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

July 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 July 29, 2021, the Company issued a press release announcing certain financial results for the quarter ended June 30, 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 July 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: July 29, 2021

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

Novocure Reports Second Quarter 2021 Financial Results and Provides Company Update

Quarterly net revenues of $133.5 million, presenting 15% growth versus the second quarter of 2020 with 79% gross margin

Invested record $50 million in research and development initiatives across brain, thoracic and abdominal programs

St. Helier, Jersey – Novocure (NASDAQ: NVCR) today reported financial results for the quarter ended June 30, 2021, highlighting commercial strength and strategic investment across clinical, product development and commercial initiatives intended to fuel future growth. 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.

Second quarter 2021 highlights include:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2021	**2020**	**% Change**	**2021**	**2020**	**% Change**
Financial, in millions						
Net revenues	$ 133.5	$ 115.9	15 %	$ 268.2	$ 217.8	23 %
Gross Profit	$ 104.9	$ 90.5	16 %	$ 213.2	$ 167.8	27 %
Net income (loss)	$ (14.6)	$ 1.7	(959) %	$ (18.8)	$ 5.6	(436) %
Adjusted EBITDA[(1)]	$ 18.1	$ 28.0	(36) %	$ 39.2	$ 43.1	(9) %
Non-financial						
Active patients at period end[(2)]	3,487	3,278	6 %	3,487	3,278	6 %
Prescriptions received in period[(3)]	1,450	1,422	2 %	2,852	2,831	1 %

(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.

“We delivered another quarter of strong performance, generating $134 million in net revenues with a 79% gross margin,” said Asaf Danziger, Novocure’s Chief Executive Officer. “The performance of our core GBM business continues to provide our company

with the financial resources to aggressively pursue multiple potential growth initiatives. We believe these investments in commercial, clinical and engineering capabilities will enable organizational readiness as we strive to extend patient survival in multiple solid tumor cancers through our Tumor Treating Fields platform."

"Looking to the future, our pipeline is primed for growth," continued William Doyle, Novocure's Executive Chairman. "We reached several notable milestones since our last earnings report, including FDA approval of our IDE supplement for the phase 3 pivotal LUNAR trial in non-small cell lung cancer (NSCLC), presentation of final data from our phase 2 pilot HEPANOVA study in advanced liver cancer, and we are actively seeking to enroll patients in our phase 2 pilot KEYNOTE-B36 trial in NSCLC. I am proud of our team's performance this quarter and look to continue our track record of execution in the second half of the year."

Second quarter 2021 financial update
For the quarter ended June 30, 2021, net revenues were $133.5 million, representing 15% growth compared to the second quarter 2020.

- In the United States, net revenues totaled $87.1 million in the quarter ended June 30, 2021, representing 7% growth compared to the same period in 2020.
- In Germany and other EMEA markets, net revenues totaled $32.7 million in the quarter ended June 30, 2021, representing 29% growth compared to the same period in 2020.
- In Japan, net revenues totaled $8.8 million in the quarter ended June 30, 2021, representing 22% growth compared to the same period in 2020.
- In Greater China, net revenues totaled $4.9 million in the quarter ended June 30, 2021, representing 130% growth compared to the same period in 2020.

For the three months ended June 30, 2021, the increase in net revenues from the second quarter of 2020 resulted primarily from an increase of 209 active patients in our currently active markets, a sustained improvement in the net revenues booked per active patient, and the launch of Optune® in China.

We recorded $8.2 million in revenues from Medicare fee-for-service beneficiaries in the second quarter 2021, a decrease of 24% from the $10.8 million recognized in the same period in 2020. The decrease in revenue from Medicare does not reflect a reduction in active Medicare patients or a decrease in the contribution we ultimately expect from Medicare beneficiaries, but instead reflects the impact from an extended appeal timeline for certain claims billed after established coverage. In the second quarter of 2021, we did not record a material amount of incremental net revenue 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 June 30, 2021 was $28.6 million compared to $25.5 million for the same period in 2020, representing an increase of 12%. 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. We continue to focus on opportunities to increase efficiencies and scale within our supply chain. This includes evaluating new materials, manufacturers and processes that could lead to lower costs. Gross margin was 79% for the three months ended June 30, 2021 compared to 78% for the three months ended June 30, 2020.

Research, development and clinical trials expenses for the three months ended June 30, 2021 were $50.3 million compared to $29.9 million for the same period in 2020, representing an increase of 68%. This was primarily due to an increase in clinical trial and personnel expenses for our phase 3 pivotal, post-marketing and label expansion trials, an increase in development and personnel expenses to support our product development programs, and increased investments in preclinical research and the expansion of our medical affairs activities.

Sales and marketing expenses for the three months ended June 30, 2021 were $34.1 million compared to $28.5 million for the same period in 2020, representing an increase of 20%. This was primarily due to an increase in personnel and professional services costs as we continue to enhance our commercial capabilities in anticipation of potential future approvals in new indications. Accordingly, we are investing heavily in our market access capabilities in order to evaluate opportunities, identify optimal access pathways and successfully gain reimbursement in new geographies.

General and administrative expenses for the three months ended June 30, 2021 were $32.8 million compared to $25.4 million for the same period in 2020, representing an increase of 29%. This was primarily due to an increase in personnel costs and professional services.

Net loss for the three months ended June 30, 2021 was $14.6 million compared to net income of $1.7 million for the same period in 2020.

At June 30, 2021, we had $899.0 million in cash, cash equivalents and short-term investments, an increase of $56.5 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.

Second quarter 2021 operating statistics

There were 3,487 active patients at June 30, 2021, representing 6% growth compared to June 30, 2020, and 1% growth compared to March 31, 2021.

- In the United States, there were 2,206 active patients at June 30, 2021, representing 3% growth compared to June 30, 2020.
- In Germany and other EMEA markets, there were 990 active patients at June 30, 2021, representing 10% growth compared to June 30, 2020.
- In Japan, there were 291 active patients at June 30, 2021, representing 24% growth compared to June 30, 2020.

Additionally, 1,450 prescriptions were received in the quarter ended June 30, 2021, representing a 2% increase compared to the same period in 2020, and a 3% increase compared to the quarter ended March 31, 2021. 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 second quarter.

- In the United States, 967 prescriptions were received in the quarter ended June 30, 2021, representing no change compared to the same period in 2020.
- In Germany and other EMEA markets, 375 prescriptions were received in the quarter ended June 30, 2021, representing 2% growth compared to the same period in 2020.
- In Japan, 108 prescriptions were received in the quarter ended June 30, 2021, representing 27% growth compared to the same period in 2020.

Second 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 $18.1 million for the three months ended June 30, 2021, a decrease of $10.0 million, or 36%, from $28.0 million for the three months ended June 30, 2020. We are encouraged by our stable financial performance in light of our aggressive investments in growth initiatives. While our Adjusted EBITDA for the six month period ended June 30, 2021 was approximately $4 million lower compared to the same period in 2020, we have invested an incremental $61 million in research & development, sales & marketing, and other operational activities to maximize future growth opportunities.

Recent clinical milestones

In April 2021, we announced that an independent data monitoring committee (DMC) informed us that the pre-specified interim analysis for the phase 3 pivotal LUNAR trial for the treatment of NSCLC was accelerated given the length of accrual and the number of events observed. 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 will provide adequate data regarding toxicity and efficacy, providing sufficient overall power, as well as potentially providing important information regarding efficacy within treatment subgroups. In May 2021, the FDA approved an investigational device exemption (IDE) supplement incorporating the recommended protocol changes and we now expect final data in 2022.

In April 2021, the FDA approved our 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 (a tradename of Merck & Co.). KEYNOTE B36 currently has five clinical trial sites actively evaluating patients for enrollment.

In May 2021, we entered into a clinical trial collaboration with GT Medical Technologies, Inc., to develop TTFields together with GT Medical Technologies' GammaTile Surgically Targeted Radiation Therapy for the treatment of recurrent GBM, expanding our research in the treatment of GBM. We plan to conduct a phase 2 pilot study to test the safety and effectiveness of neo-adjuvant TTFields followed by resection, GammaTile Therapy, and adjuvant TTFields for recurrent GBM. This clinical trial collaboration presents an important opportunity to study the radio-sensitizing effect of TTFields in solid cancer tumors with other treatment modalities.

In July 2021, we announced the final results of our phase 2 pilot HEPANOVA trial investigating TTFields together with sorafenib, a kinase inhibitor, in 27 patients with advanced liver cancer. Historical control data showed an objective response rate of 4.5% and disease control rate of 43% for patients treated with sorafenib alone. In 21 evaluable patients, HEPANOVA showed a 9.5% objective response rate and 76% disease control rate, as well as 5.8 months of progression free survival. These results are even more encouraging when considering the poor prognosis of the study population. Over half of the patients in HEPANOVA were categorized as Child-Turcotte-Pugh Class B compared to 5% in the historical control, indicating significant liver functional compromise. Of the patients who received at least 12 weeks of therapy (n=11), the disease control rate reached 91% with an objective response rate of 18%. These data demonstrate that TTFields have the potential to extend survival in advanced liver cancer. Our team, along with trial investigators, are actively designing a phase 3 pivotal trial that contemplates TTFields therapy together with the current standard of care, including immunotherapy, and have engaged the FDA regarding the use of TTFields in advanced liver cancer.

The enrollment timelines for our METIS trial are reliant on clinical site expansion in regions that continue to be materially delayed as clinical sites devote significant resources to the COVID-19 global pandemic. Our clinical affairs teams are focused on accelerating enrollment at existing clinical sites, but our efforts are challenged by a heavy reliance on virtual engagement and, as a result, we now anticipate a two-quarter delay in last patient enrollment for METIS, with final data in 2023. It is estimated that between 20% and 40% of patients with NSCLC develop brain metastases. Together with LUNAR and KEYNOTE B36, the METIS data represent an important opportunity to demonstrate the efficacy of TTFields at multiple stages of lung cancer.

Anticipated clinical milestones

- 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 2 pilot EF-33 trial with high-intensity arrays in recurrent glioblastoma (2022)
- Final data from phase 3 pivotal LUNAR trial in NSCLC (2022)
- Data from phase 3 pivotal METIS trial in brain metastases (2023)
- 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)

Conference call details
Novocure will host a conference call and webcast to discuss second quarter 2021 financial results at 8 a.m. EDT today, Thursday, July 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 1926805.

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 (TTFields). TTFields are electric fields that disrupt cancer cell division. Novocure's commercialized products are approved for the treatment of adult patients with glioblastoma and malignant pleural mesothelioma. Novocure has ongoing or completed clinical trials investigating Tumor Treating Fields in brain metastases, gastric cancer, glioblastoma, liver cancer, non-small cell lung cancer, pancreatic cancer and ovarian cancer.

Headquartered in Jersey, Novocure has U.S. operations in Portsmouth, New Hampshire, Malvern, Pennsylvania and New York City. Additionally, the company has offices in Germany, Switzerland, Japan and Israel. For additional information about us, follow @Novocure on LinkedIn and Twitter.

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 June 30,		Six months ended June 30,		Year ended December 31,
	2021	2020	2021	2020	2020
	Unaudited		Unaudited		Audited
Net revenues	$ 133,517	$ 115,925	$ 268,212	$ 217,753	$ 494,366
Cost of revenues	28,599	25,474	54,984	49,970	106,501
Gross profit	104,918	90,451	213,228	167,783	387,865
Operating costs and expenses:					
Research, development and clinical trials	50,315	29,918	96,231	55,190	132,010
Sales and marketing	34,138	28,461	65,495	57,294	118,017
General and administrative	32,760	25,404	63,885	52,012	107,437
Total operating costs and expenses	117,213	83,783	225,611	164,496	357,464
Operating income (loss)	(12,295)	6,668	(12,383)	3,287	30,401
Financial expenses (income), net	940	2,617	3,586	5,049	12,299
Income (loss) before income taxes	(13,235)	4,051	(15,969)	(1,762)	18,102
Income taxes	1,406	2,396	2,800	(7,369)	(1,706)
Net income (loss)	$ (14,641)	$ 1,655	$ (18,769)	$ 5,607	$ 19,808
Basic net income (loss) per ordinary share	$ (0.14)	$ 0.02	$ (0.18)	$ 0.06	$ 0.20
Weighted average number of ordinary shares used in computing basic net income (loss) per share	103,484,866	100,718,893	103,061,557	100,298,230	100,930,866
Diluted net income (loss) per ordinary share	$ (0.14)	$ 0.02	$ (0.18)	$ 0.05	$ 0.18
Weighted average number of ordinary shares used in computing diluted net income (loss) per share	103,484,866	107,647,802	103,061,557	107,897,907	108,877,648

Consolidated Balance Sheets
USD in thousands (except share data)

	June 30, 2021	December 31, 2020
	Unaudited	Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 349,124	$ 234,674
Short-term investments	549,907	607,902
Restricted cash	11,463	11,499
Trade receivables, net	90,436	96,699
Receivables and prepaid expenses	17,946	21,245
Inventories	26,690	27,422
Total current assets	1,045,566	999,441
LONG-TERM ASSETS:		
Property and equipment, net	11,857	11,395
Field equipment, net	12,042	11,230
Right-of-use assets	16,964	19,009
Other long-term assets	10,630	10,908
Total long-term assets	51,493	52,542
TOTAL ASSETS	$ 1,097,059	$ 1,051,983

Consolidated Balance Sheets
USD in thousands (except share data)

	June 30, 2021	December 31, 2020
	Unaudited	Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 56,785	$ 53,647
Other payables, lease liabilities and accrued expenses	59,421	59,965
Total current liabilities	116,206	113,612
LONG-TERM LIABILITIES:		
Long-term debt, net	560,562	429,905
Deferred revenue	8,352	12,139
Long-term leases	11,944	14,293
Employee benefits	2,553	5,171
Other long-term liabilities	173	337
Total long-term liabilities	583,584	461,845
TOTAL LIABILITIES	699,790	575,457
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares no par value, unlimited shares authorized; issued and outstanding: 103,641,238 shares and 102,334,276 shares at June 30, 2021 (unaudited) and December 31, 2020, respectively	—	—
Additional paid-in capital	1,044,732	1,111,435
Accumulated other comprehensive income (loss)	(1,119)	(3,832)
Retained earnings (accumulated deficit)	(646,344)	(631,077)
TOTAL SHAREHOLDERS' EQUITY	397,269	476,526
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 1,097,059	$ 1,051,983

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

	Three months ended June 30,			Six months ended June 30,		
	2021	2020	% Change	2021	2020	% Change
Net income (loss)	$ (14,641)	$ 1,655	(985)%	$ (18,769)	$ 5,607	(435)%
Add: Income tax	1,406	2,396	(41)%	2,800	(7,369)	(138)%
Add: Financial income (expenses), net	940	2,617	(64)%	3,586	5,049	(29)%
Add: Depreciation and amortization	2,480	2,601	(5)%	4,850	4,489	8 %
EBITDA	$ (9,815)	$ 9,269	(206)%	$ (7,533)	$ 7,776	(197)%
Add: Share-based compensation	27,881	18,770	49 %	46,744	35,327	32 %
Adjusted EBITDA	$ 18,066	$ 28,039	(36)%	$ 39,211	$ 43,103	(9)%

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