

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 29, 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**  
(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 February 29, 2016, the Company issued a press release announcing certain financial results for the fiscal year ended December 31, 2015. 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 29, 2016

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**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 29, 2016

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

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## Index to Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of NovoCure Limited, dated February 29, 2016

## **Novocure Reports 2015 Operating Statistics and Financial Results**

*605 active patients on Optune therapy at 2015 year end, an increase of 169 percent compared to 2014 year end*

*Publication of EF-14 phase 3 pivotal trial results in the *Journal of the American Medical Association* concludes adding TTFIELDS to maintenance temozolomide chemotherapy significantly extends progression-free and overall survival in newly diagnosed GBM*

*Conference call at 5 p.m. EST today*

**St. Helier, Jersey** – Novocure (NASDAQ: NVCR), a commercial stage oncology company pioneering a novel therapy for solid tumors, reported today 2015 operating statistics and financial results, highlighting strong growth in both prescriptions and active patients driven primarily by the October 2015 U.S. Food and Drug Administration (FDA) approval of Optune for the treatment of newly diagnosed glioblastoma (GBM).

“Upon receiving U.S. FDA approval for newly diagnosed GBM in October, our commercial team immediately started executing our commercial launch plan,” said Asaf Danziger, CEO of Novocure. “Knowing our therapy improves overall survival in newly diagnosed GBM, we operate – and will continue to operate – with a sense of urgency to get our therapy to patients. I’m extremely proud of our performance last quarter and am pleased to see this momentum continuing in 2016.”

“When one takes a step back and considers the milestones achieved by the Novocure team in 2015, it is truly inspiring,” said Novocure Executive Chairman Bill Doyle. “I believe our execution was exceptional in 2015 across functions and geographies and is a testament to our employees’ talent and dedication to our mission of bringing TTFIELDS therapy to patients with solid tumor cancers. We have an ambitious agenda for 2016 and look to extend our track record of accomplishment.”

### **Key Commercial and Regulatory Milestones**

- Received U.S. FDA approval of Optune in combination with temozolomide for the treatment of newly diagnosed GBM.
  - Published EF-14 phase 3 pivotal trial results in the *Journal of the American Medical Association (JAMA)* concluding that adding Tumor Treating Fields (TTFIELDS) to maintenance temozolomide chemotherapy significantly prolonged progression-free and overall survival of patients with newly diagnosed GBM.
  - Secured new positive coverage policies for Optune including from Aetna and Anthem, the second and third largest U.S. commercial payers, respectively. Approximately 97 million Americans now have health coverage from payers that have issued positive coverage policies for Optune.
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- Received Japanese Ministry of Health, Labour and Welfare a approval of Optune for the treatment of recurrent GBM .
- Launched the second generation Optune system in Europe. The second generation system is half the weight and half the size of the first generation system.
- Filed a premarket approval (PMA) supplement application with the U.S. FDA for the second generation Optune system.
- Filed a PMA partial amendment application with the Japanese Pharmaceuticals and Medical Devices Agency for the treatment of newly diagnosed GBM patients in combination with temozolomide.
- Presented a retrospective analysis showing Optune is safe in GBM patients with implanted non-programmable shunts, resulting in the U.S. FDA removing a pre-existing contraindication.
- Increased the U.S. sales organization from 14 individuals at the end of 2014 to 31 individuals at the end of 2015.
- Increased the number of U.S. centers certified to prescribe Optune for the treatment of GBM from 154 centers at the end of 2014 to 244 centers at the end of 2015.

**Key Research and Development Milestones**

- Presented PANOVA phase 2 pilot trial data demonstrating that TTFields may 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. The response rate for TTFields with gemcitabine was 30% compared to a response rate of 7% in gemcitabine-alone historical controls.
- Presented a prospective analysis of EF-14 phase 3 pivotal trial data showing the use of TTFields therapy with temozolomide does not adversely affect newly diagnosed GBM patients' quality of life, cognitive and functional capabilities, and ability to perform daily activities.
- Presented a post-hoc analysis of EF-14 phase 3 pivotal data showing EF-14 GBM patients who continued TTFields therapy in combination with chemotherapy, including bevacizumab, at first recurrence live longer than patients who receive chemotherapy alone.
- Presented phase 2 pilot trial data showing TTFields therapy is safe in patients with brain metastases originating from non-small cell lung cancer.
- Enrolled the first patient in STELLAR, an 80-patient phase 2 pilot trial for patients with malignant pleural mesothelioma designed to test the efficacy and safety of TTFields in combination with standard of care chemotherapy.
- Published in Scientific Reports new preclinical data on TTFields' anti-mitotic mechanism of action, which provided quantitative evidence that TTFields prevent spindles from forming properly during mitosis.

**Key Financial Milestones**

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- Completed initial public offering of Novocure ordinary shares on NASDAQ , raising \$158 million .
- Raised \$95 million in the sale of Series J convertible preferred stock.
- Secured a \$100 million term loan agreement with an affiliate of Pharmakon Advisors.

**2015 Fourth Quarter and Full Year Operating Statistics**

Prescriptions in the quarter ended Dec. 31, 2015, increased to 557 compared to 267 for the same period in 2014, representing 109 percent growth. This growth was largely achieved prior to the peer-reviewed publication of the successful EF-14 newly diagnosed GBM phase 3 pivotal clinical trial in *JAMA* on Dec. 15, 2015. Prescriptions in the full year ended Dec. 31, 2015, increased to 1,777 compared to 707 for the same period in 2014, representing 151 percent growth.

- In the United States, 499 prescriptions were written in the quarter ended Dec. 31, 2015, compared to 247 in the same period in 2014, representing 102 percent growth. In the United States, 1,607 prescriptions were written in the full year ended Dec. 31, 2015, compared to 669 in the same period in 2014, representing 140 percent growth.
- In the United States, more than 200 unique prescribers wrote a prescription for Optune in the fourth quarter of 2015, including more than 60 first-time prescribers.
- In Europe and emerging markets, 56 prescriptions were written in the quarter ended Dec. 31, 2015, compared to 20 in the same period in 2014, representing 180 percent growth. In Europe and emerging markets, 167 prescriptions were written in the full year ended Dec. 31, 2015, compared to 38 in the same period in 2014, representing 339 percent growth. Germany represents our largest currently active market in Europe and emerging markets with more than 75 percent of the prescription volume.
- In Japan, two prescriptions were written in the quarter ended Dec. 31, 2015, and three prescriptions were written in the full year ended Dec. 31, 2015, the first year of approval for Optune in this market.

Prescriptions are a leading indicator of demand. The conversion of prescriptions to new patients is driven by the prescription fill rate and the time to fill. The prescription fill rate for the year ended Dec. 31, 2015 was 73%. The relationship between filled prescriptions and active patients is primarily driven by treatment duration. Novocure expects treatment duration to increase over time 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 35 percent in the fourth quarter of 2015.

There were 605 active patients on Optune therapy at Dec. 31, 2015, compared to 225 at Dec. 31, 2014, representing 169 percent growth.

- In the United States, there were 529 active patients on Optune therapy at Dec. 31, 2015, compared to 211 at Dec. 31, 2014, representing 151 percent growth.
  - In Europe and emerging markets, there were 74 active patients on Optune therapy at Dec. 31, 2015, compared to 14 at Dec. 31, 2014, representing 429 percent growth.
  - In Japan, there were two active patients on Optune therapy at Dec. 31, 2015, the first year of approval for Optune in this market.
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For the full year ended Dec. 31, 2015, gross billings increased to \$110.8 million compared to \$45.8 million for the same period in 2014, representing 142 percent growth.

In the United States, total cash payments of \$31.0 million, net of indirect taxes paid, received during the twelve months ended Dec. 31, 2015 were recorded as revenues for Optune therapy provided to patients in the current period and prior periods. These cash payments represent an average of approximately \$14,000 per month billed in the United States. The difference between billed and paid amounts consists of indirect taxes, disputed underpayments, patient financial assistance, charitable care and discounts. Generally, Novocure's average time to collect on billed charges in 2015 was between four and five months. 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 we have not received material payments from that program and the invoices remain open as we appeal the coverage denials.

**2015 Financial Highlights**

In accordance with U.S. GAAP, Novocure accounts for revenue when cash is collected. Cost of revenues reflects costs incurred for patients receiving Optune in the applicable period. Gross margin as a percentage of revenues is affected by timing of revenue recognition based on cash collections, which often results in costs being incurred in one period that relate to revenues recognized in a later period.

**Revenues** For the year ended Dec. 31, 2015, GAAP net revenues increased to \$33.1 million compared to \$15.5 million for the same period in 2014, representing 114 percent growth. The growth was primarily driven by the increased demand for Optune therapy after the initial presentation of the EF-14 phase 3 pivotal trial data in Nov. 2014 and FDA approval of Optune for the treatment of newly diagnosed GBM in Oct. 2015.

**Cost of revenues** For the year ended Dec. 31, 2015, cost of revenues was \$20.6 million compared to \$10.0 million for the same period in 2014, representing an increase of 105 percent. The increase was primarily driven by an increase in active patients, causing increased transducer array shipments and associated warehousing and order fulfillment personnel costs. This was partially offset, amongst others, by a per unit transducer array cost reduction, due to implementation of an automated transducer array production line.

**Research, development and clinical trial expenses** For the year ended Dec. 31, 2015, research, development and clinical trial expenses were \$43.7 million compared to \$40.4 million for the same period in 2014, representing an increase of 8 percent. The increase was primarily driven by an increase in clinical trial expenses to support our five ongoing clinical trials and an increase in personnel costs.

**Sales and marketing expenses** For the year ended Dec. 31, 2015, sales and marketing expenses were \$38.9 million compared to \$21.2 million for the same period in 2014, representing an increase of 84 percent. The increase was primarily driven by an increase in

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marketing expenses to support the launch of Optune for the treatment of newly diagnosed GBM and an increase in personnel costs .

**General and administrative expenses** For the year ended Dec. 31, 2015, general and administrative expenses were \$33.9 million compared to \$24.1 million for the same period in 2014, representing 41 percent growth. The increase was primarily driven by an increase in personnel costs to support the growth of our business, an increase in legal services, facilities and costs associated with preparing for the IPO and professional services related to our new SAP ERP system.

**Non-cash share-based compensation** Personnel costs for the full year ended Dec. 31, 2015 include \$11.9 million in non-cash, share-based compensation costs, compared to \$4.6 million in 2014. 2015 non-cash share-based compensation expenses are distributed across the consolidated statement of operations as follows: \$0.2 million in cost of revenues; \$2.5 million in research, development and clinical trials; \$2.5 million in sales and marketing; and \$6.7 million in general and administrative.

**Cash, cash equivalents and short-term investments** As of Dec. 31, 2015, Novocure had \$269.4 million in cash, cash equivalents and short-term investments, compared to \$102.6 million as of Dec. 31, 2014. The increase reflects \$25.0 million drawn on the term loan, net proceeds of \$94.6 million raised through the issuance of our Series J convertible preferred shares and net proceeds of \$157.5 million raised through the initial public offering of Novocure ordinary shares.

#### **Conference Call and Webcast Details**

Novocure's management will host a conference call and webcast to discuss the financial results and provide an update on business activities. The event will be held today, Feb. 29, 2016, at 5 p.m. EST. Analysts and investors can participate in the conference call by dialing (877)726-5929 for domestic callers and (530)379-4648 for international callers, using the conference ID 39664845. The [webcast](#) can be accessed live from the Investors section of Novocure's website, [www.novocure.com](http://www.novocure.com), and will be available for replay for at least 14 days following the call.

#### **Consolidated Statements of Operations**

USD in thousands (except share and per share data)

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**Year ended December 31,**

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**Exhibit 99.1**

	<u>2015</u>	<u>2014</u>	<u>2013</u>
Net revenues	\$ 33,087	\$ 15,490	\$ 10,359
Cost of revenues	20,610	10,036	7,013
Gross profit	<u>12,477</u>	<u>5,454</u>	<u>3,346</u>
Operating costs and expenses:			
Research, development and clinical trials	43,748	40,381	34,797
Sales and marketing	38,861	21,177	16,406
General and administrative	33,864	24,052	16,602
Total operating costs and expenses	<u>116,473</u>	<u>85,610</u>	<u>67,805</u>
Operating loss	(103,996)	(80,156)	(64,459)
Financial expenses, net	(3,151)	(144)	(12,558)
Loss before income taxes	<u>(107,147)</u>	<u>(80,300)</u>	<u>(77,017)</u>
Income taxes	4,434	382	353
Net loss	<u>\$ (111,581)</u>	<u>\$ (80,682)</u>	<u>\$ (77,370)</u>
Basic and diluted net loss per ordinary share	<u>\$ (3.67)</u>	<u>\$ (6.46)</u>	<u>\$ (6.73)</u>
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	<u>30,401,603</u>	<u>12,490,017</u>	<u>11,498,392</u>

**Consolidated Balance Sheets**

USD in thousands (except share data)

	<u>December 31,</u>	
	<u>2015</u>	<u>2014</u>
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 119,423	\$ 57,613
Short-term investments	150,001	44,999
Restricted cash	87	61
Receivables and prepaid expenses	10,799	5,711
Inventories	13,594	3,446
Total current assets	<u>293,904</u>	<u>111,830</u>
Long-term Assets:		
Property and equipment, net	6,552	3,732
Field equipment, net	6,029	2,017
Severance pay fund	79	70
Other long-term assets	772	227
Total long-term assets	<u>13,432</u>	<u>6,046</u>
Total Assets	<u>\$ 307,336</u>	<u>\$ 117,876</u>
	<u>December 31,</u>	

	2015	2014
<b>Liabilities And Shareholders' Equity</b>		
Current Liabilities:		
Trade payables	\$ 16,755	\$ 10,033
Other payables and accrued expenses	11,872	7,636
Total current liabilities	<u>28,627</u>	<u>17,669</u>
Long-term Liabilities:		
Long-term loan, net of discount	23,097	-
Employee benefit liabilities	2,057	246
Other long-term liabilities	2,735	2,086
Total long-term liabilities	<u>27,889</u>	<u>2,332</u>
Total Liabilities	56,516	20,001
Commitments and Contingencies		
Shareholders' Equity:		
Share capital—		
Ordinary shares —Unlimited no par value shares authorized; Issued and outstanding: 83,778,581 shares and 13,431,414 shares at December 31, 2015 and December 31, 2014 respectively	-	-
Preferred shares —No par value, no shares authorized; Issued and outstanding: Zero shares and 58,676,017 shares at December 31, 2015 and December 31, 2014 respectively;	-	-
Additional paid-in capital	640,406	374,375
Accumulated other comprehensive loss	(1,505)	-
Accumulated deficit	<u>(388,081)</u>	<u>(276,500)</u>
Total shareholders' equity	250,820	97,875
Total Liabilities and Shareholders' Equity	<u>\$ 307,336</u>	<u>\$ 117,876</u>

### About Tumor Treating Fields (TTFields)

Tumor Treating Fields (TTFields) therapy is delivered by a portable, non-invasive medical device designed for continuous use by patients. In vitro and in vivo studies have shown that TTFields therapy slows and reverses tumor growth by inhibiting mitosis, the process by which cells divide and replicate. TTFields therapy creates low intensity, alternating electric fields within a tumor that exert physical forces on electrically charged cellular components, preventing the normal mitotic process and causing cancer cell death.

### Approved Indications

In the United States, Optune is intended as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM).

In the United States, Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.

In the United States, for the treatment of recurrent GBM, Optune is indicated following histologically-or radiologically-confirmed recurrence in the supra-tentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is

intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

In the European Union, Optune is intended for the treatment of patients with newly diagnosed GBM, after surgery and radiotherapy with adjuvant temozolomide, concomitant to maintenance temozolomide. The treatment is intended for adult patients, 18 years of age or older, and should be started more than 4 weeks after surgery and radiation therapy with adjuvant temozolomide. Treatment may be given together with maintenance temozolomide and after maintenance temozolomide is stopped.

In the European Union, Optune is also intended for the treatment of patients with recurrent GBM who have progressed after surgery, radiotherapy and temozolomide treatment for their primary disease. The treatment is intended for adult patients, 18 years of age or older, and should be started more than 4 weeks after the latest surgery, radiation therapy or chemotherapy.

In Japan, Optune (the NovoTTF-100A System) is approved for the treatment of adult patients with recurrent supra-tentorial glioblastoma after all possible surgical and radiation therapy options have been exhausted.

Patients should only use Optune under the supervision of a physician properly trained in use of the device. Full prescribing information is available at [www.optune.com/safety](http://www.optune.com/safety) or by calling toll free 1-855-281-9301 in the US or by email at [supportEMEA@novocure.com](mailto:supportEMEA@novocure.com) in the European Union.

### **About Novocure**

Novocure is a Jersey Isle oncology company pioneering a novel therapy for solid tumors called TTFIELDS. Novocure's US operations are based in Portsmouth, NH and New York, NY. 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](http://www.novocure.com) or follow us at [www.twitter.com/novocure](https://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

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those set forth in its Quarterly Report on Form 10-Q filed on Oct. 27, 2015, 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.

**Media and Investor Contact:**

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