

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

August 28, 2023
Date of Report (date of earliest event reported)

NovoCure Limited
(Exact name of registrant as specified in its charter)

Jersey (State or other jurisdiction of incorporation or organization)	001-37565 (Commission File Number)	98-1057807 (I.R.S. Employer Identification No.)
No. 4 The Forum, Grenville Street St. Helier Jersey (Address of Principal Executive Offices)		JE2 4UF (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 August 28, 2023, NovoCure Limited (the "Company" or "Novocure"), issued a press release announcing that its INNOVATE-3 trial did not meet its primary endpoint of overall survival (OS) at the final analysis.

The INNOVATE-3 trial was designed to evaluate the safety and effectiveness of TTFields together with paclitaxel in patients with platinum-resistant ovarian cancer. The primary endpoint of INNOVATE-3 was overall survival. Secondary endpoints include progression-free survival, objective response rate, severity and frequency of adverse events, time to undisputable deterioration in health-related quality of life or death, and quality of life. Enrollment in the trial closed in October 2021 with 540 patients enrolled, beginning the minimum 18-month follow-up period.

The European Network for Gynaecological Oncological Trial groups ("ENGOT") and The GOG Foundation, Inc. ("GOG"), third-party clinical trial networks, collaborated with Novocure on the trial. Both ENGOT and GOG were involved in the development and facilitation of the trial at leading cancer centers in Europe and the United States.

Novocure will work with investigators to share the full results with the scientific community.

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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of NovoCure Limited, dated August 28, 2023
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: August 28, 2023

By: /s/ Ashley Cordova

Name: Ashley Cordova

Title: Chief Financial Officer

Novocure Provides Update on Phase 3 ENGOT-ov50 / GOG-3029 / INNOVATE-3 Trial Evaluating Tumor Treating Fields Therapy in Platinum-resistant Ovarian Cancer

ROOT, Switzerland – Novocure (NASDAQ: NVCR) today announced that the phase 3 ENGOT-ov50 / GOG-3029 / INNOVATE-3 clinical trial of Tumor Treating Fields (TTFields) together with paclitaxel in patients with platinum-resistant ovarian cancer did not meet its primary endpoint of overall survival (OS) at the final analysis. Patients randomized to receive TTFields therapy plus paclitaxel (n=280) demonstrated a median OS of 12.2 months versus a median OS of 11.9 months in patients treated with paclitaxel alone (n=278) (HR: 1.008). Consistent with previously reported studies, TTFields therapy was well-tolerated with no added systemic toxicities.

“Recurrent ovarian cancer is a particularly aggressive cancer and options for patients diagnosed with platinum-resistance remain extremely limited,” said Ignace Vergote, MD, PhD, Principal Investigator and Chairman of the Belgium and Luxembourg Gynaecological Oncology Group and Professor at the Catholic University of Leuven, Belgium. “We are committed to continuing research with TTFields and exploring innovative approaches to treat this area of immense unmet need, and we are extremely grateful to all the investigators and patients for their participation in these studies.”

The ENGOT-ov50 / GOG-3029 / INNOVATE-3 trial enrolled patients with a maximum of five total prior lines of systemic therapy. An analysis of exploratory subgroups suggests a potential survival benefit in patients who received only one prior line of therapy. This signal could merit further exploration given the unmet need for the ~20% of ovarian cancer patients who have a limited response to frontline platinum-based treatment. Full evaluation of the data from the ENGOT-ov50 / GOG-3029 / INNOVATE-3 trial, including subgroup analyses, is ongoing.

“While the final results of the ENGOT-ov50 / GOG-3029 / INNOVATE-3 trial differ from our initial expectation, these data add important context to the treatment paradigm,” said David O’Malley, MD, Professor of Obstetrics and Gynecology at The Ohio State University Wexner College of Medicine and Director of the Division of Gynecologic Oncology at The James Comprehensive Cancer Center. “We see treatment exposure and number of prior therapies are relevant and can drive outcomes, and we will leverage these data as we explore and identify new opportunities to treat this deadly disease.”

“The INNOVATE-3 clinical trial set out to harness the unique mechanisms of Tumor Treating Fields to extend survival in platinum-resistant ovarian cancer” said William Doyle, Novocure’s Executive Chairman. “While today’s update is disappointing, we are encouraged by the signal identified from the exploratory analysis which suggests the potential for a clinical benefit when TTFields therapy is initiated early in a patient’s treatment journey. We are deeply grateful to the patients who participated in this clinical trial, their loved ones, and to the trial investigators.”

Novocure will work with investigators to share the full results with the scientific community.

About ENGOT-ov50 / GOG-3029 / INNOVATE-3

The ENGOT-ov50 / GOG-3029 / INNOVATE-3 clinical trial was designed to evaluate the safety and effectiveness of TTFields together with paclitaxel in patients with platinum-resistant ovarian cancer. The primary endpoint of INNOVATE-3 was overall survival. Secondary endpoints include progression-free survival, objective response rate, severity and frequency of adverse events, time to undisputable deterioration in health-related quality of life or death, and quality of life. Enrollment in the trial closed in October 2021 with 540 patients enrolled, beginning the minimum 18-month follow-up period.

The European Network for Gynaecological Oncological Trial groups ("ENGOT") and The GOG Foundation, Inc. ("GOG"), third-party clinical trial networks, collaborated with Novocure on the trial. Both ENGOT and GOG were involved in the development and facilitation of the trial at leading cancer centers in Europe and the United States.

About Ovarian Cancer

In the U.S., ovarian cancer ranks fifth in cancer deaths among women, with approximately 24,000 women diagnosed each year. Ovarian cancer incidence increases with age, and the median age at time of diagnosis is 63 years old.

Physicians use different combinations of surgery and pharmacological therapies to treat ovarian cancer, depending on the stage of the disease. Surgery is usually used in early stages of the disease and is usually combined with chemotherapy, including paclitaxel and platinum-based chemotherapy. Unfortunately, the majority of patients are diagnosed at an advanced stage when the cancer has spread outside of the ovaries to include regional tissue involvement and/or metastases. Platinum-based chemotherapy remains part of the standard of care in advanced ovarian cancer, but most patients with advanced ovarian cancer will have tumor progression or, more commonly, recurrence. Almost all patients with recurrent disease ultimately develop platinum resistance, and the prognosis for this population remains poor.

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,

malignant pleural mesothelioma and 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.

About ENGOT and BGOG (<https://engot.esgo.org> and www.bgog.eu)

The European Network of Gynaecological Oncology Trial groups (ENGOT) is a platform that guarantees that the European spirit and culture is incorporated into the medical progress in gynaecological oncology, and that all European patients and countries can participate in an active way in clinical research and progress. The ultimate goal is to bring the best treatment to gynecological cancer patients through the best science and enabling every patient in every European country to access a clinical trial. The Belgium and Luxembourg Gynaecological Oncology Group (BGOG) is one of the founding study groups of ENGOT.

About The GOG Foundation, Inc. (GOG-F) (www.gog.org)

The GOG Foundation, Inc. is a not-for-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and translational scientific research in the field of gynecologic malignancies. The GOG Foundation is committed to maintaining the highest standards in clinical trials development, execution, analysis, and distribution of results. The GOG Foundation is the only clinical trialist group in the United States that focuses its research on patients with pelvic malignancies, such as cancer of the ovary (including surface peritoneal malignancies), uterus (including endometrium, soft tissue sarcoma, and gestational trophoblastic neoplasia), cervix, and vulva. The GOG Foundation is multi-disciplinary in its approach to clinical trials, and includes gynecologic oncologists, medical oncologists, pathologists, radiation oncologists, oncology nurses, biostatisticians (including those with expertise in bioinformatics), basic scientists, quality of life experts, data managers, and administrative personnel.

About GOG Partners Program

Supported by industry, GOG Partners is structured to work directly with pharmaceutical organizations and operate clinical trials outside the National Cancer Institute (NCI) framework. The GOG Partners Program shares the same mission of the GOG Foundation dedicated to transforming the care in Gynecologic Oncology. By providing an alternative venue for patient accrual and site infrastructure support, GOG Partners has helped provide additional trials and opportunities for patients outside the national gynecologic clinical trials network.

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 “could” “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.

Investors:

Ingrid Goldberg
investorinfo@novocure.com
610-723-7427

Media:

Leigh Labrie
media@novocure.com
610-723-7428