

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

April 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 April 28, 2022, the Company issued a press release announcing certain financial results for the quarter ended March 31, 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 April 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 First Quarter 2022 Financial Results

Quarterly net revenues of \$137.5 million with 80% gross margin

Entering a transformational period with multiple clinical catalysts expected in near-term

St. Helier, Jersey – Novocure (NASDAQ: NVCR) today reported financial results for the quarter ended March 31, 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 first quarter was another period of solid execution for Novocure,” said Asaf Danziger, Novocure’s Chief Executive Officer. “Our core glioblastoma business continues to provide the financial strength for significant investment in future growth drivers. We believe these investments, especially the expansion of our clinical pipeline and product enhancements, ultimately will enable many more cancer patients to benefit from TTFields therapy.”

“2022 marks the beginning of what we expect to be a transformational period for our company and patients,” said William Doyle, Novocure’s Executive Chairman. “In 2022, we expect to release clinical data from multiple studies, complete enrollment of our third pivotal study in less than 12 months, and initiate a limited release of next generation arrays in Europe. After many years building to this point, we are excited to kick off what should be a fruitful year for Novocure.”

Financial updates for the first quarter ended March 31, 2022:

- Total net revenues for the quarter were \$137.5 million, an increase of 2% compared to the same period in 2021.
 - The United States, EMEA and Japan contributed \$97.4 million, \$27.0 million, and \$8.8 million in quarterly net revenues, respectively.
 - Revenue in Greater China from Novocure’s partnership with Zai Lab totaled \$4.4 million.
 - Gross margin for the quarter was 80%.
 - Research, development and clinical studies expenses for the quarter were \$42.2 million, a decrease of 8% from the same period in 2021. Direct clinical trial costs can fluctuate quarter-to-quarter depending on the clinical research organization services delivered and clinical trial materials procured, and we are investing aggressively in future growth and development initiatives.
 - Sales and marketing expenses for the quarter were \$37.9 million, an increase of 21% compared to the same period in 2021. This reflects increased investments in market access capabilities as well as early commercial capabilities in anticipation of potential future approvals and launches in new indications.
 - General and administrative expenses for the quarter were \$30.5 million, a decrease of 2% compared to the same period in 2021.
 - Net loss for the quarter was \$4.6 million with loss per share of \$0.04.
 - Adjusted EBITDA* for the quarter was \$26.8 million.
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- Cash, cash equivalents and short-term investments were \$932.3 million as of March 31, 2022.

Operational updates for the first quarter ended March 31, 2022:

- As of March 31, 2022, there were 3,549 active patients on therapy. Active patients from North America, EMEA and Japan contributed 2,257, 965 and 327 active patients, respectively.
- 1,384 prescriptions were received in the quarter. Prescriptions from North America, EMEA and Japan contributed 935, 347 and 102 prescriptions, respectively.

Quarterly achievements:

- In February, Novocure founder and TTFIELDS inventor Yoram Palti won the 2022 Israel Prize in Entrepreneurship and Technological Innovation. This prize is regarded as the State of Israel's highest cultural honor and recognizes Israeli citizens who have shown special excellence and a breakthrough in their field or who have made a special contribution to Israeli society.
- In March, an independent data monitoring committee ("DMC") conducted a pre-specified interim analysis of the phase 3 pivotal INNOVATE-3 study for the treatment of ovarian cancer. Following completion of the interim analysis, the DMC recommended that the study should continue to final analysis as planned. Data will be reviewed in 2023, following an 18 month follow-up period.

2022 Outlook:

- We expect to achieve active patient growth between 2% to 5% in 2022, in-line with the growth rate experienced in the first quarter of 2022. Longer term, the company continues to expect further adoption in its core GBM business.

Anticipated clinical milestones:

- Data from phase 2 pilot EF-31 study in gastric cancer (2022)
- 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 (2022)
- 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)

Conference call details

Novocure will host a conference call and webcast to discuss first quarter 2022 financial results at 8 a.m. EDT today, Thursday, April 28, 2022. 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 1476184.

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 Jersey, and with a growing global footprint, Novocure has regional operating centers in Root, Switzerland, 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 March 31, | | Year ended |
|--|------------------------------|-------------|--------------|
| | 2022 | 2021 | December 31, |
| | Unaudited | | 2021 |
| | | | Audited |
| Net revenues | \$ 137,547 | \$ 134,695 | \$ 535,031 |
| Cost of revenues | 27,727 | 26,385 | 114,877 |
| Gross profit | 109,820 | 108,310 | 420,154 |
| Operating costs and expenses: | | | |
| Research, development and clinical studies | 42,234 | 45,916 | 201,303 |
| Sales and marketing | 37,884 | 31,357 | 137,057 |
| General and administrative | 30,508 | 31,125 | 126,127 |
| Total operating costs and expenses | 110,626 | 108,398 | 464,487 |
| Operating income (loss) | (806) | (88) | (44,333) |
| Financial expenses (income), net | 1,709 | 2,646 | 7,742 |
| Income (loss) before income taxes | (2,515) | (2,734) | (52,075) |
| Income taxes | 2,132 | 1,394 | 6,276 |
| Net income (loss) | \$ (4,647) | \$ (4,128) | \$ (58,351) |
| Basic net income (loss) per ordinary share | \$ (0.04) | \$ (0.04) | \$ (0.56) |
| Weighted average number of ordinary shares used in computing basic net income (loss) per share | 104,186,120 | 102,633,545 | 103,433,274 |
| Diluted net income (loss) per ordinary share | \$ (0.04) | \$ (0.04) | \$ (0.56) |
| Weighted average number of ordinary shares used in computing diluted net income (loss) per share | 104,186,120 | 102,633,545 | 103,433,274 |

Consolidated Balance Sheets

USD in thousands (except share data)

| | March 31, 2022 | December 31, 2021 |
|----------------------------------|---------------------|---------------------|
| | Unaudited | Audited |
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 190,739 | \$ 208,802 |
| Short-term investments | 741,562 | 728,898 |
| Restricted cash | 889 | 807 |
| Trade receivables, net | 100,965 | 93,567 |
| Receivables and prepaid expenses | 17,343 | 17,025 |
| Inventories | 29,084 | 24,427 |
| Total current assets | 1,080,582 | 1,073,526 |
| LONG-TERM ASSETS: | | |
| Property and equipment, net | 25,072 | 22,693 |
| Field equipment, net | 12,792 | 12,923 |
| Right-of-use assets | 19,937 | 18,267 |
| Other long-term assets | 11,827 | 12,086 |
| Total long-term assets | 69,628 | 65,969 |
| TOTAL ASSETS | \$ 1,150,210 | \$ 1,139,495 |

Consolidated Balance Sheets

USD in thousands (except share data)

| | March 31, 2022 | December 31, 2021 |
|--|---------------------|---------------------|
| | Unaudited | Audited |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Trade payables | \$ 69,186 | \$ 72,600 |
| Other payables, lease liabilities and accrued expenses | 58,613 | 70,002 |
| Total current liabilities | 127,799 | 142,602 |
| LONG-TERM LIABILITIES: | | |
| Long-term debt, net | 563,026 | 562,216 |
| Deferred revenue | 5,511 | 6,477 |
| Long-term leases | 14,813 | 12,997 |
| Employee benefit liabilities | 3,024 | 4,543 |
| Other long-term liabilities | 156 | 166 |
| Total long-term liabilities | 586,530 | 586,399 |
| TOTAL LIABILITIES | 714,329 | 729,001 |
| COMMITMENTS AND CONTINGENCIES | | |
| SHAREHOLDERS' EQUITY: | | |
| Share capital - | | |
| Ordinary shares no par value, unlimited shares authorized; issued and outstanding: 104,559,088 shares and 103,971,263 shares at March 31, 2022 (unaudited) and December 31, 2021, respectively | — | — |
| Additional paid-in capital | 1,127,782 | 1,099,589 |
| Accumulated other comprehensive income (loss) | (1,328) | (3,169) |
| Retained earnings (accumulated deficit) | (690,573) | (685,926) |
| TOTAL SHAREHOLDERS' EQUITY | 435,881 | 410,494 |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | \$ 1,150,210 | \$ 1,139,495 |

Non-U.S. GAAP financial measures reconciliation

USD in thousands

| | <u>2022</u> | <u>2021</u> | <u>% Change</u> |
|---------------------------------------|------------------|------------------|-----------------|
| Net income (loss) | \$ (4,647) | \$ (4,128) | 13 % |
| Add: Income tax | 2,132 | 1,394 | 53 % |
| Add: Financial expenses (income), net | 1,709 | 2,646 | (35)% |
| Add: Depreciation and amortization | 2,610 | 2,370 | 10 % |
| EBITDA | \$ 1,804 | \$ 2,282 | (21)% |
| Add: Share-based compensation | 25,045 | 18,863 | 33 % |
| Adjusted EBITDA | <u>\$ 26,849</u> | <u>\$ 21,145</u> | 27 % |

Investors:

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