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 3, 2022
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 incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

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.

☐

Item 7.01 Regulation FD Disclosure

On June 3, 2022, NovoCure Limited (the "Company" or "Novocure"), jointly with Zai Lab, issued a press release announcing that the EF-31 phase 2 pilot study, testing the safety and efficacy of Tumor Treating Fields (TTFields) together with standard-of-care (chemotherapy alone or in combination with trastuzumab for HER2-positive patients) as a first-line treatment in patients with gastric adenocarcinoma, met its primary endpoint of objective response rate with supportive signals across secondary endpoints. TTFields therapy was well tolerated, with no increase in the systemic toxicity of the XELOX chemotherapy regimen or the combination regimen, and no high-grade skin toxicities were reported.

Initial analysis was conducted with a median follow-up period of 8.6 months. The primary endpoint, confirmed objective response rate, was 50%. Median progression-free survival was 7.8 months. Duration of response was 10.3 months. Median overall survival has not yet been reached with a one-year survival rate of 72%.

The EF-31 clinical study, which is a prospective, single arm, phase 2 pilot study conducted in China, included 26 patients with unresectable, locally advanced or metastatic gastroesophageal junction or gastric adenocarcinoma who were previously untreated with systemic therapy. Patients received continuous treatment with TTFields together with the XELOX chemotherapy regimen (combination of oxaliplatin and capecitabine). Trastuzumab was allowed for HER2-positive patients.

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

Exhibit No.	Description
99.1	Press Release of NovoCure Limited, dated June 3, 2022
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 3, 2022

By: /s/ Ashley Cordova
Name: Ashley Cordova
Title: Chief Financial Officer

Novocure and Zai Lab Announce EF-31 Phase 2 Pilot Study Evaluating Tumor Treating Fields Together with Standard-of-Care Chemotherapy Meets Primary Endpoint for First-Line Treatment of Gastric Cancer

Confirmed objective response rate was 50% for patients treated with TTFields together with standard-of-care chemotherapy

Duration of response was 10.3 months

One-year survival was 72%

ST. HELIER, Jersey, SHANGHAI, SAN FRANCISCO and CAMBRIDGE, Mass., June 3, 2022 – Novocure (NASDAQ: NVCR), a global oncology company working to extend survival in some of the most aggressive forms of cancer, and Zai Lab (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company, today announced that the EF-31 phase 2 pilot study, testing the safety and efficacy of Tumor Treating Fields (TTFields) together with standard-of-care (chemotherapy alone or in combination with trastuzumab for HER2-positive patients) as a first-line treatment in patients with gastric adenocarcinoma, met its primary endpoint of objective response rate with supportive signals across secondary endpoints. TTFields therapy was well tolerated, with no increase in the systemic toxicity of the XELOX chemotherapy regimen or the combination regimen, and no high-grade skin toxicities were reported.

Initial analysis was conducted with a median follow-up period of 8.6 months. The primary endpoint, confirmed objective response rate, was 50%. Median progression-free survival was 7.8 months. Duration of response was 10.3 months. Median overall survival has not yet been reached with a one-year survival rate of 72%.

“The EF-31 outcomes are encouraging in a historically difficult to treat cancer,” said Dr. Jin Li, Head of Department of Oncology, Shanghai East Hospital, Tongji University School of Medicine. “The addition of Tumor Treating Fields to standard-of-care chemotherapy could lead to impactful changes in the treatment of gastric cancer patients and I look forward to confirming these data in additional clinical studies.”

The EF-31 clinical study, which is a prospective, single arm, phase 2 pilot study conducted in China, included 26 patients with unresectable, locally advanced or metastatic gastroesophageal junction or gastric adenocarcinoma who were previously untreated with systemic therapy. Patients received continuous treatment with TTFields together with the XELOX chemotherapy regimen (combination of oxaliplatin and capecitabine). Trastuzumab was allowed for HER2-positive patients.

“TTFields therapy is a highly versatile modality with potential for broad applicability across solid tumor types and lines of therapy,” said Asaf Danziger, Novocure’s Chief Executive Officer. “We would like to thank our patients, study investigators, and our partners at Zai Lab. The EF-31 results suggest that the addition of TTFields to standard therapies may offer better patient outcomes in gastric cancer and we are eager to continue exploring these potential benefits as we look ahead to a randomized phase 3 clinical study.”

“Each year, more than one million new gastric cancer cases are diagnosed worldwide, with approximately half of all gastric cancer cases occurring in China. There is an urgent need to improve therapeutic options,” said Alan Sandler, M.D., President and Head of Global Development, Oncology at Zai Lab. “EF-31, conducted in China, represents an important milestone as Novocure and Zai work together to expand TTFields into new disease areas. We look forward to working with Novocure in future global clinical studies across multiple solid tumor indications.”

About Gastric Cancer
Gastric cancer is the third leading cause of cancer deaths worldwide and the third leading cause of cancer deaths in China. The incidence of gastric cancer is approximately 478,500 new cases annually in China, and approximately 26,000 new cases annually in the U.S.

Current therapies include surgery, chemotherapy, radiotherapy, targeted therapy and recently, immunotherapy. One of the most commonly used chemotherapy regimens for treating gastric cancer is XELOX, a combination of oxaliplatin and capecitabine. In the recent phase 3 trial (CheckMate 649, NCT-02872116, *Lancet* 2021) studying gastric cancer, the standard-of-care chemotherapy regimens showed an objective response rate range of 41% - 45%, median progression-free survival of 6.9 months, duration of response of 6.9 months, and overall survival of 11.6 months. One-year survival was 48%.

Gastric cancer is the third most-frequent cancer in China. Currently, the five-year survival rate of locally advanced or metastatic gastric cancer ranges from 5% to 20%, and the median overall survival is approximately one year.

About Tumor Treating Fields
Tumor Treating Fields NovoTTF-100L(P) is an investigational device for the treatment of gastric cancer. Safety and efficacy have not been established. Tumor Treating Fields, or TTFields, are electric fields that disrupt cancer cell division. Fundamental scientific research extends across more than two decades and, in all preclinical research to date, TTFields have demonstrated a consistent anti-mitotic effect. TTFields therapy is intended principally for use together with other standard-of-care cancer treatments. There is a growing body of evidence that supports TTFields’ broad applicability with certain other cancer therapies, including radiation therapy, certain chemotherapies and certain immunotherapies. In clinical research and commercial experience to date, TTFields therapy has exhibited no systemic toxicity, with mild to moderate skin irritation being the most common side effect. The TTFields global development program includes a network of preclinical collaborators and a broad range of clinical trials across all phases, including four phase 3 pivotal trials in a variety of tumor types. To date, more than 24,000 patients have been treated with TTFields therapy.

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 in the U.S. for the treatment of adult patients with malignant 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 Jersey, and with a growing global footprint, Novocure has regional operating centers in Root, Switzerland, 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.

About Zai Lab
Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial stage biopharmaceutical company based in China and the U.S. focused on bringing transformative medicines for oncology, autoimmune disorders, infectious diseases and neurological disorders to patients in China and around the world. Our goal is to leverage our competencies and resources to positively impact human health worldwide.

For additional information about Zai Lab, including information on our products, business activities and partnerships, research, or other events or developments, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

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 24, 2022 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.

Novocure Contacts:

Investors:
Ingrid Goldberg
investorinfo@novocure.com

610-723-7427

Media:
Leigh Labrie
media@novocure.com
610-723-7428

Zai Lab Contacts:

Investors:
Lina Zhang
+86 136-8257-6943
lina.zhang@zailaboratory.com

Media:
Danielle Halstrom / Xiaoyu Chen
215-280-3898 / +86 185-0015-5011
danielle.halstrom@zailaboratory.com / xiaoyu.chen@zailaboratory.com