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

January 9, 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 January 9, 2024, the Company issued a press release announcing that the final patient has been enrolled in the global phase 3 TRIDENT clinical trial evaluating the safety and efficacy of initiating Optune Gio® (formerly known as Optune®) concurrent with radiation therapy and temozolomide (TMZ) for the treatment of patients with newly diagnosed glioblastoma (GBM). A copy of the press release is attached hereto as Exhibit 99.1.

The information contained in item 7.01 of this Current Report shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or incorporated by reference in any filing under the Securities Act 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 January 9, 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: January 9, 2024

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

Novocure Announces Last Patient Enrolled in Phase 3 TRIDENT Trial in Newly Diagnosed Glioblastoma

Final data from the TRIDENT trial anticipated in 2026

ROOT, Switzerland – Novocure (NASDAQ: NVCR) today announced that the final patient has been enrolled in the global phase 3 TRIDENT clinical trial evaluating the safety and efficacy of initiating Optune Gio® (formerly known as Optune®) concurrent with radiation therapy and temozolomide (TMZ) for the treatment of adult patients with newly diagnosed glioblastoma (GBM).

“TTFields therapy has played a critical role in the treatment of newly diagnosed glioblastoma for nearly a decade, and the TRIDENT trial represents the potential evolution of this treatment paradigm by introducing TTFields earlier, at the same time as radiation therapy and temozolomide,” said Asaf Danziger, Novocure’s Chief Executive Officer. “Preclinical research has shown that the application of TTFields together with radiation therapy leads to a more pronounced cytotoxic effect in glioma cell lines as compared to TTFields after administration of radiation therapy. The TRIDENT study could unlock our ability to reach patients earlier in their treatment journey, further extending patient survival. We remain committed to exploring opportunities to further extend the survival horizon for patients diagnosed with glioblastoma.”

Optune Gio® is currently approved for use together with maintenance TMZ for the treatment of newly diagnosed GBM following maximal debulking surgery and the completion of radiation therapy.

The TRIDENT clinical trial is a randomized, open-label study designed to enroll 950 adult patients with newly diagnosed GBM. Following maximal debulking surgery, patients enrolled in TRIDENT were randomized to receive either TTFields therapy, concomitant with TMZ and radiation therapy, or TMZ and radiation therapy for six weeks. Following the initial six-week period, all patients receive the current standard of care – TTFields therapy together with maintenance TMZ for a period of 24 months or until a second disease progression is experienced. TRIDENT began enrolling patients in December 2020 and is the largest trial Novocure has conducted to date.

Final data from the TRIDENT trial is anticipated in 2026. The trial’s primary endpoint is overall survival. Secondary endpoints are progression-free survival, one-year and two-year survival rate, overall radiological response, next progression-free survival, progression-free survival at six and 12 months, severity and frequency of adverse events, pathological changes in resected GBM tumors following study treatments, quality of life, dependence of overall survival on TTFields dose at the tumor, and neurological assessment using the NANO scale.

About Optune Gio Optune Gio delivers Tumor Treating Fields (TTFields) therapy to the region of the tumor. Optune Gio, previously known as Optune, is a noninvasive, antimitotic cancer treatment for glioblastoma (GBM).

TTFields therapy uses electric fields to physically disrupt cell division. TTFields therapy does not stimulate or heat tissue and targets dividing cancer cells of a specific size. TTFields therapy takes advantage of the special characteristics and geometrical shape of dividing cells, which make them susceptible to the effects of the alternating electric fields. TTFields therapy causes minimal damage to healthy cells. Mild to moderate skin irritation is the most common side effect reported. TTFields therapy is approved in certain countries for the treatment of adults with glioblastoma, malignant pleural mesothelioma and pleural mesothelioma, some of the most difficult cancer types to treat.

Important Safety Information
Contraindications
Do not use Optune Gio in patients with an active implanted medical device, a skull defect (such as, missing bone with no replacement), or bullet fragments. Use of Optune Gio together with implanted electronic devices has not been tested and may theoretically lead to malfunctioning of the implanted device. Use of Optune Gio together with skull defects or bullet fragments has not been tested and may possibly lead to tissue damage or render Optune Gio ineffective.
Do not use Optune Gio in patients that are known to be sensitive to conductive hydrogels. In this case, skin contact with the gel used with Optune Gio may commonly cause increased redness and itching, and rarely may even lead to severe allergic reactions such as shock and respiratory failure.

Warnings and Precautions
Do not prescribe Optune Gio for patients that are pregnant, you think might be pregnant or are trying to get pregnant, as the safety and effectiveness of Optune Gio in these populations have not been established.
The most common (≥10%) adverse events involving Optune Gio in combination with temozolomide were thrombocytopenia, nausea, constipation, vomiting, fatigue, medical device site reaction, headache, convulsions, and depression.
The most common (≥10%) adverse events seen with Optune Gio monotherapy were medical device site reaction and headache.
The following adverse reactions were considered related to Optune Gio when used as monotherapy: medical device site reaction, headache, malaise, muscle twitching, fall and skin ulcer.
Use of Optune Gio in patients with an inactive implanted medical device in the brain has not been studied for safety and effectiveness, and use of Optune Gio in these patients could lead to tissue damage or lower the chance of Optune Gio being effective.
If the patient has an underlying serious skin condition on the scalp, evaluate whether this may prevent or temporarily interfere with Optune Gio treatment.

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, malignant pleural mesothelioma and pleural mesothelioma. Novocure has ongoing or completed clinical trials 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 as well as issues arising from the COVID-19 pandemic 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 23, 2023, 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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