

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): January 7, 2019

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 2.02 Results of Operations and Financial Condition

On January 7, 2019, the Company issued a press release announcing certain preliminary financial results and providing certain other information for the quarter and year ended December 31, 2018. A copy of the press release is attached hereto as Exhibit 99.1 (the "Press Release").

The financial data contained therein are unaudited, preliminary, based upon the Company's good faith estimates and subject to completion of the Company's financial closing procedures. While the Company expects that its final financial results for the quarter and year ended December 31, 2018, following the completion of its financial closing procedures, will generally be consistent with the information provided in the Press Release, the Company's actual results may differ materially from these estimates as a result of the completion of its financial closing procedures for the quarter and year ended December 31, 2018, as well as final adjustments and other developments that may arise between now and the time that its financial results for the quarter and year ended December 31, 2018 are finalized.

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 January 7, 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: January 7, 2019

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

Novocure Announces Fourth Quarter and Full Year 2018 Operating Statistics, Preliminary Net Revenues and Provides Company Update

Full year 2018 preliminary net revenues of \$248.0 million, representing annual growth of more than 40 percent compared to 2017

Fourth quarter and full year 2018 financial results to be reported Thursday, Feb. 28, 2019

St. Helier, Jersey – Novocure (NASDAQ: NVCR) today reported operating statistics and preliminary, unaudited net revenues and cash balances for the fourth quarter and full year 2018. Novocure plans to discuss these results with investors at the 37th Annual J.P. Morgan Healthcare Conference in San Francisco. The company also highlighted anticipated clinical and regulatory milestones, announced national reimbursement in Sweden and confirmed a Contractor Advisory Committee (CAC) meeting date set by the durable medical equipment (DME) Medicare Administrative Contractors (MACs).

Fourth quarter 2018 highlights include:

	Three months ended December 31,			Twelve months ended December 31,		
	2018	2017	% Change	2018	2017	% Change
Non-financial						
Active patients at period end (1)	2,383	1,834	30%	2,383	1,834	30%
Prescriptions received in period (2)	1,315	1,090	21%	5,060	4,119	23%
Financial, in millions (unaudited)						
Net revenues (3)	\$ 69.6	\$ 53.7	30%	\$ 248.0	\$ 177.0	40%
Cash and cash equivalents at the end of period (3)	\$ 140.6	\$ 78.6				
Short-term investments at the end of period (3)	\$ 105.3	\$ 104.7				

(1) An "active patient" is a patient who is on Optune under a commercial prescription order as of the measurement date, including patients who may be on a temporary break from treatment and who plan to resume treatment in less than 60 days.

(2) A "prescription received" is a commercial order for Optune that is received from a physician certified to treat patients with Optune for a patient not previously on Optune. Orders to renew or extend treatment are not included in this total.

(3) The preliminary, unaudited results described in this press release are estimates only and are subject to revision until the company reports its full financial results for the fourth quarter 2018 on Feb. 28, 2019.

"We continued to drive Optune adoption in the fourth quarter with full year 2018 preliminary net revenues of \$248.0 million, representing annual growth of more than 40 percent. Prescriptions for patients with newly diagnosed GBM grew to approximately

950 in the fourth quarter, driving our 16th consecutive quarter of active patient growth since the initial presentation of our EF-14 data,” said William Doyle, Novocure’s Executive Chairman. “Notably, we also expanded our geographic reach with national reimbursement in Sweden and Zai Lab’s recent launch of Optune in Hong Kong .”

“At Novocure, we are working to extend survival in some of the most aggressive forms of cancer by developing and commercializing our innovative therapy,” continued Mr. Doyle. “With an application at the FDA for mesothelioma and ongoing or planned phase 3 pivotal trials in brain metastases, non-small cell lung cancer, pancreatic cancer and ovarian cancer, we believe GBM represents just the tip of the iceberg for Tumor Treating Fields. We look forward to providing a full company update and discussing our 2018 financial results on our February conference call.”

Fourth quarter 2018 operating statistics and preliminary financial highlights

There were 2,383 active patients on Optune at December 31, 2018, representing 30 percent growth compared to December 31, 2017, and 6 percent growth compared to September 30, 2018.

- In the United States, there were 1,637 active patients on Optune at December 31, 2018, representing 24 percent growth compared to December 31, 2017.
- In Germany and other EMEA markets, there were 654 active patients on Optune at December 31, 2018, representing 28 percent growth compared to December 31, 2017.
- In Japan, there were 92 active patients on Optune at December 31, 2018, representing 4,500 percent growth compared to December 31, 2017.

Additionally, 1,315 prescriptions were received in the quarter ended December 31, 2018, representing 21 percent growth compared to the same period in 2017, and 6 percent growth compared to the quarter ended September 30, 2018.

Prescriptions for newly diagnosed GBM continued to grow, with approximately 950 Optune prescriptions in the fourth quarter written for patients with newly diagnosed GBM.

- In the United States, 941 prescriptions were received in the quarter ended December 31, 2018, representing 16 percent growth compared to the same period in 2017.
 - In Germany and other EMEA markets, 322 prescriptions were received in the quarter ended December 31, 2018, representing 15 percent growth compared to the same period in 2017.
 - In Japan, 52 prescriptions were received in the quarter ended December 31, 2018, representing 5,100 percent growth compared to the same period in 2017.
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On a preliminary, unaudited basis, for the quarter ended December 31, 2018, net revenues were \$69.6 million, representing 30 percent growth compared to the fourth quarter 2017, and full year 2018 net revenues were \$248.0 million, representing annual growth of more than 40 percent compared to 2017.

At December 31, 2018, on a preliminary, unaudited basis, Novocure had \$140.6 million in cash and cash equivalents and \$105.3 million in short-term investments, for a total balance of \$245.9 million in cash, cash equivalents and short-term investments. This represents an increase of \$18.2 million in cash and investments since September 30, 2018.

Anticipated clinical and regulatory milestones

- FDA approval for unresectable malignant pleural mesothelioma (2019)
- Initiation of phase 3 pivotal trial in recurrent ovarian cancer (2019)
- Zai Labs initiation of phase 2 pilot trial in gastric cancer (2019)
- Data from phase 2 pilot HEPANOVA trial in advanced liver cancer (2020)
- Interim analysis of phase 3 pivotal LUNAR trial in non-small cell lung cancer (2020)
- Data from phase 3 pivotal METIS trial in brain metastases (2021)
- Interim analysis of phase 3 pivotal PANOVA-3 trial in locally advanced pancreatic cancer (2021)
- Final data from phase 3 pivotal LUNAR trial in non-small cell lung cancer (2021)
- Interim analysis of phase 3 pivotal INNOVATE-3 trial in recurrent ovarian cancer (2022)

Novocure has received initial comments from the FDA on its October 2018 Humanitarian Device Exemption (HDE) application for approval in malignant pleural mesothelioma and is currently preparing its response.

Other company updates

Novocure announced today that it has finalized a pricing and reimbursement agreement for Optune in Sweden. Reimbursement decisions in Sweden are supported by a comprehensive health technology assessment. With defined reimbursement now established in Sweden, Novocure's efforts will turn to building adoption.

Novocure also announced today that the DME MACs will host a CAC meeting on March 6, 2019. The CAC meeting is intended to provide a formal mechanism for healthcare professionals to be informed of and participate in the development of the local coverage determination (LCD) for Optune for the treatment of newly diagnosed GBM. Following

the CAC meeting, the DME MACs will draft and publish a proposed LCD for public comment.

Fourth quarter and full year 2018 financial results conference call

Novocure will host a conference call and webcast to discuss fourth quarter and full year 2018 financial results on Thursday, Feb. 28, 2019 at 8 a.m. EDT. Analysts and investors can participate in the conference call by dialing 855-442-6895 for domestic callers and 509-960-9037 for international callers, using the conference ID 3956899.

The webcast, earnings slides presented during the webcast and the corporate presentation can be accessed live from the Investor Relations page of Novocure's website, www.novocure.com/investor-relations, and will be available for at least 14 days following the call.

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, liver 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, timing of clinical milestones, 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.

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