

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

February 25, 2021
Date of Report (date of earliest event reported)

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 (I.R.S. Employer Identification No.)
No. 4 The Forum, Grenville Street St. Helier Jersey (Address of Principal Executive Offices)		JE2 4UF (Zip Code)

+44 (0) 15 3475 6700
Registrant's telephone number, including area code

(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. below):

- 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))

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

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

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 25, 2021, the Company issued a press release announcing certain financial results for the quarter ended December 31, 2020. A copy of the press release is attached as Exhibit 99.1.

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 25, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 25, 2021

By: /s/ Ashley Cordova
Name: Ashley Cordova
Title: Chief Financial Officer

Novocure Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Company Update

Quarterly net revenues of \$144.0 million, representing 45 percent growth versus the fourth quarter 2019 and 9 percent growth versus the third quarter 2020

Quarterly net income of \$4.9 million with \$0.05 in earnings per share

St. Helier, Jersey – Novocure (NASDAQ: NVCR) today reported financial results for the quarter and full year ended December 31, 2020, highlighting revenue growth and financial strength as well as the advancement of the company’s clinical and product development programs. Novocure is a global oncology company working to extend survival in some of the most aggressive forms of cancer by developing and commercializing its innovative therapy, Tumor Treating Fields.

Fourth quarter 2020 highlights include:

	Three Months Ended December 31,			Twelve Months Ended December 31,		
	2020	2019	% Change	2020	2019	% Change
Financial, in millions						
Net revenues	\$ 144.0	\$ 99.2	45 %	\$ 494.4	\$ 351.3	41 %
Gross Profit	\$ 115.8	\$ 74.4	56 %	\$ 387.9	\$ 262.7	48 %
Net income (loss)	\$ 4.9	\$ 4.3	15 %	\$ 19.8	\$ (7.2)	(374)%
Adjusted EBITDA ⁽¹⁾	\$ 34.8	\$ 17.3	101 %	\$ 115.3	\$ 60.0	92 %
Non-financial						
Active patients at period end ⁽²⁾	3,411	2,909	17 %	3,411	2,909	17 %
Prescriptions received in period ⁽³⁾	1,411	1,380	2 %	5,613	5,371	5 %

⁽¹⁾ Adjusted EBITDA is a non-U.S. GAAP measurement of earnings before interest, taxes, depreciation, amortization and share-based compensation.

⁽²⁾ An “active patient” is a patient who is receiving treatment 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⁾ A “prescription received” is a commercial order for Optune or Optune Lua that is received from a physician certified to treat patients for a patient not previously on Optune or Optune Lua. Orders to renew or extend treatment are not included in this total.

“Our track record of execution continued throughout 2020 with notable progress made in advancing our three overarching priorities: to drive commercial adoption; to carry out our clinical trial programs; and to deliver product innovations to optimize Tumor Treating Fields therapy,” said William Doyle, Novocure’s Executive Chairman. “Despite the

complexities posed by the COVID-19 pandemic, we generated nearly \$500 million in net revenues and \$20 million in net income in 2020. Our financial strength positions us well to invest strategically in science and technology to unleash the potential of the Tumor Treating Fields platform.”

“As proud as we are of treating more than 18,000 patients to-date, we remain focused on extending the reach of Tumor Treating Fields therapy to many more cancer patients,” added Asaf Danziger, Novocure’s Chief Executive Officer. “With multiple clinical trials expected to read out over the next few years, we believe we are just beginning to unlock our potential to impact oncology. Acceptance of our therapy continues to build within the global oncology community, which reinforces our commitment to our mission to extend survival in some of the most aggressive forms of cancer.”

Fourth quarter 2020 financial update

For the quarter ended December 31, 2020, net revenues were \$144.0 million, representing 45% growth compared to the fourth quarter 2019.

- In the United States, net revenues totaled \$97.7 million in the quarter ended December 31, 2020, representing 48% growth compared to the same period in 2019.
- In Germany and other EMEA markets, net revenues totaled \$33.8 million in the quarter ended December 31, 2020, representing 31% growth compared to the same period in 2019.
- In Japan, net revenues totaled \$7.9 million in the quarter ended December 31, 2020, representing 42% growth compared to the same period in 2019.
- In Greater China, net revenues totaled \$4.5 million in the quarter ended December 31, 2020, representing 132% growth compared to the same period in 2019.

For the three months ended December 31, 2020, the increases primarily resulted from an increase of 502 active patients in our active markets and an increase in the net revenues per active patient per month. The increase in net revenues per active patient per month primarily was driven by improving reimbursement approval rates in the U.S.

In the fourth quarter 2020, we recorded \$9 million in revenues from Medicare fee-for-service beneficiaries billed under the coverage policy effective on September 1, 2019. We have gained a good understanding of how to ensure timely processing of Medicare claims and have sufficient experience to recognize approximately two-thirds of the expected contribution from Medicare beneficiaries. In the fourth quarter of 2020, we also recognized approximately \$11 million in incremental net revenues compared to the first half of 2020 resulting from the successful appeal of previously denied claims for Medicare fee-for-service beneficiaries billed prior to established coverage.

Cost of revenues for the three months ended December 31, 2020 was \$28.1 million compared to \$24.8 million for the same period in 2019, representing an increase of 14%. The increase in cost of revenues primarily was due to the cost of shipping arrays to a higher volume of commercial patients. Gross margin was 80% for the three months ended December 31, 2020 compared to 75% for the three months ended December 31, 2019. Gross margin continues to benefit from ongoing efficiency initiatives and increasing scale. Gross margin is also improved with revenue resulting from the successful appeal of previously denied claims for Medicare fee-for-service beneficiaries and tempered by product sales to Zai.

Research, development and clinical trials expenses for the three months ended December 31, 2020 were \$44.0 million compared to \$23.7 million for the same period in 2019, representing an increase of 85%. The increase primarily was due to increased investments in clinical trials and clinical administration personnel to advance and broaden our clinical development programs, preclinical and basic research to better understand the optimal use of Tumor Treating Fields, product development intended to optimize the delivery of Tumor Treating Fields therapy, and expanded medical affairs efforts to educate the clinical community.

We expect growth in our research and development to continue into 2021 as we work to advance our pipeline programs and increase acceptance of Tumor Treating Fields within the global oncology community. We balance our investments in research and development with our organizational capacity to effectively execute our strategic initiatives.

Sales and marketing expenses for the three months ended December 31, 2020 were \$31.4 million compared to \$26.8 million for the same period in 2019, representing an increase of 17%. This primarily was due to an increase in personnel and professional services costs to support our growing commercial business and reimbursement efforts and an increase in marketing expenses related to the launch of Optune Lua for MPM.

General and administrative expenses for the three months ended December 31, 2020 were \$28.4 million compared to \$23.7 million for the same period in 2019, representing an increase of 19%. This primarily was due to an increase in personnel costs, insurance premiums and professional services.

Net income for the three months ended December 31, 2020 was \$4.9 million compared to net income of \$4.3 million for the same period in 2019.

At December 31, 2020, we had \$842.6 million in cash and cash equivalents and short-term investments, an increase of \$516.5 million compared to \$326.1 million at December 31, 2019. The increase in our cash, cash equivalents and short-term investments primarily was due to convertible notes issued, net cash provided by operating activities and the exercise of options.

Fourth quarter 2020 operating statistics

There were 3,411 active patients at December 31, 2020, representing 17% growth compared to December 31, 2019, and 1% growth compared to September 30, 2020.

- In the United States, there were 2,193 active patients at December 31, 2020, representing 12% growth compared to December 31, 2019.
- In Germany and other EMEA markets, there were 953 active patients at December 31, 2020, representing 25% growth compared to December 31, 2019.
- In Japan, there were 265 active patients at December 31, 2020, representing 38% growth compared to December 31, 2019.

Additionally, 1,411 prescriptions were received in the quarter ended December 31, 2020, representing 2% growth compared to the same period in 2019, and a 3% increase compared to the quarter ended September 30, 2020. In the quarter ended December 31, 2020, 1,160 Optune prescriptions were written for patients with newly diagnosed glioblastoma.

- In the United States, 962 prescriptions were received in the quarter ended December 31, 2020, representing a 4% decrease compared to the same period in 2019.
- In Germany and other EMEA markets, 349 prescriptions were received in the quarter ended December 31, 2020, representing 22% growth compared to the same period in 2019.
- In Japan, 100 prescriptions were received in the quarter ended December 31, 2020, representing 8% growth compared to the same period in 2019.

Fourth quarter 2020 non-U.S. GAAP measures

We also measure our performance based upon a non-U.S. GAAP measurement of earnings before interest, taxes, depreciation, amortization and share-based compensation ("Adjusted EBITDA"). We believe Adjusted EBITDA is useful to investors in evaluating our operating performance because it helps investors compare the results of our operations from period to period by removing the impact of earnings attributable to our capital structure, tax rate and material non-cash items, specifically share-based compensation.

Adjusted EBITDA was \$34.8 million for the three months ended December 31, 2020, an increase of \$17.5 million, or 101%, from \$17.3 million for the three months ended December 31, 2019. This improvement in fundamental financial performance was driven by net revenue growth coupled with an ongoing commitment to disciplined management of expenses.

Anticipated clinical milestones

- Final data from phase 2 pilot HEPANOVA trial in advanced liver cancer (Q2 2021)
 - Interim analysis of phase 3 pivotal INNOVATE-3 trial in recurrent ovarian cancer (Q3 2021)
 - Interim analysis of phase 3 pivotal LUNAR trial in non-small cell lung cancer (Q4 2021)
 - Final data from phase 2 pilot EF-31 trial in gastric cancer (2022)
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- Interim analysis of phase 3 pivotal PANOVA-3 trial in locally advanced pancreatic cancer (2022)
- Final data from phase 3 pivotal METIS trial in brain metastases (2022)
- Final data from phase 2 pilot EF-33 trial with high-intensity arrays in recurrent glioblastoma (2022)
- Final data from phase 3 pivotal INNOVATE-3 trial in recurrent ovarian cancer (2023)
- Final data from phase 3 pivotal LUNAR trial in non-small cell lung cancer (2023)
- Final data from phase 3 pivotal PANOVA-3 trial in locally advanced pancreatic cancer (2023)

Conference call details

Novocure will host a conference call and webcast to discuss fourth quarter and full year 2020 financial results at 8 a.m. EST today, Thursday, February 25, 2021. 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 3965899.

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. Novocure has used, and intends to continue to use, its investor relations website, as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD.

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. Novocure's commercialized products are approved in certain countries for the treatment of adult patients with glioblastoma and in the U.S. for the treatment of adult patients with 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, liver cancer, gastric cancer and glioblastoma.

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, environmental, regulatory and political conditions as well as issues arising from the COVID-19 pandemic and other more specific risks and uncertainties facing Novocure such as those set forth in its Annual Report on Form 10-K filed on February 25, 2021, as amended to date, 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,	
	2020	2019	2020	2019
Net revenues	\$ 143,953	\$ 99,234	\$ 494,366	\$ 351,318
Cost of revenues	28,136	24,786	106,501	88,606
Gross profit	115,817	74,448	387,865	262,712
Operating costs and expenses:				
Research, development and clinical trials	44,002	23,741	132,010	79,003
Sales and marketing	31,359	26,804	118,017	96,675
General and administrative	28,364	23,751	107,437	87,948
Total operating costs and expenses	103,725	74,296	357,464	263,626
Operating income (loss)	12,092	152	30,401	(914)
Financial expenses (income), net	3,267	1,744	12,299	7,910
Income (loss) before income tax	8,825	(1,592)	18,102	(8,824)
Income tax	3,908	(5,852)	(1,706)	(1,594)
Net income (loss)	\$ 4,917	\$ 4,260	\$ 19,808	\$ (7,230)
Basic net income (loss) per ordinary share	\$ 0.05	\$ 0.04	\$ 0.20	\$ (0.07)
Weighted average number of ordinary shares used in computing basic net income (loss) per share	101,945,085	99,226,445	100,930,866	97,237,549
Diluted net income (loss) per ordinary share	\$ 0.04	\$ 0.04	\$ 0.18	\$ (0.07)
Weighted average number of ordinary shares used in computing diluted net income (loss) per share	110,604,714	107,911,519	108,877,648	97,237,549

Consolidated Balance Sheets

USD in thousands (except share data)

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 234,674	\$ 177,321
Short-term investments	607,902	148,769
Restricted cash	11,499	2,095
Trade receivables, net	96,699	58,859
Receivables and prepaid expenses	21,245	29,202
Inventories	27,422	23,701
Total current assets	999,441	439,947
Long-term assets:		
Property and equipment, net	11,395	9,342
Field equipment, net	11,230	7,684
Right-of-use assets, net	19,009	17,571
Other long-term assets	10,908	4,904
Total long-term assets	52,542	39,501
Total assets	\$ 1,051,983	\$ 479,448

Consolidated Balance Sheets

USD in thousands (except share data)

	December 31,	
	2020	2019
Liabilities and shareholders' equity		
Current liabilities:		
Trade payables	\$ 53,647	\$ 36,925
Other payables and accrued expenses	59,965	49,386
Total current liabilities	113,612	86,311
Long-term liabilities:		
Long-term loan, net of discount and issuance costs	429,905	149,424
Deferred revenues	12,139	7,807
Employee benefit liabilities	5,171	3,754
Long term leases	14,293	14,140
Other long-term liabilities	337	222
Total long-term liabilities	461,845	175,347
Total liabilities	575,457	261,658
Commitments and contingencies		
Shareholders' equity:		
Share capital -		
Ordinary shares - No par value, Unlimited shares authorized; Issued and outstanding: 102,334,276 shares and 99,528,435 shares at December 31, 2020 and December 31, 2019 respectively;	—	—
Additional paid-in capital	1,111,435	871,442
Accumulated other comprehensive loss	(3,832)	(2,767)
Accumulated deficit	(631,077)	(650,885)
Total shareholders' equity	476,526	217,790
Total liabilities and shareholders' equity	\$ 1,051,983	\$ 479,448

Non-U.S. GAAP financial measures reconciliation

USD in thousands

	Three months ended December 31,			Twelve months ended December 31,		
	2020	2019	% Change	2020	2019	% Change
Net income (loss)	\$ 4,917	\$ 4,260	15 %	\$ 19,808	\$ (7,230)	(374)%
Add: Income tax	3,908	(5,852)	(167)%	(1,706)	(1,594)	7 %
Add: Financial expenses (income), net	3,267	1,744	87 %	12,299	7,910	55 %
Add: Depreciation and amortization	2,473	2,467	— %	9,150	8,460	8 %
EBITDA	\$ 14,565	\$ 2,619	456 %	\$ 39,551	\$ 7,546	424 %
Add: Share-based compensation	20,273	14,699	38 %	75,721	52,416	44 %
Adjusted EBITDA	\$ 34,838	\$ 17,318	101 %	\$ 115,272	\$ 59,962	92 %

Investors:

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