

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 28, 2022
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 July 28, 2022, the Company issued a press release announcing certain financial results for the quarter ended June 30, 2022. 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 July 28, 2022
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 28, 2022

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

Novocure Reports Second Quarter 2022 Financial Results

Quarterly net revenues of \$140.9 million, a 6% increase year-over-year

Root, Switzerland – Novocure (NASDAQ: NVCR) today reported financial results for the quarter ended June 30, 2022. 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).

“The second quarter was a period of solid progress, further solidifying the fundamentals of our business,” said William Doyle, Novocure’s Executive Chairman. “We generated \$141 million in net revenues in the quarter, released promising data from our gastric cancer pilot study, announced a new pivotal trial collaboration with Merck and advanced our current late-stage clinical studies. The future is bright for Novocure and we are hopeful that our progress will enable us to treat many more cancer patients in the near future.”

“Novocure is entering a transformational period in the coming quarters,” said Asaf Danziger, Novocure’s Chief Executive Officer. “In the next 18 months, we expect to reach a number of clinical and product development milestones, including data releases from multiple pivotal trials and the limited release of our new flex arrays. We are eager to continue exploring the potential of our platform therapy and I would like to thank my Novocure colleagues for their passion and determination in advancing the science and adoption of Tumor Treating Fields.”

Financial updates for the second quarter ended June 30, 2022:

- Total net revenues for the quarter were \$140.9 million, an increase of 6% compared to the same period in 2021.
 - The United States, EMEA and Japan contributed \$108.2 million, \$18.5 million, and \$8.3 million in quarterly net revenues, respectively.
 - German revenue was impacted by a reduction in German active patient numbers and approval rates as a result of updated coverage criteria.
 - Revenue in Greater China from Novocure’s partnership with Zai Lab totaled \$5.9 million.
 - Gross margin for the quarter was 80%.
 - Research, development and clinical studies expenses for the quarter were \$57.1 million, an increase of 13% from the same period in 2021.
 - Sales and marketing expenses for the quarter were \$44.7 million, an increase of 31% compared to the same period in 2021. This reflects increased investments in early commercial and market access capabilities.
 - General and administrative expenses for the quarter were \$31.7 million, a decrease of 3% compared to the same period in 2021.
 - Net loss for the quarter was \$24.0 million with loss per share of \$0.23.
 - Adjusted EBITDA* for the quarter was \$7.3 million.
 - Cash, cash equivalents and short-term investments were \$948.5 million as of June 30, 2022.
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Operational updates for the second quarter ended June 30, 2022:

- As of June 30, 2022, there were 3,454 active patients on therapy. Active patients from North America, EMEA and Japan contributed 2,229, 879 and 346 active patients, respectively.
- 1,383 prescriptions were received in the quarter. Prescriptions from North America, EMEA and Japan contributed 954, 334 and 95 prescriptions, respectively.

Quarterly updates and achievements:

- Today, we are announcing that top-line data from the LUNAR pivotal study will be distributed in early Q1 2023 versus the final week of 2022 to ensure optimal visibility and timing for all audiences. Our clinical operations and data collection efforts remain on track.
- In May 2022, we entered into a clinical trial collaboration agreement with MSD, a tradename of Merck & Co., Inc., ("MSD") to conduct a double-blind, placebo-controlled study of TTFIELDS concomitant with pembrolizumab and maintenance temozolomide for the treatment of newly diagnosed GBM. We intend to engage the FDA in pre-submission discussions in the near-term regarding the parameters of the KEYNOTE D58 trial protocol design.
- In June 2022, we announced results of the phase 2 pilot EF-31 study evaluating the use of TTFIELDS together with standard-of-care (chemotherapy alone or in combination with trastuzumab for HER2-positive patients) as first-line treatment for gastric cancer. Initial analysis was conducted with a median follow-up period of 8.6 months. The primary endpoint, confirmed objective response rate, was 50%. Median progression-free survival was 7.8 months. Duration of response was 10.3 months. Median overall survival had not yet been reached with a one-year survival rate of 72%. We look forward to further exploration of these potential benefits as we look ahead to a randomized phase 3 clinical study.
- In June 2022, we announced the first patient has been enrolled in the phase 2 pilot KEYNOTE B36 study, conducted in collaboration with MSD. KEYNOTE B36 is designed to evaluate the safety and effectiveness of TTFIELDS together with pembrolizumab for the treatment of locally advanced or metastatic intrathoracic NSCLC that expresses PD-L1.

Anticipated clinical milestones:

- Data from phase 2 pilot EF-33 study with high-intensity arrays in recurrent GBM (2022)
 - Last patient enrollment in phase 3 pivotal METIS study in brain metastases (2022)
 - Data from phase 3 pivotal LUNAR study in NSCLC (early Q1 2023)
 - Last patient enrollment in phase 3 pivotal PANOVA-3 study in locally advanced pancreatic cancer (2023)
 - Data from phase 3 pivotal INNOVATE-3 study in recurrent ovarian cancer (2023)
 - Data from phase 3 pivotal METIS study in brain metastases (2023)
 - Data from phase 3 pivotal PANOVA-3 study in locally advanced pancreatic cancer (2024)
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Conference call details

Novocure will host a conference call and webcast to discuss second quarter 2022 financial results at 8 a.m. EDT today, Thursday, July 28, 2022. Analysts and investors can participate in the conference call by using the following [registration link](#), and dial-in details will be provided.

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 malignant pleural mesothelioma. Novocure has ongoing or completed clinical studies investigating Tumor Treating Fields in brain metastases, gastric cancer, glioblastoma, liver cancer, non-small cell lung cancer, pancreatic cancer and ovarian cancer.

Headquartered in Root, Switzerland and with a growing global footprint, Novocure has regional operating centers in Portsmouth, New Hampshire and Tokyo, as well as a research center in Haifa, Israel. For additional information about the company, please visit Novocure.com and follow @Novocure on LinkedIn and Twitter.

***Non-GAAP Financial Measurements**

We 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.

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 study 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 24, 2022, 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 June 30,		Six months ended June 30,		Year ended
	2022	2021	2022	2021	December 31,
	Unaudited		Unaudited		Audited
Net revenues	\$ 140,866	\$ 133,517	\$ 278,413	\$ 268,212	\$ 535,031
Cost of revenues	28,503	28,599	56,230	54,984	114,877
Gross profit	112,363	104,918	222,183	213,228	420,154
Operating costs and expenses:					
Research, development and clinical studies	57,075	50,315	99,309	96,231	201,303
Sales and marketing	44,750	34,138	82,634	65,495	137,057
General and administrative	31,666	32,760	62,174	63,885	126,127
Total operating costs and expenses	133,491	117,213	244,117	225,611	464,487
Operating income (loss)	(21,128)	(12,295)	(21,934)	(12,383)	(44,333)
Financial expenses (income), net	2,228	940	3,937	3,586	7,742
Income (loss) before income taxes	(23,356)	(13,235)	(25,871)	(15,969)	(52,075)
Income taxes	652	1,406	2,784	2,800	6,276
Net income (loss)	\$ (24,008)	\$ (14,641)	\$ (28,655)	\$ (18,769)	\$ (58,351)
Basic net income (loss) per ordinary share	\$ (0.23)	\$ (0.14)	\$ (0.27)	\$ (0.18)	\$ (0.56)
Weighted average number of ordinary shares used in computing basic net income (loss) per share	104,627,789	103,484,866	104,408,164	103,061,557	103,433,274
Diluted net income (loss) per ordinary share	\$ (0.23)	\$ (0.14)	\$ (0.27)	\$ (0.18)	\$ (0.56)
Weighted average number of ordinary shares used in computing diluted net income (loss) per share	104,627,789	103,484,866	104,408,164	103,061,557	103,433,274

Consolidated Balance Sheets

USD in thousands (except share data)

	June 30, 2022	December 31, 2021
	Unaudited	Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 367,014	\$ 208,802
Short-term investments	581,503	728,898
Restricted cash	749	807
Trade receivables, net	97,563	93,567
Receivables and prepaid expenses	18,195	17,025
Inventories	29,531	24,427
Total current assets	1,094,555	1,073,526
LONG-TERM ASSETS:		
Property and equipment, net	26,561	22,693
Field equipment, net	12,377	12,923
Right-of-use assets	18,281	18,267
Other long-term assets	10,898	12,086
Total long-term assets	68,117	65,969
TOTAL ASSETS	\$ 1,162,672	\$ 1,139,495

Consolidated Balance Sheets

USD in thousands (except share data)

	June 30, 2022	December 31, 2021
	Unaudited	Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 79,910	\$ 72,600
Other payables, lease liabilities and accrued expenses	55,489	70,002
Total current liabilities	135,399	142,602
LONG-TERM LIABILITIES:		
Long-term debt, net	563,846	562,216
Deferred revenue	4,541	6,477
Long-term leases	13,377	12,997
Employee benefit liabilities	3,598	4,543
Other long-term liabilities	239	166
Total long-term liabilities	585,601	586,399
TOTAL LIABILITIES	721,000	729,001
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares no par value, unlimited shares authorized; issued and outstanding: 104,727,685 shares and 103,971,263 shares at June 30, 2022 (unaudited) and December 31, 2021, respectively	—	—
Additional paid-in capital	1,158,348	1,099,589
Accumulated other comprehensive income (loss)	(2,095)	(3,169)
Retained earnings (accumulated deficit)	(714,581)	(685,926)
TOTAL SHAREHOLDERS' EQUITY	441,672	410,494
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 1,162,672	\$ 1,139,495

Non-U.S. GAAP financial measures reconciliation

USD in thousands

	Three months ended June 30,			Six months ended June 30,		
	2022	2021	% Change	2022	2021	% Change
Net income (loss)	\$ (24,008)	\$ (14,641)	64 %	\$ (28,655)	\$ (18,769)	53 %
Add: Income tax	652	1,406	(54)%	2,784	2,800	(1)%
Add: Financial expenses (income), net	2,228	940	137 %	3,937	3,586	10 %
Add: Depreciation and amortization	2,654	2,480	7 %	5,264	4,850	9 %
EBITDA	\$ (18,474)	\$ (9,815)	88 %	\$ (16,670)	\$ (7,533)	121 %
Add: Share-based compensation	25,823	27,881	(7)%	50,868	46,744	9 %
Adjusted EBITDA	\$ 7,349	\$ 18,066	(59)%	\$ 34,198	\$ 39,211	(13)%

Investors:

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