

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 9, 2016

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.)

Le Masurier House
La Rue Le Masurier
St. Helier, Jersey JE2 4YE
(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))
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Item 2.02. Results of Operations and Financial Condition

On May 9, 2016, the Company issued a press release announcing certain financial results for the quarter ended March 31, 2016. A copy of the press release is attached 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, dated May 9, 2016

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 9, 2016

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

Index to Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May 9, 2016

Novocure Reports First Quarter 2016 Financial Results and Provides Company Update

Increasing adoption of Optune with 755 prescriptions received in the first quarter 2016, an increase of 73 percent from the first quarter 2015 and 36 percent from the fourth quarter 2015

797 active patients at March 31, 2016, an increase of 114 percent from March 31, 2015 and 32 percent from December 31, 2015

First quarter 2016 reported revenues of \$13.1 million, reflecting 151 percent growth versus first quarter 2015

More than 112 million Americans have coverage of Optune as a treatment for newly diagnosed and/or recurrent glioblastoma

Phase 2 pilot PANOVA results presented at ASCO GI suggest Tumor Treating Fields plus chemotherapy may be safe as first-line treatment and improve survival of patients with advanced pancreatic cancer

Conference call at 5 p.m. EDT today

St. Helier, Jersey – Novocure (NASDAQ: NVCR), a commercial stage oncology company pioneering a novel therapy for solid tumors, today reported financial results for the first quarter ended March 31, 2016, highlighting strong growth in prescriptions, active patients and reported revenues.

First quarter 2016 highlights include:

	Three months ended March 31,		
	2016	2015	% change
Non-financial			
Prescriptions received in period (1)	755	437	73%
Active patients at period end (2)	797	372	114%
Financial, in millions (unaudited)			
Revenues (3)	\$ 13.1	\$ 5.2	151%
Net loss	\$ (35.4)	\$ (23.3)	
Cash and cash equivalents at the end of period	\$ 115.9	\$ 74.2	

Short-term investments at the end of period	\$	119.8	\$	22.0
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- (1) A “prescription received” is a commercial order for Optune that is received from a physician certified to treat patients with Tumor Treating Fields (TTFields) therapy for a patient not previously on TTFields therapy. Orders to renew or extend treatment are not included in this total. In the future, Novocure may have regulatory approvals and commercial programs for multiple clinical indications, at which time Novocure will recognize a commercial order as a prescription for the same patient for each clinical indication treated. For example, in the future, a patient may have a prescription for the treatment of lung cancer and a prescription for the treatment of brain metastases from the lung cancer.
- (2) An “active patient” is a patient who is on TTFields therapy 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.
- (3) For the reported periods, all revenues were recognized when cash was collected and all other revenue recognition criteria had been met.

“I am pleased to see commercial momentum building following the October 2015 FDA approval of Optune for the treatment of newly diagnosed GBM and the December 2015 publication of EF-14 phase 3 pivotal trial results in the *Journal of the American Medical Association*,” commented Asaf Danziger, Chief Executive Officer. “Our sales and marketing teams are intensely focused on the education of oncologists as we introduce a completely new treatment modality to the market. I am extremely proud of the hard-earned progress we have made in the two quarters since approval.”

Mr. Danziger continued, “I believe that we are well positioned to deliver substantial year-over-year growth in 2016. We expect the incorporation of Optune for newly diagnosed GBM into treatment guidelines, the launch, pending FDA approval, of our second generation Optune system in the United States, and the continued expansion of our U.S. and German sales forces to provide additional catalysts to support our commercial execution. We are committed to bringing Optune to all GBM patients who may benefit from it.”

Wilco Groenhuisen, Chief Financial Officer, stated, “2015 started a transformational phase for Novocure with the October FDA approval of Optune for newly diagnosed GBM. I am pleased to report triple digit growth in both active patients and revenues in the first quarter of 2016 compared to the same period in 2015 and believe we will continue to see significant year-over-year growth in operating statistics and revenues throughout 2016.”

“As our commercial teams focus on execution within the glioblastoma indication, our R&D team continues to make progress toward developing TTFIELDS for a variety of additional solid tumors,” added William Doyle, Chairman. “We have five ongoing or completed phase 2 pilot trials in brain metastases, non-small cell lung cancer, ovarian cancer, pancreatic cancer and mesothelioma. We plan to open phase 3 pivotal trials in brain metastases and non-small cell lung cancer in 2016. In addition to our clinical development activities, our engineering team continues its work to improve all aspects of TTFIELDS delivery to enhance ease-of-use for patients.”

2016 First Quarter Operating Statistics and Financial Update

Prescriptions in the quarter ended March 31, 2016, increased by 318 prescriptions, or 73 percent, compared to the same period in 2015. The increase in prescriptions was driven primarily by commercial activities in the United States after the October 2015 U.S. Food and Drug Administration (FDA) approval of Optune for the treatment of newly diagnosed glioblastoma (GBM), increased commercial activities in Germany, and enhanced awareness of Optune following the December 2015 publication of EF-14 phase 3 pivotal trial results in the *Journal of the American Medical Association*.

- In the United States, 684 prescriptions were received in the quarter ended March 31, 2016, an increase of 273 prescriptions, or 66 percent, compared to the same period in 2015.
- In Germany and other EMEA markets, 71 prescriptions were received in the quarter ended March 31, 2016, an increase of 45 prescriptions, or 173 percent, compared to the same period in 2015.

The conversion of prescriptions to new patients is driven by the prescription fill rate and the time to fill the prescription. The prescription fill rate for the 12 months ended March 31, 2016, was 75 percent. The increase or decrease in active patients in any given period reflects the number of new patients less the number of patients discontinuing therapy. The rate of patients discontinuing therapy is determined by the treatment duration for patients starting therapy in prior periods. Novocure expects average treatment duration of its total active patient population to increase as the ratio of newly diagnosed GBM to recurrent GBM active patients increases. The portion of Optune prescriptions for newly diagnosed GBM was more than 50 percent in the first quarter of 2016.

There were 797 active patients on Optune therapy at March 31, 2016, an increase of 425 active patients, or 114 percent, compared to March 31, 2015. The increase in active

patients was driven both by prescription growth and by an increase in the percentage of newly diagnosed GBM patients who started Optune in prior periods.

- In the United States, there were 699 active patients on Optune therapy at March 31, 2016, an increase of 352 active patients, or 101 percent, compared to March 31, 2015.
- In Germany and other EMEA markets, there were 98 active patients on Optune therapy at March 31, 2016, an increase of 73 active patients, or 292 percent, compared to March 31, 2015.

For the 12 months ended March 31, 2016, the average cash payment received was more than \$14,000 per charged month in the United States. The difference between billed and paid amounts consists of patient financial assistance, charitable care, discounts, disputed underpayments and indirect taxes. Generally, Novocure's average time to collect on billed charges ranges between four and five months in the United States. The "payment amount" and "average time to collect" metrics do not include Novocure's experience with patients covered by the Medicare fee-for-service program, as Novocure has not received material payments from the Medicare fee-for-service program, or Novocure's experience with patients outside of the United States.

For the three months ended March 31, 2016, revenues increased to \$13.1 million compared to \$5.2 million for the same period in 2015, representing 151 percent growth. This growth was primarily driven by increased Optune adoption.

For the three months ended March 31, 2016, cost of revenues increased to \$8.0 million compared to \$3.9 million for the same period in 2015, representing 105 percent growth. This was primarily driven by an increase in the cost of transducer array shipments due to an increase in active Optune patients as well as increased personnel costs to establish infrastructure necessary to support an increasing volume of shipments to patients.

Research, development and clinical trials expenses for the three months ended March 31, 2016, were \$11.4 million compared to \$9.9 million for the same period in 2015, representing growth of 15 percent. This growth was primarily due to increased personnel costs and increased expenses related to clinical education and investigator-sponsored trials, partially offset by reduced expenses related to the development of the second generation Optune system.

Sales and marketing expenses for the three months ended March 31, 2016, were \$13.3 million compared to \$6.4 million for the same period in 2015, representing growth of 109

percent. This growth was primarily due to increased personnel costs as well as increased marketing expenses to expand commercial operations in the United States and Germany and to establish commercial operations in Switzerland and Japan.

General and administrative expenses for the three months ended March 31, 2016, were \$12.3 million compared to \$7.0 million for the same period in 2015, representing growth of 76 percent. This growth was primarily due to increased personnel costs as well as increased expenses related to professional services and activities associated with being a public company.

Personnel costs for the three months ended March 31, 2016, included \$5.5 million in non-cash share-based compensation expenses, comprised of \$0.1 million in cost of revenues; \$0.8 million in research, development and clinical trials; \$1.3 million in sales and marketing; and \$3.2 million in general and administrative expenses. Total non-cash share-based compensation expenses for Q1 2015 were \$1.8 million.

Net losses for the three months ended March 31, 2016, were \$35.4 million compared to \$23.3 million for the same period in 2015.

As of March 31, 2016, we had \$115.9 million in cash and cash equivalents and \$119.8 million in short-term investments for a total balance of \$235.8 million in cash, cash equivalents and short-term investments.

Other first quarter 2016 corporate achievements

- **Expanded coverage:** Novocure expanded coverage of Optune for the treatment of newly diagnosed and/or recurrent GBM to include more than 63 million additional lives through new policies with Anthem, Cigna, Humana, Regence Blue Cross Blue Shield, Preferred One, Univera Healthcare, and Asuris Northwest Health. This brought the total number of covered lives to more than 107 million in the United States as of March 31, 2016. Subsequent to the quarter end, positive coverage policies were issued by Group Health Cooperative Washington and Idaho, and Blue Cross Blue Shield of Michigan, bringing the total number of covered lives to more than 112 million in the United States as of May 1, 2016.
 - **Second generation Optune system European launch:** All Optune patients in Europe are now on the second generation of Optune, which is less than half the weight and half the size of the original commercial system.
 - **PANOVA phase 2 pilot data in pancreatic cancer:** Results from the first cohort of the PANOVA trial were presented at ASCO GI suggesting TFields therapy
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plus chemotherapy may be safe as first-line treatment and improve survival of patients with advanced pancreatic cancer. Progression free survival and overall survival of patients treated with TTFIELDS combined with gemcitabine were more than double those of gemcitabine-treated historical controls. Of the evaluable tumors, 30 percent had partial response and another 30 percent had stable disease.

- **Recognition as a clinical cancer advance by ASCO:** Phase 3 pivotal trial results of TTFIELDS in combination with temozolomide for the treatment of newly diagnosed GBM were selected for inclusion in the American Society of Clinical Oncology's *Clinical Cancer Advances 2016: Annual Report on Progress against Cancer*. The report reviews the recent top advances and emerging trends in clinical cancer research that are leading to improved cancer treatments for patients.

Anticipated milestones over the next nine months

- **NCCN guidelines update:** With the October 2015 FDA approval of Optune for the treatment of newly diagnosed GBM, Novocure expects that Optune should be added to the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for Central Nervous System Cancers for newly diagnosed GBM in 2016.
 - **FDA approval for the second generation Optune system:** In December 2015, Novocure filed a premarket approval (PMA) supplement application with the FDA seeking approval of the second generation of Optune for the approved indications. The company subsequently received and, in April 2016, responded to questions from the FDA on the PMA supplement application. Assuming no further FDA comments or requests for additional information, the company hopes to begin marketing the second generation Optune system in the United States in the third quarter of 2016.
 - **PANOVA phase 2 pilot trial last patient in:** Following the approval of nab-paclitaxel, a taxane-based chemotherapy, for the treatment of advanced pancreatic cancer, the PANOVA study was expanded to include 20 additional patients treated with TTFIELDS in combination with nab-paclitaxel and gemcitabine. Novocure expects to finish enrollment of the second patient cohort in 2016 and, with an expected six months follow-up, anticipates phase 2 pilot data will be available for presentation in 2017.
 - **INNOVATE phase 2 pilot trial last patient in:** In October 2014, the INNOVATE trial opened to study TTFIELDS together with weekly paclitaxel for patients with recurrent ovarian cancer. The trial is expected to finish enrollment in 2016 and,
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with an expected six months follow-up, Novocure anticipates phase 2 pilot data will be available for presentation in 2017.

- **METIS phase 3 pivotal trial first patient in:** Based upon pre-clinical data showing TTFields can prevent metastatic seeding *in vivo* and the established safety and efficacy of TTFields in GBM, Novocure believes TTFields could be an effective treatment for patients with brain metastases. Novocure submitted a pre-submission package to the FDA for discussion and feedback in December 2015 and submitted a full investigational device exemption (IDE) application in April 2015. The open-label randomized study will test the effectiveness of TTFields following stereotactic radiosurgery (SRS) compared with watchful waiting alone in patients with brain metastases stemming from non-small cell lung cancer. Novocure plans to open the trial in mid-2016 subject to FDA approval of the IDE.
- **LUNAR phase 3 pivotal trial first patient in:** Novocure has completed a phase 2 pilot trial in advanced non-small cell lung cancer and is planning a randomized phase 3 pivotal trial for the treatment of non-small cell lung cancer. Given recent preclinical research of TTFields in combination with PD-1 inhibitors, the company is currently reviewing the protocol design to possibly capitalize on the potential synergies with taxane-based chemotherapies and the potential additivity with PD-1 inhibitors. The company plans to open the trial in late 2016 subject to FDA approval of the IDE.
- **Japanese approval for newly diagnosed GBM:** Novocure submitted a partial amendment application to the Japanese Pharmaceuticals and Medical Devices Agency for the treatment of newly diagnosed GBM patients in December 2015 and hopes to receive Japanese Ministry of Health, Labour and Welfare (MHLW) approval in late 2016. The MHLW approved the use of Optune in patients with recurrent GBM in March 2015. The company plans to wait until MHLW approval for newly diagnosed GBM before submitting an application for public reimbursement in Japan.

Conference call details

Novocure will host a conference call and [webcast](#) to discuss first quarter 2016 financial results today, Monday, May 9, at 5 p.m. EDT. This event can be accessed from the [Investor Relations page](#) of Novocure.com. A replay of the discussion will be available on Novocure's website for at least 14 days following the call.

About Novocure

Novocure is a commercial-stage oncology company developing a novel, proprietary therapy called Tumor Treating Fields, or TTFields, for the treatment of solid tumor cancers. Headquartered in Jersey, Novocure has U.S. operations in Portsmouth, New Hampshire, Malvern, Pennsylvania, and New York. Additionally, the company has

offices in Germany, Switzerland and Japan, and a research center in Haifa, 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, achievement of 2016 corporate goals, 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 March 1, 2016, 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.

Condensed Interim Consolidated Statements of Operations

USD in thousands (except share and per share data)

	Three months ended		Year ended
	March 31,		December 31,
	2016	2015	2015
	Unaudited		Audited
Revenues	\$ 13,053	\$ 5,208	\$ 33,087
Cost of revenues	7,982	3,897	20,610
Gross profit	5,071	1,311	12,477
Operating costs and expenses:			
Research, development and clinical trials	11,445	9,927	43,748
Sales and marketing	13,308	6,355	38,861
General and administrative	12,256	6,975	33,864
Total operating costs and expenses	37,009	23,257	116,473
Operating loss	(31,938)	(21,946)	(103,996)
Financial expenses, net	(549)	(591)	(3,151)
Loss before income tax expense	(32,487)	(22,537)	(107,147)
Income tax expense	2,950	736	4,434
Net loss	\$ (35,437)	\$ (23,273)	\$ (111,581)
Basic and diluted net loss per Ordinary share	\$ (0.42)	\$ (1.77)	\$ (3.67)
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share	84,397,164	13,140,321	30,401,603

Condensed Interim Consolidated Balance Sheets

USD in thousands (except share data)

	March 31, 2016	December 31, 2015
	Unaudited	Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 115,932	\$ 119,423
Short-term investments	119,842	150,001
Restricted cash	86	87
Receivables and prepaid expenses	11,335	10,799
Inventories	16,446	13,594
Total current assets	<u>263,641</u>	<u>293,904</u>
LONG-TERM ASSETS:		
Property and equipment, net	7,090	6,552
Field equipment, net	7,211	6,029
Severance pay fund	84	79
Other long-term assets	992	772
Total long-term assets	<u>15,377</u>	<u>13,432</u>
TOTAL ASSETS	<u>\$ 279,018</u>	<u>\$ 307,336</u>

	March 31, 2016	December 31, 2015
	Unaudited	Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 18,578	\$ 16,755
Other payables and accrued expenses	10,850	11,872
Total current liabilities	29,428	28,627
LONG-TERM LIABILITIES:		
Long-term loan, net of discount	23,193	23,097
Accrued severance pay	2,823	2,057
Other long-term liabilities	3,148	2,735
Total long-term liabilities	29,164	27,889
TOTAL LIABILITIES	58,592	56,516
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares no par value, unlimited shares authorized ; issued and outstanding: 84,426,720 shares and 83,778,581 shares at March 31, 2016 and December 31, 2015, respectively	-	-
Additional paid-in capital	645,919	640,406
Accumulated other comprehensive loss	(1,975)	(1,505)
Accumulated deficit	(423,518)	(388,081)
Total shareholders' equity	220,426	250,820
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 279,018	\$ 307,336

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