

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

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2023  
or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number 001-37565

**NovoCure Limited**

(Exact Name of Registrant as Specified in Its Charter)

**Jersey**

(State or Other Jurisdiction of  
Incorporation or Organization)

**98-1057807**

(I.R.S. Employer  
Identification No.)

**No. 4 The Forum**

**Grenville Street**

**St. Helier, Jersey JE2 4UF**

(Address of Principal Executive Offices, including zip code)

Registrant's telephone number, including area code: **+44 (0) 15 3475 6700**

Securities registered pursuant to Section 12(b) of the Act:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
Ordinary shares, no par value per share	NVCR	NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act:

**None**

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer

Non-accelerated filer  Smaller reporting company

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the outstanding common equity of the registrant held by non-affiliates as of the last business day of the registrant's most recently completed second fiscal quarter was \$ 1,415,046,375 .

The number of shares of the registrant's ordinary shares outstanding as of February 16, 2024 was 107,093,432 .

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement for its 2024 annual meeting of shareholders are incorporated by reference into Items 10, 11, 12, 13, and 14 of Part III of this Form 10-K. Such definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2023.

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#### **CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

In addition to historical facts or statements of current condition, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements contained in this report are based on our current plans, expectations, hopes, beliefs, intentions or strategies concerning future developments and their impact on us. Forward-looking statements contained in this report constitute our expectations or forecasts of future events as of the date this report was filed with the Securities and Exchange Commission and are not statements of historical fact. You can identify these statements by the fact that they do not relate strictly to historical or current facts. Such statements may include words such as "anticipate," "will," "estimate," "expect," "project," "intend," "should," "plan," "believe," "hope," and other words and terms of similar meaning in connection with any discussion of, among other things, future operating or financial performance, strategic initiatives and business strategies, regulatory or competitive environments, our intellectual property and research and development related to our Tumor Treating Fields ("TTFields") devices marketed under various brand names, including "Optune Gio," "Optune Lua," and software, tools and other items to support and optimize the delivery of TTFields therapy (collectively, the "Products"). In particular, these forward-looking statements include, among others, statements about:

- our research and development, clinical study and commercialization activities and projected expenditures;
- the further commercialization of our Products for current and future indications;
- our business strategies and the expansion of our sales and marketing efforts in the United States ("U.S.") and in other countries;
- the market acceptance of our Products for current and future indications by patients, physicians, third-party payers and others in the healthcare and scientific community;
- our plans to pursue the use of our Products for the treatment of indications other than glioblastoma ("GBM") and malignant pleural mesothelioma ("MPM");
- our estimates regarding revenues, expenses, capital requirements and needs for additional financing;
- our ability to obtain regulatory approvals for the use of our Products in indications other than GBM and MPM;
- our ability to acquire from third-party suppliers the supplies needed to manufacture our Products;
- our ability to manufacture adequate supply of our Products;
- our ability to secure and maintain adequate coverage from third-party payers to reimburse us for our Products for current and future indications;
- our ability to receive payment from third-party payers for use of our Products for current and future indications;
- our ability to maintain, develop, protect, defend or enforce our intellectual property position;
- our ability to manage the risks associated with business disruptions caused by natural disasters, extreme weather events, pandemics such as COVID-19 (coronavirus) or international conflict or other disruptions outside of our control;
- our cash needs; and
- our prospects, financial condition and results of operations.

These forward-looking statements involve a number of risks and uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Factors which may cause such differences to occur include those risks and uncertainties set forth under Part I, Item 1A, Risk Factors, of this Annual Report on Form 10-K, as well as other risks and uncertainties set forth from time to time in the reports we file with the U.S. Securities and Exchange Commission the ("SEC"). We do not intend to update publicly any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

## **Summary of Risk Factors**

The following is a summary of some of the risks and uncertainties that could materially adversely affect our business, financial condition and results of operations. You should read this summary together with the more detailed description of each risk factor contained below.

### **Risks relating to the manufacturing, marketing and sales of our products**

- We currently have only two products approved for use for specific indications. Our ability to expand our product line and their uses requires regulatory approval, which is costly and requires significant time and effort to obtain.
- To date, we have generated only occasional and intermittent operating profits, and we have a history of incurring substantial operating losses. As we expand, we may experience difficulties managing our growth.
- To obtain approvals for new products and indications and to continue to market our existing products, we are required to conduct preclinical and clinical studies and other testing. Our clinical studies could be delayed or otherwise adversely affected by many factors, including difficulties in enrolling patients and problems with third-party providers. Continued testing of our products may not yield successful results and could reveal currently unknown safety hazards associated with our products. 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.
- Our products do not have a significant history in the marketplace, as a result we may have difficulty:
  - developing an adequate sales and marketing organization or contracting with third parties to assist us in doing so;
  - achieving market acceptance of our products by healthcare professionals, patients and/or third-party payers; and
  - securing and maintaining adequate coverage and reimbursement from third-party payers, including governmental agencies in the countries where we market our products.
- We depend on single-source suppliers and manufacturers for some of our components, the loss of which could prevent or delay shipments of our products to customers or delay our clinical studies.
- Quality control problems with respect to materials supplied by third-party suppliers could prevent or delay shipments of our products to customers or delay our clinical studies.
- We face competition from numerous competitors.
- Because of the specialized nature of our business, the termination of relationships with our key employees, consultants and advisors may be detrimental to our business.
- Product liability suits, whether or not meritorious, could be brought against us and result in expensive and time-consuming litigation, payment of substantial damages and/or expenses and an increase in our insurance rates.
- Other future litigation and regulatory actions could have a material adverse impact on the Company.
- We are subject to fluctuations in global economic, political, environmental, and industry conditions, some of which may be unfavorable, including as a result of the COVID-19 or similar pandemic.
- Our products and infrastructure face certain risks, including from cyber security breaches and data leakage. We are also subject to privacy and data security laws.

### **Risks relating to the regulation of our business**

- Legislative and regulatory changes in the U.S. and in other countries regarding healthcare and government-sponsored programs may adversely affect us.
- We are subject to extensive post-marketing regulation by the U.S. Federal Drug Administration ("FDA") and comparable authorities in other jurisdictions, which could cause us to incur significant costs to maintain compliance.
- Modifications to our products may require regulatory approvals and our regulators may not agree with our conclusions regarding whether new approvals are required. Regulatory authorities may require us to cease promoting or to recall the modified versions of our products until such approvals are obtained.
- In addition to FDA requirements, we will spend considerable time and money complying with other federal, state, local and foreign rules, regulations and guidance.
- If we, our collaborative partners, our contract manufacturers, or our component suppliers fail to comply with regulations, the manufacturing and distribution of our products could be interrupted.
- Our products could be subject to recalls that could harm our reputation and financial results.
- 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.
- We are not permitted to promote the use of our products for unapproved or off-label uses.
- We pay taxes in multiple jurisdictions and adverse determinations by governmental authorities or changes in tax laws, rates or our status under which tax jurisdictions apply to us could increase our tax burden or subject our shareholders to additional taxes.
- 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.
- Safety issues concerning lithium-ion batteries could have a material adverse impact on our business.

### **Risks relating to intellectual property**

- If we fail to maintain, develop, protect, defend or enforce our intellectual property rights, competitors may be able to develop competing therapies.
- Intellectual property litigation and disputes may cause us to incur substantial costs, divert attention from the management of our business, harm our reputation, or require us to remove certain products from the market.
- Changes in U.S. patent law could impair our ability to protect our devices.

**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.
- 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.
- U.S. shareholders may not be able to enforce civil liabilities against us.
- We have borrowed a significant amount of debt and have the ability to borrow additional debt in the future.
- Transactions relating to our convertible notes may dilute the ownership interest of existing shareholders, or may otherwise depress the price of our ordinary shares.

## PART I

### ITEM 1. BUSINESS

#### Overview

We are a global oncology company with a proprietary platform technology called Tumor Treating Fields ("TTFields"), which are electric fields that exert physical forces to kill cancer cells via a variety of mechanisms. Our key priorities are to drive commercial adoption of Optune Gio® and Optune Lua®, our commercial TTFields therapy devices, and to advance clinical and product development programs intended to extend overall survival in some of the most aggressive forms of cancer.

Optune Gio is approved by the U.S. Food and Drug Administration ("FDA") under the Premarket Approval ("PMA") pathway for the treatment of adult patients with newly diagnosed glioblastoma ("GBM") together with temozolomide, a chemotherapy drug, and for adult patients with GBM following confirmed recurrence after chemotherapy as monotherapy treatment. We also have a CE certificate to market Optune Gio for the treatment of GBM in the European Union ("EU"), as well as approval or local registration in the United Kingdom ("UK"), Japan, Canada and certain other countries. Optune Lua is approved by the FDA under the Humanitarian Device Exemption ("HDE") pathway to treat malignant pleural mesothelioma and pleural mesothelioma (together, "MPM") together with standard chemotherapies. We have also received CE certification in the EU and approval or local registration to market Optune Lua in certain other countries. We market Optune Gio and Optune Lua in multiple countries around the globe with the majority of our revenues coming from the use of Optune Gio in the U.S., Germany and Japan. We are actively evaluating opportunities to expand our international footprint.

We believe the physical mechanisms of action behind TTFields therapy may be broadly applicable to solid tumor cancers. We are focusing our research and development activities in areas of greatest anticipated value creation. This includes non-small cell lung cancer, brain cancers, and pancreatic cancer.

In 2023, we announced results from our phase 3 LUNAR study evaluating the use of TTFields together with standard therapies following platinum-based treatment failure in the treatment of patients with metastatic non-small cell lung cancer ("NSCLC"). Patients treated with TTFields therapy and standard therapies demonstrated a statistically significant and clinically meaningful improvement in overall survival over standard therapies alone. The LUNAR study also showed a statistically significant and clinically meaningful improvement in overall survival when patients were treated with TTFields therapy and immune checkpoint inhibitors, as compared to those treated with immune checkpoint inhibitors alone, and a positive trend in overall survival when patients were treated with TTFields therapy and docetaxel versus docetaxel alone. In December 2023, we filed a PMA application with the FDA seeking approval for the use of TTFields therapy together with standard systemic therapies for the treatment of NSCLC following progression on or after platinum-based therapy. In January 2024, we announced the FDA had accepted this submission for filing. We are investing in pre-commercial launch activities and anticipate a decision in the second half of 2024.

We have several ongoing or planned trials which will further explore the use of TTFields therapy in the treatment of NSCLC, including the phase 3 METIS and LUNAR-2 trials, as well as the phase 2 KEYNOTE B36 and LUNAR-4 trials. In addition to our trials in NSCLC, we have multiple ongoing or planned trials in our brain and pancreatic cancer programs, including the phase 3 TRIDENT, KEYNOTE D58 and PANNOVA-3 trials, and the phase 2 PANNOVA-4 trial.

We anticipate expanding our clinical pipeline over time to study the safety and efficacy of TTFields therapy for additional solid tumor indications and combinations with other cancer treatment modalities.

Our therapy is delivered through a medical device and we continue to advance our Products with the intention to extend survival and maintain quality of life for patients. We have several product development programs underway that are designed to optimize the delivery of TTFields to the target tumor and enhance patient ease of use. Our intellectual property portfolio contains hundreds of issued patents and numerous patent applications pending worldwide. We believe we possess global commercialization rights to our Products in oncology and are well-positioned to extend those rights into the future as we continue to find innovative ways to improve our Products.

In 2018, we granted Zai Lab (Shanghai) Co., Ltd. ("Zai") a license to commercialize our Products in China, Hong Kong, Macau and Taiwan ("Greater China") under a License and Collaboration Agreement (the "Zai Agreement"). The Zai Agreement also establishes a development partnership intended to accelerate the development of TTFields therapy in multiple solid tumor cancer indications. For additional information, see Note 12 to the Consolidated Financial Statements.

Our ordinary shares are quoted on the NASDAQ Global Select Market under the symbol "NVCR." We were incorporated in the Bailiwick of Jersey in 2000. Daily management and control of the Company are located in Switzerland, with additional operating centers located around the world.

### **Our therapy**

When cancer develops, rapid and uncontrolled division of unhealthy cells occurs. Electrically charged proteins within the cell are critical for cell division, making the rapidly dividing cancer cells vulnerable to electrical interference. TTFields therapy is a treatment that uses electric fields which exert physical forces to kill cancer via a variety of mechanisms.

All cells are surrounded by a bilipid membrane, which separates the interior of the cell, or cytoplasm, from the space around it. This membrane prevents low frequency electric fields from entering the cell. TTFields, however, have a unique frequency range, between 100 to 500 kHz, enabling the electric fields to penetrate the cancer cell membrane. As healthy cells differ from cancer cells in their division rate, geometry and electric properties, the frequency of TTFields can be tuned to specifically affect the cancer cells while leaving healthy cells mostly unaffected.

Whether cells are healthy or cancerous, cell division, or mitosis, is the same. When mitosis starts, charged proteins within the cell, or microtubules, form the mitotic spindle. The spindle is built on electric interaction between its building blocks. During division, the mitotic spindle segregates the chromosomes, pulling them in opposite directions. As the daughter cells begin to form, electrically polarized molecules migrate towards the midline to make up the mitotic cleavage furrow. The furrow contracts and the two daughter cells separate. TTFields can interfere with these conditions. When TTFields are present in a dividing cancer cell, they cause the electrically charged proteins to align with the directional forces applied by the field, thus preventing the mitotic spindle from forming. Electrical forces also interrupt the migration of key proteins to the cell midline, disrupting the formation of the mitotic cleavage furrow. Interfering with these key processes disrupts mitosis and can lead to cell death.

Our track record of fundamental scientific research extends across more than two decades and, in all of our preclinical research to date, the application of TTFields has demonstrated a consistent anti-mitotic effect. Preclinical work suggests that the well-established impairment created by the physical effect of TTFields to tumor cells results in a series of changes to cell processes that downregulate DNA damage response, interfere with cell movement and migration, and increase anti-tumor immunity. Research is ongoing to further refine and build upon our understanding of TTFields' several mechanisms of action. Beyond our internal research efforts, we provide independent researchers with preclinical laboratory bench systems, known as inovitro™ and inovivo™, and we grant funding to support basic and translational research on TTFields therapy. We also support independent research through our Investigator-Sponsored Trials and Preclinical Material Transfer Agreement programs in order to enhance our understanding of the optimal use of TTFields therapy.

TTFields therapy is intended principally for use together with other standard-of-care cancer treatments. There is a growing body of evidence that supports TTFields therapy's broad applicability with certain other cancer therapies, including radiation therapy, certain chemotherapies and certain immunotherapies. In our clinical research and commercial experience to date, TTFields therapy has exhibited no systemic toxicity, with mild to moderate skin irritation being the most common side effect.

### **Our technology**

TTFields therapy is delivered through a portable medical device. The complete devices, called Optune Gio and Optune Lua (for head and thoracic treatment, respectively), include a portable electric field generator, arrays, rechargeable batteries and accessories. Sterile, single-use arrays are placed directly on the skin in the region surrounding the tumor and connected to the electric field generator to deliver therapy. Arrays are changed when hair growth or the hydrogel reduces array adhesion to the skin. The therapy is designed to be delivered continuously throughout the day and night, and efficacy is strongly correlated to time on therapy. When the device is turned on, TTFields are continuously generated within the specific region of the body covered by the arrays. Healthy tissues located outside of this region remain unaffected by the therapy. The electric field generator can be run from a standard power outlet or carried with a battery in a specially designed bag that we provide to patients.

We plan to use the same field generator technology across all indications for which our Products are approved. We plan to specifically target individual solid tumor types by optimizing field generator parameters such as frequency and power output. Our arrays have been developed and are in use, either commercially or clinically, for application on the head, thorax and abdomen.

Through engineering efforts, we plan to continue to advance our Products to optimize TTFields therapy for patients. We have several product development programs underway designed to extend survival and enhance quality of life. Our product development programs are primarily focused on enhancements to the field generator, arrays and software applications. Our product development initiatives include, but are not limited to: continually improving our arrays to be thinner, lighter and more flexible, next generation array layout mapping software, development of a third generation device that optimizes the use of electric fields to treat tumors, and patient-centered software that enables scaled patient support as we prepare to treat larger patient populations across multiple indications. Our ultimate goal is to optimize the energy delivered to patients' tumors, potentially improving efficacy. Any enhancements will be subject to applicable regulatory reviews and approvals.

#### Our commercial business

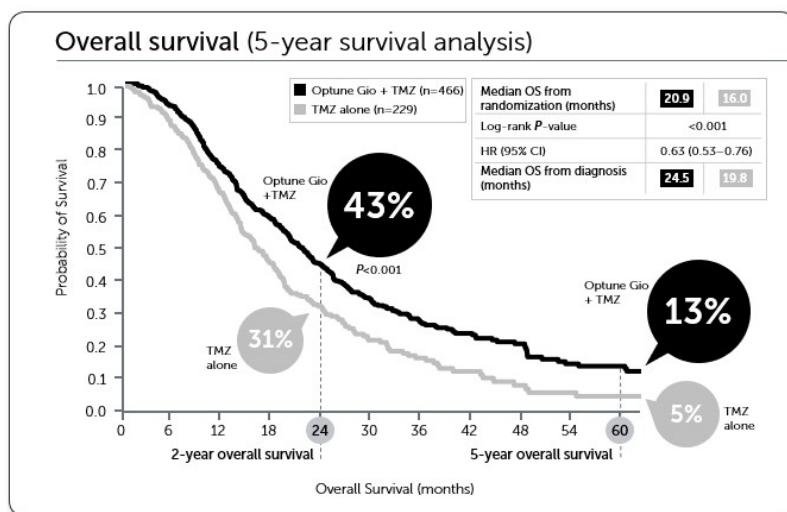
Optune Gio is currently marketed for the treatment of GBM, the most common form of primary brain cancer and an aggressive disease for which there are few effective treatment options. Optune Lua is currently marketed for the treatment of MPM, a rare cancer that has been strongly linked to asbestos exposure. We market Optune Gio and Optune Lua in multiple countries around the globe with the majority of our revenues coming from the use of Optune Gio in the U.S., Germany and Japan.

#### Treatment of newly diagnosed GBM

In 2015, we received FDA approval to market Optune Gio (then known as Optune) for the treatment of adult patients with newly diagnosed supratentorial GBM in combination with temozolomide. The FDA approved Optune Gio for newly diagnosed GBM based on the EF-14 study ("EF-14"), which was a randomized phase 3 clinical study which compared, post radiation, Optune Gio plus temozolomide versus temozolomide alone for the treatment of newly diagnosed GBM. The primary endpoint of the study was progression-free survival and a powered secondary endpoint was overall survival.

In EF-14, Optune Gio plus temozolomide demonstrated unprecedented five-year survival results. Median overall survival was extended by nearly five months (median overall survival of 20.9 months versus 16.0 months for temozolomide alone). Median progression-free survival was extended by 2.7 months to 6.7 months for Optune Gio plus temozolomide from 4.0 months for temozolomide alone. The final EF-14 data were published in the *Journal of the American Medical Association* in 2017.

The following graph presents the overall survival data in the intent-to-treat population from our five-year analysis:



The extension of progression-free and overall survival in patients receiving Optune Gio in combination with temozolamide in EF-14 was not specific to any prognostic subgroup or tumor genetic marker and was consistent regardless of MGMT methylation status, extent of resection, age, performance status or gender. Optune Gio was safely combined with temozolamide with no significant increase in serious adverse events compared with temozolamide alone. The most common side effect related to Optune Gio was mild to moderate skin irritation.

Quality of life data from a pre-specified analysis of EF-14 demonstrated that patients treated with Optune Gio and temozolamide maintained quality of life over time and across predefined daily-functioning domains. Both healthcare professionals and patients reported stable quality of life evaluation scores up to one year of Optune Gio use. Physical, role, social, emotional and cognitive functioning for patients treated with Optune Gio and temozolamide all remained stable and comparable with patients treated with temozolamide alone.

The National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology<sup>®</sup> (NCCN Guidelines<sup>®</sup>) for Central Nervous Systems Cancers were updated to include alternating electric fields therapy (Optune Gio) in combination with temozolamide following standard brain radiation therapy with concurrent temozolamide as a Category 1 recommended postoperative adjuvant treatment option for patients with newly diagnosed supratentorial GBM.

A post-hoc analysis of EF-14 showed that more time on Optune Gio predicted increased survival in newly diagnosed GBM patients. An Optune Gio monthly usage threshold as low as 50 percent correlated with significantly improved outcomes in patients treated with Optune Gio together with temozolamide compared to patients treated with temozolamide alone. The greater the patients' monthly usage of Optune Gio, the better their outcomes. Patients who used Optune Gio more than 90 percent of the time (n=43) had the greatest chance of survival: a median survival of 24.9 months from randomization and a five-year probability of survival of 29.3 percent.

A separate post-hoc analysis of EF-14 showed that higher intensities at the tumor bed were associated with increased survival in newly diagnosed GBM patients. Patients treated with Optune Gio at higher intensities (greater than or equal to 1.06 V/cm; n=119) had a median overall survival of 24.3 months compared to a median overall survival of 21.6 months for patients treated with Optune Gio at lower intensities (less than 1.06 V/cm; n=221).

In these analyses, both time on therapy and higher intensity were associated with improved overall survival, independent of each other. In addition, patients who used Optune Gio at least 18 hours per day at higher intensity levels (n=78) had a median overall survival of 25.1 months (95% CI 20.8-39.4).

#### ***Treatment of recurrent GBM***

We initially received FDA approval for Optune Gio in 2011 for use as a monotherapy treatment for adult patients with GBM, following confirmed recurrence after chemotherapy. The FDA approved Optune Gio based on the EF-11 study ("EF-11"), a randomized, phase 3 clinical study.

EF-11 was a multi-center, active controlled clinical study of 237 adults with recurrent GBM. Participants received either Optune Gio as a monotherapy (n=120) or the physician's choice of chemotherapy (n=117). Chemotherapies chosen for the active control arm included mainly bevacizumab, nitrosoureas and temozolamide. The primary endpoint was superiority in overall survival. Overall survival for patients treated with Optune Gio alone and active chemotherapy was 6.6 months and 6.0 months, respectively (p=0.27: HR = 0.86). The study demonstrated that Optune Gio provided clinically comparable survival with an overall better quality of life.

More objective radiological responses were observed in the Optune Gio group than in the active control chemotherapy group (14 patients versus 7 patients). Three patients in the Optune Gio alone arm had a complete response versus no patients in the active chemotherapy arm.

In 2020, the EF-19 post-approval registry, which was a post-approval study required as a condition of FDA approval, confirmed the effectiveness and safety of Optune Gio as monotherapy and further strengthened Optune Gio's clinical profile in recurrent GBM. The EF-19 study studied Optune Gio as a monotherapy for the treatment of recurrent GBM in 192 patients compared to the 117 recurrent GBM patients who received best standard of care chemotherapy in Novocure's EF-11 registration study. Optune Gio as monotherapy reduced the risk of death with fewer adverse events compared to best standard of care chemotherapy. For patients who received at least one course of therapy, Optune Gio prolonged survival by a median 1.7 months. No new safety signals were noted.

#### ***Treatment of MPM***

In 2019, we received FDA approval via the HDE pathway to market Optune Lua (then known as NovoTTF-100L) for the treatment of adult patients with unresectable, locally advanced or metastatic MPM concurrent with pemetrexed

and platinum-based chemotherapy. The FDA approved OptuneLua for MPM based on the STELLAR study ("STELLAR"). STELLAR was a single-arm, open-label, multi-center study designed to test the safety and efficacy of OptuneLua in combination with pemetrexed combined with cisplatin or carboplatin in patients with unresectable, previously untreated MPM. The study was powered to prospectively determine the overall survival in patients treated with OptuneLua plus chemotherapy. Secondary endpoints included overall response rate (per mRECIST criteria), progression-free survival and safety.

STELLAR investigated safety and efficacy among 80 patients treated with OptuneLua plus standard of care chemotherapy. In STELLAR, the median overall survival was 18.2 months (95% CI, 12.1-25.8 months) across all patients treated with OptuneLua plus chemotherapy. The median overall survival was 21.2 months for patients with epithelioid MPM (n=53) and 12.1 months for patients with non-epithelioid MPM (n=27). 62% of patients enrolled in STELLAR who used OptuneLua plus chemotherapy were still alive at one year, with 42% of patients alive at two years. The disease control rate in patients with at least one follow-up CT scan performed (n=72) was 97%. 40% of patients had a partial response, 57% had stable disease, and 3% had progressive disease. The median progression-free survival was 7.6 months (95% CI, 6.7-8.6 months).

There was no increase in serious systemic adverse events when OptuneLua was added to chemotherapy. Mild-to-moderate skin irritation was the only device-related side effect with OptuneLua. The STELLAR data were published in *The Lancet Oncology* in 2019.

#### **Our commercial markets**

We have built a commercial organization and market OptuneGio for the treatment of GBM in multiple countries in North America, Europe and Asia.

In 2024, we estimate that approximately:

- 15,000 people will be diagnosed with GBM or tumors that typically progress to GBM in the U.S. Of this population, we estimate that approximately 8,200 patients who are candidates for treatment with OptuneGio based upon the rate of disease progression and medical eligibility will actively seek treatment.
- 4,600 people will be diagnosed with GBM or tumors that typically progress to GBM in Germany. Of this population, we estimate that approximately 2,500 patients who are candidates for treatment with OptuneGio based upon the rate of disease progression and medical eligibility will actively seek treatment.
- 2,200 people will be diagnosed with GBM or tumors that typically progress to GBM in Japan. Of this population, we estimate that approximately 1,200 patients who are candidates for treatment with OptuneGio based upon the rate of disease progression and medical eligibility will actively seek treatment.

We believe there are many more patients who could benefit from treatment with TTFIELDS therapy than are currently on therapy. We continue to focus on increasing penetration for GBM. In the future, we anticipate strategically expanding into additional geographic markets and additional indications, pending regulatory approval.

#### **Commercial execution**

As of December 31, 2023, we had 126 sales force colleagues globally. Healthcare providers must undergo a certification training in order to prescribe our Products.

Our sales and marketing efforts are principally focused on driving adoption of OptuneGio for the treatment of GBM among both neuro-oncologists and radiation oncologists. In certain countries, neurosurgeons and medical oncologists also drive adoption. We continue to focus on driving key academic center engagements.

We currently operate as a direct-to-patient distributor of our Products, except for Japan. In Japan, we distribute OptuneGio through hospitals and provide patient support services under a contractual arrangement with the hospital. Once an eligible patient is identified by a certified prescriber, the healthcare provider's office submits a prescription order form and supporting documentation to us. We employ a team of Device Support Specialists who provide technical training to the patient and any caregivers. Once treatment is initiated, we provide 24/7 technical support for patients and caregivers as well as assistance with insurance reimbursement. We also provide the healthcare provider and the patient with a usage report for monitoring patient time on therapy. We believe we have the experience and expertise to scale our sales and marketing efforts.

## **Billing and reimbursement**

We provide our Products directly to patients following receipt of a prescription order and a signed patient service agreement (except in Japan as described above). The number of active patients on therapy and the amount of net revenue recognized per active patient are our principal revenue drivers. An active patient is a patient who is receiving treatment under a commercial prescription order as of the measurement date, including patients who may be on a temporary break from treatment and who plan to resume treatment in less than 60 days. Growth in the number of active patients is a factor of both new patient starts and treatment duration.

We bill payers a single monthly fee for a month of therapy and we bear the financial risk of securing payment from third-party payers and patients in all markets except for Japan. We distribute our Products through hospitals in Japan with the hospitals receiving reimbursement from the government-mandated insurance program and in turn contracting with us for the equipment, supplies and services necessary to treat patients with our Product.

We maintain a monthly list price for our therapy in the U.S. and set list prices outside of the United States that are approximately equivalent to this price, subject to currency fluctuations. We typically negotiate discounts from our list price with healthcare payers, and in certain cases we accept government-mandated discounts from our list prices in order to secure reimbursement for our Products.

We continue to work with payers to expand access to Optune Gio for patients with GBM. As of December 31, 2023, we have received national reimbursement for Optune Gio in Austria, France, Germany, Israel, Japan, Sweden and Switzerland.

In the U.S., a substantial majority of Americans with private health insurance had coverage of Optune Gio for newly diagnosed GBM and/or recurrent GBM as of December 31, 2023. As of September 2019, Americans who are beneficiaries of the Medicare fee-for-service program also have coverage of Optune Gio for newly diagnosed GBM. We are actively appealing Medicare fee-for-service coverage denials up to and including the Administrative Law Judge ("ALJ") process with Centers for Medicare and Medicaid Services ("CMS") and believe the outstanding denied and appealed claims that were most accessible were largely exhausted in 2022.

## **Our development pipeline**

Based on the results of our preclinical research, we have developed a pipeline strategy to advance TTFIELDS therapy through phase 2 and phase 3 studies across multiple solid tumor types. We anticipate expanding our clinical pipeline over time to include additional solid tumor cancer indications.

### ***Current Development Pipeline***

	Phase 2	Phase 3	Anticipated Timing of Data
<b>Primary Brain Cancers</b>			
Glioblastoma	TRIDENT	→	Data anticipated in 2026
<b>Thoracic Cancers</b>			
Non-small cell lung cancer	LUNAR-2	→	
	KEYNOTE B36	→	
	METIS	→	Top-line data anticipated in Q1 2024
<b>Abdominal Cancers</b>			
Pancreatic cancer	PANOVA-3	→	Top-line data anticipated in Q4 2024
	PANOVA-4	→	

The solid tumor cancers subject to our phase 2 and phase 3 studies, as well as the studies themselves, are described in greater detail below. In addition to our studies in tumors of the head, thorax and abdomen, we continue

to conduct research in our approved indications to further advance the scientific evidence supporting the use of TTFields therapy in GBM and to gather additional information about our therapy's optimal use.

### **Glioblastoma**

GBM is the most common and aggressive form of primary brain cancer. It is estimated that approximately 15,000 patients are diagnosed with GBM or tumors that typically progress to GBM each year in the U.S. Following diagnosis, standard of care treatment includes surgical resection, followed by radiotherapy with concomitant chemotherapy, followed by TTFields therapy together with maintenance chemotherapy.

#### *TRIDENT phase 3 trial*

In January 2024, the final patient was enrolled in our TRIDENT trial ("TRIDENT"), a phase 3 study testing the potential survival benefit of initiating Optune Gio concurrent with radiation therapy and maintenance temozolomide in patients with newly diagnosed GBM. The primary endpoint is overall survival. Secondary endpoints include, but are not limited to, progression-free survival, survival rates at one and two years, overall radiological response, severity and frequency of adverse effects, pathological changes in resected GBM tumors post treatment, quality of life, and correlation of overall survival to TTFields dose. TRIDENT was designed to accrue 950 patients with a 24-month minimum follow-up period after the last patient is enrolled. Final data from the TRIDENT trial is anticipated in 2026.

#### *2-THE-TOP phase 2 trial*

In November 2023, Dr. David Tran, Chief of the Division of Neuro-Oncology at the University of Southern California Keck School of Medicine and co-Director of the USC Keck Brain Tumor Center, presented updated data from the phase 2 2-THE-TOP study testing the safety and efficacy of TTFields therapy together with pembrolizumab and maintenance temozolomide for the treatment of adult patients with newly diagnosed GBM. The primary endpoint was progression-free survival, as compared to a case-matched cohort of 56 patients from the EF-14 study. Secondary endpoints included overall survival and toxicity.

A total of 26 patients were recruited to the study with a median age of 60.5 years. Median progression-free survival was 12.0 months versus 5.8 months (hazard ratio=0.377, P=0.0026). Median overall survival was 24.8 months versus 14.6 months in controls (hazard ratio=0.522, P=0.047). Residual tumor size positively correlated with the objective response and survival. Six of 15 (40%) patients with measurable disease achieved partial to complete response. Molecular analyses confirmed robust T cell activation by TTFields via T1IFN-dependent plasmacytoid dendritic cells (Spearman coefficient=-0.8, P=0.014). Successful clonal replacement of the most expanded T cell clones after pembrolizumab strongly predicted objective responses to the triple combination in a Cox hazard ratio fit model (concordance rate = 0.876, P = 0.031). The most common adverse events were thromboses (15%), seizures (12%), and metabolic disturbances (8%). Additional molecular analyses will be conducted and updated in the future.

The 2-THE-TOP study concluded that the triple combination of TTFields therapy, temozolomide, and pembrolizumab is well tolerated and demonstrated promising efficacy in newly diagnosed GBM patients. In 2022, we entered into a clinical collaboration agreement with MSD, a trademark of Merck & Co., Inc., ("MSD") to conduct a double-blind, placebo-controlled phase 3 trial further exploring the efficacy of this therapy regimen. The phase 3 KEYNOTE D58 trial will utilize the regimen of TTFields therapy concomitant with pembrolizumab and maintenance temozolomide for the treatment of newly diagnosed GBM. Novocure and MSD are currently finalizing the design of the KEYNOTE D58 protocol, with trial launch anticipated in 2024.

### **Non-small cell lung cancer**

Lung cancer is the most common cause of cancer-related death worldwide, and NSCLC accounts for approximately 85% of all lung cancers. It is estimated that approximately 193,000 patients are diagnosed with NSCLC each year in the U.S.

Physicians use different combinations of surgery, radiation and pharmacological therapies to treat NSCLC, depending on the stage of the disease. Surgery, which may be curative in a subset of patients, is usually used in early stages of the disease. A combination of radiation, platinum-based chemotherapies, and immune checkpoint inhibitors, or targeted therapies, are the first line standard of care treatment for locally advanced or metastatic

NSCLC. Today, the standard of care for second line treatment is evolving and often includes immune checkpoint inhibitors, docetaxel, platinum-based chemotherapy or pemetrexed.

#### *LUNAR phase 3 trial*

In 2021, we enrolled the last patient in our LUNAR trial ("LUNAR"), a phase 3 study testing the effectiveness of TTFields therapy in combination with immune checkpoint inhibitors or docetaxel versus immune checkpoint inhibitors or docetaxel alone for patients with stage 4 NSCLC who progressed during or after platinum-based therapy. It is estimated that approximately 30,000 patients actively seek treatment for stage 4 NSCLC after progressing during or after platinum-based therapy each year in the U.S. The primary endpoint was superior overall survival of patients treated with TTFields therapy plus immune checkpoint inhibitors or docetaxel versus immune checkpoint inhibitors or docetaxel alone.

In June 2023, we presented positive results from the LUNAR study which met its primary endpoint with a statistically significant and clinically meaningful 3-month improvement in median overall survival with TTFields therapy added to standard therapies (hazard ratio=0.74, P=0.035). Patients randomized to receive TTFields therapy together with standard therapies (n=137) demonstrated median overall survival of 13.2 months compared to 9.9 months in patients treated with standard therapies alone (n=139). Patients randomized to receive TTFields therapy and physician's choice immune checkpoint inhibitor (n=66) demonstrated a median overall survival of 18.5 months, a profound extension compared to the median overall survival of 10.8 months demonstrated by patients that received immune checkpoint inhibitor alone (n=68; hazard ratio=0.63; P=0.03). Patients randomized to receive TTFields therapy and docetaxel (n=71) had a positive survival trend with a median overall survival of 11.1 months vs 8.7 months (n=71; hazard ratio=0.81, P=0.28). TTFields therapy was well-tolerated with no added systemic toxicities and few grade 3 (no grade 4 or 5) device-related adverse events.

In August 2023, the data from the LUNAR study were published in *The Lancet Oncology*, and additional data detailing the LUNAR study have since been presented at multiple medical congresses. In December 2023, we submitted a PMA application to the FDA based upon the LUNAR results, seeking approval for the use of TTFields therapy together with standard systemic therapies for the treatment of NSCLC following progression on or after platinum-based therapy, which has since been accepted for filing by the FDA. We have also filed applications for use to the necessary regulatory bodies in Europe and Japan.

#### *LUNAR-2 phase 3 trial*

In July 2023, the FDA accepted the investigation device exemption for the LUNAR-2 clinical trial ("LUNAR-2"), a randomized, phase 3 study evaluating the efficacy of TTFields therapy concomitant with pembrolizumab and platinum-based chemotherapy for the treatment of patients with metastatic NSCLC. The two primary endpoints of LUNAR-2 are overall survival and progression-free survival. Secondary endpoints include, but are not limited to, progression-free survival and overall survival according to patient histology, progression-free survival and overall survival according to patient tumor proportion score, one-, two-, and three-year survival rates, objective response rate, duration of response, disease control rate and severity and frequency of adverse effects. LUNAR-2 is designed to accrue 734 patients with a 21-month follow-up following the enrollment of the last patient.

#### *KEYNOTE B36 phase 2 trial*

In 2022, the first patient was enrolled in our KEYNOTE B36 trial ("KEYNOTE B36"), a phase 2 study evaluating the safety and efficacy of TTFields therapy together with the anti-PD-1 therapy pembrolizumab for the treatment of first-line metastatic NSCLC. The primary endpoint is progression-free survival. Secondary endpoints include, but are not limited to, overall survival, objective response rate, duration of response, disease control rate and severity and frequency of adverse effects. Enrollment in KEYNOTE B36 is ongoing. The trial is designed to accrue 100 patients with a 12-month minimum follow-up period after the last patient is enrolled. KEYNOTE B36 is the result of a clinical study collaboration with MSD.

#### **Brain metastases**

Metastatic cancer is cancer that has spread from the place where it first started to another place in the body. In metastasis, cancer cells break away from where they first formed (the primary cancer), travel through the blood or lymph system, and form new tumors (the metastatic tumors) in other parts of the body. The exact incidence of brain metastases is unknown because no national cancer registry documents brain metastases, and estimates from

scientific literature vary greatly based on the study methodology applied. It is estimated that between 100,000 and 240,000 new cases are diagnosed in the U.S. each year with brain metastases estimated to occur in between 10% to 40% of all cancer patients.

Brain metastases are commonly treated with a combination of surgery and radiation. Chemotherapy is often given for the primary tumor, but many chemotherapy agents do not cross the blood brain barrier and are thus ineffective in the treatment of brain metastases. When brain metastases appear, they are either surgically removed or treated with radiation using stereotactic radiosurgery ("SRS") when possible. Whole brain radiation therapy, although effective in delaying progression or recurrence of brain metastases when given either before or after SRS, is associated with neurotoxicity and a significant decline in cognitive functioning. Thus, whole brain radiation therapy is often delayed until later in the disease course and is often used as a last resort. This practice results in a window of unmet need after localized surgery and SRS are used and before whole brain radiation therapy is administered to delay or prevent the additional spread of brain metastases.

#### *METIS phase 3 trial*

In March 2023, we enrolled the final patient in our METIS study ("METIS"), a phase 3 study testing the effectiveness of SRS plus TTFields therapy compared to SRS alone in patients with brain metastases resulting from NSCLC. It is estimated that between 20 to 40% of patients with NSCLC develop brain metastases, with an estimated 38,000 to 77,000 patients diagnosed each year in the U.S. with brain metastases resulting from NSCLC. The primary endpoint of METIS is time to first intracranial progression. Secondary endpoints include, but are not limited to, time to neurocognitive failure, overall survival and radiological response rate following study treatments. METIS is designed to accrue 270 patients with a minimum 12-month follow-up period following the final patient enrollment. Top-line data is anticipated in the first quarter of 2024.

#### **Pancreatic cancer**

Pancreatic cancer is one of the most lethal cancers and is the third most frequent cause of death from cancer in the U.S. While overall cancer incidence and death rates are remaining stable or declining, the incidence and death rates for pancreatic cancer are increasing. It is estimated that approximately 60,000 patients are diagnosed with pancreatic cancer each year in the U.S. Pancreatic cancer has a five-year relative survival rate of just 10 percent.

Physicians use different combinations of surgery, radiation and pharmacological therapies to treat pancreatic cancer, depending on the stage of the disease. For patients with locally advanced pancreatic cancer involving encasement of arteries but no extra-pancreatic disease, the standard of care is surgery followed by chemotherapy with or without radiation. Unfortunately, the majority of locally advanced cases are diagnosed once the cancer is no longer operable, generally leaving chemotherapy with or without radiation as the only treatment option.

#### *PANOVA-3 phase 3 trial*

In February 2023, the final patient was enrolled in our PANOVA-3 trial ("PANOVA-3"), a phase 3 study evaluating the efficacy of TTFields therapy together with nab-paclitaxel and gemcitabine versus nab-paclitaxel and gemcitabine alone as a front-line treatment for unresectable locally advanced pancreatic cancer. It is estimated that approximately 48,000 patients are diagnosed with unresectable pancreatic cancer each year in the U.S.

The primary endpoint of PANOVA-3 is overall survival. Secondary endpoints include, but are not limited to, progression-free survival, local progression-free survival, objective response rate, one-year survival rate, quality of life, pain-free survival, resectability rate and frequency and severity of adverse events. A pre-specified interim analysis was completed in July 2023, with the recommendation that the trial proceed to final analysis. PANOVA-3 is designed to enrolled 556 patients with an 18-month minimum follow-up period after the last patient is enrolled. Top-line data from the PANOVA-3 trial is anticipated in the fourth quarter of 2024.

#### *PANOVA phase 2 trial*

In 2018, we published the results of our phase 2 study in advanced pancreatic adenocarcinoma, the PANOVA study ("PANOVA"), examining TTFields therapy in combination with standard of care chemotherapy.

PANOVA was a multicenter, non-randomized, open-label study. The study included 40 patients with locally advanced or metastatic pancreatic cancer whose tumors could not be removed surgically and who had not received chemotherapy or radiation therapy prior to the clinical study. Patients were enrolled between 2014 and 2016 in two

cohorts: The first cohort of 20 patients received TTFields therapy with standard doses of gemcitabine alone. The second cohort of 20 patients received TTFields therapy with standard doses of nab-paclitaxel plus gemcitabine.

In the first cohort, efficacy results showed that progression-free survival and overall survival of patients treated with TTFields therapy combined with gemcitabine were more than double those of gemcitabine-treated historical controls. Median progression-free survival in the TTFields therapy-treated group was 8.3 months (compared to 3.7 months in the gemcitabine historical control), with locally advanced patients reaching a median progression-free survival of 10.3 months and patients with metastatic disease reaching a median progression-free survival of 5.7 months. The median overall survival for all patients was 14.9 months (compared to 6.7 months in the gemcitabine historical control). Median overall survival was not reached in locally advanced patients and 86% of patients were alive at end of follow up. Patients with metastatic disease experienced a median overall survival of 8.3 months. One-year survival was 55% (compared to 22% in the gemcitabine historical control). Of 11 patients with available CT scans, 5 (45%) had a partial response (compared to 7% with gemcitabine alone), 5 (45%) had stable disease, which means that the cancer is neither decreasing nor increasing in extent or severity, and 1 (10%) had progressive disease.

In the second cohort, efficacy results showed that progression-free survival and overall survival of patients treated with TTFields therapy combined with nab-paclitaxel plus gemcitabine were more than double those of nab-paclitaxel plus gemcitabine-treated historical controls. Median progression-free survival in the TTFields therapy-treated group was 12.7 months (compared to 5.5 months in the nab-paclitaxel plus gemcitabine historical control) and median overall survival was not yet reached. The one-year survival rate was 72% (compared to 35% in nab-paclitaxel plus gemcitabine historical control). Of the 15 patients with available CT scans, 6 (40%) had a partial response (compared to 23% with the nab-paclitaxel plus gemcitabine alone), 7 (47%) had stable disease and 2 (13%) had progressive disease.

Safety results from both cohorts suggested that TTFields therapy plus first-line chemotherapies nab-paclitaxel and/or gemcitabine may be tolerable and safe in patients with advanced pancreatic cancer. Patients reported no serious adverse events related to TTFields therapy.

#### *PANOVA-4 phase 2 trial*

In 2023, the first patient was enrolled in the phase 2 PANOVA-4 trial ("PANOVA-4") evaluating the safety and efficacy of TTFields therapy together with atezolizumab, gemcitabine and nab-paclitaxel in the treatment of metastatic pancreatic cancer. The primary endpoint of PANOVA-4 is disease control rate. Secondary endpoints include, but are not limited to, overall survival, progression-free survival, one-year survival, objective response rate and frequency and severity of adverse events. PANOVA-4 is designed to accrue 76 patients with a 12-month follow-up following enrollment of the last patient. PANOVA-4 is the result of a clinical study collaboration with Roche.

#### **Other Clinical Results**

In addition to our current development pipeline, we have conducted phase 2 and phase 3 clinical trials exploring the use of TTFields therapy in a variety of other solid tumor cancers. These trials are described in greater detail below.

#### **Gastric cancer**

##### *EF-31 phase 2 trial*

In 2022, we announced the final results from our EF-31 phase 2 study, a single-arm study evaluating the safety and efficacy of TTFields therapy together with XELOX chemotherapy (and trastuzumab for HER2-positive patients) as first-line treatment for patients with unresectable gastric adenocarcinoma or gastroesophageal junction adenocarcinoma in partnership with Zai. In 26 evaluable patients, the primary endpoint, confirmed objective response rate, was 50%, median progression-free survival was 7.8 months, duration of response was 10.3 months and median overall survival had not yet been reached with a one-year survival rate of 72%.

#### **Liver cancer**

##### *HEPANOVA phase 2 trial*

In 2021, we announced the final results of our HEPANOVA phase 2 trial, a single-arm study evaluating the safety and efficacy of TTFields therapy in combination with sorafenib for the treatment of advanced hepatocellular cancer.

In 21 evaluable patients, HEPANOVA showed a 9.5% objective response rate and 76% disease control rate, as well as 5.8 months of progression free survival, compared to historical control data showing a 4.5% objective response rate and 43% disease control rate for patients treated with sorafenib alone.

#### **Ovarian cancer**

##### *INNOVATE-3 phase 3 trial*

In August 2023, we announced preliminary results from the phase 3 INNOVATE-3 trial ("INNOVATE-3"), studying the effectiveness of TTFields therapy with paclitaxel in patients with platinum-resistant ovarian cancer. INNOVATE-3 did not meet its primary endpoint of overall survival at the final analysis. Patients randomized to receive TTFields therapy plus paclitaxel (n=280) demonstrated a median overall survival of 12.2 months compared to a median overall survival of 11.9 months in patients treated with paclitaxel alone (n=278) (hazard ratio=1.008). Consistent with previously reported studies, TTFields therapy was well-tolerated with no added systemic toxicities. Post-hoc analyses of the INNOVATE-3 results are ongoing and we expect to present findings at upcoming medical congresses.

#### **Zai License and Collaboration Agreement**

In 2018, we announced a strategic collaboration with Zai. The collaboration agreement grants Zai a license to commercialize our Products in Greater China and establishes a development partnership intended to accelerate the development of TTFields therapy in multiple solid tumor cancer indications. Zai has launched Optune Gio for the treatment of newly diagnosed GBM in Hong Kong and mainland China and is seeking marketing authorization for GBM in Taiwan. For additional information, see Note 12 to the Consolidated Financial Statements.

#### **Manufacturing and supply chain**

We outsource production of all of our system components to qualified partners. Disposable array manufacturing, the dominant activity in our manufacturing supply chain, includes several specialized processes. Production of the durable system components follows standard electronic medical device methodologies.

We have supply agreements in place with our third-party manufacturing partners. While we currently obtain some critical materials for use in certain jurisdictions from single source suppliers, we have developed or are in the process of developing and obtaining regulatory approval for second sources for critical materials in all jurisdictions. We hold safety stocks of single source components in quantities that we believe are sufficient to protect against possible supply chain disruptions. We anticipate that the diversification of our supply chain will both ensure a continuity of supply and reduce costs.

#### **Intellectual property**

We believe we possess global commercialization rights to our Products in oncology and are well-positioned to extend those rights into the future as we continue to find innovative ways to improve our Products. Our robust global patent and intellectual property portfolio consists of hundreds of issued patents in multiple jurisdictions covering various aspects of our devices and related technology. In the U.S., our patents have expected expiration dates between 2024 and 2041. We have also filed several hundred additional patent applications worldwide, that, if issued, may protect aspects of our platform beyond the current last-to-expire patent in the relevant market. These pending applications cover innovations relating to our arrays, field generators and software platform, in addition to other topics related to TTFields therapy. Our reliance on intellectual property involves certain risks, as described under the heading "Risk factors—Risks relating to intellectual property."

In addition to our patent portfolio, we further protect our intellectual property by maintaining the confidentiality of our trade secrets, know-how and other confidential information. Given the length of time and expense associated with bringing device candidates through development and regulatory approval to the market place, the healthcare industry has traditionally placed considerable importance on obtaining patent protection and maintaining trade secrets, know-how and other confidential information for significant new technologies, products and processes.

Our policy is to require each of our employees, consultants and advisors to execute a confidentiality agreement before beginning their employment, consulting or advisory relationship with us. These agreements generally provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of their relationship with us except in limited circumstances. These

agreements also generally provide that we own, or the individual is required to assign to us, all inventions conceived by the individual in the course of rendering services to us. Despite measures taken to protect our intellectual property, unauthorized parties may copy certain aspects of our products or obtain and use information that we believe is proprietary.

Pursuant to our strategic collaboration with Zai, we granted Zai a license to commercialize TTFields therapy in Greater China. For additional information, see Note 12 to the Consolidated Financial Statements.

### **Competition**

The market for cancer treatments is intensely competitive, subject to rapid change and significantly affected by new product and treatment introductions and other activities of industry participants. The general bases of competition are overall effectiveness, side effect profile, cost, availability of reimbursement and general market acceptance of a product as a suitable cancer treatment.

Our intellectual property portfolio is continuously expanding as we find new and unique ways to improve TTFields therapy. We believe these intellectual property rights would provide an obstacle to the introduction of state of the art TTFields therapy devices by a competitor. However, competitors may be able to offer less sophisticated TTFields therapy devices that utilize technology described in expired patents and/or choose to market their system(s) in countries where we have limited or no enforceable intellectual property rights. Competitors could also pursue alternative technologies for the application of TTFields into a patient that we did not foresee or protect. We are aware of a few third parties in the United States and China developing devices and filing for intellectual property protection related to TTFields therapy.

Beginning in 2021, several of our early patents covering technology included in our Products began expiring in the U.S. and elsewhere. Even after the expiration of our patents, we believe that potential market entrants applying low-intensity, alternating electric fields to solid tumors will have to undertake their own clinical studies and regulatory submissions to prove equivalence to our Products, a necessary step in receiving regulatory approvals for a competing product, all while avoiding infringing our unexpired patents.

Presently, the traditional biotechnology, pharmaceutical and medical technology industries expend significant resources in developing novel and proprietary therapies for the treatment of solid tumors, including GBM, MPM and other indications that we are currently investigating. As we work to increase market acceptance of our Products, we compete with companies commercializing or investigating other anti-cancer therapies, some of which are in clinical studies for GBM or MPM that currently specifically exclude patients who have been or are being treated with our Products. The introduction of competing therapies could materially impact our business and financial results.

### **Government regulation**

In the U.S., our Products and our operations are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDCA"). In the EU member states where we market our Products and operate, we are currently subject to, *inter alia*, the Medical Device Regulation ("MDR") as implemented into national legislation by the EU member states, and as amended from time to time, as well as local applicable law. The MDR replaced the Medical Device Directive ("MDD") on May 26, 2021. In Switzerland, our Products and operations are subject to, *inter alia*, the Medical Devices Ordinance, which implements the MDR into Swiss law (See "Foreign approvals and CE mark" below). In Japan, our Products and operations are subject to regulation by the Pharmaceuticals and Medical Device Agency ("PMDA") under the Pharmaceuticals and Medical Devices Act ("PMD Act"). In the UK, our Products and operations are subject to, *inter alia*, the Medical Devices Regulations 2002 and the Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (the "UK Regulations"), which implements the MDR and MDR like provisions into UK law. In addition, our Products must meet the requirements of a large and growing body of national, regional and international standards that govern the preclinical and clinical testing, manufacturing, labeling, certification, storage, recordkeeping, advertising, promotion, export and marketing and distribution, among other things, of our Products for current and future indications.

In the U.S., advertising and promotion of medical devices, in addition to being regulated by the FDA, is also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. In the EU, advertising and promotion is subject to not only the general provisions of the MDR, but also general EU advertising rules on misleading and comparative advertising and unfair commercial practices, as implemented at the EU member state level, such as the Heilmittelwerbegesetz in Germany. In the UK, advertising and promotion is subject to the UK Regulations, general guidance and enforcement of the Medicines and Healthcare products Regulatory Agency (MHRA), and adherence to the Association of British HealthTech Industries (ABHI) Code of Ethical Business

Practices. Promotional activities for FDA-regulated products of other companies have been the subject of government enforcement actions brought under healthcare laws and consumer protection statutes. In addition, we are required to meet analogous regulatory requirements in countries outside the U.S., which can change rapidly with relatively short notice. Competitors can also initiate litigation alleging false advertising for our promotional efforts under the Lanham Act, or under similar state laws.

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are also subject to extensive regulation.

Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in any number of regulatory enforcement actions, or civil or criminal liability.

#### **Food and Drug Administration**

The FDA regulates the development, testing, manufacturing, labeling, storage, recordkeeping, promotion, marketing, distribution and service of medical devices in the U.S. to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical devices manufactured in the U.S. to international markets and the importation of medical devices manufactured abroad. The FDA has broad post-market and regulatory enforcement powers to ensure compliance with the FDCA.

The FDA governs the following activities that we perform or that are performed on our behalf:

- product design, development and manufacture;
- product safety, testing, labeling and storage;
- record keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions and repair or recall of products.

We have registered three of our facilities with the FDA. We are subject to announced and unannounced inspections by the FDA to determine our compliance with the Quality System Regulation ("QSR") and other regulations and these inspections include the manufacturing facilities of our suppliers.

#### ***FDA's premarket clearance and approval requirements***

Unless an exemption applies, before we can commercially distribute medical devices in the U.S., we must obtain, depending on the type of device, either prior 510(k) clearance or premarket approval ("PMA") from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risks are placed in either class I or II, which typically requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low-risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in class III, generally requiring PMA.

#### ***Premarket approval (PMA) and Humanitarian Device Exemption (HDE) pathways***

Optune Gio and Optune Lua are classified as Class III devices as they are deemed to be life-sustaining devices. Accordingly, we were required to receive PMA for Optune Gio, which the FDA granted in April 2011 and October 2015 for the treatment of recurrent and newly diagnosed supratentorial GBM, respectively, in adult patients. We expect that we will be required to receive PMA for the use of our Products for future indications.

A PMA must be supported by extensive data, including from technical tests, preclinical studies and clinical studies, manufacturing information and intended labeling to demonstrate, to the FDA's satisfaction, the safety and effectiveness of a medical device for its intended use. During the PMA review period, the FDA will typically request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA.

as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the QSR. Prior to approval of the Optune Gio PMA for the treatment of recurrent GBM, we and our critical component suppliers were each inspected by the FDA.

New PMAs or PMA supplements are required for modifications that affect the safety or effectiveness of our devices, including, for example, certain types of modifications to a device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require any or as extensive clinical data as the original PMA required, or the convening of an advisory panel. The FDA requires a company to make the determination as to whether a new PMA or PMA supplement application is to be filed. If a company determines that neither a new PMA nor a PMA supplement application is required for modifications, it must nevertheless notify the FDA of these modifications in its PMA Annual Report. The FDA may review a company's decisions when reviewing the PMA Annual Report and require the filing of an application.

As is typical with medical device companies, we have received approval for a number of post-approval PMA supplements for GBM, including for modifications to Optune Gio's electric field generator, arrays, software, manufacturing processes and labeling. Future modifications may be considered by us as the need arises, some of which we may deem to require a PMA supplement application and others to require reporting in our PMA Annual Report.

For class III devices intended to treat disease affecting 8,000 individuals or less per year in the U.S., called Humanitarian Use Devices ("HUD"), the FDA has a separate marketing authorization pathway called the HDE. Approval basis for an HDE is a "reasonable assurance of safety" and that the probable benefit to health outweighs risk of injury from its use, which means a traditional phase 3 study usually is not required to support approval.

In 2019, the FDA approved Optune Lua (then known as "NovoTTF-100L") for the treatment of MPM under the HDE pathway. Devices approved through an HDE application are subject to certain requirements, including specific labeling restrictions and the requirement that a facility's institutional review board ("IRB") or Local Committee approve the use of the device before it can be distributed in that facility. In addition, there is a general prohibition on profiting from sales of devices approved under the HDE standard. As part of the approval process, we applied for an exemption from this limitation, which the FDA granted. Otherwise, HDE approved devices are generally required to follow the same requirements as PMA approved devices, including the supplement process.

#### ***Clinical studies***

Clinical studies are generally required to support approval of a PMA or HDE. Such studies generally require an Investigational Device Exemption ("IDE") approval from the FDA for a specified number of patients and study sites, unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. Clinical studies are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical studies must be conducted under the oversight of an IRB for the relevant clinical study sites and must comply with FDA regulations, including those relating to current Good Clinical Practices ("cGCPs"). To conduct a clinical study, we also are required to obtain the patients' informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the respective IRB could suspend a clinical study at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a study is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the U.S.

Post-approval studies are also typically required as a condition of PMA to reinforce the reasonable assurance of safety and effectiveness. Such studies are conducted in the post-market setting with the approved device, often to address the long-term use of the device or other discrete questions that may have been raised based on the clinical data from the IDE clinical study. The FDA required a post-approval registry study as a condition of approval for Optune Gio for recurrent GBM, which we completed.

Clinical studies involving pharmacological/immunological therapy candidates may be regulated under FDA's drug regulations. Unless exempt, such studies require authorization from FDA of an Investigational New Drug Application ("IND") for a specified number of patients and study sites. As with IDE studies, IND studies are subject to extensive monitoring, recordkeeping and reporting requirements, must be conducted under the oversight of an IRB, must comply with FDA drug or biologic regulations, and are required to obtain informed consent that complies with FDA requirements and state and federal privacy and human subject protection regulations. IND clinical studies can be

suspended at any time by us, the FDA or an IRB for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if an IND study is completed, the results of clinical testing may not be sufficient to obtain FDA approval to market the product.

#### **Foreign approvals and CE mark**

Market access, sales and marketing of medical devices outside of the U.S. are subject to foreign regulatory requirements that vary widely from country to country. In the European Economic Area ("EEA"), for Novocure's devices these include the requirement to obtain a CE Certificate and to affix a CE mark to our Products. In the EEA, whether or not we have obtained FDA approval, 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. Apart from low risk medical devices (Class I with no measuring function and which are not sterile), a conformity assessment procedure requires the intervention of a notified body. 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. Following the issuance of this CE Certificate, we can draw up a declaration of conformity and affix the CE mark to the devices covered by this CE Certificate. The time required to CE mark our devices or to obtain approval from other non-U.S. authorities may be longer or shorter than that required for FDA approval. Moreover, the MDR, which became applicable on May 26, 2021, with transitional provisions for "legacy" devices under the MDD, imposed new, stricter requirements that we must comply with in order to obtain CE Certificates for new devices, and to renew the CE Certificates for our MDD-Products when these expire, or at the latest, December 31, 2027 or 2028, depending on the device, whichever comes first. In addition, as of May 25, 2021, in the absence of a new MRA, Switzerland is now considered a non-EU "third country" with respect to medical devices, meaning that movement of our Products bearing a CE mark from the EEA to Switzerland is subject to additional requirements. In the UK, we were able to market and sell our Products under the CE mark until June 2023. Thereafter, our Products have been regulated under the UK Regulations.

In the EEA, before carrying out a clinical investigation with a non-CE marked device to assess its safety or performance when in accordance with its intended use, the study sponsor must receive a positive opinion from the local ethics committee and approval from the national competent authority in the relevant EEA member states in which the clinical investigation will be conducted. When a CE marked medical device is used in a clinical study in accordance with its intended use, the approval of the national competent authorities is not required for the use of such medical device in the study. In Japan, we must obtain approvals from the Ministry of Health, Labour, and Welfare ("MHLW") to market our devices. Each regulatory approval process outside of the U.S. includes all the risks associated with FDA regulation, as well as country-specific regulations.

#### **Pervasive and continuing regulation**

After a device is placed on the market, numerous regulatory requirements apply depending upon the country in which the device is being marketed. These may include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process for products marketed in the U.S.;
- labeling regulations and FDA and equivalent competent authority in other jurisdictions requiring promotion be truthful and non-misleading and prohibiting the promotion of products for uncleared, unapproved or off-label uses;
- approval of product modifications that affect the safety or effectiveness of one of our devices that has been approved or is the subject of a CE Certificate;
- Medical Device Reporting regulations of the FDCA and medical device vigilance, which require that manufacturers comply with FDA or equivalent competent authority requirements in other jurisdictions to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a

way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;

- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's and equivalent competent authority's recall authority, whereby they can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

Our devices could be subject to voluntary recall if we, the FDA or another applicable regulatory authority determine, for any reason, that our devices pose a risk of injury or are otherwise defective. Moreover, the FDA and other applicable regulatory authorities can order a mandatory recall if there is a reasonable probability that our device would cause serious adverse health consequences or death.

The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA to determine our compliance with the QSR and other regulations and these inspections include the manufacturing facilities of our subcontractors. We are also subject to FDA's broad regulatory enforcement power around promotional activities. Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other applicable regulatory authorities, which may result in sanctions, including, but not limited to:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement and/or refunds;
- recall, detention or seizure of our devices;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for approval of device candidates or a modified version of Optune Gio;
- withdrawal of PMA/HDE approvals or suspension, variation or withdrawal of CE Certificates that have already been granted;
- refusal to grant export approval for our devices; or
- civil and/or criminal prosecution by the U.S. Department of Justice or other enforcement authorities outside of the U.S.

To date, our facilities and those of our critical suppliers have been inspected by several relevant regulatory authorities in order to obtain regulatory approval of our Products. No inspectional observations were identified were issued following these inspections.

#### ***Durable medical equipment accreditation and licensing and other requirements***

In the U.S., we are subject to accreditation and licensing requirements as a durable medical equipment ("DME") supplier in most states and must meet the supplier standards of Medicare, Medicaid and other federal healthcare programs. Certain states require that DME providers maintain an in-state location. Although we believe we are in compliance with all applicable federal and state regulations regarding accreditation and licensure requirements and similar requirements in other jurisdictions, if we are found to be noncompliant, we could lose our accreditation or

licensure in such states or our supplier rights under such federal healthcare programs, which could prohibit us from selling our current or future devices to patients in such state or to that federal healthcare program.

#### ***Healthcare regulatory matters***

In addition to FDA restrictions on the marketing of medical devices, several other U.S. federal and state laws have been applied to restrict certain business practices in the healthcare industry and penalize unlawful conduct. These laws include the federal Anti-Kickback Statute, the federal prohibition on physician self-referrals (commonly known as the "Stark Law") and the federal False Claims Act.

The U.S. federal Anti-Kickback Statute is a criminal, intent-based statute that prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration to induce or in return for purchasing, leasing, ordering, recommending or arranging for the purchase, lease, order or recommendation of any healthcare item or service that may be paid for, in whole or in part, by Medicare, Medicaid or another federal healthcare program. Among other arrangements, this statute has been interpreted to apply to financial arrangements between medical device manufacturers on one hand and prescribers and purchasers on the other. Although there are a number of statutory exceptions and regulatory safe harbors that protect certain common activities from prosecution under the law, the exceptions and safe harbors are drawn narrowly and practices that involve the provision of remuneration intended to induce ordering, purchasing, leasing or recommending of a medical device may be subject to scrutiny if they do not qualify for an exception or safe harbor. In some cases, our practices may not meet all of the technical elements for protection under a federal Anti-Kickback Statute exception or safe harbor. Similarly, as a supplier, we are also subject to the federal beneficiary anti-inducement statute, which prohibits us from offering any remuneration to a beneficiary of Medicare or Medicaid that is likely to influence that beneficiary's choice of therapy, unless an exception applies. This can include, but is not limited to, the provision of inappropriate financial assistance to purchase our Products. Recent government investigations and enforcement actions have focused on the provision of financial assistance to patients by providers and suppliers. As noted, there are established exceptions from liability, but we cannot guarantee that all of our practices will fall squarely within those exceptions.

As a DME supplier, we also are subject to the Stark law, which is a strict liability law that prohibits Medicare payments for certain "designated health services" ("DHS") including DME ordered by physicians who, personally or through an immediate family member, have an ownership interest in or a compensation arrangement with the furnishing DHS entity. The Stark law contains a number of specific exceptions that, if met, permit physicians who have certain financial relationships with a DHS entity to make referrals to that entity and for that entity to bill Medicare for such services.

The False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. The government has pursued numerous cases under the False Claims Act in connection with the off-label promotion of medical products and various other health care law violations. Notably, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The majority of states also have statutes or regulations similar to the federal Anti-Kickback Statute, Stark Law and False Claims Act laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, that apply regardless of the payer (e.g., including private/commercial payors or cash-pay scenarios).

Numerous federal and state laws and regulations, including the Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH" and collectively "HIPAA"), govern the collection, dissemination, use, security and privacy of individually identifiable health information. We believe we are in substantial compliance with such applicable laws and regulations, including HIPAA.

HIPAA also includes a number of federal criminal provisions, including for healthcare fraud and for false statements relating to healthcare matters. The healthcare fraud provision prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers. The false statements provision prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Many states have similar healthcare fraud laws or insurance fraud laws that apply to claims for healthcare reimbursement.

Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

Legislation similar to the federal Anti-Kickback Statute, the Stark Law and False Claims Act has been adopted in foreign countries, including a number of EU member states.

In the EU, the General Data Protection Regulation ("GDPR") has applied since May 25, 2018. The GDPR harmonizes data privacy laws and rules for the processing of personal data, including patient and employee data, across the EU and repeals and replaces Directive 95/46/EC of the European Parliament and of the Council of October 24, 1995, and applicable national laws. The GDPR has added a number of strict data protection and security requirements for companies processing personal data of EU residents, including when such data is transferred outside the EU.

In the U.S., the federal Physician Payment Sunshine Act ("Sunshine Act") requires certain manufacturers of drugs, medical devices, biologicals or medical supplies that participate in U.S. federal health care programs to track and then report certain payments and transfers of value given to "Covered Recipients." The term "Covered Recipients" currently includes U.S.-licensed physicians and teaching hospitals, and, for reports submitted on or after January 1, 2022, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. The Sunshine Act requires that manufacturers collect this information on a yearly basis and then report it to Centers for Medicare & Medicaid Services by the 90th day of each subsequent year. We have adopted policies and codes of conduct regarding our interactions with Covered Recipients and believe we are in material compliance with the Sunshine Act. However, our failure to adhere to these requirements could materially adversely impact our business and financial results. Additionally, a number of states have transparency reporting requirements similar to (and in some cases broader than) the Sunshine Act, and regulations similar to the Sunshine Act have been adopted in foreign countries including a number of EU member states.

In addition, the U.S. Foreign Corrupt Practices Act ("FCPA") prohibits corporations and individuals from engaging in certain activities to obtain or retain business outside the U.S. or to influence a person working in an official capacity in a foreign country. It is illegal to pay, offer to pay or authorize the payment of anything of value to any official of another country, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in that capacity. Legislation similar to the FCPA has been adopted in foreign countries, including a number of EU member states.

#### **Human Capital Resources**

As of December 31, 2023, we had 1,453 employees, compared to 1,320 employees as of December 31, 2022. We believe relations with our employees are good.

To achieve commercial success for our Products, we believe we must continue to develop and grow our sales and marketing, patient support and research and development teams, along with the necessary staff to support it. Developing and managing a growing organization is a difficult, expensive and time consuming process. To be successful we must:

- recruit and retain adequate numbers of effective and experienced sales and marketing, patient support and research and development personnel;
- effectively train our personnel on the benefits and risks of our Products and healthcare compliance; and
- manage geographically disbursed business operations.

We compete with other medical device, pharmaceutical and life sciences companies to recruit, hire, train and retain the personnel that we anticipate we will need. Because our current Products require, and we anticipate our future Products will require, physician training and education, we expect that our sales and marketing and patient support teams will continue to grow substantially as we expand our approved indications and markets.

In November 2023, we announced a series of actions to strengthen and optimize our business operations to support near-term growth drivers and long-term value creation. The plan included a reduction in headcount of approximately 200 employees or 13% of our then current workforce. Field-based commercial and field-based medical employees were minimally affected. We expect that the workforce reduction, along with other actions, will enable us to fund future growth priorities without an associated increase in expected forward operating cash burn. We continue to

focus resources on our global commercial infrastructure and launch preparation ahead of our anticipated indication in metastatic non-small cell lung cancer and on high-potential research and development programs.

#### **Available information**

Our corporate website address is [www.novocure.com](http://www.novocure.com). Our website is an inactive textual reference and nothing on our website is incorporated by reference in this Annual Report. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. These filings are also available on the SEC's website at [www.sec.gov](http://www.sec.gov).

We may use our website as a means of disclosing material information and for complying with our disclosure obligations under Regulation Fair Disclosure promulgated by the SEC. Accordingly, investors should monitor our website, in addition to following our press releases, SEC filings, public conference calls, webcasts and our social media accounts.

## ITEM 1A. RISK FACTORS

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 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 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. 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 temozolamide, 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 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 occasional and intermittent operating profits, and we have a history of incurring substantial operating losses.***

We were founded in 2000 and have only occasionally and intermittently generated 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 with well-established cancer treatment modalities like surgery, radiation, pharmacological and immunocologic 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 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 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); 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 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 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 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 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 codes for new indications.

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 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 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. 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 issued new draft guidance regarding coverage of emerging technologies that does not specifically address whether our future Products will obtain coverage. While these are only guidelines and they 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 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.

***A pandemic, such as the COVID-19 pandemic could materially adversely impact our business.***

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, 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 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 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 pandemic or outbreak may impact our business and clinical studies will depend on 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 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.

***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 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 were able to market and sell our Products under the CE mark until June 2023. Going forward, our Products are 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 the U.S., EU member states, the UK, Switzerland, Israel, Japan, and other jurisdictions are 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 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 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 Lu 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 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 2024 and 2041. 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 re-hear 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.***

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 interest 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.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 1C. CYBERSECURITY**

As a medical device manufacturer that directly interacts with both healthcare professionals and patients, we recognize data privacy and cybersecurity as fundamental imperatives. Like all companies of our size, computer system complexity, and geographic reach, our information systems are subject to constant probing from outside actors and potentially vulnerable to internal and external malicious intrusion, cyberattacks and computer viruses. Because the techniques used to obtain unauthorized access or sabotage systems change frequently and, generally, are not recognized until launched against a target, we maintain a multifaceted approach to assessing, identifying and managing our material risks related to cybersecurity threats. This approach is integrated into our overall risk management processes. We use both technology-based solutions (e.g., anti-virus software, automated intrusion detection systems, spam filters, encrypted virtual private networks) and human-based solutions (e.g., data management policies, outside penetration testing, employee training and testing, independent audits) to defend against cybersecurity threats. We reinforce our commitment to a strong cybersecurity culture through security training and awareness programs. Education on topics such as data security, privacy practices, email and mobile security as well as tailored topics such as secure programming for developers make our employees aware of the need to make sound cybersecurity decisions. Our goal is to promote a culture of thorough security and impress upon our employees that everyone has a part to play in securing corporate data and information systems.

We have obtained both ISO 13485 (quality management systems for medical devices) and ISO 27001 (information security management systems) certifications, which require independent annual auditing to obtain and maintain. In addition to our commitment to secure our employees', customers' and patients' data, as well as intellectual property, we take steps to ensure data integrity and protection standards are maintained throughout our supply chain. We understand that supply chains are vulnerable to increasing risks from cybersecurity threats. Cybersecurity threats to our supply chain are accounted for by performing risk assessments by our dedicated cybersecurity staff. These analyses take into account the type and amount of data being accessed and the supplier's ability to employ and maintain cybersecurity health and is also verified through third-party assessments and certifications. Supply chain vendors are monitored to ensure that risks remain mitigated and mechanisms are in place to allow for tracking and reporting of any material supplier cybersecurity events. Data security requirements are also included in all key vendor contracts. All vendors that handle personal information are required to provide appropriate protection in accordance with our policies and applicable regulations and laws.

Our Board of Directors has primary oversight over our risk management activities and has specifically delegated cybersecurity risk management oversight to its Audit Committee, which is comprised entirely of independent directors. At least on a quarterly basis, our information security management provides updates on our cybersecurity activities and to the extent any cybersecurity incidents may have occurred. On at least an annual basis, our information security management team engages in a thorough discussion and review of our cybersecurity practices and procedures that are designed to monitor the prevention, detection, mitigation, and remediation of cybersecurity incidents. Our information security management team is led jointly by our Vice President, IT Infrastructure and Cybersecurity and our Director of Privacy.

We have dedicated privacy and cybersecurity officers and committees with established processes to assess, identify, manage and investigate all potential privacy and cybersecurity risks and incidents. As a medical device manufacturer with a global presence, we are compliant with privacy laws and regulations in all jurisdictions where we conduct business. In the U.S., the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH" and collectively "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 General Data Protection Regulation ("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. Our policies and procedures are all designed to ensure compliance with these obligations.

**ITEM 2. PROPERTIES**

Our global headquarters and operating center is located in Root, Switzerland, our U.S. operating center is located in Portsmouth, New Hampshire, and our research and development operations are located in Haifa, Israel, all of which

are leased. In December 2021 we acquired a property in downtown Portsmouth, New Hampshire that will become our U.S. flagship location. Construction on the property is expected to be completed in 2024. We also lease additional office and warehouse space across North America, Europe, Israel and Japan. We believe that our current facilities are adequate for our present purposes, but we may need additional space as we continue to grow and expand our operations. We believe that suitable additional or alternative office, laboratory, and manufacturing space would be available as required in the future on commercially reasonable terms.

### **ITEM 3. LEGAL PROCEEDINGS**

In June 2023, a putative class action lawsuit was filed against the Company, its Executive Chairman and its Chief Executive Officer. The complaint, later amended to add our Chief Financial Officer as a defendant, purports to be brought on behalf of a class of persons and/or entities who purchased or otherwise acquired ordinary shares of the Company from January 5, 2023 through June 5, 2023, and alleges material misstatements and/or omissions in the Company's public statements with respect to the results from its phase 3 LUNAR clinical trial. The Company believes that the action is without merit and plans to defend the lawsuit vigorously.

In addition, from time to time, we are involved in various legal proceedings, claims, investigations and litigation that arise in the ordinary course of our business. Litigation is inherently uncertain. Accordingly, we cannot predict with certainty the outcome of these matters. After considering a number of factors, including (but not limited to) the views of legal counsel, the nature of contingencies to which the Company is subject and prior experience, management believes that the ultimate disposition of these legal actions will not materially affect its consolidated financial position or results of operations.

### **ITEM 4. MINE SAFETY DISCLOSURES**

None

#### **Information about our Executive Officers**

Our executive officers are elected by and serve at the discretion of our board of directors. The following table lists information about our executive officers:

Name	Age	Position
Asaf Danziger	57	Chief Executive Officer and Director
William Doyle	61	Executive Chairman and Director
Barak Ben-Arye	48	General Counsel
Ashley Cordova	44	Chief Financial Officer
Moshe Giladi	54	Chief Science Officer
Wilhelmus Groenhuysen	66	Chief Operating Officer
Francis Leonard	44	Executive Vice President, President Novocure Oncology
Nicholas Leupin	50	Chief Medical Officer
Michael Puri	54	Chief Human Resources Officer
Uri Weinberg	46	Chief Innovation Officer

*Asaf Danziger* has served as our Chief Executive Officer since 2002 and has been a director of NovoCure since 2012. From 1998 to 2002, Mr. Danziger was CEO of Cybro Medical, a subsidiary of Imagyn Medical Technologies, Inc. Mr. Danziger holds a B.Sc. in material engineering from Ben Gurion University of the Negev, Israel.

*William Doyle* has served as our Executive Chairman since 2016, as Chairman of the Board since 2009 and as a member of our Board of Directors since 2004. Mr. Doyle has been the managing director of WFD Ventures LLC, a private venture capital firm he co-founded, since 2002. Prior to 2002, Mr. Doyle was a member of Johnson & Johnson's Medical Devices and Diagnostics Group Operating Committee and was Vice President, Licensing and Acquisitions. While at Johnson & Johnson, Mr. Doyle was also chairman of the Medical Devices Research and Development Council, and Worldwide president of Biosense-Webster, Inc. and a member of the board of directors of Cordis Corporation and Johnson & Johnson Development Corporation, Johnson & Johnson's venture capital subsidiary. Earlier in his career, Mr. Doyle was a management consultant in the healthcare group of McKinsey & Company. Mr. Doyle is also a member of the Governing Board of the Pershing Square Sohn Cancer Research Alliance. From 2014 to 2016 he was a member of the investment team at Pershing Square Capital Management L.P., a private investment firm and from November 2016 to January 2021, Mr. Doyle served as the Executive

Chairman of BlinkHealth LLC, which has developed a pharmacy-as-a-service, e-commerce platform. Mr. Doyle has been a director of Elanco Animal Health, Inc. since 2020 and ProKidney, Inc. since 2022. Mr. Doyle previously served as a director of Optinose, Inc., a commercial-stage specialty pharmaceuticals company, from 2004 to 2020 and director of Minerva Neurosciences, Inc., from 2017 to 2023. Mr. Doyle holds an S.B. in materials science and engineering from the Massachusetts Institute of Technology and an M.B.A. from Harvard Business School. Mr. Doyle serves on Harvard Business School's Board of Dean's Advisors and MIT's Institute of Medical Engineering & Science Visiting Committee.

*Barak Ben-Arye* has been our General Counsel since April 2022 and prior to that was our Vice President, EMEA Counsel since June 2019 and our Senior Director, EMEA Counsel since joining us in 2018. Mr. Ben-Arye served as the Chief Executive Officer of Gaash Business and Agriculture, Cooperative Agricultural Society Ltd., an Israeli cooperative association engaged in industry, agriculture, commerce, real estate and tourism, from 2014 to 2018. Prior to joining Gaash, he worked for Raved, Magriso, Benkel & Co., an international law firm in Tel Aviv (later merged into Shibolet & Co.) from 2005 to 2013, last serving as a partner in the firm's hi-tech and life science department. Mr. Ben-Arye earned his Bachelor of Laws and his Bachelor of Business Administration from Reichman University (IDC Herzliya) in Israel.

*Ashley Cordova* has been our Chief Financial Officer since September 2020. From October 2018 to August 2020, Ms. Cordova served as our Senior Vice President, Finance and Investor Relations. Ms. Cordova joined us in June 2014 as Director of Global Treasury. In March 2015, she became our Senior Director, Investor Relations and Global Treasury, and in July 2016, she became our Vice President, Finance and Investor Relations. Prior to joining us, Ms. Cordova served in various financial roles at Zoetis Inc. from 2012 to 2014 and Pfizer Inc. from 2005 to 2012. Ms. Cordova graduated with a bachelor's degree in Music and Business from Furman University, and earned her International Master of Business Administration from the University of South Carolina.

*Moshe Giladi, Ph.D.*, has been our Chief Science Officer since July 2023. Dr. Giladi joined Novocure in 2005 and most recently held the title of Senior Vice President of Preclinical Research. He holds a Ph.D. in Microbiology and Biochemistry and a master's degree in business administration from Tel Aviv University.

*Wilhelmus Groenhuysen* has been our Chief Operations Officer since September 2020 and prior to that was our Chief Financial Officer since 2012. He has served on the Board of Optinose Inc., a commercial-stage specialty pharmaceuticals company, since October 2017. From 2007 to 2011, Mr. Groenhuysen worked for Cephalon, Inc., a U.S. biopharmaceutical company, last serving as executive vice president and chief financial officer, where he had responsibility for worldwide finance, commercial operations and risk management. From 1987 to 2007, Mr. Groenhuysen worked for Philips Group in various assignments in Europe, Asia and the United States, the latest of which started in 2002 when he was promoted to chief financial officer and senior vice president of Philips Electronics North America Corporation. Mr. Groenhuysen holds a Master's Degree in Business Economics from VU University Amsterdam and graduated as a Registered Public Controller at VU University Amsterdam.

*Frank Leonard* has been our Executive Vice President, President Novocure Oncology since January 2024. Mr. Leonard joined Novocure in 2010, and most recently served as President, CNS Cancers U.S. Prior to joining Novocure, Mr. Leonard was a venture capital investor focused on high-impact medical technologies. Mr. Leonard holds an A.B. from Harvard and an M.A. from the London School of Economics and Political Science.

*Nicholas Leupin, M.D., Ph.D.*, has served as our Chief Medical Officer since January 2024. Dr. Leupin previously served as Chief Medical Officer of Molecular Partners AG since August 2019. Prior to that Dr. Leupin served as Chief Medical Officer of argenx from 2016. Dr. Leupin holds an M.D. from the University of Bern, an M.B.A. from Jones International University and a Ph.D. from the Université Bourgogne-Franche-Comté.

*Michael Puri* has served as our Chief Human Resources Officer since September 2023. Mr. Puri previously served as Vice President, HR Integration lead at CSL Limited, following the company's acquisition of Vifor Pharma, where he served as Chief Human Resources Officer from 2015 to 2022. He also served as Chief Human Resources Officer at GrandVision, an international leader in optical retailing, from 2013 to 2015. Mr. Puri has also held leadership positions at Staples, Inc. and UCB S.A., a global biopharma company. He earned his bachelor's degree in economics from the University of Nantes and his master's degree in strategic marketing from the Grenoble Business School.

*Uri Weinberg, M.D., Ph.D.*, has served as our Chief Innovation Officer since January 2023, where he is responsible for expanding the innovative potential of Tumor Treating Fields therapy. Since joining Novocure in 2008, he has held several positions throughout his tenure with the Company and most recently held the position of Chief Science Officer since 2020. Dr. Weinberg holds an M.D. Ph.D. from the Technion – Israel Institute of Technology.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our ordinary shares are quoted on the NASDAQ Global Select Market under the symbol "NVCR."

#### Holders of Ordinary Shares

As of February 16, 2024, there were 17 holders of record of our ordinary shares. On February 16, 2024, the last reported sale price of our ordinary shares on the NASDAQ Global Select Market was \$16.14 per share.

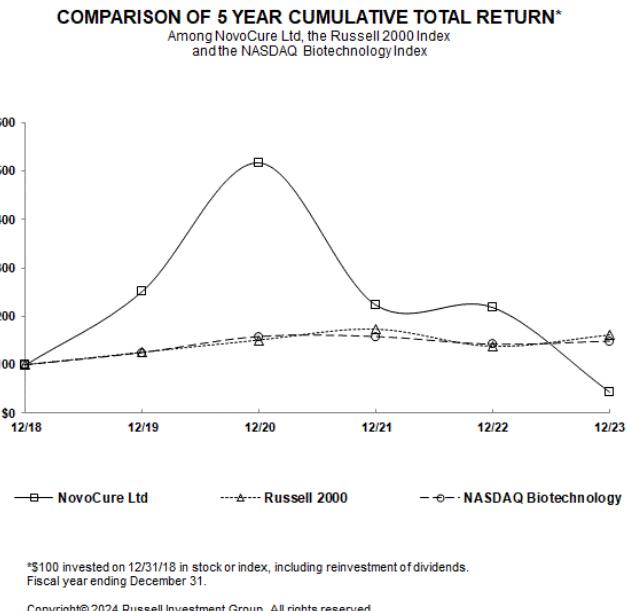
#### Dividend Policy

We have not paid any dividends on our ordinary shares since our inception and do not anticipate paying any dividends on our ordinary shares in the foreseeable future.

#### Performance Graph

The following performance graph is being furnished as part of this annual report and shall not be deemed "filed" with the SEC or incorporated by reference into any of our filings under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The graph below matches our cumulative 5-Year total shareholder return on our ordinary shares with the cumulative total returns of the Russell 2000 index and the Nasdaq Biotechnology index. The graph tracks the performance of a \$100 investment in our ordinary shares and in each index (with the reinvestment of all dividends) from December 31, 2018 to December 31, 2023. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends; however, no dividends have been declared on our ordinary shares to date. The shareholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



	12/18	12/19	12/20	12/21	12/22	12/23
NovoCure Ltd	100.00	251.70	516.85	224.25	219.09	44.59
Russell 2000	100.00	125.52	150.58	172.90	137.56	160.85
NASDAQ Biotechnology	100.00	125.11	158.17	158.20	142.19	148.72

#### Recent Sales of Unregistered Securities

Not applicable

#### Issuer Purchases of Equity Securities

Not applicable.

#### Securities Authorized for Issuance Under Equity Compensation Plans

The following table gives information about our ordinary shares that may be issued upon the exercise of stock options and vesting of restricted stock units, as applicable, under all of our existing equity compensation plans as of December 31, 2023, including the 2003 Share Option Plan (the "2003 Plan"), the 2013 Share Option Plan (the "2013 Plan"), the 2015 Omnibus Incentive Plan (the "2015 Plan") and the Employee Share Purchase Plan (the "ESPP"). Each of the 2003 Plan, the 2013 Plan, the 2015 Plan and the ESPP has been approved by the Company's shareholders.

#### Equity Compensation Plan Information

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Future Issuance (Excludes Securities Reflected in Column (a))	
			Remaining Available for Future Issuance (Excludes Securities Reflected in Column (a))	Number of Securities Remaining Available for Future Issuance (Excludes Securities Reflected in Column (a))
Equity compensation plans approved by shareholders	14,352,573	\$ 23.84	—	28,632,049
Equity compensation plans not approved by shareholders	—	—	—	—
<b>Total</b>	<b>14,352,573</b>	<b>\$ 23.84</b>	<b>—</b>	<b>28,632,049</b>

#### ITEM 6. [RESERVED]

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to provide information to assist you in better understanding and evaluating our financial condition and results of operations. We encourage you to read this MD&A in conjunction with our consolidated financial statements and the notes thereto included in Part II, Item 8 of this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. Please refer to the information under the heading "Cautionary Note Regarding Forward-Looking Statements" elsewhere in this report. References to the words "we," "our," "us," and the "Company" in this report refer to NovoCure Limited, including its consolidated subsidiaries.

### Commentary on Results of Operations

#### **Net revenues**

Our revenues are primarily derived from patients using our Products in our active markets. We charge for treatment with our Products on a monthly basis. Our potential net revenues per patient are determined by our ability to secure payment, the monthly fee we collect and the number of months that the patient remains on therapy.

We also receive revenues pursuant to the Zai Agreement. For additional information regarding the Zai Agreement, see Note 12 to the Consolidated Financial Statements.

#### **Cost of revenues**

We contract with third parties to manufacture our Products. Our cost of revenues is primarily comprised of the following:

- disposable arrays;
- depreciation expense for the field equipment, including the electric field generator used by patients; and
- personnel and overhead costs such as facilities, freight and depreciation of property, plant and equipment associated with managing our inventory, warehousing and order fulfillment functions.

#### **Operating expenses**

Our operating expenses consist of research, development and clinical studies, sales and marketing and general and administrative expenses. Personnel costs are a significant component for each category of operating expenses and consist of wages, benefits and bonuses. Personnel costs also include share-based compensation.

##### *Research, development and clinical studies*

Our research, development and clinical studies activity is focused on advancing TTFields therapy through clinical studies across multiple solid tumor types and improving the efficacy and usability of our devices. Research, development and clinical studies costs, including direct and allocated expenses, are expensed as incurred and consist primarily of the following:

- personnel costs for those employees involved in our preclinical and basic research, clinical development programs, clinical affairs, product development and regulatory activities;
- costs to conduct research, product development and clinical study activity through agreements with contract research organizations and other third parties;
- manufacturing expenses associated with our Products, including durable components and disposable arrays, utilized in clinical studies and other research;
- costs associated with publications, presentations and investigator-sponsored trials;
- professional fees related to regulatory approvals and conformity assessment procedures; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment and laboratory and other supplies.

The following table summarizes our research, development and clinical study expenses by program for the years ended December 31, 2023, 2022 and 2021:

U.S. dollars in thousands	Year ended December 31,		
	2023	2022	2021
Preclinical and basic research	\$ 18,936	\$ 16,922	\$ 15,580
Clinical development programs:			
LUNAR	6,846	6,905	9,069
LUNAR - 2	2,999	—	—
INNOVATE - 3	7,810	9,494	17,708
METIS	5,758	8,480	7,056
PANOVA - 3	18,243	22,185	15,026
TRIDENT	20,348	12,162	12,588
Other clinical studies	6,640	5,524	4,634
Clinical administration	25,363	22,690	19,764
Product development	18,219	15,323	15,248
Clinical affairs	15,935	19,891	24,486
Other research and development costs (1)	44,138	35,719	32,547
Share based compensation	31,827	30,790	27,597
Research, development and clinical studies	<u>\$ 223,062</u>	<u>\$ 206,085</u>	<u>\$ 201,303</u>

(1) Other research, development and clinical study costs include regulatory affairs, quality assurance, intellectual property, product safety, allocated facilities and other overhead costs.

We are committed to investing strategically to maximize the growth potential of the TTFields therapy platform. As such, we are prioritizing clinical programs which have the greatest value potential in solid tumors where TTFields therapy has established efficacy, including glioblastoma, non-small cell lung cancer and pancreatic cancer.

#### *Sales and marketing*

Sales and marketing expenses consist primarily of personnel costs, travel, marketing and promotional activities, medical education, market access, commercial shipping and facilities costs. Over the next few years, we expect to continue to make significant expenditures associated with selling and marketing our Products, primarily in connection with continued commercialization in North America, the EU and Japan for the treatment of our approved indications. We are prioritizing launch readiness, including field-based commercial and field-based medical team hiring, for the anticipated approval of TTFields therapy for the treatment of metastatic non-small cell lung cancer following progression on or after platinum-based therapies.

#### *General and administrative*

General and administrative expenses consist primarily of personnel, professional fees and facilities costs. General and administrative personnel costs include our executive, finance, human resources, information technology and legal functions. These costs also include our contributions to support industry and patient groups. Our professional fees consist primarily of accounting, information technology, legal and other consulting costs. We expect that general and administrative expenses will increase to support our growth.

In addition, we incur significant legal and accounting costs related to compliance with SEC rules and regulations, including the costs of achieving and maintaining compliance with Section 404 of the Sarbanes-Oxley Act of 2002 and compliance with rules of the NASDAQ Stock Market, as well as insurance, investor relations and other costs associated with being a public company.

#### *Financial expenses, net*

Financial expenses, net, primarily consists of bank fees, credit facility interest expense and related debt issuance costs, interest income from cash balances and short-term investments and gains (losses) from foreign currency

transactions. Our reporting currency is the U.S. dollar. We have historically held substantially all of our cash balances in U.S. dollar denominated accounts to minimize the risk of translational currency exposure.

#### **Critical accounting policies and estimates**

In accordance with U.S. GAAP, in preparing our financial statements we must make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of net revenues and expenses during the reporting period. We develop and periodically change these estimates and assumptions based on historical experience and on various other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates.

The critical accounting policies requiring estimates, assumptions and judgments that we believe have the most significant impact on our consolidated financial statements are described below.

#### **Revenue recognition**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606) (ASU 2014-09), an updated standard on revenue recognition and issued subsequent amendments to the initial guidance in March 2016, April 2016, May 2016 and December 2016 within ASU 2016-08, 2016-10, 2016-12 and 2016-20, respectively. The Company adopted the standard effective January 1, 2018 using the modified retrospective method for all contracts. The reported results for 2018 and thereafter reflect the application of Accounting Standards Codification ("ASC") 606 guidance. The amount of revenue recognized reflects the consideration to which we expect to be entitled to receive in exchange for our Products. For additional information, see Note 2(m) to the Consolidated Financial Statements.

We also receive revenues pursuant to the Zai Agreement. For additional information regarding the Zai Agreement, see Note 12 to the Consolidated Financial Statements.

#### **Share-based compensation**

Under the FASB's ASC 718, Compensation-Stock Compensation, we measure and recognize compensation expense for share options granted to our employees and directors and for our ESPP based on the fair value of the awards on the date of grant. The fair value of share options is estimated at the date of grant using the Black-Scholes option pricing model and for market condition awards we also use the Monte-Carlo simulation model. Both models requires management to apply judgment and make estimates, including:

- beginning with the first quarter of 2022, the computation of expected volatility is based on the historical volatility the Company's shares, beginning with the first quarter of 2021 and prior to the first quarter of 2022, the computation of expected volatility is based on a combination of actual historical share price volatility of comparable publicly-traded companies and the historical volatility the Company's shares. Prior to the first quarter of 2021, due to the lack of sufficient historical information for the Company, the computation was based on actual historical volatility of comparable publicly-traded companies;
- beginning with the first quarter of 2021, the expected term of options granted is calculated using the Company's historical and future exercise behavior. Prior to the first quarter of 2021, it was calculated using the average between the vesting period and the contractual term to the expected term of the options in effect at the time of grant;
- the risk-free interest rate, which we base on the yield curve of U.S. Treasury securities with periods commensurate with the expected term of the options being valued; and
- the expected dividend yield, which we estimate to be zero based on the fact that we have never paid cash dividends and have no present intention to pay cash dividends.

For information about our ESPP, see Note 15 to the Consolidated Financial Statements.

We recognize share-based compensation costs only for those shares expected to vest over the requisite vesting period of the award, which is generally the option vesting term of four years, using the accelerated method.

We recognize compensation costs for the value of performance stock units ("PSU") over the performance period when the vesting conditions become probable in accordance with ASC 718.

The table below summarizes the assumptions that were used to estimate the fair value of the options granted to employees during the periods presented:

	Year ended December 31,		
	2023	2022	2021
Expected term (years)	5.50-6.00	5.33-5.83	5.50-6.00
Expected volatility	63%-70%	60%-62%	60%-63%
Risk-free interest rate	3.48%-4.79%	1.58%-4.23%	0.78%-1.27%
Dividend yield	0.00%	0.00%	0.00%

If any of the assumptions used in the Black-Scholes option pricing model change significantly, share-based compensation for future awards may differ materially from the awards granted previously.

So long as our ordinary shares are publicly traded in a liquid market, we will rely on the daily trading price of our ordinary shares when we estimate the fair value of options granted.

We incurred share-based compensation expense of \$115.6 million, \$107.0 million and \$94.9 million during the years ended December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023, we have unrecognized compensation expense of \$98.6 million, which is expected to be recognized over a weighted average period of approximately 1.64 years. We expect to continue to grant equity awards in the future, and to the extent that we do, our recognized share-based compensation expense will likely increase. For additional information, see Note 15 to the Consolidated Financial Statements.

#### ***Long-lived assets***

Property and equipment and field equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful life of the relevant asset. We make estimates of the useful life of our property and equipment and field equipment, based on similar assets purchased in the past and our historical experience with such similar assets, in order to determine the depreciation expense to be recorded for each reporting period.

Our field equipment consists of equipment being utilized under rental agreements accounted for on a monthly basis as an operating lease, as well as service pool equipment. Service pool equipment is equipment owned and maintained by us that is swapped for equipment that needs repair or maintenance by us while being used by a patient. We record a provision for any excess, lost or damaged equipment when warranted based on an assessment of the equipment.

We assess impairment whenever events or changes in circumstances indicate that the carrying amount of the asset is impaired or the estimated useful life is no longer appropriate. Circumstances such as changes in technology or in the way an asset is being used may trigger an impairment review. For additional information, see Notes 2(i) and 2(j) to the Consolidated Financial Statements.

#### ***Inventories***

Inventories are stated at the lower of cost or net realizable value. We regularly evaluate the ability to realize the value of inventory. If the inventories are deemed damaged, if actual demand for our devices declines, or if market conditions are less favorable than those projected, inventory write-offs may be required. For additional information, see Note 2(h) to the Consolidated Financial Statements.

#### ***Income taxes***

As part of the process of preparing our consolidated financial statements, we are required to calculate our income taxes based on taxable income by jurisdiction. We make certain estimates and judgments in determining our income taxes, including assessment of our uncertain tax positions, for financial statement purposes. Significant changes to these estimates may result in an increase or decrease to our tax provision in the subsequent period when such a change in estimate occurs.

Uncertain tax positions are based on estimates and assumptions that have been deemed reasonable by management. Our estimates of unrecognized tax benefits and potential tax benefits may not be representative of actual outcomes.

For additional information, see Note 14 to the Consolidated Financial Statements.

## Results of operations

The following discussion provides an analysis of our results of operations and reasons for material changes therein for 2023 as compared to 2022. See "Results of Operations" in Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations in the Company's 2022 Annual Report on Form 10-K, filed with the SEC on February 23, 2023, for an analysis of the 2022 results as compared to 2021.

The following table sets forth our consolidated statements of operations data:

	Year ended December 31,		
U.S. dollars in thousands, except share and per share data	2023	2022	2021
Net revenues	\$ 509,338	\$ 537,840	\$ 535,031
Cost of revenues	128,280	114,867	114,877
Gross profit	381,058	422,973	420,154
Operating costs and expenses:			
Research, development and clinical studies	223,062	206,085	201,303
Sales and marketing	226,809	173,658	137,057
General and administrative	164,057	132,753	126,127
Total operating costs and expenses	613,928	512,496	464,487
Operating income (loss)	(232,870)	(89,523)	(44,333)
Financial (expenses) income, net	41,130	7,677	(7,742)
Income (loss) before income tax	(191,740)	(81,846)	(52,075)
Income tax	15,303	10,688	6,276
Net income (loss)	\$ (207,043)	\$ (92,534)	\$ (58,351)
Basic and diluted net income (loss) per ordinary share	\$ (1.95)	\$ (0.88)	\$ (0.56)
Weighted average number of ordinary shares used in computing basic and diluted net income (loss) per share	106,391,178	104,660,476	103,433,274

The following table details the share-based compensation expense included in costs and expenses:

	Year ended December 31,		
U.S. dollars in thousands	2023	2022	2021
Cost of revenues	\$ 6,587	\$ 4,690	\$ 3,471
Research, development and clinical studies	31,827	30,790	27,597
Sales and marketing	35,968	28,826	22,673
General and administrative	41,226	42,649	41,159
Total share-based compensation expense	\$ 115,608	\$ 106,955	\$ 94,900

## Key performance indicators

We believe certain commercial operating statistics are useful to investors in evaluating our commercial business as they help investors evaluate and compare the adoption of our Products from period to period. The number of active patients on therapy is our principal revenue driver. An "active patient" is a patient who is receiving treatment under a commercial prescription order as of the measurement date, including patients who may be on a temporary break from treatment and who plan to resume treatment in less than 60 days. Prescriptions are a leading indicator of demand. A "prescription received" is a commercial order for Optune Gio or Optune Lua that is received from a physician certified to treat patients with our Products for a patient not previously on Optune Gio or Optune Lua. Orders to renew or extend treatment are not included in this total.

The following table includes certain commercial operating statistics for and as of the end of the periods presented.

Operating statistics	December 31,		
	2023	2022	2021
Active patients at period end			
United States	2,162	2,164	2,259
International markets:			
Germany	525	467	563
Japan	375	369	307
Other international	693	430	458
International markets - Total	1,593	1,266	1,328
Total	3,755	3,430	3,587
Year ended December 31,			
Prescriptions received in period			
United States	3,912	3,790	3,770
International markets:			
Germany	792	830	924
Japan	354	381	436
Other international	1,025	528	532
International markets - Total	2,171	1,739	1,892
Total	6,083	5,529	5,662

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

	Year ended December 31,			
	2023	2022	Change	% Change
Net revenues	\$ 509,338	\$ 537,840	\$ (28,502)	(5) %

**Net revenues.** Net revenues decreased by \$28.5 million, or 5%, to \$509.3 million for the year ended December 31, 2023 from \$537.8 million for the year ended December 31, 2022. The decrease resulted primarily from \$48.4 million in reduced collections from denied or appealed claims in the U.S., partially offset by an increase of \$14.1 million resulting from improved reimbursement approval rates in Germany and \$11.7 million from our launch in France.

Following regulatory approval and prior to the establishment of coverage criteria, we have treated on-label patients in the U.S. at risk and appealed denied claims for commercial and Medicare fee-for-service beneficiaries on a case-by-case basis. For the year ended December 31, 2023, we recorded \$5 million in revenue from the successful appeal of previously denied claims for Medicare fee-for-service beneficiaries billed prior to established coverage, a decrease of \$27 million from \$32 million recorded for the year ended December 31, 2022. We believe collections from these claims that were most accessible were largely exhausted in 2022 and the remaining outstanding claims will take time to collect. As a result, we expect future net revenue to more closely reflect core drivers of net revenue: number of active patients on therapy, duration of therapy, and net realized price per month.

	Year ended December 31,			
	2023	2022	Change	% Change
Cost of revenues	\$ 128,280	\$ 114,867	\$ 13,413	12 %

**Cost of revenues.** Our cost of revenues were \$128.3 million for the year ended December 31, 2023, an increase of \$13.4 million, or 12%, from \$114.9 million for the year ended December 31, 2022. Excluding sales to Zai, cost of revenues per active patient per month were \$2,714 for the year ended December 31, 2023 compared to \$2,481 for the year ended December 31, 2022 driven by higher costs of arrays from our initial roll out of a next generation array and an increase in capacity of patient support services in anticipation of new indications.

Cost of revenues per active patient is calculated by dividing the cost of revenues for the year less product sales to Zai for the year by the average of the active patients at the end of the each quarter in the current year and the end

of the year active patients from the prior year. This annual figure is then divided by twelve to estimate the monthly cost of revenues per active patient. Sales to Zai are deducted because they are made at burdened cost and in anticipation of future royalties from Zai, and Zai patient counts are not included in our active patient population. Product's cost sold to Zai totaled \$12.0 million for the year ended December 31, 2023 compared to \$11.1 million for the year ended December 31, 2022.

Gross margin was 75% for the year ended December 31, 2023 and 79% for the year ended December 31, 2022. We expect that our gross margins will continue to be impacted by current and future product enhancements, such as the ongoing launch of next generation arrays. We continue to focus on opportunities to increase efficiencies and scale within our supply chain. This includes evaluating new materials, manufacturers, and processes that could lead to lower cost.

	Year ended December 31,			
	2023	2022	Change	% Change
<b>Operating expenses:</b>				
Research, development and clinical studies	\$ 223,062	\$ 206,085	\$ 16,977	8 %
Sales and marketing	226,809	173,658	53,151	31 %
General and administrative	164,057	132,753	31,304	24 %
<b>Total operating expenses</b>	<b>\$ 613,928</b>	<b>\$ 512,496</b>	<b>\$ 101,432</b>	<b>20 %</b>

*Research, development and clinical studies expenses.* Research, development and clinical studies expenses increased by \$17.0 million, or 8%, to \$223.1 million for the year ended December 31, 2023 from \$206.1 million for the year ended December 31, 2022. The change is primarily due to an increase of \$11.0 million in costs incurred in support of ongoing and anticipated clinical trial launches and regulatory filings.

Total research and development expenses can fluctuate period-to-period dependent upon the amount of clinical research organization services delivered, clinical materials procured and the number of trials actively underway within a given period.

*Sales and marketing expenses.* Sales and marketing expenses increased by \$53.2 million, or 31%, to \$226.8 million for the year ended December 31, 2023 from \$173.7 million for the year ended December 31, 2022. The change primarily was due to an increase of \$37.6 million in costs associated with geographic expansion and pre-launch activities intended to increase awareness of TTFIELDS therapy in anticipation of our launch in NSCLC, as well as an increase in non-cash personnel costs of \$7.1 million.

*General and administrative expenses.* General and administrative expenses increased by \$31.3 million, or 24%, to \$164.1 million for the year ended December 31, 2023 from \$132.8 million for the year ended December 31, 2022. The change was due to increases of \$20.2 million in costs associated with increased personnel and services to support our anticipated launch in NSCLC and new geographies, as well as \$11.1 million in costs associated with information technology services and personnel.

	Year ended December 31,			
	2023	2022	Change	% Change
<b>Financial (expenses) income, net</b>	<b>\$ 41,130</b>	<b>\$ 7,677</b>	<b>\$ 33,453</b>	<b>436 %</b>

*Financial (expenses) income, net.* Financial income, net, increased by \$33.5 million, or 436%, to \$41.1 million income for the year ended December 31, 2023 from \$7.7 million income for the year ended December 31, 2022. The increase was primarily driven by an increase in interest income of \$30.4 million and a decrease of foreign exchange expenses of \$3.1 million.

	Year ended December 31,			
	2023	2022	Change	% Change
<b>Income tax</b>	<b>\$ 15,303</b>	<b>\$ 10,688</b>	<b>\$ 4,615</b>	<b>43 %</b>

*Income taxes.* Income tax expenses increased by \$4.6 million, or 43%, resulting in a tax expense of \$15.3 million for the year ended December 31, 2023 compared to a tax expense of \$10.7 million for the year ended December 31, 2022. The increase reflects a change in the mix of applicable statutory tax rates in active jurisdictions.

#### **Non-GAAP financial measures**

We also measure our performance based upon a non-U.S. GAAP measurement of earnings before interest, taxes, depreciation, amortization and share-based compensation ("Adjusted EBITDA"). We believe Adjusted EBITDA is useful to investors in evaluating our operating performance because it helps investors evaluate and compare the results of our operations from period to period by removing the impact of earnings attributable to our capital structure, tax rate and material non-cash items, specifically share-based compensation.

We calculate Adjusted EBITDA as operating income before financial expenses and income taxes, net of depreciation, amortization and share-based compensation. The following table reconciles net loss (which is the most directly comparable U.S. GAAP operating performance measure) to Adjusted EBITDA.

	<i>Year ended December 31,</i>		
	2023	2022	2021
Net income (loss)	\$ (207,043)	\$ (92,534)	\$ (58,351)
Add: Income tax	15,303	10,688	6,276
Add: Financial expenses (income), net	(41,130)	(7,677)	7,742
Add: Depreciation and amortization	10,969	10,624	10,251
EBITDA	\$ (221,901)	\$ (78,899)	\$ (34,082)
Add: Share-based compensation	115,608	106,955	94,900
Adjusted EBITDA	<u>\$ (106,293)</u>	<u>\$ 28,056</u>	<u>\$ 60,818</u>

Adjusted EBITDA decreased by \$134.3 million, or 479%, to \$(106.3) million for the year ended December 31, 2023 from \$28.1 million for the year ended December 31, 2022. This decrease was primarily attributable to increased growth investments intended to expand our capacity to treat larger patient populations, to enhance commercial capabilities and to increase awareness of TTFields in anticipation of potential future approvals in new indications, and a reduction in revenue as described above.

#### **Liquidity and capital resources**

We have incurred significant losses and cumulative negative cash flows from operations with only limited and intermittent operating profits since our founding in 2000. As of December 31, 2023, we had an accumulated deficit of \$985.5 million. To date, we primarily have financed our operations through the issuance and sale of equity and the proceeds from long-term loans.

At December 31, 2023, we had \$240.8 million in cash and cash equivalents and \$669.8 million in short-term investments. At December 31, 2023, our cash, cash equivalents and short-term investments totaled \$910.6 million, a decrease of \$58.8 million compared to \$969.4 million at December 31, 2022. The decrease was primarily due to net cash used in operating activities partially offset by the net cash provided by the exercise of options.

We believe our cash, cash equivalents and short-term investments as of December 31, 2023 are sufficient for our operations for at least the next 12 months based on our existing business plan and our ability to control the timing of significant expense commitments. We expect that our research, development and clinical expenses, sales and marketing expenses and general and administrative expenses will continue to increase over the next several years and may outpace our gross profit. As a result, we may need to raise additional capital to fund our operations.

The following summary of our cash flows for the periods indicated has been derived from our consolidated financial statements, which are included elsewhere in this Annual Report:

U.S. dollars in thousands	Year ended December 31,		
	2023	2022	2021
Net cash provided by (used in) operating activities	\$ (73,336)	\$ 30,788	\$ 82,756
Net cash provided by (used in) investing activities	184,148	(139,957)	(144,834)
Net cash provided by (used in) financing activities	15,787	15,491	25,702
Effect of exchange rate changes on cash and cash equivalents	131	(97)	(188)
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 126,730	\$ (93,775)	\$ (36,564)

#### **Operating activities**

Net cash used in operating activities primarily represents our net loss for the periods presented. Adjustments to net loss for non-cash items include share-based compensation, depreciation, amortization and asset write-downs. Operating cash flows are also impacted by changes in operating assets and liabilities, principally trade payables, deferred revenues, other payables, prepaid expenses, inventory and trade receivables.

Net cash used in operating activities was \$73.3 million for the year ended December 31, 2023 compared to \$30.8 million provided by operating activities for the year ended December 31, 2022 a decrease of \$ 104.1 million. The decrease in net cash from operating activities was driven by a decrease in gross profits of \$41.9 million driven by a revenue decrease of \$28.5 million and an increase in costs of revenue of \$13.4 million. In addition, the decrease in net cash from operating activities was driven by increased expenses, primarily driven by a \$84.5 million increase in sales, marketing, general and administrative expenses to enhance our capabilities in anticipation of potential future approvals of new indications and entry into potential new markets, and a \$17.0 million increase in research and development expenses. In addition, finance income increased by \$33.5 million driven by higher interest returns on our investments, tax expenses increased by \$ 4.6 million and share based compensation increased by \$8.7 million.

Upcoming use of cash in operations will include payments in the normal course of business of \$43.1 million in purchase obligations with certain of our suppliers, primarily for the purchase of Product components along with other commitments to purchase goods or services. These amounts include approximately \$34.5 million of commitments with three major suppliers. We make such commitments through a combination of purchase orders, supplier contracts, and open orders based on projected demand information. We also have employment agreements with certain employees that require the funding of a specific level of payments if certain events, such as a change in control or termination without cause, occur. In the course of normal business operations, we also have agreements with contract service providers to assist in the performance of our research and development (including clinical studies) and manufacturing activities. We could also enter into additional collaborative research, contract research, manufacturing and supplier agreements in the future, which may require up-front payments and even long-term commitments of cash.

#### **Investing activities**

Our investing activities primarily consist of capital expenditures to purchase property and equipment and field equipment, as well as investments in and redemptions of our short-term investments.

Net cash provided by investing activities was \$184.1 million for the year ended December 31, 2023 compared to net cash used in investing activities of \$140.0 million for the year ended December 31, 2022. The net cash provided by investing activities for 2023 was primarily attributable to net proceeds of \$211.2 million from short-term investments, offset by \$27.1 million invested in property and equipment. The net cash used in investing activities for 2022 was primarily attributable to \$21.4 million in property and equipment and the net purchase of \$118.6 million in short-term investments.

#### **Financing activities**

To date, our primary financing activities have been the sale of equity and the proceeds from long-term loans.

Net cash provided by financing activities was \$15.8 million for the year ended December 31, 2023 compared to \$15.5 million for the year ended December 31, 2022. The net cash provided by financing activities for 2023 was primarily attributable to \$11.4 million in proceeds from the exercise of options and \$4.4 million in proceeds from the issuance of shares pursuant to the ESPP. The net cash provided by financing activities for 2022 was primarily

attributable to \$10.3 million in proceeds from the exercise of options and \$5.2 million in proceeds from the issuance of shares pursuant to the ESPP.

#### **Convertible Notes**

On November 5, 2020, we issued \$575.0 million aggregate principal amount of 0% Convertible Senior Notes due 2025 (the "Notes"). The net proceeds from the offering were approximately \$558.4 million. We intend to use the net proceeds to further advance our clinical and product development programs and to invest in associated pre-commercial and commercial activities, as well as for general corporate purposes.

The Notes are senior unsecured obligations. The Notes do not bear regular interest, and the principal amount of the Notes will not accrete. Special interest, if any, payable in accordance with the terms of the Notes will be payable in cash semi-annually in arrears on May 1 and November 1 of each year, beginning on May 1, 2021. The Notes mature on November 1, 2025, unless earlier repurchased, redeemed or converted.

The Notes are convertible at an initial conversion rate of 5.9439 ordinary shares per \$1,000 principal amount of the Notes, which is equivalent to an initial conversion price of approximately \$168.24 per ordinary share. In January 2021, we irrevocably elected to settle all conversions of Notes by a combination of cash and our ordinary shares and that the cash portion per \$1,000 principal amount of Notes for all conversion settlements shall be \$1,000. Accordingly, from and after the date of the election, upon conversion of any Notes, holders of Notes will receive, with respect to each \$1,000 principal amount of Notes converted, cash in an amount up to \$1,000 and the balance of the conversion value, if any, in our ordinary shares.

The Notes were not redeemable prior to November 6, 2023, except in the event of certain tax law changes. We may redeem for cash all or any portion of the Notes, at our option, on or after November 6, 2023 if the last reported sale price of our ordinary shares has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid special interest, if any, to, but excluding, the redemption date. No sinking fund is provided for the Notes.

Prior to the close of business on the business day immediately preceding August 1, 2025, the Notes are convertible at the option of the holders only upon the satisfaction of certain conditions and during certain periods and if we exercise our right to redeem the Notes as permitted or required by the indenture. On or after August 1, 2025 until the close of the business on the business day immediately preceding the maturity date, holders may convert all or any portion of their Notes at the conversion rate at any time irrespective of the foregoing conditions.

#### **Term loan credit facility**

On November 6, 2020, we entered into a new three-year \$150.0 million senior secured revolving credit facility with a syndicate of relationship banks (the "2020 Credit Facility").

On February 17, 2023, we gave irrevocable notice to the administrative agent under the 2020 Credit Facility that we terminated all commitments, effective February 22, 2023. This effectively terminated the 2020 Credit Facility, as our ability to borrow and our obligations to comply with all covenants ended on such date. The liens and guaranties in favor of the lenders are released. There were no early termination fees payable and as of February 22, 2023 we had no outstanding balance borrowed under the 2020 Credit Facility. On November 6, 2023, the 2020 Credit Facility expired pursuant to its terms.

As of December 31, 2023, we had no outstanding balance borrowed or any other liability outstanding under the 2020 Credit Facility.

#### **Overview**

We are a global oncology company with a proprietary platform technology called Tumor Treating Fields ("TTFields"), which are electric fields that exert physical forces to kill cancer cells via a variety of mechanisms. Our key priorities are to drive commercial adoption of Optune Gio® and Optune Lua®, our commercial TTFields therapy devices, and to advance clinical and product development programs intended to extend overall survival in some of the most aggressive forms of cancer.

Optune Gio is approved by the U.S. Food and Drug Administration ("FDA") under the Premarket Approval ("PMA") pathway for the treatment of adult patients with newly diagnosed glioblastoma ("GBM") together with temozolomide, a chemotherapy drug, and for adult patients with GBM following confirmed recurrence after chemotherapy as monotherapy treatment. We also have a CE certificate to market Optune Gio for the treatment of GBM in the

European Union ("EU"), as well as approval or local registration in the United Kingdom ("UK"), Japan, Canada and certain other countries. Optune Lua is approved by the FDA under the Humanitarian Device Exemption ("HDE") pathway to treat malignant pleural mesothelioma and pleural mesothelioma (together, "MPM") together with standard chemotherapies. We have also received CE certification in the EU and approval or local registration to market Optune Lua in certain other countries. We market Optune Gio and Optune Lua in multiple countries around the globe with the majority of our revenues coming from the use of Optune Gio in the U.S., Germany and Japan. We are actively evaluating opportunities to expand our international footprint.

We believe the physical mechanisms of action behind TTFields therapy may be broadly applicable to solid tumor cancers. We are focusing our research and development activities in areas of greatest anticipated value creation. This includes non-small cell lung cancer, brain cancers, and pancreatic cancer.

In 2023, we announced results from our phase 3 LUNAR study evaluating the use of TTFields together with standard therapies following platinum-based treatment failure in the treatment of patients with metastatic non-small cell lung cancer ("NSCLC"). Patients treated with TTFields therapy and standard therapies demonstrated a statistically significant and clinically meaningful improvement in overall survival over standard therapies alone. The LUNAR study also showed a statistically significant and clinically meaningful improvement in overall survival when patients were treated with TTFields therapy and immune checkpoint inhibitors, as compared to those treated with immune checkpoint inhibitors alone, and a positive trend in overall survival when patients were treated with TTFields therapy and docetaxel versus docetaxel alone. In December 2023, we filed a PMA application with the FDA seeking approval for the use of TTFields therapy together with standard systemic therapies for the treatment of NSCLC following progression on or after platinum-based therapy. In January 2024, we announced the FDA had accepted this submission for filing. We are investing in pre-commercial launch activities and anticipate a decision in the second half of 2024.

We have several ongoing or planned trials which will further explore the use of TTFields therapy in the treatment of NSCLC, including the phase 3 METIS and LUNAR-2 trials, as well as the phase 2 KEYNOTE B36 and LUNAR-4 trials. In addition to our trials in NSCLC, we have multiple ongoing or planned trials in our brain and pancreatic cancer programs, including the phase 3 TRIDENT, KEYNOTE D58 and PANNOVA-3 trials, and the phase 2 PANNOVA-4 trial. We anticipate expanding our clinical pipeline over time to study the safety and efficacy of TTFields therapy for additional solid tumor indications and combinations with other cancer treatment modalities.

The table below presents the current status of the ongoing clinical trials in our pipeline and anticipated timing of data.

	Phase 2	Phase 3	Anticipated Timing of Data
<b>Primary Brain Cancers</b>			
Glioblastoma	TRIDENT	→	Data anticipated in 2026
<b>Thoracic Cancers</b>			
Non-small cell lung cancer	LUNAR-2	→	
	KEYNOTE B36	→	
Brain metastases from NSCLC	METIS	→	Top-line data anticipated in Q1 2024
<b>Abdominal Cancers</b>			
Pancreatic cancer	PANNOVA-3	→	Top-line data anticipated in Q4 2024
	PANNOVA-4	→	

Our therapy is delivered through a medical device and we continue to advance our Products with the intention to extend survival and maintain quality of life for patients. We have several product development programs underway that are designed to optimize the delivery of TTFields to the target tumor and enhance patient ease of use. Our intellectual property portfolio contains hundreds of issued patents and numerous patent applications pending.

worldwide. We believe we possess global commercialization rights to our Products in oncology and are well-positioned to extend those rights into the future as we continue to find innovative ways to improve our Products.

In 2018, we granted Zai Lab (Shanghai) Co., Ltd. ("Zai") a license to commercialize our Products in China, Hong Kong, Macau and Taiwan ("Greater China") under a License and Collaboration Agreement (the "Zai Agreement"). The Zai Agreement also establishes a development partnership intended to accelerate the development of TTFields therapy in multiple solid tumor cancer indications. For additional information, see Note 12 to the Consolidated Financial Statements.

#### **Impact of COVID-19**

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. Since the pandemic began, we have followed the guidance of the WHO, the U.S. Centers for Disease Control and Prevention, and local health authorities in all of our active markets and will continue to do so. The COVID-19 pandemic did not have a material impact on our financial results through the fourth quarter of 2023. The pandemic is not having a direct impact on our day-to-day operations; however, we are still observing lingering impacts that might continue to impact our business and clinical studies in the future. For example, in many locations staffing levels at clinical trial sites have not returned to pre-pandemic levels, and our ability to conduct and monitor clinical studies may be impacted.

Given the aggressive nature of the cancers that we treat, we believe that the fundamental value proposition of the TTFields platform remains unchanged. We continue to evaluate and plan for the potential effects of a possible COVID-19 resurgence or other similar outbreak on our business moving forward. The extent to which the COVID-19 pandemic or other outbreak may impact our business and clinical studies in the future will depend on further developments, which are highly uncertain and cannot be predicted with confidence.

#### **Impact of Current Events**

On October 7, 2023, the State of Israel was attacked by and subsequently declared war on Hamas. As of the date of this filing, we believe that there is no immediate risk to our business facilities or operations. Our supply chain teams are working to increase stock levels to mitigate distribution and service risks from our suppliers in Israel.

On January 19, 2024, President Biden signed into law a continuing resolution that allowed the U.S. government to continue to be funded and operating through March 1, 2024 (some government departments can continue operating through March 8, 2024). If full appropriations or continuing resolutions are not enacted, it is likely that some U.S. Food and Drug Administration functions would be required to stop working until they are funded. As a result, the review process for new products and clinical trials could be delayed.

We view our operations and manage our business in one operating segment. Our net revenues were \$509.3 million for the year ended December 31, 2023, \$537.8 million for the year ended December 31, 2022 and \$535.0 million for the year ended December 31, 2021. Our net loss was \$207.0 million for the year ended December 31, 2023, net loss was \$92.5 million for the year ended December 31, 2022 and net loss was \$58.4 million for the year ended December 31, 2021. As of December 31, 2023, we had an accumulated deficit of \$985.5 million.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to various market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates and foreign currency exchange rates. We do not hold or issue financial instruments for trading purposes. There were no material quantitative changes in our market risk exposures between the year ended December 31, 2023 and the year ended December 31, 2022.

##### ***Interest rate sensitivity***

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. Our cash, cash equivalents and short-term investment accounts as of December 31, 2023 totaled \$910.6 million and consist of cash, cash equivalents and short-term investments with maturities of less than one year from the date of purchase. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of the interest rates in the United States. We are subject to interest rate fluctuation exposure through our investment in money market instruments which bear a variable interest rate. However, because of portfolio diversification, the

short-term nature of the instruments in our portfolio and our intent to hold non-money market instruments to maturity, a 10% change in market interest rates would not be expected to have a material impact on our financial condition or our results of operations.

***Foreign currency exchange risk***

Our consolidated results of operations and cash flow are subject to fluctuations due to changes in foreign currency exchange rates. All of our revenues are generated in the local currency for commercial markets. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States, Switzerland, Germany, Israel and Japan. Our consolidated results of operations and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates. The effect of a hypothetical 10% change in foreign currency exchange rates applicable to our business would not have a material impact on our historical consolidated financial statements. We do not currently hedge our foreign currency exchange risk; however we may engage in hedging transactions in the future.

**ITEM 8. FINANCIAL STATEMENTS****NovoCure Limited****Index to consolidated financial statements**

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## **Report of Independent Registered Public Accounting Firm**

To the Shareholders and the Board of Directors of NovoCure Limited

### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of NovoCure Limited and subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive income (loss), changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2023 and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 22, 2024 expressed an unqualified opinion thereon.

### **Basis for Opinion**

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### **Critical Audit Matter**

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

#### **Revenue recognition – Measuring variable consideration**

*Description of the Matter* As per the Company's consolidated statements of operations, the net revenues recognized during the fiscal year of 2023 amounted to a sum of \$509 million, which included variable consideration estimates. As described in Note 2 to the consolidated financial statements, the transaction price is determined based on the consideration to which the Company will be entitled to in exchange for providing Optune solution. The company provides certain patients with implicit price concessions, which results in variable consideration. The Company adjusts the transaction price for estimated implicit price concessions to reflect the revenues which the Company expects to receive.

Auditing the Company's measurement of variable consideration involved challenging judgment because the calculation involves uncertainty and subjective management assumptions about estimates of expected price concessions. The implicit discount includes both an estimate of claims that will pay at an amount less than billed and an estimate of claims that will not pay within a given time horizon. The implicit discount adjustments to the transaction price are due to concessions, not collectability concerns driven by payer credit risk.

*How We Addressed the Matter in Our Audit* We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the Company's process to calculate variable consideration, including the underlying assumptions about estimates of expected price concessions.

Our audit procedures included, among others, evaluating the methodology used, analyzing the significant assumptions, and testing the accuracy and completeness of the underlying data used in management's calculation. This included testing inputs of the calculation by reconciliation of the data between the various information systems, performing independent recalculation of the Company's estimate and evaluating the historical accuracy of management's estimates by comparing such estimates to subsequent actual results.

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

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

Tel-Aviv, Israel  
February 22, 2024

## **Report of Independent Registered Public Accounting Firm**

To the Shareholders and the Board of Directors of NovoCure Limited

### **Opinion on Internal Control over Financial Reporting**

We have audited NovoCure Limited and subsidiaries' internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control–Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO Criteria). In our opinion, NovoCure Limited and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive income (loss) changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2022 and the related notes, and our report dated February 22, 2024 expressed an unqualified opinion thereon.

### **Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### **Definition and Limitations of Internal Control Over Financial Reporting**

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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

Tel-Aviv, Israel  
February 22, 2024

**NovoCure Limited and subsidiaries**

**Consolidated balance sheets**

	December 31,	
	2023	2022
<b>U.S. dollars in thousands</b>		
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 240,821	\$ 115,326
Short-term investments	669,795	854,099
Restricted cash	1,743	508
Trade receivables, net	61,221	86,261
Receivables and prepaid expenses	22,677	25,959
Inventories	38,152	29,376
<b>Total current assets</b>	<b>1,034,409</b>	<b>1,111,529</b>
Long-term assets:		
Property and equipment, net	51,479	32,678
Field equipment, net	11,384	12,684
Right-of-use assets	34,835	23,596
Other long-term assets	14,022	11,161
<b>Total long-term assets</b>	<b>111,720</b>	<b>80,119</b>
<b>Total assets</b>	<b>\$ 1,146,129</b>	<b>\$ 1,191,648</b>

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

**NovoCure Limited and subsidiaries**

**Consolidated balance sheets**

	December 31,	
	2023	2022
<b>U.S. dollars in thousands, except share and per share data</b>		
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Trade payables	\$ 94,391	\$ 85,197
Other payables, lease liabilities and accrued expenses	84,724	73,580
Total current liabilities	<u>179,115</u>	<u>158,777</u>
Long-term liabilities:		
Long-term debt, net	568,822	565,509
Deferred revenues	—	2,878
Long term leases	27,420	18,762
Employee benefit liabilities	8,258	4,404
Other long-term liabilities	<u>18</u>	<u>148</u>
Total long-term liabilities	<u>604,518</u>	<u>591,701</u>
Total liabilities	<u>783,633</u>	<u>750,478</u>
Commitments and contingencies		
Shareholders' equity:		
Share capital -		
Ordinary shares - No par value, Unlimited shares authorized; Issued and outstanding: 107,075,754 shares and 105,049,411 shares at December 31, 2023 and December 31, 2022 respectively;	—	—
Additional paid-in capital	1,353,468	1,222,063
Accumulated other comprehensive income (loss)	( 5,469 )	( 2,433 )
Retained earnings (accumulated deficit)	<u>( 985,503 )</u>	<u>( 778,460 )</u>
Total shareholders' equity	<u>362,496</u>	<u>441,170</u>
Total liabilities and shareholders' equity	<u>\$ 1,146,129</u>	<u>\$ 1,191,648</u>

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

**NovoCure Limited and subsidiaries**

**Consolidated statements of operations**

	Year ended December 31,		
	2023	2022	2021
<b>U.S. dollars in thousands, except share and per share data</b>			
Net revenues	\$ 509,338	\$ 537,840	\$ 535,031
Cost of revenues	128,280	114,867	114,877
<b>Gross profit</b>	<b>381,058</b>	<b>422,973</b>	<b>420,154</b>
 <b>Operating costs and expenses:</b>			
Research, development and clinical studies	223,062	206,085	201,303
Sales and marketing	226,809	173,658	137,057
General and administrative	164,057	132,753	126,127
<b>Total operating costs and expenses</b>	<b>613,928</b>	<b>512,496</b>	<b>464,487</b>
 Operating income (loss)	( 232,870 )	( 89,523 )	( 44,333 )
Financial (expenses) income, net	41,130	7,677	( 7,742 )
 Income (loss) before income taxes	( 191,740 )	( 81,846 )	( 52,075 )
Income tax	15,303	10,688	6,276
<b>Net income (loss)</b>	<b>\$ ( 207,043 )</b>	<b>\$ ( 92,534 )</b>	<b>\$ ( 58,351 )</b>
 Basic and diluted net income (loss) per ordinary share	\$ ( 1.95 )	\$ ( 0.88 )	\$ ( 0.56 )
Weighted average number of ordinary shares used in computing basic and diluted net income (loss) per share	<u>106,391,178</u>	<u>104,660,476</u>	<u>103,433,274</u>

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

**NovoCure Limited and subsidiaries**

**Consolidated statements of comprehensive income (loss)**

U.S. dollars in thousands	Year ended December 31,		
	2023	2022	2021
Net income (loss)	\$ ( 207,043 )	\$ ( 92,534 )	\$ ( 58,351 )
<u>Other comprehensive income (loss), net of tax :</u>			
Change in foreign currency translation adjustments	1,473	1,425	302
Unrealized gain (loss) from debt securities	445	( 445 )	—
Pension benefit plan	( 4,954 )	( 244 )	361
Total comprehensive income (loss)	<u>\$ ( 210,079 )</u>	<u>\$ ( 91,798 )</u>	<u>\$ ( 57,688 )</u>

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

**NovoCure Limited and subsidiaries**

**Statements of changes in shareholders' equity**

U.S. dollars in thousands, except share data	Ordinary shares		Additional paid-in capital	Accumulated other comprehensive income (loss)	Retained earnings (accumulated deficit)	Total shareholders' equity
	(Shares)					
Balance as of December 31, 2020	102,334,276		\$ 1,111,435	\$ ( 3,832 )	\$ ( 631,077 )	\$ 476,526
Share-based compensation	—		94,900	—	—	94,900
Exercise of options	1,585,617		21,182	—	—	21,182
Issuance of shares in connection with employee stock purchase plan	51,370		4,546	—	—	4,546
Cumulative effect adjustment resulting from ASU 2020-06 early adoption (see Note 2(y))	—		( 132,474 )	—	3,502	( 128,972 )
Other comprehensive income (loss) net of tax expense of \$ 0	—		—	663	—	663
Net income (loss)	—		—	—	( 58,351 )	( 58,351 )
Balance as of December 31, 2021	103,971,263		1,099,589	( 3,169 )	( 685,926 )	410,494
Share-based compensation	—		106,955	—	—	106,955
Exercise of options	991,884		10,295	—	—	10,295
Issuance of shares in connection with employee stock purchase plan	86,264		5,224	—	—	5,224
Other comprehensive income (loss) net of tax expense of \$ 0	—		—	736	—	736
Net income (loss)	—		—	—	( 92,534 )	( 92,534 )
Balance as of December 31, 2022	105,049,411		1,222,063	( 2,433 )	( 778,460 )	441,170
Share-based compensation	—		115,608	—	—	115,608
Exercise of options	1,823,851		11,381	—	—	11,381
Issuance of shares in connection with employee stock purchase plan	202,492		4,416	—	—	4,416
Other comprehensive income (loss), net of tax expense of \$ 0	—		—	( 3,036 )	—	( 3,036 )
Net income (loss)	—		—	—	( 207,043 )	( 207,043 )
Balance as of December 31, 2023	107,075,754		\$ 1,353,468	\$ ( 5,469 )	\$ ( 985,503 )	\$ 362,496

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

**NovoCure Limited and subsidiaries**

**Consolidated statements of cash flows**

U.S. dollars in thousands	Year ended December 31,		
	2023	2022	2021
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ (207,043)	\$ (92,534)	\$ (58,351)
<b>Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:</b>			
Depreciation and amortization	10,969	10,624	10,251
Accrued interest	(95)	(2,216)	(94)
Asset write-downs and impairment of field equipment	493	955	649
Share-based compensation	115,608	106,955	94,900
Foreign currency remeasurement loss (gain)	161	(3,256)	3,231
Decrease (increase) in accounts receivables and prepaid expenses	29,414	2,547	5,270
Amortization of discount (premium)	(23,084)	(1,536)	3,101
Decrease (increase) in inventories	(8,919)	(4,342)	2,483
Decrease (increase) in other long-term assets	4,072	7,107	4,519
Increase (decrease) in accounts payables and accrued expenses	14,869	14,257	27,777
Increase (decrease) in other long-term liabilities	(9,781)	(7,773)	(10,980)
<b>Net cash provided by (used in) operating activities</b>	<b>\$ (73,336)</b>	<b>\$ 30,788</b>	<b>\$ 82,756</b>
<b>Cash flows from investing activities:</b>			
Purchase of property, equipment and field equipment	(27,093)	(21,358)	(24,170)
Proceeds from maturity of short-term investments	1,214,982	1,179,289	958,000
Purchase of short-term investments	(1,003,741)	(1,297,888)	(1,078,664)
<b>Net cash provided by (used in) investing activities</b>	<b>\$ 184,148</b>	<b>\$ (139,957)</b>	<b>\$ (144,834)</b>

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

**NovoCure Limited and subsidiaries**

**Consolidated statements of cash flows**

U.S. dollars in thousands	Year ended December 31,		
	2023	2022	2021
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of shares, net	\$ 4,416	\$ 5,224	\$ 4,546
Repayment of long-term debt	( 10 )	( 28 )	( 26 )
Exercise of options	11,381	10,295	21,182
Net cash provided by (used in) financing activities	\$ 15,787	\$ 15,491	\$ 25,702
<b>Effect of exchange rate changes on cash, cash equivalents and restricted cash</b>			
	\$ 131	\$ ( 97 )	\$ ( 188 )
Increase (decrease) in cash, cash equivalents and restricted cash	126,730	( 93,775 )	( 36,564 )
Cash, cash equivalents and restricted cash at the beginning of the year	115,834	209,609	246,173
<b>Cash, cash equivalents and restricted cash at the end of the year</b>	<b>\$ 242,564</b>	<b>\$ 115,834</b>	<b>\$ 209,609</b>
<b>Supplemental cash flow activities:</b>			
Cash paid during the year for:			
Income taxes paid (refunded), net	\$ 13,665	\$ 5,480	\$ 3,110
Interest paid	\$ 6	\$ 41	\$ 101
Reconciliation of cash, cash equivalents and restricted cash:			
Cash and cash equivalents	\$ 240,821	\$ 115,326	\$ 208,802
Restricted cash	\$ 1,743	\$ 508	\$ 807
<b>Total cash, cash equivalents and restricted cash</b>	<b>\$ 242,564</b>	<b>\$ 115,834</b>	<b>\$ 209,609</b>
Non-cash activities:			
Right-of-use assets obtained in exchange for lease liabilities	\$ 18,063	\$ 12,117	\$ 5,387
Purchase of property incurred but unpaid at period end	\$ 1,714	\$ —	\$ —

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

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### **NovoCure Limited and subsidiaries**

### **Notes to consolidated financial statements**

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

#### **Note 1: Organization**

NovoCure Limited (including its consolidated subsidiaries, the "Company") was incorporated in the Bailiwick of Jersey and is principally engaged in the development, manufacture and commercialization of Tumor Treating Fields ("TTFields") devices, including Optune Gio and Optune Lua (collectively, its "Products"), for the treatment of solid tumor cancers. The Company currently markets its Products in the United States ("U.S."), Germany, Japan and certain other countries. The Company also has a License and Collaboration Agreement (the "Zai Agreement") with Zai Lab (Shanghai) Co., Ltd. ("Zai") to market the Company's Products in China, Hong Kong, Macau and Taiwan ("Greater China"). See Note 12.

During the year ended December 31, 2019, the Company implemented changes to its corporate entity operating structure, including transferring certain intellectual property to its Swiss subsidiary, primarily to align corporate entities with the Company's evolving operations and business model. As of January 1, 2022, the effective place of daily management and control of the Company moved to Switzerland and the Company has become a Swiss tax resident.

In November 2023, the Company announced a series of actions to strengthen and optimize its business operations to support near-term growth drivers and long-term value creation. The plan included a reduction in headcount of approximately 200 employees or 13 % of the Company's then current workforce. The Company expects to incur total one-time costs related to the workforce reduction of approximately \$ 7,000 across the fourth quarter of 2023 and the first quarter of 2024. Restructuring costs (including severance pay, garden leave payments, etc.) in the amount of \$ 6,231 were included in the financial statements for the year ended December 31, 2023, of which \$ 262 are attributable to Cost of Goods Sold, \$ 2,070 to Research and Development, \$ 2,404 to Sales and Marketing and \$ 1,495 to General and Administrative expenses. Of these amounts, \$ 2,753 have been paid in 2023. The \$ 6,231 is offset by forfeited equity-based compensation expense and accrual reversals in the amount of \$ 9,313 and \$ 3,041 , respectively, which relate to the terminated employees' exits from the Company's equity and cash incentive plans.

#### **Note 2: Basis of presentation and significant accounting policies**

The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

##### **a. Use of estimates:**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company evaluates on an ongoing basis its assumptions, including those related to contingencies, deferred taxes, tax liabilities, useful-life of field equipment, right-of-use assets and lease liabilities, convertible notes, pension liabilities, revenue, accrued expenses and share-based compensation costs. The Company's management believes that the estimates, judgment and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities at the dates of the consolidated financial statements, and the reported amounts of net revenue and expenses during the reporting period. Actual results could differ from those estimates.

##### **b. Financial statements in U.S. dollars:**

The accompanying financial statements have been prepared in U.S. dollars in thousands, except for share and per-share data.

The Company finances its operations in U.S. dollars and a substantial portion of its costs and revenues from its primary markets is incurred in U.S. dollars. As such, the Company's management believes that the U.S. dollar is the currency of the primary economic environment in which NovoCure Limited and certain subsidiaries operate. The Company's reporting currency is U.S. dollars.

Transactions and balances denominated in U.S. dollars are presented at their original amounts. Monetary accounts maintained in currencies other than the U.S. dollar are re-measured into dollars in accordance with Accounting Standards Codification (ASC) No. 830-10, "Foreign Currency Matters." All transaction gains and losses of the re-

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**NovoCure Limited and subsidiaries**

**Notes to consolidated financial statements**

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

measurement of monetary balance sheet items are reflected in the consolidated statements of operations as financial income or expenses, as applicable.

For a subsidiary whose functional currency has been determined to be its local currency, assets and liabilities are translated at year-end exchange rates and statement of operations items are translated at average exchange rates prevailing during the year. Such translation adjustments are recorded as a separate component of accumulated other comprehensive income (loss) in shareholders' equity.

**c. Principles of consolidation:**

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Intercompany transactions and balances, including unrealized profits from intercompany sales, have been eliminated upon consolidation.

**d. Cash equivalents:**

Cash equivalents are short-term, highly liquid investments that are readily convertible into cash with a maturity of three months or less at the date acquired.

**e. Short-term investments:**

The Company accounts for investments in debt securities in accordance with ASC 320, "Investments—Debt and Equity Securities." Management determines the appropriate classification of its investments in marketable debt securities at the time of purchase and reevaluates such determinations at each balance sheet date.

Available-for-sale debt securities are carried at fair value, with the unrealized gains and losses, net of tax, reported in accumulated other comprehensive income (loss) in shareholders' equity. Realized gains and losses on sale of investments are included in financial (expenses) income, net and are derived using the specific identification method for determining the cost of securities sold.

The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization together with interest on securities is included in financial (expenses) income, net.

Each reporting period, the Company evaluates whether declines in fair value below amortized cost are due to expected credit losses, as well as the Company's ability and intent to hold the investment until a forecasted recovery occurs. Allowance for credit losses on available-for-sale debt securities are recognized in the Company's consolidated statements of operation, and any remaining unrealized losses, net of taxes, are included in accumulated other comprehensive income (loss) in stockholders' equity.

Held-to-maturity debt securities are stated at amortized cost of which is adjusted for amortization of premiums and accretion of discounts to maturity and any credit losses. Such amortization, interest or credit losses are included in the consolidated statement of operations as financial income or expenses, as appropriate.

As of December 31, 2023 and 2022, all securities are classified as held-to-maturity since the Company has the intent and ability to hold the securities to maturity and, accordingly, debt securities are stated at amortized cost.

For the years ended December 31, 2023, 2022 and 2021, no credit losses have been identified.

**f. Restricted cash**

The Company has restricted cash used as security for the use of Company credit cards and cash management, presented in short-term assets. Additionally, the Company has pledged bank deposits to cover bank guarantees related to facility rental agreements, fleet lease agreements and customs payments presented in other long-term assets (see Note 12).

**g. Trade receivables:**

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**NovoCure Limited and subsidiaries**

**Notes to consolidated financial statements**

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

The Company's trade receivables balance contains billed and unbilled commercial activities. The Company records an allowance for credit losses, if identified. The Company periodically reviews its customers' credit risk and payment history. To date, the Company has not experienced any material credit losses related to counter-party risk.

**h. Inventories:**

Inventories are stated at the lower of cost or net realizable value. Cost is determined using the weighted average method. The Company regularly evaluates its ability to realize the value of inventory. If the inventories are deemed damaged, if actual demand for the Company's devices deteriorates, or if market conditions are less favorable than those projected, inventory write-offs may be required.

Inventory write-offs of \$ 681 , \$ 917 and \$ 1,045 , respectively, were recorded for the years ended December 31, 2023, 2022 and 2021.

**i. Property and equipment:**

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets at the following rates:

	%
Computers and laboratory equipment	15 - 33
Office furniture	6 - 33
Production equipment	20
Leasehold improvements	Over the shorter of the term of the lease or its useful life

Land and assets held within construction in progress are not depreciated. Construction in progress is related to the construction or development of property and equipment that is not yet ready for its intended use.

**j. Field equipment:**

Field equipment is stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful life of the field equipment, which was determined to be 18 to 60 months. Field equipment is equipment being utilized under service agreements, and accounted for in accordance with ASC 842 on a monthly basis as an operating lease (see Note 2(x)). The Company records a write-off provision for any excess, lost or damaged equipment when warranted based on an assessment of the equipment. Write-offs for equipment are included in cost of revenues (see Note 7).

**k. Impairment of long-lived assets:**

The Company's long-lived assets are reviewed for impairment in accordance with ASC 360-10, "Property, Plant and Equipment," whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Recoverability of an asset to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the asset. If such asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. During the three years ended December 31, 2023, no impairment losses have been identified.

**l. Other long-term assets:**

Restricted deposits, long-term lease deposits associated with office rent and vehicles under operating leases, prepaid and vendors down payments are presented in other long-term assets.

**m. Revenue recognition:**

Our Products are comprised of two main components: (1) an electric field generator and (2) arrays and related accessories. We retain title to the electric field generator, and the patient is provided replacement arrays and technical support for the device during the term of treatment. The electric field generator and arrays are always supplied and function together and are not sold on a standalone basis.

The Company uses the portfolio approach to apply the standard to portfolios of contracts with similar characteristics.

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**NovoCure Limited and subsidiaries**

**Notes to consolidated financial statements**

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

To recognize revenue under ASC 606, the Company applies the following five steps:

1. *Identify the contract with a patient.* A contract with a patient exists when (i) the Company enters into an enforceable contract with a patient that defines each party's rights regarding delivery of and payment for a Product, (ii) the contract has commercial substance and (iii) the Company determines that collection of substantially all consideration for such Product is probable based on the payer's intent and ability to pay the promised consideration. The evidence of a contract generally consists of a prescription, a patient service agreement and the verification of the assigned payer for the contract and intention to collect.

2. *Identify the performance obligations in the contract.* Our contracts include the lease of the device, the supply obligation of disposable arrays and technical support for the term of treatment. To the extent a contract includes multiple promised products and/or services, the Company must apply judgment to determine whether those products and/or services are capable of being distinct in the context of the contract. If these criteria are not met the promised products and/or services are accounted for as a combined performance obligation. In the Company's case, the device, support, and disposables are provided as one inseparable package of monthly treatment for a single monthly fee. For more information, see Note 2(x).

3. *Determine the transaction price.* The transaction price is determined based on the consideration to which the Company will be entitled in exchange for providing a Product to the patient. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing either the expected value method or the most likely amount method depending on the nature of the variable consideration. In determining the transaction price, the Company includes variable consideration if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. The Company reassesses variable consideration at each reporting period and, if necessary, these estimates are adjusted to reflect the anticipated amounts to be collected when those facts and circumstances become known.

The Company has agreements with many payers that define explicit discounts off the gross transaction price. In addition to the explicit discounts negotiated with each payer, the Company expects to receive, in aggregate for a given portfolio, less than the gross revenue net of explicit discounts. ASC 606 requires that the Company recognize this variable consideration as an implicit discount at the time the goods or services are provided. The implicit discount includes both an estimate of claims that will pay at an amount less than billed and an estimate of claims that will not pay within a given time horizon. The estimation of implicit discount adjustments to the transaction price are based on historical price concession experience within payors and expected future concession. If actual amounts of consideration ultimately received differ from the Company's estimates, the Company adjusts these estimates, which would affect net revenue in the period such adjustments become known.

4. *Allocate the transaction price to performance obligations in the contract.* If a contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. As discussed above, there is a combined performance obligation under the Company's contracts and, therefore, the monthly transaction price determined for the performance obligation will be recognized over time ratably over the monthly term of the treatment.

5. *Recognize revenue when or as the Company satisfies a performance obligation.* The Company satisfies performance obligations over time. Revenue is recognized at the time the related performance obligation is satisfied by transferring a promised service to a patient. The patient consumes the benefits of treatment on a daily basis over the monthly term. As this criterion is met, the revenues will be recognized over the monthly term. For more information, see Note 2(x).

The Company elected the short-term contract exemption for the remaining transaction price disclosures, as the Company's contracts have an original expected duration of less than one year.

Revenues are presented net of indirect taxes.

The Company has elected to apply the practical expedient for financing component for transactions in which the difference between the payment date and the revenue recognition timing is up to 12 months. Payment terms between the Company and its payors are typically up to twelve months, and vary by the type of payer, country of sale and the products or services offered.

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**NovoCure Limited and subsidiaries**

**Notes to consolidated financial statements**

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

Net revenues in the years ended December 31, 2023, 2022 and 2021 also include amounts recognized pursuant to the Zai Agreement. For additional information, see Note 13.

**n. Charitable care:**

The Company provides treatment at no charge to patients who meet certain criteria under its charitable care policy. Because the Company does not pursue collection of amounts determined to qualify as charity, they are not reported as revenue. The Company's costs of care provided under charitable care were \$ 2,692 , \$ 3,009 and \$ 4,204 for the years ended December 31, 2023, 2022 and 2021, respectively. These amounts were determined by applying charitable care as a percentage of gross billings to total cost of goods sold.

**o. Shipping and handling costs:**

The Company does not separately bill its customers for shipping and handling costs associated with shipping Products to its customers. These direct shipping and handling costs of \$ 2,871 , \$ 3,211 and \$ 2,958 for the years ended December 31, 2023, 2022 and 2021, respectively, are included in Sales and Marketing costs.

**p. Accounting for share-based compensation:**

The Company accounts for share-based compensation in accordance with ASC 718, "Compensation—Stock Compensation." ASC 718 requires companies to estimate the fair value of share-based compensation awards on the date of grant using an option-pricing model. The value of the award is recognized as an expense over the requisite service periods in the Company's consolidated statements of operations. The Company's policy is to account for forfeitures as they occur.

The Company recognizes compensation costs for the value of awards granted using the accelerated method over the requisite service period of the award, which for restricted share units is two or three years and for option awards, which is two or four years .

The Company recognizes compensation costs for the value of performance stock units ("PSU") over the performance period when the vesting conditions become probable in accordance with ASC 718.

The Company applies the Black-Scholes model as it believes it is the most appropriate fair value method for all equity awards and for the Employee Share Purchase Plan (the "ESPP"). For market condition awards, the Company also applies the Monte-Carlo simulation model. The Black-Scholes model requires a number of assumptions, of which the most significant are the share price, expected volatility and the expected award term.

Beginning with the first quarter of 2022, the computation of expected volatility is based on the historical volatility the Company's shares, beginning with the first quarter of 2021 and prior to the first quarter of 2022, the computation of expected volatility is based on a combination of actual historical share price volatility of comparable publicly-traded companies and the historical volatility the Company's shares. Prior to the first quarter of 2021, due to the lack of sufficient historical information for the Company, the computation was based on actual historical volatility of comparable publicly-traded companies. Beginning with the first quarter of 2021, the expected term of options granted is calculated using the Company's historical and future exercise behavior. Prior to the first quarter of 2021, it was calculated using the average between the vesting period and the contractual term to the expected term of the options in effect at the time of grant. The Company has historically not paid dividends and has no foreseeable plans to pay dividends and, therefore, uses an expected dividend yield of zero in the option pricing model. The risk-free interest rate is based on the yield of U.S. treasury bonds with equivalent terms.

**q. Fair value of financial instruments:**

The carrying amounts of cash and cash equivalents, short-term investments, restricted cash, receivables and prepaid expenses, trade receivables, trade payables and other accounts payable and accrued expenses approximate their fair value due to the short-term maturity of such instruments.

The Company accounts for certain assets and liabilities at fair value under ASC 820, "Fair Value Measurements and Disclosures." Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

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**NovoCure Limited and subsidiaries**

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

The hierarchy below lists three levels of fair value based on the extent to which inputs used in measuring fair value are observable in the market. The Company categorizes each of its fair value measurements in one of these three levels based on the lowest level input that is significant to the fair value measurement in its entirety.

The three levels of inputs that may be used to measure fair value are as follows:

Level 1 - Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets;

Level 2 - Includes other inputs that are directly or indirectly observable in the marketplace, other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets with insufficient volume or infrequent transactions, or other inputs that are observable (model-derived valuations in which significant inputs are observable), or can be derived principally from or corroborated by observable market data; and

Level 3 - Unobservable inputs which are supported by little or no market activity.

The availability of observable inputs can vary from instrument to instrument and is affected by a wide variety of factors, including, for example, the type of instrument, the liquidity of markets and other characteristics particular to the transaction. To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment and the instrument is categorized as Level 3.

**r. Basic and diluted net loss per share:**

Basic net income (loss) per share is computed based on the weighted average number of ordinary shares outstanding during each period. Diluted net income per share is computed based on the weighted average number of ordinary shares outstanding during the period, plus potential dilutive shares considered outstanding during the period, in accordance with ASC 260-10, as determined under the treasury stock method.

**s. Income taxes:**

The Company accounts for income taxes in accordance with ASC 740-10, "Income Taxes." ASC 740-10 prescribes the use of the liability method whereby deferred tax asset and liability account balances are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, to reduce deferred tax assets to their estimated realizable value, if needed.

The Company established reserves for uncertain tax positions based on the evaluation of whether or not the Company's uncertain tax position is "more likely than not" to be sustained upon examination. The Company records interest and penalties pertaining to its uncertain tax positions in the financial statements as income tax expense.

**t. Concentration of risks:**

Our cash, cash equivalents, short-term investments and trade receivables are potentially subject to a concentration of risk. Cash, cash equivalents and short-term investments are invested at top tier financial institutions globally. As such, these investments may be in excess of insured limitations or not insured in certain jurisdictions. Generally, these investments may be redeemed upon demand and therefore, bear minimal risk.

Our trade receivables are due from numerous governments and federal and state agencies that are paid from their respective budgets, and from hundreds of health insurance companies. The Company does not believe that there are significant default risks associated with these governments, agencies and health insurance companies based upon the Company's historical experience with them.

The Company has no off-balance sheet concentrations of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

**u. Retirement, pension and severance plans:**

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### **NovoCure Limited and subsidiaries**

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

The Company has a 401(k) retirement savings plan for its U.S. employees. Each eligible employee may elect to contribute a portion of the employee's compensation to the plan. Company contributions to the plan are at the sole discretion of the Company's Board of Directors. Currently, the Company provides a matching contribution of 50 % of the employee's contributions, up to a maximum of three percent ( 3 %) of the employee's annual salary. The Company began making matching contributions as of January 1, 2019. For the years ended December 31, 2023, 2022 and 2021, the Company had made matching contributions in the amount of \$ 2,375 and \$ 2,083 and \$ 1,967 , respectively, pursuant to the plan.

The Company sponsors a defined benefit plan (the "Swiss Plan") for all its employees in Switzerland for retirement benefits, as well as benefits on death or long-term disability, whereby the employee and the Company contribute a portion of the employee's compensation to the plan. The Swiss Plan is part of a collective pension foundation "AXA Foundation for Occupational Benefits". This is a semi-autonomous pension foundation, meaning that the underlying investment risk and the longevity are born by the pension foundation itself. Disability and death risks are reinsured with AXA insurance. Notwithstanding, the Company and its employees bear the risk of having to pay recovery contributions in a financial distress situation. The Company accounts for this risk in accordance with ASC 715, "Compensation – Retirement Benefits" (see Note 9). The pension expense for the years ended December 31, 2023, 2022 and 2021 was \$ 2,672 , \$ 2,104 and \$ 1,494 , respectively.

Israeli law generally requires payment of severance pay upon dismissal of an employee or upon termination of employment in certain other circumstances. The Company contributes to employee pension plans to fund its severance liabilities. According to Section 14 of Israel Severance Pay Law, the Company makes deposits on behalf of its employees with respect to the Company's severance liability and therefore no obligation is provided for in the financial statements. Severance pay liabilities with respect to employees who are not subject to Section 14, are provided for in the financial statements based upon the number of years of service and the latest monthly salary and the related deposits are recorded as an asset based on the cash surrender value. Contributions pursuant to these obligations for the years ended December 31, 2023, 2022 and 2021 amounted to \$ 1,735 , \$ 1,594 and \$ 1,466 , respectively.

### **v. Contingent liabilities:**

The Company accounts for its contingent liabilities in accordance with ASC 450, "Contingencies." A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter.

### **w. Other comprehensive income (loss):**

The Company accounts for comprehensive income (loss) in accordance with ASC 220, "Comprehensive Income." ASC 220 establishes standards for the reporting and display of comprehensive income (loss) and its components. Comprehensive income (loss) generally represents all changes in shareholders' equity during the period except those resulting from investments by, or distributions to, shareholders. The accumulated other comprehensive income (loss), net of taxes, relates to a pension liability, unrealized gain (loss) from debt securities and foreign currency translation adjustments.

### **x. Leases:**

#### **1. Lessee accounting:**

The Company determines if an arrangement is a lease and the classification of that lease at inception based on: (1) whether the contract involves the use of a distinct identified asset, (2) whether the Company obtains the right to substantially all the economic benefits from the use of the asset throughout the period, and (3) whether the Company has a right to direct the use of the asset. The Company elected to not recognize a lease liability or right-of-use ("ROU") asset for leases with a term of twelve months or less. The Company also elected the practical expedient to not separate lease and non-lease components for its leases.

ROU assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make minimum lease payments arising from the lease. ROU assets are initially measured at amounts, which represents the discounted present value of the lease payments over the lease, plus any initial direct costs

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incurred. The ROU assets are reviewed for impairment. The lease liability is initially measured at lease commencement date based on the discounted present value of minimum lease payments over the lease term. The implicit rate within the operating leases are generally not determinable; therefore, the Company uses the Incremental Borrowing Rate ("IBR") based on the information available at commencement date in determining the present value of lease payments. The Company's IBR is estimated to approximate the interest rate on similar terms and payments and in economic environments where the leased asset is located.

Certain leases include options to extend or terminate the lease. An option to extend the lease is considered in connection with determining the ROU asset and lease liability when it is reasonably certain that the Company will exercise that option. An option to terminate is considered unless it is reasonably certain that the Company will not exercise the option.

**2. Lessor accounting - Operating leases:**

ASC 842 provides lessors with an optional practical expedient, by class of underlying asset, not to separate non-lease components from the associated lease component and, instead, to account for those components as a single component if the non-lease components otherwise would be accounted for under the revenue guidance (ASC 606) and both of the following criteria are met:

- a. The timing and pattern of transfer of the lease component and the non-lease component(s) are the same; and
- b. The lease component would be classified as an operating lease if it were accounted for separately.

The Company's product supply agreements include the right to use the device (lease component), the supply obligation of disposable arrays and technical support for the term of treatment (non-lease component).

If the lease component is the predominant component, the Company accounts for all revenues under such lease as a single component in accordance with the lease accounting standard. Conversely, if the non-lease component is the predominant component, all revenues under such lease are accounted for in accordance with the revenue recognition accounting standard. The Company's operating leases qualify for the single component accounting, and the non-lease component in each of the Company's leases is predominant. Therefore, The Company accounts for all revenues from its operating leases in accordance with the revenue recognition accounting standard.

**y. Convertible note:**

Prior to January 1, 2021, the Company accounted for its convertible senior notes in accordance with ASC 470-20 "Debt with Conversion and Other Options". Pursuant to ASC Subtopic 470-20, issuers of certain convertible debt instruments, such as the convertible senior notes, that have a net settlement feature and may be settled wholly or partially in cash upon conversion are required to separately account for the liability (debt) and equity (conversion option) components of the instrument. The Company allocated the proceeds from issuance between the liability component and the embedded conversion option, or equity component. The liability component at issuance is recognized at fair value, based on the fair value of a similar instrument of similar credit rating and maturity that does not have a conversion feature. The equity component is based on the excess of the principal amount of the convertible senior notes over the fair value of the liability component and is recorded in additional paid-in capital. The equity component, net of issuance costs is presented within additional paid-in-capital and is not remeasured as long as it continues to meet the conditions for equity classification. The Company allocated the total issuance costs incurred to the liability and equity components of the convertible senior notes based on the same proportions as the proceeds from the notes.

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2020-06, Accounting for Convertible Instruments and Contracts in an Entity's Own Equity (ASU 2020-06), which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. Among other changes, ASU 2020-06 removes from GAAP the liability and equity separation model for convertible instruments with a cash conversion feature, and as a result, after adoption, entities will no longer separately present in equity an embedded conversion feature for such debt. Similarly, the embedded conversion feature will no longer be amortized into income as interest expense over the life of the instrument. Instead, entities will account for a convertible debt instrument wholly as debt unless (1) a convertible instrument contains features that require bifurcation as a derivative under Accounting Standards Codification ("ASC Topic 815"), Derivatives and Hedging, or (2) a convertible debt instrument was issued at a

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substantial premium. Additionally, ASU 2020-06 requires the application of the if-converted method to calculate the impact of convertible instruments on diluted earnings per share (EPS), which is consistent with the Company's accounting treatment under the current standard. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, with early adoption permitted for fiscal years beginning after December 15, 2020, and can be adopted on either a fully retrospective or modified retrospective basis. The Company early adopted ASU 2020-06, effective January 1, 2021 on a modified retrospective basis.

The impact of the Company's adoption of ASU 2020-06 on the balance sheet as of January 1, 2021 was an increase in long term debt, net of \$ 128,972 , a decrease in additional paid-in capital of \$ 132,474 , and a decrease in accumulated deficit of \$ 3,502 . Interest expense recognized in future periods will be reduced as a result of accounting for the convertible debt instrument as a single liability measured at its amortized cost. For additional information see Note 10 of these audited consolidated financial statements.

### **z. Recently Issued Accounting Pronouncements:**

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-07.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* , which requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-09.

### **Note 3: Cash and Cash equivalents and Short-term investments**

Cash equivalents include items almost as liquid as cash with maturity periods of three months or less when purchased, and short-term investments include items with maturity dates between three months and one year when purchased. As of December 31, 2023 and 2022, the Company's cash and cash equivalents and short-term investments were composed of:

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	December 31, 2023							
	Fair value level	Adjusted cost basis	Unrealized gains	Unrealized losses	Fair market value	Recorded basis	Cash and cash equivalents	Short-term investments (2)
Cash		\$ 9,955	\$ —	\$ —	\$ 9,955	\$ 9,955	\$ 9,955	\$ —
Money market funds	Level 1	227,166	—	—	227,166	227,166	227,166	—
Certificate of deposits and term deposits	Level 2	153,169	—	—	153,169	153,169	3,700	149,469
HTM securities (1)								
U.S. Treasury bills	Level 1	\$ 78,844	\$ 55	\$ ( 110 )	\$ 78,789	\$ 78,844	\$ —	\$ 78,844
Government and governmental agencies	Level 2	\$ 24,940	\$ 13	\$ —	\$ 24,953	\$ 24,940	\$ —	\$ 24,940
Corporate debt securities	Level 2	\$ 416,542	\$ 486	\$ ( 149 )	\$ 416,879	\$ 416,542	\$ —	\$ 416,542
		\$ 520,326	\$ 554	\$ ( 259 )	\$ 520,621	\$ 520,326	\$ —	\$ 520,326
Total		\$ 910,616	\$ 554	\$ ( 259 )	\$ 910,911	\$ 910,616	\$ 240,821	\$ 669,795

	December 31, 2022							
	Fair value level	Adjusted cost basis	Unrealized gains	Unrealized losses	Fair market value	Recorded basis	Cash and cash equivalents	Short-term investments
Cash		\$ 9,697	\$ —	\$ —	\$ 9,697	\$ 9,697	\$ 9,697	\$ —
Money market funds	Level 1	105,629	—	—	105,629	105,629	105,629	—
Certificate of deposits, notes and term deposits	Level 2	316,946	—	—	316,946	316,946	—	316,946
HTM securities (1)								
U.S. Treasury bills	Level 1	188,030	8	( 540 )	187,498	188,030	—	188,030
Government and governmental agencies	Level 2	44,357	12	( 12 )	44,357	44,357	—	44,357
Corporate debt securities	Level 2	304,766	1,066	( 587 )	305,245	304,766	—	304,766
Total		\$ 537,153	\$ 1,086	\$ 1,139 )	\$ 537,100	\$ 537,153	\$ —	\$ 537,153
		\$ 969,425	\$ 1,086	\$ 1,139 )	\$ 969,372	\$ 969,425	\$ 115,326	\$ 854,000
		\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —

) Changes in fair value of held-to-maturity ("HTM") securities are presented for disclosure purposes as required by ASC 320 "Investments — Debt Securities" and are recorded as finance expenses only if the unrealized loss is identified as a credit loss.

) Pursuant to a bank guaranty, \$ 16,650 of short-term investments are pledged. See Note 12.

In November 2022, the Company transferred all of its AFS portfolio to HTM as part of the Company's investment strategy. Such transfers are made at fair value at the date of transfer, The net unrealized loss on these securities at the date of transfer was \$ 911 . These securities continue to be reported in accumulated comprehensive income (loss) and are amortized over the remaining lives of the securities as an adjustment to the yield. As of December 31, 2023 and 2022, the balance was fully amortized and \$ 445 , respectively.

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In accordance with ASC No. 820, the Company measures its money market funds at fair value. The fair value of the money market funds and HTM securities, which is presented for disclosure purposes, is classified within Level 1 or Level 2. This is because these assets are valued using quoted market prices or alternative pricing sources and models utilizing market observable inputs.

As of December 31, 2023 and 2022, all investments and equivalents mature in one year or less.

Unrealized losses from debt securities are primarily attributable to changes in interest rates. The Company does not believe any remaining unrealized losses represent impairments based on the evaluation of available evidence.

**Note 4: Receivables and prepaid expenses**

The following table sets forth the Company's receivables and prepaid expenses:

	<b>December 31,</b>	
	<b>2023</b>	<b>2022</b>
Advances to and receivables from suppliers	\$ 10,564	\$ 7,151
Government authorities	5,261	12,389
Prepaid expenses	6,784	6,195
Others	68	224
	<b>\$ 22,677</b>	<b>\$ 25,959</b>

**Note 5: Inventories**

Inventories are stated at the lower of cost or net realizable value. The weighted average methodology is applied to determine cost. The following table sets forth the Company's inventories:

	<b>December 31,</b>	
	<b>2023</b>	<b>2022</b>
Raw materials	\$ 10,265	\$ 4,314
Work in process	9,796	9,321
Finished goods	18,091	15,741
	<b>\$ 38,152</b>	<b>\$ 29,376</b>

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**Note 6: Property and equipment, net**

The following table sets forth the Company's property and equipment, net:

	December 31,	
	2023	2022
<b>Cost:</b>		
Computers and laboratory equipment	\$ 31,383	\$ 24,804
Office furniture	4,023	2,627
Production equipment	7,641	3,513
Land and building	\$ 24,696	\$ 15,988
Leasehold improvements	11,696	9,346
<b>Total cost</b>	<b>\$ 79,439</b>	<b>\$ 56,278</b>
Accumulated depreciation and amortization	( 27,960 )	( 23,600 )
<b>Depreciated cost</b>	<b>\$ 51,479</b>	<b>\$ 32,678</b>

The Company capitalized software costs according to FASB's ASC 350-40, "Accounting for the Costs of Computer Software Developed or Obtained for Internal Use." Cumulative capitalization as of December 31, 2023 and 2022 was \$ 18,241 and \$ 13,192 , respectively. Amortization of capitalized software costs for the years ended December 31, 2023, 2022 and 2021 was \$ 1,274 , \$ 1,056 and \$ 1,084 , respectively.

Depreciation expense was \$ 3,939 , \$ 3,105 and \$ 2,812 for the years ended December 31, 2023, 2022 and 2021, respectively.

Write downs of \$ 10 , \$ 344 and \$ 10 were identified for the years ended December 31, 2023, 2022 and 2021, respectively.

**Note 7: Field equipment, net**

The following table sets forth the Company's field equipment, net:

	December 31,	
	2023	2022
<b>Field equipment</b>		
Field equipment	\$ 38,237	\$ 36,727
Accumulated depreciation	( 26,853 )	( 24,043 )
<b>Field equipment, net</b>	<b>\$ 11,384</b>	<b>\$ 12,684</b>

Depreciation expense was \$ 5,756 , \$ 6,463 and \$ 6,355 for the years ended December 31, 2023, 2022 and 2021, respectively. Write downs of \$ 483 , \$ 611 and \$ 639 were identified for the years ended December 31, 2023, 2022 and 2021, respectively.

**Note 8: Other payables, lease liabilities and accrued expenses**

The following table sets forth the Company's other payables and accrued expenses:

	December 31,	
	2023	2022
<b>Employees and payroll accruals</b>		
Employees and payroll accruals	\$ 51,044	\$ 40,778
Deferred revenues	16,224	18,028
Government authorities	9,134	8,660
Other	8,322	6,114
<b>Other</b>	<b>\$ 84,724</b>	<b>\$ 73,580</b>

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The Company's liability in respect of the Swiss Plan (see Note 2(u)) is the projected benefit obligation calculated using the projected unit credit method. The projected benefit obligation as of December 31, 2023 represents the actuarial present value of the estimated future payments required to settle the obligation that is attributable to employee service rendered before that date. Swiss Plan assets are recorded at fair value. Pension expense is presented in the payroll expenses in the various functions in which the employees are engaged. Actuarial gains and losses arising from differences between the actual and the expected return on the Swiss Plan assets are recognized in accumulated other comprehensive income (loss) and amortized over the requisite service period. The Swiss Plan is part of a collective pension foundation of pooled investments managed by a top tier insurance company. The Company and the employees pay retirement contributions, which are defined as a percentage of the employees' covered salaries. The basis for the determination of the interest on employee's savings account is the return on plan assets, considering legal minimum requirements. The targeted allocation for these funds is as follows:

**Asset Allocation by Category as of December 31, 2023:**

Asset Category:	Asset allocation (%)
Debt Securities	33 %
Real Estate	25 %
Equity Securities	34 %
Others	8 %
<b>Total</b>	<b>100 %</b>

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The following table sets forth the Swiss Plan's funded status and amounts recognized in the consolidated financial statements for the year ended December 31, 2023 and 2022:

	December 31,	
	2023	2022
<b>Change in Benefit Obligation</b>		
Projected benefit obligation at beginning of year	\$ 29,435	\$ 29,975
Interest cost	850	62
Company service cost	2,992	2,725
Employee contributions	2,517	1,631
Prior service cost	( 768 )	484
Benefits paid	6,726	423
Actuarial loss	9,305	( 5,865 )
Projected benefit obligation at end of year	<u>\$ 51,057</u>	<u>\$ 29,435</u>
<b>Change in Plan Assets</b>		
Fair value of plan assets at beginning of year	\$ 25,531	\$ 25,967
Actual return on plan assets	4,699	( 4,937 )
Employer contributions	3,776	2,446
Employee contributions	2,518	1,631
Benefits paid	6,726	424
Fair value of plan assets at end of year	<u>\$ 43,250</u>	<u>\$ 25,531</u>
<b>Funded Status at End of year</b>		
Excess of obligation over assets	<u>\$ 7,807</u>	<u>\$ 3,904</u>
<b>Change in Accrued Benefit Liability</b>		
Accrued benefit liability at beginning of year	\$ ( 3,904 )	\$ ( 4,008 )
Company contributions made during year	3,776	2,446
Net periodic benefit cost for year	( 3,058 )	( 2,078 )
Net decrease (increase) in accumulated other comprehensive loss	( 4,621 )	( 264 )
Accrued benefit liability at end of year	<u>\$ ( 7,807 )</u>	<u>\$ ( 3,904 )</u>
	December 31,	
	2023	2022
Non-current plan assets	\$ 43,250	\$ 25,531
Non-current liability	51,057	29,435
Accrued benefit liability at end of year	<u>\$ ( 7,807 )</u>	<u>\$ ( 3,904 )</u>
<b>Projected Benefit Payments</b>		
Projected year 1	\$ 1,138	\$ 539
Projected year 2	1,102	744
Projected year 3	1,546	983
Projected year 4	1,577	1,065
Projected year 5	958	578
Projected years 6-10	20,127	16,940

The fair value of the plan assets is the estimated cash surrender value of the insurance contract at December 31, 2023. The level of inputs used to measure fair value was Level 2.

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	Year ended December 31,	
	2023	2022
<b>Net Periodic Benefit Cost</b>		
Service cost	\$ 2,992	\$ 2,725
Interest cost (income)	850	62
Expected return on plan assets	( 1,210 )	( 701 )
Amortization of actuarial (gain) loss	94	117
Amortization of prior service costs	( 54 )	( 99 )
Total net periodic benefit cost	<u><u>\$ 2,672</u></u>	<u><u>\$ 2,104</u></u>
<b>Weighted average assumptions:</b>		
Discount rate as of December 31	<u><u>1.40 %</u></u>	<u><u>2.30 %</u></u>
Expected long-term rate of return on assets	<u><u>3.00 %</u></u>	<u><u>3.50 %</u></u>
Rate of compensation increase	<u><u>1.50 %</u></u>	<u><u>1.50 %</u></u>
Mortality and disability assumptions (*)	<u><u>BVG 2020 GT</u></u>	<u><u>BVG 2020 GT</u></u>

(\*) Mortality data used for actuarial calculation.

**Note 10: Long-term debt, net**

The following table sets forth the Company's long-term debt, net:

	December 31,	
	2023	2022
0 % Convertible Senior Notes (a)	\$ 568,822	\$ 565,509
Credit facility (b)	—	—
	<u><u>\$ 568,822</u></u>	<u><u>\$ 565,509</u></u>

**a. Convertible Notes**

On November 5, 2020, the Company issued \$ 575,000 aggregate principal amount of 0 % Convertible Senior Notes due 2025 (the "Notes"). The net proceeds from the offering were approximately \$ 558,400 .

The Notes are senior unsecured obligations of the Company. The Notes do not bear regular interest, and the principal amount of the Notes will not accrete. Special interest, if any, payable in accordance with the terms of the Notes will be payable in cash semi-annually in arrears on May 1 and November 1 of each year, beginning on May 1, 2021. The Notes mature on November 1, 2025, unless earlier repurchased, redeemed or converted.

The Notes are convertible into cash, the Company's ordinary shares or a combination of cash and the Company's ordinary shares at the Company's election at an initial conversion rate of 5.9439 ordinary shares per \$1,000 principal amount of the Notes, which is equivalent to an initial conversion price of approximately \$ 168.24 per ordinary share.

In January 2021, the Company irrevocably elected to settle all conversions of Notes by a combination of cash and the Company's ordinary shares and that the cash portion per \$ 1,000 principal amount of Notes for all conversion settlements shall be \$ 1,000 . Accordingly, from and after the date of the election, upon conversion of any Notes,

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holders of Notes will receive, with respect to each \$ 1,000 principal amount of Notes converted, cash in an amount up to \$ 1,000 and the balance of the conversion value, if any, in ordinary shares (the "Conversion Shares").

The Notes are not redeemable prior to November 6, 2023, except in the event of certain tax law changes. The Company may redeem for cash all or any portion of the Notes, at the Company's option, on or after November 6, 2023 if the last reported sale price of the Company's ordinary shares has been at least 130 % of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption at a redemption price equal to 100 % of the principal amount of the Notes to be redeemed, plus accrued and unpaid special interest, if any, to, but excluding, the redemption date. No sinking fund is provided for the Notes.

Prior to the close of business on the business day immediately preceding August 1, 2025, the Notes are convertible at the option of the holders only upon the satisfaction of certain conditions and during certain periods as described below and if the Company exercises its right to redeem the Notes as permitted or required by the Indenture as described below. On or after August 1, 2025 until the close of the business on the business day immediately preceding the maturity date, holders may convert all or any portion of their Notes at the conversion rate at any time irrespective of the foregoing conditions.

If holders of at least \$ 3,000 aggregate principal amount of the Notes provide the Company with reasonable evidence that the trading price per \$ 1,000 principal amount of Notes (the "Note Trading Price") on any trading day would be less than 98 % of the product of the last reported sale price of the Ordinary Shares on such trading day and the conversion rate on such trading day (the "Trigger Note Price"), the Company shall follow the process for obtaining the Note Trading Price as provided in the Indenture on a daily basis until the Note Trading Price exceeds the Trigger Note Price. During this time, if during any five consecutive trading day period (the "Measurement Period") the Note Trading Price is less than 98 % of the Trigger Note Price, the Company must notify the holders and the trustee of such an event and the holders may convert their Notes into Ordinary Shares at any time during the five business day period immediately after.

If the Company intends to (i) issue warrants/rights/options to existing shareholders with an exercise price less than the ten-day trailing last trading price average or (ii) distribute to shareholders assets, securities or rights with a value per share greater than 10 % of the last reported trading price, then the Company must give holders of the Notes thirty-five ( 35 ) trading days' notice of such event, at which time a holder may convert their Notes during such 35 trading day period (or until the Company revokes its decision to issue/distribute the securities, whichever comes sooner).

In addition, upon the occurrence of a fundamental change (as defined in the indenture), holders may require the Company to repurchase for cash all or any portion of their Notes at a fundamental change repurchase price equal to 100 % of the principal amount of the Notes to be repurchased, plus accrued and unpaid special interest, if any, to, but excluding, the fundamental change repurchase date. In addition, following certain corporate events that occur prior to the maturity date or if the Company delivers a notice of redemption, the Company will, in certain circumstances, increase the conversion rate for a holder who elects to convert its Notes in connection with such a corporate event or notice of redemption, as the case may be.

As of December 31, 2023, the conditions allowing holders of the Notes to convert were not met. The Notes are therefore not convertible as of December 31, 2023 and are classified as long-term liability.

The net carrying amount of the liability of the Convertible Notes (see note 2(y) for additional information) as of December 31, 2023 and 2022 are as follows:

	December 31,	
	2023	2022
<b>Liability component, net:</b>		
Principal amount	\$ 575,000	\$ 575,000
Unamortized issuance costs	( 6,178 )	( 9,491 )
Net carrying amount of liability component (1)	\$ 568,822	\$ 565,509

.) An effective interest rate determines the fair value of the Notes, therefore they are categorized as Level 3 in accordance with ASC 820, "Fair Value Measurements and Disclosures." The estimated fair value of the Net

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carrying amount of liability component of the Notes as of December 31, 2023 and 2022 were \$ 515,962 and \$ 455,091 , respectively.

The net carrying amount of the liability is represented by the principal amount of the Notes, less total issuance costs plus any amortization of issuance costs. The total issuance costs upon issuance of the Notes were \$ 16,561 and are amortized to interest expense using the effective interest rate method over the contractual term of the Notes. Interest expense is recognized at an annual effective interest rate of 0.59 % over the contractual term of the Notes. Amortization of debt issuance costs, included in finance expenses, for the years ended December 31, 2023, 2022 and 2021 was \$ 3,313 , \$ 3,293 , and \$ 3,339 , respectively.

#### **b. 2020 Credit Facility**

On November 6, 2020, the Company entered into a three-year \$ 150.0 million senior secured revolving credit facility with a syndicate of relationship banks (the "2020 Credit Facility").

On February 17, 2023, the Company gave irrevocable notice to the administrative agent under the 2020 Credit Facility that the Company terminated all commitments, effective February 22, 2023. This effectively terminated the 2020 Credit Facility, as the Company's ability to borrow and the Company's obligations to comply with all covenants ended on such date. The liens and guaranties in favor of the lenders are released. There were no early termination fees payable and as of February 22, 2023 the Company had no outstanding balance borrowed under the 2020 Credit Facility. On November 6, 2023, the 2020 Credit Facility expired pursuant to its terms.

As of December 31, 2023, the Company had no outstanding balance borrowed or any other liability outstanding under the 2020 Credit Facility.

#### **Note 11: Other long-term liabilities**

	<b>December 31,</b>	
	<b>2023</b>	<b>2022</b>
Leasehold improvements financing and other	\$ —	\$ 72
Unrecognized tax benefits (Note 14(e))	18	76
	<b>\$ 18</b>	<b>\$ 148</b>

#### **Note 12: Commitments and contingent liabilities**

##### **a. Operating leases**

The facilities of the Company are leased under various operating lease agreements for periods ending no later than 2044. The Company also has the option to extend the term of certain facility lease agreements and these are included in the calculation of right-of-use assets. The Company also leases motor vehicles under various operating leases, which expire on various dates, the latest of which is in 2026.

Under ASC 842, all leases with durations greater than 12 months, including non-cancellable operating leases, are recognized on the balance sheet. The aggregated present value of lease payments is recorded as a long-term asset titled right-of-use assets. The corresponding lease liabilities are split between other payables and long-term lease liabilities, and as of December 31, 2023, are as follows:

	<b>December 31,</b>
	<b>2023</b>
<b>Future minimum lease payments:</b>	
2024	\$ 8,748
2025	8,126
2026	6,558
2027	5,315
2028	4,553
Thereafter	<b>9,039</b>

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Total future minimum lease payments	\$ 42,339
Less imputed interest	( 6,695 )
Net present value of future minimum lease payments	<u>\$ 35,644</u>
Current year end	
Short-term lease liabilities	\$ 8,224
Long-term lease liabilities	27,420
Net present value of future minimum lease payments	<u>\$ 35,644</u>
Weighted average of remaining operating lease term (years)	<u>6.68</u>
Weighted average of operating lease discount rate	<u>5.59 %</u>

Lease and rental expense for the years ended December 31, 2023, 2022 and 2021 was \$ 8,196 , \$ 7,108 , and \$ 7,349 , respectively.

**b. Bank guarantee and pledges**

As of December 31, 2023 and 2022 the Company pledged bank deposits of \$ 2,848 and \$ 2,296 , respectively, to cover bank guarantees in respect of its leases of operating facilities and obtained guarantees by the bank for the fulfillment of the Company's lease commitments of \$ 3,216 and \$ 2,459 , respectively. In addition, € 15,000 (\$ 16,650 ) of the Company's short term investments are pledged to a bank as guarantee for the Company's due execution of cash concentration agreements.

**c. Zai License and Collaboration Agreement**

On September 10, 2018, the Company entered into the Zai Agreement. Under the Zai Agreement, the Company granted Zai exclusive rights to commercialize the Company's Products in the field of oncology in China, Hong Kong, Macau and Taiwan ("Greater China"). The Zai Agreement also established a development partnership for the Company's Products in multiple solid tumor indications. In partial consideration for the license grant to Zai for Greater China, the Company was entitled to a non-refundable, up-front license fee in the amount of \$ 15,000 (the "License Fee"). The Zai Agreement also provides for certain development, regulatory and commercial milestone payments totaling up to \$ 78,000 . Furthermore, pursuant to the Zai Agreement, Zai will pay the Company tiered royalties at percentage rates from 10 up to the mid-teens on the net sales of the licensed products in Greater China. Zai is purchasing licensed products for commercial use exclusively from the Company at the Company's fully burdened manufacturing cost.

**d. Legal Proceedings**

In June 2023, a putative class action lawsuit was filed against the Company, its Executive Chairman and its Chief Executive Officer. The complaint, later amended to add our Chief Financial Officer as a defendant, purports to be brought on behalf of a class of persons and/or entities who purchased or otherwise acquired ordinary shares of the Company from January 5, 2023 through June 5, 2023, and alleges material misstatements and/or omissions in the Company's public statements with respect to the results from its phase 3 LUNAR clinical trial. The Company believes that the action is without merit and plans to defend the lawsuit vigorously. As of December 31, 2023, the Company has not accrued any amounts in respect of this claim, as it believes liability is not probable and the amount of any potential liability cannot be reasonably estimated.

**e. Purchase Obligations**

As of December 31, 2023, the Company has \$ 43,075 in purchase obligations with certain of its suppliers.

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**Note 13: Revenue recognition**

**a. Net revenues**

The Company's net revenues by geographic region, based on the patient's location are summarized as follows:

	<b>Year ended December 31,</b>		
	<b>2023</b>	<b>2022</b>	<b>2021</b>
United States	\$ 349,743	\$ 406,894	\$ 353,110
International markets:			
Germany	60,210	46,120	93,939
Japan	31,668	32,781	34,640
Other international markets	44,493	30,713	30,577
International markets - Total	136,371	109,614	159,156
Greater China (1)	23,224	21,332	22,765
Total net revenues	\$ 509,338	\$ 537,840	\$ 535,031

.) For additional information, see c below.

The company's net revenues by performance period are as follows:

	<b>Year ended December 31,</b>		
	<b>2023</b>	<b>2022</b>	<b>2021</b>
Net revenues recognized in the reporting period from performance obligations satisfied in:			
Reporting period	\$ 492,089	\$ 480,266	\$ 508,337
Previous periods	17,249	57,574	26,694
Total net revenues	\$ 509,338	\$ 537,840	\$ 535,031

**b. Contract balances**

The following table provides information about trade receivables, unbilled receivables and contract liabilities from contracts with customers::

	<b>December 31,</b>	
	<b>2023</b>	<b>2022</b>
Trade receivables	\$ 56,970	\$ 84,069
Unbilled receivables	\$ 4,251	\$ 2,192
Deferred revenues (short-term contract liabilities)	\$ (16,224)	\$ (18,028)
Deferred revenues (long-term contract liabilities)	\$ —	\$ (2,878)

During the years ended December 31, 2023, 2022 and 2021, the Company recognized \$ 18,028, \$ 17,762 and \$ 17,765, respectively, which were included in the deferred revenues (short-term contract liability) balance at January 1, 2023, 2022 and 2021.

**c. Zai agreement:**

The Company recognizes revenue pursuant to the License Agreement with Zai (see note 12) in accordance with ASC 606, "Revenue Recognition from Customers." The License Fee was deferred and recognized over the performance period commencing September 10, 2018 ("Zai Performance Period"). The potential development and regulatory milestones will be included in the transaction price when the Company concludes that achievement of the milestones is probable, and that recognition of revenue related to the milestones will not result in a significant reversal in amounts recognized in future periods, and as such have been excluded from the transaction price until

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such probability is achieved. Revenue from royalty payments are recognized in accordance with ASC 606 in the period accrued. Revenues from sales of product or rendering services are recognized upon shipping the products or rendering the services and satisfying the performance obligation.

During the year ended December 31, 2020, the Company triggered milestone payments of \$ 10,000 in the aggregate, which, along with the License Fee, are deferred and recognized over the remainder of the Zai Performance Period on a straight-line basis. For the three years ended December 31, 2023, no additional milestones were included in the transaction price.

**Note 14: Income taxes**

**a. Tax provision:**

As of January 1, 2022, the effective place of daily management and control of the Company moved to Switzerland and the Company has become a Swiss tax resident. As a result, the income tax disclosures have been presented in accordance with the Company's current country of tax residency.

Income (loss) before income taxes is as follows:

	Year ended December 31,		
	2023	2022	2021
Swiss	\$ ( 281,685 )	\$ ( 269,621 )	\$ ( 145,591 )
Non-Swiss	89,945	187,775	93,516
Total income (loss) before income taxes	\$ ( 191,740 )	\$ ( 81,846 )	\$ ( 52,075 )

The provision (benefit) for income taxes from continuing operations is comprised of:

	Year ended December 31,		
	2023	2022	2021
Current:			
Swiss	\$ 2,163	\$ 469	\$ 281
Non-Swiss	13,140	10,219	5,995
Total current	\$ 15,303	\$ 10,688	\$ 6,276
Deferred:			
Swiss	\$ —	\$ —	\$ —
Non-Swiss	—	—	—
Total deferred	—	—	—
Total income tax provision	\$ 15,303	\$ 10,688	\$ 6,276

**b. Theoretical tax**

The Company's effective tax rate is affected by the tax rates in the various jurisdictions in which the Company operates. Under Swiss law, the Company is subject to income tax at the federal level at a statutory rate of 8.5 % as well as at the cantonal and communal levels, resulting in an aggregate corporate tax rate of 11.9 %.

For purposes of comparability, the Company used the Swiss federal statutory rate for the 2023, 2022 and 2021 tax years when presenting the Company's reconciliation of the income tax provision.

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A reconciliation of the provision for income taxes compared with the amounts at the Swiss rate was:

	Year ended December 31,		
	2023	2022	2021
Income (loss) before income taxes	\$ ( 191,740 )	\$ ( 81,846 )	\$ ( 52,075 )
Swiss federal statutory rate	8.5 %	8.5 %	8.5 %
Income tax at federal Swiss rate	\$ ( 16,298 )	\$ ( 6,957 )	\$ ( 4,426 )
Change in valuation allowance	13,427	( 14,238 )	11,643
Foreign taxes rate differential	10,620	25,716	1,601
Return to provision true-ups	10,854	( 1,020 )	2,416
Research and development credits	( 6,483 )	( 4,898 )	( 2,216 )
Share based compensation	2,332	5,318	( 4,636 )
Withholding Taxes	435	548	273
Effect of tax law change	6	5,681	—
Other	410	538	1,621
Income tax	<u>\$ 15,303</u>	<u>\$ 10,688</u>	<u>\$ 6,276</u>
Effective tax rate	( 8.0 )%	( 13.1 )%	( 12.1 )%

**c. Deferred income tax**

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows:

	December 31,	
	2023	2022
<b>Deferred tax assets:</b>		
Unamortized intangible assets	\$ 153,450	\$ 153,450
Net operating loss carryforwards	\$ 99,743	\$ 65,472
Impact of revenue recognition	\$ 79,934	\$ 82,972
Share based compensation	\$ 32,639	\$ 30,009
Lease liabilities	\$ 8,128	\$ 5,846
Capitalized research and development	\$ 2,783	\$ 16,730
Research and development credits	\$ 1,615	\$ 8,992
Other temporary differences	\$ 7,809	\$ 7,089
Total gross deferred tax assets	<u>\$ 386,101</u>	<u>\$ 370,560</u>
Less: valuation allowance	<u>( 375,375 )</u>	<u>( 361,358 )</u>
Total deferred tax assets	<u>10,726</u>	<u>9,202</u>
<b>Deferred tax liabilities:</b>		
Right of use assets	7,962	5,785
Fixed assets	1,914	1,730
Other liabilities	850	1,687
Total gross deferred tax liabilities	<u>\$ 10,726</u>	<u>\$ 9,202</u>
Net deferred taxes assets (liability)	<u>\$ —</u>	<u>\$ —</u>

**d. Carryforward loss:**

In Switzerland, the Company had \$ 821,963 of net operating carryforwards (NOLs) available at the Federal level, of which \$ 794,203 are also available at the cantonal and communal level. These NOLs expire from 2026 through

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2030. Additionally, the Company had \$ 29,357 of non-Swiss NOLs as of December 31, 2023, of which \$ 1,968 carry forward indefinitely, and the remainder expire from 2024 through 2042.

#### **e. Uncertain tax benefits:**

A reconciliation of the beginning and ending balances of uncertain tax benefits is as follows:

	<b>December 31,</b>		
	<b>2023</b>	<b>2022</b>	<b>2021</b>
Balance at beginning of the year	\$ 76	\$ 154	\$ 297
Additions (reductions) for taxes positions related to prior years	( 58 )	( 78 )	( 143 )
Balance at the end of the year	<u><u>\$ 18</u></u>	<u><u>\$ 76</u></u>	<u><u>\$ 154</u></u>

The Company recognizes interest and penalties related to unrecognized tax benefits in tax expense. During the years ended December 31, 2023, 2022 and 2021, the Company accrued \$ 2 , \$ 2 and \$ 5 , respectively, for interest and penalties expenses related to uncertain tax positions.

The Company files income tax returns in the Switzerland and various foreign jurisdictions. Currently, the Company is under examination by the tax authorities in Israel for the tax years 2019 and 2020 and is not under examination by any other tax authority. Additional tax years within the period from 2019 to 2022 remain subject to examination by Swiss, U.S. and other tax authorities.

#### **Note 15: Share capital**

Share capital is composed as follows:

	<b>Issued and outstanding</b>	
	<b>Number of shares</b>	<b>December 31,</b>
	<b>2023</b>	<b>2022</b>
Ordinary shares no par value	107,075,754	105,049,411

#### **Equity incentive plans:**

##### **Stock option plan**

Until the IPO in October 2015, the Company maintained and granted option awards under the 2003 Share Option Plan (the "2003 Plan") and the 2013 Equity Incentive Share Option Plan (the "2013 Plan") for the Company's officers, directors, employees and advisors. The 2003 Plan and the 2013 Plan terminated as of the IPO as to future awards, but they continue to govern option awards previously granted thereunder.

In September 2015, the Company adopted the 2015 Omnibus Incentive Plan (the "2015 Plan"). The Company's shareholders approved the 2015 Plan in September 2015. Under the 2015 Plan, the Company can issue various types of equity compensation awards such as restricted shares, performance shares, restricted stock units ("RSUs"), performance share units ("PSUs"), long-term cash award and other share-based awards. Options granted under the 2015 Plan generally have a vesting period of two or four years and expire ten years after the date of grant. RSUs granted under the 2015 Plan vest in equal installments over two or three years . PSUs granted under the 2015 Plan generally vest have a vesting period between three and six years , as performance targets are attained. Options, RSUs and PSUs granted under the 2015 Plan that are canceled before expiration become available for future grants.

On December 31, 2023, in accordance with the terms of the 2015 Plan, the number of shares available for issuance under the 2015 Plan automatically increased by 4 % of the Company's outstanding ordinary shares as of December 30, 2023. As a result, the number of shares available for issuance under the 2015 Plan increased from 43,465,227 shares to 47,743,427 shares. As of December 31, 2023, 22,896,258 ordinary shares are available for grant under the 2015 Plan.

##### **Employee Stock Purchase Plan**

In September 2015, the Company adopted an ESPP to encourage and enable eligible employees to acquire ownership of the Company's ordinary shares purchased through accumulated payroll deductions on an after-tax

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basis. The ESPP is intended to be an "employee stock purchase plan" within the meaning of Section 423 of the Code and the provisions of the ESPP will be construed in a manner consistent with the requirements of such section. The Company began its offerings under the ESPP on August 1, 2016. The Company issued 202,492 ordinary shares for the plan period from January 1, 2023 through December 31, 2023.

The terms of the ESPP provide that on December 31 of each year, the number of shares available for purchase by eligible employees who participate in the ESPP automatically increases by 1 % of the Company's outstanding ordinary shares outstanding, unless the Company determines that such an increase is not necessary. The Company determined that an such increase was not necessary and no such increase took place. As of December 31, 2023, 5,735,791 ordinary shares are available for offering under the ESPP.

The fair value of share-based awards was estimated using the Black-Scholes model for all equity grants and for market condition awards. The Company also applied the Monte-Carlo simulation model, with the following underlying assumptions:

	Year ended December 31,		
	2023	2022	2021
<b>Stock Option Plans</b>			
Expected term (years)	5.50 - 6.00	5.33 - 5.83	5.50 - 6.00
Expected volatility	63 %- 70 %	60 %- 62 %	60 %- 63 %
Risk-free interest rate	3.48 %- 4.79 %	1.58 %- 4.23 %	0.78 %- 1.27 %
Dividend yield	0.00 %	0.00 %	0.00 %
<b>ESPP</b>			
Expected term (years)	0.50	0.50	0.50
Expected volatility	56 %- 122 %	51 %- 77 %	54 %- 81 %
Risk-free interest rate	4.76 %- 5.38 %	0.19 %- 2.52 %	0.05 %- 0.09 %
Dividend yield	0.00 %	0.00 %	0.00 %

A summary of the status of the Company's options to purchase ordinary shares as of December 31, 2023 and changes during the year ended on that date is presented below:

	Year ended December 31, 2023		
	Number of options	Weighted average exercise price	Aggregate intrinsic value
Outstanding at beginning of year	8,786,364	\$ 37.27	
Granted	1,192,916	55.65	
Exercised	( 827,078 )	13.73	
Forfeited and cancelled	( 612,695 )	65.82	
Outstanding at end of year	<u>8,539,507</u>	\$ 40.07	\$ 10,631
Exercisable options	<u>6,724,151</u>	\$ 31.60	\$ 10,271

A summary of the status of the Company's RSUs and PSUs as of December 31, 2023 and changes during the year ended on that date is presented below:

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	Year ended December 31, 2023		
	Number of RSUs/PSUs	Weighted average grant date fair value price	Aggregate intrinsic value
Unvested at beginning of year	5,377,459	\$ 66.87	
Granted	1,878,261	57.60	
Vested	( 996,773 )	84.24	
Forfeited and cancelled	( 445,881 )	72.12	
Unvested at end of year (1)	<u>5,813,066</u>	\$ 60.52	\$ 86,790

.) Includes PSUs that have a mix of service, market and other milestone performance vesting conditions which are vested upon achievements of market and performance conditions which are not probable, as of December 31, 2023, in accordance with ASC 718 as follows:

	December 31, 2023		
	Number of PSUs	Fair value at grant date per PSU	Total fair value at grant date
2,703,85\$	48.16	130,218	
220,533	76.97	16,974	
249,402	80.59	20,099	
15,210	87.66	1,333	
10,53\$	94.94	1,000	
161,912	114.26	18,500	
<u>3,361,441</u>	<u>\$</u>	<u>188,127</u>	

These PSUs will be expensed over the performance period when the vesting conditions become probable in accordance with ASC 718.

The total equity-based compensation expense related to all of the Company's equity incentive plans recognized for the years ended December 31, 2023, 2022 and 2021, was comprised as follows:

	Year ended December 31,		
	2023	2022	2021
Cost of revenues	\$ 6,587	\$ 4,690	\$ 3,471
Research, development and clinical studies	31,827	30,790	27,597
Sales and marketing	35,968	28,826	22,673
General and administrative	41,226	42,649	41,159
<b>Total share-based compensation expense</b>	<b>\$ 115,608</b>	<b>\$ 106,955</b>	<b>\$ 94,900</b>

As of December 31, 2023, unamortized share-based compensation costs amounted to \$ 98,565 and are expected to be recognized over a weighted average period of approximately 1.64 years.

The weighted average grant date exercise price of the Company's options granted during the years ended December 31, 2023, 2022 and 2021 were \$ 55.65 , \$ 78.69 and \$ 149.96 per share, respectively.

The weighted average grant date fair value of the Company's options granted during the years ended December 31, 2023, 2022 and 2021 were \$ 33.77 , \$ 44.70 and \$ 81.93 per share, respectively.

The weighted average grant date fair values of the Company's options forfeited and cancelled during the years ended December 31, 2023, 2022 and 2021 were \$ 36.54 , \$ 86.79 and \$ 62.77 , respectively.

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The fair values of the Company's RSUs and PSUs vested during the years ended December 31, 2023, 2022 and 2021 were \$ 83,968 , \$ 44,818 and \$ 29,960 , respectively.

The aggregate intrinsic values for the options exercised during the years ended December 31, 2023, 2022 and 2021 were \$ 49,679 , \$ 26,436 and \$ 143,695 , respectively. The aggregate intrinsic value is calculated as the difference between the per share exercise price and the deemed fair value of the Company's ordinary shares for each share subject to an option multiplied by the number of shares subject to options at the date of exercise. The Company deemed the fair value of the Company's ordinary shares to be \$ 14.93 , \$ 73.35 and \$ 75.08 per share as of December 31, 2023, 2022, and 2021, respectively.

Options outstanding as of December 31, 2023 are as follows:

Exercise price	Number of options outstanding	Weighted average remaining contractual term	Number of options exercisable	Weighted average remaining contractual term
		(years)		(years)
\$				
0.00 - 10.00	495,359	2.94	495,359	2.94
10.01 - 20.00	2,613,654	3.58	2,392,761	3.00
20.01 - 30.00	1,584,459	3.41	1,584,459	3.41
30.01 - 40.00	365,769	6.27	237,310	4.48
40.01 - 60.00	1,091,894	5.47	1,035,401	5.25
60.01 - 100.00	2,019,484	7.84	776,561	6.75
100.01 - 160.00	359,626	7.20	193,920	7.16
160.01 - 220.00	9,262	7.42	8,380	7.43
	<u>8,539,507</u>	<u>5.0</u>	<u>6,724,151</u>	<u>4.1</u>

**Note 16: Financial (expenses) income, net**

The following table sets forth the Company's total financial expenses, net:

	Year ended December 31,		
	2023	2022	2021
<b>Financial expenses:</b>			
Interest expense	\$ ( 6 )	\$ ( 41 )	\$ ( 101 )
Revolving credit facility fee	( 58 )	( 558 )	( 588 )
Amortization of discount and issuance costs	( 3,313 )	( 3,293 )	( 3,339 )
Foreign currency translation losses	( 797 )	( 3,523 )	( 4,032 )
Bank charges and others	( 732 )	( 698 )	( 779 )
	<u>\$ ( 4,906 )</u>	<u>\$ ( 8,113 )</u>	<u>\$ ( 8,839 )</u>
<b>Financial income:</b>			
Amortization of investments premium	\$ 26,397	\$ 4,829	\$ 306
Interest income	19,639	10,961	791
	<u>\$ 46,036</u>	<u>\$ 15,790</u>	<u>\$ 1,097</u>
<b>Total financial (expenses) income, net</b>	<b>\$ 41,130</b>	<b>\$ 7,677</b>	<b>\$ ( 7,742 )</b>

**Note 17: Basic and diluted net income (loss) per share**

Basic net income (loss) per share is computed based on the weighted average number of ordinary shares outstanding during each period. Diluted net income per share is computed based on the weighted average number of ordinary shares outstanding during the period, plus potential dilutive shares (deriving from options, RSUs, PSUs,

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convertible notes and the ESPP) considered outstanding during the period, in accordance with ASC 260-10, as determined under the treasury stock method.

The following table sets forth the computation of the Company's basic and diluted net loss per ordinary share:

	Year ended December 31,		
	2023	2022	2021
Net income (loss) attributable to ordinary shares as reported	\$ ( 207,043 )	\$ ( 92,534 )	\$ ( 58,351 )
Net income (loss) used in computing basic net income (loss) per share	\$ ( 207,043 )	\$ ( 92,534 )	\$ ( 58,351 )
Adjustment needed in calculating diluted net income (loss) per share	—	—	—
Net income (loss) used in computing diluted net income (loss) per share	<u>\$ ( 207,043 )</u>	<u>\$ ( 92,534 )</u>	<u>\$ ( 58,351 )</u>
Weighted average number of ordinary shares used in computing basic and diluted net income (loss) per share	106,391,178	104,660,476	103,433,274
Potentially dilutive shares that were excluded from the computation of basic and diluted net income (loss) per share:			
Options	6,950,781	6,387,275	7,201,495
RSUs and PSUs	1,423,377	822,421	1,017,799
Conversion of convertible note	—	—	262,903
ESPP	161,627	62,910	42,725
Weighted anti-dilutive shares outstanding which were not included in the diluted calculation	<u>8,535,785</u>	<u>7,272,606</u>	<u>8,524,922</u>
Basic and diluted net income (loss) per ordinary share	<u>\$ ( 1.95 )</u>	<u>\$ ( 0.88 )</u>	<u>\$ ( 0.56 )</u>

**Note 18: Supplemental information**

The Company operates as one reporting segment. The following table presents long-lived assets by location:

	December 31,	
	2023	2022
United States	\$ 41,634	\$ 30,012
Israel	8,317	7,180
Switzerland	7,733	5,084
Others	5,179	3,086
Total long-lived assets	<u>\$ 62,863</u>	<u>\$ 45,362</u>

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

**(a) Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. We believe that a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

**(b) Management's Annual Report on Internal Control over Financial Reporting**

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d- 15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with general accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, it used the criteria established in Internal Control- Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on such assessment, management has concluded that, as of December 31, 2023, our internal control over financial reporting is effective based on those criteria.

**(c) Attestation Report of the Registered Public Accounting Firm**

The effectiveness of our internal control over financial reporting as of December 31, 2023, has been audited by Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, an independent registered public accounting firm, as stated in their attestation report, which is included herein.

**(d) Changes in Internal Control over Financial Reporting**

There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

(a) None.

**(b) Securities Trading Plans of Executive Officers and Directors**

Rule 10b5-1 under the Exchange Act provides an affirmative defense that enables prearranged transactions in securities in a manner that avoids concerns about initiating transactions at a future date while possibly in possession of material nonpublic information. Our Insider Trading Policy permits our executive officers and directors to enter into trading plans designed to comply with Rule 10b5-1.

During the three-month period ending December 31, 2023, neither we nor any of our executive officers or directors adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that are intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) promulgated under the Securities Exchange Act of 1934, as amended or adopted or terminated a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K).

**ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

### **PART III**

#### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by Item 10 is incorporated herein by reference to the information contained under the captions "Proposal 1 — Election of Directors," "Corporate Governance," "Delinquent Section 16(A) Reports" and "Proposal 2 – Approval and Ratification of Appointment of Independent Registered Public Accounting Firm" in our definitive proxy statement related to the 2024 annual meeting of shareholders.

#### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item 11 is incorporated by reference to the information contained under the caption "2023 Director Compensation," "Compensation Discussion and Analysis — Executive Compensation" and "Compensation Committee Report" in our definitive proxy statement related to the 2024 annual meeting of shareholders.

#### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by Item 12 regarding the ownership of our ordinary shares is incorporated by reference to the information contained under the caption "Information About Stock Ownership — Security Ownership of Certain Beneficial Owners And Management" in our definitive proxy statement related to the 2024 annual meeting of shareholders.

The information required by Item 12 with respect to securities authorized for issuance under our equity compensation plans is provided under the caption "Equity Compensation Plan Information" in Part II, Item 5 hereof.

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by Item 13 is incorporated by reference to the information contained under the captions "Proposal 1 – Election of Directors," "Corporate Governance," and "Certain Relationships and Related Party Transactions" in our definitive proxy statement related to the 2024 annual meeting of shareholders.

#### **ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information required by Item 14 is incorporated by reference to the information contained under the caption "Proposal 2 – Approval and Ratification of Appointment of Independent Registered Public Accounting Firm" in our definitive proxy statement related to the 2024 annual meeting of shareholders.

**PART IV****ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES****(a) DOCUMENTS FILED AS PART OF THIS REPORT**

The following is a list of our consolidated financial statements and our subsidiaries and supplementary data included in this Annual Report on Form 10-K under Item 8 of Part II hereof:

**1. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA**

Report of Independent Registered Public Accounting Firm.

Consolidated Balance Sheets as of December 31, 2023, 2022 and 2021.

Consolidated Statements of Operations for the years ended December 31, 2023, 2022 and 2021.

Consolidated Statement of Comprehensive Loss for the years ended December 31, 2023, 2022 and 2021.

Consolidated Statements of Shareholders' Equity for the years ended December 31, 2023, 2022 and 2021

Consolidated Statements of Cash Flows for the years ended December 31, 2023, 2022 and 2021.

Notes to Consolidated Financial Statements.

**2. FINANCIAL STATEMENT SCHEDULES**

Schedules are omitted because they are not applicable or are not required, or because the required information is included in the consolidated financial statements or notes thereto.

**(b) EXHIBITS**

The following is a list of exhibits filed as part of this Annual Report on Form 10-K. Where so indicated by footnote, exhibits that were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

**EXHIBIT INDEX**

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	<a href="#">Memorandum of Association</a>	S-1/A	9/21/15	3.3	
3.2	<a href="#">Amended and Restated Articles of Association</a>	8-K	6/10/22	3.1	
4.1	<a href="#">Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934</a>	10-K	2/23/23	4.1	
4.2	<a href="#">Eleventh Amended and Restated Investors Rights Agreement, dated June 1, 2015</a>	DRS	6/24/15	4.2	
4.3	<a href="#">Tenth Amended and Restated Registration Rights Agreement, dated June 1, 2015</a>	DRS	6/24/15	4.3	
4.4	<a href="#">Indenture, dated November 5, 2020, between NovoCure Limited, and U.S. Bank National Association</a>	8-K	11/5/20	4.1	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
4.5	<a href="#">Form of 0% Convertible Senior Note due 2025 (included in Exhibit 4.4)</a>	8-K	11/5/20	4.2	
10.1	<a href="#">Credit Agreement dated November 6, 2020 among NovoCure Limited, the subsidiary borrowers party thereto, the lenders party thereto and J.P. Morgan Chase Bank, N.A., as administrative agent</a>	8-K	11/9/20	10.1	
10.2	<a href="#">License and Collaboration Agreement, dated as of September 10, 2018, between NovoCure Limited and Zai Lab (Shanghai) Co., Ltd.</a>	10-Q	10/25/18	10.2	
10.3	<a href="#">Settlement Agreement with the Technion, dated February 10, 2015</a>	DRS/A	8/11/15	10.13	
10.4	<a href="#">2003 Share Option Plan#</a>	DRS	6/24/15	10.3	
10.5	<a href="#">2013 Share Option Plan#</a>	DRS	6/24/15	10.4	
10.6	<a href="#">2015 Omnibus Incentive Plan#</a>	S-1/A	9/21/15	10.5	
10.7	<a href="#">Employee Share Purchase Plan#</a>	S-1/A	9/21/15	10.15	
10.8	<a href="#">Form of Non-Qualified Stock Option Agreement pursuant to the 2015 Omnibus Incentive Plan (U.S. individuals)#</a>	S-1/A	9/21/15	10.17	
10.9	<a href="#">Form of Incentive Stock Option Agreement pursuant to the 2015 Omnibus Incentive Plan (U.S. individuals)#</a>	S-1/A	9/21/15	10.18	
10.10	<a href="#">2015 Omnibus Incentive Plan, including 2015 Omnibus Incentive Plan Sub-Plan for Grantees Subject to Israeli Taxation and 2015 Omnibus Incentive Plan Sub-Plan for Switzerland#</a>	8-K	12/22/15	10.1	
10.11	<a href="#">Form of Incentive Stock Option Agreement pursuant to the 2015 Omnibus Incentive Plan for use in connection with the 2015 Omnibus Incentive Plan Sub-Plan for Grantees Subject to Israeli Taxation (non-102(b) grants)#</a>	8-K	12/22/15	10.2	
10.12	<a href="#">Form of Incentive Stock Option Agreement pursuant to the 2015 Omnibus Incentive Plan for use in connection with the 2015 Omnibus Incentive Plan Sub-Plan for Grantees Subject to Israeli Taxation (102(b) grants)#</a>	8-K	12/22/15	10.3	
10.13	<a href="#">Form of Stock Option Award Agreement based on the 2015 Omnibus Incentive Plan for use in connection with the 2015 Omnibus Incentive Plan Sub-Plan for Switzerland#</a>	8-K	12/22/15	10.4	
10.14	<a href="#">Form of Incentive Stock Option Agreement pursuant to the 2015 Omnibus Incentive Plan for use in Japan#</a>	8-K	12/22/15	10.5	
10.15	<a href="#">Form of Stock Option Award Agreement based on the 2015 Omnibus Incentive Plan for use in Germany#</a>	10-K	3/1/16	10.25	
10.16	<a href="#">Form of Incentive Stock Option Agreement pursuant to the 2015 Omnibus Incentive Plan#</a>	8-K	5/12/17	10.1	
10.17	<a href="#">Form of Non-Qualified Stock Option Agreement pursuant to the 2015 Omnibus Incentive Plan#</a>	8-K	5/12/17	10.2	
10.18	<a href="#">Form of Incentive Stock Option Agreement pursuant to the NovoCure Limited 2015 Omnibus Incentive Plan – Form of Performance Option Agreement for Israel#</a>	8-K	4/4/18	10.1	
10.19	<a href="#">Form of Indemnification Agreement</a>	8-K	3/22/16	10.1	
10.20	<a href="#">Employment Agreement, dated as of May 11, 2016, by and between Novocure USA LLC and William F. Doyle#</a>	8-K	5/13/16	10.1	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.21	<a href="#">Amendment #1 to Employment Agreement between Novocure USA LLC and William F. Doyle dated February 24, 2021#</a>	10-K	2/25/21	10.23	
10.22	<a href="#">Israeli SubPlan to the NovoCure Limited Employee Share Purchase Plan#</a>	8-K	6/30/16	10.1	
10.23	<a href="#">Non-Employee Director Compensation Program#</a>				X
10.24	<a href="#">Employment Agreement, dated as of October 10, 2016, by and between NovoCure (Israel) Ltd. and Asaf Danziger#</a>	8-K	10/14/16	10.1	
10.25	<a href="#">Amended and Restated Employment Agreement dated as of September 1, 2020 by and between Novocure USA LLC and Wilhelmus GroenhuySEN#</a>	8-K	8/13/20	10.1	
10.26	<a href="#">Employment Agreement, dated as of October 10, 2016, by and between NovoCure USA LLC and Michael J. Ambrogi#</a>	8-K	10/14/16	10.3	
10.27	<a href="#">Employment Agreement, dated as of September 1, 2020, by and between NovoCure USA LLC and Ashley Cordova#</a>	8-K	8/13/20	10.2	
10.28	<a href="#">Employment Agreement, dated as of July 25, 2018, between Novocure USA LLC and Pritesh Shah#</a>	10-Q	10/25/18	10.1	
10.29	<a href="#">Form of Restricted Share Unit Award Notice pursuant to the 2015 Omnibus Incentive Plan – Form of Agreement for USA#</a>	10-K	2/23/17	10.28	
10.30	<a href="#">Form of Restricted Share Unit Award Notice pursuant to the 2015 Omnibus Incentive Plan – Form of Agreement for Israel#</a>	10-K	2/23/17	10.29	
10.31	<a href="#">Form of Restricted Share Unit Award Notice pursuant to the 2015 Omnibus Incentive Plan – Form of Agreement for Switzerland#</a>	10-K	2/23/17	10.30	
10.32	<a href="#">Form of Restricted Share Unit Award Notice pursuant to the 2015 Omnibus Incentive Plan – Form of Agreement for Japan#</a>	10-K	2/23/17	10.31	
10.33	<a href="#">Form of Restricted Share Unit Award Notice pursuant to the 2015 Omnibus Incentive Plan – Form of Agreement for Germany#</a>	8-K	4/4/18	10.2	
10.34	<a href="#">Form of Performance-Based Share Unit Award for Executive Chairman and Chief Executive Officer#</a>	8-K	3/6/20	10.1	
10.35	<a href="#">Form of Performance-Based Share Unit Award for Certain Executive Officers#</a>	8-K	3/6/20	10.2	
10.36	<a href="#">First Addendum dated June 9, 2020 to License and Collaboration Agreement, dated as of September 10, 2018, between NovoCure Limited and Zai Lab (Shanghai) Co., Ltd.**</a>	10-K	2/25/21	10.40	
10.37	<a href="#">Purchase and Sale Agreement dated December 1, 2021 by and between 64 Vaughan Mall, LLC and Novocure Inc.</a>	10-K	2/24/22	10.41	
10.38	<a href="#">Construction Agreement dated December 30, 2021 by and between Hanover Development Corporation and Novocure Inc.**</a>	10-K	2/24/22	10.42	
10.39	<a href="#">Amendment No. 1 dated as of December 6, 2021 to Credit Agreement dated as of November 6, 2020</a>	10-K	2/24/22	10.43	
10.40	<a href="#">Employment Agreement, dated as of January 3, 2024, between Novocure USA LLC and Frank Leonard#</a>	8-K	1/4/24	10.1	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.41	<a href="#">Employment Agreement, dated as of January 3, 2024, between Novocure USA LLC and Pritesh Shah#</a>	8-K	1/4/24	10.2	
19	<a href="#">NovoCure Limited Policy Statement on Securities Trades by Company Officers, Directors and Employees</a>				X
21	<a href="#">Subsidiaries</a>				X
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm</a>				X
31.1	<a href="#">Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended</a>				X
31.2	<a href="#">Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended</a>				X
32.1*	<a href="#">Certification of Principal Executive Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350</a>				X
32.2*	<a href="#">Certification of Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350</a>				X
97	<a href="#">Novocure Limited Amended and Restated Policy on Recoupment of Incentive Compensation Effective as of October 2, 2023</a>				X
101.INS	Inline XBRL Instance Document				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	Inline XBRL Extension Presentation Linkbase Document				X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				X

\* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of NovoCure Limited under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

† Confidential treatment has been granted for certain information set forth in this exhibit. Such information has been omitted and filed separately with the Securities and Exchange Commission.

# Compensation plans and arrangements for executive officers and others.

\*\* Portions of the referenced exhibit have been omitted pursuant to Item 601(b)(10) of Regulation S-K

This Annual Report on Form 10-K includes trademarks of NovoCure Limited and other persons. All trademarks or trade names referred to herein are the property of their respective owners.

#### ITEM 16. FORM 10-K SUMMARY

None.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 22, 2024

NovoCure Limited

By: /s/ Asaf Danziger

Asaf Danziger

Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Date:	Signature	Title
February 22, 2024	<u>/s/ Asaf Danziger</u> Asaf Danziger	Chief Executive Officer and Director (Principal Executive Officer)
February 22, 2024	<u>/s/ Ashley Cordova</u> Ashley Cordova	Chief Financial Officer (Principal Financial and Accounting Officer)
February 22, 2024	<u>/s/ William F. Doyle</u> William F. Doyle	Executive Chairman and Director
February 22, 2024	<u>/s/ Jeryl L. Hilleman</u> Jeryl L. Hilleman	Director
February 22, 2024	<u>/s/ David T. Hung</u> David T. Hung	Director
February 22, 2024	<u>/s/ Kinyip Gabriel Leung</u> Kinyip Gabriel Leung	Director
February 22, 2024	<u>/s/ Martin J. Madden</u> Martin J. Madden	Director
February 22, 2024	<u>/s/ Allyson Ocean</u> Allyson Ocean	Director
February 22, 2024	<u>/s/ Timothy J. Scannell</u> Timothy J. Scannell	Director
February 22, 2024	<u>/s/ Kristin Stafford</u> Kristin Stafford	Director
February 22, 2024	<u>/s/ William A. Vernon</u> William A. Vernon	Director

**NovoCure Limited**  
**Non-Employee Director Compensation Program**

**1. General.** This Non-Employee Director Compensation Program (this Program) is adopted by the Board of Directors (the Board) of NovoCure Limited, a public limited company incorporated under the laws of Jersey, Channel Islands (the Company). For purposes of this Program, a “Non-Employee Director” shall mean a director of the Company who is not an employee of, or compensated consultant to, the Company or any of its subsidiaries.

**2. Annual Cash Compensation.** Each Non-Employee Director shall be entitled to an annual cash retainer fee of \$55,000 (the “Annual Retainer”). In addition to the Annual Retainer payments, Non-Employee Directors will be entitled to an annual cash retainer of (a) \$25,000 for serving as the chairperson of the Board’s Audit Committee (the “Audit Committee”), (b) \$20,000 for serving as the chairperson of the Board’s Compensation Committee (the “Compensation Committee”), (c) \$13,000 for serving as the chairperson of the Board’s Nominating and Governance Committee (the “Nominating Committee”), and (d) \$35,000 for serving as the lead independent director of the Board. In addition to the Annual Retainer payments, Non-Employee Directors will be entitled to an annual cash retainer of (a) \$15,000 for serving as a member of the Board’s Audit Committee, (b) \$10,000 for serving as a member of the Compensation Committee, and (c) \$7,000 for serving as a member of the Nominating Committee. The Annual Retainer, any annual retainer for serving as the chairperson of a committee and any annual retaining for serving as a member of a committee shall be pro-rated for any partial period of service. All cash compensation payable to Non-Employee Directors shall be payable in arrears on a quarterly basis within thirty days following the end of each fiscal quarter.

**3. Equity Awards to Non-Employee Directors.** On the date of each annual meeting of the Company’s shareholders (Annual Meeting) or such other date duly authorized by the Compensation Committee or the Board, the Compensation Committee or the Board may consider a grant of equity award(s) under the Company’s 2015 Omnibus Incentive Plan or any other applicable Company equity incentive plan then-maintained by the Company (the “Plan”) consistent with the terms below.

*Initial Awards.* Each Non-Employee Director who is initially elected or appointed to the Board on or after the Effective Date shall be granted on (a) in case of appointment between the Annual Meetings, the last trading day of the month following such election or appointment or, if such date falls during a companywide closed trading window, then on the first day on which such trading window opens and (b) in case of election by shareholders at an Annual Meeting, the date of such Annual Meeting, a non-qualified share option (an “Initial Award”) under the Plan to purchase that number of shares to the Company’s ordinary shares such that the award has an aggregate Grant Date Fair Value of \$667,000 (subject to rounding of shares to the nearest whole number). No Non-Employee Director shall be granted more than one Initial Award. For purposes of this Program, “Grant Date Fair Value” shall mean the fair value of an award as of the date of grant as determined in accordance with ASC Topic 718, “Share-Based Payment”, using the Black-Scholes pricing model (or other acceptable valuation model as in use from time to time) and the valuation assumptions used by the Company in accounting for options as of such date of grant.

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An Initial Award shall vest annually in equal installments over three years on the anniversary of the date of grant of such Initial Award (the "Grant Anniversary Date"), subject to the Non-Employee Director's continued service to the Company; provided, however, that in the case of Initial Awards granted on the date of the Company's Annual Meeting if a subsequent Annual Meeting is held prior to the Grant Anniversary Date, the annual vesting for such year shall occur the day immediately preceding the date of the Annual Meeting Date in such year, subject to the Non-Employee Director's continued service to the Company on such date.

**Annual Awards.** A Non-Employee Director who has served as a member of the Board for at least six months prior to the date of the Company's annual meeting of shareholders shall be granted equity award(s) under the Plan consisting of non-qualified share options and/or restricted share units (collectively, the "Annual Awards"). The Compensation Committee or the Board shall allocate, at the election of each Non-Employee Director either (i) 50% of the Grant Date Fair Value of the equity award to restricted share units and the remainder to non-qualified share options, or (ii) 100% of the Grant Date Fair Value of the equity award to non-qualified share options. Each Director shall make their election in writing not later than the day immediately preceding the date of each Annual Meeting; provided, however, if a Director has made an election with respect to the prior year's Annual Meeting and intends to retain the same election for the upcoming Annual Meeting, no further election is necessary. The total aggregate Grant Date Fair Value of the equity award(s) shall equal \$375,000 (subject to rounding of shares to the nearest whole number).

Each Annual Award shall vest in full on the earlier of (a) Grant Anniversary Date or (b) the day immediately preceding the date of the next Annual Meeting, subject to the Non-Employee Director's continued service to the Company.

Any equity awards made pursuant to this Program and then-outstanding shall vest in full immediately prior to a Change in Control (as defined in the Plan), subject to Non-Employee Director's continued service to the Company on such date.

4. **Effective Date.** This Program shall be effective as of February 21, 2024 (the Effective Date). The terms of this Program shall supersede any prior compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors.

5. **Expense Reimbursements.** Each Non-Employee Director will be entitled to reimbursement for all reasonable and documented expenses incurred in the performance of his or her duties as a director of the Company, including up to \$5,000 per year in tax preparation services related to their service as a director, pursuant to the terms of any applicable Company expense reimbursement policy that is in effect from time to time.

6. **Program Subject to Amendment, Modification and Termination.** This Program may be amended, modified or terminated by the Board or Compensation Committee at any time, or from time to time, in their sole discretion. No Non-Employee Director shall have any rights hereunder unless and until an Award (as defined in the Plan) is actually granted under the Plan. Without limiting the generality of the foregoing, the Board and Compensation Committee hereby expressly reserve the authority to terminate this Program during any year up and until the election of directors at a given Annual Meeting.

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7. Taxes. The Company is not responsible for the tax consequences under federal, foreign, provincial, state or local law with respect to any compensation, fees, equity awards or other payments made pursuant to this Program.

**NOVOCURE LIMITED**

**POLICY STATEMENT ON SECURITIES TRADES BY COMPANY OFFICERS, DIRECTORS AND EMPLOYEES**

**Introduction**

In the normal course of business, employees, officers and directors of NovoCure Limited (the “**Company**”) may use or have access to confidential and material information that is not generally available to the investing public. You, as an employee, officer or director of the Company, have an important ethical and legal obligation not to engage in trading in (or gifting of) securities while in possession of material non-public information (“**insider trading**”) and to maintain the confidentiality of such non-public information. Insider trading is a crime; you and the Company may be subject to severe civil and criminal penalties as a result of insider trading or as a result of unauthorized disclosure of material non-public information.

The Company has adopted this policy statement on securities trades by Company officers, directors and employees (this “**Policy**”) to prevent violations of the U.S. insider trading laws by the Company’s officers, directors and employees and to avoid even the appearance of improper conduct by these persons. Each of the Company’s General Counsel, Chief Financial Officer, and Lead Corporate and Securities Counsel has been designated by the Company as a compliance officer for administering this Policy (each, a “**Compliance Officer**”), and any questions regarding interpretation of this Policy should be addressed to them or members of the Legal Department. The Company may from time to time designate other persons as a Compliance Officer for administering this Policy and a Compliance Officer may temporarily delegate their duties to a member of the Legal Department when such Compliance Officer is unavailable.

This Policy does not apply to open market purchases of the Company’s securities by the Company, as such activity is not permitted without prior consent of the Company’s shareholders pursuant to the terms of the Company’s Memorandum and Articles of Association.

Executive officers, directors and those employees who have been designated by the Company as insiders because they have access to material non-public information concerning the Company, and each of their family members (as defined below) and members of their households (collectively, the “**Insiders**”) are subject to special requirements concerning transactions in the Company’s securities.

This policy will be filed as an exhibit to the Company’s annual report on Form 10-K as required by such form.

**Insiders should pay particular attention to Section 13 below, regarding pre-clearance of certain transactions conducted in Company securities.**

**Policy**

**1. Prohibitions.**

- a. **No Trading on Inside Information.** You may not trade in the securities of the Company, directly or indirectly through family members or other persons or entities, while you are

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aware of material non-public information relating to the Company (except pursuant to a pre-cleared trading plan that complies with this Policy and Rule 10b5-1, as described in Section 5 below). Similarly, you may not trade in the securities of any other company if you are aware of material non-public information about that company that you obtained in the course of your employment with the Company. More information about what constitutes material information is provided in Section 3(a) below. Trading in the securities of a company includes the direct purchase and sale of those securities, and also includes the purchase and sale of any option, future or other derivative security that references the company's securities. For purposes of this Policy, trading also includes any other disposition of Company securities, including as a gift.

- b. **Blackout Periods.** No employee, including Insiders, may trade any Company securities during the two full trading day period following dissemination of the Company's annual or quarterly operating results on SEC Forms 10-K and 10-Q, respectively (See Section 3(b) below for more information). Insiders may generally trade in Company securities after such period until the fifth calendar day of the third month of the fiscal quarter. Employees and Insiders may also be subject to Event-Specific Blackout Periods under Section 13(e) below, during which they may not trade in the Company's securities. Employees and Insiders, as applicable, will be informed that they are subject to an Event-Specific Blackout Period by a Compliance Officer if the employee or Insider requests permission to trade or gift the Company's securities at a time when an Event-Specific Blackout Period is in effect. Unless a valid Rule 10b5-1 plan is in place (see Section 5(a) below), the triggering of a limit or stop-loss order is considered an improper trade if made during a blackout period. Employees should ensure any such orders are cancelled or suspended from triggering during any blackout period
- c. **No Tipping.** You may not pass material non-public information regarding a company on to others, including, without limitation, your family members, friends or acquaintances or recommend to anyone trading in any securities of that company when you are aware of such information, whether or not you receive any benefit from the other person's use of that information. This practice, known as "**tipping**," violates the securities laws and can result in the same civil and criminal penalties that apply to insider trading, even though you did not trade and did not gain any benefit from another's trading.
- d. **Disclosure of Information to Others.** The Company is required under Regulation FD of the Securities and Exchange Commission (the "**SEC**") to avoid the selective disclosure of material non-public information. The Company has established procedures for releasing material information in a manner that is designed to achieve broad public dissemination of material information immediately upon its release. You may not, therefore, disclose information to anyone outside the Company, including family members and friends, other than in accordance with those procedures. You also may not discuss the Company or its business on any social media platform, blog, chatroom, networking site or similar internet-based forum except in compliance with the Company's Disclosure of Material Information Policy and the Company's Employee Social Media Policy.
- e. **No Hedging or Pledging.** The Company considers it inappropriate for any director, officer or employee to enter into speculative transactions in Company securities. Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds, forward sales contracts and the

purchase or sale of puts, calls, options or other derivative securities based on the Company's securities by its directors, officers or employees. Therefore, directors, officers and employees are prohibited from engaging in any such transactions or similar transactions. Additionally, no director, officer or employee may pledge Company securities individually owned or through a family trust as collateral for any loan (**including using Company securities in a securities margin account, even if the Company's securities are not acquired on margin**), nor may any director, officer or employee hold Company securities owned individually or through a family trust in an account in which Company securities are purchased on margin.

- f. General. You may not assist anyone who is engaged in any of the above activities. In addition to applying to the Company's securities, these prohibitions apply to information about and securities of other companies with which the Company has a relationship and as a result of which you may acquire material non-public information, e.g., any third parties conducting clinical trials, suppliers, licensees, licensors, joint venturers or companies with which the Company is considering entering into or terminating a material business relationship or other material transaction.

These prohibitions also apply to your family members, including your spouse or domestic partner, any family members or other persons who live in your home, and any family members who do not live in your home but whose transactions in Company securities are directed by you or subject to your influence or control ("family members"). For directors who are affiliated with any entity that is a holder of the Company's securities, this Policy also applies to such entities. You will be held responsible for ensuring that securities transactions by any of these people or entities comply with this Policy.

## 2. *Penalties.*

If you engage in any of the above activities, you may subject yourself, the Company, its officers and directors and other supervisory personnel to civil and criminal liability under federal and state securities laws.

- a. Civil and Criminal Penalties. Insiders may be subject to criminal and civil fines and penalties as well as imprisonment for engaging in transactions in a company's securities or tipping others at a time when such Insiders have knowledge of material non-public information relating to that company. The SEC has imposed large penalties for tipping even when the disclosing person did not profit from the trading. The SEC, the stock exchanges and the Financial Industry Regulatory Authority use sophisticated electronic surveillance techniques to uncover insider trading.
- b. Controlling Person Liability. If the Company fails to take appropriate steps to prevent illegal insider trading, the Company may have "controlling person" liability for a trading violation, potentially resulting in significant civil and criminal penalties. The civil penalties can extend personal liability to the Company's directors, officers and other supervisory personnel if they fail to take appropriate steps to prevent insider trading.
- c. Company Sanctions. Failure to comply with this Policy may also subject you to Company-imposed sanctions, up to and including termination of your employment for cause, whether or not your failure to comply with this Policy results in a violation of law.

## 3. *Key Concepts.*

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a. **Material Information.** Information is material if there is a substantial likelihood that a reasonable investor would consider the information important, as part of the total mix of available information, in deciding whether to buy, sell or hold a security. If disclosure of the information is likely to affect the market price of a security, the information is probably material. A few examples of the type of information that would usually be considered material are:

- projections of future earnings or losses or other earnings guidance;
- earnings or other internal financial information that is inconsistent with the consensus expectations of the investment community;
- increases or decreases in dividend payments, stock splits, securities offerings or other major events regarding the Company's securities;
- possible mergers and acquisitions or major purchases or sales of assets;
- the initiation or termination of significant contracts;
- changes in senior or executive management;
- significant product development milestones, including favorable (or unfavorable) data or clinical progress or results;
- developments related to U.S. Food and Drug Administration (FDA) or other regulatory approvals;
- the gain or loss of major suppliers or vendors;
- developments in actual or threatened litigation;
- significant cybersecurity incidents, vulnerabilities and breaches; or
- unusual gains or losses in major operations and financial liquidity problems.

Note that this list is merely illustrative and not exhaustive.

It is important to keep in mind that material information need not be something that has happened or definitely will happen; information that something is likely to happen, or even just that it may happen, may be considered material. Material information may be positive or negative.

Materiality determinations are often challenged with the benefit of hindsight and therefore any question about whether particular information is material should be resolved in favor of not trading. If you have any question as to whether particular information is material, you should not trade or communicate the information to anyone, without prior approval by a Compliance Officer.

b. **Non-public Information.** "Non-public" information is any information that has not been disclosed generally to the investing public. One must be able to point to some fact or event to show that the information is generally public, such as inclusion in the Company's reports filed with the SEC or the issuance of a press release or reference to the information in publications of general circulation in the United States securities market, such as The Wall Street Journal or the New York Times. Even after the Company has released information to the press and the information has been reported, at least two full trading days must be allowed for the investing public to absorb and evaluate the information before you may trade in the Company's securities. This means you may

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not trade until the third trading day after the information is announced to the public. For example, if the Company announced its financial earnings before trading began on a Tuesday, the first time you could buy or sell Company securities would be the opening of the market on Thursday (assuming you were not then aware of other material non-public information). However, if the Company announced its earnings after the start of trading on a Tuesday, the earliest you could buy or sell the Company's securities would be the start of trading on Friday.

#### *4. Restrictions on Short-Term, Speculative Trading.*

The Company has determined that there is a substantial likelihood of the appearance of improper conduct by Company personnel when they engage in certain types of short-term or speculative trading. Therefore, you are prohibited from directly or indirectly selling any equity security of the Company if you do not own the security sold (so-called "short selling"). It is possible to temporarily "short" Company securities, even if you own them (so-called "short selling against the box" or "shorting the box"). Because these transactions involve using the securities held as collateral for the later repurchase of the shorted securities, this type of transaction in Company securities is also prohibited.

#### *5. Exceptions.*

- a. Approved 10b5-1 Plans. Trades by officers, directors and other employees covered by this Policy that are executed pursuant to a pre-cleared 10b5-1 plan are not subject to the prohibition on trading on the basis of material non-public information contained in Section 1(a) of this Policy, during a blackout period contained in Section 1(b) of this Policy, or to the restrictions set forth in the Company's pre-clearance procedures and blackout period described in Section 13 of this Policy.

Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the **Exchange Act**) provides an affirmative defense from insider trading liability under the U.S. federal securities laws for trading plans that meet certain requirements. A 10b5-1 plan must be in writing and entered into at a time when you are not aware of material non-public information and not during any applicable blackout period. With respect to any 10b5-1 plan you enter, you must act in good faith and not as part of a plan or scheme to evade the prohibitions of the securities laws and must continue to act in good faith for the duration of the plan. Once the plan is adopted, you must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded or the date of the trade. The plan must either specify (including by formula) the amount, pricing and timing of transactions in advance or delegate discretion over those matters to an independent third party. Any 10b5-1 plan that is modified must meet all requirements of a newly adopted 10b5-1 plan, as if adopted on the date of modification.

The Company requires that each 10b5-1 plan (or the form of the 10b5-1 trading plan, provided such form has sufficient details to determine compliance with this Policy) be approved in advance by a Compliance Officer in accordance with Section 13 hereof. 10b5-1 plans may not be adopted or modified during a blackout period. Notwithstanding anything herein to the contrary, it is the individual's responsibility to comply with this Policy, the requirements of Rule 10b5-1, including applicable restrictions on overlapping plans and single-trade plans, Rule 144 under the Securities Act of 1933, as amended (the **Securities Act**), and the requirements of Section 16 of the Exchange Act (and its

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related rules), regardless of whether the Company's Compliance Officer approves a 10b5-1 plan.

For **directors and executive officers** (as defined in Rule 16a-1(f), "executive officers"), SEC rules require a waiting period of the later of (i) ninety (90) days after the date the Rule 10b5-1 plan is adopted or (ii) two business days following the filing of the Company's financial results in a Form 10-Q or Form 10-K for the completed fiscal quarter in which the plan was adopted, but in any event up to a maximum of 120 days after adoption of the plan. The rules also require the same waiting period for amendments to Rule 10b5-1 plans.

For **employees who are not executive officers**, SEC rules require a waiting period of thirty (30) days between the date the Rule 10b5-1 plan is adopted and the date of the first possible transaction under the plan. The rules also require a waiting period of thirty (30) days between the date of any amendment to a Rule 10b5-1 plan with respect to a plan's amount, timing or pricing of the purchase, sale or gift of the securities and the effectiveness of such amendment.

The Company will disclose the adoption and termination of Rule 10b5-1 plans by directors and executive officers and indicate in any required trading disclosures (such as Form 4) if a transaction was affected under a Rule 10b5-1 plan as required by the SEC.

- b. **Company Plans.** This Policy does not apply to the exercise of an employee stock option, to the exercise of any right to acquire the Company's securities pursuant to a warrant or any equity incentive plan or similar plan, or to the exercise of a tax withholding right pursuant to which you elect to have the Company withhold shares subject to an option to satisfy tax withholding requirements (although such transactions are still subject to reporting requirements for directors and executive officers). This Policy does apply, however, to any sale of the underlying stock or to a cashless exercise of an option through a broker, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option or warrant.

#### **6. No Other Exceptions.**

Other than as set forth in Sections 5 and 13 herein, there are no exceptions to the prohibitions and restrictions set forth in this Policy. Transactions in the Company's securities that are otherwise necessary for personal reasons, such as personal financial commitments or emergencies, do not excuse you from compliance with this Policy and are prohibited if you possess material non-public information.

**It is important to note that the federal securities laws prohibit trading based on the mere fact that you are aware of material non-public information; it is no excuse that your reasons for trading were not based on that information.**

#### **7. Inadvertent Disclosure.**

If material non-public information is inadvertently disclosed by any employee, officer or director, you should immediately report the facts to a Compliance Officer so that the Company may take appropriate remedial action. Refer to the Company's Disclosure of Material Information Policy for more information.

#### **8. Post-Termination Transactions.**

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This Policy continues to apply to your transactions in Company securities even after you have terminated your employment or other connections to the Company and its affiliates. If you are in possession of material non-public information when your employment terminates, you may not trade in Company securities until that information has become public or is no longer material. Similarly, if you depart while subject to a blackout period, you remain subject to that blackout period.

*9. Company Assistance.*

If you have any questions about specific information or proposed transactions, or as to the applicability or interpretation of this Policy or the propriety of any desired action, you are encouraged to contact a Compliance Officer or member of the Legal Department.

*10. Confidentiality Guidelines.*

To provide more effective protection against the disclosure of material non-public information, the Company has adopted guidelines (attached hereto) with which you should familiarize yourself. These guidelines are not intended to be exhaustive. Additional measures to secure the confidentiality of information should be undertaken as deemed appropriate under the circumstances. If you have any doubt as to your responsibilities under these guidelines, please seek clarification and guidance from a Compliance Officer or a member of the Legal Department before you act. Do not try to resolve any uncertainties on your own.

*11. Personal Responsibility.*

The ultimate responsibility for adhering to this Policy and avoiding improper trading lies with you. If you violate this Policy, you may be subject to disciplinary action up to and including termination for cause.

*12. No New Legal Liabilities; Compliance with Securities Laws.*

This Policy does not impose on the Company's employees, officers or directors or on the Company itself any new legal liabilities to which they would not otherwise be subjected. The restrictions contained in this Policy are in addition to other restrictions on trading imposed by the U.S. securities laws that may apply to you, such as the Securities Act, the Exchange Act and the rules and regulations promulgated under each, including, for example and without limitation, Section 16 of the Exchange Act and Rule 144 under the Securities Act.

*13. Pre-clearance of all Transactions by Insiders; Approval of Rule 10b5-1 Plans*

a. General. All Insiders must obtain the prior approval of a Compliance Officer for any transactions they conduct in the Company's securities, including gifts. Transactions effected pursuant to an approved 10b5-1 trading plan will not require further pre-clearance at the time of the transaction if the plan complies with Rule 10b5-1.

b. Procedure. A request for pre-clearance should be submitted to a Compliance Officer at least two trading days in advance of the proposed transaction. Pre-clearance of a transaction does not constitute legal advice or a recommendation by the Company or any of its employees or agents that you should engage in the subject transaction. If pre-clearance of the transaction is denied, the fact of such denial must be kept confidential by you. Compliance Officers must always be kept fully informed of material developments. Approvals are valid only for three (3) trading days from the time provided. However, if the Insider becomes in possession of material non-public information during this period,

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the Insider may not proceed with the proposed transaction. A minimum of two trading days must pass before a pre-clearance request can be effective. For example, if a request is submitted before the market opens on Monday and is approved, it will become effective when the market opens Wednesday for a three (3) day period: Wednesday, Thursday and Friday. If the transaction order is not placed within the three (3) trading days period, pre-clearance for the transaction must be requested again. Requests submitted after the market opens will be deemed received the following day. The primary market for the Company's securities is The Nasdaq Global Select Market ("NasdaqGS"), which typically opens at 9:30am Eastern Time. For example, if a request is received on a Monday after 9:30am Eastern Time (if that particular Monday is a day on which the NasdaqGS is not open, such as U.S. holiday), it will be considered to have been received on Tuesday. **Exception:** if the planned securities trade will be made and pre-clearance is obtained electronically through the broker associated with the Company's equity plan administrator, then (i) the request for pre-clearance may be obtained in advance of the proposed transaction at any time once the blackout period ends and (ii) such approvals are valid until the next blackout period begins, however, if the Insider becomes in possession of material non-public information during this period, the Insider may not proceed with the proposed transaction .

All trading plans under Rule 10b5-1 must be approved by a Compliance Officer. As noted above, transactions effected pursuant to an approved trading plan will not require further pre-clearance at the time of the transaction.

- c. **Reporting Transactions.** Insiders shall submit to a Compliance Officer a copy of any trade order or confirmation relating to the purchase or sale of the Company's securities within one business day of any such transaction. Insiders must also report all gifts to a Compliance Officer within one business day of any such gift. This information is necessary to enable the Company to monitor transactions in our securities by Insiders and ensure that all such transactions are properly reported. Your adherence to this policy is vital to your protection as well as the Company's. **Exception:** it is not necessary to provide this information if the securities trade was made through the broker associated with the Company's equity plan administrator.
- d. **Quarterly Blackout Periods.** The Company's announcement of its quarterly financial results almost always has the potential to have a material effect on the market for the Company's securities. Therefore, to avoid even the appearance of trading (or gifting) while aware of material non-public information, Insiders will only be pre-cleared to trade (or gift) in the Company's securities during the period in any fiscal quarter (including the year-end) commencing forty-eight (48) hours following the date and time of public disclosure of the financial results for the prior fiscal quarter and ending on the fifth calendar day of the third month of the fiscal quarter.

The Company may on occasion issue interim earnings guidance or other potentially material information by means of a press release, an SEC filing on Form 8-K or other means designed to achieve widespread dissemination of the information. You should anticipate that trades are unlikely to be pre-cleared while the Company is in the process of assembling the information to be released and until the information has been released and fully absorbed by the market.

- e. **Event-Specific Blackout Periods.** From time to time, an event may occur that is material to the Company and is known by only a few Insiders and other employees. So long as

the event remains material and non-public, Insiders and employees as are designated by a Compliance Officer may not trade in the Company's securities. The existence of an event-specific blackout will not be announced except to those who are aware of the event giving rise to the blackout. If, however, an Insider requests permission to trade in the Company's securities at a time when an event-specific blackout is in effect, a Compliance Officer will inform the requester of the existence of a blackout period without necessarily disclosing the reason for the blackout. Any person made aware of the existence of an event-specific blackout should not disclose the existence of the blackout to any other person. The failure of a Compliance Officer to designate a person as being subject to an event-specific blackout will not relieve that person of the obligation not to trade while aware of material non-public information.

f. Hardship Exceptions. A person who is subject to a quarterly earnings blackout period and who has an unexpected and urgent need to sell Company securities in order to generate cash may, only in appropriate circumstances, be permitted to sell even during the blackout period. Hardship exceptions may be granted only by a Compliance Officer and must be requested at least two days in advance of the proposed trade. A hardship exception may be granted only if a Compliance Officer concludes that the person requesting a hardship exception has adequately demonstrated that he or she is not in possession of material non-public information. Under no circumstance will a hardship exception be granted during an event-specific blackout period.

*14. Amendment.*

This policy may be amended from time to time by the Board of Directors or the Nominating and Corporate Governance Committee.

Adopted: October 2, 2015

Revised: July 27, 2016

Revised: October 25, 2017

Revised: July 24, 2019

Revised: September 4, 2019

Revised: October 30, 2019

Revised: July 28, 2021

Revised: July 26, 2022

Revised: February 22, 2023

Revised: July 26, 2023

#### **CONFIDENTIALITY GUIDELINES**

The following guidelines establish procedures with which every employee, officer and director should comply in order to maximize the security of confidential inside information. Note that these guidelines are merely illustrative and not exhaustive:

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- a. declining any comment with respect to outside inquiries (from analysts, stock brokers, the press, etc.) and referring them immediately to the Company's Compliance Officer or such other person designated by the Company to be addressed;
- b. using code names for sensitive projects;
- c. using passwords to restrict access to sensitive information on the computer system;
- d. limiting access to particular physical areas where material non-public information is likely to be documented or discussed;
- e. locking up or shredding confidential documents;
- f. not discussing confidential matters in public places such as elevators, hallways, restrooms or eating facilities where conversations might be heard;
- g. marking sensitive documents "Confidential" and using sealed envelopes marked "Confidential";
- h. restricting the copying of sensitive documents;
- i. obtaining written confidentiality agreements from outsiders allowed access to confidential information;
- j. maintaining and periodically reviewing the list of persons who have access to confidential information and limiting access of especially sensitive materials to senior personnel and others on a need to know basis;
- k. never leaving confidential documents unattended;
- l. specifically informing employees who are exposed to confidential information of the sensitive nature of such information and the need to maintain confidentiality; and
- m. in emailing or telecopying sensitive matters, verifying that you have the correct email address or telecopy number and that someone with authorized access to the information will be available to receive it at the incoming email address or telecopy machine.

**SUBSIDIARIES OF NOVOCURE LIMITED**

<b>Name of Subsidiary and Name Under Which It Does Business</b>	<b>Jurisdiction of Incorporation</b>
Novocure Austria GmbH	Austria
Novocure Belgium S.r.l.	Belgium
Novocure Canada, Inc.	Canada
Novocure Capital S.à.r.l.	Luxembourg
Novocure Denmark ApS	Denmark
NovoCure (Israel) Ltd.	Israel
Novocure France SAS	France
NovoCure GmbH	Germany
Novocure GmbH	Switzerland
Novocure Inc.	Delaware
Novocure Italy S.r.L.	Italy
Novocure K.K.	Japan
Novocure Luxembourg S.à.r.l.	Luxembourg
Novocure Netherlands B.V.	Netherlands
Novocure Poland Sp. z o.o.	Poland
Novocure Singapore Pte. Ltd.	Singapore
Novocure Spain S.L.	Spain
Novocure Sweden AB	Sweden
Novocure USA LLC	Delaware
Novocure UK Limited	United Kingdom

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-8 No. 333-209854) pertaining to the NovoCure Limited Employee Share Purchase Plan, the NovoCure Limited 2015 Omnibus Incentive Plan, the NovoCure Limited 2013 Share Option Plan and the Standen Limited 2003 Share Option Plan,
- (2) Registration Statement (Form S-8 No. 333-217619) pertaining to the NovoCure Limited Employee Share Purchase Plan and the NovoCure Limited 2015 Omnibus Incentive Plan,
- (3) Registration Statement (Form S-8 No. 333-224606) pertaining to the NovoCure Limited 2015 Omnibus Incentive Plan,
- (4) Registration Statement (Form S-8 No. 333-232896) pertaining to the NovoCure Limited Employee Share Purchase Plan, the NovoCure Limited 2015 Omnibus Incentive Plan,
- (5) Registration Statement (Form S-8 No. 333-236862) pertaining to the NovoCure Limited Employee Share Purchase Plan, the NovoCure Limited 2015 Omnibus Incentive Plan,
- (6) Registration Statement (Form S-8 No. 333-253499) pertaining to the NovoCure Limited Employee Share Purchase Plan, the NovoCure Limited 2015 Omnibus Incentive Plan, and
- (7) Registration Statement (Form S-8 No. 333-262965) pertaining to the NovoCure Limited 2015 Omnibus Incentive Plan;
- (8) Registration Statement (Form S-8 No. 333-269926) pertaining to the NovoCure Limited 2015 Omnibus Incentive Plan;

of our reports dated February 22, 2024, with respect to the consolidated financial statements of NovoCure Limited and the effectiveness of internal control over financial reporting of NovoCure Limited included in this Annual Report (Form 10-K) of NovoCure Limited for the year ended December 31, 2023.

/s/ KOST FORER GABBAY AND KASIERER

A member of Ernst & Young Global

Tel Aviv, Israel

February 22, 2024

I, Asaf Danziger, certify that:

1. I have reviewed this Annual Report on Form 10-K of NovoCure Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role

Date: February 22, 2024

/s/ Asaf Danziger

Asaf Danziger

Chief Executive Officer and Director

(Principal Executive Officer)  
in the registrant's internal controls over financial reporting.

**CERTIFICATIONS**

I, Ashley Cordova, certify that:

1. I have reviewed this Annual Report on Form 10-K of NovoCure Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: February 22, 2024

/s/ Ashley Cordova \_\_\_\_\_

Ashley Cordova

Chief Financial Officer

(Principal Accounting and Financial Officer)

**NOVOCURE LIMITED  
CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of NovoCure Limited (the "Company") on Form 10-K for the fiscal year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Asaf Danziger, Chief Executive Officer (Principal Executive Officer) of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

*/s/ Asaf Danziger*

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Asaf Danziger

Chief Executive Officer

(Principal Executive Officer)

Date: February 22, 2024

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff on request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of NovoCure Limited under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

**NOVOCURE LIMITED  
CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of NovoCure Limited (the "Company") on Form 10-K for the fiscal year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ashley Cordova, Chief Financial Officer (Principal Financial and Accounting Officer) of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

*/s/* Ashley Cordova

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Ashley Cordova  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

Date: February 22, 2024

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff on request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of NovoCure Limited under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

**NOVOCURE LIMITED**  
**AMENDED AND RESTATED POLICY ON RECOUPMENT**  
**OF INCENTIVE COMPENSATION**  
**EFFECTIVE AS OF OCTOBER 2, 2023**

The Board of Directors (the "Board") of NovoCure Limited ("Company") has adopted this Policy on Recoupment of Incentive Compensation (the "Clawback Policy" or "Policy") to comply with the rules found in 229 C.F.R. §240.10D-1 (the "Recovery Rule") and the related listing rules of the Nasdaq Global Select Market or such other United States stock exchange on which the Company has listed its Ordinary Shares from time to time ("Exchange"), and, to the extent this Policy is any manner deemed inconsistent with such rules, this Policy shall be treated as retroactively amended to be compliant with such rules.

1. Definitions. As used herein, the terms "Financial Reporting Measure," "Incentive-Based Compensation," and "Received" shall have the meanings as set forth in section (d) of the Recovery Rule. As used herein, the term "Executive Officer" shall mean those persons designated by resolution of the Board of Directors as "executive officers" and any other persons identified pursuant to 17 CFR 229.401(b).

2. Application of the Policy. This Policy shall only apply if the Company is required to prepare an accounting restatement due to the material noncompliance of the issuer with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

3. Recovery Period. The Incentive-Based Compensation subject to recovery pursuant to paragraph 5 of this Policy below is the Incentive-Based Compensation Received after the person began service as an Executive Officer and during the three completed fiscal years immediately preceding the date that the Company is required to prepare an accounting restatement as described in paragraph 2 of this Policy, provided that the person served as an Executive Officer at any time during the performance period applicable to the Incentive-Based Compensation in question (the "Recovery Period"). The date the Company is required to prepare an accounting restatement shall be determined pursuant to Recovery Rule section (b)(1)(ii).

a. Notwithstanding the foregoing, the Policy shall only apply if the Incentive-Based Compensation is Received (1) while the issuer has a class of securities listed on an Exchange and (2) on or after July 27, 2023.

b. See Recovery Rule Section (b)(1)(i) for certain circumstances under which the Policy will apply to Incentive-Based Compensation Received during a transition period arising due to a change in the Company's fiscal year within or immediately following the three completed fiscal years referenced above.

4. Erroneously Awarded Compensation. The amount of Incentive-Based Compensation subject to recovery pursuant to paragraph 5 of this Policy below ("Erroneously Awarded Compensation") is the amount of Incentive-Based Compensation Received that exceeds the amount of Incentive Based-Compensation that otherwise would have been Received had it been

determined based on the restated amounts and shall be computed without regard to any taxes paid. For Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in an accounting restatement: (1) the amount shall be based on a reasonable estimate of the effect of the accounting restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received; and (2) the Company will maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange.

5. The Company shall recover reasonably promptly any Erroneously Awarded Compensation except to the extent that the conditions of paragraphs (a), (b), or (c) below apply. The Compensation Committee of the Board (the "Committee") shall determine the repayment schedule for each amount of Erroneously Awarded Compensation in a manner that complies with this "reasonably promptly" requirement. Such determination shall be consistent with any applicable legal guidance, by the U.S. Securities and Exchange Commission, Exchange rule, regulation or interpretation, judicial opinion, or otherwise. The determination of "reasonably promptly" may vary from case to case and the Committee is authorized to adopt additional rules to further describe what repayment schedules satisfy this requirement.

a. Erroneously Awarded Compensation need not be recovered if the direct expense paid to a third party to assist in enforcing the Policy would exceed the amount to be recovered and the Committee has made a determination that recovery would be impracticable. Before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Erroneously Awarded Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange.

b. Erroneously Awarded Compensation need not be recovered if recovery would violate home country law where that law was adopted prior to November 28, 2022. Before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on violation of home country law, the Company shall obtain an opinion of home country counsel, acceptable to the Exchange, that recovery would result in such a violation and shall provide such opinion to the Exchange.

c. Erroneously Awarded Compensation need not be recovered if recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the registrant, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

6. The Committee shall have oversight of this Policy and recommend determinations to the Board for its final review and approval. All determinations made, reviewed and/or approved by the Board shall be final and binding. Notwithstanding the foregoing, the Committee or Board may amend or change the terms of this Policy at any time for any reason, including as required to comply with the rules of the SEC and the Exchange. Further, the exercise by the Committee of any rights pursuant to this Policy shall be without prejudice to any other rights that the Company or the Committee may have with respect to any Executive Officer subject to this Policy.

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7. To the extent any Company equity incentive plan or any employment agreement between the Company and/or any of its subsidiaries and any Executive Officer that incorporates by reference or otherwise refers to a term in any "clawback policy," "recoupment policy" or the requirements of Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, such reference shall mean this Policy, as the same may be amended from time-to-time.

8. Notwithstanding anything to the contrary in any other policy of the Company or its subsidiaries or any agreement between the Company and/or its subsidiaries and an Executive Officer, no Executive Officer shall be indemnified by the Company or its subsidiaries against the loss of any Erroneously Awarded Compensation.

Adopted: July 26, 2017

Revised: July 26, 2023 (effective October 2, 2023)