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 27, 2023
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 27, 2023, the Company issued a press release announcing certain financial results for the quarter ended June 30, 2023. 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 27, 2023
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 27, 2023

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

Novocure Reports Second Quarter 2023 Financial Results

Quarterly net revenues of $126 million with 3,571 active patients on therapy as of June 30, 2023

Phase 3 LUNAR trial in non-small cell lung cancer met primary and key secondary survival endpoints, the first of four phase 3 trials to readout by year-end 2024

Interim analysis for fully enrolled phase 3 PANOVA-3 trial in pancreatic cancer concluded with recommendation to proceed to final analysis

Root, Switzerland – Novocure (NASDAQ: NVCR) today reported financial results for the quarter ended June 30, 2023. 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 sound execution and expansion at Novocure,” said Asaf Danziger, Novocure’s Chief Executive Officer. “Our restructured commercial organization has begun driving greater penetration in key markets, the launch of Optune® in France has been a resounding success, and we are preparing to introduce our next generation arrays in more markets later this year. We believe there are many more patients who can benefit from TTFields therapy and we are determined to reach them.”

“The positive results from the LUNAR trial in non-small cell lung cancer mark the beginning of the next chapter at Novocure, as we strive to extend survival for patients diagnosed with difficult-to-treat tumors,” said William Doyle, Novocure’s Executive Chairman. “With three more phase 3 trials set to read out by the end of 2024 and a new generation of trials slated to launch, our determination and commitment are strengthened by the prospect of potentially treating many more patients across a number of new indications in the coming years.”

Financial updates for the second quarter ended June 30, 2023:

- Total net revenues for the quarter were $126.1 million, a decrease of 11% compared to the same period in 2022. The decrease resulted primarily from $13.4 million in reduced collections from previously denied or appealed claims in the U.S.
    - The United States, Germany and Japan contributed $87.0 million, $15.7 million and $7.9 million, respectively, with our other active markets contributing $8.7 million.
    - Revenue in Greater China from Novocure’s partnership with Zai Lab totaled $6.8 million.
- Gross margin for the quarter was 73%.
- Research, development and clinical studies expenses for the quarter were $55.4 million, a decrease of 3% from the same period in 2022. This primarily reflects reduced costs associated with recently completed trials in the quarter. Total clinical trial expenses can fluctuate quarter-to-quarter dependent upon the

amount of clinical research organization services delivered, clinical materials procured and number of trials actively underway. As our current phase 3 clinical trials near completion, we expect to backfill our clinical trial pipeline with new phase 2 and 3 trials.

- Sales and marketing expenses for the quarter were $58.5 million, an increase of 31% compared to the same period in 2022. This increase reflects increased investments associated with geographic expansion and pre-launch activities intended to increase awareness of TTFields therapy in anticipation of future approvals in new indications.
- General and administrative expenses for the quarter were $40.8 million, an increase of 29% compared to the same period in 2022. This reflects increased personnel and project costs to support larger patient populations, new geographic launches, supply chain expansion and information technology enhancements.
- Net loss for the quarter was $57.4 million with loss per share of $0.54.
- Adjusted EBITDA* for the quarter was $(27.2) million.
- Cash, cash equivalents and short-term investments were $940.8 million as of June 30, 2023.

Operational updates for the second quarter ended June 30, 2023:

- 1,556 prescriptions were received in the quarter, an increase of 13% compared to the same period in 2022. Prescriptions from the United States, Germany and Japan contributed 981, 204 and 92 prescriptions, respectively, with the remaining 279 prescriptions received in our other active markets.
- As of June 30, 2023, there were 3,571 active patients on therapy. Active patients from the United States, Germany and Japan contributed 2,200, 499 and 352 active patients, respectively, with the remaining 520 active patients contributed by our other active markets.

Quarterly updates and achievements:

- In June, we presented positive results from the phase 3 LUNAR trial evaluating the use of TTFields therapy together with standard therapies for the treatment of metastatic non-small cell lung cancer (NSCLC) following platinum-failure. The LUNAR trial met its primary endpoint with a statistically significant and clinically meaningful 3-month improvement in median overall survival (OS) with TTFields therapy added to standard therapies (HR=0.74, P=0.035). Patients randomized to receive TTFields therapy together with standard therapies demonstrated median OS of 13.2 months compared to 9.9 months in patients treated with standard therapies alone. Patients randomized to receive TTFields therapy and physician’s choice immune checkpoint inhibitor (ICI) demonstrated a median OS of 18.5 months, a profound extension compared to the median OS of 10.8 months demonstrated by patients that received ICI alone (HR=0.63; P=0.03). Patients randomized to receive TTFields therapy and docetaxel had a positive survival trend with a median OS of 11.1 months vs 8.7 months. TTFields therapy was well-tolerated with no added systemic toxicities and few grade 3 (no grade 4 or 5) device-related adverse events. These data are expected to serve as the basis for a PMA submission to the FDA in the second half of 2023.

- In July, we announced that an independent data monitoring committee (DMC) reviewed the safety and efficacy data for all patients in the fully enrolled PANOVA-3 clinical trial. The interim analysis resulted in a DMC recommendation that the clinical trial proceed to final analysis. The PANOVA-3 study accrued 556 patients as of February 2023 and data will be reviewed in 2024, following an 18-month follow-up period.
- In July, the U.S. Food and Drug Administration accepted the investigation device exemption for the LUNAR-2 clinical trial, a randomized, phase 3 study testing the safety and effectiveness of TTFields therapy concomitant with pembrolizumab and platinum-based chemotherapy in patients with metastatic NSCLC. The two primary endpoints of LUNAR-2 are overall survival and progression-free survival. LUNAR-2 is designed to accrue 734 patients with a 21-month follow-up following the enrollment of the last patient.

Anticipated clinical milestones:

- Data from phase 3 INNOVATE-3 clinical trial in recurrent ovarian cancer (2H 2023)
- Top-line data from phase 3 METIS clinical trial in brain metastases (Q1 2024)
- Data from phase 3 PANOVA-3 clinical trial in locally advanced pancreatic cancer (2H 2024)

Conference call details

Novocure will host a conference call and webcast to discuss second quarter 2023 financial results at 8:00 a.m. EDT today, Thursday, July 27, 2023. To access the conference call by phone, use the following conference call registration link and dial-in details will be provided. To access the webcast, use the following webcast registration link.

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, malignant pleural mesothelioma and 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 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 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.

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 23, 2023, and subsequent filings 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,
	2023	2022	2023	2022	2022
	Unaudited		Unaudited		Audited
Net revenues	$ 126,051	$ 140,866	$ 248,233	$ 278,413	$ 537,840
Cost of revenues	34,018	28,503	63,632	56,230	114,867
Gross profit	92,033	112,363	184,601	222,183	422,973
Operating costs and expenses:					
Research, development and clinical studies	55,427	57,075	115,131	99,309	206,085
Sales and marketing	58,488	44,750	109,657	82,634	173,658
General and administrative	40,778	31,666	82,722	62,174	132,753
Total operating costs and expenses	154,693	133,491	307,510	244,117	512,496
Operating income (loss)	(62,660)	(21,128)	(122,909)	(21,934)	(89,523)
Financial income (expenses), net	8,756	(2,228)	17,925	(3,937)	7,677
Income (loss) before income taxes	(53,904)	(23,356)	(104,984)	(25,871)	(81,846)
Income taxes	3,514	652	5,495	2,784	10,688
Net income (loss)	$ (57,418)	$ (24,008)	$ (110,479)	$ (28,655)	$ (92,534)
Basic and diluted net income (loss) per ordinary share	$ (0.54)	$ (0.23)	$ (1.04)	$ (0.27)	$ (0.88)
Weighted average number of ordinary shares used in computing basic and diluted net income (loss) per share	106,289,073	104,627,789	105,979,791	104,408,164	104,660,476

Consolidated Balance Sheets
USD in thousands (except share data)

	June 30, 2023	December 31, 2022
	Unaudited	Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 156,978	$ 115,326
Short-term investments	783,837	854,099
Restricted cash	516	508
Trade receivables, net	70,988	86,261
Receivables and prepaid expenses	20,148	25,959
Inventories	33,023	29,376
Total current assets	1,065,490	1,111,529
LONG-TERM ASSETS:		
Property and equipment, net	41,156	32,678
Field equipment, net	11,519	12,684
Right-of-use assets	26,278	23,596
Other long-term assets	14,572	11,161
Total long-term assets	93,525	80,119
TOTAL ASSETS	$ 1,159,015	$ 1,191,648

Consolidated Balance Sheets
USD in thousands (except share data)

	June 30, 2023	December 31, 2022
	Unaudited	Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 82,536	$ 85,197
Other payables, lease liabilities and accrued expenses	67,551	73,580
Total current liabilities	150,087	158,777
LONG-TERM LIABILITIES:		
Long-term debt, net	567,150	565,509
Deferred revenues	807	2,878
Long-term leases	20,329	18,762
Employee benefit liabilities	4,840	4,404
Other long-term liabilities	119	148
Total long-term liabilities	593,245	591,701
TOTAL LIABILITIES	743,332	750,478
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares no par value, unlimited shares authorized; issued and outstanding: 106,605,331 shares and 105,049,411 shares at June 30, 2023 (unaudited) and December 31, 2022, respectively	—	—
Additional paid-in capital	1,306,603	1,222,063
Accumulated other comprehensive income (loss)	(1,981)	(2,433)
Retained earnings (accumulated deficit)	(888,939)	(778,460)
TOTAL SHAREHOLDERS' EQUITY	415,683	441,170
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 1,159,015	$ 1,191,648

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

	Three months ended June 30,			Six months ended June 30,		
	2023	2022	% Change	2023	2022	% Change
Net income (loss)	$ (57,418)	$ (24,008)	139 %	$ (110,479)	$ (28,655)	286 %
Add: Income tax	3,514	652	439 %	5,495	2,784	97 %
Add: Financial expenses (income), net	(8,756)	2,228	(493)%	(17,925)	3,937	(555)%
Add: Depreciation and amortization	2,721	2,654	3 %	5,443	5,264	3 %
EBITDA	$ (59,939)	$ (18,474)	224 %	$ (117,466)	$ (16,670)	605 %
Add: Share-based compensation	32,740	25,823	27 %	71,824	50,868	41 %
Adjusted EBITDA	$ (27,199)	$ 7,349	(470)%	$ (45,642)	$ 34,198	(233)%

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