16,650	14,309
Accumulated deficit	(71,909)	(61,581)	(55,102)
Total equity	38,736	6,952	12,721

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should carefully consider the risks we describe below, in addition to the other information set forth elsewhere in this Annual Report, including our financial statements and the related notes beginning on page F-1, before deciding to invest in our ordinary shares (the "Ordinary Shares") or our American Depositary Shares ("ADSs"). The risks and uncertainties described below in this annual report on Form 20-F for the year ended December 31, 2019 are not the only risks facing us. We may face additional risks and uncertainties not currently known to us or that we currently deem to be immaterial. Any of the risks described below or incorporated by reference in this Form 20-F, and any such additional risks, could materially adversely affect our reputation, business, financial condition or results of operations. In such case, you may lose all or part of your investment.

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 $10.3 million and $6.5 million for the years ended December 31, 2019 and 2018, respectively. As a result of ongoing losses, as of December 31, 2019, we had an accumulated deficit of $71.9 million. While we have sold and leased Deep TMS systems in various markets over the last few years, primarily for MDD and recently also for OCD, we expect to continue to incur significant sales and marketing, product development, regulatory and other expenses as we continue to expand our commercialization efforts to increase adoption of Deep TMS and expand existing relationships with our customers, to obtain regulatory clearances or approvals for Deep TMS in additional countries and for additional indications, and to develop new enhancements or features to our existing Deep TMS systems. Furthermore, our general and administrative expenses increased following our offering of ADSs on Nasdaq in April 2019 due to the increased costs associated with being a public company in the United States. The net losses we incur may fluctuate significantly from period to period. We will need to generate additional revenues to achieve and sustain profitability and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. Our failure to achieve or maintain profitability could negatively impact the value of the ADSs.

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

We believe that our existing capital, other sources of liquidity will be sufficient to meet our capital requirements. To date we have funded our operations primary through offerings of our securities, research and development grants from the Israel Innovation Authority and other sources, 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, 2019, we had 107 employees, including 28 employees in sales and marketing. Our operating results are directly dependent upon the sales and marketing efforts of our sales and customer support team and, to a lesser extent, on our independent third party distributors outside of the United States. If our employees or our independent distributors fail to adequately promote, market and sell or lease our Deep TMS systems, our revenues could significantly decrease and/or fail to meet our targets.

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

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

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

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

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

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

Medicare coverage for Deep TMS as a treatment for MDD generally requires that certain, specified clinical criteria relating to medical necessity are met (and documented). In particular, subject to variations by payor and locale, under most applicable payor policies, Deep TMS may be covered for MDD if: (i) prescribed by a licensed physician, knowledgeable in the use of TMS (ii) as a treatment for an adult with a confirmed diagnosis of MDD and no contraindications, (iii) where there is sufficient documentation of: (a) failure of a trial of psychotherapy known to be effective in treating MDD without significant improvement in depressive symptoms and (b) one of the following:

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

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

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

(4) Individual is a candidate for electroconvulsive therapy (ECT) and TMS is less burdensome to the patient.

Reimbursement for Deep TMS as an MDD treatment is also generally limited to 36 treatment sessions.

Obtaining and maintaining adequate reimbursement of Deep TMS for OCD, or for any future indications, as applicable, may be difficult. Currently, there is no third-party coverage of Deep TMS as a treatment for OCD, as payors that have evaluated Deep TMS for OCD coverage have not yet concluded that it is a reasonable and necessary therapy for OCD. We are working to gather and submit additional clinical data in order to sufficiently demonstrate the efficacy of Deep TMS for the treatment of OCD. These efforts may be expensive and time-consuming. Therefore, it may take significant time to obtain sufficient reimbursement coverage of Deep TMS for OCD. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement compared to existing approved biologics and other therapies. There may be significant delays in obtaining coverage and reimbursement for newly approved therapies in the United States, and coverage may be more limited than the indications for which the product is approved by the FDA or similar regulatory authorities outside the United States. Further, there is no guarantee that Deep TMS will ever be adequately covered or reimbursed for OCD or any other future indication for which we obtain authorization, if any.

In addition, the U.S. federal government and state legislatures have continued to implement cost containment programs, including price controls and restrictions on coverage and reimbursement. To contain costs, governmental healthcare programs and third-party payers are increasingly challenging the price, scrutinizing the medical necessity and reviewing the cost-effectiveness of medical treatments.

Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets, including Japan, have government-managed healthcare systems that govern reimbursement for psychiatric treatments and procedures. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. If adequate levels of reimbursement from third-party payers outside of the United States, including Japan, are not obtained, international sales and lease transactions for the Deep TMS system may not materialize or grow significantly.

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

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

We rely on suppliers for most of the components used in manufacturing Deep TMS, including the computer controlling the stimulator, the helmet and the arm of the helmet, and we may not have sufficient contractual assurances for the long-term supply of these components. We 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. In addition, we rely on the outsourcing company utilized for the manufacture of certain components in our newer systems, including our proprietary stimulator and various other components. For us to be successful, our suppliers and contract manufacturer must be able to provide us with components in sufficient quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. While these suppliers have generally met our demand requirements on a timely basis in the past, their ability and willingness to continue to do so going forward may be limited for several reasons, including our lack of long-term agreements with those suppliers, our relative importance as a customer of those suppliers, or, as applicable, their ability to produce the components for or provide assembly services to manufacture our Deep TMS systems. An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these components, if we cannot obtain an acceptable substitute.

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

We face risks associated with our international business.

We currently market and sell Deep TMS systems outside of the United States in various countries and/or intend to market and expand the commercialization of Deep TMS in other markets, including Japan, Europe and various 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 at various stages of completed, ongoing or planned clinical trials of Deep TMS for new indications. Development of medical devices includes pre-clinical studies and sometimes clinical trials, and is a long, expensive and uncertain process, subject to delays and failure at any stage. Clinical trials for Deep TMS involve certain specific risks, including factors related to trial design and patient enrollment. Additionally, if we are unable to recruit a sufficient number of patients for our clinical trials, we may be unable to generate sufficient data to support marketing authorization. Moreover, our research and development, pre-clinical and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities. We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials, which would cause us or regulatory authorities to delay or suspend clinical trials, or delay the analysis of data from completed or ongoing clinical trials. We estimate that clinical trials involving various indications of Deep TMS will continue for several years; however, such trials may also take significantly longer to complete and may cost more money than we have expected. Furthermore, the data obtained from the studies and trials may be inadequate to support regulatory authorizations or to enable market acceptance of certain indications of Deep TMS. Failure can occur at any stage of testing, and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of the current, or a future, version of, Deep TMS, for any particular indication, including but not limited to:

- delays in securing clinical investigators or trial sites for the clinical trials;
- delays in obtaining institutional review board and other regulatory approvals to commence a clinical trial;
- slower than anticipated patient recruitment and enrollment;
- negative or inconclusive results from clinical trials;
- unforeseen safety issues;
- an inability to monitor patients adequately during or after treatment;
- placement of a clinical trial on hold by the FDA, institutional review boards/ethics committees or other regulatory authorities;
- changes in governmental regulations or administrative actions, including governmental changes in permissible endpoints or other measures utilized in clinical trials;
- problems with investigator or patient compliance with the trial protocols;
- the FDA or other regulators disagreeing as to the design, protocol or implementation of our clinical trials;
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials;
- the quality of the products falling below acceptable standards; and
- the inability to manufacture sufficient quantities of our products to commence or complete clinical trials.

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

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

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

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

We are currently involved in a number of research and development collaborations with third parties relating to the development of new technology and additional uses of Deep TMS. These and any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results or may change their strategic focus due to the acquisition of competitive products,
- availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development 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

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

- decreased demand for Deep TMS;
- injury to our reputation and brand;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients;
- product recalls;
- material defense costs;
- loss of revenues;
- the inability to commercialize new indications, enhancements or features; and
- diversion of management attention from pursuing our business strategy.

Our existing product liability insurance coverage may be inadequate to protect us from any liabilities we might incur. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage, our business could suffer. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, a recall of some of our products, whether or not related to a product liability claim, could result in significant costs and loss of customers.

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

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include liability, public liability, 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.

Our operations could be affected by the outbreak of the Coronavirus.

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

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

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

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

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

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

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

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

We rely on the use of technology and may become subject to cyber-terrorism or other compromises and shut-downs.

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

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

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

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

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

Our success depends in part on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures, technologies and market pressures. Accordingly, from time to time, we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our current products or expand the breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including:

- difficulty assimilating or integrating acquired or licensed technologies, products or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- diversion of management's attention from our core business and disruption of ongoing operations;
- adverse effects on existing business relationships with suppliers, distributors and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- potential loss of key employees of the acquired businesses; and
- increased legal and accounting compliance costs.

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

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures, languages 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 Dr. David Zacut, the chairman of our board of directors, Christopher R. von Jako, our president and chief executive officer, Hadar Levy, our chief financial officer and chief operating officer and Dr. Yiftach Roth, our chief scientist, would likely result in a significant loss in the knowledge and experience that we possess and could significantly delay or prevent successful product development and other business objectives. There is intense competition from numerous medical device, pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions, seeking to employ qualified individuals in the technical fields in which we operate, and we may not be able to attract and retain the qualified personnel necessary for the successful development and commercialization of Deep TMS.

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

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

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

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

Risks Related to Government Regulation

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

We are subject to extensive regulation in the United States and elsewhere, including by the FDA, FTC and their foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical trials; product safety; marketing, sales and distribution; premarket clearance and approval; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export.

The regulations to which we are subject are complex and stringently enforced. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

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

An element of our strategy is to continue to upgrade our Deep TMS systems, add new enhancements and features and expand clearance or approval of the Deep TMS System to include new indications. In the United States, before we can market a new medical device, or claim new or expanded indications for use or introduce a significant modification to an existing product, we must first receive either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, *de novo* classification, or premarket approval application (PMA), from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to a PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. However, some devices are automatically subject to the PMA pathway regardless of the level of risk they pose because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that FDA review such devices in accordance with the *de novo* classification procedure, which allows a manufacturer whose novel device would otherwise require a PMA prior to marketing to request down-classification of the device on the basis that the device presents low or moderate risk. If the FDA grants the *de novo* classification request, the applicant will then receive authorization to market the device. This device type can then be used as a predicate device for future 510(k) submissions.

We received marketing authorization of our MDD indication through the 510(k) clearance process and we have made changes to our system for the MDD indication through subsequent 510(k) clearances. We received marketing authorization of our OCD indication through the *de novo* classification process, but will be permitted to make changes to our system for the OCD indication through subsequent 510(k) clearances. Competitors may seek 510(k) clearance of a TMS device for an OCD indication and use our *de novo* classification as a predicate device in their submission. The process of obtaining regulatory authorization to market a medical device can be costly and time consuming, and we may not be able to successfully obtain authorizations on a timely basis, if at all.

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

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

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay authorization of our future products under development or impact our ability to modify our currently marketed products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, 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.

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

Any modifications to our existing products may require new 510(k) clearance; however, future modifications may be subject to the substantially more costly, time-consuming and uncertain PMA process. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could cause our sales to decline.

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

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

The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA's QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. Compliance with the QSR is necessary to receive FDA clearance or approval to market new products and is necessary for a manufacturer to be able to continue to market cleared or approved devices in the United States. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing. Foreign regulatory authorities also impose manufacturing quality requirements, that may differ from the FDA requirements, with which we must comply.

We or our third-party suppliers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA or foreign jurisdiction requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals or clearances; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals of Deep TMS for additional indications; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us or our employees.Any of these actions could significantly and negatively impact supply of our Deep TMS systems. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and suffer reduced revenues and increased costs.

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

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

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

Deep TMS system has been authorized for marketing by the FDA only for MDD 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." However, we cannot guarantee that all of our employees, representatives, and agents will abide by our marketing policies. If the FDA determines that our promotional materials, training or other marketing activities constitute promotion of an off-label or unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as laws prohibiting false claims for reimbursement.

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

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

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in clearance of future products.

The FDA and foreign regulatory bodies have the authority to require, and in the United States companies are expected to voluntarily, the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. An FDA recall, whether mandatory or voluntary, may be based on a finding that there is reasonable probability that the device could cause serious injury or death. A government mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new authorization for the device before we may market or distribute the corrected device. Seeking such authorization may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of corrective actions, even if they are not reportable to the FDA. We may initiate voluntary corrective actions for our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales.

Any adverse event involving Deep TMS systems could result in voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as exposing us to private litigation, would require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

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

Sales of our Deep TMS systems outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. While the regulations of some countries may not impose barriers to marketing and selling Deep TMS systems or only require notification, others require that we or our distributors obtain the approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or approvals, can be expensive and time-consuming, and we or our distributors may not receive regulatory approvals in each country in which we plan to market Deep TMS or we may be unable to do so on a timely basis. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for FDA authorization, and requirements for such registrations, clearances or approvals may significantly differ from FDA requirements. If we modify our Deep TMS systems, we or our distributors may need to apply for additional regulatory approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we or our distributors have received. If we or our distributors are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

Regulatory authorization by the FDA and/or the permission to affix the CE Mark does not ensure clearance or approval by regulatory authorities in other jurisdictions, and clearance or approval by one or more foreign regulatory authorities does not ensure clearance or approval by the FDA, the EU and/or the regulatory authorities in other foreign countries. However, a failure or delay in obtaining regulatory clearance or approval in one country may have a negative effect on the regulatory process in others.

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

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

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

- the federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal government funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Private individuals, commonly known as "whistleblowers," can bring civil False Claims Act *qui tam* actions, on behalf of the government and such individuals and may share in amounts paid by the entity to the government in recovery or settlement. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of $11,181 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 Patient Protection and Affordable Care Act (PPACA) was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may impact our business, the PPACA:

- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- expands the eligibility criteria for Medicaid programs.

Some of the provisions of the PPACA have yet to be implemented, and there have been judicial and Congressional challenges to modify, limit, or repeal certain aspects of the PPACA since its enactment and have continued to evolve. Since taking office, President Trump has continued to support the repeal of all or portions of the PPACA, and in January 2017, he signed Executive Orders designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA to the maximum extent permitted by law. Due to such efforts, certain elements of the PPACA have been invalidated or suspended, which has, in turn, led to additional challenges against the law as a whole. For example, the Tax Cuts and Jobs Act of 2017 included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate. As a result, there is significant uncertainty regarding future healthcare reform and its impact on our operations. in December 2018, a district court in Texas held that the individual mandate is unconstitutional and that the rest of the PPACA is, therefore, invalid. On appeal, the Fifth Circuit Court of Appeals affirmed the holding on the individual mandate but remanded the case back to the lower court to reassess whether and how such holding affects the validity of the rest of the PPACA. Substantial uncertainty remains as to the future of the PPACA after the U.S. Supreme Court declined to expedite its review of the Fifth Circuit's holding on January 21, 2020. It is, thus, unlikely that these issues will be resolved before the next presidential election in November 2020. The current administration may seek to pass additional reform measures before the upcoming election. We cannot predict the outcome of the election, nor can we predict the healthcare-reform-related initiatives that the newly elected (or re-elected, as applicable) administration will put forth thereafter. There is no way to know whether, and to what extent, if any, the PPACA will remain in-effect in the future, and it is unclear how judicial decisions, subsequent appeals, election-related measures, or other efforts to repeal and replace or, possibly, to restore the PPACA will impact the U.S. healthcare industry or our business.

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

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

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

Risks Related to Our Intellectual Property

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

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

We and our licensors try to protect our proprietary position by, among other things, filing U.S., European, and other patent applications related to Deep TMS, as well as inventions and improvements that may be important to the continuing development of Deep TMS. While we generally apply for patents in those countries where we intend to make, have made, use, or sell patented products, we may not accurately predict all of the countries where patent protection will ultimately be desirable. If we fail to timely file a patent application in any such country, we may be precluded from doing so at a later date. In addition, we cannot assure you that:

- any of our future processes or product indications will be patentable;
- our processes or product indications will not infringe upon the patents of third parties; or
- we will have the resources to defend against charges of patent infringement or other violation or misappropriation of intellectual property by third parties or to protect our own intellectual property rights against infringement, misappropriation or violation by third parties.

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

Patent rights are territorial; thus, the patent protection we do have will only extend to those countries in which we have issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the United States and the European Union. Therefore, we cannot assure you that the patents issued, if any, as a result of our foreign patent applications will have the same scope of coverage as our U.S. patents. Competitors may successfully challenge our patents, produce similar products that do not infringe our patents, or produce products in countries where we have not applied for patent protection or that do not respect our patents. Furthermore, it is not possible to know the scope of claims that will be allowed in published applications and it is also not possible to know which claims of granted patents, if any, will be deemed enforceable in a court of law.

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

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

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

The lives of our patents may not be sufficient to effectively protect our products and business.

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

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

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

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

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

Our license agreement with Yeda provides for in-licensed rights to both a second family of patent applications and a third family of patent applications that covers additional characteristics of Deep TMS (including several Deep TMS coils and stimulators and methods of use), and we have commissioned research at the Weizmann Institute related to the Deep TMS under this agreement.

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

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

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

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

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

If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us.

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

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

Legal proceedings or third-party claims of intellectual property infringement and other challenges may require us to spend substantial time and money and could prevent us from developing or commercializing Deep TMS.

The development, manufacture, use, offer for sale, sale or importation of Deep TMS may infringe on the claims of third-party patents or other intellectual property rights. The nature of claims contained in unpublished patent filings around the world is unknown to us and it is not possible to know which countries patent holders may choose for the extension of their filings under the Patent Cooperation Treaty, or other mechanisms. Therefore, there is a risk that we could adopt a technology without knowledge of a pending patent application, which technology would infringe a third-party patent once that patent is issued. The cost to us of any intellectual property litigation or other infringement proceeding, even if resolved in our favor, could be substantial. Any claims of patent infringement, even those without merit, could be expensive and time consuming to defend; cause us to cease making, licensing or using products that incorporate the challenged intellectual property; require us to redesign, reengineer or rebrand Deep TMS, if feasible; cause us to stop from engaging in normal operations and activities, including developing and new indications for Deep TMS; and divert management's attention and resources. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation or defense of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may also absorb significant management time. Consequently, we may not be able to manufacture, use, offer for sale, sell or import our Deep TMS systems in the event of an infringement action.

Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

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

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

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

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

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

Patent law outside the United States may be different than in the United States. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, if at all. A failure to obtain sufficient intellectual property protection in any foreign country could materially and adversely affect our business, results of operations and future prospects. Moreover, we may participate in opposition proceedings to determine the validity of our foreign patents or our competitors' foreign patents, which could result in substantial costs and divert management's resources and attention. Additionally, due to uncertainty in patent protection law, we have not filed applications in many countries where significant markets exist.

Risks Related to Our Functions in Israel

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

Aspects of our business are located in Israel. Accordingly, our business will be directly influenced by the political, economic and military conditions affecting Israel at any given time. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries. These conflicts involved missile strikes against civilian targets in various parts of Israel including most recently, central Israel, and negatively affected business conditions in Israel. In addition, Israel faces threats from more distant neighbors, in particular, Iran. A change in the security and political situation in Israel and in the economy could impede the raising of the funds required to finance our research and development plans and to create joint ventures with third parties and could otherwise have a material adverse effect on our business, operating results and financial condition.

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

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

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

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

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, under certain circumstances, further offerings of our shares to the public in any stock exchange whether in Israel or abroad, is subject to the approval of the IIA.

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

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

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

We are incorporated in Israel. Members of our current senior management and directors reside in Israel (and most of our assets reside outside of the United States). Therefore, a judgment obtained against us or any of these persons in the United States, including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It may also be difficult to effect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel.

Even if an Israeli court agrees to hear such a claim, it may determine that Israeli, and not U.S., law is applicable to the claim. Under Israeli law, if U.S. law is found to be applicable to such a claim, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would be governed by Israeli law. There is little binding case law in Israel addressing these matters. See “Enforceability of Civil Liabilities” for additional information on your ability to enforce civil claim against us and our senior management and directors.

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

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

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

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

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

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

Some of our operations in Israel may entitle us to certain tax benefits under the Law for the Encouragement of Capital Investments, 5719-1959, or the Investment Law, once we begin to generate taxable income. If we do not meet the requirements for maintaining these benefits, they may be reduced or cancelled and the relevant operations would be subject to Israeli corporate tax at the standard rate, which is set at 23% in 2018 and thereafter. In addition to being subject to the standard corporate tax rate, we could be required to refund any tax benefits that we may receive in the future, plus interest and penalties thereon. Even if we continue to meet the relevant requirements, the tax benefits that our current "Technology Enterprise" is entitled to may not be continued in the future at their current levels or at all. If these tax benefits were reduced or eliminated, the amount of taxes that we pay would likely increase, as all of our operations would consequently be subject to corporate tax at the standard rate, which could adversely affect our results of operations. Additionally, if we increase our activities outside of Israel, for example, by way of acquisitions, our increased activities may not be eligible for inclusion in Israeli tax benefits programs. See "Material Tax Considerations—Israeli Tax Considerations and Government Programs—Tax Benefits Under the 2017 Amendment" for additional information concerning these tax benefits.

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

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

Risks Related to our ADSs and Ordinary Shares

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

The share price of publicly traded medical device companies has been highly volatile and is likely to remain highly volatile in the future. The market price of the ADSs or ordinary shares on either 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 24% of our outstanding ordinary shares as of March 22, 2020. Accordingly, these persons are able to significantly influence, though not independently determine, the outcome of matters required to be submitted to our shareholders for approval, including decisions relating to the election of our board of directors, and the outcome of any proposed merger or consolidation of our company. These interests may not be consistent with those of our other shareholders. In addition, these persons' significant interest in us may discourage third parties from seeking to acquire control of us, which may adversely affect the market price of our ordinary shares.

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

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

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

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

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

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

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

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

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

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

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

You will not have the same voting rights as the holders of our ordinary shares and may not receive voting materials in time to be able to exercise your right to vote.

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

Our ordinary shares and ADSs are traded on different markets and this may result in price variations.

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

We do not intend to pay dividends for at least the next several years

We do not anticipate paying any cash dividends for at least the next several years. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of the ADSs will be the investors' sole source of gain for at least the next several years. In addition, Israeli law limits our ability to declare and pay dividends, and may subject us to certain Israeli taxes. For more information, see "Dividend Policy."

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

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

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

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

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

As a foreign private issuer whose shares are listed on The Nasdaq Global Market, we are permitted to follow certain home country corporate governance practices instead of certain requirements of the rules of The Nasdaq Global Market. Pursuant to the "foreign private issuer exemption":

- we established a quorum requirement such that the quorum for any meeting of shareholders is two or more shareholders holding at least 33 1/3% of our voting rights, which complies with Nasdaq requirements; however, if the meeting is adjourned for lack of quorum, the quorum for such adjourned meeting will be two or more shareholders, having any percentage of our voting rights;

- we also follow Israeli corporate governance practice in lieu of Nasdaq Marketplace Rule 5635(c), which requires shareholder approval for certain dilutive events (such as issuances that will result in a change of control, certain transactions other than a public offering involving issuances of a 20% or greater interest in us and certain acquisitions of the shares or assets of another company) and prior to an issuance of securities when a stock option or purchase plan is to be established or materially amended or other equity compensation arrangement made or materially amended, pursuant to which stock may be acquired by officers, directors, employees or consultants. By contrast, under the Israeli Companies Law, shareholder approval is required (subject to certain limited exceptions) for, among other things: (a) transactions with directors concerning the terms of their service (including indemnification, exemption, and insurance for their service or for any other position that they may hold at a company); (b) extraordinary transactions with controlling shareholders of publicly held companies; (c) terms of office and employment or other engagement of our controlling shareholder, if any, or such controlling shareholder's relative; (d) approval of transactions with the company's Chief Executive Officer with respect to his or her compensation, whether in accordance with the approved compensation policy of the company or not, or transactions with officers of the company not in accordance with the approved compensation policy; (e) approval of the compensation policy of the company for office holders and (f) certain private placements involving the issuance of 20% or more of our total voting rights, or private placements as a result of which a person will become a controlling shareholder of the company. In addition, under the Companies Law, a merger requires approval of the shareholders of each of the merging companies; and

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

Otherwise, we comply with the rules generally applicable to U.S. domestic companies listed on the Nasdaq Global Market. However, we may in the future decide to use the foreign private issuer exemption with respect to some or all of the other Nasdaq corporate governance rules. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on the Nasdaq Global Market may provide less protection than is accorded to investors of domestic issuers. See "Management—Foreign Private Issuer and Controlled Company Status."

In addition, as a foreign private issuer, we are exempt from the rules and regulations under the United States Securities Exchange Act of 1934, as amended, or the Exchange Act, related to the furnishing and content of proxy statements (including disclosures with respect to executive compensation), and our officers, directors, and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as domestic companies whose securities are registered under the Exchange Act.

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

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

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

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

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

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

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

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

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

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

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of the ADSs.

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