

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 26, 2023
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 26, 2023, the Company issued a press release announcing certain financial results for the quarter ended September 30, 2023. 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 26, 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: October 26, 2023

By: /s/ Ashley Cordova

Name: Ashley Cordova

Title: Chief Financial Officer

Novocure Reports Third Quarter 2023 Financial Results

Quarterly net revenues of \$127 million with 3,639 active patients on therapy as of September 30, 2023

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

“We are focused on extending survival in some of the most aggressive forms of cancer,” said Asaf Danziger, Novocure’s Chief Executive Officer. “This quarter we continued our very successful launch in France and took significant strides in the rollout of our new arrays, which are thinner, lighter and more flexible than our first-generation product. We are eager to build on this momentum as we prepare to treat significantly larger patient populations in the coming years.”

“In Q3, we made considerable progress towards our goal of treating patients with non-small cell lung cancer,” said William Doyle, Novocure’s Executive Chairman. “Primary data from our phase 3 LUNAR clinical trial were published in *The Lancet Oncology*; and multiple post-hoc analyses were presented at major medical congresses, further illuminating the strength of the LUNAR clinical trial results. We look forward to completing the regulatory steps required to launch in our key markets.”

Financial updates for the third quarter ended September 30, 2023:

- Total net revenues for the quarter were \$127.3 million, a decrease of 3% compared to the same period in 2022. The decrease resulted primarily from \$14.5 million in reduced collections from denied or appealed claims in the U.S.
 - The United States, Germany and Japan contributed \$86.2 million, \$14.7 million and \$7.6 million, respectively, with our other active markets contributing \$12.1 million.
 - Revenue in Greater China from Novocure’s partnership with Zai Lab totaled \$6.8 million.
 - Gross margin for the quarter was 75%.
 - Research, development and clinical studies expenses for the quarter were \$53.6 million, an increase of 3% from the same period in 2022. This primarily reflects the increase in quality assurance, regulatory affairs, product development and safety costs in anticipation of clinical trial launches and regulatory filings. 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 \$58.0 million, an increase of 40% compared to the same period in 2022. This primarily reflects increased costs associated with geographic expansion and pre-launch activities intended to
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increase awareness of TTFields therapy in anticipation of future approvals in new indications.

- General and administrative expenses for the quarter were \$41.9 million, an increase of 29% compared to the same period in 2022. This primarily 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 \$49.5 million with loss per share of \$0.46.
- Adjusted EBITDA* for the quarter was \$(29.1) million.
- Cash, cash equivalents and short-term investments were \$921.2 million as of September 30, 2023.

Operational updates for the third quarter ended September 30, 2023:

- 1,467 prescriptions were received in the quarter, an increase of 6% compared to the same period in 2022. Prescriptions from the United States, Germany and Japan contributed 920, 163 and 85 prescriptions, respectively, with the remaining 299 prescriptions received in our other active markets.
- As of September 30, 2023, there were 3,639 active patients on therapy. Active patients from the United States, Germany and Japan contributed 2,179, 492 and 353 active patients, respectively, with the remaining 615 active patients contributed by our other active markets.

Quarterly updates and achievements:

- In August, the primary data from the phase 3 LUNAR clinical trial were published in *The Lancet Oncology*. These data will serve as the basis for a Premarket Approval submission to the U.S. Food and Drug Administration later this year.
- In September, the first patient was enrolled in the phase 2 PANOVA-4 clinical trial evaluating the safety and efficacy of TTFields therapy together with atezolizumab, gemcitabine and nab-paclitaxel in the treatment of metastatic pancreatic cancer. The PANOVA-4 trial is the result of a clinical study collaboration with Roche.
- In October, we entered an agreement with Stanford University to establish the Stanford School of Medicine Tumor Treating Fields Research Program, intended to support both preclinical and clinical trials exploring the use of TTFields.
- In August, we announced the phase 3 INNOVATE-3 clinical trial for the treatment of platinum-resistant ovarian cancer did not meet the primary endpoint of overall survival at final analysis. An exploratory subgroup analysis suggested a potential survival benefit in patients who received only one prior line of therapy. Consistent with previously reported studies, TTFields therapy was well-tolerated with no added systemic toxicities. Full evaluation of the trial data, including subgroup analyses, is ongoing and we will work with trial investigators to share the full results with the scientific community in the future.

Anticipated clinical milestones:

- Top-line data from phase 3 METIS clinical trial in brain metastases (Q1 2024)
 - Top-line data from phase 3 PANOVA-3 clinical trial in locally advanced pancreatic cancer (H2 2024)
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Conference call details

Novocure will host a conference call and webcast to discuss third quarter 2023 financial results at 8:00 a.m. EDT today, Thursday, October 26, 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 September 30,		Nine months ended September 30,		Year ended
	2023	2022	2023	2022	December 31,
	Unaudited		Unaudited		2022
					Audited
Net revenues	\$ 127,321	\$ 130,998	\$ 375,554	\$ 409,411	\$ 537,840
Cost of revenues	32,092	29,749	95,724	85,979	114,867
Gross profit	95,229	101,249	279,830	323,432	422,973
Operating costs and expenses:					
Research, development and clinical studies	53,623	51,956	168,754	151,265	206,085
Sales and marketing	57,964	41,395	167,621	124,029	173,658
General and administrative	41,887	32,509	124,609	94,683	132,753
Total operating costs and expenses	153,474	125,860	460,984	369,977	512,496
Operating income (loss)	(58,245)	(24,611)	(181,154)	(46,545)	(89,523)
Financial income (expenses), net	10,023	1,194	27,948	(2,743)	7,677
Income (loss) before income taxes	(48,222)	(23,417)	(153,206)	(49,288)	(81,846)
Income taxes	1,263	3,159	6,758	5,943	10,688
Net income (loss)	\$ (49,485)	\$ (26,576)	\$ (159,964)	\$ (55,231)	\$ (92,534)
Basic and diluted net income (loss) per ordinary share	\$ (0.46)	\$ (0.25)	\$ (1.51)	\$ (0.53)	\$ (0.88)
Weighted average number of ordinary shares used in computing basic and diluted net income (loss) per share	106,772,814	104,884,583	106,219,194	104,552,803	104,660,476

Consolidated Balance Sheets

USD in thousands (except share data)

	September 30, 2023	December 31, 2022
	Unaudited	Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 154,860	\$ 115,326
Short-term investments	766,388	854,099
Restricted cash	1,652	508
Trade receivables, net	65,133	86,261
Receivables and prepaid expenses	23,163	25,959
Inventories	36,806	29,376
Total current assets	1,048,002	1,111,529
LONG-TERM ASSETS:		
Property and equipment, net	45,564	32,678
Field equipment, net	11,357	12,684
Right-of-use assets	29,014	23,596
Other long-term assets	12,416	11,161
Total long-term assets	98,351	80,119
TOTAL ASSETS	\$ 1,146,353	\$ 1,191,648

Consolidated Balance Sheets

USD in thousands (except share data)

	September 30, 2023	December 31, 2022
	Unaudited	Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 79,668	\$ 85,197
Other payables, lease liabilities and accrued expenses	77,493	73,580
Total current liabilities	157,161	158,777
LONG-TERM LIABILITIES:		
Long-term debt, net	567,986	565,509
Deferred revenues	—	2,878
Long-term leases	22,054	18,762
Employee benefit liabilities	5,373	4,404
Other long-term liabilities	75	148
Total long-term liabilities	595,488	591,701
TOTAL LIABILITIES	752,649	750,478
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares no par value, unlimited shares authorized; issued and outstanding: 106,748,270 shares and 105,049,411 shares at September 30, 2023 (unaudited) and December 31, 2022, respectively	—	—
Additional paid-in capital	1,334,120	1,222,063
Accumulated other comprehensive income (loss)	(1,992)	(2,433)
Retained earnings (accumulated deficit)	(938,424)	(778,460)
TOTAL SHAREHOLDERS' EQUITY	393,704	441,170
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 1,146,353	\$ 1,191,648

Non-U.S. GAAP financial measures reconciliation

USD in thousands

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	% Change	2023	2022	% Change
Net income (loss)	\$ (49,485)	\$ (26,576)	86 %	\$ (159,964)	\$ (55,231)	190 %
Add: Income tax	1,263	3,159	(60)%	6,758	5,943	14 %
Add: Financial expenses (income), net	(10,023)	(1,194)	739 %	(27,948)	2,743	(1,119)%
Add: Depreciation and amortization	2,803	2,659	5 %	8,246	7,924	4 %
EBITDA	\$ (55,442)	\$ (21,952)	153 %	\$ (172,908)	\$ (38,621)	348 %
Add: Share-based compensation	26,346	26,305	— %	98,170	77,173	27 %
Adjusted EBITDA	\$ (29,096)	\$ 4,353	(768)%	\$ (74,738)	\$ 38,552	(294)%

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