

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): February 28, 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 February 28, 2019, the Company issued a press release announcing certain financial results for the quarter and full year ended December 31, 2018. 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 February 28, 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: February 28, 2019

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

Novocure Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Company Update

Quarterly net revenues of \$69.7 million, representing 30 percent growth versus the fourth quarter 2017 and 8 percent growth versus the third quarter 2018

Full year 2018 net revenues of \$248.1 million, representing annual growth of 40 percent compared to 2017

Three additional phase 3 clinical trials ongoing studying the use of Optune in brain metastases, non-small-cell lung cancer and pancreatic cancer

St. Helier, Jersey – Novocure (NASDAQ: NVCR) today reported financial results for the quarter and year ended December 31, 2018, highlighting continued revenue growth, anticipated clinical and regulatory milestones and a strong cash position. 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.

Fourth quarter and full year 2018 highlights include:

	Three months ended December 31,			Year 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						
Net revenues	\$ 69.7	\$ 53.7	30%	\$ 248.1	\$ 177.0	40%
Net income (loss)	\$ (15.6)	\$ (10.9)	43%	\$ (63.6)	\$ (61.7)	3%
Cash and cash equivalents at the end of period	\$ 140.6	\$ 78.6				
Short-term investments at the end of period	\$ 105.3	\$ 104.7				
Total cash, cash equivalents and short-term investments at the end of period	\$ 245.9	\$ 183.3				

- (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.

“2018 was an extremely productive year for Novocure,” said William Doyle, Novocure’s Executive Chairman. “Highlights included annual revenue growth of 40 percent, the presentation of our STELLAR data in mesothelioma, the first patient enrollment in our PANOVA-3 phase 3 trial for pancreatic cancer and our collaboration agreement with Zai Labs in China. We continued to grow our glioblastoma business globally and invested more than \$50 million in research and development in 2018.”

“At Novocure, we are working to extend survival in some of the most aggressive forms of cancer by developing and commercializing Tumor Treating Fields,” continued Mr. Doyle. “With 2018 revenues approaching \$250 million, four indications in our late stage pipeline and significant cash on hand, we believe we enter 2019 well-positioned to deliver both continued near-term growth and significant long-term value.”

Fourth quarter 2018 operating statistics and financial update

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. The increase in active patients was driven by increased commercial adoption and by continued growth in prescriptions for patients with newly diagnosed GBM, who typically have a longer duration of treatment with Optune.

- 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 significant growth in the first year with reimbursement approval for Optune in Japan.

There were 1,315 prescriptions 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, 9 41 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 significant growth in the first year with reimbursement approval for Optune in Japan.

For the three months ended December 31, 2018, net revenues were \$69.7 million, representing 30 percent growth versus the same period in 2017 and 8 percent growth versus the three months ended September 30, 2018. This growth was primarily driven by an increase in active patients.

For the three months ended December 31, 2018, cost of revenues was \$23.0 million compared to \$15.6 million for the same period in 2017, representing an increase of 47 percent. The increase was primarily driven by the cost of shipping transducer arrays to a higher volume of commercial patients and a one-time increase of \$2.7 million in non-recoverable indirect taxes.

Research, development and clinical trials expenses for the three months ended December 31, 2018, were \$15.0 million compared to \$10.0 million for the same period in 2017, representing an increase of 50 percent. This was primarily due to an increase in clinical trial and personnel expenses for our METIS, LUNAR, and PANOVA-3 trials and an increase in personnel costs associated with regulatory and medical affairs.

Sales and marketing expenses for the three months ended December 31, 2018, were \$21.2 million compared to \$16.0 million for the same period in 2017, representing an increase of 32 percent. This was primarily due to increased marketing expenses, increases in personnel costs associated with a larger sales force globally and increased share-based compensation expense.

General and administrative expenses for the three months ended December 31, 2018, were \$19.1 million compared to \$16.5 million for the same period in 2017, representing an increase of 16 percent. This was primarily due to an increase in share-based compensation and an increase in professional services.

Personnel costs for the three months ended December 31, 2018, included \$10.6 million in non-cash share-based compensation expenses, comprised of \$0.4 million in cost of

revenues; \$ 1.3 million in research, development and clinical trials ; \$ 2.1 million in sales and marketing; and \$ 6.9 million in general and administrative expenses. Total non-cash share-based compensation expenses for the fourth quarter 2017 were \$ 6.4 million .

Net loss for the three months ended December 31, 2018, was \$15.6 million compared to net loss of \$10.9 million for the same period in 2017.

At December 31, 2018, we 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)

Conference call details

Novocure will host a conference call and webcast to discuss fourth quarter and full year 2018 financial results today, 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.

Contractor advisory committee meeting details

The durable medical equipment Medicare administrative contractors (DME MACs) plan to host a contractor advisory committee on March 6, 2019 from 9 a.m. to 4 p.m. EDT to

discuss the scientific evidence underlying Novocure's local coverage decision reconsideration request.

The meeting agenda is available on the DME MAC web sites. Morning and afternoon sessions of the contractor advisory committee meeting can be viewed live on the Centers for Medicare and Medicaid Services YouTube channel. A recording of the meeting will also be posted on the DME MAC web sites following the meeting.

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, 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 product is approved for the treatment of adult patients with glioblastoma. Novocure has ongoing or completed clinical trials investigating Tumor Treating Fields in mesothelioma, 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.

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, development of potential products, interpretation of clinical results, prospects for regulatory approval, manufacturing development and capabilities, market prospects for its products, 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.

Consolidated Statements of Operations

USD in thousands (except share and per share data)

	Three months ended December 31,		Twelve months ended December 31,	
	2018	2017	2018	2017
	Unaudited		Audited	
Net revenues	\$ 69,674	\$ 53,661	\$ 248,069	\$ 177,026
Cost of revenues	23,028	15,640	80,048	55,609
Gross profit	46,646	38,021	168,021	121,417
Operating costs and expenses:				
Research, development and clinical trials	15,034	10,048	50,574	38,103
Sales and marketing	21,208	16,025	77,663	63,528
General and administrative	19,068	16,454	73,456	59,114
Total operating costs and expenses	55,310	42,527	201,693	160,745
Operating income (loss)	(8,664)	(4,506)	(33,672)	(39,328)
Financial expenses (income), net	2,160	2,384	12,270	9,169
Income (loss) before income taxes	(10,824)	(6,890)	(45,942)	(48,497)
Income taxes	4,807	4,055	17,617	13,165
Net income (loss)	\$ (15,631)	\$ (10,945)	\$ (63,559)	\$ (61,662)
Basic and diluted net income (loss) per ordinary share	\$ (0.17)	\$ (0.12)	\$ (0.69)	\$ (0.70)
Weighted average number of ordinary shares used in computing basic and diluted net income (loss) per share	93,083,298	89,389,364	91,828,043	88,546,719

Consolidated Balance Sheets

USD in thousands (except share data)

	December 31, 2018	December 31, 2017
	<u>Audited</u>	<u>Audited</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 140,622	\$ 78,592
Short-term investments	105,256	104,719
Restricted cash	2,134	2,126
Trade receivables	36,523	29,567
Receivables and prepaid expenses	14,279	8,105
Inventories	22,555	22,025
Total current assets	<u>321,369</u>	<u>245,134</u>
LONG-TERM ASSETS:		
Property and equipment, net	8,442	9,031
Field equipment, net	6,924	9,036
Severance pay fund	113	111
Other long-term assets	2,945	1,986
Total long-term assets	<u>18,424</u>	<u>20,164</u>
TOTAL ASSETS	<u>\$ 339,793</u>	<u>\$ 265,298</u>

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
	<u>Audited</u>	<u>Audited</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 26,708	\$ 17,206
Other payables and accrued expenses	37,852	32,996
Total current liabilities	<u>64,560</u>	<u>50,202</u>
LONG-TERM LIABILITIES:		
Long-term loan, net of discount and issuance costs	149,268	97,342
Employee benefit liabilities	2,683	2,453
Deferred Revenues	9,929	-
Other long-term liabilities	1,094	1,737
Total long-term liabilities	<u>162,974</u>	<u>101,532</u>
TOTAL LIABILITIES	<u>227,534</u>	<u>151,734</u>
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares no par value, unlimited shares authorized; issued and outstanding: 93,254,185 shares and 89,478,032 shares at December 31, 2018 and December 31, 2017, respectively	-	-
Additional paid-in capital	757,314	697,165
Accumulated other comprehensive income (loss)	(1,400)	(1,343)
Retained earnings (accumulated deficit)	(643,655)	(582,258)
Total shareholders' equity	<u>112,259</u>	<u>113,564</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 339,793</u>	<u>\$ 265,298</u>

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