

Risk Factors Comparison 2024-02-22 to 2023-02-23 Form: 10-K

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An investment in our ordinary shares involves a high degree of risk. Investors and prospective investors should carefully consider all of the information in this Annual Report on Form 10-K, including the risks and uncertainties described below. Any of the following risks could have a material adverse effect on our business, prospects, financial condition and results of operations. In any such case, the trading price of our ordinary shares could decline, and you could lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes thereto. Risks relating to our business and our Products Our business and prospects depend heavily on Optune **Gio**, which is currently approved only for the treatment of GBM, and Optune Lua, which is currently approved only for the treatment of MPM, **with approvals pending for NSCLC**. If we are unable to increase sales of our Products, obtain further regulatory approvals and commercialize our Products for the treatment of additional indications, or are significantly delayed or limited in doing so, our business and prospects will be materially harmed. To date we have received FDA regulatory approval under the PMA pathway and certain approvals in other jurisdictions for the use of Optune **Gio** for the treatment of adult patients with newly diagnosed GBM **in combination when used together** with certain forms of chemotherapy and for the treatment of adult patients with recurrent GBM as monotherapy. Optune **Gio** has a CE mark affixed for the treatment of GBM in the EU and Switzerland. We have also received FDA approval under the HDE pathway to market Optune Lua for unresectable, locally advanced or metastatic, MPM **in combination when used together** with standard chemotherapies. Optune Lua is also CE Certified for the same indication in the EU and Switzerland. However, such approvals and maintaining the CE Certificates of Conformity, and related CE marking, of our Products, as applicable, do not guarantee future revenues for these indications. Further, until we receive FDA and analogous approval in other jurisdictions for the use of our Products for other indications, almost all of our revenues will derive from sales and royalties from sales of Optune **Gio** for the treatment of newly diagnosed and recurrent GBM ~~and Optune Lua for MPM~~. The commercial success of our Products and our ability to generate and maintain revenues from the sale of our Products will depend on a number of factors, including: • our ability to develop and obtain additional regulatory approvals and further commercialize our Products for additional indications; • our ability to expand into new markets and future indications; • the acceptance of our Products by patients and the healthcare community, including physicians and third- party payers (both private and governmental), as therapeutically effective and safe; • the accomplishment of various scientific, engineering, clinical, regulatory and other goals, which we sometimes refer to as milestones, on our anticipated timeline; • the relative cost, safety and efficacy of alternative therapies; • our ability to obtain and maintain sufficient coverage or reimbursement by private and governmental third- party payers and to comply with applicable health care **coverage** laws and regulations; • the ability of our third- party manufacturers to manufacture our Products in sufficient quantities with acceptable quality; • our ability to provide marketing, distribution and customer support for our Products; • the presence of competitive products in our active indications; • results of future clinical studies relating to our Products or other competitor products for similar indications; • compliance with applicable laws and regulatory requirements, in particular in the EU; • the maintenance of our existing regulatory approvals; and • the consequences of any reportable adverse events involving our Products. In addition, the promotion of our Products is limited to approved indications, which vary by geography. The labelling for Optune **Gio** in the U. S. is limited in certain respects (for example, it is approved specifically for glioblastomas of the supratentorial region of the brain, is indicated for use in the treatment of newly diagnosed GBM only when used together with temozolomide, and limited to use by adults ages 22 and older), which may limit the number of patients to whom it is prescribed. Similarly, the label for Optune Lua also contains certain limitations that may adversely affect adoption, including the requirement in the United States (applicable to all HDE- approved devices) to display on all marketing materials that the efficacy of the Product has not been established, as well as a limitation for use by adults ages 22 and older, and the absence of ~~pivotal phase 3~~ clinical data. Our ability to generate future revenues will also depend on achieving regulatory approval of, and eventual commercialization of, our Products for additional indications and in additional geographies, which is not guaranteed. Our near- term prospects are substantially dependent on our ability to obtain regulatory approvals on the timetable we have anticipated, and thereafter to further successfully commercialize our Products for additional indications. Regulatory changes or actions in areas in which we operate or propose to operate may further affect our ability to obtain regulatory approvals on our anticipated timetable. If we are not able to receive such approvals, meet other anticipated milestones, or further commercialize our Products, or are significantly delayed or limited in doing so, our business and prospects will be materially harmed and we may need to reduce expenses by delaying, reducing or curtailing the development of our Products and we may need to raise additional capital to fund our operations, which we may not be able to obtain on favorable terms, if at all. To date, we have generated only ~~limited~~ **occasional** and intermittent operating profits, and we have a history of incurring substantial operating losses. We were founded in 2000 and have only ~~recently~~ **occasionally** and intermittently **generated** ~~started generating limited~~ operating profits. We have otherwise had a history of **and expect to continue** incurring substantial operating losses. We anticipate continuing to incur significant costs associated with commercializing our Products for approved indications including product sales, marketing, manufacturing, and distribution expenses. We expect our research, development, and clinical study expenses to increase in connection with our ongoing activities and as additional indications enter late- stage clinical development and as we advance our product development. Our expenses could increase beyond expectations if, for example, we are required by the FDA, or other regulatory agencies or similar governing bodies, to change manufacturing processes for our Products or to perform clinical, nonclinical or other types of studies in addition to those that we

currently anticipate. Our revenues are dependent, in part, upon the size of the markets in the jurisdictions in which we receive regulatory approval, the accepted price for our Products and the ability to obtain **coverage for our Products and thereafter** reimbursement at the accepted applicable price. If the number of addressable patients is not as significant as we estimate, the indications approved by regulatory authorities are narrower than we expect or the eligible population for treatment is narrowed by competition, regulatory approvals, physician choice or treatment guidelines, we may not generate significant revenues. If we are not able to generate significant revenues, we may never be sustainably profitable. Our clinical studies could be delayed or otherwise adversely affected by many factors, including difficulties in enrolling patients. Clinical testing can be costly and take many years, and the outcome is uncertain and susceptible to varying interpretations. Moreover, success in preclinical and early clinical studies does not ensure that large- scale studies will be successful or predict final results. Acceptable results in early studies may not be replicable in later studies. A number of companies in the oncology industry have suffered significant setbacks in advanced clinical studies, even after promising results in earlier studies. Negative or inconclusive results or adverse events or incidents during a clinical study could cause the clinical study to be redone or terminated. In addition, failure to appropriately construct clinical studies could result in high rates of adverse events or incidents, which could cause a clinical study to be suspended, redone or terminated. **We may be unable to obtain reimbursement for our Products where our Products are already part of the approved standard of care. We may be unable to obtain other drugs or therapies that are to be used together with our Products in a given protocol, either due to supply issues, recall or the ability to obtain materials in an efficient or economically feasible manner.** Our failure or the failure of third- party participants in our studies to comply with their obligations to follow protocols and / or legal requirements may also result in our inability to use the affected data in our submissions to regulatory authorities. The timely completion of clinical studies depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical studies for a variety of reasons, including: • the severity of the disease under investigation; • the limited size and nature of the patient population; • the patient eligibility criteria defined in our protocol and other clinical study protocols ; **• standards of care may vary by geographic region, affecting whether our protocols may be valid in a given region** ; • the nature of the study protocol, including the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; • difficulties and delays in clinical studies that may occur as a result of the COVID- 19 **or similar** pandemic; • the ability to obtain IRB approval at clinical study locations; • clinicians’ and patients’ perceptions as to the potential advantages, disadvantages and side effects of our Products in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are pursuing; • availability of other clinical studies that exclude use of our Products; • the possibility or perception that enrolling in a Product’ s clinical study may limit the patient’ s ability to enroll in future clinical studies for other therapies due to protocol restrictions; • the possibility or perception that our software is not secure enough to maintain patient privacy; • patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; • the availability of appropriate clinical study investigators, support staff, drugs and other therapeutic supplies and proximity of patients to clinical sites; • physicians’ or our ability to obtain and maintain patient consents; and • the risk that patients enrolled in clinical studies will choose to withdraw from or otherwise not be able to complete a clinical study. If we have difficulty enrolling and retaining a sufficient number or diversity of patients to conduct our clinical studies as planned, or encounter other difficulties, we may need to delay, terminate or modify ongoing or planned clinical studies, any of which would have an adverse effect on our business. If we are unable to continue the development of an adequate sales and marketing organization or contract with third parties to assist us, we may not be able to successfully commercialize our Products for current and future indications. To achieve commercial success for our Products, we must continue to compliantly develop and grow our sales and marketing organization and, as necessary, enter into sales and distribution relationships with third parties to market and sell our Products. Developing and managing a sales and marketing organization is a difficult, expensive and time consuming process. We may not be able to successfully develop adequate sales and marketing capabilities to achieve our growth objectives. We compete with other medical device, pharmaceutical and life sciences companies to recruit, hire, train and retain the sales and marketing personnel that we anticipate we will need, and the nature of our Products may make it more difficult to compete for sales and marketing personnel. In addition, because our current Products require, and we anticipate our future Products will require, physician training and education, our sales and marketing organization may need to grow substantially as we expand our approved indications and markets. As a consequence, our expenses associated with building up and maintaining our sales force and marketing capabilities may be disproportionate to the revenues we may be able to generate on sales of our Products. If we are unable to establish adequate sales and marketing capabilities or successful sales and distribution relationships, we may fail to realize the full revenue potential of our Products for current and future indications, and we may not be able to achieve the necessary growth in a cost- effective manner or realize a positive return on our investment. In our current and future sales and distribution agreements with other companies, we generally do not and may not have control over the resources or degree of effort that any of these third parties may devote to our Products, and if they fail to devote sufficient time and resources to the marketing of our Products, or if their performance is substandard, our revenues may be adversely affected. The success of our business may be dependent on the actions of our collaborative partners. Our global business strategy includes, in part, the consummation of collaborative arrangements with companies who will support the development and commercialization of our Products and technology. For example, we have exclusively licensed rights to commercialize our Products in the field of oncology in Greater China to Zai pursuant to an agreement that also establishes a development partnership for Tumor Treating Fields (“ TTFields ”) **therapy** in multiple solid tumor indications. Zai is responsible for the development and commercialization of our Products in Greater China at its sole cost with certain assistance from us. We have also entered into several clinical collaborations with third parties to test our Products and technology together with other products and technologies. When we collaborate with a third party for development and commercialization of a Product in a particular territory, we can expect to relinquish some or all of the control over the future

success of that Product to the third party in that territory. In addition, our collaborative partners may have the right to abandon research or development projects and terminate applicable agreements, including payment obligations, prior to or upon the expiration of the agreed- upon terms. We may not be successful in establishing or maintaining collaborative arrangements on acceptable terms or at all, collaborative partners may terminate funding before completion of projects, our Products may not achieve the criteria for milestone payments, our collaborative arrangements may not result in successful product commercialization, our Products may not receive acceptable pricing and we may not derive any revenue from such arrangements. Additionally, our collaborators may not perform their obligations as expected or in compliance with study protocols or applicable laws. Our collaborators may also be subject to additional risks in their particular territories, such as a lack of intellectual property protections and / or enforcement or the possibility of nationalization. Acts or omissions by collaborators may disqualify study data for use in regulatory submissions and / or create liability for us in the jurisdictions in which we operate. Any disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development or commercialization, might cause delays or termination of the research, development or commercialization of Products, might lead to additional responsibilities for us with respect to developing or commercializing Products, or might result in litigation or arbitration, any of which would be time- consuming and expensive. To the extent that we are not able to develop and maintain collaborative arrangements, we would need to devote substantial capital to undertake development and commercialization activities on our own in order to further expand our global reach, and we may be forced to limit the territories in which we commercialize our Products. We may not be successful in achieving market acceptance of our Products by healthcare professionals, patients and / or third- party payers in the timeframes we anticipate, or at all, which could have a material adverse effect on our business, prospects, financial condition and results of operations. Our business model is predicated on achieving market acceptance of our Products as a monotherapy or ~~together in combination~~ with well- established cancer treatment modalities like surgery, radiation, pharmacological and immunologic therapies. We may not achieve market acceptance of our Products for current or future indications within the timeframes we have anticipated, or at all, for a number of different reasons, including the following factors: • it may be difficult to gain ~~or maintain~~ broad acceptance of our Products because they are new technologies and involve a novel mechanism of action and, as such, physicians may be reluctant to prescribe our Products without prior experience or additional data or training; • physicians may be reluctant to prescribe our Products due to their perception that the supporting clinical study designs have limitations, as they are, for example, unblinded; • physicians at large academic universities and medical centers may prefer to enroll patients into clinical studies instead of prescribing our Products; • it may be difficult to gain broad acceptance at community hospitals where the number of patients seeking treatment may be more limited than at larger medical centers, and such community hospitals may not be willing to invest in the resources necessary for their physicians to become trained to use our Products, which could lead to reluctance to prescribe our Products; • patients may be reluctant to use our Products for various reasons, including a perception that the treatment is untested or difficult to use (for example, they will need to shave the areas on their bodies where the arrays are applied) or a perception that our software is not secure; • our Products may have side effects (for example, dermatitis where the arrays are placed) and our Products cannot be worn in all circumstances (for example, they cannot get wet and are difficult to wear in high temperatures); and • the price of our Products includes a monthly fee for use of the device and therefore, as the duration of the treatment course increases, the overall price will increase correspondingly and, when used ~~together in combination~~ with other treatments, the overall cost of treatment will be greater than using a single type of treatment. In particular, our Products may not achieve market acceptance for current or future indications because of the following additional factors: • achieving patient acceptance could be difficult because we are targeting devastating diseases with poor prognoses, and not all patients with potentially short lifespans are willing to comply with requirements of treatment with our Products, such as the need to use our Products for ~~at least 18 hours~~ **a certain amount of time** per day, carrying around a device and shaving the area where the arrays are worn, and other patients may forego our Products for financial, privacy, cosmetic, visibility or mobility reasons; • achieving patient compliance is difficult because the recommended use of our currently marketed Products is throughout the day, requiring patients to wear the device nearly continuously, which to some extent restricts physical mobility because the battery must be frequently exchanged and recharged, and the patient or a caregiver must ensure that it remains continuously operable and this may also impact the pool of patients to whom physicians may be willing to prescribe our Products; • certain patients are contraindicated to using our Products due to a variety of factors, including, but not limited to, those who have an active implanted medical device, those who have a skull defect, and those who are sensitive to conductive hydrogels; • there are certain perceived limitations to our study designs or data obtained from our clinical studies; • efficacy may also be limited in instances where patients take a break from the device **, for example** when experiencing skin rashes ~~or~~ while bathing or swimming (because our Products should not get wet) ~~or while traveling~~; and • patients may decline therapy or prescribers may be unwilling to prescribe our Products due to certain adverse events reported in clinical studies by patients treated with our Products as monotherapy include medical device site reaction, headache, malaise, muscle twitching, fall and skin ulcer; additional adverse events reported in clinical studies by patients treated with our Products ~~in combination when used together~~ with chemotherapies in addition to the above, were thrombocytopenia, nausea, constipation, vomiting, fatigue and other side effects consistent with treatment with chemotherapies. In addition, even if we are successful in achieving market acceptance of our Products for GBM or MPM, we may be unsuccessful in achieving market acceptance of our Products for other indications, such as brain metastases ~~from~~ NSCLC, **NSCLC**, pancreatic cancer, ovarian cancer and other solid tumor cancers, because certain radiation, chemotherapies and / or systemic medical therapies may become or remain the preferred standard of care for these indications. There may be other factors that are presently unknown to us that also may negatively impact our ability to achieve market acceptance of our Products. If we do not achieve market acceptance of our Products in the timeframes we anticipate, or are unable to achieve market acceptance at all, our business, prospects, financial condition and results of operations could be materially adversely affected. Failure to secure and maintain adequate coverage and reimbursement from

third- party payers could adversely affect acceptance of our Products and reduce our revenues. We expect that the vast majority of our revenues will come from third- party payers either directly to us in markets where we provide our Products or plan to provide our device candidates to patients or indirectly via payments made to hospitals or other entities providing our Products or which may in the future provide our device candidates to patients. In the U. S., private payers cover the largest segment of the population, with the remainder either uninsured or covered by governmental payers. The majority of the third- party payers outside the U. S. are government agencies, government sponsored entities or other payers operating under significant regulatory requirements from national or regional governments. Third- party payers may decline to cover and reimburse certain procedures, supplies or services. Additionally, some third- party payers may decline to cover and reimburse our Products for a particular patient even if the payer has a favorable coverage policy addressing our Products or previously approved reimbursement for our Products. Additionally, private and government payers may consider the cost of a treatment in approving coverage or in setting reimbursement for the treatment. Private and government payers around the world are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of governments around the world. Adoption of additional price controls and cost- containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures by both private and public payers, could further limit our revenues and operating results. If third- party payers do not consider our Products or the **combination-use** of our Products **together** with additional treatments to be cost- justified under a required cost- testing model, they may not cover our Products for their populations or, if they do, the level of reimbursement may not be sufficient to allow us to sell our Products on a profitable basis. Reimbursement for the treatment of patients with medical devices around the world is governed by complex mechanisms established on a national or sub- national level in each country. These mechanisms vary widely among countries, can be informal, somewhat unpredictable, and evolve constantly, reflecting the efforts of these countries to reduce public spending on healthcare. As a result, obtaining and maintaining reimbursement for the treatment of patients with medical devices has become more challenging globally. We cannot guarantee that the use of our Products will receive reimbursement approvals and cannot guarantee that our existing reimbursement approvals will be maintained in any country. We provide financial assistance to certain patients in certain markets who qualify based on established financial and other criteria. Primarily, we provide financial assistance to patients where we have or are actively pursuing coverage and reimbursement. This financial assistance is intended to defray out- of- pocket costs for our Products for patients who begin treatment but who are unable to pay for the costs of their treatment not covered by insurance. Our costs associated with this program could increase if payers increase the cost- sharing burden of patients or we do not obtain coverage and reimbursement and we elect to continue providing financial assistance in those markets. Additionally we provide charitable donations to foundations that can then provide financial assistance to those receiving health care coverage from federal or state funded programs. Enforcement actions and changes to government regulations related to manufacturer- sponsored and independent charitable patient assistance programs could reduce our ability to support patients financially in the future. Our failure to secure or maintain adequate coverage or reimbursement for our Products by third- party payers in the U. S. or in the other jurisdictions in which we market our Products could have a material adverse effect on our business, revenues and results of operations and cause our stock price to decline. We may not be successful in securing and maintaining reimbursement codes necessary to facilitate accurate and timely billing for our Products or physician services attendant to our Products. Third- party payers, healthcare systems, government agencies or other groups often issue reimbursement codes to facilitate billing for products and physician services used in the delivery of healthcare. Within the U. S., the billing codes most directly related to our Products are contained in the Healthcare Common Procedure Coding System (" HCPCS code set"). The HCPCS code set contains Level I codes that describe physician services, also known as Common Procedural Terminology codes (" CPT codes") and Level II codes that primarily describe products. CMS is responsible for issuing the HCPCS Level II codes. The American Medical Association issues HCPCS Level I codes. We have secured unique HCPCS Level II codes that describe **Optune our Products** and we are able to use these codes in the U. S. to bill third- party payers. Loss of these codes or any alteration in the reimbursement amounts attached to these codes would materially impact our operating results. We do not **expect to obtain different** have a unique HCPCS Level II code **codes** for **new indications** **Optune Lua at this time**. No CPT codes currently exist to describe physician services related to the delivery of therapy using our Products. We may not be able to secure CPT codes for physician services related to our Products. Our future revenues and results may be affected by the absence of CPT codes, as physicians may be less likely to prescribe the therapy when there is no certainty that adequate reimbursement will be available for the time, effort, skill, practice expense and malpractice costs required to provide the therapy to patients. Outside the U. S., but excluding Germany and Japan, we have not secured codes to describe our Products or to document physician services related to the delivery of therapy using our Products. The failure to obtain and maintain these codes could affect the future growth of our business. There is no assurance that Medicare or the Medicare Administrative Contractors will provide, or continue to provide, coverage or adequate payment rates for our Products. We anticipate that a significant portion of patients using our Products will be beneficiaries under the Medicare fee- for- service program **in the U. S, including a majority of our Optune Lua patients for NSCLC, once approved in that indication**. Failure to secure or maintain coverage or maintain adequate reimbursement from Medicare would reduce our revenues and may also affect the coverage and reimbursement decisions of other third- party payers in the U. S. and elsewhere. Medicare classifies Optune **Gio and Optune Lua** as durable medical equipment (" DME"). Medicare has the authority to issue national coverage determinations or to defer coverage decisions to its regional Medicare Administrative Contractors (" MACs"). The fact that only two MACs administer the entire DME program may negatively affect our ability to petition individual medical policy decision- makers at the MACs for coverage. The absence of a positive coverage determination or a future restriction to existing coverage from Medicare or the DME MACs would materially affect our future revenues. Additionally, Medicare has the authority to publish the reimbursement amounts for DME products. Medicare has published a reimbursement amount for Optune **Gio** that falls below the median reimbursement that we have established with non- Medicare payers.

Medicare may in the future publish reimbursement amounts for our Products that do not reflect then- current prices for our Products or Medicare may decrease existing reimbursement amounts published for our Products. Medicare fee schedules are frequently referenced by private payers in the U. S. and around the world. Medicare' s publication of reimbursement amounts for our Products that are below our Products' established prices could materially reduce our revenues and operating results with respect to non- Medicare payers in the U. S. and our other active markets. Medicare has assigned the billing codes describing **Optune our Products** to the DME category for products that require frequent and substantial servicing. DME items in this billing category are billed monthly and payment is not capped after a time period. If Medicare revises its payment category classifications for our Products, this action could materially reduce our revenues and operating results. CMS requires prior authorization for certain DME items. Claims for such items that did not receive prior authorization before they were furnished to a beneficiary will be automatically denied. In the event Medicare adds one of our Products to the list of items requiring prior authorization, our ability to bill and secure reimbursement for patients who would otherwise be covered to use our Product under the Medicare fee- for- service program may be reduced. The Medicare fee- for- service program **has** denied coverage for all claims prior to the September 1, 2019 effective date for the DME MAC LCD, which provides coverage for Optune **Gio** for the treatment of newly diagnosed GBM subject to certain conditions and restrictions. We expect that Medicare will continue to deny essentially all claims that do not meet the coverage policy terms. Although we are actively appealing these coverage denials, we are unable to bill the vast majority of our existing Medicare fee- for- service patients for amounts not paid by Medicare. Therefore, we are absorbing and may continue to absorb the costs of treatment for amounts not paid by Medicare. We appeal Medicare coverage denials through the Medicare appeals process: redetermination by a MAC, reconsideration by a Qualified Independent Contractor, hearing before an Administrative Law Judge (“ ALJ ”) at the Office of Medicare Hearings and Appeals, review by the Medicare Appeals Council, and judicial review in U. S. District Court. **Currently, there is a considerable backlog of appeals at the ALJ level and there are significant delays in the assignment of ALJ cases.** We cannot provide any assurance that our outstanding ALJ appeals will be favorably decided. Further, we anticipate that, even if we are successful in winning our appeals, we will experience a significant delay in securing reimbursement for Medicare patients when Medicare' s DME MACs deny coverage for patients who start therapy. While we have obtained Medicare coverage for our existing Products, we cannot provide any assurance that we can access transitional, expedited, or expanded Medicare coverage for our future Products. CMS **has is expected to issue issued rules new draft guidance** regarding coverage of emerging technologies **that does ; however, no not specific specifically information is available about address whether our future Products will obtain coverage. While these are only guidelines and the they** content of the expected rules and **remain in draft form subject to final issuance,** we cannot provide any assurance that any new rules regarding emerging technologies would be applicable to our future Products. We depend on single- source suppliers for some of our components. The loss of these suppliers could prevent or delay shipments of our Products, delay our clinical studies or otherwise adversely affect our business. In certain jurisdictions, we source some of the components of our Products from only a single vendor **or manufacturer**. If any one of these single- source suppliers were to fail to continue to provide components to us on a timely basis, or at all, our business and reputation could be harmed. Our policy is to seek and maintain second- source suppliers, but we can provide no assurance that we will secure or maintain such suppliers. We have developed or are in the process of developing and obtaining regulatory approval for second sources for components in all jurisdictions. Various steps must be taken before securing these suppliers, including qualifying these suppliers in accordance with regulatory requirements, but we may never receive such approvals. The risks associated with the failure of our suppliers to comply with strictly enforced regulatory requirements as described below are exacerbated by our dependence on single- source suppliers. If we experience any deficiency in the quality of, delay in or loss of availability of any components supplied to **or manufactured for** us by third- party suppliers, or if we switch suppliers or components, we may face additional regulatory delays and the manufacture and delivery of our Products would be interrupted for an extended period of time, which could materially adversely affect our business, prospects, financial condition and results of operations. If we are required to obtain prior regulatory approval from the FDA or regulatory authorities or similar governing bodies in other jurisdictions or to conduct a new conformity assessment procedure and obtain new CE Certificates of Conformity in the EU to use different suppliers or components for our Products, regulatory approval or the CE Certificates of Conformity for our Products may not be received on a timely basis, or at all, which would have a material adverse effect on our business, prospects, financial condition and results of operations. Quality control problems with respect to devices and components supplied by third- party suppliers could have a material adverse effect on our reputation, our clinical studies or the commercialization of our Products and, as a result, a material adverse effect on our business, prospects, financial condition and results of operations. Our Products, which are manufactured by third parties, are highly technical and are required to meet exacting specifications. Any quality control problems that we experience with respect to the devices and components supplied by third- party suppliers could have a material adverse effect on our reputation, our attempts to complete our clinical studies, our operating expenses or the commercialization of our Products. The failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action, including warning letters, product recalls, suspension or termination of distribution, product seizures or civil penalties. If we experience any delay in the receipt or deficiency in the quality of products supplied to us by third- party suppliers, or if we have to switch to replacement suppliers, we may face additional regulatory delays and the manufacture and delivery of our Products would be interrupted for an extended period of time, which would materially adversely affect our business, prospects, financial condition and results of operations. If the third parties on which we rely to conduct our preclinical and clinical studies and to assist us with research and development do not perform as contractually required or expected, we may not be able to obtain regulatory approvals for or commercialize our Products. We do not have the ability to independently conduct certain of our preclinical and development activities or any of our clinical studies for our Products; therefore, we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators, contract laboratories and collaborative partners, to conduct such studies. We and these third parties are required to

comply with current good clinical practices (" cGCPs"), which are regulations and guidelines enforced by the FDA under the medical device Quality System Regulation (" QSR") and comparable regulatory authorities in other jurisdictions for clinical development. We and these third parties are also required to comply with current good laboratory practices (" cGLPs"), which are regulations and guidelines enforced by the FDA and comparable regulatory authorities in other jurisdictions for nonclinical laboratory studies. If we or any of these third parties fail to comply with applicable cGLP and cGCP regulations, the data generated in our nonclinical studies and clinical studies may be deemed unreliable and the FDA or regulatory authorities in other jurisdictions may require us to perform additional nonclinical or clinical studies before approving our applications. We cannot be certain that, upon inspection or review of our data, such regulatory authorities will determine that any of our nonclinical studies or clinical studies comply with the applicable cGLP or cGCP regulations. Additionally, any third parties conducting our preclinical, clinical and other development programs are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and other development programs. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our development activities or clinical studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our Products or successfully commercialize our Products on a timely basis, if at all, and our business, prospects and results of operations may be adversely affected. Continued testing of our Products may not yield successful results and could reveal currently unknown aspects or safety hazards associated with our Products. Our research and development programs are designed to test the safety and efficacy of our Products and TTFields through extensive preclinical and clinical testing. Even if our ongoing and future preclinical and clinical studies are completed as planned, we cannot be certain that their results will support our claims or that the FDA and other regulatory authorities will agree with our conclusions. Success in preclinical studies and early clinical studies does not ensure that later clinical studies will be successful, and we cannot be sure that the later studies will replicate the results of prior studies and preclinical studies. The clinical study process may fail to demonstrate that our device candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a device candidate and may delay development of others. It is also possible that patients enrolled in clinical studies will experience adverse side effects that have not been previously observed. In addition, our preclinical and clinical studies for our device candidates involve a relatively small patient population and, as a result, these studies may not be indicative of future results. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent further commercialization of our Products, including the following: • Preclinical and clinical testing for our Products may not produce the desired effect, may be inconclusive or may not be predictive of safety or efficacy results obtained in future clinical studies, following long- term use or in much larger populations; • unanticipated adverse events or other side effects that are not currently known may occur during our clinical studies that may preclude additional regulatory approval or result in additional limitations to commercial use if approved; and • the data collected from our clinical studies may not reach statistical significance or otherwise not be sufficient to support FDA or other regulatory approval. If unacceptable side effects arise in the development of our Products for future indications, we could suspend or terminate our clinical studies or the FDA or other regulatory authorities could order us to cease clinical studies or deny approval of our device candidates for any or all targeted indications, narrow the approved indications for use or otherwise require restrictive product labeling or marketing or require further clinical studies, which may be time- consuming and expensive and may not produce results supporting FDA or other regulatory approval of our Products in a specific indication. Treatment- related side effects could also affect patient recruitment or the ability of enrolled patients to complete the study or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have a need to train medical personnel using our device candidates to understand the side effect profiles for our clinical studies and upon any commercialization of our Products for future indications. Inadequate training in recognizing or managing the potential side effects of our Products could result in patient injury or death. Any of these occurrences may harm our business, prospects and financial condition significantly. Any delay or termination of our clinical studies will delay the filing of submissions for regulatory approvals of our Products and ultimately our ability to commercialize our Products and generate revenues. Furthermore, we may abandon our Products for indications that we previously believed to be promising. Over time, we expect to make modifications to our Products that are designed to improve efficacy, reduce side effects, enhance the user experience and other purposes. It is possible that our patients will not accept these developments or see them as improvements, necessitating abandoning the development or spending additional development efforts to refine the modification. Any of these events could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. We face competition from numerous competitors, which may make it more difficult for us to achieve significant market penetration and which may allow our competitors to develop additional oncology treatments to compete with our Products. The oncology market is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. Our Products primarily compete with radiation and pharmacological therapies. We may face additional competition as advancements are made in the field of anti- cancer therapies and as we enter additional oncological markets. To date, we have conducted clinical studies where our Products are used together with a certain subset of other anti- cancer therapies. Many of our competitors are large, well- capitalized companies with significantly greater market share and resources than we have. As a consequence, they are able to spend more aggressively on product development, marketing, sales and other initiatives than we can. Many of these competitors could have: • significantly greater name recognition and experience; • established distribution networks and / or relationships with government agencies, healthcare professionals, patients and third- party payers; • additional product lines, and the ability to offer rebates or bundle products to offer higher discounts or more competitive pricing or other incentives to gain a competitive

advantage; and • greater financial and human resources for research and development, sales and marketing, patent litigation and / or acquisitions. Although we believe our Products represent a treatment modality that can be used together with other cancer treatment modalities, our current and future competitors may at any time develop additional drugs, biologics or devices for the treatment of GBM, MPM, or other solid tumors that could be more effective from a therapeutic or cost- basis perspective than using our Products. In our currently- approved indications, if current or future competitors develop a product that proves to be superior or comparable to our Products, our revenues may decline. In addition, some of our competitors may compete by lowering the price of their cancer treatments. If these competitors' products were to gain acceptance by healthcare professionals, patients or third- party payers, a downward pressure on prices could result. If prices were to fall, we may not be able to improve our gross margins or sales growth sufficiently to be sustainably profitable. For future indications, other companies could view us as a competitor and attempt to block our market entry or otherwise hinder our Product growth in a market. We are aware of third parties in the United States and China developing devices and filing for intellectual property protection related to TTFields, which, if approved, may directly compete with our Products. Competitors could also pursue lawsuits to invalidate our patents or develop alternative technologies for the application of TTFields into a patient that we did not foresee or protect. As we expand, we may experience difficulties managing our growth. Our anticipated growth will place a significant strain on our management and on our operational and financial resources and systems. We could face challenges inherent in efficiently managing a more complex business with an increased number of employees over large geographic distances, including the need to implement appropriate systems, policies, benefits and compliance programs. Failure to manage our growth effectively could materially adversely affect our business. Additionally, our anticipated growth will increase the demands placed on our third- party suppliers, resulting in an increased need to carefully monitor the available supply of components and services and to scale up our quality assurance programs. There is no guarantee that our suppliers will be able to support our anticipated growth. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals. Because of the specialized nature of our business, the termination of relationships with our key employees, consultants and advisors may prevent us from successfully operating our business, including developing our Products, conducting clinical studies, commercializing our Products and obtaining any necessary financing. We are highly dependent on the members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements with each of our key executives, any of them could leave our employment at any time. We do not have " key person" insurance on any of our employees. The loss of the services of one or more of our current employees might impede the achievement of our business objectives. The competition for qualified personnel in the oncology and medical device fields is intense, and we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. Our future success depends upon our ability to attract, retain and motivate highly skilled employees. In order to commercialize our Products successfully, we will be required to expand our workforce, particularly in the areas of research and development and clinical studies, sales and marketing and supply chain management. These activities will require the addition of new personnel and the development of additional expertise by existing management personnel. We face intense competition for qualified individuals from numerous pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions. We may not be able to attract and retain these individuals on acceptable terms or at all. Failure to do so could materially harm our business. Product liability suits, whether or not meritorious, could be brought against us due to alleged defective devices or for the misuse of our Products, which could result in expensive and time- consuming litigation, payment of substantial damages and / or expenses and an increase in our insurance rates. If our current or future devices are defectively designed or manufactured, contain defective components or are misused, or if someone claims any of the foregoing, whether or not meritorious, we may become subject to substantial and costly litigation. For example, we may be sued if our Products cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. This may occur if our Products are misused or damaged, have a sudden failure or malfunction (including with respect to safety features) or are otherwise impaired due to wear and tear. Even absent a product liability suit, malfunctions of our Products or misuse by physicians or patients would need to be remedied swiftly in order to maintain continuous use and ensure efficacy of our Products. Any product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the device, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our Products. Even successful defense may require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • decreased demand for our Products; • injury to our reputation; • withdrawal of clinical study participants and inability to continue clinical studies; • initiation of investigations by regulators; • costs to prepare for and defend the related litigation; • a diversion of management' s time and our resources; • substantial monetary awards to study participants or patients; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenues; • exhaustion of any available insurance and our capital resources; • the inability to commercialize any device candidate; and • a decline in our share price. Product liability claims could divert management' s attention from our core business, be expensive to defend and result in sizable damage awards against us. We may not have sufficient insurance coverage for all claims. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and could reduce revenues. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, if any, which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Even if our agreements with our third- party manufacturers and suppliers entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. Other future litigation and regulatory actions could have a material adverse impact on the Company. From time to time, we may be subject to

litigation and other legal and regulatory proceedings relating to our business or investigations or other actions by governmental agencies, including as described in Part I, Item 3 "Legal Proceedings" of this Annual Report on Form 10-K. No assurances can be given that the results of these or new matters will be favorable to us. An adverse resolution of lawsuits, arbitrations, investigations or other proceedings or actions could have a material adverse effect on our financial condition and results of operations, including as a result of non-monetary remedies. Defending ourselves in these matters may be time-consuming, expensive and disruptive to normal business operations and may result in significant expense and a diversion of management's time and attention from the operation of our business, which could impede our ability to achieve our business objectives. Additionally, any amount that we may be required to pay to satisfy a judgment, settlement, fine or penalty may not be covered by insurance. Subject to the Jersey Companies Law, our articles of association permit us to indemnify any director against any liability, to purchase and maintain insurance against any liability for any director and to provide any director with funds (whether by loan or otherwise) to meet expenditures incurred or to be incurred by such director in defending any criminal, regulatory or civil proceedings or in connection with an application for relief (or to enable any such director to avoid incurring such expenditure). In addition, we have entered into indemnification agreements with each of our directors and officers to indemnify them against certain liabilities and expenses arising from their being a director or officer to the maximum extent permitted by Jersey law. In the event we are required to make such payments to our directors and officers, there can be no assurance that any of these payments will not be material. Global economic, political and industry conditions constantly change and unfavorable conditions may have a material adverse effect on our business and results of operations. We are a global company with worldwide operations. Volatile economic, political and market conditions, such as political or economic instability, civil unrest, trade sanctions, majority hostilities or acts of terrorism in the regions in which we operate may have a negative impact on our operating results and our ability to achieve our business objectives. We may not have insight into economic and political trends that could emerge and negatively affect our business. In addition, significant or volatile changes in **interest rates or** exchange rates between the U. S. dollar and other currencies may have a material adverse impact upon our liquidity, revenues, costs and operating results. In particular, we have research facilities located in Israel, and certain key suppliers manufacture their goods in Israel. Due to the high-conflict nature of this area, Israel could be subject to additional political, economic and military confines, which could result in a material adverse effect on our operations. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in the agreements. Additionally, natural disasters and public health emergencies, such as extreme weather events and the COVID-19 **or other pandemic pandemics**, could have a significant adverse effect on our business, including interruption of our commercial and clinical operations, supply chain disruption, endangerment of our personnel, fewer patient visits, increased patient drop-out rates, delays in recruitment of new patients, and other delays or losses of materials and results. **The A pandemic, such as the** COVID-19 pandemic could materially adversely impact our business. **As On May 5, 2023, the World Health Organization ("WHO") declared the end of the COVID-19 pandemic as a public health emergency of international concern, however the WHO maintains that the virus remains a global health threat. While the threat** COVID-19 pandemic continues around the globe, we have experienced and **will likely continue, if a similar pandemic or outbreak were to occur, would** experience disruptions that could severely impact our business and clinical studies, which could include: • delays and / or difficulties in onboarding active patients and enrolling patients in our clinical studies; • delays and / or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff; • declines in prescriptions written due to a perception that our Products are difficult to administer remotely or if patients are unwilling to travel to treatment sites or receive in-home treatment assistance from us or other caregivers; • reductions in third-party reimbursements, which could materially affect our revenue, as most of our patients rely on third-party payers to cover the cost of our Products and a material number of our patients could lose access to their private health insurance plan if they or someone in their family lose their job; • diversion of healthcare resources away from conducting clinical studies, including the diversion of hospitals serving as our clinical study sites and hospital staff supporting the conduct of our clinical studies; • interruption of key clinical study activities, such as clinical study site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others; • staff disruptions and turnover internally and at treatment sites and third-party providers who provide support, either directly as a result of illness or indirectly as a result of vaccine mandates and other changes in terms of employment; • delays in receiving approval from local regulatory authorities or IRBs to initiate our planned clinical studies; • delays in clinical sites receiving the supplies and materials needed to conduct our clinical studies; • interruption in global shipping that may affect the transport of active patient and clinical study materials; • changes in local regulations as part of a response to **a pandemic or the COVID-19 outbreak** that may require us to change the ways in which our clinical studies are conducted, which may result in unexpected costs, or to discontinue the clinical studies altogether; • delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; • disruption of our supply chain as our suppliers and common carriers are unable to meet our requirements to provide us the materials we need for clinical study and active patient care needs; • indirect consequences of **a the COVID-19 pandemic or outbreak** on the global economy in general, such as an increase in bankruptcies of our key suppliers, or the inability of our third-party payers to meet their obligations reimburse us in a timely fashion or at all; • postponements and cancellations of key conferences and meetings and travel restrictions could interfere with our ability to interact with key thought leaders in the field, leading to a disruption in the rate of adoption of our technology; • access restrictions at offices, hospitals, and treatment centers, and stakeholder illness could interfere with the ability of our sales force to engage in face-to-face visits with providers, leading to a disruption in the rate of adoption of our technology; • increases in expenditures for technology and other tools necessary to

provide patient care in an environment where both patient and care-giver travel is restricted and access to in-person interaction is limited; • refusal of the FDA to accept data from clinical studies in affected geographies outside the United States; and • patient delays in seeking or receiving treatment, either due to fear of infection or lack of access to treatment and study sites, leading to fewer diagnoses of the indications our Products are approved to treat or more advanced progression of the disease, which may contraindicate the use of our Products or disqualify the patient from participating in a given study. The **extent to which a global status of the COVID-19 pandemic or outbreak continues to rapidly evolve. The extent to which the pandemic** may impact our business and clinical studies will depend on **future developments the specific issues surrounding such event**, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing guidelines, business closures or business disruptions and the effectiveness of actions taken to contain and treat the disease. The response to **the a pandemic or outbreak** may result in permanent changes to the environment in which we operate as described above in ways we are unable to predict. ~~The COVID-19 pandemic may also have the effect of heightening many of the other risks described herein.~~ We are increasingly dependent on information technology systems and subject to privacy and security laws. Our Products and our systems and infrastructure face certain risks, including from cyber security breaches and data leakage. We increasingly rely upon technology systems and infrastructure. Our technology systems, including our Products, are potentially vulnerable to breakdown or other interruption by fire, power loss, system malfunction, unauthorized access and other events. Likewise, data privacy breaches by employees and others with both permitted and unauthorized access to our Products and our systems may pose a risk that protected patient information ("PI") may be exposed to unauthorized persons or to the public, or may be permanently lost. The increasing use and evolution of technology, including cloud-based computing, creates additional opportunities for the unintentional dissemination of information, intentional destruction of confidential information stored in our systems or in non-encrypted portable media or storage devices. We could also experience a business interruption, information theft of confidential information, or reputational damage from industrial espionage attacks, malware or other cyber incidents, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party service providers or other business partners. The size and complexity of our computer systems, and scope of our geographic reach, make us potentially vulnerable to information technology system breakdowns, internal and external malicious intrusion, cyberattacks and computer viruses. Because the techniques used to obtain unauthorized access, or to sabotage systems, change frequently and generally are not recognized until launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology infrastructure or properly manage third-party contractors who perform data management services on our behalf, then a security breach could subject us to, among other things, transaction errors, business process inefficiencies, the loss of customers, damage to our reputation, business disruptions or the loss of or damage to intellectual property. Such security breaches could expose us to a risk of loss of information, litigation, penalties, remediation costs and potentially significant liability to customers, employees, business partners and regulatory authorities, including, for example, under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") in the United States and Regulation 2016 / 679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data under GDPR in the EU. If our data management systems (including third party data management systems) do not effectively collect, secure, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, or human error, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations will be impaired. Any such impairment could materially and adversely affect our financial condition and results of operations. While we have invested heavily in the protection of data and information technology and in related training, there can be no assurance that our efforts will prevent significant breakdowns, breaches in our systems or other cyber incidents or ensure compliance with all applicable security and privacy laws, regulations and standards, including with respect to third-party service providers that utilize sensitive personal information, including PI, on our behalf. A security breach, whether of our Products, systems or third-party hosting services we utilize, could disrupt treatments being provided by our Products, disrupt access to our customers' stored information, such as patient treatment data and health information, and could lead to the loss of, damage to or public disclosure of such data and information, including patient health information. Such an event could have serious negative consequences, including possible patient injury, regulatory action, fines, penalties and damages, reduced demand for our Products, an unwillingness of customers to use our Products, harm to our reputation and brand and time-consuming and expensive litigation, any of which could have a material adverse effect on our financial results. We carry a limited amount of insurance for cybersecurity liability, and our insurance coverage may be inadequate. In the future, our insurance coverage may be expensive or not be available on acceptable terms or in sufficient amounts, if at all. Risks relating to the regulation of our business Our device candidates must undergo rigorous preclinical and clinical testing and we must obtain regulatory approvals, which could be costly and time-consuming and subject us to unanticipated delays or prevent us from marketing any devices. Our research and development activities, as well as the manufacturing and marketing of our Products, are subject to regulation, including regulation for safety, efficacy and quality, by the FDA in the U. S. In the EU member states where we market our Products and operate, we are subject to, inter alia, the Medical Device Regulation ("MDR"), which applies directly in all EU member states. In Switzerland, our Products and operations are subject to, inter alia, the Medical Devices Ordinance, which implements the MDR into Swiss law. In the United Kingdom, our Products and operation are subject to, inter alia, the Medical Devices Regulations 2002 and the Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (the "UK **Re-Regulations**"). which implements the MDR and MDR like provisions into UK law. We are regulated by comparable authorities in other countries. Regulations promulgated by the regulatory authorities in our applicable jurisdictions are wide-ranging and govern, among other things: • the conduct of preclinical and clinical studies; • product design, development, manufacturing, testing, storage and shipping; • product labeling, advertising and promotion; • premarket clearance, approval and conformity assessment

procedures, as well as for modifications introduced in marketed products; • post-market surveillance and monitoring; • reporting of adverse events or incidents and implementation of corrective actions, including product recalls; • interactions with healthcare professionals and patients; and • product sales and distribution. We cannot be certain if or when the FDA, comparable regulatory agencies in other jurisdictions or our notified body might request additional or modified studies on our Products, under what conditions such studies might be requested, or the required size or length of any such studies. The data collected from our clinical studies may not be sufficient to support regulatory approval in the U. S., Japan and other countries or to obtain a CE Certificate in the EU for our various future device candidates. Even if we believe the data collected from our clinical studies are sufficient, the FDA and comparable regulatory bodies in other jurisdictions have substantial discretion in the assessment and approval or conformity assessment processes and may disagree with our interpretation of the data. Our failure to adequately demonstrate the safety and efficacy of any of our device candidates would delay or prevent regulatory approval in the U. S., Japan and other countries or delay or prevent a CE Certificate in the EU (and therefore be unable to affix the CE mark) for our device candidates, which could prevent us from being sustainably profitable. In addition, any change in the laws or regulations that govern the clearance and approval processes relating to our current and future devices could make it more difficult and costly to obtain clearance or approval for new devices, or to produce, market and distribute our Products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new devices would have an adverse effect on our ability to expand our business. We intend to market our Products in a number of international markets in addition to our current markets. In order to market our Products in any jurisdiction and for other indications or purposes, we may be required to obtain separate regulatory approvals or CE Certificates for our Products, as applicable. The requirements governing the conduct of clinical studies and manufacturing and marketing of our device candidates outside the U. S. vary widely from country to country. CE Certificates and regulatory approvals in other jurisdictions may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical study designs. CE Certification processes and regulatory approvals in other jurisdictions include essentially all of the risks associated with the FDA approval processes. Some regulatory agencies in other jurisdictions must also approve prices of our Products. Approval of a Product by the FDA does not guarantee approval of the same product by the health authorities of other countries or CE marking of our Products in the EU and vice versa. In addition, changes in regulatory policy in the U. S. or in other countries for the approval or CE marking of a medical device during the period of product development and regulatory agency review or notified body review of each submitted new application may cause delays or rejections. In the European Economic Area (“ EEA ”), we are required to obtain a CE Certificate and to affix a CE mark to our Products. In the EEA, our devices must be subject to conformity assessment procedure involving an EEA notified body, a private organization accredited by an EEA member state to conduct conformity assessment procedures under the MDR. The notified body typically audits and examines the device’s technical documentation, including the clinical evaluation, and the quality system for the manufacture, design and final inspection of our devices before issuing a CE Certificate demonstrating compliance with the relevant requirements or the quality system requirements laid down in the relevant Annexes to the MDR. The MDR became active on May 26, 2021 and replaced Council Directive 93 / 42 / EEC concerning medical devices (“ MDD ”) with transitional provisions for " legacy" devices under the MDD. The MDR introduced significant changes to the regulatory framework for medical devices in the EU →, including new, stricter requirements that we must comply with in order to obtain CE Certificates for new product candidates, and to renew the CE Certificates for our " legacy" MDD- Products when they expire or by December 31, 2027 or 2028, depending on device class, whichever occurs first. These changes may prevent or delay the CE Certification of our device candidates or impact our ability to modify our Products on a timely basis. In particular, the delay in the publication of key MDR guidance documents at EU level and the limited availability of qualified notified bodies might affect our ability to timely comply and demonstrate such compliance with the new requirements or delay the MDR CE Certification of our device candidates. Further, as a result of the implementation of the MDR, our notified body (as well as many other notified bodies throughout the EEA) has suffered a significant backlog in issuing CE Certificate renewals. In the UK, we ~~may continue~~ **were able** to market and sell our Products under the CE mark until June 2023. ~~Thereafter~~ **Going forward**, our Products ~~are~~ **will be** regulated under the UK Regulations. There can be no assurance that the UK Regulations will be interpreted by UK regulators in the same manner as the MDR in the future, which may prevent or delay the UK CE certification of our device candidates or impact our ability to modify our Products on a timely basis. We may choose to, or may be required to, suspend, repeat or terminate our clinical studies if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the studies are not well designed. Clinical studies must be conducted in accordance with the FDA’s cGCPs and the equivalent laws and regulations applicable in other jurisdictions in which the clinical studies are conducted. The clinical studies are subject to oversight by the FDA, regulatory agencies in other jurisdictions, ethics committees and institutional review boards at the medical institutions where the clinical studies are conducted. In addition, clinical studies must be conducted with device candidates produced under the FDA’s QSR and in accordance with the applicable regulatory requirements in the other jurisdictions in which the clinical studies are conducted. The conduct of clinical studies may require large numbers of test patients. The FDA or regulatory agencies in other jurisdictions might delay or terminate our clinical studies of a device candidate for various reasons, including: • the device candidate may have unforeseen adverse side effects or may not appear to be more effective than current therapies; • we may not agree with the FDA, a regulatory authority in another jurisdiction or an ethics committee regarding the protocol for the conduct of a clinical study; • new therapies may become the standard of care while we are conducting our clinical studies, which may require us to revise or amend our clinical study protocols or terminate a clinical study; or • fatalities may occur during a clinical study due to medical problems that may or may not be related to clinical study treatments. Furthermore, the process of obtaining and maintaining regulatory approvals in the U. S. and other jurisdictions and CE Certification in the EU for new therapeutic products is lengthy, expensive and uncertain. It can vary substantially, based on the type, complexity and novelty of the product involved. Accordingly, any of our device candidates could take a significantly longer time than we expect

to, or may never, gain regulatory approval or obtain CE Certification in the EU, which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. The process of obtaining and maintaining regulatory approvals may be further complicated when we seek approval for indications involving the use of our products together with pharmacological / immunological therapies and therapy candidates. If our regulators determine that the predominant questions stem from the pharmacological / immunological therapy in the study, they may require us and our partners to conduct the study under trial rules and regulations governing pharmacological / immunological therapies, which may differ significantly from medical device requirements. Adhering to pharmacological / immunological regulations and requirements governing clinical trials could make it more difficult to enroll study sites and patients, increase compliance costs and lengthen the time it takes to complete the study. Legislative and regulatory changes in the U. S. and in other countries regarding healthcare insurance and government- sponsored reimbursement programs (such as Medicare in the United States) may adversely affect our business and financial results. We rely to a material degree on highly regulated private and government- run health insurance programs for our revenue in most of the countries in which we operate. The laws and regulations regarding health care programs, both public and private, are driven by public policy considerations that may be unrelated to the direct provision of patient care, such as lowering costs or requiring or limiting access to healthcare options. These laws and regulations are very complicated and there are many requirements we must satisfy in order for our Products to become and remain eligible for reimbursement under these programs. In many cases we may have limited negotiating power when negotiating reimbursement rates for our Products. In the future, lawmakers and regulators could also pass additional healthcare laws and implement other regulatory changes at both the national and local levels. These laws and regulations could potentially affect coverage and reimbursement for our Products. However, we cannot predict the ultimate content, timing or effect of any future healthcare initiatives or the impact any future legislation or regulation will have on us. **Governmental authorities in** ~~With respect to countries outside the U. S., the national competent authorities in the~~ EU member states, the UK, Switzerland, Israel, Japan, and other jurisdictions are ~~also~~ increasingly active in their goal of reducing public spending on healthcare. We cannot, therefore, guarantee that the treatment of patients with our Products would be reimbursed in any particular country or, if successfully included on reimbursement lists, whether we will remain on such lists. We are subject to extensive post- marketing regulation by the FDA and comparable authorities in other jurisdictions, which could impact the sales and marketing of our Products and could cause us to incur significant costs to maintain compliance. In addition, we may become subject to additional regulation in other jurisdictions as we increase our efforts to market and sell Optune **Gio** or Optune Lua and future Products outside of the U. S. We market and sell our Products, and expect to market and sell future Products, subject to extensive regulation by the FDA and numerous other federal, state and governmental authorities in other jurisdictions. These regulations are broad and relate to, among other things, the conduct of preclinical and clinical studies, product design, development, manufacturing, labeling, testing, product storage and shipping, premarket clearance and approval, conformity assessment procedures, premarket clearance and approval of modifications introduced in marketed products, post- market surveillance and monitoring, reporting of adverse events and incidents, pricing and reimbursement, interactions with healthcare professionals, interactions with patients, information security, advertising and promotion and product sales and distribution. Although we have received FDA approval to market Optune **Gio** in the U. S. for the treatment of adult patients with newly diagnosed GBM (together with temozolomide) and recurrent GBM and approval to market Optune Lua for adults patients with MPM, we will require additional FDA approval to market our Products for other indications. We may be required to obtain approval of a new PMA, HDE or PMA / HDE supplement application for modifications made to our Products. This approval process is costly and uncertain, and it could take one to three years, or longer, from the time the application is filed with the FDA. We may make modifications in the future that we believe do not or will not require additional approvals, **such as the introduction of software products that we have assessed as not subject to FDA regulation and that are intended for use by users of our Products**. If the FDA disagrees, and requires new PMAs, HDEs, or PMA / HDE supplements for the modifications, we may be required to recall and to stop marketing the modified versions of our Products. In addition, before our Products can be marketed in the EU, our Products must obtain a CE Certificate from a notified body. New intended uses of CE marked medical devices falling outside the scope of the current CE Certificate require a completely new conformity assessment before the device can be CE marked and marketed in the EU for the new intended use. The process required to gather necessary information and draw up documentation in order to obtain CE Certification of a medical device in the EU can be expensive and lengthy and its outcome can be uncertain. We may make modifications to our Products in the future that we believe do not or will not require notifications to our notified body or new conformity assessments to permit the maintenance of our current CE Certificate. If the competent authorities of the EU member states or our notified body disagree and require the conduct of a new conformity assessment, the modification of the existing CE Certificate or the issuance of a new CE Certificate, we may be required to recall or suspend the marketing of the modified versions of our Products. In Japan, new medical devices or new therapeutic uses of medical devices falling outside the scope of the existing approval by the MHLW require a new assessment and approval for each such new device or use. Accordingly, we may be required to obtain a new approval from MHLW before we launch a modified version of our Products or the use of our Products for additional indications. Approval time frames from the MHLW vary from simple notifications to review periods of one or more years, depending on the complexity and risk level of the device. In addition, importation into Japan of medical devices is subject to " Quality Management System (QMS) Ordinance," which includes the equivalent of " Good Import" regulations in the U. S. As with any highly regulated market, significant changes in the regulatory environment could adversely affect our ability to commercialize ~~Optune our Products~~ **in** Japan. In the U. S. and other jurisdictions, we also are subject to numerous post- marketing regulatory requirements, which include regulations under the QSR related to the manufacturing of our Products, labeling regulations and medical device reporting regulations, which require us to report to the FDA or comparable regulatory authorities in other jurisdictions and our notified body if our Products cause or contributes to a death or serious injury, or malfunction in a way that would likely cause or

contribute to a death or serious injury. In addition, these regulatory requirements may in the future change in a way that adversely affects us. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by the FDA or comparable regulatory authorities in other jurisdictions and notified bodies, which may include any of the following sanctions: • untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; • unanticipated expenditures to address or defend such actions; • patient notification, or orders for repair, replacement or refunds; • voluntary or mandatory recall, withdrawal or seizure of our current or future devices; • administrative detention by the FDA or other regulatory authority in another jurisdiction of medical devices believed to be adulterated or misbranded; • operating restrictions, suspension or shutdown of production; • refusal or delay of our requests for PMA or analogous approval for new intended uses for or modifications to our Products or for approval of new devices; • refusal or delay in obtaining CE Certificates for new intended uses for or modifications to our Products; • suspension, variation or withdrawal of the CE Certificates granted by our notified body in the EU; • prohibition or restriction of Products being placed on the market; • operating restrictions; • suspension or withdrawal of PMA or analogous approvals that have already been granted; • refusal to grant export approval for our Products or any device candidates; or • criminal prosecution. The occurrence of any of these events could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Over time, we expect to make modifications to our Products that are designed to improve efficacy, reduce side effects, enhance the user experience and other purposes. Modifications to our Products may require approvals of new PMAs, HDEs, or PMA / HDE supplement applications, modified or new CE Certificates and analogous regulatory approvals in other jurisdictions or even require us to cease promoting or to recall the modified versions of our Products until such clearances, approvals or modified or new CE Certificates are obtained, and the FDA, comparable regulatory authorities in other jurisdictions or our notified body may not agree with our conclusions regarding whether new approvals are required. Any modification to a device approved through the PMA or HDE pathway that impacts the safety or effectiveness of the device requires submission to the FDA and FDA approval of a PMA supplement application or even a new PMA or HDE application, as the case may be. The FDA requires a company to make the determination as to whether a new PMA, HDE or PMA / HDE supplement application is to be filed, but the FDA may review the company's decision. For example, in the past, we have made initial determinations that certain modifications did not require the filing of a new PMA or PMA / HDE supplement application and have notified the FDA of these changes in our PMA Annual Report, but after its review of our PMA Annual Report, the FDA requested that we submit these modifications to the FDA as a PMA supplement application. From time to time, we may make other changes to the devices, software, packaging, manufacturing facilities and manufacturing processes and may submit additional PMA / HDE supplement applications for these changes. FDA may conduct a facility inspection as part of its review and approval process. In addition, it is possible that the FDA will require a human factors (user interface) study. It is also possible that the FDA may require additional clinical data. We can provide no assurance that we will receive FDA approval for these changes on a timely basis, or at all. We also may make additional changes in the future that we may determine do not require the filing of a new PMA, HDE or PMA / HDE supplement application. The FDA may not agree with our decisions regarding whether the filing of new PMAs, HDEs or PMA / HDE supplement applications are required. In addition, any substantial change introduced to a medical device or to the quality system certified by our notified body requires a new conformity assessment of the device and can lead to changes to the CE Certificates or the preparation of a new CE Certificate of Conformity. Substantial changes may include, among others, the introduction of a new intended use of the device, a change in its design or a change in the company's suppliers. Responsibility for determination that a modification constitutes a substantial change lies with the manufacturer of the medical device. We must inform the notified body that conducted the conformity assessment of the Products we market or sell in the EU of any planned substantial changes to our quality system or changes to our Products that could, among other things, affect compliance with the MDR or the devices' intended use. The notified body will then assess the changes and verify whether they affect the Product's conformity with the Essential Requirements laid down in Annex I to the MDR or the conditions for the use of the device. If the assessment is favorable, the notified body will issue a new CE Certificate or an addendum to the existing CE Certificate attesting compliance with the Essential Requirements laid down in Annex I to the MDR. There is a risk that the competent authorities of the EU member states or our notified body may disagree with our assessment of the changes introduced to our Products. The competent authorities of the EU member states or our notified body also may come to a different conclusion than the FDA on any given product modification. In addition, "legacy" medical devices that have obtained a CE Certification under the MDD may in principle continue to be marketed under such CE Certificate until the CE Certificate expires but at the latest by December 31, 2027 or 2028, depending on device class, under transitional provisions as amended in February 2023, provided that the manufacturer complies with the MDR's additional requirements related to post-marketing surveillance, market surveillance, vigilance, and registration of economic operators and of devices. However, if such medical devices undergo a significant change in their design or intended use, we would need to obtain a new CE Certificate under the MDR for these devices. If the FDA disagrees with us and requires us to submit a new PMA, HDE, or PMA / HDE supplement application for then-existing modifications and / or the competent authorities of the EU member states or our notified body disagree with our assessment of the change introduced in a product, its design or its intended use, we may be required to cease promoting or to recall the modified product until we obtain approval and / or until a new conformity assessment has been conducted in relation to the product, as applicable. In addition, we could be subject to significant regulatory fines or other penalties. Furthermore, our Products could be subject to recall if the FDA, comparable regulatory authorities in other jurisdictions, or our notified body determine, for any reason, that our Products are not safe or effective or that appropriate regulatory submissions were not made. Any recall or requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenues and potential operating restrictions imposed by the FDA, comparable foreign regulatory authorities in other jurisdictions, or our notified body. Delays in receipt or failure to receive approvals / certification, or the failure to comply with any other existing or

future regulatory requirements, could reduce our sales, profitability and future growth prospects. In addition to FDA requirements, we will spend considerable time and money complying with other federal, state, local and foreign rules, regulations and guidance and, if we are unable to fully comply with such rules, regulations and guidance, we could face substantial penalties. We are subject to extensive regulation by the U. S. federal government and the states and other countries in which we conduct our business. U. S. federal government healthcare laws apply when we submit a claim on behalf of a U. S. federal healthcare program beneficiary, or when a customer submits a claim for an item or service that is reimbursed under a U. S. federal government- funded healthcare program, such as Medicare or Medicaid. The laws that affect our ability to operate our business in addition to the Federal Food, Drug, and Cosmetic Act and FDA regulations include, but are not limited to, the following: • the Federal Anti- Kickback Statute, an intent- based federal criminal statute which prohibits knowingly and willfully offering, providing, soliciting or receiving remuneration of any kind to induce or reward, or in return for, referrals or the purchase, lease, order or recommendation or arranging of any items or services reimbursable by a federal healthcare program; • the Federal Civil False Claims Act, which imposes civil penalties, including through civil whistleblower or " qui tam" actions, for knowingly submitting or causing the submission of false or fraudulent claims of payment to the federal government, knowingly making, using or causing to be made or used a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government; • the Federal Criminal False Claims Act, which is similar to the Federal Civil False Claims Act and imposes criminal liability on those that make or present a false, fictitious or fraudulent claim to the federal government; • Medicare laws and regulations that prescribe requirements for coverage and reimbursement, including the conditions of participation for DME suppliers, and laws prohibiting false claims or unduly influencing selection of products for reimbursement under Medicare and Medicaid; • healthcare fraud statutes that prohibit false statements and improper claims to any third- party payer; • the Federal Physician Self- Referral Law, commonly known as the Stark law, which, absent an applicable exception, prohibits physicians from referring Medicare and Medicaid patients to an entity for the provision of certain designated health services (" DHS "), including DME, if the physician (or a member of the physician' s immediate family) has an impermissible financial relationship with that entity and prohibits the DHS entity from billing for such improperly referred services; • the Federal Beneficiary Anti- Inducement Statute, which prohibits the offering of any remuneration to a beneficiary of Medicare or Medicaid that is likely to influence that beneficiary' s choice of provider or supplier. This can include, but is not limited to, inappropriate provision of patient services including financial assistance. Recent government investigations have focused on this particular prohibition. There are established exceptions from liability, but we cannot guarantee that all of our practices will fall squarely within those exceptions; • similar state anti-kickback, false claims, insurance fraud and self- referral laws, which may not be limited to government- reimbursed items, as well as state laws that require us to maintain permits or licenses to distribute DME; • federal and state accreditation and licensing requirements applicable to DME providers and equivalent requirements in other jurisdictions; • the U. S. Foreign Corrupt Practices Act, which can be used to prosecute companies in the U. S. for arrangements with physicians or other parties outside the U. S. if the physician or party is a government official of another country and the arrangement violates the law of that country; • the Federal Trade Commission Act, the Lanham Act and similar federal and state laws regulating truthfulness in advertising and consumer protection; and • the Federal Physician Payments Sunshine Act, the French Sunshine Act and similar state and foreign laws, which require periodic reporting of payments and other transfers of value made to U. S. and French- licensed physicians, teaching hospitals, and in the U. S., physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse- midwives. Similar laws exist in the EU, individual EU member states and other countries. These laws are complemented by EU or national professional codes of practices. HIPAA provides data privacy and security provisions for safeguarding medical information. Additionally, states in the U. S. are enacting local privacy laws (e. g., California). In the EU, the GDPR harmonizes data privacy laws and rules on the processing of personal data, including patient and employee data, across the EU. The GDPR has a number of strict data protection and security requirements for companies processing data of EU residents, including when such data is transferred outside of the EU. Additionally, we need to comply with analogous privacy laws in other jurisdictions in which we operate, such as the Israeli Privacy Protection Law, the Asia Pacific Economic Cooperation Privacy Framework, and Japan' s Act on the Protection of Personal Information. The laws and codes of practices applicable to us are subject to evolving interpretations. Moreover, certain U. S. federal and state laws regarding healthcare fraud and abuse and certain laws in other jurisdictions regarding interactions with healthcare professionals and patients are broad and we may be required to restrict certain of our practices to be in compliance with these laws. Healthcare fraud and abuse laws also are complex and even minor, inadvertent irregularities, or even the perception of impropriety, can potentially give rise to claims that a statute has been violated. Any violation of these laws could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Similarly, if there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which likewise could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Fines and penalties for violations of these laws and regulations could include severe criminal and civil penalties, including, for example, significant monetary damages, exclusion from participation in the federal healthcare programs and permanent disbarment of key employees. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business, our prospects and our financial results. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management' s attention from the operation of our business and damage our reputation. In addition, although we believe that we have the required licenses, permits and accreditation to dispense our Products in the future, a regulator could find that we need to obtain additional licenses or permits. We also may be subject to mandatory reaccreditation and other requirements in order to maintain our billing privileges. Failure to satisfy those requirements could cause us to lose our privileges to bill governmental and private payers. If

we are required to obtain permits or licenses that we do not already possess, we also may become subject to substantial additional regulation or incur significant expense. To ensure compliance with Medicare, Medicaid and other regulations, federal and state governmental agencies and their agents, including DME MACs, may conduct audits of our operations to support our claims submitted for reimbursement of items furnished to beneficiaries and health care providers. Depending on the nature of the conduct found in such audits and whether the underlying conduct could be considered systemic, the resolution of these audits could adversely impact our revenue, financial condition and results of operations. If we, our collaborative partners, our contract manufacturers or our component suppliers fail to comply with the FDA's QSR or equivalent regulations established in other countries, the manufacturing and distribution of our Products could be interrupted, and our Product sales and results of operations could suffer. We, our collaborative partners, our contract manufacturers and our component suppliers are required to comply with the FDA's QSR and the equivalent quality system requirements imposed by the laws and regulations in other jurisdictions, which are a complex regulatory framework that covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our Products. We cannot assure you that our facilities or our contract manufacturers' or component suppliers' facilities would pass any future quality system inspection. If our or any of our contract manufacturers' or component suppliers' facilities fails a quality system inspection, the manufacturing or distribution of our Products could be interrupted and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse quality system inspection could force a suspension or shutdown of our packaging and labeling operations or the manufacturing operations of our contract manufacturers, and lead to suspension, variation or withdrawal of our regulatory approvals or a recall of our Products. If any of these events occurs, we may not be able to provide our customers with our Products on a timely basis, our reputation could be harmed and we could lose customers, any or all of which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Our Products may in the future be subject to recalls that could harm our reputation, business and financial results. The FDA and similar governmental authorities in other jurisdictions have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, governmental bodies in other jurisdictions have the authority to require the recall of our Products in the event of material deficiencies or defects in design or manufacture. Distributors and manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our manufacturers could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. Requirements for the reporting of product recalls to the competent authorities are imposed in other jurisdictions in which our Products are or would be marketed in the future. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or to the competent authorities of other countries. In the future, we may initiate voluntary recalls involving our Products that we determine do not require notification of the FDA or to other equivalent non- U. S. authorities. If the FDA or the equivalent non- U. S. authorities disagree with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA and the equivalent non- U. S. authorities could take enforcement action if we fail to report the recalls when they were conducted. Recalls of our Products would divert managerial and financial resources and could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. If our Products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions. Under the FDA Medical Device Reporting regulations and the equivalent regulations applicable in other jurisdictions in which our Products are or may be marketed in the future, medical device manufacturers are required to report to the FDA and to the equivalent non- U. S. authorities information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA or to the equivalent authorities in other jurisdictions within the required time frames, or at all, the FDA or the equivalent authorities in other jurisdictions could take enforcement action against us. Any such adverse event involving our Products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results. We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our Products for unapproved or off- label uses. Medical devices may be marketed only for the indications for which they are approved. Our promotional materials and training materials must comply with FDA regulations and other applicable laws and regulations governing the promotion of our Products in the U. S. and other jurisdictions. Currently, Optune **Gio** is approved for treatment of adult patients with newly diagnosed GBM (together with temozolomide) and recurrent GBM in the U. S. and is approved for treatment of adult patients with GBM in Japan. In the EU and Switzerland, we have CE marked ~~the~~ Optune **Gio** for the treatment of newly diagnosed GBM (together with temozolomide), recurrent GBM, and advanced NSCLC (together with standard- of- care chemotherapy). Optune **Gio** is also approved in Israel and in Australia for the treatment of recurrent GBM and newly diagnosed GBM (together with temozolomide). The Optune Lua System is only approved in the U. S., the EU and Switzerland for the treatment of unresectable, locally advanced or metastatic MPM. If the FDA or the competent authorities in other jurisdictions, including the EU member states, determine that our promotional materials or training constitutes promotion of an unapproved use, they could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled or warning letter, an injunction, seizure, civil fines and criminal penalties. It is also possible that

authorities in other federal, state or national enforcement in other jurisdictions might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and the commercialization of our Products could be impaired. We pay taxes in multiple jurisdictions and adverse determinations by taxing or other governmental authorities or changes in tax laws, rates or our status under which tax jurisdictions apply to us could increase our tax burden or otherwise affect our financial condition or results of operations, as well as subject our shareholders to additional taxes. The amount of taxes we pay is subject to a variety of tax laws in the various jurisdictions in which we and our subsidiaries are organized and operate. Our domestic and international tax liabilities are dependent on the location of earnings among these various jurisdictions. Such tax liabilities could be affected by changes in tax or other laws, treaties, and regulations, as well as the interpretation or enforcement thereof by tax or other governmental entities in any relevant jurisdiction. The amount we pay in tax to any particular jurisdiction depends, in part, on the correct interpretation of the tax laws in such jurisdiction, and we have made a number of determinations as to the effect of such tax laws in our particular circumstances. In some cases, the determinations we have made as to the effect of the tax laws in a particular jurisdiction depend on the continuing effectiveness of administrative rulings we have received from the tax authorities in that jurisdiction, while in other cases, our determinations are based on the reasoned judgment of our tax advisors. Although we believe that we are in compliance with the administrative rulings we have received, that the assumptions made by our tax advisors in rendering their advice remain correct, and that as a result we are in compliance with applicable tax laws in the jurisdictions where we and our subsidiaries are organized and operate, a taxing authority in any such jurisdiction may challenge our interpretation of those laws and assess us or any of our subsidiaries with additional taxes, penalties, fees and interest. Additionally, from time to time, proposals can be made and legislation can be introduced to change the tax laws, regulations or interpretations thereof (possibly with retroactive effect) of various jurisdictions or limit tax treaty benefits that, if enacted, could materially increase our tax burden, increase our effective tax rate or otherwise have a material adverse impact on our financial condition and results of operations. **For example, the Organization for Economic Cooperation and Development (OECD) has secured agreements from many countries to push forward with proposals to fundamentally rewrite international tax rules, which could impact the amount of tax we will pay in the future**. It is possible that these changes could adversely affect our business. While we monitor proposals and other developments that would materially impact our tax burden and effective tax rate and investigate our options accordingly, we could still be subject to increased taxation on a going forward and retroactive basis no matter what action we undertake if certain legislative proposals or regulatory changes are enacted, certain tax treaties are amended and / or our interpretation of applicable tax or other laws is challenged and determined to be incorrect. Any alternative interpretations of applicable tax laws asserted by a tax authority or changes in tax laws, regulations or accounting principles that limit our ability to take advantage of tax treaties between jurisdictions, modify or eliminate the deductibility of various currently deductible payments, increase the tax burden of operating or being resident in a particular country, result in transfer pricing adjustments or otherwise require the payment of additional taxes, may have a material adverse effect on our cash flows, financial condition and results of operations. The termination or revision of any of our tax rulings or indirect tax exemptions that we have or may have in the future may have a material adverse effect on our cash flows, financial condition and results of operations. We are affected by and subject to environmental laws and regulations that could be costly to comply with or that may result in costly liabilities. We are subject to environmental laws and regulations, including those that impose various environmental controls on the manufacturing, transportation, storage, use and disposal of batteries and hazardous chemicals and other materials used in, and hazardous waste produced by, the manufacturing of our Products. We incur and expect to continue to incur costs to comply with these environmental laws and regulations. Additional or modified environmental laws and regulations, including those relating to the manufacture, transportation, storage, use and disposal of materials used to manufacture our Products or restricting disposal or transportation of batteries, may be imposed that may result in higher costs. In addition, we cannot predict the effect that additional or modified environmental laws and regulations may have on us, our third- party suppliers of equipment, batteries and our Products or our customers. For example, we and our suppliers rely on the exemption in European Directive 2011 / 65 / EU relating to the restriction of the use of certain hazardous substances in electrical and electronic equipment, set out in Annex IV, relating to lead content in our arrays. To the extent this exemption is revoked or amended, it may have a material impact on our business and results of operations. Safety issues concerning lithium- ion batteries could have a material adverse impact on our business. Our Products use lithium- ion batteries. On rare occasions, lithium- ion cells can rapidly release the energy they contain by venting smoke, heat, and flames in a manner that can ignite nearby materials as well as other lithium- ion cells. A failure in the lithium- ion battery contained in a Product could occur, which could result in accidents, casualty or damages, and subject us to lawsuits, product recalls, or redesign efforts. In addition, we store a significant number of lithium- ion cells at our facilities. Any failure of battery cells or a safety issue or fire related to the cells could disrupt our operations. Such damage or injury could lead to adverse publicity and potentially a safety recall. The transportation of lithium and lithium- ion batteries is regulated worldwide. Laws regulating the transportation of batteries have been and may be enacted which could impose additional costs that could harm our ability to be profitable. If additional restrictions are put in place that limit our ability to ship our Products by air freight or on water borne cargo, such restrictions could have an adverse effect on our supply chain, our inventory management procedures and processes and our ability to fill prescriptions and service patients in a timely manner, which could have a material adverse effect on our business, prospects, financial condition and results of operations. In addition, compliance with future worldwide or International Air Transport Association approval process and regulations could require significant time and resources from our technical staff and, if redesign were necessary, could delay the introduction of new Products. Risks relating to intellectual property If we fail to **maintain, develop,** protect, **defend or** sustain, further build and enforce our intellectual property rights, including to our proprietary technology, trade secrets or know how, competitors may be able to develop competing therapies. Our success

depends, in part, on our ability to obtain and maintain protection for our Products and technologies under the patent laws or other intellectual property laws of the U. S. and other countries. The standards that the U. S. Patent and Trademark Office ("USPTO") and its counterparts in other jurisdictions use to grant patents are not always applied predictably or uniformly and can change. Consequently, we cannot be certain as to whether pending patent applications will result in issued patents, and we cannot be certain as to the type and extent of patent claims that may be issued to us in the future. Any issued patents may not contain claims that will permit us to stop competitors from using similar technology. Our current intellectual property portfolio consists of hundreds of issued patents in multiple jurisdictions covering various aspects of our devices and related technology. The legal scope of our patents vary, with some having broad coverage and others having narrow coverage, for example being limited to certain intensities and frequencies. Our patent position is generally uncertain and involves complex legal and factual questions. In the U. S., our patents have expected expiration dates between 2023-2024 and 2041. ~~In~~ **Starting in** 2021, several patents covering technology included in our Products **have** expired in the U. S. and elsewhere. Patent expiration could adversely affect our ability to protect our Products and future product development and our competitors may develop and market competing products. We have also filed additional patent applications in several countries that may never be issued. Consequently, our operating results and financial position could be materially adversely affected. In addition, due to the extensive time needed to develop, test and obtain regulatory approval for our treatment therapies, any patents that protect our Product candidates may expire early during commercialization. This may reduce or eliminate any market advantages that such patents may give us and harm our financial position. If we fail to develop and successfully launch new Products prior to the expiration of patents for our existing Products, our sales and achieving patient acceptance with respect to those Products could decline significantly. We may not be able to develop and successfully launch more advanced replacement Products before these and other patents expire. We have limited intellectual property rights outside of our key markets. In some countries outside the U. S., we do not have any intellectual property rights, and our intellectual property rights in other countries outside the U. S. have a different scope and strength compared to our intellectual property rights in the U. S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U. S. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement rights are not as strong as those in the U. S. These products may compete with our devices, and our patents or other intellectual property rights may not be effective or adequate to prevent such competition. For a variety of reasons, we may decide not to file for patent protection for certain of our intellectual property. Our patent rights underlying TTFields and our Products may not be adequate, and our competitors or customers may design around our proprietary technologies or independently develop similar or alternative technologies or products that are equal or superior to ours without infringing on any of our patent rights. In addition, the patents licensed or issued to us may not provide a competitive advantage, and may be insufficient to prevent others from commercializing products similar or identical to ours. The occurrence of any of these events could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Our existing and future patent portfolio also may be vulnerable to legal challenges worldwide. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change from country to country, particularly as new technologies develop. As a result of the uncertainties of patent law in general, we cannot predict how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Any attempt to enforce our intellectual property rights may also be time-consuming and costly, may divert the attention of management from our business, may ultimately be unsuccessful or may result in a remedy that is not commercially valuable. Such attempts may also provoke third parties to assert claims against us or result in our intellectual property being narrowed in scope or declared to be invalid or unenforceable. In addition, we rely on certain proprietary trade secrets, know-how and other confidential information. We have taken measures to protect our unpatented trade secrets, know-how and other confidential information, including the use of confidentiality and assignment of inventions agreements with our employees, consultants and certain contractors. It is possible, however, that these persons may breach or challenge the agreements, that our trade secrets may otherwise be misappropriated or that competitors may independently develop or otherwise discover our trade secrets. There is therefore no guarantee that we will be able to obtain, maintain and enforce the intellectual property rights that may be necessary to protect and grow our business and to provide us with a meaningful competitive advantage, and our failure to do so could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. The oncology and medical device industries are characterized by patent and other intellectual property litigation and disputes, and any litigation, dispute or claim against us may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our business, harm our reputation and require us to remove certain devices from the market. Whether a product infringes a patent or violates other intellectual property rights involves complex legal and factual issues, the determination of which is often uncertain. Any intellectual property dispute, even a meritless or unsuccessful one, would be time consuming and expensive to defend and could result in the diversion of our management's attention from our business and result in adverse publicity, the disruption of research and development and marketing efforts, injury to our reputation and loss of revenues. Any of these events could negatively affect our business, prospects, financial condition and results of operations. Third parties may assert that TTFields, our Products, the methods employed in the use of our Products or other activities infringe on their patents. Such claims may be made by competitors seeking to obtain a competitive advantage or by other parties, many of whom have significantly larger intellectual property portfolios than we have. Additionally, in recent years, individuals and groups have begun purchasing intellectual property assets for the purpose of making claims of infringement and attempting to extract settlements from companies like ours. With respect to our current Products, the risk of infringement claims is exacerbated by the fact that there are numerous issued and pending patents relating to the treatment of cancer. Because patent applications can take many years to issue, and in many cases remain unpublished for many months after filing, there may be

applications now pending of which we are unaware that may later result in issued patents that our Products may infringe. There could also be existing patents that one or more components of our Products or other device candidates may inadvertently infringe. As the number of competitors in the market or other device candidates grows, the possibility of inadvertent patent infringement by us or a patent infringement claim against us increases. To the extent we gain greater market visibility, our risk of being subject to such claims is also likely to increase. If a third party's patent was upheld as valid and enforceable and we were found to be infringing, we could be prevented from making, using, selling, offering to sell or importing our Products or other device candidates, unless we were able to obtain a license under that patent or to redesign our systems to avoid infringement. A license may not be available at all or on terms acceptable to us, and we may not be able to redesign our Products to avoid any infringement. Modification of our Products or development of device candidates to avoid infringement could require us to conduct additional clinical studies and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. If we are not successful in obtaining a license or redesigning our devices, we may be unable to make, use, sell, offer to sell or import our devices and our business could suffer. We may also be required to pay substantial damages and undertake remedial activities, which could cause our business to suffer. We may also be subject to claims alleging that we infringe or violate other intellectual property rights, such as copyrights or trademarks, may have to defend against allegations that we misappropriated trade secrets, and may face claims based on competing claims of ownership of our intellectual property. The confidentiality and assignment of inventions agreements that our employees, consultants and other third parties sign may not in all cases be enforceable or sufficient to protect our intellectual property rights. In addition, we may face claims from third parties based on competing claims to ownership of our intellectual property. We also employ individuals who were previously employed at other medical device companies, and as such we may be subject to claims that such employees have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of their former employers. Any such litigation, dispute or claim could be costly to defend and could subject us to substantial damages, injunctions or other remedies, which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our devices. As is the case with other medical device companies, our success is heavily dependent on our intellectual property rights, and particularly on our patent rights. Obtaining and enforcing patents in the medical device industry involves both technological and legal complexity, and is therefore costly, time consuming and inherently uncertain. In addition, the U. S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Certain U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could further negatively impact the value of our patents, narrow the scope of available patent protection or weaken the rights of patent owners. Risks relating to our ordinary shares and capital structure The market price for our ordinary shares may be volatile, which could result in substantial losses. The market price for our ordinary shares may be volatile and subject to wide fluctuations in response to factors such as publication of clinical studies relating to our Products, our system candidates or a competitor's product, actual or anticipated fluctuations in our quarterly results of operations, changes in financial estimates by securities research analysts, negative publicity, studies or reports, changes in the economic performance or market valuations of other companies that operate in our industry, changes in the availability of third-party reimbursement in the U. S. or other countries, changes in governmental regulations or in the status of our regulatory approvals or applications, announcements by us or our competitors of material acquisitions, strategic partnerships, joint ventures or capital commitments, intellectual property litigation, release of transfer restrictions on our outstanding ordinary shares, and economic or political conditions in the U. S. or elsewhere. Our ordinary shares are issued under the laws of Jersey, which may not provide the level of legal certainty and transparency afforded by incorporation in a U. S. state. We are incorporated under the laws of the Bailiwick of Jersey, Channel Islands. Jersey legislation regarding companies is largely based on English corporate law principles. However, there can be no assurance that Jersey law will not change in the future or that it will serve to protect investors in a similar fashion afforded under corporate law principles in the U. S., which could adversely affect the rights of investors. U. S. shareholders may not be able to enforce civil liabilities against us. We are a Jersey entity with most of our assets located outside of the U. S. Although we have appointed an agent for service of process in the U. S. for purposes of U. S. federal securities laws, a number of our directors and executive officers and a number of directors of each of our subsidiaries are not residents of the U. S., and all or a substantial portion of the assets of such persons are located outside the U. S. As a result, it may not be possible for investors to effect service of process within the U. S. upon such persons or to enforce against them judgments obtained in U. S. courts predicated upon the civil liability provisions of the federal securities laws of the U. S. We have been advised by our Jersey lawyers that the courts of Jersey would recognize any final and conclusive judgment under which a sum of money is payable (not being a sum payable in respect of taxes or other charges of a like nature or in respect of a fine or other penalty) obtained against us in the courts of any other territory in respect of certain enforceable obligations in accordance with the principles of private international law as applied by Jersey law (which are broadly similar to the principles accepted under English common law) and such judgment would be sufficient to form the basis of proceedings in the Jersey courts for a claim for liquidated damages in the amount of such judgment. In such proceedings, the Jersey courts would not rehear the case on its merits save in accordance with such principles of private international law. Obligations may not necessarily be enforceable in Jersey in all circumstances or in accordance with their terms; and in particular, but without limitation: (i) any agreement purporting to provide for a payment to be made in the event of a breach of such agreement would not be enforceable to the extent that the Jersey courts were to construe such payment to be a penalty that was excessive, in that it unreasonably exceeds the maximum damages that an obligee could have suffered as a result of the breach of an obligation; (ii) the Jersey

courts may refuse to give effect to any provision in an agreement that would involve the enforcement of any revenue or penal laws in other jurisdictions; and (iii) the Jersey courts may refuse to allow unjust enrichment or to give effect to any provisions of an agreement (including provisions relating to contractual interest on a judgment debt) that it considers usurious. We have borrowed a significant amount of debt and have the ability to borrow additional debt in the future, which could adversely affect our financial condition and results of operations and our ability to react to changes in our business. ~~We currently have two significant debt arrangements outstanding.~~ On November 5, 2020, we issued \$ 575 million of 0 % Convertible Senior Notes due 2025 (the “ Convertible Notes ”). The Convertible Notes are senior unsecured obligations. The Convertible Notes do not bear regular interest, and mature on November 1, 2025, unless earlier repurchased, redeemed or converted. The Notes are not redeemable prior to November 6, 2023 and are convertible into a combination of cash and ordinary shares on or after August 1, 2025, or earlier upon certain events. **While our existing material indebtedness does not accrue interest, our ability to incur indebtedness in the future and service that indebtedness could be impacted by interest and currency rate fluctuations .** Our existing indebtedness and any additional indebtedness we may incur otherwise could require us to divert funds identified for other purposes for debt service and impair our liquidity position. The fact that a substantial portion of our cash flow from operations could be needed to make payments on our indebtedness could have important consequences, including the following:

- increasing our vulnerability to general adverse economic and industry conditions or increased interests rates;
- limiting the availability of our cash flow for other purposes and our flexibility in planning for or reacting to changes in our business and the markets in which we operate, which would place us at a competitive disadvantage compared to our competitors that may have less exposure to debt;
- limiting our ability to borrow additional funds for working capital, capital expenditures and other investments; and
- failing to comply with the covenants in our debt agreements could result in all of our indebtedness becoming immediately due and payable.

Our ability to obtain necessary funds through borrowing, as well as our ability to service our indebtedness, will depend on our ability to generate cash flow from operations. Our ability to generate cash is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control. If our business does not generate sufficient cash flow from operations or if future borrowings are not available to us under our outstanding borrowings or otherwise in amounts sufficient to enable us to fund our liquidity needs, our financial condition and results of operations may be adversely affected. Our inability to make scheduled payments on our debt obligations in the future would require us to refinance all or a portion of our indebtedness on or before maturity, sell assets or seek additional equity investment. We may not be able to take any of such actions on a timely basis, on terms satisfactory to us or at all. Transactions relating to our Convertible Notes may dilute the ownership interest of existing shareholders, or may otherwise depress the price of our ordinary shares. The conversion of some or all of our Convertible Notes would dilute the ownership interests of existing shareholders to the extent we deliver shares upon conversion of any of such notes. Our Convertible Notes are convertible at the option of their holders prior to their scheduled terms under certain circumstances. In connection with the conversion of our Convertible Notes, we may deliver to the holders of such notes a significant number of our ordinary shares. Any sales in the public market of our ordinary shares issuable upon such conversion could adversely affect prevailing market prices of our ordinary shares. In addition, the existence of our Convertible Notes may encourage short selling by market participants because the conversion of such notes could be used to satisfy short positions, or anticipated conversion of such notes into our ordinary shares could depress the price of our ordinary shares. ~~47-46~~