

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

Date of Report (Date of earliest event reported): September 5, 2018

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
(IRS Employer
Identification No.)

Second Floor, No. 4 The Forum
Grenville Street
St. Helier, Jersey JE2 4UF
(Address of Principal Executive Offices)

Registrant's telephone number, including area code: **+44 (0)15 3475 6700**

N/A

(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. to Form 8-K):

- 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))

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 September 5, 2018, NovoCure Limited issued a press release announcing certain results from its phase 2 STELLAR trial. A copy of the press release is attached hereto as Exhibit 99.1.

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 September 5, 2018

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: September 6, 2018

By: /s/ Wilhelmus Groenhuysen
Name: Wilhelmus Groenhuysen
Title: Chief Financial Officer

Tumor Treating Fields Plus Standard of Care Chemotherapy Significantly Extends Median Overall Survival by 6.1 months in STELLAR Phase 2 Registration Trial in Mesothelioma Compared to Historical Control

Mesothelioma patients who received Tumor Treating Fields with pemetrexed and cisplatin or carboplatin experienced median overall survival of 18.2 months compared to 12.1 months in historical control with no increase in systemic toxicity

Results support the use of Tumor Treating Fields in first potential indication outside of the brain

Company to host analyst and investor briefing Sept. 25, 2018

St. Helier, Jersey – Novocure (NASDAQ: NVCR) announced final results from its STELLAR phase 2 registration trial in mesothelioma, demonstrating a significant extension in median overall survival among patients treated with Tumor Treating Fields plus standard of care chemotherapy compared to historical control data of patients who received standard of care chemotherapy alone. Malignant pleural mesothelioma patients who received Tumor Treating Fields with pemetrexed and cisplatin or carboplatin experienced median overall survival of 18.2 months (95 percent CI, 12.1-25.8 months) compared to 12.1 months in a historical control. Tumor Treating Fields is a cancer therapy that uses electric fields tuned to specific frequencies to disrupt cell division, inhibiting tumor growth and causing affected cancer cells to die. The final STELLAR results will be presented at the IASLC 19th World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer (IASLC) on Sept. 25, 2018, in Toronto.

“The final results of the STELLAR trial demonstrate an impressive extension of median overall survival in the treatment of malignant pleural mesothelioma with no increase in systemic toxicity,” said Giovanni Luca Ceresoli, MD, Head of Pulmonary Oncology at the Humanitas Gavazzeni Hospital in Bergamo, Italy, and an investigator in the STELLAR trial. “Mesothelioma patients face an urgent unmet need for additional therapies that improve survival. Based on these data, I believe Tumor Treating Fields represent an extremely promising therapeutic option that, if approved, should be added to standard of care chemotherapy for the treatment of malignant pleural mesothelioma.”

Secondary endpoints also were improved compared to the historical control. Patients who received Tumor Treating Fields in combination with pemetrexed and cisplatin or carboplatin experienced a median progression free survival of 7.6 months (95 percent CI, 6.7-9.8 months) compared to 5.7 months in the historical control. Partial responses were seen in 40.3 percent of patients, and clinical benefit, either partial response or stable disease, was seen in 97.2 percent of patients. No serious device-related adverse events

were reported. Skin irritation was reported in 4.6 percent of patients using Tumor Treating Fields, with only 4 patients (5 percent) reporting grade 3 skin irritation.

The single-arm, open-label, multi-center trial was designed to test the efficacy and safety of Tumor Treating Fields in combination with standard of care chemotherapy, pemetrexed combined with cisplatin or carboplatin, in 80 patients with unresectable, previously untreated malignant pleural mesothelioma. The primary endpoint was overall survival and secondary endpoints were response rate, progression free survival and adverse events. Median age of patients was 67, 84 percent were male, 56 percent were smokers, 16 percent had metastatic disease, 44 percent had an ECOG PS of 1, and 66 percent had epithelioid histology. The historical control for this trial was the 2003 pemetrexed phase 3 registration trial, which had a similar percentage of patients with epithelioid histology.

Novocure received a Humanitarian Use Device (HUD) designation for the use of Tumor Treating Fields for the treatment of malignant pleural mesothelioma in 2017 and plans to submit a Humanitarian Device Exemption (HDE) application to the U.S. Food and Drug Administration (FDA) for approval later this year.

“We are extremely pleased by the results of the STELLAR trial,” said Dr. Eilon Kirson, Novocure’s Chief Science Officer and Head of Research and Development. “We believe the results support the use of Tumor Treating Fields in our first indication outside of the brain. We are now one step closer to commercializing Tumor Treating Fields as a treatment for malignant pleural mesothelioma.”

Novocure will host an analyst and investor briefing Tuesday, Sept. 25, 2018 from 12:30 p.m. to 2 p.m. EDT in Toronto to review data presented at IASLC and to provide a general update on research and development activities. The event will be webcast live and can be accessed from the Investor Relations page of Novocure’s website, www.novocure.com/investor-relations. The webcast will be available for replay for at least 14 days following the event.

Tumor Treating Fields in combination with standard of care chemotherapy is an investigational treatment for malignant pleural mesothelioma and is not approved for this indication.

About Malignant Pleural Mesothelioma

Malignant pleural mesothelioma is a rare thoracic solid tumor cancer that has been strongly linked to asbestos exposure. It has a long latency period of at least 20-30 years following exposure, and global incidence is still increasing in countries where asbestos is still in use. There are approximately 3,000 new cases of mesothelioma annually in the

United States. The prognosis of mesothelioma patients is very poor, with a median overall survival of approximately 12 months in most reported studies.

About Novocure

Novocure is an oncology company developing a profoundly different cancer treatment utilizing a proprietary therapy called Tumor Treating Fields, the use of electric fields tuned to specific frequencies to disrupt solid tumor cancer cell division. Novocure's commercialized product is approved for the treatment of adult patients with glioblastoma. Novocure has ongoing or completed clinical trials investigating Tumor Treating Fields in brain metastases, non-small cell lung cancer, pancreatic cancer, ovarian cancer and mesothelioma.

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 anticipated scientific progress on its research programs, clinical trial progress, development of potential products, interpretation of clinical results, prospects for regulatory submission and 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 more specific risks and uncertainties facing Novocure such as those set forth in its Annual Report on Form 10-K filed on February 22, 2018, 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.

Media and Investor Contact:

Ashley Cordova

acordova@novocure.com
212-767-7558