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

April 13, 2021
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 April 13, 2021, NovoCure Limited (the "Company" or "Novocure"), issued a press release announcing an update regarding its phase 3 pivotal LUNAR trial of Tumor Treating Fields (TTFields) in stage 4 non-small cell lung cancer (NSCLC) following platinum failure. Following a routine review of the study by an independent data monitoring committee (DMC), Novocure was informed that the pre-specified interim analysis for the LUNAR trial would be accelerated given the length of accrual and the number of events observed, to date. The interim analysis included data from 210 patients accrued to the LUNAR trial through February 2021. After review of the interim analysis report, the DMC concluded that the LUNAR trial should continue with no evidence of increased systemic toxicity.

The DMC also stated that it is likely unnecessary and possibly unethical for patients randomized to the control arm to continue accrual to 534 patients with 18 months follow-up. The DMC recommended a reduced sample size of approximately 276 patients with 12 months follow-up which it believes will provide sufficient overall power for both primary and secondary endpoints. The DMC recommended no other changes to the design of the trial. Novocure remains blinded to all data.

Novocure has notified the U.S. Food and Drug Administration (FDA) of the DMC recommendations and of its intent to submit an Investigational Device Exemption (IDE) supplement incorporating the recommended protocol adjustments.

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 April 13, 2021
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: April 13, 2021

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

Novocure Announces Update on Phase 3 Pivotal LUNAR Trial of Tumor Treating Fields in Non-Small Cell Lung Cancer

Pre-specified interim analysis concluded with favorable recommendation to continue the LUNAR trial

DMC stated accrual to 534 patients is likely unnecessary and possibly unethical for patients randomized to control arm and recommended a shortened trial

St. Helier, Jersey – Novocure (NASDAQ: NVCR) today announced an update regarding its phase 3 pivotal LUNAR trial of Tumor Treating Fields (TTFields) in stage 4 non-small cell lung cancer (NSCLC) following platinum failure. Following a routine review of the study by an independent data monitoring committee (DMC), Novocure was informed that the pre-specified interim analysis for the LUNAR trial would be accelerated given the length of accrual and the number of events observed, to date. The interim analysis included data from 210 patients accrued to the LUNAR trial through February 2021. After review of the interim analysis report, the DMC concluded that the LUNAR trial should continue with no evidence of increased systemic toxicity.

The DMC also stated that it is likely unnecessary and possibly unethical for patients randomized to the control arm to continue accrual to 534 patients with 18 months follow-up. The DMC recommended a reduced sample size of approximately 276 patients with 12 months follow-up which it believes will provide sufficient overall power for both primary and secondary endpoints. The DMC recommended no other changes to the design of the trial. Novocure remains blinded to all data.

The primary endpoint of the LUNAR trial is superior overall survival when patients are treated with TTFields plus immune checkpoint inhibitors or docetaxel versus immune checkpoint inhibitors or docetaxel alone. The final analysis will also include an analysis of overall survival in the immune checkpoint inhibitor and docetaxel treatment subgroups.

Novocure has notified the U.S. Food and Drug Administration (FDA) of the DMC recommendations and of its intent to submit an Investigational Device Exemption (IDE) supplement incorporating the recommended protocol adjustments.

“We are very pleased with the DMC recommendations, which we believe support the potential for TTFields to make a significant difference in treatment outcomes for patients with non-small cell lung cancer, whether used together with immune checkpoint inhibitors or docetaxel,” said William Doyle, Novocure’s Executive Chairman. “The accelerated interim analysis with an encouraging outcome adds to the accumulating evidence of Tumor Treating Fields’ broad potential across a range of hard-to-treat cancers.”

“Combination therapy is a cornerstone of cancer care, and we believe using TTFields together with other cancer treatments, including immunotherapies, may lead to better outcomes for some patients,” continued Mr. Doyle. “We are very encouraged that, consistent with our expectations, the DMC concluded that TTFields exhibited no systemic toxicity. We will continue to develop TTFields as a limited toxicity backbone therapy upon which other standard-of-care and emerging cancer treatments can be added.”

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. and approximately 46,000 patients receive second-line treatment for stage 4 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. TTFields is intended principally for use together with other standard-of-care treatments, and LUNAR was designed to generate data that contemplates multiple outcomes, all of which Novocure believes will be clinically meaningful.

“The completion of the LUNAR interim analysis is an important milestone for Novocure,” said Asaf Danziger, Novocure’s CEO. “We are grateful to the DMC members for their diligence, guidance and support, and are looking forward to working closely with the FDA on amendments to the protocol given the DMC’s recommendations. Pending regulatory approval, the recommended protocol adjustments could accelerate trial completion by more than a year. We look forward to sharing final data from the LUNAR trial as quickly as possible.”

About LUNAR
LUNAR is a phase 3 pivotal trial testing the effectiveness of TTFields 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 46,000 patients receive second-line treatment for stage 4 NSCLC each year in the U.S. The primary endpoint is superior overall survival of patients treated with TTFields plus immune checkpoint inhibitors or docetaxel versus immune checkpoint inhibitors or docetaxel alone. TTFields is intended principally for use in combination with other standard-of-care treatments, and LUNAR was designed to generate data that contemplates multiple outcomes, all of which Novocure believes will be clinically meaningful.

About Tumor Treating Fields
Tumor Treating Fields, or TTFields, are electric fields that disrupt cancer cell division.

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. 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.

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

Fundamental scientific research extends across two decades and, in all preclinical research to date, TTFields has demonstrated a consistent anti-mitotic effect. The TTFields global development program includes a broad range of clinical trials across all phases, included four phase 3 pivotal trials in a variety of tumor types. To date, more than 18,000 patients have been treated with TTFields.

Use of Tumor Treating Fields for the treatment of NSCLC is investigational only.

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, TTFields. TTFields are electric fields that disrupt cancer cell division. Novocure’s commercialized products are approved for the treatment of adult patients with glioblastoma and malignant pleural mesothelioma. Novocure has ongoing clinical trials

investigating TTFields in brain metastases, gastric cancer, glioblastoma, liver cancer, non-small cell lung cancer, pancreatic cancer and ovarian cancer.

Headquartered in Jersey, Novocure has U.S. operations in Portsmouth, New Hampshire, Malvern, Pennsylvania and New York City. Additionally, the company has offices in Germany, Switzerland, Japan and Israel. For additional information about the company, please visit www.novocure.com or follow us at www.twitter.com/novocure.

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 LUNAR progress and timelines, interpretation of the LUNAR interim analysis, anticipated scientific progress on its research programs, clinical trial 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, 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 25, 2021, 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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