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): May 23, 2019

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)	(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. ☐

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

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

Item 7.01 Regulation FD Disclosure.

On May 23 , the Company issued a press release announcing that the U.S. Food and Drug Administration has approved the Company's NovoTTF-100L System in combination with pemetrexed plus platinum-based chemotherapy for the first-line treatment of unresectable, locally advanced or metastatic, malignant pleural mesothelioma. A copy of the press release is attached as Exhibit 99.1.

Item 9.01 Financ ial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of NovoCure Limited, dated May 23, 2019

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: May 24 , 2019

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

FDA Approves the NovoTTF-100L™ System in Combination with Chemotherapy for the Treatment of Malignant Pleural Mesothelioma

NovoTTF-100L, a Tumor Treating Fields delivery system, is the first FDA-approved mesothelioma treatment in more than 15 years

In the STELLAR trial, malignant pleural mesothelioma patients treated with Tumor Treating Fields plus platinum-based chemotherapy experienced a median overall survival of 18.2 months

St. Helier, Jersey – Novocure (NASDAQ: NVCR) today announced that the U.S. Food and Drug Administration (FDA) has approved the NovoTTF-100L System in combination with pemetrexed plus platinum-based chemotherapy for the first-line treatment of unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM). NovoTTF-100L is a non-invasive, antimitotic cancer treatment that delivers Tumor Treating Fields to the region of the tumor. Tumor Treating Fields therapy uses electric fields tuned to specific frequencies to disrupt solid tumor cancer cell division.

NovoTTF-100L is the first treatment for MPM approved by the FDA in more than 15 years. Preclinical data showed that human mesothelioma cells are highly sensitive to Tumor Treating Fields. In the STELLAR registration trial, 80 unresectable MPM patients treated with Tumor Treating Fields plus chemotherapy experienced a median overall survival of 18.2 months (95% CI 12.1-25.8).

MPM is a rare cancer that has been strongly linked to asbestos exposure. Approximately 3,000 people are diagnosed with MPM in the United States annually. Prior to the FDA approval of NovoTTF-100L, pemetrexed plus cisplatin was the only FDA-approved therapy for patients with unresectable MPM.

NovoTTF-100L for MPM is classified as a Humanitarian Use Device (HUD) and was approved under Humanitarian Device Exemption (HDE). The HDE pathway was created to encourage companies to innovate in rare diseases with underserved patient populations. The FDA approved Optune®, another Tumor Treating Fields delivery system, under the Premarket Authorization (PMA) pathway in 2011 for the treatment of glioblastoma (GBM). Since 2011, more than 12,000 patients with GBM have been treated with Tumor Treating Fields.

“Since 2000, we have been developing and commercializing Tumor Treating Fields to extend survivals in some of the most aggressive forms of cancer,” said Bill Doyle, Novocure’s Executive Chairman. “FDA approval of NovoTTF-100L provides patients with the first FDA-approved treatment for MPM in more than 15 years and, as our first FDA-

approved torso cancer indication, marks a major milestone for Novocure . We are thankful for the patients, caregivers and health care providers who partnered with us to make this possible. ”

“MPM is a devastating disease, with only 10 to 20 percent of patients being candidates for surgery to remove the tumor,” said Mary Hesdorffer, NP, Executive Director of the Mesothelioma Applied Research Foundation. “Typically, mesothelioma patients who cannot have surgery receive palliative care to mitigate their symptoms. NovoTTF-100L provides unresectable MPM patients with a treatment option that may improve survival. We are encouraged by the FDA approval and hope it is just the beginning of innovation in the treatment of this aggressive disease.”

Efficacy outcomes in the STELLAR trial
The FDA approval is based on the results of the STELLAR trial. STELLAR was a prospective, single-arm trial designed to study the safety and efficacy of NovoTTF-100L plus chemotherapy first-line in patients with unresectable MPM. The trial included 80 patients with unresectable and previously untreated MPM who were candidates for treatment with pemetrexed and cisplatin or carboplatin. The trial was powered to prospectively determine the overall survival in patients treated with NovoTTF-100L plus chemotherapy. Secondary endpoints included overall response rate (per mRECIST criteria), progression free survival and safety.

The median overall survival was 18.2 months (95% CI 12.1-25.8) across all patients treated with NovoTTF-100L plus chemotherapy. The median overall survival was 21.2 months for patients with epithelioid MPM (n=53) and 12.1 months for patients with non-epithelioid MPM (n=21). More than half, 62 percent, of patients (n=80) enrolled in the STELLAR trial who used NovoTTF-100L plus chemotherapy were still alive at one year. The disease control rate in patients with at least one follow-up CT scan performed (n=72) was 97 percent. 40 percent of patients had a partial response, 57 percent had stable disease, and 3 percent had progressive disease. The median progression free survival was 7.6 months.

In addition, the STELLAR trial demonstrated that NovoTTF-100L could be combined with chemotherapy. There was no increase in serious systemic adverse events when NovoTTF-100L was added to chemotherapy. Mild-to-moderate skin irritation was the most common device-related side effect with NovoTTF-100L.

Caution: Federal law restricts this device to sale by or on the order of a physician. Humanitarian Device. Authorized by Federal Law for use in the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma

concurrently with pemetrexed and platinum based chemotherapy. The effectiveness of this device for this use has not been demonstrated.

About Novocure
Novocure is a global oncology company working to extend survival in some of the most aggressive forms of cancer by developing and commercializing its innovative therapy, Tumor Treating Fields. Tumor Treating Fields is a cancer therapy that uses electric fields tuned to specific frequencies to disrupt solid tumor 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 Tumor Treating Fields in brain metastases, non-small cell lung cancer, pancreatic cancer, ovarian cancer and liver 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 .

Approved Indications
The NovoTTF-100L System is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy.

Optune is intended as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM).

Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery, and completion of radiation therapy together with concomitant standard of care chemotherapy.

For the treatment of recurrent GBM, Optune is indicated following histologically- or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

Important Safety Information
Contraindications
Do not use the NovoTTF-100L System in patients with MPM with implantable electronic medical devices such as pacemakers or implantable automatic defibrillators, etc. Do not use Optune in patients with GBM with an implanted medical device, a skull defect (such

as, missing bone with no replacement), or bullet fragments. Use of Optune together with skull defects or bullet fragments has not been tested and may possibly lead to tissue damage or render Optune ineffective.

Use of the NovoTTF-100L System for MPM or Optune for GBM together with implanted electronic devices has not been tested and may lead to malfunctioning of the implanted device.

Do not use the NovoTTF-100L System for MPM or Optune for GBM in patients known to be sensitive to conductive hydrogels. Skin contact with the gel used with the NovoTTF-100L System and Optune may commonly cause increased redness and itching, and may rarely lead to severe allergic reactions such as shock and respiratory failure.

Warnings and Precautions
The NovoTTF-100L System and Optune can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure®.

The most common (≥10%) adverse events involving the NovoTTF-100L System in combination with chemotherapy in patients with MPM were anemia, constipation, nausea, asthenia, chest pain, fatigue, device skin reaction, pruritus, and cough.

Other potential adverse effects associated with the use of the NovoTTF-100L System include: treatment related skin toxicity, allergic reaction to the plaster or to the gel, electrode overheating leading to pain and/or local skin burns, infections at sites of electrode contact with the skin, local warmth and tingling sensation beneath the electrodes, muscle twitching, medical site reaction and skin breakdown/skin ulcer.

The most common (≥10%) adverse events involving Optune in combination with chemotherapy in patients with GBM were thrombocytopenia, nausea, constipation, vomiting, fatigue, convulsions, and depression.

The most common (≥10%) adverse events related to Optune treatment alone in patients with GBM were medical device site reaction and headache. Other less common adverse reactions were malaise, muscle twitching, and falls related to carrying the device.

If the patient has an underlying serious skin condition on the treated area, evaluate whether this may prevent or temporarily interfere with the NovoTTF-100L System and Optune treatment.

Do not prescribe the NovoTTF-100L System or Optune for patients that are pregnant, you think might be pregnant or are trying to get pregnant, as the safety and effectiveness of NovoTTF-100L System and Optune in these populations have not been established.

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 28, 2019, 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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