

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

June 6, 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 June 6, 2023, NovoCure Limited (the "Company" or "Novocure"), issued a press release announcing that on that day it will present positive results from the phase 3 LUNAR clinical trial evaluating the use of Tumor Treating Fields (TTFields) therapy together with standard therapies for the treatment of non-small cell lung cancer (NSCLC) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. The press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Novocure will host an investor event at 2 p.m. CDT on Tuesday, June 6, 2023. The event will include a presentation and discussion of the LUNAR clinical trial data, featuring leading thoracic oncologists, investigators, and Novocure leadership. A live webcast of the event will be available on the investor relations page of www.novocure.com. For more information or to request in-person attendance, please contact Novocure investor relations (investorinfo@novocure.com).

The information contained in this Item 7.01 of 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 8.01 Other Events

On June 6, 2023 at the 2023 ASCO Annual Meeting, Novocure will present positive results from the phase 3 LUNAR clinical trial. The LUNAR trial met its primary endpoint with a statistically significant and clinically meaningful 3-month improvement in median overall survival (OS) when TTFields therapy was added to standard therapies (HR: 0.74, P=0.035).

Patients randomized to receive TTFields therapy together with standard therapies (n=137) demonstrated median OS of 13.2 months compared to 9.9 months in patients treated with standard therapies alone (n=139). A profound OS benefit from TTFields therapy was demonstrated in the immune checkpoint inhibitor (ICI) subgroup. Patients randomized to receive TTFields therapy and physician’s choice ICI (n=66) demonstrated a median OS of 18.5 months versus a median OS of 10.8 months in patients treated with ICIs alone (n=68; HR=0.63; P=0.03). Patients randomized to receive TTFields therapy and docetaxel (n=71) had a positive survival trend with a median OS of 11.1 months vs 8.7 months in patients treated with docetaxel alone (n=71). TTFields therapy was well-tolerated with no added systemic toxicities and few grade 3 (no grade 4 or 5) device-related adverse events.

Baseline characteristics were well balanced between cohorts: median age was 64 years (range, 22-86); 65% male; 96% of patients had an ECOG performance status of 0-1. Patients were enrolled at sites in North America (30%), Western Europe (30%), Eastern Europe (30%) and East Asia (9%). One-year survival rates for patients treated with TTFields therapy together with standard therapies was 53% versus 42% for patients treated with standard therapies alone (P=0.04). A landmark three-year survival analysis for patients treated with TTFields therapy together with standard therapies demonstrated a nearly threefold improvement, extending to 18% versus 7% for patients treated with standard therapies alone (P=0.015). Median progression-free survival (PFS) for patients treated with TTFields therapy together with standard therapies was 4.8 months versus 4.1 months in patients treated with standard therapies alone.

Of patients randomized, 89% had one prior line of systemic therapy and 31% of patients randomized had been treated with an ICI (58% of patients randomized to the docetaxel cohort and 2% of patients randomized to the ICI cohort). ICIs were approved for first-line NSCLC in 2017 during the conduct of the LUNAR study, and PD-L1 expression data were collected thereafter in geographic regions where ICIs had been adopted. Tumor Proportion Scores were available for 151 patients globally (55%) and were well balanced across the cohorts. In all patients treated with ICI and with measured Tumor Proportion Scores, 63% had PD-L1 expression >1%, which is in-line with real-world data. PD-L1 expression data were collected from 83% of patients (69 of 83 patients) enrolled at U.S. sites and were well balanced across the four cohorts.

PD-L1 Status:

PD-L1 Expression	TTFields + SOC (n=137)	SOC (n=139)	TTFields + ICI (n=66)	ICI (n=68)	TTFields + DTX (n=71)	DTX (n=71)
<1%	17%	17%	18%	24%	16%	10%
1-49%	27%	29%	26%	27%	28%	31%
>50%	7%	13%	8%	12%	7%	14%

DTX = docetaxel; ICI = immune checkpoint inhibitor; SOC = standard of care

Novocure has submitted the LUNAR clinical trial results for publication in a leading, peer-reviewed medical journal. The LUNAR clinical trial data are expected to serve as the basis for a Premarket Approval (PMA) submission to the U.S. Food and Drug Administration in the second half of 2023.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of NovoCure Limited, dated June 6, 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: June 6, 2023

By: /s/ Ashley Cordova

Name: Ashley Cordova

Title: Chief Financial Officer

LUNAR Phase 3 Clinical Trial Demonstrates Statistically Significant and Clinically Meaningful Extension in Overall Survival for Patients with Metastatic Non-Small Cell Lung Cancer After Platinum-Based Therapies

Tumor Treating Fields therapy together with standard of care provided a statistically significant and clinically meaningful 3-month improvement in median overall survival versus standard of care with no added systemic toxicities

Tumor Treating Fields therapy together with immune checkpoint inhibitors resulted in an unprecedented 8-month improvement in median overall survival

LUNAR is the first phase 3 clinical trial in more than seven years to show a significant extension in overall survival in metastatic non-small cell lung cancer post-platinum therapy

Data from the LUNAR trial to be presented today during the 2023 ASCO Annual Meeting

Novocure to host investor conference call at 2 p.m. CDT

Root, Switzerland – Novocure (NASDAQ: NVCR) today is presenting positive results from the phase 3 LUNAR clinical trial evaluating the use of Tumor Treating Fields (TTFields) therapy together with standard therapies for the treatment of non-small cell lung cancer (NSCLC) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. The LUNAR trial met its primary endpoint with a statistically significant and clinically meaningful 3-month improvement in median overall survival (OS) when TTFields therapy was added to standard therapies (HR: 0.74, $P=0.035$).

Patients randomized to receive TTFields therapy together with standard therapies (n=137) demonstrated median OS of 13.2 months compared to 9.9 months in patients treated with standard therapies alone (n=139). A profound OS benefit from TTFields therapy was demonstrated in the immune checkpoint inhibitor (ICI) subgroup. Patients randomized to receive TTFields therapy and physician's choice ICI (n=66) demonstrated a median OS of 18.5 months versus a median OS of 10.8 months in patients treated with ICIs alone (n=68; HR=0.63; $P=0.03$). Patients randomized to receive TTFields therapy and docetaxel (n=71) had a positive survival trend with a median OS of 11.1 months vs 8.7 months in patients treated with docetaxel alone (n=71). TTFields therapy was well-tolerated with no added systemic toxicities and few grade 3 (no grade 4 or 5) device-related adverse events.

"The results of the LUNAR study are highly encouraging," said primary investigator Tician Leal, M.D., a researcher and medical oncologist at Winship Cancer Institute of Emory University and associate professor and director of the Thoracic Medical Oncology Program in the Department of Hematology and Medical Oncology at Emory University School of Medicine in Atlanta. "The LUNAR trial is the first study in more than seven years to show a significant improvement in overall survival in metastatic non-small cell lung cancer post-platinum chemotherapy. I am heartened by this progress and the potential of this innovative therapy to help many metastatic lung cancer patients in need of new treatment choices following platinum therapy, without added systemic toxicity."

Baseline characteristics were well balanced between cohorts: median age was 64 years (range, 22-86); 65% male; 96% of patients had an ECOG performance status of 0-1. Patients were enrolled at sites in North America (30%), Western Europe (30%), Eastern Europe (30%) and East Asia (9%). One-year survival rates for patients treated with TTFIELDS therapy together with standard therapies was 53% versus 42% for patients treated with standard therapies alone ($P=0.04$). A landmark three-year survival analysis for patients treated with TTFIELDS therapy together with standard therapies demonstrated a nearly threefold improvement, extending to 18% versus 7% for patients treated with standard therapies alone ($P=0.015$). Median progression-free survival (PFS) for patients treated with TTFIELDS therapy together with standard therapies was 4.8 months versus 4.1 months in patients treated with standard therapies alone.

Of patients randomized, 89% had one prior line of systemic therapy and 31% of patients randomized had been treated with an ICI (58% of patients randomized to the docetaxel cohort and 2% of patients randomized to the ICI cohort). ICIs were approved for first-line NSCLC in 2017 during the conduct of the LUNAR study, and PD-L1 expression data were collected thereafter in geographic regions where ICIs had been adopted. Tumor Proportion Scores were available for 151 patients globally (55%) and were well balanced across the cohorts. In all patients treated with ICI and with measured Tumor Proportion Scores, 63% had PD-L1 expression $>1\%$, which is in-line with real-world data. PD-L1 expression data were collected from 83% of patients (69 of 83 patients) enrolled at U.S. sites and were well balanced across the four cohorts.

PD-L1 Status:

PD-L1 Expression	TTFIELDS + SOC (n=137)	SOC (n=139)	TTFIELDS + ICI (n=66)	ICI (n=68)	TTFIELDS + DTX (n=71)	DTX (n=71)
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Novocure has submitted the LUNAR clinical trial results for publication in a leading, peer-reviewed medical journal. The LUNAR clinical trial data are expected to serve as the basis for a Premarket Approval (PMA) submission to the U.S. Food and Drug Administration in the second half of 2023.

“I would like to thank our patients, their families and caregivers for participating in the LUNAR trial,” said William Doyle, Novocure’s Executive Chairman. “I would also like to thank Dr. Leal and all of our investigators for their expertise and dedication to advancing the care of patients. The LUNAR trial results represent tremendous progress for the treatment of metastatic non-small cell lung cancer, and the LUNAR trial demonstrates the broad and versatile potential of TTFIELDS therapy in improving the survival of cancer patients with high unmet needs. We are energized by the LUNAR results and are moving forward quickly to make TTFIELDS therapy available to patients with metastatic non-small cell lung cancer.”

Novocure is dedicated to advancing TTFields therapy for patients with solid tumors. The LUNAR clinical trial is the first of four phase 3 clinical trials expected to readout by the end of 2024 studying the use of TTFields therapy for the treatment of solid tumors of the brain, torso and abdomen. Based on the strength of the LUNAR data, Novocure intends to launch additional phase 3 trials evaluating TTFields therapy in earlier lines of treatment and together with ICIs and other standards of care.

Investor Event details

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About LUNAR

LUNAR is a phase 3 trial testing the safety and effectiveness of TTFields therapy when used together with ICI or docetaxel (experimental arm) versus ICI or docetaxel alone (control arm) for patients with metastatic NSCLC who progressed during or after platinum-based therapy. It is estimated that approximately 46,000 patients receive second-line treatment for metastatic NSCLC each year in the U.S. The primary endpoint is superior overall survival of patients treated with TTFields therapy plus ICI or docetaxel versus ICI or docetaxel alone. The powered secondary endpoints are superior overall survival of patients treated with TTFields therapy plus ICI versus ICI cohort and superior overall survival of patients treated with TTFields therapy plus docetaxel versus docetaxel alone. TTFields therapy is intended principally for use with other concomitant 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 NSCLC

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. Since 1991, radiation with a combination of platinum-based chemotherapy drugs has been the first-line standard of care for locally advanced or metastatic NSCLC. Certain immune checkpoint inhibitors have been approved for the first-line treatment of NSCLC and the standard of care in this setting appears to be evolving rapidly. The standard of care for second-line treatment is also evolving and may include platinum-based chemotherapy for patients who received immune checkpoint inhibitors as their first-line regimen, pemetrexed, docetaxel or immune checkpoint inhibitors.

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 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, 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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