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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

March 27, 2024
Date of Report (date of earliest event reported)

NovoCure Limited

(Exact name of registrant as specified in its charter)

Jersey	**001-37565**	**98-1057807**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

No. 4 The Forum, Grenville Street St. Helier Jersey	**JE2 4UF**
(Address of Principal Executive Offices)	(Zip Code)

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

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, no par value	NVCR	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

☐

Item 7.01 Regulation FD Disclosure

On March 27, 2024, NovoCure Limited (the "Company" or "Novocure"), issued a press release announcing that its phase 3 METIS clinical trial trial met its primary endpoint, demonstrating a statistically significant improvement in time to intracranial progression for adult patients treated with Tumor Treating Fields (TTFields) therapy and supportive care compared to supportive care alone in the treatment of patients with 1-10 brain metastases from non-small cell lung cancer (NSCLC) following stereotactic radiosurgery (SRS).Preliminary analyses of key secondary endpoints (time to neurocognitive failure, overall survival, and radiological response rate) did not demonstrate statistical significance. Certain secondary endpoints showed positive trends in favor of treatment with TTFields therapy, including time to distant progression and quality of life. Full analysis of secondary endpoints is ongoing. Novocure intends to submit these data to regulatory authorities. Novocure also intends to publish these findings in a peer-reviewed scientific journal and share them at an upcoming scientific congress.
METIS [NCT02831959] is a phase 3 trial of stereotactic radiosurgery with or without TTFields therapy for patients with 1-10 brain metastases from NSCLC. 298 adult patients were enrolled in the trial and randomized to receive either TTFields therapy with supportive care or supportive care alone following SRS. Supportive care consisted of, but was not limited to, treatment with steroids, anti-epileptic drugs, anticoagulants, pain control or nausea control medications. Patients in both arms of the study were eligible to receive systemic therapy for their NSCLC at the discretion of their treating physician. Patients with known tumor mutations for which targeted agents are available were excluded from the trial. The primary endpoint of the METIS trial is time to first intracranial progression, as measured from the date of first SRS treatment to intracranial progression or neurological death (per RANO-BM criteria), whichever occurs first. Time to intracranial progression was calculated according to the cumulative incident function. Patient scans were evaluated by a blinded, independent radiologic review committee. Secondary endpoints include, but are not limited to, time to distant progression, time to neurocognitive failure, overall survival, time to second intracranial progression, quality of life and adverse events. Key secondary endpoints (time to neurocognitive failure, overall survival, and radiological response rate) were planned to be used in labeling claims, if successful. Patients were stratified by the number of brain metastases (1-4 or 5-10 metastases), prior systemic therapy, and tumor histology. Patients were allowed to crossover to the experimental TTFields therapy arm following confirmation of second intracranial progression.

The information contained in this Current Report shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of NovoCure Limited, dated March 27, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NovoCure Limited
(Registrant)

Date: March 27, 2024

By: /s/ Ashley Cordova
Name: Ashley Cordova
Title: Chief Financial Officer

METIS Phase 3 Clinical Trial Met Primary Endpoint, Demonstrating Statistically Significant Extension in Time to Intracranial Progression for Patients with Brain Metastases from Non-Small Cell Lung Cancer

The METIS trial demonstrated 21.9 months median time to intracranial progression for patients treated with Tumor Treating Fields and supportive care compared to 11.3 months for patients treated with supportive care alone

Novocure to host investor conference call at 8 a.m. EDT

ROOT, Switzerland – Novocure (NASDAQ: NVCR) today announced the phase 3 METIS clinical trial met its primary endpoint, demonstrating a statistically significant improvement in time to intracranial progression for adult patients treated with Tumor Treating Fields (TTFields) therapy and supportive care compared to supportive care alone in the treatment of patients with 1-10 brain metastases from non-small cell lung cancer (NSCLC) following stereotactic radiosurgery (SRS). Patients treated with TTFields therapy and supportive care exhibited a median time to intracranial progression of 21.9 months compared to 11.3 months in patients treated with supportive care alone for brain metastasis (n=298; hazard ratio=0.67; *P*=0.016). Median TTFields therapy treatment duration was 16 weeks and median usage was 67%. Consistent with previous studies, TTFields therapy was well-tolerated with sustained quality of life and neurocognitive function. Baseline characteristics were well balanced between arms.

“Patients with brain metastases from non-small cell lung cancer are frequently treated with radiosurgery but face a high likelihood of rapid brain relapse,” said Minesh Mehta, MD, Chief of Radiation Oncology and Deputy Director at Miami Cancer Institute, part of Baptist Health South Florida. “In this international, multicenter, phase 3 trial, the use of TTFields therapy significantly delayed time to brain relapse, with associated improvement in quality of life and stable cognition. This is a major benefit and is potentially practice changing.”

Preliminary analyses of key secondary endpoints (time to neurocognitive failure, overall survival, and radiological response rate) did not demonstrate statistical significance. Certain secondary endpoints showed positive trends in favor of treatment with TTFields therapy, including time to distant progression and quality of life. Full analysis of secondary endpoints is ongoing.

“Novocure’s willingness to pursue areas of considerable unmet need, like the patient population studied in METIS, is a point of pride for our company,” said Asaf Danziger, Novocure’s Chief Executive Officer. “We are so pleased with the positive outcome of this trial and encouraged by TTFields’ performance. I would like to thank everyone involved with METIS, especially our courageous patients and dedicated investigators, for their contributions to the trial and for meaningfully contributing to the evolution of treatment of brain metastases from NSCLC.”

Novocure intends to submit these data to regulatory authorities. Novocure also intends to publish these findings in a peer-reviewed scientific journal and share them at an upcoming scientific congress.

Conference Call Details
Novocure will host a conference call and webcast to discuss the METIS topline results at 8:00 a.m. EST today, March 27th. To access the conference call by phone, use the

following conference call registration link and dial-in details will be provided. To access the webcast, use the following webcast registration link.

The webcast and slides presented during the webcast can be accessed live from the Investor Relations page of Novocure's website, www.novocure.com/investor-relations, and will be available for at least 14 days following the call. Novocure has used, and intends to continue to use, its investor relations website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD.

About METIS
METIS [NCT02831959] is a phase 3 trial of stereotactic radiosurgery with or without TTFields therapy for patients with 1-10 brain metastases from NSCLC. 298 adult patients were enrolled in the trial and randomized to receive either TTFields therapy with supportive care or supportive care alone following SRS. Supportive care consisted of, but was not limited to, treatment with steroids, anti-epileptic drugs, anticoagulants, pain control or nausea control medications. Patients in both arms of the study were eligible to receive systemic therapy for their NSCLC at the discretion of their treating physician. Patients with known tumor mutations for which targeted agents are available were excluded from the trial.

The primary endpoint of the METIS trial is time to first intracranial progression, as measured from the date of first SRS treatment to intracranial progression or neurological death (per RANO-BM criteria), whichever occurs first. Time to intracranial progression was calculated according to the cumulative incident function. Patient scans were evaluated by a blinded, independent radiologic review committee. Secondary endpoints include, but are not limited to, time to distant progression, time to neurocognitive failure, overall survival, time to second intracranial progression, quality of life and adverse events. Key secondary endpoints (time to neurocognitive failure, overall survival, and radiological response rate) were planned to be used in labeling claims, if successful. Patients were stratified by the number of brain metastases (1-4 or 5-10 metastases), prior systemic therapy, and tumor histology. Patients were allowed to crossover to the experimental TTFields therapy arm following confirmation of second intracranial progression.

About Brain Metastases
Brain metastases are a secondary tumor formed when cancer cells break away from the primary tumor and travel through the blood or lymph system to form new tumors (or metastases) in the brain. Brain metastasis are a negative prognostic factor in NSCLC and adversely impact neurocognitive function and quality of life. Approximately 25% of patients with NSCLC have brain metastasis at diagnosis, and lifetime risk among patients with NSCLC is approximately 50%. Neurologic symptoms are present in approximately 60-75% of patients with brain metastasis, and seizures, focal neurologic deficits, headaches, and altered mental status are common. Treatment options for patients with brain metastasis from NSCLC are limited to neurosurgery, SRS, whole brain radiation therapy, or combinations of these options. However, given the neurotoxicity and significant decline in cognitive functioning, whole brain radiation therapy (WBRT) is an unfavorable treatment option. New therapeutic options are needed for greater intracranial control while minimizing the risk of neurocognitive adverse events.

About Tumor Treating Fields Therapy
Tumor Treating Fields (TTFields) are electric fields that exert physical forces to kill cancer cells via a variety of mechanisms. TTFields do not significantly affect healthy cells because

they have different properties (including division rate, morphology, and electrical properties) than cancer cells. The multiple, distinct mechanisms of TTFields therapy work together to selectively target and kill cancer cells. Due to its multimechanistic actions, TTFields therapy can be added to cancer treatment modalities in approved indications and demonstrates enhanced effects across solid tumor types when used with chemotherapy, radiotherapy, immune checkpoint inhibition, or PARP inhibition in preclinical models. TTFields therapy provides clinical versatility that has the potential to help address treatment challenges across a range of solid tumors. To learn more about Tumor Treating Fields therapy and its multifaceted effect on cancer cells, visit tumortreatingfields.com.

About Novocure
Novocure is a global oncology company working to extend survival in some of the most aggressive forms of cancer through the development and commercialization of its innovative therapy, Tumor Treating Fields. Novocure's commercialized products are approved in certain countries for the treatment of adult patients with glioblastoma and malignant pleural mesothelioma. Novocure has ongoing or completed clinical studies investigating Tumor Treating Fields in brain metastases, gastric cancer, glioblastoma, liver cancer, non-small cell lung cancer, pancreatic cancer and ovarian cancer.

Headquartered in Root, Switzerland and with a growing global footprint, Novocure has regional operating centers in Portsmouth, New Hampshire and Tokyo, as well as a research center in Haifa, Israel. For additional information about the company, please visit Novocure.com and follow @Novocure on LinkedIn and Twitter.

Forward-Looking Statements
In addition to historical facts or statements of current condition, this press release may contain forward-looking statements. Forward-looking statements provide Novocure's current expectations or forecasts of future events. These may include statements regarding anticipated scientific progress on its research programs, clinical study progress, development of potential products, interpretation of clinical results, prospects for regulatory approval, manufacturing development and capabilities, market prospects for its products, coverage, collections from third-party payers and other statements regarding matters that are not historical facts. You may identify some of these forward-looking statements by the use of words in the statements such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe" or other words and terms of similar meaning. Novocure's performance and financial results could differ materially from those reflected in these forward-looking statements due to general financial, economic, environmental, regulatory and political conditions and other more specific risks and uncertainties facing Novocure such as those set forth in its Annual Report on Form 10-K filed on February 22, 2024, and subsequent filings with the U.S. Securities and Exchange Commission. Given these risks and uncertainties, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. Furthermore, Novocure does not intend to update publicly any forward-looking statement, except as required by law. Any forward-looking statements herein speak only as of the date hereof. The Private Securities Litigation Reform Act of 1995 permits this discussion.

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