Novocure Ltd
Form 10-Q
May 10, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2016

or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number 001-37565

NovoCure Limited

(Exact Name of Registrant as Specified in Its Charter)

Jersey (Channel Islands)	98-1057807
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

Le Masurier House

La Rue Le Masurier

St. Helier, Jersey JE2 4YE

(Address of principal executive offices)

+44 (0) 15 3475 6700

(Registrant's Telephone Number, Including Area Code)

Not Applicable

(Former Name, Former Address and Former Fiscal Year, If Changed Since Last Report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes x No o.

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	x (Do not check if a smaller reporting company)	Smaller reporting company	o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Class	Outstanding as of May 6, 2016
Ordinary shares, no par value	84,519,932 Shares

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

In addition to historical facts or statements of current condition, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements contained in this report are based on our current plans, expectations, hopes, beliefs, intentions or strategies concerning future developments and their impact on us. Forward-looking statements contained in this report constitute our expectations or forecasts of future events as of the date this report was filed with the Securities and Exchange Commission and are not statements of historical fact. You can identify these statements by the fact that they do not relate strictly to historical or current facts. Such statements may include words such as “anticipate,” “will,” “estimate,” “expect,” “project,” “intend,” “should,” “plan,” “believe and other words and terms of similar meaning in connection with any discussion of, among other things, future operating or financial performance, strategic initiatives and business strategies, regulatory or competitive environments, our intellectual property and delivery system research and development. In particular, these forward-looking statements include, among others, statements about:

- our research and development, clinical trial and commercialization activities and projected expenditures;
- the further commercialization of Optune, our first tumor treating fields (“TTFields”) delivery system, and our other TTFields delivery system candidates;
- our business strategies and the expansion of our sales and marketing efforts in the United States and in other countries;
- the market acceptance of Optune and our other TTFields delivery systems by patients, physicians, third-party payers and others in the healthcare and scientific community;
- our plans to pursue the use of TTFields for the treatment of other solid tumor cancers;
- our estimates regarding revenues, expenses, capital requirements and needs for additional financing;
- our ability to obtain regulatory approvals for additional indications and any future TTFields delivery systems;
- our ability to acquire the supplies needed to manufacture our TTFields delivery systems from third-party suppliers;
- our ability to manufacture adequate supply;
- our ability to secure adequate coverage from third-party payers to reimburse us for Optune or future TTFields delivery systems;
- our ability to maintain and develop our intellectual property position;
- our cash needs; and
- our prospects, financial condition and results of operations.

These forward-looking statements involve a number of risks and uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Factors which may cause such differences to occur include those risks and uncertainties set forth under Part I, Item 1A., “Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, as well as other risks and uncertainties set forth from time to time in the reports we file with the U.S. Securities and Exchange Commission. We do not intend to update publicly any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

TRADEMARKS

This Quarterly Report on Form 10-Q includes trademarks of NovoCure Limited and other persons. All trademarks or trade names referred to herein are the property of their respective owners

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NovoCure Limited

Quarterly Report on Form 10-Q

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Item 1. Financial Statements

NOVOCURE LIMITED AND SUBSIDIARIES

CONDENSED INTERIM CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	March 31, 2016 Unaudited	December 31, 2015 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 115,932	$ 119,423
Short-term investments	119,842	150,001
Restricted cash	86	87
Receivables and prepaid expenses	11,335	10,799
Inventories	16,446	13,594
Total current assets	263,641	293,904
LONG-TERM ASSETS:		
Property and equipment, net	7,090	6,552
Field equipment, net	7,211	6,029
Severance pay fund	84	79
Other long-term assets	992	772
Total long-term assets	15,377	13,432
TOTAL ASSETS	$ 279,018	$ 307,336

The accompanying notes are an integral part of these unaudited condensed interim consolidated financial statements.

NOVOCURE LIMITED AND SUBSIDIARIES

CONDENSED INTERIM CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands (except share data)

	March 31, 2016 Unaudited	December 31, 2015 Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$18,578	$16,755
Other payables and accrued expenses	10,850	11,872
Total current liabilities	29,428	28,627
LONG-TERM LIABILITIES:		
Long-term loan, net of discount and issuance costs	23,193	23,097
Employee benefit liabilities	2,823	2,057
Other long-term liabilities	3,148	2,735
Total long-term liabilities	29,164	27,889
TOTAL LIABILITIES	58,592	56,516
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares no par value, unlimited shares authorized ; issued and outstanding: 84,426,720 shares and 83,778,581 shares at March 31, 2016 and December 31, 2015, respectively	-	-
Additional paid-in capital	645,919	640,406
Accumulated other comprehensive loss	(1,975)	(1,505)
Accumulated deficit	(423,518)	(388,081)
Total shareholders' equity	220,426	250,820
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$279,018	$307,336

The accompanying notes are an integral part of these unaudited condensed interim consolidated financial statements.

NOVOCURE LIMITED AND SUBSIDIARIES

CONDENSED INTERIM CONSOLIDATED STATEMENTS OF OPERATIONS

U.S. dollars in thousands (except share and per share data)

	Three months ended		Year ended
	March 31, 2016 Unaudited	2015	December 31, 2015 Audited
Net revenues	$13,053	$5,208	$33,087
Cost of revenues	7,982	3,897	20,610
Gross profit	5,071	1,311	12,477
Operating costs and expenses:			
Research, development and clinical trials	11,445	9,927	43,748
Sales and marketing	13,308	6,355	38,861
General and administrative	12,256	6,975	33,864
Total operating costs and expenses	37,009	23,257	116,473
Operating loss	(31,938)	(21,946)	(103,996)
Financial expenses, net	549	591	3,151
Loss before income tax expense	(32,487)	(22,537)	(107,147)
Income tax expense	2,950	736	4,434
Net loss	$(35,437)	$(23,273)	$(111,581)
Basic and diluted net loss per ordinary share	$(0.42)	$(1.77)	$(3.67)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	84,397,164	13,140,321	30,401,603

CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE INCOME

U.S. dollars in thousands

	Three months ended March 31,		Year ended

U.S. dollars in thousands	2016	2015	December 31, 2015
Net loss	$(35,437)	$(23,273)	$(111,581)
Other comprehensive loss, net of tax :			
Pension benefit plan	(470)	-	(1,505)
Total comprehensive loss	$(35,907)	$(23,273)	$(113,086)

The accompanying notes are an integral part of these unaudited condensed interim consolidated financial statements.

NOVOCURE LIMITED AND SUBSIDIARIES

CONDENSED INTERIM STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

U.S. dollars in thousands (except share data)

	Ordinary shares Shares	Preferred shares Shares	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total shareholders' equity
Balance as of January 1, 2015 (audited)	13,431,414	58,676,017	$374,375	$ -	$(276,500)	$ 97,875
Share-based compensation to employees	-	-	11,860	-	-	11,860
Exercise of options and warrants	731,665	-	2,038	-	-	2,038
Issuance of series J preferred shares, net (a)	-	4,068,500	94,599	-	-	94,599
Issuance of shares and options in respect of settlement, net of fair value of shares provided as indemnification	(1,005,210)	-	-	-	-	-
Issuance of ordinary shares upon IPO and exercise of over-allotment, net (b)	7,876,195	-	157,534	-	-	157,534
Conversion of preferred shares to ordinary shares	62,744,517	(62,744,517)	-	-	-	-
Other comprehensive loss, net of tax benefit	-	-	-	(1,505)	-	(1,505)
Net loss	-	-	-	-	(111,581)	(111,581)
Balance as of December 31, 2015 (audited)	83,778,581	-	640,406	(1,505)	(388,081)	250,820
Share-based compensation to employees	-	-	5,456	-	-	5,456
Exercise of options and warrants	648,139	-	57	-	-	57
Other comprehensive loss, net of tax benefit	-	-	-	(470)	-	(470)
Net loss	-	-	-	-	(35,437)	(35,437)
	84,426,720	-	$645,919	$ (1,975)	$(423,518)	$ 220,426

Balance as of March 31,
2016 (unaudited)

(a) Net of issuance expenses of $319

(b) Net of issuance expenses (including underwriter fees) of $15,742

The accompanying notes are an integral part of these unaudited condensed interim consolidated financial statements.

NOVOCURE LIMITED AND SUBSIDIARIES

CONDENSED INTERIM CONSOLIDATED CASH FLOWS

U.S. dollars in thousands

	Three months ended		Year ended
	March 31, 2016 Unaudited	2015	December 31, 2015 Audited
Cash flows from operating activities:			
Net loss	$(35,437)	$(23,273)	$(111,581)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,103	524	3,153
Asset write-downs and impairment	5	31	46
Accrued interest expense	637	412	672
Share-based compensation to employees	5,456	1,812	11,860
Amortization of discount (premium)	(17)	55	329
Increase in receivables and prepaid expenses	(536)	(947)	(5,088)
Increase in inventories	(2,852)	(3,732)	(10,148)
Increase in other long-term assets	(167)	(10)	(381)
Increase (decrease) in trade payables	1,823	(672)	6,961
Increase (decrease) in other payables and accrued expenses	(1,643)	(2,719)	3,579
Increase in employee benefit liabilities, net	238	7	133
Increase in other long-term liabilities	413	46	581
Net cash used in operating activities	$(30,977)	$(28,466)	$(99,884)
Cash flows from investing activities:			
Purchase of property and equipment	$(1,002)	$(609)	$(4,667)
Purchase of field equipment	(1,826)	(1,038)	(5,604)
Decrease (increase) in restricted cash	1	(73)	(26)
Proceeds from maturity of short-term investments	150,000	45,000	104,000
Purchase of short-term investments	(119,728)	(21,997)	(208,998)
Net cash provided by (used in) investing activities	$27,445	$21,283	$(115,295)
Cash flows from financing activities:			
Proceeds from issuance of shares, net	$-	$-	$252,133
Proceeds from long-term loan, net	-	23,806	22,886
Repayment of other long-term loan	(16)	(16)	(63)
Purchase of shares in respect of settlement	-	(5)	(5)
Exercise of options and warrants	57	3	2,038
Net cash provided by financing activities	$41	$23,788	$276,989
Increase (decrease) in cash and cash equivalents	(3,491)	16,605	61,810
Cash and cash equivalents at the beginning of the period	119,423	57,613	57,613

Cash and cash equivalents at the end of the period	$115,932	$74,218	$119,423
Supplemental cash flow activities:			
Cash paid during the period for:			
Income taxes	$1,582	$95	$1,489
Interest	$664	$6	$1,688
Non-cash investing activity:			
Long-term loan issuance costs and discount	$-	$1,085	$-

The accompanying notes are an integral part of these unaudited condensed interim consolidated financial statements

NOVOCURE LIMITED AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share data)

NOTE 1: ORGANIZATION AND BASIS OF PRESENTATION

Organization. NovoCure Limited (including its consolidated subsidiaries, the "Company") was incorporated in Jersey and is principally engaged in the development, manufacture and commercialization of TTFields for the treatment of solid tumors. Since inception, the Company has devoted substantially all of its efforts to developing a family of products to deliver TTFields for a variety of solid tumor indications, raising capital and recruiting personnel. The Company has regulatory approvals and clearances in certain countries for Optune, its first TTFields delivery system, to treat glioblastoma. The Company commenced marketing Optune in the United States at the end of 2011, in certain countries in Europe in 2014 and in Japan in 2015.

Financial statement preparation. The accompanying condensed consolidated financial statements include the accounts of the Company and its consolidated subsidiaries, and intercompany accounts and transactions have been eliminated. In the opinion of the Company's management, the condensed consolidated financial statements reflect all adjustments, which are normal and recurring in nature, necessary for fair financial statement presentation. The preparation of these condensed consolidated financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in these condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. These condensed consolidated financial statements and accompanying notes should be read in conjunction with the Company's annual consolidated financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (the "2015 10-K") filed with the Securities and Exchange Commission (the "SEC") on March 1, 2016.

The significant accounting policies applied in the audited annual consolidated financial statements of the Company as disclosed in the 2015 10-K are applied consistently in these unaudited interim consolidated financial statements.

Recently Issued Accounting Pronouncements. In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02-Leases (ASC 842), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of their classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases, direct financing leases and operating leases. ASC 842 supersedes the previous leases standard, ASC 840. The standard is effective on January 1, 2019, with early adoption permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The amendments in ASU 2016-09 affect all entities that issue share-based payment awards to their employees and involve multiple aspects of the accounting for share-based payment transactions, including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted in any interim or annual period. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

NOTE 2: SHORT-TERM INVESTMENTS

The Company invests in marketable U.S. Treasury Bills ("T-bills") that are classified as held-to-maturity securities. The amortized cost and recorded basis of the T-bills are presented as short-term investments in the amount of $119,842 and $150,001 as of March 31, 2016 and December 31, 2015, respectively, and their estimated fair value as of March 31, 2016 and December 31, 2015 was $119,778 and $149,978, respectively.

NOTE 3: INVENTORIES

Inventories are stated at the lower of cost or market. The weighted average methodology is applied to determine cost. As of March 31, 2016 and December 31, 2015, the Company's inventories were composed of:

	March 31, 2016 Unaudited	December 31, 2015 Audited
Raw materials	$ 3,593	$ 3,518
Work in progress	6,138	4,618
Finished products	6,715	5,458
Total	$ 16,446	$ 13,594

NOTE 4: COMMITMENTS AND CONTINGENT LIABILITIES

The facilities of the Company are leased under various operating lease agreements for periods ending no later than 2023. The Company also leases motor vehicles under various operating leases, which expire on various dates, the latest of which is in 2019.

As of March 31, 2016 and December 31, 2015, the Company pledged bank deposits of $317 and $133, respectively, to cover bank guarantees in respect of its leases of operating facilities and obtained guarantees by the bank for the fulfillment of the Company's lease commitments of $472 and $283, respectively.

NOTE 5: SHARE CAPITAL

In January 2016, warrants for a total of 975,644 ordinary shares with an exercise price of $18.09 per shares were cashlessly exercised, resulting in the issuance of 315,155 ordinary shares.

NOTE 6: EQUITY INCENTIVE PLAN

In September 2015, the Company adopted the 2015 Omnibus Incentive Plan (the "2015 Plan"). The 2015 Plan replaced the 2013 Share Option Plan. Under the 2015 Plan, the Company can issue various types of equity compensation awards such as restricted shares, performance shares, restricted stock units, performance units, long-term cash award

and other share-based awards.

The options granted under the 2015 Plan generally have a four-year vesting period and expire ten years after the date of grant. Options granted under the 2015 Plan that are cancelled or forfeited before expiration become available for future grant.

As of March 31, 2016, 13,260,713 ordinary shares were available for grant under the 2015 Plan.

A summary of the status of the Company's option plans as of March 31, 2016 and changes during the period then ended is presented below:

	Three months ended March 31, 2016 Unaudited	
	Number of options	Weighted average exercise price
Outstanding at beginning of year	10,134,829	$ 8.20
Granted	1,711,575	14.45
Exercised	(332,984)	0.17
Forfeited and cancelled	(24,620)	16.54
Outstanding as of March 31, 2016	11,488,800	9.35
Exercisable options	5,871,196	4.18
Vested and expected to vest	11,303,362	$ 9.27

NOTE 6: EQUITY INCENTIVE PLAN (Cont.)

The fair value of share-based awards was estimated using the Black-Scholes option-pricing model for all grants with the following underlying assumptions:

	Three months ended		Year ended
	March 31, 2016 Unaudited	2015	December 31, 2015 Audited
Expected term (years)	6.25	6.25	6.25
Expected volatility	59.80%-60.19%	65.80%	59.00%-65.80%
Risk-free interest rate	1.52%-1.88%	1.90 %	1.74%-2.05%
Dividend yield	0%	0%	0%

The total non-cash share-based compensation expenses related to all of the Company's equity-based awards recognized for the three months ended March 31, 2016 and 2015 and the year ended December 31, 2015 were:

	Three months ended		Year ended
	March 31, 2016 Unaudited	2015	December 31, 2015 Audited
Cost of revenues	$141	$13	$ 174
Research, development and clinical trials	763	421	2,529
Sales and marketing	1,290	408	2,496
General and administrative	3,262	970	6,661
Total share-based compensation expense	$5,456	$1,812	$ 11,860

In September 2015, the Company adopted an employee share purchase plan ("ESPP") to encourage and enable eligible employees to acquire ownership of the Company's ordinary shares purchased through accumulated payroll deductions on an after-tax basis. In the United States, the ESPP is intended to be an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code and the provisions of the ESPP will be construed in a manner consistent with the requirements of such section. The Company intends to begin offerings under the ESPP in 2016. As of Mach 31, 2016, 1,667,785 ordinary shares were available to be purchased by eligible employees under the ESPP and no shares have been offered under the ESPP.

NOTE 7: SUPPLEMENTAL INFORMATION

The Company operates in a single reportable segment.

The following table presents long-lived assets by location:

	March 31, 2016 Unaudited	December 31, 2015 Audited
United States	$ 7,358	$ 6,600
Switzerland	4,770	4,204
Israel	1,775	1,376
Others	397	401
Total	$ 14,300	$ 12,581

The Company's revenues by geographic region, based on the customer's location, are summarized as follows:

	Three months ended		Year ended December 31,
	March 31, 2016	2015	2015
	Unaudited		Audited
United States	$12,013	$4,974	$ 30,961
Europe, Japan and other markets	1,040	234	2,126
Total	$13,053	$5,208	$ 33,087

NOTE 8: SUBSEQUENT EVENTS

In April and May 2016, certain investors and employees exercised an aggregate of 1,349,489 warrants and options to purchase ordinary shares, resulting in the issuance of 1,096,752 ordinary shares. Warrants to purchase 888,219 ordinary shares were exercised cashlessly, resulting in the issuance of 635,482 ordinary shares. The total purchase price received by the Company related to the warrant and option exercises was $847.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to provide information to assist you in better understanding and evaluating our financial condition and results of operations. We encourage you to read this MD&A in conjunction with our consolidated financial statements for the period ended March 31, 2016 included in Part I, Item 1 of this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under Part I, Item 1A, "Risk Factors", of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (the "2015 10-K"), our actual results may differ materially from those anticipated in these forward-looking statements. References to the words "we," "our," "us," and the "Company" in this report refer to NovoCure Limited, including its consolidated subsidiaries.

Overview

We are a commercial-stage oncology company developing a novel, proprietary therapy called TTFields for the treatment of solid tumor cancers. TTFields is a low-toxicity anti-mitotic treatment that uses low-intensity, intermediate frequency, alternating electric fields to exert physical forces on key molecules inside cancer cells, disrupting the basic machinery necessary for normal cell division, leading to cancer cell death. Physicians have typically treated patients with solid tumors using one or a combination of three principal treatment modalities—surgery, radiation and pharmacological therapies. Despite meaningful advancements in each of these modalities, a significant unmet need to improve survival and quality of life remains. We believe we will establish TTFields as a new treatment modality for a variety of solid tumors that increases survival without significantly increasing side effects when used in combination with other cancer treatment modalities.

We were founded in 2000 and operated as a development stage company through December 31, 2011. We initially received U.S. Food and Drug Administration ("FDA") approval for Optune, our first commercial TTFields delivery system, in 2011 for use as a monotherapy treatment for adult patients with glioblastoma brain cancer, or GBM, following confirmed recurrence after chemotherapy. In November 2014, our phase 3 pivotal trial of Optune in combination with chemotherapy for patients with newly diagnosed GBM met its endpoints after a pre-specified interim analysis showed significant improvements in both progression free and overall survival. In October 2015, we received FDA approval to market Optune for the treatment of adult patients with newly diagnosed GBM in combination with temozolomide, a chemotherapy drug. We anticipate that Optune will be added to the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for Central Nervous System Cancers for newly diagnosed GBM in 2016.

We have built a commercial organization and launched Optune in the United States, Germany, Switzerland and Japan, which we refer to as our currently active markets. As we enter each new market, our commercial activities focus initially on establishing the required in-market infrastructure, certifying physicians to prescribe Optune and obtaining a defined reimbursement pathway. Once established, our commercial efforts turn to increasing adoption. We believe that TTFields will transform the standard of care for patients with GBM.

In December 2015, we submitted a partial amendment application to the Japanese Pharmaceuticals and Medical Devices Agency in connection with our application for approval of Optune for the treatment of patients with newly diagnosed GBM. We hope to receive Japanese Ministry of Health, Labour and Welfare (MHLW) approval for this indication in late 2016. The MHLW approved the use of Optune to treat patients with recurrent GBM in March 2015. We plan to wait until we receive MHLW approval for the use of Optune to treat patients with newly diagnosed GBM before we submit an application for public reimbursement of Optune in Japan.

We continue to invest in the improvement of Optune to enhance ease of use for patients. In the fourth quarter of 2015, we began making our second generation Optune system available to patients in Europe. In December 2015, we filed a PMA supplement application with the FDA, seeking approval to market the second generation of Optune in the United States for its approved indications. We subsequently received and, in April 2016, responded to questions from the FDA on the PMA supplement application. Assuming that we do not receive additional comments or requests for information from the FDA, we hope to begin marketing our second generation Optune system in the United States in the third quarter of 2016.

We have researched the biological effects of TTFields extensively. Because TTFields are delivered regionally, act only on mitotic cells and are tuned to target cells of a specific size, there is minimal damage to healthy cells. We believe our pre-clinical and clinical research demonstrates that TTFields' mechanism of action affects fundamental aspects of cell division and can have broad applicability across a variety of solid tumors. We have demonstrated in pre-clinical studies that TTFields can offer additive or synergistic benefits in combination with radiation, chemotherapy, and immunotherapy, which may lead to greater efficacy than radiation, chemotherapy, and immunotherapy alone, without appearing to increase the side effects of the other cancer treatments. In addition to our clinical and commercial progress in GBM, we are currently planning or conducting clinical trials evaluating the use of TTFields in brain metastases, non-small-cell lung cancer ("NSCLC"), pancreatic cancer, ovarian cancer and mesothelioma.

Results from the first cohort of our PANOVA trial, a phase 2 pilot trial in advanced pancreatic adenocarcinoma examining TTFields in combination with chemotherapy, were presented at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium in January 2016. The first cohort was designed to test the feasibility, safety and preliminary efficacy of TTFields in combination with gemcitabine, a chemotherapy drug, and included 20 patients with advanced pancreatic cancer whose tumors could not be removed surgically and who had not received chemotherapy or radiation therapy prior to the clinical trial. Efficacy results based on the 20 patients in the first cohort showed that progression free survival, or PFS, and overall survival, or OS, of patients treated with TTFields combined with gemcitabine were more than double those of gemcitabine-treated historical controls. Median PFS in the TTFields-treated group was 8.3 months (compared to 3.7 months in gemcitabine historical controls) and median OS was 14.9 months (compared to 6.7 months in gemcitabine historical controls). Median one-year survival was 55% (compared to 22% in gemcitabine historical controls). Thirty percent of the evaluable tumors (n=19) had partial responses (compared to 7% with gemcitabine alone) and another 30% had stable disease. Adverse events reported in this combination study were comparable to those reported with gemcitabine alone, suggesting minimal added toxicities due to TTFields. The only delivery system-related toxicities were mild-to-moderate local rash beneath the transducer arrays, which was seen in 10 of the 20 patients. Following the approval of nab-paclitaxel, a taxane-based chemotherapy, for the treatment of advanced pancreatic cancer, the PANOVA study was expanded to include 20 additional patients treated with TTFields in combination with nab-paclitaxel and gemcitabine. We expect to finish enrollment of the second patient cohort in 2016 and, with an expected six month follow-up period, we anticipate that phase 2 pilot data will be available for presentation in 2017.

We anticipate expanding our clinical pipeline over time to study the safety and efficacy of TTFields for additional solid tumor indications.

We own all commercialization rights to TTFields in oncology. Our robust global patent and intellectual property portfolio consists of over 50 issued patents, with numerous additional patent applications pending worldwide. We believe we will maintain exclusive rights to market TTFields for all solid tumor indications in our key markets through the life of our patents.

Financial Overview. We expect to continue to incur significant expenses and operating losses for at least the next several years. We expect our research, development and clinical trials expenses to increase in connection with our ongoing activities, and as additional indications enter late-stage clinical development. In addition, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We may need additional funding to support the continuation of our operating activities. Until we can generate substantial revenues (which may not occur), we expect to finance our cash needs through our existing cash, cash equivalents, and short-term investments, equity issuances or additional debt, and possibly also from collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We will need to generate significant revenues to achieve profitability, and we may never do so.

Critical accounting policies and estimates

In accordance with U.S. GAAP, in preparing our financial statements, we must make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of net revenues and expenses during the reporting period. We develop and periodically change these estimates and assumptions based on historical experience and on various other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates.

The critical accounting policies requiring estimates, assumptions and judgments that we believe have the most significant impact on our consolidated financial statements can be found in our 2015 Form 10-K. There have been no

material changes to our critical accounting policies and estimates as compared to the critical accounting policies and estimates described in our 2015 Form 10-K.

Results of Operations

We account for revenue when cash is collected and all other revenue recognition criteria have been met. We report certain operating statistics to provide additional insight into the commercial performance of Optune in our currently active markets.

Prescriptions are a leading indicator of Optune demand. The conversion of prescriptions to new patients is driven by the prescription fill rate and the time to fill. The prescription fill rate for the twelve months ended March 31, 2016 was 75%. The increase in or decrease of active patients in any given period reflects the number of new patients starting on therapy, driven by filled prescriptions, as compared to the number of patients discontinuing therapy, which reflects the treatment duration for patients starting in prior periods.

The following table includes certain commercial operating statistics for and as of the end of the periods presented.

	Three months ended March 31,	
Operating statistics	2016	2015
Prescriptions received in period (1)		
United States	684	411
Germany, Switzerland and other EMEA markets (2)	71	26
Japan (2)	-	-
	755	437
Active patients at period end (3)		
United States	699	347
Germany, Switzerland and other EMEA markets (2)	98	25
Japan (2)	-	-
	797	372

(1) A “prescription received” is a commercial order for Optune that is received from a physician certified to treat patients with TTFields therapy for a patient not previously on TTFields therapy. Orders to renew or extend treatment are not included in this total. In the future, we may have regulatory approvals and commercial programs for multiple clinical indications, at which time we will recognize a commercial order as a prescription for the same patient for each clinical indication treated. For example, in the future, a patient may have a prescription for the treatment of lung cancer and a prescription for the treatment of brain metastases from the lung cancer.

(2) As we enter each new market, our commercial activities focus initially on establishing the required in-market infrastructure, certifying physicians to prescribe Optune and obtaining a defined reimbursement pathway. Once established, our commercial efforts turn to increasing adoption.

(3) An “active patient” is a patient who is on TTFields therapy 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.

We view our operations and manage our business in one operating segment. For the three month period ended March 31, 2016, our net revenues were $13.1 million and our net losses were $35.4 million. Our net loss for the three month period ended March 31, 2016 includes $5.5 million in non-cash share-based compensation expense. As of March 31, 2016, we had an accumulated deficit of $423.5 million.

Three months ended March 31, 2016 compared to three months ended March 31, 2015

	Three Months Ended March 31,				
	2016	2015	Change	% Change	
Net revenues	$13,053	$5,208	$7,845	151	%

Net revenues. Substantially all of our revenues are derived from patients using our TTFields delivery system, marketed as Optune in our currently active markets. We charge patients or their third-party healthcare payers directly on a monthly basis and bear the financial risk of securing payment in the United States and Europe.

We account for revenue when cash is collected and other revenue recognition criteria have been met as we have not yet built up sufficient history with each individual third-party payer to reliably estimate their individual payment patterns. As a result, revenue in

the reported periods is a mixture of amounts collected from patients using Optune in the period and amounts collected for use of Optune in prior periods.

Net revenues increased by $7.8 million, or 151%, to $13.1 million for the three months ended March 31, 2016 from $5.2 million for the three months ended March 31, 2015. The increase was primarily due to an increase of $7.0 million in commercial sales of Optune in the United States, driven by an increase in Optune adoption as well as to an increase of $0.8 million in commercial sales of Optune in our other currently active markets, also driven by an increase in Optune adoption .

Cost of revenues. Our cost of revenues is comprised primarily of (i) cost of the disposable transducer arrays purchased from third-party manufacturers, (ii) depreciation expense for field equipment, including the electric field generator used by patients and (iii) personnel, warranty and overhead costs such as facilities, freight and depreciation of property, plant and equipment associated with managing our inventory, warehousing and order fulfillment functions. Our cost of revenues increased by $4.1 million, or 105%, to $8.0 million for the three months ended March 31, 2016 from $3.9 million for the three months ended March 31, 2015. The change was due to an increase in Optune adoption, resulting in a $2.2 million increase in the cost of transducer array shipments and a $1.2 million increase in personnel costs to establish the infrastructure necessary to support an increasing volume of shipments.

Operating Expenses. Our operating expenses consist of research, development and clinical trials, sales and marketing and general and administrative expenses. Personnel costs are a significant component for each category of operating expenses and consist of wages, benefits and bonuses. Personnel costs also include share-based compensation.

	Three Months Ended March 31,				
	2016	2015	Change	% Change	
Research, development and clinical trials	$11,445	$9,927	$1,518	15	%
Sales and marketing	13,308	6,355	6,953	109	%
General and administrative	12,256	6,975	5,281	76	%
	$37,009	$23,257	$13,752		
Non-cash expenses:					
Share-based compensation expense	$5,315	$1,799	$3,516	195	%
Other non-cash expenses	606	179	427	239	%
Total non-cash expenses	$5,921	$1,978	$3,943	199	%
Total operating expenses, net of non-cash expenses	$31,088	$21,279	$9,809	46	%

Research, development and clinical trials expenses. Research, development and clinical trials expenses increased by $1.5 million, or 15%, to $11.4 million for the three months ended March 31, 2016 from $9.9 million for the three months ended March 31, 2015. The change was primarily due to an increase of $1.6 million in personnel costs (including an increase of $0.4 million in share-based compensation), and an increase of $0.4 million in general expenses primarily related to clinical education and investigator-sponsored trials, partially offset by a decrease of $0.4 million in expenses related to the development of our second generation Optune system.

Sales and marketing expenses. Sales and marketing expenses increased by $6.9 million, or 109%, to $13.3 million for the three months ended March 31, 2016 from $6.4 million for the three months ended March 31, 2015. The change was primarily due to an increase of $4.0 million in personnel costs (including an increase of $0.9 million in share-based compensation) and an increase of $2.8 million in marketing expenses, reflecting our increased commercial operations in the United States and Germany and our ongoing efforts to establish commercial operations in Switzerland and Japan.

General and administrative expenses. General and administrative expenses increased by $5.3 million, or 76%, to $12.3 million for the three months ended March 31, 2016 from $7.0 million for the three months ended March 31, 2015. The change was primarily due to an increase of $3.8 million in personnel costs (including an increase of $2.3 million in share-based compensation), and an increase of $0.8 million in professional services to support our enterprise resource planning system implementation and public company-related activities.

Financial expenses, net. Financial expenses, net primarily consists of interest expense and related debt issuance costs under our Loan and Security Agreement dated as of January 7, 2015, between us, as borrower, and Biopharma Secured Investments III Holdings Cayman LP, as lender (the "Term Loan Credit Facility"), interest income from cash balances and short-term investments and gains (losses) from foreign currency transactions.

	Three Months Ended March 31,			
	2016	2015	Change	% Change
Income tax expenses	$2,950	$736	$2,214	301 %

Income taxes. Income taxes increased by $2.2 million to $2.9 million for the three months ended March 31, 2016. The change was primarily attributable to an increase in the statutory tax provisions for Switzerland and the United States as well as an increase in our provision for uncertain tax positions.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have financed our operations primarily through the issuance and sale of equity and the proceeds from long-term loans. As of March 31, 2016, we had received a total of $614.0 million from these activities. As of March 31, 2016, we had an accumulated deficit of $423.5 million since inception.

Our net losses were $35.4 million for the three months ended March 31, 2016 and $111.6 million for the year ended December 31, 2015. Our net losses primarily resulted from costs incurred in connection with our pre-clinical and clinical trial programs, costs incurred in our commercial launch efforts, and general and administrative costs necessary to operate as a multi-national oncology business.

As of March 31, 2016, we had $115.9 million of cash and cash equivalents, and $119.8 million of short-term investments. We believe our cash and cash equivalents and short term investments as of March 31, 2016, as well as the $75 million available to be drawn under our Term Loan Credit Facility through June 30, 2016, are sufficient for our operations for at least the next 12 months based on our existing business plan and our ability to control the timing of significant expense commitments. We expect that our research, development and clinical trials expenses, sales and marketing expenses and general and administrative expenses will continue to increase over the next several years. As a result, we may need to raise additional capital in the future to fund our operations.

	Three Months Ended

	March 31, 2016	2015
	(in thousands)	
Net cash used in operating activities	$(30,977)	$(28,466)
Net cash provided by investing activities	27,445	21,283
Net cash provided by financing activities	41	23,788
Net increase in cash and cash equivalents	(3,491)	16,605
Changes in short-term investments (included in investing activities)	(30,272)	(23,003)
Net increase in cash, cash equivalents and short-term investments	$(33,763)	$(6,398)

Operating activities

Net cash used in operating activities primarily represents our net loss for the periods presented. Adjustments to net loss for non-cash items include depreciation, share-based compensation and accrued interest. Operating cash flows are also impacted by changes in operating assets and liabilities, principally inventories, prepaid expenses, trade payables and accrued expenses.

Net cash used in operating activities was $31.0 million for the three months ended March 31, 2016, as compared to $28.5 million for the three months ended March 31, 2015, reflecting a net loss of $35.4 million and a change of $2.7 million in our net operating assets and liabilities, partially offset by non-cash charges of $7.2 million.

The change in our net operating assets and liabilities was primarily the result of an increase in our inventories of $2.9 million necessary to meet anticipated demand and an increase in trade payables of $1.8 million, partially offset by decrease in other payables

of $1.6 million and other receivables of $0.5 million. Non-cash charges included $5.5 million of share-based compensation, $1.1 million of depreciation and $0.6 million of accrued interest related to our Term Loan Credit Facility.

Investing activities

Our investing activities consist primarily of capital expenditures to purchase property and equipment and field equipment, as well as investments in and redemptions of our short-term investments.

Net cash provided by investing activities was $27.4 million in the three months ended March 31, 2016 attributable to our receipt of $150.0 million from the maturity of short-term investments, partially offset by the purchase of new short-term investments of $119.7 million, purchases of $1.0 million of property and equipment and purchases of $1.8 million of field equipment. Net cash used in investing activities for the same period in 2015 was $21.2 million, attributable to the receipt of $45.0 million from the maturity of short-term investments, partially offset by the purchase of $22.0 million of short-term investments, purchases of property and equipment of $0.6 million and purchases of field equipment of $1.0 million and an increase in restricted cash of $0.1 million.

Financing activities

To date, our primary financing activities have been the sale of equity and the proceeds from long-term loans.

Net cash provided by financing activities was de minimis for the three months ended March 31, 2016. Net cash provided by financing activities was $23.8 million in the same period of 2015, attributable to a draw under our Term Loan Credit Facility.

Our material outstanding indebtedness consists of our Term Loan Credit Facility, which provides for up to $100.0 million of borrowings in up to four draws, the first of which was made on January 30, 2015 in the amount of $25.0 million of principal resulting in $23.8 million of proceeds net of discount and issuance costs, net. Interest on the outstanding loan is 10% annually, payable quarterly in arrears. As of March 31, 2016, the aggregate principal balance of amounts outstanding under the Term Loan Credit Facility was approximately $25.0 million. Our ability to access the remaining $75.0 million under the Term Loan Credit Facility expires on June 30, 2016. We may prepay the term loans, in whole, at any time, and must prepay in the event of a change of control, in each case, subject to a pay-down fee, prepayment premium and/or make-whole payment. The funding fee payable on the amount drawn on the funding date is 1.5%, the placement fee payable on the amount drawn on the funding date is 1.25%, the pay-down fee on all principal payments to be paid on the date such payments are made is 0.75% and the pre-payment fee if we prepay outstanding loan amounts prior to the first, second or third year from the initial funding date is 3.0%, 2.0% or 1.0%, respectively.

All obligations under the Term Loan Credit Facility are guaranteed by certain of our current and future domestic direct and indirect subsidiaries. In addition, the obligations under the Term Loan Credit Facility are secured by a first-priority security interest in substantially all of the property and assets of, as well as the equity interests owned by, us and the other guarantors.

The Term Loan Credit Facility has a minimum liquidity covenant, which is tested quarterly. In addition, we must meet certain pro forma net sales requirements. The Term Loan Credit Facility contains other customary covenants.

Contractual Obligations and Commitments

There were no material changes in our commitments under contractual obligations during the three months ended March 31, 2016.

The total amount of unrecognized tax benefits for uncertain tax positions was $2.0 million and $1.6 million at March 31, 2016 and December 31, 2015, respectively. Payment of these obligations would result from settlements with taxing authorities. We do not expect a significant tax payment related to these obligations within the next year.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under SEC rules.

JOBS Act Election

The Jumpstart our Business Startups Act of 2012, or the JOBS Act, permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We

have irrevocably elected to "opt out" of the exemption for the delayed adoption of certain accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have been no material changes to the Company's quantitative and qualitative disclosures about market risk from the disclosure provided in the Company's 2015 Form 10-K.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2016. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2016, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2016, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended March 31, 2016, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

As of the filing date of this Quarterly Report on Form 10-Q, there were no material legal proceedings.

Item 1A. Risk Factors

There have been no material changes to the Company's risk factors from those disclosed in the Company's 2015 Form 10-K.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

In January 2016, warrants for a total of 975,644 ordinary shares with an exercise price of $18.09 per share were cashlessly exercised, resulting in the issuance of 315,155 ordinary shares. In January 2016, an employee exercised options to purchase 332,984 ordinary shares at a price per share of $0.17. We believe that each of these instances was exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), in reliance on Regulation S under the Securities Act, under Section 4(a)(2) of the Securities Act regarding transactions not involving a public offering and under Rule 701 promulgated under the Securities Act.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On May 4, 2016, our Board of Directors appointed William A. Vernon to serve as Lead Independent Director.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
10.1	Employment Agreement with Michael Ambrogi and the Company, dated December 30, 2010 #				X
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
32.1*	Certification of Principal Executive Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350				X
32.2*	Certification of Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350				X
101.INS	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	XBRL Extension Presentation Linkbase Document				X

* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of NovoCure Limited under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

Compensation plans and arrangements for executive officers and others

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 thereunto duly authorized.

NovoCure Limited

Date: May 10, 2016 /s/ Wilco Groenhuysen
Wilco Groenhuysen
Chief Financial Officer
(principal financial and accounting officer

and duly authorized officer)