

NovoCure Ltd
Form 10-Q
October 25, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2018

or

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

No. 4 The Forum

Grenville Street

St. Helier, Jersey JE2 4UF

(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 No .

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes No .

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	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.

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

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

Class	Outstanding as of October 18, 2018
Ordinary shares, no par value	93,013,564 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 delivery system, and our other Tumor Treating Fields 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 Tumor Treating Fields delivery systems by patients, physicians, third-party payers and others in the healthcare and scientific community;
- our plans to pursue the use of Tumor Treating Fields for the treatment of solid tumor cancers other than glioblastoma (“GBM”);
- our estimates regarding revenues, expenses, capital requirements and needs for additional financing;
- our ability to obtain regulatory approvals for the use of Tumor Treating Fields in cancers other than GBM and any future delivery systems;
- our ability to acquire the supplies needed to manufacture our 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 our delivery systems;
- our ability to receive reimbursement from third-party payers for use of our delivery systems;
- our ability to maintain and develop our intellectual property position;
- the impact of acts of terrorism, cybersecurity attacks or intrusions;
- our cash needs;
- our ongoing legal proceedings and tax audits; 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, 2017, 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.

NovoCure Limited

Quarterly Report on Form 10-Q

TABLE OF CONTENTS

	Page
<u>Cautionary Note</u>	
<u>Regarding Forward</u>	
<u>Looking Statements</u>	ii
<u>Trademarks</u>	ii
<u>PART I—FINANCIAL</u>	
<u>INFORMATION</u>	
Item 1. <u>Financial</u>	
<u>Statements</u>	2
Item 2. <u>Management’s</u>	
<u>Discussion</u>	
<u>and Analysis</u>	
<u>of Financial</u>	
<u>Condition and</u>	
<u>Results of</u>	
<u>Operations</u>	13
Item 3. <u>Quantitative</u>	
<u>and</u>	
<u>Qualitative</u>	
<u>Disclosures</u>	
<u>About Market</u>	
<u>Risk</u>	21
Item 4. <u>Controls and</u>	
<u>Procedures</u>	22
<u>PART II—OTHER</u>	
<u>INFORMATION</u>	
Item 1. <u>Legal</u>	
<u>Proceedings</u>	23
Item 1A. <u>Risk Factors</u>	23
Item 2. <u>Unregistered</u>	
<u>Sales of</u>	
<u>Equity</u>	
<u>Securities and</u>	
<u>Use of</u>	
<u>Proceeds</u>	23
Item 3. <u>Defaults</u>	23
<u>Upon Senior</u>	

	<u>Securities</u>	
Item 4.	<u>Mine Safety</u>	
	<u>Disclosures</u>	23
Item 5.	<u>Other</u>	
	<u>Information</u>	23
Item 6.	<u>Exhibits</u>	24
	<u>Signatures</u>	25

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

NOVOCURE LIMITED AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	September 30, 2018 Unaudited	December 31, 2017 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 122,959	\$ 78,592
Short-term investments	104,743	104,719
Restricted cash	2,199	2,126
Trade receivables	35,388	29,567
Receivables and prepaid expenses	9,895	8,105
Inventories	21,641	22,025
Total current assets	296,825	245,134
LONG-TERM ASSETS:		
Property and equipment, net	8,564	9,031
Field equipment, net	7,300	9,036
Severance pay fund	114	111
Other long-term assets	2,709	1,986
Total long-term assets	18,687	20,164
TOTAL ASSETS	\$ 315,512	\$ 265,298

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

NOVOCURE LIMITED AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

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

	September 30, 2018 Unaudited	December 31, 2017 Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 20,053	\$ 17,206
Other payables and accrued expenses	28,034	32,996
Total current liabilities	48,087	50,202
LONG-TERM LIABILITIES:		
Long-term loan, net of discount and issuance costs	149,231	97,342
Employee benefit liabilities	2,347	2,453
Other long-term liabilities	911	1,737
Total long-term liabilities	152,489	101,532
TOTAL LIABILITIES	200,576	151,734
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares no par value, unlimited shares authorized; issued and outstanding:		
93,007,844 shares and 89,478,032 shares at September 30, 2018 (unaudited) and		
December 31, 2017, respectively	-	-
Additional paid-in capital	744,087	697,165
Accumulated other comprehensive income (loss)	(1,127)	(1,343)
Retained earnings (accumulated deficit)	(628,024)	(582,258)
Total shareholders' equity	114,936	113,564
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 315,512	\$ 265,298

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

NOVOCURE LIMITED AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three months ended		Nine months ended		Year ended
	September 30,	September 30,	September 30,	September 30,	December 31,
	2018	2017	2018	2017	2017
	Unaudited		Unaudited		Audited
Net revenues	\$64,756	\$50,109	\$178,395	\$123,365	\$177,026
Cost of revenues	18,949	15,153	57,020	39,969	55,609
Gross profit	45,807	34,956	121,375	83,396	121,417
Operating costs and expenses:					
Research, development and clinical trials	13,074	9,273	35,540	28,055	38,103
Sales and marketing	19,124	16,387	56,455	47,503	63,528
General and administrative	18,855	15,215	54,388	42,660	59,114
Total operating costs and expenses	51,053	40,875	146,383	118,218	160,745
Operating income (loss)	(5,246)	(5,919)	(25,008)	(34,822)	(39,328)
Financial expenses (income), net	2,397	2,156	10,110	6,785	9,169
Income (loss) before income taxes	(7,643)	(8,075)	(35,118)	(41,607)	(48,497)
Income taxes	4,051	3,423	12,810	9,110	13,165
Net income (loss)	\$(11,694)	\$(11,498)	\$(47,928)	\$(50,717)	\$(61,662)
Basic and diluted net income (loss) per ordinary share	\$(0.13)	\$(0.13)	\$(0.52)	\$(0.57)	\$(0.70)
Weighted average number of ordinary shares used in					
computing basic and diluted net income (loss) per share	92,911,375	89,125,646	91,409,619	88,265,835	88,546,719

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

U.S. dollars in thousands

	Three months ended		Nine months ended		Year ended
	September 30,	September 30,	September 30,	September 30,	December 31,
	2018	2017	2018	2017	2017
	Unaudited	Unaudited	Unaudited	Unaudited	Audited
Net income (loss)	\$(11,694)	\$(11,498)	\$(47,928)	\$(50,717)	\$(61,662)
Other comprehensive income (loss), net of tax:					
Change in foreign currency translation adjustments	(2)	(2)	19	8	8
Pension benefit plan	147	279	197	413	532
Total comprehensive income (loss)	\$(11,549)	\$(11,221)	\$(47,712)	\$(50,296)	\$(61,122)

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

NOVOCURE LIMITED AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

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

	Ordinary shares Shares	Additional paid-in capital	Accumulated		Total shareholders' equity
			other comprehensive loss	Retained earnings (accumulated deficit)	
Balance as of December 31, 2017 (audited)	89,478,032	\$ 697,165	\$ (1,343)	\$ (582,258)	\$ 113,564
Proceeds from issuance of shares	54,386	938	-	-	938
Share-based compensation to employees	-	29,205	-	-	29,205
Exercise of options and warrants and vested RSUs	3,475,426	16,779	-	-	16,779
Cumulative effect adjustment on retained earnings (*)	-	-	-	2,162	2,162
Other comprehensive income (loss), net of tax benefit of \$21	-	-	216	-	216
Net income (loss)	-	-	-	(47,928)	(47,928)
Balance as of September 30, 2018 (Unaudited)	93,007,844	\$ 744,087	\$ (1,127)	\$ (628,024)	\$ 114,936

(*) Resulting from the adoption of ASC 606.

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

NOVOCURE LIMITED AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Three months ended		Nine months ended		Year ended
	September 30,	September 30,	September 30,	September 30,	December 31,
	2018	2017	2018	2017	2017
	Unaudited		Unaudited		Audited
Cash flows from operating activities:					
Net income (loss)	\$(11,694)	\$(11,498)	\$(47,928)	\$(50,717)	\$(61,662)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:					
Depreciation and amortization	2,311	2,053	6,801	5,524	7,677
Asset write-downs and impairment of field equipment	178	72	320	206	241
Share-based compensation to employees	10,479	8,629	29,205	20,760	27,116
Decrease (increase) in trade receivables	2,255	(9,112)	(3,016)	(16,661)	(23,228)
Amortization of discount (premium)	(555)	17	1,502	226	252
Decrease (increase) in receivables and prepaid expenses	1,322	5,986	(1,789)	4,525	1,979
Decrease (increase) in inventories	(1,735)	504	385	907	3,524
Decrease (increase) in other long-term assets	155	(238)	(743)	(532)	(554)
Increase (decrease) in trade payables	(381)	983	2,848	(4,213)	(1,150)
Increase (decrease) in other payables and accrued expenses	3,220	4,830	(5,608)	8,308	14,460
Increase (decrease) in employee benefit liabilities, net	31	113	108	352	440
Increase (decrease) in other long-term liabilities	52	208	(764)	1,079	(2,229)
Net cash provided by (used in) operating activities	\$5,638	\$2,547	\$(18,679)	\$(30,236)	\$(33,134)
Cash flows from investing activities:					
Purchase of property and equipment	\$(573)	\$(544)	\$(2,164)	\$(1,951)	\$(2,459)
Purchase of field equipment	(780)	(1,208)	(2,754)	(3,469)	(4,907)
Proceeds from maturity of short-term investments	45,000	-	150,000	120,000	120,000
Purchase of short-term investments	(44,652)	-	(148,786)	(104,006)	(104,006)
Net cash provided by (used in) investing activities	\$(1,005)	\$(1,752)	\$(3,704)	\$10,574	\$8,628
Cash flows from financing activities:					
Proceeds from issuance of shares, net	\$-	\$-	\$938	\$781	\$1,540
Proceeds from long-term loan, net	-	-	149,150	-	-
Proceeds from other long-term loans	-	-	-	19	19
Repayment of long-term loan	-	-	(100,000)	-	-
Repayment of other long-term loan	(22)	(19)	(63)	(56)	(76)
Exercise of options and warrants	3,924	1,732	16,779	3,095	3,685
Net cash provided by (used in) financing activities	\$3,902	\$1,713	\$66,804	\$3,839	\$5,168

Effect of exchange rate changes on cash and cash equivalents	\$(2)	\$(2)	\$19	\$8	\$8
Increase (decrease) in cash, cash equivalents and restricted cash	8,533	2,506	44,440	(15,815)	(19,330)
Cash, cash equivalents and restricted cash at beginning of period	116,625	81,727	80,718	100,048	100,048
Cash, cash equivalents and restricted cash at the end of the period	\$125,158	\$84,233	\$125,158	\$84,233	\$80,718
Supplemental cash flow activities:					
Cash paid during the period for:					
Income taxes	\$4,145	\$2,335	\$16,159	\$7,237	\$10,286
Interest	\$3,454	\$2,561	\$9,879	\$7,603	\$10,162

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

NOVOCURE LIMITED AND SUBSIDIARIES

NOTES TO UNAUDITED 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 the Bailiwick of Jersey and is principally engaged in the development, manufacture and commercialization of Tumor Treating Fields for the treatment of solid tumors. The Company has regulatory approvals and clearances in certain countries for Optune, its first Tumor Treating Fields delivery system, to treat adult patients with glioblastoma (“GBM”).

Financial statement preparation. The accompanying consolidated financial statements include the accounts of the Company and intercompany accounts and transactions have been eliminated. In the opinion of the Company’s management, the consolidated financial statements reflect all adjustments, which are normal and recurring in nature, necessary for fair financial statement presentation for the periods presented. The preparation of these 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 consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. These 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, 2017 (the “2017 10-K”) filed with the Securities and Exchange Commission (the “SEC”) on February 22, 2018.

The significant accounting policies applied in the audited annual consolidated financial statements of the Company as disclosed in the 2017 10-K are applied consistently in these unaudited interim consolidated financial statements, except as noted below:

Recently Adopted Accounting Pronouncements. In May 2014, FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606) (ASU 2014-09), an updated standard on revenue recognition and issued subsequent amendments to the initial guidance in March 2016, April 2016, May 2016 and December 2016 within ASU 2016-08, 2016-10, 2016-12 and 2016-20, respectively (collectively, “ASC 606”). The core principle of the new standard is for companies to recognize revenue to depict the transfer of goods and services to patients in amounts that reflect the consideration to which the company expects to be entitled in exchange for those goods and services. In addition, the new standard requires expanded disclosures. The Company has adopted the standard effective January 1, 2018 using the modified retrospective method for all contracts. The reported results for 2018 reflect the application of ASC 606 guidance while the reported results for 2017 were prepared under the guidance of ASC 605, Revenue Recognition (ASC 605). The amount of revenue recognized in 2018 reflects the consideration to which the Company expects to be entitled to receive in exchange for Optune.

In preparation for adoption of the standard, the Company has implemented internal controls and key system functionality to enable the preparation of financial information, including the assessment of the impact of the standard. The Company uses the portfolio approach to apply the standard to portfolios of contracts with similar characteristics. Adoption of the standard resulted in an increase to trade receivables of \$2,807, deferred revenues of \$645 and a cumulative impact to the Company's accumulated deficit as of January 1, 2018 of \$2,162.

Optune is comprised of two main components: (1) an electric field generator and (2) transducer arrays and related accessories. We retain title to the electric field generator, and the patient is provided replacement transducer arrays and technical support for the device during the term of treatment. The electric field generator and transducer arrays are always supplied and function together and are not sold on a standalone basis.

To recognize revenue under ASC 606, the Company applies the following five steps:

1. Identify the contract with a patient. A contract with a patient exists when (i) the Company enters into an enforceable contract with a patient that defines each party's rights regarding delivery of and payment for Optune, (ii) the contract has commercial substance and (iii) the Company determines that collection of substantially all consideration for Optune is probable based on the payer's intent and ability to pay the promised consideration. The evidence of a contract generally consists of a prescription, a patient service agreement and the verification of the assigned payer for the contract and intention to collect.

2. Identify the performance obligations in the contract. Optune contracts include the lease of the device, the supply obligation of disposable transducer arrays and technical support for the term of treatment. To the extent a contract includes multiple promised products and/or services, the Company must apply judgment to determine whether those products and/or services are capable of being distinct in the context of the contract. If these criteria are not met the promised products and/or services are accounted for as

a combined performance obligation. In the Company's case, Optune's device, support, and disposables are provided as one inseparable package of monthly treatment for a single monthly fee.

3. Determine the transaction price. The transaction price is determined based on the consideration to which the Company will be entitled in exchange for providing Optune to the patient. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing either the expected value method or the most likely amount method depending on the nature of the variable consideration. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. The Company has agreements with many payers that define explicit discounts off the gross transaction price. In addition to the explicit discounts negotiated with each payer, the Company expects to receive, in aggregate for a given portfolio, less than the gross revenue net of explicit discounts. ASC 606 requires that the Company recognize this variable consideration as an implicit discount in the billing period. The implicit discount includes both an estimate of claims that will pay at an amount less than billed and an estimate of claims that will not pay within a given time horizon. The implicit discount adjustments to the transaction price are due to concessions, not collectability concerns driven by payer credit risk.

4. Allocate the transaction price to performance obligations in the contract. If a contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. As discussed above, there is one performance obligation under the Company's contracts and, therefore, the monthly transaction price determined for the performance obligation will be recognized over time ratably over the monthly term of the treatment.

5. Recognize revenue when or as the Company satisfies a performance obligation. The Company satisfies performance obligations over time as discussed above. Revenue is recognized at the time the related performance obligation is satisfied by transferring a promised service to a patient. The patient consumes the benefits of Optune treatment on a daily basis over the monthly term. As this criterion is met, the revenues will be recognized over the monthly term.

The impact of our adoption of ASC 606 on our condensed consolidated statements of income for the three and nine months ended September 30, 2018 was as follows: net revenue increased by \$901 and decreased by \$4,629, respectively; net loss decreased by \$827 and increased by \$4,543, respectively; and our basic and diluted net loss per ordinary share increased by \$0.01 and decreased by \$0.05, respectively. The impact of our adoption of Topic 606 on our balance sheet as of September 30, 2018 was a decrease in trade receivables of \$2,223, an increase to other payables and accrued expenses (deferred revenues net of tax provision) of \$960 and an accumulated deficit as of September 30, 2018 of \$2,381.

In August 2016, FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments. ASU 2016-15 eliminates the diversity in practice related to the classification of certain cash receipts and payments for debt prepayment or extinguishment costs, the maturing of a zero coupon bond, the settlement of contingent liabilities arising from a business combination, proceeds from insurance settlements, distributions from certain equity method investees and beneficial interests obtained in a financial asset securitization. ASU 2016-15 designates the appropriate cash flow classification, including requirements to allocate certain components of these cash receipts and payments among operating, investing and financing activities. The retrospective transition method, requiring adjustment to all comparative periods presented, is required unless it is impracticable for some of the amendments, in which case those amendments would be prospectively as of the earliest date practicable. The Company adopted the standard effective as of January 1, 2018, and the adoption of this standard did not have an impact on the Company's consolidated financial statements.

In November 2016, FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash. This standard requires the presentation of the statement of cash flows to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents. The standard is effective for fiscal years and the interim periods within those fiscal years beginning after December 15, 2017. The Company adopted the standard retrospectively to all periods presented effective as of January 1, 2018.

Recent Accounting Pronouncements. In February 2016, FASB issued 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 currently anticipates adopting the new standard effective

January 1, 2019 and is evaluating the impact of the adoption of this standard on its consolidated financial statements. The provisions of ASU 2016-02 are to be applied using a modified retrospective approach.

In July 2018, the FASB issued ASU No. 2018-11, "Targeted Improvements - Leases (Topic 842)." This update provides an optional transition method that allows entities to elect to apply the standard prospectively at its effective date, versus recasting the prior periods presented. If elected, an entity would recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company is evaluating the impact of the adoption of this standard on its consolidated financial statements.

In June 2016, FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. ASU 2016-13 amends the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology, which will result in the more timely recognition of losses. ASU 2016-13 also applies to employee benefit plan accounting, with an effective date of the first quarter of fiscal 2020. The amendments in this update are effective for fiscal years beginning after December 31, 2019, including interim periods within those fiscal years. The Company is currently assessing the impact of the adoption of this standard on its consolidated financial statements, footnote disclosures and employee benefit plans' accounting.

In June 2018, FASB issued ASU 2018-07 to expand the scope of ASC Topic 718, Compensation - Stock Compensation, to include share-based payment transactions for acquiring goods and services from nonemployees. The pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018, with early adoption permitted. The Company is evaluating the effects 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 \$104,743 and \$104,719 as of September 30, 2018 and December 31, 2017, respectively, and their estimated fair value as of September 30, 2018 and December 31, 2017 was \$104,674 and \$104,655, 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 September 30, 2018 and December 31, 2017, the Company's inventories were composed of:

	September 30, 2018 Unaudited	December 31, 2017 Audited
Raw materials	\$ 2,049	\$ 4,276
Work in progress	6,507	8,435
Finished products	13,085	9,314
Total	\$ 21,641	\$ 22,025

NOTE 4: COMMITMENTS AND CONTINGENT LIABILITIES

The facilities of the Company are leased under various operating lease agreements for periods ending no later than 2024. The Company also leases motor vehicles under various operating leases, which expire on various dates, the latest of which is in 2021.

As of September 30, 2018 and December 31, 2017, the Company pledged bank deposits of \$1,147 and \$1,038, respectively, to cover bank guarantees in respect of its leases of operating facilities and obtained bank guarantees for the fulfillment of the Company's lease and other contractual commitments of \$1,307 and \$1,202, respectively.

In the first quarter of 2018, the Company made a milestone payment of \$5.5 million (the "Milestone Payment") to the Technion Research and Development Foundation ("Technion") pursuant to the settlement agreement dated February 10, 2015 (the "Settlement Agreement"). Pursuant to the Settlement Agreement, and in exchange for a release of potential disputes regarding intellectual property developed by our founder and previously assigned to us, the Company was obligated to pay the Milestone Payment to Technion in the quarter following the quarter in which the Company achieved \$250.0 million of cumulative net sales (as defined in the Settlement Agreement) (the "Net Sales Milestone"). The Company achieved the Net Sales Milestone in the fourth quarter of 2017.

- 9 -

NOTE 5: LONG TERM LOAN

On February 7, 2018, the Company and certain of its subsidiaries entered into a Loan and Security Agreement (“2018 Loan Agreement”) with BioPharma Credit PLC pursuant to which such lender made a term loan to the Company in the principal amount of \$150 million (the “2018 Credit Facility”). The term loan, which was drawn in full upon execution of the 2018 Loan Agreement, bears interest at 9.0% per annum, payable quarterly in arrears. The Company used a portion of the proceeds of the 2018 Credit Facility to repay in full the Company’s obligations under its then-existing term loan credit facility and is using the remaining proceeds to fund general corporate purposes.

The 2018 Credit Facility will mature on February 7, 2023, at which time any unpaid principal and accrued unpaid interest in respect of the term loan will be due and payable. The Company may prepay the term loan, in full, at any time. The Company must prepay the term loan (i) in full or in part upon the entry into certain licensing arrangements and (ii) in full in the event of a change of control. In each case, any prepayment (whether permitted or mandatory) is subject to a prepayment premium and/or make-whole payment. The pre-payment fee if the Company prepays outstanding loan amounts prior to February 7, 2021 is 2.0% and is 1.0% if made after the February 7, 2021 but prior to February 7, 2022.

All obligations under the 2018 Credit Facility are guaranteed by the Company’s current and future direct and indirect subsidiaries. In addition, the obligations under the 2018 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, the Company and certain of the other guarantors. The 2018 Credit Facility contains other customary covenants.

Total net issuance costs of the 2018 Credit Facility, which were \$768 as of September 30, 2018, are presented net of the 2018 Credit Facility proceeds and are amortized to interest expense over the five year term of the loan using the effective interest method.

On February 7, 2018, the Company’s 2015 term loan credit facility was terminated upon the Company’s repayment in full of the term loan issued thereunder. The un-amortized discount in the amount of \$1,160 and issuance costs in the amount of \$1,399 were fully amortized and included in the Company’s first quarter finance expenses.

NOTE 6: SHARE CAPITAL

For the nine months ended September 30, 2018, warrants to purchase 504,225 ordinary shares with an exercise price of \$3.59 per share were cashlessly exercised, resulting in the issuance of 437,081 ordinary shares. Also, warrants to purchase 3,879 ordinary shares with an exercise price of \$3.59 per share were exercised for cash. For the nine months ended September 30, 2018, options to purchase 2,486,026 ordinary shares were exercised, resulting in the issuance of 2,484,048 ordinary shares.

NOTE 7: EQUITY INCENTIVE PLANS

In September 2015, the Company adopted the 2015 Omnibus Incentive Plan (the “2015 Plan”). Under the 2015 Plan, the Company can issue various types of equity compensation awards such as share options, restricted shares, performance shares, restricted stock units (“RSUs”), performance units, long-term cash awards and other share-based

awards.

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 grants. RSUs granted under the 2015 Plan vest in equal installments over a three-year period. As of September 30, 2018, 10,207,157 ordinary shares were available for grant under the 2015 Plan.

- 10 -

A summary of the status of the Company's option plans as of September 30, 2018 and changes during the period then ended is presented below:

	Nine months ended September 30, 2018 Unaudited	
	Weighted average	
	Number	exercise price
	of options	price
Outstanding at beginning of year	14,806,027	\$ 10.64
Granted	2,424,058	23.40
Exercised	(2,486,026)	6.77
Forfeited and cancelled	(178,093)	14.68
Outstanding as of September 30, 2018	14,565,966	\$ 13.37
Exercisable options	5,885,994	\$ 10.42

A summary of the status of the Company's RSUs as of September 30, 2018 and changes during the period then ended is presented below:

	Nine months ended September 30, 2018 Unaudited	
	Weighted average	
	Number	grant date fair value
	of RSUs	price
Unvested at beginning of year	1,651,219	\$ 9.66
Granted	521,305	23.08
Vested	(550,418)	9.66
Forfeited and cancelled	(15,220)	15.28
Unvested as of September 30, 2018	1,606,886	\$ 13.96

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 began its offerings under the ESPP on August 1, 2016. As of September 30, 2018, 2,223,319 ordinary shares were available to be purchased by eligible employees under the ESPP and 314,207 shares had been issued under the ESPP.

The fair value of share-based awards was estimated using the Black-Scholes model for all equity grants. For market condition awards, the Company also applied the Monte-Carlo simulation model, with the following underlying assumptions:

	Nine months ended		Year ended
	September 30, 2018	2017	December 31, 2017
	Unaudited		Audited
Stock Option Plans			
Expected term (years)	5.50-6.25	5.50-6.25	5.50-6.25
Expected volatility	52%-55%	57%-59%	57%-59%
Risk-free interest rate	2.70%-2.89%	1.97%-2.23%	1.97%-2.23%
Dividend yield	0.00%	0.00%	0.00%
ESPP			
Expected term (years)	0.50	0.50	0.50
Expected volatility	45%-53%	76%-82%	76%-82%
Risk-free interest rate	1.61%-2.14%	0.62%-1.13%	0.62%-1.13%
Dividend yield	0.00%	0.00%	0.00%

The total non-cash share-based compensation expense related to all of the Company's equity-based awards recognized for the three and nine months ended September 30, 2018 and 2017 and the year ended December 31, 2017 was:

	Three months ended September 30, 2018		Nine months ended September 30, 2018		Year ended December 31, 2017
	Unaudited		Unaudited		Audited
Cost of revenues	\$464	\$79	\$891	\$353	\$467
Research, development and clinical trials	1,223	972	3,415	2,645	3,587
Sales and marketing	1,979	1,874	5,309	4,264	3,784
General and administrative	6,813	5,704	19,590	13,498	19,278
Total share-based compensation expense	\$10,479	\$8,629	\$29,205	\$20,760	\$27,116

NOTE 8: SUPPLEMENTAL INFORMATION

The Company operates in a single reportable segment.

The following table presents long-lived assets by location:

	September 30, 2018	December 31, 2017
	Unaudited	Audited
United States	\$9,032	\$10,372
Switzerland	2,411	5,114
Israel	2,352	2,081
Others	2,069	500
Total	\$15,864	\$18,067

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

		Three months ended September 30, 2018		Nine months ended September 30, 2018		Year ended December 31, 2017
		Unaudited		Unaudited		Audited

Edgar Filing: NovoCure Ltd - Form 10-Q

United States	\$44,469	\$35,300	\$124,206	\$95,826	\$134,688
EMEA (*)	18,295	14,757	50,692	27,316	42,035
Japan	1,992	52	3,497	223	303
Total	\$64,756	\$50,109	\$178,395	\$123,365	\$177,026
(*) including Germany	\$17,536	\$14,664	\$48,545	\$26,880	\$40,215

NOTE 9: ZAI LAB LICENSE AGREEMENT

On September 10, 2018, the Company entered into a License and Collaboration Agreement (the “Zai Agreement”) with Zai Lab (Shanghai) Co., Ltd. (“Zai”). Under the Zai Agreement, the Company granted Zai exclusive rights to commercialize Tumor Treating Fields in the field of oncology in China, Hong Kong, Macau and Taiwan (the “Territory”). The Zai Agreement also established a development partnership for Tumor Treating Fields in multiple solid tumor indications. In partial consideration for the license grant to Zai for the Territory, Zai will pay the Company a non-refundable, up-front license fee in the amount of \$15 million, as well as certain development, regulatory and commercial milestone payments up to \$78 million, and tiered royalties at percentage rates from 10 up to the mid-teens on the net sales of the licensed products in the Territory. The Company expects to receive the \$15 million up-front license fee in the fourth quarter 2018.

Zai will purchase licensed products for commercial use exclusively from the Company at the Company’s fully burdened manufacturing cost.

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 and the notes thereto for the period ended September 30, 2018 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, 2017 (the "2017 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 global oncology company developing a proprietary platform technology called Tumor Treating Fields, the use of electric fields tuned to specific frequencies to disrupt solid tumor cancer cell division. Our key priorities are to drive commercial adoption of Optune, our first commercial Tumor Treating Fields delivery system, for the treatment of glioblastoma ("GBM") and to advance programs testing the efficacy and safety of Tumor Treating Fields in multiple solid tumor indications through our clinical pipeline.

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 in 2011 for use as a monotherapy treatment for adult patients with GBM following confirmed recurrence after chemotherapy. 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 have also received approval to market Optune in the European Union ("EU"), Switzerland, Japan and certain other countries. We have built a commercial organization and launched Optune in the United States, Germany, Austria, Switzerland, Israel and Japan, which we refer to as our currently active markets.

In March 2018, the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology® (NCCN Guidelines®) for Central Nervous Systems Cancers were updated to include alternating electric field therapy as a Category 1 treatment for patients with newly diagnosed GBM in conjunction with temozolomide after maximal safe resection and completion of radiation therapy. The updated recommendation follows the publication of Novocure's EF-14 phase 3 pivotal trial five-year survival results in the Journal of the American Medical Association (JAMA) in December 2017. The EF-14 five-year survival results demonstrated Optune plus temozolomide significantly improved survival outcomes in patients with newly diagnosed GBM compared to temozolomide alone. A Category 1 recommendation indicates, based upon high-level evidence, that there is uniform NCCN consensus that the intervention is appropriate.

We continue to work with payers to expand access to Optune for patients with newly diagnosed and recurrent GBM. As of September 30, 2018, we estimate that more than 237 million Americans had coverage of Optune for newly diagnosed and/or recurrent GBM. Additionally, we had signed contracts to establish Optune as an in-network benefit for more than 220 million American lives. The percentage of our U.S. active patient population who are beneficiaries of the Medicare fee-for-service program, which has denied coverage for our claims to date, continues to range from 20 to 25 percent.

In June 2018, we submitted a local coverage determination ("LCD") reconsideration request to the Medicare durable medical equipment ("DME") Medicare Administrative Contractors ("MACs"). Per Centers for Medicare and Medicaid Services ("CMS") and Medicare policy, the two DME MACs will issue a single joint policy applicable in all DME regions. Our decision to file for coverage followed the announcement by CMS that it had developed a methodology

that will recognize current commercial pricing for newly covered DME items and that commercial pricing information will be taken into account when establishing a new fee schedule amount. We believe this methodology reflects the significant progress made during our multi-year dialogue with CMS and will generate a commercially acceptable price for Optune in the U.S. for the Medicare fee-for-service program.

In October 2018, the DME MACs confirmed that they have accepted the LCD reconsideration request for the treatment of newly diagnosed GBM and plan to take steps to publish a final LCD for newly diagnosed GBM. The MACs will not reconsider the LCD for recurrent GBM at this time. The MACs also confirmed that they plan to follow a new process during the LCD reconsideration, which reflects policy changes in response to 21st Century Cures Act requirements and stakeholder comments. Under the new LCD reconsideration process, the DME MACs plan to assemble a contractor advisory committee (“CAC”) prior to publishing a proposed LCD. The proposed LCD will be subject to a 45-day public comment period and, following the CAC and comment period, a final LCD will be published. The LCD will take effect at least 45 calendar days following publication of the final LCD to allow adequate notice to the provider community. The DME MACs have not provided a specific timeline, but have confirmed that they are working diligently on the process for Optune.

In Germany, we are able to bill healthcare payers for individual cases and each case is evaluated individually on its merits and under the payer's specific rules for such cases. In September 2018, the German Federal Joint Committee ("G-BA") announced that it will evaluate Optune for newly diagnosed GBM without the need to develop additional evidence through a clinical trial. This decision starts the regular methods evaluation process for newly diagnosed GBM through IQWiG, the German Institute for Quality and Efficiency in Healthcare. This is an acceleration of our previously anticipated timeline to secure national reimbursement for Optune in Germany through the 137e pathway. We will continue to bill payers for individual cases as we advance through the reimbursement review process in Germany.

We have received national reimbursement for Optune in Japan and Austria, and we are pursuing reimbursement for Optune in Switzerland and Israel.

We have researched the biological effects of Tumor Treating Fields extensively. Tumor Treating Fields uses electric fields tuned to specific frequencies to disrupt cancer cell division, inhibiting tumor growth and causing affected cancer cells to die. Because Tumor Treating Fields is delivered regionally, acts only on dividing cells (a biological process known as mitosis) and is frequency-tuned to target cancer cells of a specific size, we believe there is minimal damage to healthy cells. We believe our pre-clinical and clinical research demonstrates that Tumor Treating Fields' mechanism of action affects fundamental aspects of cell division and may have broad applicability across a variety of solid tumors. We have demonstrated in preclinical studies that Tumor Treating Fields can offer additive or synergistic benefits in combination with other anti-cancer agents, which may lead to greater efficacy without significantly increasing the side effects.

We believe we have a robust global patent and intellectual property portfolio, with numerous patent applications pending worldwide. We believe we will maintain exclusive rights to market Tumor Treating Fields for all solid tumor indications in our key markets through the life of our patents.

In September 2018, we presented the final results of our STELLAR registration trial in mesothelioma. The STELLAR data demonstrated a significant extension in median overall survival among patients treated with Tumor Treating Fields plus standard of care chemotherapy compared to historical control data of patients who received standard of care chemotherapy alone. Malignant pleural mesothelioma patients who received Tumor Treating Fields with pemetrexed and cisplatin or carboplatin experienced median overall survival of 18.2 months (95 percent CI, 12.1-25.8 months) compared to 12.1 months in a historical control. No serious device-related adverse events were reported. In October 2018, we submitted a Humanitarian Device Exemption (HDE) application to the FDA for approval in malignant pleural mesothelioma and we anticipate a 2019 launch in the United States, pending regulatory approval. We cannot be certain what additional studies, if any, the FDA may request to support our HDE application.

Devices approved under an HDE application are subject to certain requirements, including potential profit limitations. We believe that it is likely that the FDA will determine that Tumor Treating Fields for the treatment of malignant pleural mesothelioma meets the eligibility criteria to obtain an exemption from this profit limitation.

We are currently planning or conducting clinical trials evaluating the use of Tumor Treating Fields in brain metastases, non-small-cell lung cancer ("NSCLC"), pancreatic cancer, ovarian cancer and liver cancer. We anticipate expanding our clinical pipeline over time to study the safety and efficacy of Tumor Treating Fields for additional solid tumor indications.

In June 2018, we opened a single-arm, phase 2 pilot clinical trial in liver cancer, the HEPANOVA trial, which will study Tumor Treating Fields in combination with sorafenib, a chemotherapy drug, as a treatment in 25 patients with advanced liver cancer. We anticipate first patient enrollment in the fourth quarter of 2018.

- 14 -

The table below presents the current status of the ongoing or completed clinical trials in our pipeline and our expected next milestone for each.

In October 2018 at the American Society for Radiation Oncology (ASTRO) 2018 Annual Meeting, we presented an analysis of patient data from our EF-14 phase 3 pivotal trial which demonstrated that a higher dose of Tumor Treating Fields to the tumor bed was associated with improved overall survival, independent of compliance. For Tumor Treating Fields, dose is a factor of higher power density ($\geq 1.00 \text{ mW/cm}^2$), a measure of energy, and monthly usage, or compliance. Based upon this data, we believe that optimizing the power density of Tumor Treating Fields could further improve patient outcomes.

In September 2018, we announced a strategic collaboration with Zai Lab (Shanghai) Co., Ltd., a Shanghai-based biopharmaceutical company (“Zai”). The agreement grants Zai an exclusive license to commercialize Tumor Treating Fields in China, Hong Kong, Macau and Taiwan (collectively, the “Territory”) and establishes a development partnership for Tumor Treating Fields in multiple solid tumor indications. We will receive a \$15 million upfront payment and are eligible to receive additional payments upon achievement of certain development, regulatory and commercial milestones. We are also eligible to receive a tiered royalty on net sales of the licensed products in the Territory ranging from 10 percent to the mid-teens. Zai will purchase licensed products for commercial use exclusively from the Company at the Company’s fully burdened manufacturing cost.

Financial Overview. We view our operations and manage our business in one operating segment. For the three and nine months ended September 30, 2018, our net revenues were \$64.8 million and \$178.4 million, respectively, and our net loss was \$11.7 million and \$47.9 million, respectively. Our net loss for the three and nine months ended September 30, 2018 includes \$10.5 million and \$29.2 million, respectively, in non-cash share-based compensation expense. As of September 30, 2018, we had an accumulated deficit of \$628.0 million.

Critical Accounting Policies and Estimates

In accordance with U.S. generally accepted accounting principles (“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 2017 10-K. We adopted ASU 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, and ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date as of January 1, 2018. For additional information, see Note 1 to our Unaudited Consolidated Financial Statements. There were no other material changes to our critical accounting policies and estimates as compared to the critical accounting

policies and estimates described in our 2017 10-K.

Commentary on Results of Operations

Net revenues. Substantially all of our revenues are derived from patients using Optune in our currently active markets. We charge patients or their third-party healthcare payers on a monthly basis. Our potential net revenues per patient are determined by our ability to secure payment from payers, the monthly fee we collect and the number of months that the patient remains on therapy.

Cost of revenues. We contract with third-party manufacturers that manufacture Optune. Our cost of revenues is primarily comprised of the following:

- disposable transducer arrays;

- 15 -

depreciation expense for the field equipment, including the electric field generator used by patients; and 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.

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.

Financial expenses, net. Financial expenses, net primarily consists of credit facility interest expense and related debt issuance costs, interest income from cash balances and short-term investments and gains (losses) from foreign currency transactions. Our reporting currency is the U.S. dollar. We have historically held substantially all of our cash balances in U.S. dollar denominated accounts to minimize the risk of translational currency exposure.

Results of Operations

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

Operating statistics	September 30,			
	2018	2017		
Active patients at period end (1)				
United States	1,602	1,234		
EMEA (*)	581	448		
Japan	69	1		
	2,252	1,683		
(*) including Germany	399	331		
	Three months ended	Nine months ended		
	September 30,	September 30,		
	2018	2017	2018	2017
Gross billings (in millions)	\$139.2	\$101.9	\$401.0	\$262.3
Prescriptions received in period (2)				
United States	907	805	2,800	2,293
EMEA (*)	288	270	835	731
Japan	48	1	110	5
	1,243	1,076	3,745	3,029
(*) including Germany	235	202	635	553

(1) An “active patient” is a patient who is on Optune 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.

(2) A “prescription received” is a commercial order for Optune that is received from a physician certified to treat patients with Optune for a patient not previously on Optune. Orders to renew or extend treatment are not included in this

total.

For the third quarter 2018, we estimate an average global penetration rate of 26% in our currently active markets, with 28% in the United States, 25% in Germany and 13% in Japan. Newly diagnosed GBM grew to represent 75% of our total prescription volume in the three months ended September 30, 2018 with more than 930 prescriptions written for patients with newly diagnosed GBM in the quarter.

Three months ended September 30, 2018 compared to three months ended September 30, 2017(All dollar figures in tables are in thousands unless otherwise indicated)

	Three months ended September 30,				
	2018	2017	Change	% Change	
Net revenues	\$64,756	\$50,109	\$14,647	29	%

- 16 -

Net revenues. Net revenues increased \$14.7 million, or 29%, to \$64.8 million for the three months ended September 30, 2018 from \$50.1 million for the three months ended September 30, 2017. Revenue growth was driven by increased Optune adoption in the United States and Germany and continuing launch efforts in Japan, partially offset by the absence of one-time benefits from the 2017 cash to accrual revenue recognition transition.

	Three months ended September 30,		%		
	2018	2017	Change	Change	
Cost of revenues	\$18,949	\$15,153	\$3,796	25	%
Non-cash expenses:					
Share-based compensation expense	\$464	\$79	\$385	487	%
Depreciation	1,741	1,453	288	20	%
Total non-cash expenses	\$2,205	\$1,532	\$673	44	%
Total cost of revenues, net of non-cash expenses (non-GAAP) (*)	\$16,744	\$13,621	\$3,123	23	%

*This non-GAAP metric has been included because management believes that it provides for a more accurate year to year comparison of our operating expenses without the impact of non-cash items. This measure allows investors to better understand and evaluate our operating results in the same manner as management, to compare financial results across accounting periods and to better understand the long-term performance of our core business in future periods. In addition, management finds it useful to exclude certain non-cash expenses to assist in budgeting, planning and forecasting future periods. Management discusses this measure with the Audit Committee of our Board of Directors, when appropriate, for the purposes of reviewing our performance and the use of our cash resources.

Cost of revenues. Our cost of revenues increased by \$3.8 million, or 25%, to \$18.9 million for the three months ended September 30, 2018 from \$15.2 million for the three months ended September 30, 2017. The increase resulted primarily from the cost of shipping transducer arrays to a higher volume of commercial patients, as well as an increase in field equipment depreciation. Cost of revenues includes \$0.5 million of non-cash share-based compensation.

Operating Expenses.

	Three months ended September 30,		%		
	2018	2017	Change	Change	
Research, development and clinical trials	\$13,074	\$9,273	\$3,801	41	%
Sales and marketing	19,124	16,387	2,737	17	%
General and administrative	18,855	15,215	3,640	24	%
Total operating expenses	\$51,053	\$40,875	\$10,178	25	%

Non-cash expenses:					
Share-based compensation expense	\$ 10,015	\$ 8,550	\$ 1,465	17	%
Other non-cash expenses	570	600	(30)	(5	%)
Total non-cash expenses	\$ 10,585	\$ 9,150	\$ 1,435	16	%
Total operating expenses, net of non-cash expenses (non-GAAP) (*)	\$ 40,468	\$ 31,725	\$ 8,743	28	%

Research, development and clinical trials expenses. Research, development and clinical trials expenses increased \$3.8 million, or 41 %, to \$13.1 million for the three months ended September 30, 2018 from \$9.3 million for the three months ended September 30, 2017. The change is primarily due to an increase in clinical trial and personnel expenses for our METIS, LUNAR and PANOVA-3 trials and an increase in costs associated with medical affairs. These expenses include \$1.2 million of non-cash share-based compensation.

Sales and marketing expenses. Sales and marketing expenses increased \$2.7 million, or 17%, to \$19.1 million for the three months ended September 30, 2018 from \$16.4 million for the three months ended September 30, 2017. The change was primarily due to

increases in our sales force globally, increased marketing and market access expenses and increased facility expenses to support our geographical expansion. These expenses include \$2.0 million of non-cash share-based compensation.

General and administrative expenses. General and administrative expenses increased \$3.6 million, or 24%, to \$18.9 million for the three months ended September 30, 2018 from \$15.2 million for the three months ended September 30, 2017. The change was primarily due to an increase in share based compensation and an increase in professional services. These expenses included \$6.8 million of non-cash share-based compensation expense.

	Three months ended September 30,			
	2018	2017	Change	% Change
Financial expenses (income), net	\$2,397	\$2,156	\$ 241	11 %

Financial expenses, net. Financial expenses increased \$0.2 million, or 11%, to \$2.4 million for the three months ended September 30, 2018 from \$2.2 million for the three months ended September 30, 2017. The change was primarily due interest expenses on our new \$150 million term loan credit facility. For additional information, see Note 5 to our Unaudited Consolidated Financial Statements.

	Three months ended September 30,			
	2018	2017	Change	% Change
Income taxes	\$4,051	\$3,423	\$ 628	18 %

Income taxes. Income taxes increased \$0.6 million, or 18%, to \$4.1 million for the three months ended September 30, 2018 from \$3.4 million for the three months ended September 30, 2017. The increase was primarily a result of a higher number of active patients, partially offset by a change in the mix of applicable statutory tax rates in certain active jurisdictions.

Nine months ended September 30, 2018 compared to nine months ended September 30, 2017

(All dollar figures in tables are in thousands unless otherwise indicated)

	Nine months ended September 30,			
	2018	2017	Change	% Change
Net revenues	\$ 178,395	\$ 123,365	\$ 55,030	45 %

Net revenues. Net revenues increased \$55.0 million, or 45%, to \$178.4 million for the nine months ended September 30, 2018 from \$123.4 million for the nine months ended September 30, 2017. Revenue growth was driven by increased Optune adoption in the United States and Germany, continuing launch efforts in Japan and by an improvement in the gross-to-net revenue spread, partially offset by the absence of one-time benefits from the 2017 cash to accrual revenue recognition transition.

	Nine months ended September 30,		Change	% Change	
	2018	2017			
Cost of revenues	\$57,020	\$39,969	\$17,051	43	%
Non-cash expenses:					
Share-based compensation expense	\$891	\$353	\$538	152	%
Depreciation	4,909	3,775	1,134	30	%
Total non-cash expenses	\$5,800	\$4,128	\$1,672	41	%
Total cost of revenues, net of non-cash expenses (non-GAAP) (*)	\$51,220	\$35,841	\$15,379	43	%

Cost of revenues. Our cost of revenues increased by \$17.1 million, or 43%, to \$57.0 million for the nine months ended September 30, 2018 from \$40.0 million for the nine months ended September 30, 2017. The increase resulted primarily from the cost of shipping transducer arrays to a higher volume of commercial patients, as well as an increase in field equipment depreciation. Cost of revenues includes \$0.9 million of non-cash share-based compensation.

Operating Expenses.

	Nine months ended September 30,				
	2018	2017	Change	% Change	
Research, development and clinical trials	\$35,540	\$28,055	\$7,485	27	%
Sales and marketing	56,455	47,503	8,952	19	%
General and administrative	54,388	42,660	11,728	27	%
Total operating expenses	\$146,383	\$118,218	\$28,165	24	%
Non-cash expenses:					
Share-based compensation expense	\$28,314	\$20,407	\$7,907	39	%
Other non-cash expenses	1,892	1,749	143	8	%
Total non-cash expenses	\$30,206	\$22,156	\$8,050	36	%
Total operating expenses, net of non-cash expenses (non-GAAP) (*)	\$116,177	\$96,062	\$20,115	21	%

Research, development and clinical trials expenses. Research, development and clinical trials expenses increased \$7.5 million, or 27%, to \$35.5 million for the nine months ended September 30, 2018 from \$28.0 million for the nine months ended September 30, 2017. The change is primarily due to an increase in clinical trial and personnel expenses for our METIS, LUNAR and PANOVA-3 trials and an increase in costs associated with medical affairs. These expenses include \$3.4 million of non-cash share-based compensation.

Sales and marketing expenses. Sales and marketing expenses increased \$9.0 million, or 19%, to \$56.5 million for the nine months ended September 30, 2018 from \$47.5 million for the nine months ended September 30, 2017. The change was primarily due to increased marketing and market access expenses, increases in our sales force globally and increased facility expenses to support our geographical expansion. These expenses include \$5.3 million of non-cash share-based compensation.

General and administrative expenses. General and administrative expenses increased \$11.7 million, or 27%, to \$54.4 million for the nine months ended September 30, 2018 from \$42.7 million for the nine months ended September 30, 2017. The change was primarily due to an increase in share based compensation and an increase in professional services. These expenses included \$19.6 million of non-cash share-based compensation expense.

	Nine months ended September 30,				
	2018	2017	Change	% Change	
Financial expenses (income), net	\$10,110	\$6,785	\$3,325	49	%

Edgar Filing: NovoCure Ltd - Form 10-Q

Financial expenses, net. Financial expenses increased \$3.3 million, or 49%, to \$10.1 million for the nine months ended September 30, 2018 from \$6.8 million for the nine months ended September 30, 2017. The change was primarily due to accelerated amortization costs triggered by the repayment of our 2015 term loan credit facility and interest expenses on our new \$150 million term loan credit facility. For additional information, see Note 5 to our Unaudited Consolidated Financial Statements.

	Nine months ended September 30,			
	2018	2017	Change	% Change
Income taxes	\$12,810	\$9,110	\$3,700	41 %

Income taxes. Income taxes increased \$3.7 million, or 41%, to \$12.8 million for the nine months ended September 30, 2018 from \$9.1 million for the nine months ended September 30, 2017. The increase was primarily a result of a higher number of active patients, partially offset by a change in the mix of applicable statutory tax rates in certain active jurisdictions.

Liquidity and Capital Resources

We have incurred significant losses and cumulative negative cash flows from operations since our founding in 2000. We were operated as a development stage company through December 31, 2011. Since that time, we have been actively engaged in the global commercialization of Optune, as well as the research and development of other applications of Tumor Treating Fields. We anticipate continuing to incur significant costs associated with commercializing our delivery systems for approved indications. 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. Please refer to the risk factor entitled “To date, we have incurred substantial operating losses,” in Part I, Item 1A “Risk Factors” of our 2017 10-K for additional information. We expect to continue to incur significant expenses and operating losses for at least the next several years. Until we can generate substantial revenues (which may not occur), we expect to finance our cash needs through our existing cash, cash equivalents, 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.

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 September 30, 2018, we had received a total of \$784.1 million from these activities. As of September 30, 2018, we had an accumulated deficit of \$628.0 million.

Our net losses were \$47.9 million for the nine months ended September 30, 2018 and \$61.7 million for the year ended December 31, 2017. Our net losses primarily resulted from costs incurred in connection with our pre-clinical and clinical trial programs, costs incurred in our commercial efforts, and general and administrative costs necessary to operate as a multi-national oncology business.

In the first quarter of 2018, we made a milestone payment of \$5.5 million (the “Milestone Payment”) to the Technion Research and Development Foundation (“Technion”) pursuant to the settlement agreement dated February 10, 2015 (the “Settlement Agreement”). We previously accrued for the anticipated Milestone Payment in the fourth quarter of 2016. We have no further financial obligations to Technion under the Settlement Agreement. For additional information, see Note 4 to our Unaudited Consolidated Financial Statements.

As of September 30, 2018, we had \$123.0 million of cash and cash equivalents and \$104.7 million of short-term investments. We believe our cash and cash equivalents and short-term investments as of September 30, 2018, are sufficient for our operations for at least the next twelve months, based upon 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 and may outpace our gross profits. As a result, we may need to raise additional capital to fund our operations.

Nine months ended	
September 30,	
2018	2017

Edgar Filing: NovoCure Ltd - Form 10-Q

Net cash provided by (used in) operating activities	\$(18,679)	\$(30,236)
Net cash provided by (used in) investing activities	(3,704)	10,574
Net cash provided by (used in) financing activities	66,804	3,839
Net increase (decrease) in cash, cash equivalents and restricted cash	44,421	(15,823)
Effect of exchange rates on cash, cash equivalents and restricted cash	19	8
Changes in short-term investments	24	(15,401)
Net increase (decrease) in cash, cash equivalents, short-term investments and restricted cash	\$44,464	\$(31,216)

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 share-based compensation, depreciation and amortization, accrued interest and impairments. Operating cash flows are also impacted by changes in operating assets and liabilities, principally trade receivables, prepaid expenses, inventories, trade payables and accrued expenses.

- 20 -

Net cash used in operating activities was \$18.7 million for the nine months ended September 30, 2018, as compared to \$30.2 million for the nine months ended September 30, 2017, reflecting a net loss of \$47.9 million and a change of \$8.6 million in our net operating assets and liabilities, partially offset by non-cash charges of \$37.8 million.

The change in our net operating assets and liabilities was primarily the result of an increase in trade payables of \$2.8 million and a decrease in inventories of \$0.4 million offset by a decrease in other payables of \$5.6 million, an increase in trade receivables of \$3.0 million, an increase in other receivables of \$1.8 million, a decrease in other long-term liabilities of \$0.8 million and an increase in other long term assets of \$0.7 million. Non-cash charges included \$29.2 million of share-based compensation, \$6.8 million of depreciation and amortization and \$1.5 million of amortization of discount.

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 used in investing activities was \$3.7 million for the nine months ended September 30, 2018, compared to \$10.6 million provided by investing activities for the nine months ended September 30, 2017, reflecting an increase attributable to our receipt of \$150 million from the maturity of short-term investments, offset by the purchase of \$148.8 million of new short-term investments, purchases of \$2.8 million of field equipment, and purchases of \$2.2 million of property and equipment.

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 \$66.8 million for the nine months ended September 30, 2018, as compared to \$3.8 million for the nine months ended September 30, 2017, reflecting net proceeds from long-term loan of \$149.1 million, proceeds of \$16.8 million from the exercise of warrants and options and proceeds of \$0.9 million from the issuance of shares through our employee share purchase plan, partially offset by the repayment of long-term loan of \$100.0 million.

Our material outstanding indebtedness consists of our term loan credit facility. As of September 30, 2018, the aggregate principal balance of amounts outstanding under the term loan credit facility was \$150.0 million. We may prepay the term loan, in full, at any time. We must prepay the term loan (i) in full or in part upon the entry into certain licensing arrangements and (ii) in full in the event of a change of control. In each case, any prepayment (whether permitted or mandatory) is subject to a prepayment premium and/or make-whole payment. The pre-payment fee if we prepay outstanding loan amounts prior to February 7, 2021 is 2.0% and is 1.0% if made after the February 7, 2021 but prior to February 7, 2022.

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 contains other customary covenants.

Contractual Obligations and Commitments

Except as noted below, there were no material changes in our commitments under contractual obligations during the three months ended September 30, 2018.

The total amount of unrecognized tax benefits for uncertain tax positions was \$0.1 million and \$2.8 million at September 30, 2018 and December 31, 2017, respectively. The tax audit in Israel concluded in the first quarter of 2018, resulting in a payment of \$2.5 million in the second quarter of 2018.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There have been no material changes from the information disclosed in our 2017 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 our disclosure controls and procedures as of September 30, 2018. 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 September 30, 2018, our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2018, 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 September 30, 2018, 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

There have been no material changes to our legal proceedings disclosed in the 2017 10-K.

Item 1A. Risk Factors

There have been no material changes to our risk factors disclosed in Part I, Item 1A “Risk Factors to our 2017 10-K except as noted below.

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

In July 2018, William F. Doyle exercised warrants to purchase 2,330 ordinary shares with an exercise price of \$3.59 per share. In addition, in July 2018, an investor in our 2007 Series E preferred shares offering cashlessly exercised warrants to purchase 302,533 ordinary shares with an exercise price of \$3.59 per share, resulting in the issuance of 269,869 ordinary shares. We believe that these issuances were exempt from registration under the Securities Act of 1933, as amended (the “Securities Act”), in reliance on Section 4(a)(2) of the Securities Act regarding transactions not involving a public offering.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by	
		Reference Form Date	Filed Number Herewith
10.1#	<u>Employment Agreement, dated as of July 25, 2018, between Novocure USA LLC and Pritesh Shah</u>		X
10.2	<u>License and Collaboration Agreement, dated as of September 10, 2018, between NovoCure Limited and Zai Lab (Shanghai) Co., Ltd.</u>		X
31.1	<u>Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended</u>		X
31.2	<u>Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended</u>		X
32.1*	<u>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</u>		X
32.2*	<u>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</u>		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.

Confidential portion of this exhibit has been omitted and filed separately with the SEC pursuant to a request for confidential treatment.

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: October 25, 2018 /s/ Wilco Groenhuysen
Wilco Groenhuysen
Chief Financial Officer
(principal financial and accounting officer
and duly authorized officer)