

**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 5, 2023

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 | (Commission File | (I.R.S. Employer Identification No.) |
| incorporation or organization) | Number) |  |
| **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.

**o**



**Item 7.01 Regulation FD Disclosure**

On January 5, 2023, NovoCure Limited (the "Company" or "Novocure"), issued a press release announcing that its LUNAR studymet its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival over standard therapies alone.

The LUNAR study is a pivotal, open-label, randomized trial evaluating the safety and efficacy of Tumor Treating Fields (TTFields) together with physician’s choice immune checkpoint inhibitor or docetaxel for the treatment of stage 4 non-small cell lung cancer (NSCLC) following progression while on or after treatment with platinum-based therapy.

Novocure plans to release the full results of the LUNAR study at a future medical conference. Novocure expects to file a Premarket Approval application with the U.S. Food and Drug Administration ("FDA") in the second half of 2023. Novocure also expects to file for a CE Mark in the European Union concurrently with the FDA submission.

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**

1. *Exhibits*

|  |  |  |
| --- | --- | --- |
|  | Exhibit No. | Description |
|  |  |  |  |  |  |
|  | 99.1 |  | Press Release of NovoCure Limited, dated January 5, 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: January 5, 2023

By: /s/ Ashley Cordova

Name: Ashley Cordova

Title: Chief Financial Officer

Exhibit 99.1

**Novocure Announces Pivotal LUNAR Study in Non-Small Cell Lung Cancer Met Primary Overall Survival Endpoint**

*The LUNAR study met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival*

*The full LUNAR data will be presented at a future medical congress*

**ROOT, Switzerland** – Novocure (NASDAQ: NVCR) today announced the LUNAR study met its primary endpoint,demonstrating a statistically significant and clinically meaningful improvement in overall survival over standard therapies alone. The LUNAR study is a pivotal, open-label, randomized study evaluating the safety and efficacy of Tumor Treating Fields (TTFields) together with standard therapies for stage 4 non-small cell lung cancer (NSCLC) following progression while on or after treatment with platinum-based therapy.

The LUNAR study also showed a statistically significant and clinically meaningful improvement in overall survival when patients were treated with TTFields and immune checkpoint inhibitors (ICI), as compared to those treated with immune checkpoint inhibitors alone, and a positive trend in overall survival when patients were treated with TTFields and docetaxel versus docetaxel alone. Patient enrollment was well balanced between the ICI and docetaxel cohorts of the experimental and control arms, and control arms performed in line with prior studies. TTFields therapy was well tolerated by patients enrolled in the experimental arm of the study.

“We are thrilled about the positive readout of the LUNAR study. Prior to LUNAR, the last phase 3 trial to lead to meaningful improvement in overall survival in late-stage, platinum-resistant non-small cell lung cancer was six years ago, underlining the difficulty in treating this disease,” said William Doyle, Novocure’s Executive Chairman. “We are particularly pleased by the profound performance of the TTFields together with immunotherapy, which has the potential to meaningfully extend patient survival beyond what was previously possible. I would like to thank our patients and investigators for their courage and dedication in completing LUNAR. And, I would like to thank Novocure’s employees for their unrelenting commitment to patients and their perseverance in propelling Novocure to this major milestone.”

Novocure plans to release the full results of the LUNAR study at a future medical conference. Novocure expects to file a Premarket Approval application with the U.S. Food and Drug Administration in the second half of 2023. Novocure also expects to file for a CE Mark in the European Union concurrently with the FDA submission.

**About LUNAR**

LUNAR is a pivotal study testing the safety and effectiveness of TTFields when used together with immune checkpoint inhibitors or docetaxel (experimental arm) versus immune checkpoint inhibitors or docetaxel alone (control arm) 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. The powered secondary endpoints are superior overall survival of patients treated with TTFields plus immune checkpoint inhibitor versus immune checkpoint inhibitor alone (ICI cohort) and superior overall survival of patients treated with TTFields plus docetaxel versus docetaxel alone (docetaxel cohort). TTFields is intended principally for use with other concomitant standard-of-care treatments, and LUNAR was

Exhibit 99.1

designed to generate data that contemplates multiple outcomes, all of which Novocure believes will be clinically meaningful.

**About Non-Small Cell Lung Cancer**

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 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.

Exhibit 99.1

**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 24, 2022, 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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