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

April 29, 2021
Date of Report (date of earliest event reported)

NovoCure Limited

(Exact name of registrant as specified in its charter)

Jersey	**001-37565**	**98-1057807**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

No. 4 The Forum, Grenville Street St. Helier Jersey	**JE2 4UF**
(Address of Principal Executive Offices)	(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 April 29, 2021, the Company issued a press release announcing certain financial results for the quarter ended March 31, 2021. A copy of the press release is attached as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of NovoCure Limited, dated April 29, 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: April 29, 2021

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

Novocure Reports First Quarter 2021 Financial Results and Provides Company Update

Quarterly net revenues of $134.7 million with 80% gross margin

Interim analysis for phase 3 pivotal LUNAR trial in non-small cell lung cancer concluded with favorable recommendation to continue the trial with reduced sample size

St. Helier, Jersey – Novocure (NASDAQ: NVCR) today reported financial results for the quarter ended March 31, 2021, highlighting continued commercial strength despite changes in patterns of care in some regions driven by COVID-19, as well as continued progress across 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 (TTFields). TTFields are electric fields that disrupt cancer cell division.

First quarter 2021 highlights include:

	Three Months Ended March 31,		
	2021	**2020**	**% Change**
Financial, in millions			
Net revenues	$ 134,695	$ 101,828	32 %
Gross Profit	$ 108,310	$ 77,332	40 %
Net income (loss)	$ (4,128)	$ 3,952	(204) %
Adjusted EBITDA[(1)]	$ 21,145	$ 15,064	40 %
Non-financial			
Active patients at period end[(2)]	3,454	3,095	12 %
Prescriptions received in period[(3)]	1,402	1,409	— %

(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.

"Over the last several months, we have made progress across multiple clinical development programs intended to determine Tumor Treating Fields' optimal use," said William Doyle, Novocure's Executive Chairman. "We continued to increase our understanding of the potential benefits of Tumor Treating Fields when used together

with immunotherapies and continued to enroll patients in five late-stage clinical trials in multiple solid tumor types. The accelerated interim analysis of the LUNAR trial and the upcoming HEPANOVA data presentation represent the beginning of what we expect to be an exciting few years of data readouts from our pipeline."

"Our track record of consistent execution and financial strength continued in the first quarter of 2021," added Asaf Danziger, Novocure's Chief Executive Officer. "We generated $135 million in net revenues with an 80% gross margin, and we invested $46 million in research and development intended to fuel future growth. With 3,454 active patients on therapy at the end of the quarter, we have treated nearly 20,000 patients globally, to date."

First quarter 2021 financial update
For the quarter ended March 31, 2021, net revenues were $134.7 million, representing 32% growth compared to the first quarter 2020.

- In the United States, net revenues totaled $85.9 million in the quarter ended March 31, 2021, representing 24% growth compared to the same period in 2020.
- In Germany and other EMEA markets, net revenues totaled $35.0 million in the quarter ended March 31, 2021, representing 43% growth compared to the same period in 2020.
- In Japan, net revenues totaled $8.3 million in the quarter ended March 31, 2021, representing 28% growth compared to the same period in 2020.
- In Greater China, net revenues totaled $5.5 million in the quarter ended March 31, 2021, representing 237% growth compared to the same period in 2020.

For the three months ended March 31, 2021, the increase in net revenues from the first quarter of 2020 resulted primarily from an increase of 359 active patients in our currently active markets and a durable improvement in the net revenues booked per active patient.

We recorded $9.4 million in revenues from Medicare fee-for-service beneficiaries billed under the coverage policy effective on September 1, 2019 in the first quarter 2021, an increase of 32% from the $7.1 million recognized in the same period in 2020. We have gained a good understanding of how to ensure timely processing of Medicare claims and we believe that we have sufficient experience to recognize approximately two-thirds of the expected contribution from Medicare beneficiaries. In the first quarter of 2021, incremental net revenues resulting from the successful appeal of previously denied claims for Medicare fee-for-service beneficiaries billed prior to established coverage reverted to normalized levels from the first half of 2020.

Cost of revenues for the three months ended March 31, 2021 was $26.4 million compared to $24.5 million for the same period in 2020, representing an increase of 8%. The increase in cost of revenues was primarily due to the cost of shipping transducer arrays to a higher volume of commercial patients and increasing shipments of

equipment to Zai Lab. Gross margin was 80% for the three months ended March 31, 2021 compared to 76% for the three months ended March 31, 2020.

Research, development and clinical trials expenses for the three months ended March 31, 2021 were $45.9 million compared to $25.3 million for the same period in 2020, representing an increase of 82%. This was primarily due to an increase in clinical trial and personnel expenses for our phase 3 pivotal and post-marketing trials, an increase in development and personnel expenses to support our product development programs, increased investments in preclinical research and the expansion of our medical affairs activities.

Sales and marketing expenses for the three months ended March 31, 2021 were $31.4 million compared to $28.8 million for the same period in 2020, representing an increase of 9%. This was primarily due to an increase in personnel and professional services costs to support our growing commercial business and reimbursement efforts.

General and administrative expenses for the three months ended March 31, 2021 were $31.1 million compared to $26.6 million for the same period in 2020, representing an increase of 17%. This was primarily due to an increase in personnel costs and professional services.

Net loss for the three months ended March 31, 2021 was $4.1 million compared to net income of $4.0 million for the same period in 2020.

At March 31, 2021, we had $864.4 million in cash and cash equivalents and short-term investments, an increase of $21.8 million compared to $842.6 million at December 31, 2020. The increase in our cash, cash equivalents and short-term investments was primarily due to the cash flow from operations and the exercise of options.

First quarter 2021 operating statistics
There were 3,454 active patients at March 31, 2021, representing 12% growth compared to March 31, 2020, and 1% growth compared to December 31, 2020.

- In the United States, there were 2,183 active patients at March 31, 2021, representing 8% growth compared to March 31, 2020.
- In Germany and other EMEA markets, there were 1,000 active patients at March 31, 2021, representing 18% growth compared to March 31, 2020.
- In Japan, there were 271 active patients at March 31, 2021, representing 22% growth compared to March 31, 2020.

Additionally, 1,402 prescriptions were received in the quarter ended March 31, 2021, representing no change compared to the same period in 2020, and a 1% decrease compared to the quarter ended December 31, 2020. We believe the prolonged disruption caused by COVID-19 is resulting in increased volatility across global health care systems, such as fluctuations in patient volumes and changes in patterns of care in certain regions, which had some impact on our business in the first quarter.

- In the United States, 917 prescriptions were received in the quarter ended March 31, 2021, representing a 7% decrease compared to the same period in 2020.
- In Germany and other EMEA markets, 382 prescriptions were received in the quarter ended March 31, 2021, representing 16% growth compared to the same period in 2020.
- In Japan, 103 prescriptions were received in the quarter ended March 31, 2021, representing 10% growth compared to the same period in 2020.

First quarter 2021 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 shared-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 $21.1 million for the three months ended March 31, 2021, an increase of $6.1 million, or 40%, from $15.1 million for the three months ended March 31, 2020. This improvement in fundamental financial performance was driven by net revenue growth coupled with an ongoing commitment to disciplined management of expenses.

Recent clinical milestones
Earlier this April, we disclosed that an independent data monitoring committee (DMC) informed Novocure that the pre-specified interim analysis for the phase 3 pivotal LUNAR trial for the treatment of non-small cell lung cancer (NSCLC) was accelerated given the length of accrual and the number of events observed, to date. The interim analysis included data from 210 patients accrued through February 2021. After review of the interim analysis, the DMC concluded that the LUNAR trial should continue with no evidence of increased systemic toxicity. The DMC went on to comment that the continued accrual to 534 patients as proposed in the original protocol, given the current rate of accrual and the interim data presented, is likely unnecessary and possibly unethical for patients randomized to control. For this reason, the DMC recommended an adjustment of accrual to approximately 276 patients with a 12-month follow-up following the enrollment of the last patient. The DMC believes this amended protocol would provide adequate data regarding toxicity and efficacy, providing sufficient overall power, as well as potentially providing important information regarding efficacy within treatment subgroups.

In April, we concluded our phase 2 pilot HEPANOVA trial investigating TTFields together with sorafenib, a kinase inhibitor, in 25 patients with advanced liver cancer. We have submitted an abstract for presentation at an upcoming medical conference in late June

and look forward to discussing the full data set with clinicians, investigators and investors in the future.

In April, the U.S. Food and Drug Administration (FDA) approved our investigational device exemption (IDE) application to initiate the KEYNOTE-B36 phase 2 pilot trial to study TTFields with pembrolizumab in first-line NSCLC through our clinical collaboration with MSD (Merck & Co., Inc., Kenilworth, NJ, USA). We are currently evaluating clinical trial sites for initiation.

Anticipated clinical milestones

- FDA response to IDE supplement incorporating recommended protocol changes to phase 3 pivotal LUNAR trial in NSCLC (Q2 2021)
- Presentation of full 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)
- Data from phase 2 pilot EF-31 trial in gastric cancer (2022)
- Interim analysis of phase 3 pivotal PANOVA-3 trial in locally advanced pancreatic cancer (2022)
- Data from phase 3 pivotal METIS trial in brain metastases (2022)
- 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 PANOVA-3 trial in locally advanced pancreatic cancer (2023)
- Final data from phase 3 pivotal LUNAR trial in NSCLC (to be determined pending FDA approval of IDE supplement)

Conference call details

Novocure will host a conference call and webcast to discuss first quarter 2021 financial results at 8 a.m. EDT today, Thursday, April 29, 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 2286525.

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 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 December 31,
	2021	2020	2020
	Unaudited		Audited
Net revenues	$ 134,695	$ 101,828	$ 494,366
Cost of revenues	26,385	24,496	106,501
Gross profit	108,310	77,332	387,865
Operating costs and expenses:			
Research, development and clinical trials	45,916	25,271	132,010
Sales and marketing	31,357	28,834	118,017
General and administrative	31,125	26,608	107,437
Total operating costs and expenses	108,398	80,713	357,464
Operating income (loss)	(88)	(3,381)	30,401
Financial expenses (income), net	2,646	2,432	12,299
Income (loss) before income tax	(2,734)	(5,813)	18,102
Income tax	1,394	(9,765)	(1,706)
Net income (loss)	$ (4,128)	$ 3,952	$ 19,808
Basic net income (loss) per ordinary share	$ (0.04)	$ 0.04	$ 0.20
Weighted average number of ordinary shares used in computing basic net income (loss) per share	102,633,545	99,877,567	100,930,866
Diluted net income (loss) per ordinary share	$ (0.04)	$ 0.04	$ 0.18
Weighted average number of ordinary shares used in computing diluted net income (loss) per share	102,633,545	108,100,623	108,877,648

Consolidated Balance Sheets
USD in thousands (except share data)

	March 31, 2021	December 31, 2020
	Unaudited	Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 314,547	$ 234,674
Short-term investments	549,855	607,902
Restricted cash	11,430	11,499
Trade receivables, net	92,514	96,699
Receivables and prepaid expenses	18,922	21,245
Inventories	27,968	27,422
Total current assets	1,015,236	999,441
LONG-TERM ASSETS:		
Property and equipment, net	11,733	11,395
Field equipment, net	12,132	11,230
Right-of-use assets	17,741	19,009
Other long-term assets	10,788	10,908
Total long-term assets	52,394	52,542
TOTAL ASSETS	$ 1,067,630	$ 1,051,983

Consolidated Balance Sheets
USD in thousands (except share data)

	March 31, 2021	December 31, 2020
	Unaudited	Audited
The accompanying notes are an integral part of these unaudited consolidated financial statements.		
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 52,703	$ 53,647
Other payables, lease liabilities and accrued expenses	57,784	59,965
Total current liabilities	110,487	113,612
LONG-TERM LIABILITIES:		
Long-term debt, net	559,584	429,905
Deferred revenue	9,577	12,139
Long-term leases	12,708	14,293
Employee benefits	2,963	5,171
Other long-term liabilities	177	337
Total long-term liabilities	585,009	461,845
TOTAL LIABILITIES	695,496	575,457
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares no par value, unlimited shares authorized; issued and outstanding: 103,187,460 shares and 102,334,276 shares at March 31, 2021 (unaudited) and December 31, 2020, respectively	—	—
Additional paid-in capital	1,005,785	1,111,435
Accumulated other comprehensive income (loss)	(1,948)	(3,832)
Retained earnings (accumulated deficit)	(631,703)	(631,077)
TOTAL SHAREHOLDERS' EQUITY	372,134	476,526
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 1,067,630	$ 1,051,983

Non-U.S. GAAP financial measures reconciliation
USD in thousands

	Three months ended March 31,		
	2021	2020	% Change
Net income (loss)	$ (4,128)	$ 3,952	(204)%
Add: Income tax	1,394	(9,765)	(114)%
Add: Financial income (expenses), net	2,646	2,432	9 %
Add: Depreciation and amortization	2,370	1,888	26 %
EBITDA	$ 2,282	$ (1,493)	(253)%
Add: Share-based compensation	18,863	16,557	14 %
Adjusted EBITDA	$ 21,145	$ 15,064	40 %

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