

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

October 28, 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 October 28, 2021, the Company issued a press release announcing certain financial results for the quarter ended September 30, 2021. 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 October 28, 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: October 28, 2021

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

Novocure Reports Third Quarter 2021 Financial Results and Provides Company Update

Quarterly net revenues of \$133.6 million with 77% gross margin

Last patient enrolled in phase 3 pivotal INNOVATE-3 trial for recurrent ovarian cancer

St. Helier, Jersey – Novocure (NASDAQ: NVCR) today reported financial results for the quarter ended September 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.

Third quarter 2021 highlights include:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	% Change	2021	2020	% Change
Financial, in millions						
Net revenues	\$ 133.6	\$ 132.7	1 %	\$ 401.8	\$ 350.4	15 %
Gross Profit	\$ 103.4	\$ 104.3	(1) %	\$ 316.6	\$ 272.0	16 %
Net income (loss)	\$ (13.1)	\$ 9.3	(241) %	\$ (31.9)	\$ 14.9	(314) %
Adjusted EBITDA ⁽¹⁾	\$ 19.9	\$ 37.3	(47) %	\$ 59.2	\$ 80.4	(26) %
Non-financial						
Active patients at period end ⁽²⁾	3,502	3,361	4 %	3,502	3,361	4 %
Prescriptions received in period ⁽³⁾	1,380	1,371	1 %	4,232	4,202	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.

"The third quarter was another period of solid execution at Novocure," said William Doyle, Novocure's Executive Chairman. "We generated \$134 million in net revenues and invested \$48 million across our research, clinical and product development initiatives. We recently completed enrollment in our phase 3 INNOVATE-3 trial and our phase 2 EF-31 trial, and announced a new collaboration with global oncology leader,

Roche. The fundamentals of our business are strong, and we are energized by the opportunities before us to help many more cancer patients and to drive the growth of our company.”

“As we look ahead, we are nearing a key inflection point for patients and our organization as several of our late-stage clinical trials approach full enrollment,” added Asaf Danziger, Novocure’s Chief Executive Officer. “We have completed enrollment in our INNOVATE-3 trial studying recurrent ovarian cancer, and our LUNAR trial studying non-small cell lung cancer is expected to enroll the final patient by year-end. As this cycle of late-stage trials nears conclusion, we are eager to further explore the efficacy of TTFields in new indications, together with other treatment modalities, and in partnerships with global oncology leaders.”

Third quarter 2021 financial update

For the quarter ended September 30, 2021, net revenues were \$133.6 million, representing 1% growth compared to the third quarter 2020.

- In the United States, net revenues totaled \$88.0 million in the quarter ended September 30, 2021, representing a 5% decrease compared to the same period in 2020.
- In EMEA markets, net revenues totaled \$30.3 million in the quarter ended September 30, 2021, representing 7% growth compared to the same period in 2020.
- In Japan, net revenues totaled \$8.8 million in the quarter ended September 30, 2021, representing 17% growth compared to the same period in 2020.
- In Greater China, net revenues totaled \$6.5 million in the quarter ended September 30, 2021, representing 52% growth compared to the same period in 2020.

For the three months ended September 30, 2021, the increase in net revenues from the third quarter of 2020 resulted primarily from an increase of 141 active patients in our currently active markets and the launch of Optune® in China.

We recorded \$10.6 million in revenues from Medicare fee-for-service beneficiaries in the third quarter 2021, an increase of 9% from the \$9.7 million recognized in the same period in 2020. We believe we have completed the administrative ramp-up associated with processing Medicare claims and efficiently pursuing appeals. In the third 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 September 30, 2021 was \$30.2 million compared to \$28.4 million for the same period in 2020, representing an increase of 6%. 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 77% for the three months ended

September 30, 2021 compared to 79% for the three months ended September 30, 2020.

Research, development and clinical trials expenses for the three months ended September 30, 2021 were \$48.1 million compared to \$32.8 million for the same period in 2020, representing an increase of 47%. This was primarily due to an increase in clinical trial and personnel expenses for our phase 3 pivotal 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 September 30, 2021 were \$32.6 million compared to \$29.4 million for the same period in 2020, representing an increase of 11%. 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.

General and administrative expenses for the three months ended September 30, 2021 were \$31.2 million compared to \$27.1 million for the same period in 2020, representing an increase of 15%. This was primarily due to an increase in personnel costs and professional services.

Net loss for the three months ended September 30, 2021 was \$13.1 million compared to net income of \$9.3 million for the same period in 2020.

At September 30, 2021, we had \$933.8 million in cash, cash equivalents and short-term investments, an increase of \$91.2 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.

Third quarter 2021 operating statistics

There were 3,502 active patients at September 30, 2021, representing 4% growth compared to September 30, 2020.

- In North America, there were 2,223 active patients at September 30, 2021, representing no change compared to September 30, 2020.
- In EMEA markets, there were 987 active patients at September 30, 2021, representing 9% growth compared to September 30, 2020.
- In Japan, there were 292 active patients at September 30, 2021, representing 21% growth compared to September 30, 2020.

Additionally, 1,380 prescriptions were received in the quarter ended September 30, 2021, representing 1% growth compared to the same period in 2020.

- In North America, 931 prescriptions were received in the quarter ended September 30, 2021, representing a 3% decrease compared to the same period in 2020.
- In EMEA markets, 339 prescriptions were received in the quarter ended September 30, 2021, representing 3% growth compared to the same period in 2020.
- In Japan, 110 prescriptions were received in the quarter ended September 30, 2021, representing 28% growth compared to the same period in 2020.

Third 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 \$19.9 million for the three months ended September 30, 2021, a decrease of \$17.4 million, or 47%, from \$37.3 million for the three months ended September 30, 2020. The decrease was driven by increased investments in research and development activities intended to further our exploration of TTFields therapy, and in sales and marketing readiness initiatives in anticipation of future potential launches in new indications. Adjusted EBITDA as a percentage of net revenues reached 15% in the quarter, despite research and development investment reaching 36% of third quarter net revenues. We believe these focused investments are critical to our efforts to realize the long-term potential of the TTFields platform.

Recent achievements

- In September, the FDA granted breakthrough device designation to the NovoTTF-200T™ system for the treatment of advanced liver cancer, in part based on clinical data from Novocure's phase 2 HEPANOVA trial. Our team, along with trial investigators, are actively designing a phase 3 pivotal trial studying the efficacy of TTFields together with atezolizumab and bevacizumab for the first-line treatment of patients with unresectable or metastatic liver cancer.
 - In September, we announced a clinical trial collaboration with Roche to evaluate the use of TTFields together with atezolizumab for the treatment of metastatic pancreatic cancer.
 - In October, we announced the last patient had been enrolled in our phase 2 pilot EF-31 trial for the treatment of gastric cancer.
 - Today, we announced that the last patient was enrolled in our phase 3 pivotal INNOVATE-3 trial for the treatment of recurrent ovarian cancer.
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Anticipated clinical milestones

- Data from phase 2 pilot EF-31 trial in gastric 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)
- Last patient enrollment in phase 3 pivotal PANOVA-3 trial in locally advanced pancreatic cancer (2023)
- 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 (2024)

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, October 28, 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 6394785.

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, visit Novocure.com and 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 September 30,		Nine months ended September 30,		Year ended
	2021	2020	2021	2020	December 31,
	Unaudited		Unaudited		2020
					Audited
Net revenues	\$ 133,606	\$ 132,660	\$ 401,818	\$ 350,413	\$ 494,366
Cost of revenues	30,206	28,395	85,190	78,365	106,501
Gross profit	103,400	104,265	316,628	272,048	387,865
Operating costs and expenses:					
Research, development and clinical trials	48,141	32,818	144,372	88,008	132,010
Sales and marketing	32,580	29,364	98,075	86,658	118,017
General and administrative	31,231	27,061	95,116	79,073	107,437
Total operating costs and expenses	111,952	89,243	337,563	253,739	357,464
Operating income (loss)	(8,552)	15,022	(20,935)	18,309	30,401
Financial expenses (income), net	1,981	3,983	5,567	9,032	12,299
Income (loss) before income taxes	(10,533)	11,039	(26,502)	9,277	18,102
Income taxes	2,591	1,755	5,391	(5,614)	(1,706)
Net income (loss)	\$ (13,124)	\$ 9,284	\$ (31,893)	\$ 14,891	\$ 19,808
Basic net income (loss) per ordinary share	\$ (0.13)	\$ 0.09	\$ (0.31)	\$ 0.15	\$ 0.20
Weighted average number of ordinary shares used in computing basic net income (loss) per share	103,731,147	101,234,306	103,281,380	100,601,427	100,930,866
Diluted net income (loss) per ordinary share	\$ (0.13)	\$ 0.09	\$ (0.31)	\$ 0.14	\$ 0.18
Weighted average number of ordinary shares used in computing diluted net income (loss) per share	103,731,147	108,643,814	103,281,380	108,113,416	108,877,648

Consolidated Balance Sheets

USD in thousands (except share data)

	September 30, 2021	December 31, 2020
	Unaudited	Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 689,837	\$ 234,674
Short-term investments	243,948	607,902
Restricted cash	855	11,499
Trade receivables, net	94,129	96,699
Receivables and prepaid expenses	17,595	21,245
Inventories	22,642	27,422
Total current assets	<u>1,069,006</u>	<u>999,441</u>
LONG-TERM ASSETS:		
Property and equipment, net	11,699	11,395
Field equipment, net	12,553	11,230
Right-of-use assets	16,460	19,009
Other long-term assets	10,735	10,908
Total long-term assets	<u>51,447</u>	<u>52,542</u>
TOTAL ASSETS	<u>\$ 1,120,453</u>	<u>\$ 1,051,983</u>

Consolidated Balance Sheets

USD in thousands (except share data)

	September 30, 2021	December 31, 2020
	Unaudited	Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 60,005	\$ 53,647
Other payables, lease liabilities and accrued expenses	64,544	59,965
Total current liabilities	<u>124,549</u>	<u>113,612</u>
LONG-TERM LIABILITIES:		
Long-term debt, net	561,388	429,905
Deferred revenue	7,464	12,139
Long-term leases	11,478	14,293
Employee benefits	2,031	5,171
Other long-term liabilities	379	337
Total long-term liabilities	<u>582,740</u>	<u>461,845</u>
TOTAL LIABILITIES	<u>707,289</u>	<u>575,457</u>
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares no par value, unlimited shares authorized; issued and outstanding: 103,817,566 shares and 102,334,276 shares at September 30, 2021 (unaudited) and December 31, 2020, respectively	—	—
Additional paid-in capital	1,073,532	1,111,435
Accumulated other comprehensive income (loss)	(900)	(3,832)
Retained earnings (accumulated deficit)	<u>(659,468)</u>	<u>(631,077)</u>
TOTAL SHAREHOLDERS' EQUITY	<u>413,164</u>	<u>476,526</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 1,120,453</u>	<u>\$ 1,051,983</u>

Non-U.S. GAAP financial measures reconciliation

USD in thousands

	Three months ended September 30,			Nine months ended September 30,		
	2021	2020	% Change	2021	2020	% Change
Net income (loss)	\$ (13,124)	\$ 9,284	(241)%	\$ (31,893)	\$ 14,891	(314)%
Add: Income tax	2,591	1,755	48 %	5,391	(5,614)	(196)%
Add: Financial income (expenses), net	1,981	3,983	(50)%	5,567	9,032	(38)%
Add: Depreciation and amortization	2,734	2,188	25 %	7,584	6,677	14 %
EBITDA	\$ (5,818)	\$ 17,210	(134)%	\$ (13,351)	\$ 24,986	(153)%
Add: Share-based compensation	25,758	20,121	28 %	72,502	55,448	31 %
Adjusted EBITDA	\$ 19,940	\$ 37,331	(47)%	\$ 59,151	\$ 80,434	(26)%

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