

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): May 2, 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.

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

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

Item 2.02 Results of Operations and Financial Condition

On May 2, 2019, the Company issued a press release announcing certain financial results for the quarter ended March 31, 2019 . 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 May 2, 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: May 2, 2019

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

Novocure Reports First Quarter 2019 Financial Results and Provides Company Update

Quarterly net revenues of \$73.3 million, representing 41 percent growth versus the first quarter 2018 and 5 percent growth versus the fourth quarter 2018

Mesothelioma humanitarian device exemption application under FDA review

Enrollment ongoing in four phase 3 pivotal trials, creating a significant market expansion opportunity in some of the most aggressive forms of cancer

St. Helier, Jersey – Novocure (NASDAQ: NVCR) today reported financial results for the quarter ended March 31, 2019, highlighting continued revenue growth, an advancing clinical pipeline 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.

First quarter 2019 highlights include:

	<u>2019</u>	<u>Three months ended March 31, 2018</u>	<u>% Change</u>
Non-financial			
Active patients at period end (1)	2,631	2,009	31%
Prescriptions received in period (2)	1,310	1,258	4%
Financial, in million			
Net revenues	\$ 73.3	\$ 52.1	41%
Net loss	\$ (12.2)	\$ (20.7)	-41%
Cash and cash equivalents at the end of period	\$ 152.1	\$ 111.6	36%
Short-term investments at the end of period	\$ 104.5	\$ 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.

“With more than 2,600 patients on Optune as of March 31, 2019, we delivered another quarter of strong financial performance. We posted \$73.3 million in net revenues in the first quarter 2019 with year-over-year revenue growth of 41 percent,” said Asaf Danziger, Novocure’s Chief Executive Officer. “We also strengthened our balance sheet, adding more than \$10 million in cash, cash equivalents and short-term investments in the first quarter. We continued to fund our increased investments in clinical trials and Optune technology improvements with cash flow from the GBM business.”

“Our clinical pipeline continues to advance. Our HDE application for malignant pleural mesothelioma is under review at the FDA and, with the first patient enrolled in our INNOVATE-3 trial in March, enrollment is now ongoing in four phase 3 pivotal trials, creating a significant market expansion opportunity,” added William Doyle, Novocure’s Executive Chairman. “We believe we are at an important inflection point, transitioning to cash generation while expanding globally, driving clinical trials and investing in technology improvements as we work to extend survival in some of the most aggressive forms of cancer.”

First quarter 2019 operating statistics and financial update

There were 2,631 active patients on Optune at March 31, 2019, representing 31 percent growth versus March 31, 2018, and 10 percent growth versus December 31, 2018. The increase in active patients was driven primarily by prescription growth in EMEA and Japan and the ongoing benefit from continued growth in prescriptions for patients with newly diagnosed GBM globally.

- In the United States, there were 1,778 active patients on Optune at March 31, 2019, representing 23 percent growth versus March 31, 2018.
- In Germany and other EMEA markets, there were 735 active patients on Optune at March 31, 2019, representing 35 percent growth versus March 31, 2018.
- In Japan, there were 118 active patients on Optune at March 31, 2019, representing 490 percent growth versus March 31, 2018.

Additionally, 1,310 prescriptions were received in the three months ended March 31, 2019, representing four percent growth compared to the same period in 2018, and flat versus the three months ended December 31, 2018.

- In the United States, 925 prescriptions were received in the three months ended March 31, 2019, representing a two percent decline compared to the same period in 2018.
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- In Germany and other EMEA markets, 330 prescriptions were received in the three months ended March 31, 2019, representing 17 percent growth compared to the same period in 2018.
- In Japan, 55 prescriptions were received in the three months ended March 31, 2019, representing 83 percent growth compared to the same period in 2018.

For the three months ended March 31, 2019, net revenues were \$73.3 million, representing 41 percent growth versus the same period in 2018. Revenue growth was primarily driven by an increase of 622 active patients in our currently active markets, representing 31 percent growth, and an increase in net revenues per active patient. The increase in net revenues per active patient was primarily driven by improving reimbursement approval rates in Germany and by growth in Austria and Japan.

For the three months ended March 31, 2019, cost of revenues was \$19.8 million compared to \$18.2 million for the same period in 2018, representing an increase of 9 percent. The increase in cost of revenues was primarily due to the cost of shipping transducer arrays to a higher volume of active patients. Gross margin was 73% for the three months ended March 31, 2019 compared to 65% for the three months ended March 31, 2018.

Research, development and clinical trials expenses for the three months ended March 31, 2019, were \$17.0 million compared to \$11.1 million for the same period in 2018, representing an increase of 53 percent. This was primarily due to an increase in clinical trial and personnel expenses for our INNOVATE-3, LUNAR, METIS and PANOVA-3 trials and an increase in costs associated with medical affairs, regulatory and engineering.

Sales and marketing expenses for the three months ended March 31, 2019, were \$22.3 million compared to \$18.1 million for the same period in 2018, representing an increase of 23 percent. This was primarily due to increased marketing expenses and increased personnel costs associated with a larger sales force globally.

General and administrative expenses for the three months ended March 31, 2019, were \$20.2 million compared to \$17.3 million for the same period in 2018, representing an increase of 17 percent. This was primarily due to an increase in personnel costs and an increase in professional services.

Personnel costs for the three months ended March 31, 2019, included \$9.7 million in non-cash share-based compensation expenses, comprised of \$0.4 million in cost of revenues; \$1.2 million in research, development and clinical trials; \$2.0 million in sales

and marketing; and \$ 6.1 million in general and administrative expenses. Total non-cash share-based compensation expenses for the first quarter 2018 were \$ 8.5 million.

Net loss for the three months ended March 31, 2019, was \$12.2 million, or \$0.13 per share, compared to net loss of \$20.7 million for the same period in 2018, or \$0.23 per share, representing an improvement of 41 percent.

At March 31, 2019, we had \$152.1 million in cash and cash equivalents and \$104.5 million in short-term investments, for a total balance of \$256.6 million in cash, cash equivalents and short-term investments.

Anticipated clinical and regulatory milestones

- FDA approval for unresectable malignant pleural mesothelioma (2019)
- Zai Lab 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)
- Final data from phase 3 pivotal PANOVA-3 trial in locally advanced pancreatic cancer (2022)
- Final data from phase 3 pivotal INNOVATE-3 trial in recurrent ovarian cancer (2024)

Conference call details

Novocure will host a conference call and [webcast](#) to discuss first quarter 2018 financial results today, Thursday, May 2, 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 8956998.

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 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, 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 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 March 31,		Year ended
	2019	2018	December 31,
	Unaudited		Audited
Net revenues	\$ 73,309	\$ 52,125	\$ 248,069
Cost of revenues	19,814	18,238	80,048
Gross profit	53,495	33,887	168,021
Operating costs and expenses:			
Research, development and clinical trials	17,042	11,104	50,574
Sales and marketing	22,333	18,135	77,663
General and administrative	20,238	17,325	73,456
Total operating costs and expenses	59,613	46,564	201,693
Operating loss	(6,118)	(12,677)	(33,672)
Financial expenses, net	2,371	4,853	12,270
Loss before income taxes	(8,489)	(17,530)	(45,942)
Income taxes	3,661	3,194	17,617
Net loss	\$ (12,150)	\$ (20,724)	\$ (63,559)
Basic and diluted net loss per ordinary share	\$ (0.13)	\$ (0.23)	\$ (0.69)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	94,811,282	89,985,612	91,828,043

Consolidated Balance Sheets

USD in thousands (except share data)

	<u>March 31, 2019</u>	<u>December 31, 2018</u>
	Unaudited	Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 152,067	\$ 140,622
Short-term investments	104,535	105,256
Restricted cash	2,094	2,134
Trade receivables	39,220	36,523
Receivables and prepaid expenses	13,619	14,279
Inventories	24,138	22,555
Total current assets	<u>335,673</u>	<u>321,369</u>
LONG-TERM ASSETS:		
Property and equipment, net	8,421	8,442
Field equipment, net	7,266	6,924
Right-of-use assets, net	13,920	-
Other long-term assets	4,975	3,058
Total long-term assets	<u>34,582</u>	<u>18,424</u>
TOTAL ASSETS	<u>\$ 370,255</u>	<u>\$ 339,793</u>

Consolidated Balance Sheets

USD in thousands (except share data)

	March 31, 2019	December 31, 2018
	Unaudited	Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 29,943	\$ 26,708
Other payables, lease liabilities and accrued expenses	41,005	37,852
Total current liabilities	70,948	64,560
LONG-TERM LIABILITIES:		
Long-term loan, net of discount and issuance costs	149,305	149,268
Deferred revenue	9,407	9,929
Employee benefit liabilities	2,823	2,683
Long-term lease liabilities	11,015	-
Other long-term liabilities	363	1,094
Total long-term liabilities	172,913	162,974
TOTAL LIABILITIES	243,861	227,534
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares no par value, unlimited shares authorized; issued and outstanding: 95,692,797 shares and 93,254,185 shares at March 31, 2019 (unaudited) and December 31, 2018, respectively	-	-
Additional paid-in capital	783,941	757,314
Accumulated other comprehensive loss	(1,742)	(1,400)
Accumulated deficit	(655,805)	(643,655)
Total shareholders' equity	126,394	112,259
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 370,255	\$ 339,793

Media and Investor Contact:

Ashley Cordova

acordova@novocure.com

212-767-7558