

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 10, 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 1.01 Entry Into a Material Definitive Agreement.

On September 10, 2018, NovoCure Limited (the “Company”) entered into a License and Collaboration Agreement (the “Agreement”) with Zai Lab (Shanghai) Co., Ltd. (“Zai”).

Under the terms of the Agreement, the Company exclusively licensed the rights to perform clinical studies, sublicense to affiliates and third parties (subject to the Company’s consent), sell, offer for sale and import Tumor Treating Fields products in the field of oncology (each, a “Licensed Product” and collectively, the “Licensed Products”) to Zai in China, Hong Kong, Macau and Taiwan (the “Territory”). In partial consideration for the license grant to Zai for the Territory, Zai will pay the Company a non-refundable, up-front license fee in the amount of \$15 million, as well as certain development, regulatory and commercial milestone payments up to \$78 million, and tiered royalties at percentage rates from 10 up to the mid-teens on the net sales of the Licensed Products in the Territory.

Zai will purchase Licensed Products exclusively from the Company at the Company’s fully burdened manufacturing cost. The Company and Zai have agreed in principle on the supply terms and will finalize a supply agreement following the execution of the Agreement.

The Agreement is effective from and after September 10, 2018, and continues, on a region-by-region and Licensed Product-by-Licensed Product basis, in effect until the expiration of and payment by Zai of all of Zai’s royalty payment obligations applicable to such Licensed Product and such region as specified in the Agreement. Each party may terminate the Agreement upon the material breach of the Agreement by the other party, subject to certain cure periods. In addition, Zai may terminate the Agreement for convenience on twelve months’ prior notice prior to commercializing a Licensed Product and on eighteen months’ prior notice after commercializing a Licensed Product, and the Company may terminate the Agreement due to Zai’s diligence failure or material FCPA violation, subject to certain cure periods and dispute resolution mechanisms if disputes arise with respect to such failure or material violation, each as defined in the Agreement.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by the Agreement, a copy of which the Company intends to file as an exhibit to the Company’s Quarterly Report on Form 10-Q for the quarter ending September 30, 2018.

Item 7.01 Regulation FD Disclosure

On September 12, 2018, the Company issued a press release announcing the Agreement. 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 12, 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 12, 2018

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

Novocure and Zai Lab Announce Strategic Collaboration with a License Agreement for Tumor Treating Fields in Greater China

Zai Lab granted license to commercialize oncology platform technology Tumor Treating Fields, including the brand name Optune®, in China, Hong Kong, Macau and Taiwan

Zai Lab will support enrollment of Chinese patients to certain clinical trials investigating Tumor Treating Fields, intended to accelerate clinical trial enrollment

Tumor Treating Fields currently marketed in the U.S., the EU and Japan for the treatment of glioblastoma and in advanced clinical development for multiple solid tumor indications

St. Helier, Jersey and Shanghai – Novocure (NASDAQ: NVCR), a global oncology company developing a proprietary platform technology called Tumor Treating Fields, and Zai Lab (NASDAQ: ZLAB), a Shanghai-based innovative biopharmaceutical company, announced today an exclusive license agreement for Tumor Treating Fields, including the brand name Optune, in Greater China and a global strategic development collaboration. This agreement will enable Novocure to access the Chinese market and is intended to accelerate clinical trial enrollment. For Zai Lab, this agreement will add a complementary commercial stage oncology asset to its innovative pipeline.

“The Zai Lab team is passionate about bringing innovative treatments to patients in need, a passion we share at Novocure,” said Novocure’s Executive Chairman Bill Doyle. “We believe this collaboration supports our mission of making Tumor Treating Fields available to patients throughout the world and will accelerate the development of Tumor Treating Fields in indications beyond glioblastoma (GBM).”

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. Tumor Treating Fields is currently marketed under the brand name Optune in the U.S., the EU, Switzerland, Japan and certain other countries for the treatment of GBM and is in advanced clinical development for multiple solid tumor indications. Novocure reported trailing 12-month revenues from Optune of \$217 million as of June 30, 2018, representing 60 percent year-over-year revenue growth Q2 2018 versus Q2 2017. While Optune is not yet approved for commercialization in China, the technology was included and recommended with Level 1 evidence as a treatment for GBM in China’s Glioma Treatment Guideline published in 2016.

“There are approximately 45,000 newly diagnosed GBM patients annually in China,” said Lvhua Wang, Associate Director of China National Cancer Center and Vice President of China Society of Clinical Oncology. “Temozolomide is currently the only approved therapy for GBM in China so there are limited choices for one of the most deadly cancers. I am eagerly anticipating Tumor Treating Fields approval in China.”

Novocure granted Zai Lab an exclusive license to commercialize Tumor Treating Fields in China, Hong Kong, Macau and Taiwan. Zai Lab will be responsible for regulatory submissions in Greater China and will work to establish Tumor Treating Fields as an oncology treatment in this territory.

Preclinical and clinical research demonstrated that Tumor Treating Fields’ mechanism of action affected fundamental aspects of cell division and may have broad applicability across a variety of solid tumors. In addition to GBM, Novocure and Zai Lab will collaborate on development activities for Tumor Treating Fields in multiple solid tumor indications, including Novocure’s ongoing phase 3 pivotal trials in non-small cell lung cancer (NSCLC) and pancreatic cancer, and a phase 3 pivotal trial in ovarian cancer planned to open later this year. In addition, Zai Lab will conduct a phase 2 pilot trial to investigate Tumor Treating Fields in gastric cancer in China. China has one of the highest incidence rates of gastric cancer in the world, with approximately 680,000 new cases annually. Gastric cancer is the second leading cause of cancer death in men and women in China.

“Optune has demonstrated strong efficacy in a very challenging and difficult to treat cancer, GBM,” said Dr. Samantha Du, CEO of Zai Lab. “Optune was approved in Japan without the need for a local bridging trial and we hope for similar rapid development in China. In addition, Tumor Treating Fields has the potential to treat a variety of solid tumors, which we believe are complementary to Zai Lab’s existing late-stage oncology assets and represent strong commercial synergy for us.”

Novocure will receive a \$15 million upfront payment and is eligible to receive additional payments upon achievement of certain development, regulatory and commercial milestones. Novocure is also eligible to receive a royalty on net sales of the licensed products in Greater China ranging from 10 percent to the mid-teens.

China Renaissance served as sole financial advisor to Novocure for the transaction.

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 in the United States and Europe 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, mesothelioma 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.

About Zai Lab

Zai Lab (NASDAQ:ZLAB) is a Shanghai-based innovative biotech company focused on bringing transformative therapies for cancer, autoimmune and infectious diseases to patients in China and around the world. The Company's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates targeting the fast-growing segments of China's pharmaceutical market and addressing global unmet medical needs. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its partners' and its own products in order to impact human health worldwide.

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.

Zai Lab Forward-Looking Statements

This press release includes certain disclosures which contain "forward-looking statements." You can identify forward-looking statements because they contain words such as "anticipate" and "expected." Forward-looking statements are based on Zai Lab's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2017, and its other filings with the Securities and Exchange Commission. Zai Lab undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

Media and Investor Contact for Novocure:

Ashley Cordova
acordova@novocure.com
212-767-7558

Media and Investor Contacts for Zai Lab:

Zai Lab
Billy Cho
+86 21 6163 7322
billy.cho@zailaboratory.com

Investors: Jill Steier
Burns McClellan, on behalf of Zai Lab
212-213-0006, ext. 367, jsteier@burnsmc.com

Media: Nancie Steinberg / Robert Flamm, Ph.D.
Burns McClellan, on behalf of Zai Lab
212-213-0006, ext. 318 / 364, nsteinberg@burnsmc.com / rflamm@burnsmc.com