

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): July 25, 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 July 25, 2019, the Company issued a press release announcing certain financial results for the quarter ended June 30, 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 July 25, 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: July 25, 2019

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

Novocure Reports Second Quarter 2019 Financial Results and Provides Company Update

Quarterly net revenues of \$86.7 million, representing 41 percent growth versus the second quarter 2018

The NovoTTF-100L™ System FDA approved to treat malignant pleural mesothelioma in combination with standard chemotherapies, Novocure's first FDA-approved torso indication

Medicare released final local coverage determination and fee schedule amount providing coverage and pricing of Optune® for newly diagnosed glioblastoma

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 three and six months ended June 30, 2019, highlighting a track record of execution, strengthening financial performance and an advancing clinical pipeline. 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.

Second quarter 2019 highlights include:

	Three months ended June 30,			Six months ended June 30,		
	2019	2018	% Change	2019	2018	% Change
Non-financial						
Active patients at period end (1)	2,726	2,169	26%	2,726	2,169	26%
Prescriptions received in period (2)	1,362	1,244	9%	2,672	2,502	7%
Financial, in millions						
Net revenues	\$ 86.7	\$ 61.5	41%	\$ 160.0	\$ 113.6	41%
Gross profit	\$ 65.6	\$ 41.7	57%	\$ 119.1	\$ 75.6	58%
Net loss	\$ (1.3)	\$ (15.5)	92%	\$ (13.4)	\$ (36.2)	63%
Cash, cash equivalents and short-term investments at end of period	\$ 284.6	\$ 219.0	30%	\$ 284.6	\$ 219.0	30%

- (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.

"The second quarter was transformative for Novocure. We achieved our first ever quarter of positive operating income driven by record quarterly net revenues of \$86.7 million with more than 2,700 patients on Optune at quarter end," said Asaf Danziger, Novocure's CEO. "Our torso device, NovoTTF-100L, was approved by the FDA to treat malignant pleural mesothelioma in combination with standard chemotherapies via the Humanitarian Device Exemption pathway. For the first time in over 15 years, there's a new FDA-approved treatment for mesothelioma."

"Our momentum continues into the third quarter. Last week, Medicare released a final local coverage determination and fee schedule amount which provides coverage and pricing of Optune for newly diagnosed GBM, effective September 1, 2019. In response to public comments, the final coverage criteria eliminated or revised many of the restrictions originally proposed," stated Bill Doyle, Novocure's Executive Chairman. "Our focus is unwavering on disciplined execution intended to deliver both sustainable near-term growth from existing indications and significant long-term shareholder value from our pipeline."

Second quarter 2019 operating statistics and financial update

There were 2,726 active patients on Optune at June 30, 2019, representing 26 percent growth versus June 30, 2018, and four percent growth versus March 31, 2019. The increase in active patients was driven primarily by prescription growth in the United States and Japan and the ongoing benefit from continued growth in prescriptions for patients with newly diagnosed GBM globally.

- In the United States, there were 1,846 active patients on Optune at June 30, 2019, representing 17 percent growth versus June 30, 2018.
- In Germany and other EMEA markets, there were 737 active patients on Optune at June 30, 2019, representing 32 percent growth versus June 30, 2018.
- In Japan, there were 143 active patients on Optune at June 30, 2019, representing 286 percent growth versus June 30, 2018.

Additionally, 1,362 prescriptions were received in the three months ended June 30, 2019, representing nine percent growth compared to the same period in 2018, and four percent growth compared to the three months ended March 31, 2019.

- In the United States, 989 prescriptions were received in the three months ended June 30, 2019, representing four percent growth to the same period in 2018.
- In Germany and other EMEA markets, 299 prescriptions were received in the three months ended June 30, 2019, representing 13 percent growth compared to the same period in 2018.
- In Japan, 74 prescriptions were received in the three months ended June 30, 2019, representing 131 percent growth compared to the same period in 2018.

For the three months ended June 30, 2019, net revenues were \$86.7 million, representing 41 percent growth versus the same period in 2018. Revenue growth was primarily driven by an increase of 557 active patients in our currently active markets, representing 26 percent growth, and an increase in net revenues per active patient. The increase in net revenues per active patient was primarily driven by improved reimbursement rates, which we believe are sustainable. The improved reimbursement rates also resulted in an additional benefit of approximately \$5 million to second quarter net revenues that we do not expect to be as significant in future quarters.

Cost of revenues was \$21.1 million compared to \$19.8 million for the same period in 2018, representing an increase of 6 percent. The increase in cost of revenues was primarily due to the cost of shipping transducer arrays to a higher volume of active patients partially offset by a reduction in the cost of goods per active patient driven by ongoing efficiency initiatives and scale. Gross margin was 76% compared to 68% for the same period in 2018.

Research, development and clinical trials expenses were \$19.5 million compared to \$11.4 million for the same period in 2018, representing an increase of 71 percent. This was primarily due to an increase in clinical trial and personnel expenses for our phase 3 pivotal trials and an increase in costs associated with medical affairs, regulatory and engineering.

Sales and marketing expenses were \$23.7 million compared to \$19.2 million for the same period in 2018, representing an increase of 24 percent. This was primarily due to increased marketing expenses related to the launch of NovoTTF-100L for malignant pleural mesothelioma and increased personnel costs.

General and administrative expenses were \$21.2 million compared to \$18.2 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.

Net loss was \$ 1.3 million, or \$0.01 per share, compared to net loss of \$ 15.5 million for the same period in 2018, or \$0.17 per share, representing an improvement of 94 percent.

At June 30, 2019, we had \$180.1 million in cash and cash equivalents and \$104.5 million in short-term investments, for a total balance of \$284.6 million in cash, cash equivalents and short-term investments.

Anticipated clinical and regulatory milestones

- Zai Lab initiation of phase 2 pilot trial in gastric cancer (2019)
- Data from phase 2 pilot HEPANOVA trial in advanced liver cancer (H2 2020)
- Interim analysis of phase 3 pivotal LUNAR trial in non-small cell lung cancer (H2 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 (2022)
- 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 second quarter 2019 financial results today, Thursday, July 25, 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 1438824.

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 is a cancer therapy that uses electric fields tuned to specific frequencies to disrupt solid tumor cancer cell

division. Novocure's commercialized products are approved for the treatment of adult patients with glioblastoma and malignant pleural mesothelioma. Novocure has ongoing or completed clinical trials investigating Tumor Treating Fields in 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 Report on Form 10-Q filed on July 25, 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 June 30,		Six months ended June 30,		Year ended December 31,	
	2019	2018	2019	2018	2018	
	Unaudited		Unaudited		Audited	
Net revenues	\$ 86,713	\$ 61,514	\$ 160,022	\$ 113,639	\$ 248,063	
Cost of revenues	21,106	19,833	40,920	38,071	80,048	
Gross profit	65,607	41,681	119,102	75,568	168,015	
Operating costs and expenses:						
Research, development and clinical trials	19,454	11,362	36,496	22,466	50,574	
Sales and marketing	23,708	19,196	46,041	37,331	77,663	
General and administrative	21,249	18,208	41,487	35,533	73,456	
Total operating costs and expenses	64,411	48,766	124,024	95,330	201,693	
Operating income (loss)	1,196	(7,085)	(4,922)	(19,762)	(33,678)	
Financial expenses (income), net	1,239	2,860	3,610	7,713	12,270	
Income (loss) before income taxes	(43)	(9,945)	(8,532)	(27,475)	(45,948)	
Income taxes	1,227	5,565	4,888	8,759	17,617	
Net income (loss)	\$ (1,270)	\$ (15,510)	\$ (13,420)	\$ (36,234)	\$ (63,559)	
Basic and diluted net income (loss) per ordinary share	\$ (0.01)	\$ (0.17)	\$ (0.14)	\$ (0.40)	\$ (0.68)	
Weighted average number of ordinary shares used in computing basic and diluted net income (loss) per share	96,356,317	91,331,862	95,583,802	90,658,735	91,828,043	

Consolidated Balance Sheets

USD in thousands (except share data)

	June 30, 2019	December 31, 2018
	Unaudited	Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 180,073	\$ 140,622
Short-term investments	104,511	105,256
Restricted cash	2,110	2,134
Trade receivables	42,533	36,523
Receivables and prepaid expenses	15,302	14,279
Inventories	25,454	22,555
Total current assets	<u>369,983</u>	<u>321,369</u>
LONG-TERM ASSETS:		
Property and equipment, net	8,399	8,442
Field equipment, net	7,466	6,924
Right-of-use assets, net	14,659	-
Other long-term assets	5,682	3,058
Total long-term assets	<u>36,206</u>	<u>18,424</u>
TOTAL ASSETS	<u>\$ 406,189</u>	<u>\$ 339,793</u>

Consolidated Balance Sheets

USD in thousands (except share data)

	June 30, 2019	December 31, 2018
	Unaudited	Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 30,069	\$ 26,708
Other payables, lease liabilities and accrued expenses	43,498	37,852
Total current liabilities	73,567	64,560
LONG-TERM LIABILITIES:		
Long-term loan, net of discount and issuance costs	149,344	149,268
Deferred revenue	8,874	9,929
Employee benefit liabilities	3,610	2,683
Long-term lease liabilities	11,582	-
Other long-term liabilities	306	1,094
Total long-term liabilities	173,716	162,974
TOTAL LIABILITIES	247,283	227,534
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares no par value, unlimited shares authorized; issued and outstanding: 97,858,876 shares and 93,254,185 shares at June 30, 2019 (unaudited) and December 31, 2018, respectively	-	-
Additional paid-in capital	818,338	757,314
Accumulated other comprehensive income (loss)	(2,357)	(1,400)
Retained earnings (accumulated deficit)	(657,075)	(643,655)
Total shareholders' equity	158,906	112,259
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 406,189	\$ 339,793

Media and Investor Contact:

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