

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): April 17, 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 April 17, 2018, NovoCure Limited issued a press release announcing certain results from its phase 2 pilot 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 April 17, 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: April 17, 2018

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

Novocure Reports Positive Top-line Results from STELLAR Phase 2 Pilot Trial in Mesothelioma

Final STELLAR data exceeded the results of the interim analysis for all efficacy endpoints

Novocure plans to submit a Humanitarian Device Exemption application to the FDA for approval

St. Helier, Jersey – Novocure (NASDAQ: NVCR) announced today positive top-line results from its STELLAR phase 2 pilot trial in mesothelioma demonstrating clinically meaningful improvements in overall survival and progression free survival among patients who received Tumor Treating Fields plus standard of care chemotherapy, pemetrexed and cisplatin or carboplatin, compared to historical control data of patients who received standard of care chemotherapy alone.

The final data exceeded the results of the interim analysis presented in December 2016 at the International Association for the Study of Lung Cancer (IASLC) 17th World Conference on Lung Cancer for all efficacy endpoints. No device-related serious adverse events were reported. Novocure will submit the full data for presentation at an upcoming medical conference.

“We are extremely pleased with these topline results, which bring us one step closer to realizing the potential for a new treatment for mesothelioma patients in desperate need,” said Dr. Eilon Kirson, Novocure’s Chief Science Officer and Head of Research and Development. “Mesothelioma is the first torso indication for which Novocure will pursue FDA approval. The STELLAR data reinforce our belief that Tumor Treating Fields may be a broadly applicable platform technology for the treatment of solid tumors. We look forward to sharing the detailed results of the study with the lung cancer community at an upcoming medical conference.”

Novocure previously received Humanitarian Use Device (HUD) designation for the use of Tumor Treating Fields for the treatment of pleural mesothelioma. Based upon the final STELLAR data, Novocure plans to submit a Humanitarian Device Exemption (HDE) application to the FDA for approval. An approved HDE would allow Novocure to market Tumor Treating Fields in combination with standard of care chemotherapy as a treatment for pleural mesothelioma in the United States.

Tumor Treating Fields in combination with standard of care chemotherapy is an investigational treatment for pleural mesothelioma and is not approved for this indication. These results are preliminary top-line data and are subject to further analysis.

About STELLAR

The STELLAR trial is a phase 2 pilot single-arm, open-label, multi-center trial 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 historical control for this trial is the results of the 2003 pemetrexed phase 3 FDA registration trial.

An interim analysis of the first 42 patients enrolled in the trial with an average follow-up time of 11.5 months was presented at the International Association for the Study of Lung Cancer in December 2016. The one-year survival rate of patients treated with Tumor Treating Fields combined with pemetrexed and cisplatin or carboplatin was 80 percent (compared to 50 percent in pemetrexed and cisplatin-alone historical controls). Median progression free survival in the Tumor Treating Fields-treated group was 7.3 months (compared to 5.7 months in pemetrexed and cisplatin-alone historical controls) and one-year survival rate was 79.7 percent (compared to 50.3 percent in pemetrexed and cisplatin-alone historical controls). Median overall survival had not yet been reached. No device-related serious adverse events had been reported to date.

About Mesothelioma

Malignant 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 a global oncology company developing a proprietary platform technology 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 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.

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