NovoCure Ltd
Form 10-Q
May 02, 2019

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 March 31, 2019

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 Incorporation or Organization)	(I.R.S. Employer 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)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, no par value	NVCR	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (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 April 25, 2019
Ordinary shares, no par value	95,766,474 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,” “hope,” 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 Tumor Treating Fields delivery system research and development, including Optune. 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 for current and future indications;
- 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 for current and future indications by patients, physicians, third-party payers and others in the healthcare and scientific community;
- our plans to pursue the use of Optune 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 Optune and any future delivery systems in cancers other than GBM;
- our ability to acquire from third-party suppliers the supplies needed to manufacture Optune;
- our ability to manufacture adequate supply;
- our ability to secure and maintain adequate coverage from third-party payers to reimburse us for Optune and the use of software and systems to support and optimize the delivery of treatment with Optune for current and future indications;
- our ability to receive payment from third-party payers for use of Optune and the use of software and systems to support and optimize the delivery of treatment with Optune for current and future indications;
- 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, 2018, 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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NOVOCURE LIMITED AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	March 31, 2019 Unaudited	December 31, 2018 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 152,067	$ 140,622
Short-term investments	104,535	105,256
Restricted cash	2,094	2,134
Trade receivables	39,220	36,523
Receivables and prepaid expenses	13,619	14,279
Inventories	24,138	22,555
Total current assets	335,673	321,369
LONG-TERM ASSETS:		
Property and equipment, net	8,421	8,442
Field equipment, net	7,266	6,924
Right-of-use assets, net	13,920	-
Other long-term assets	4,975	3,058
Total long-term assets	34,582	18,424
TOTAL ASSETS	$ 370,255	$ 339,793

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)

	March 31, 2019 Unaudited	December 31, 2018 Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$29,943	$26,708
Other payables, lease liabilities and accrued expenses	41,005	37,852
Total current liabilities	70,948	64,560
LONG-TERM LIABILITIES:		
Long-term loan, net of discount and issuance costs	149,305	149,268
Deferred revenue	9,407	9,929
Employee benefit liabilities	2,823	2,683
Long-term lease liabilities	11,015	-
Other long-term liabilities	363	1,094
Total long-term liabilities	172,913	162,974
TOTAL LIABILITIES	243,861	227,534
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares no par value, unlimited shares authorized; issued and outstanding:		
95,692,797 shares and 93,254,185 shares at March 31, 2019 (unaudited) and		
December 31, 2018, respectively	-	-
Additional paid-in capital	783,941	757,314
Accumulated other comprehensive income (loss)	(1,742)	(1,400)
Retained earnings (accumulated deficit)	(655,805)	(643,655)
Total shareholders' equity	126,394	112,259
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$370,255	$339,793

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 March 31,		Year ended December 31,
	2019	2018	2018
	Unaudited		Audited
Net revenues	$73,309	$52,125	$248,069
Cost of revenues	19,814	18,238	80,048
Gross profit	53,495	33,887	168,021
Operating costs and expenses:			
Research, development and clinical trials	17,042	11,104	50,574
Sales and marketing	22,333	18,135	77,663
General and administrative	20,238	17,325	73,456
Total operating costs and expenses	59,613	46,564	201,693
Operating income (loss)	(6,118)	(12,677)	(33,672)
Financial expenses (income), net	2,371	4,853	12,270
Income (loss) before income taxes	(8,489)	(17,530)	(45,942)
Income taxes	3,661	3,194	17,617
Net income (loss)	$(12,150)	$(20,724)	$(63,559)
Basic and diluted net income (loss) per ordinary share	$(0.13)	$(0.23)	$(0.69)
Weighted average number of ordinary shares used in computing basic and diluted net income (loss) per share	94,811,282	89,985,612	91,828,043

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

U.S. dollars in thousands

	Three months ended March 31,		Year ended December 31,
	2019	2018	2018

	Unaudited		Audited
Net income (loss)	$(12,150)	$(20,724)	$(63,559)
Other comprehensive income (loss), net of tax:			
Change in foreign currency translation adjustments	(261)	10	27
Pension benefit plan	(81)	5	(84)
Total comprehensive income (loss)	$(12,492)	$(20,709)	$(63,616)

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 other comprehensive loss	Retained earnings (accumulated deficit)	Total shareholders' equity
Balance as of December 31, 2018 (audited)	93,254,185	$ 757,314	$ (1,400)	$ (643,655)	$ 112,259
Share-based compensation to employees	-	9,649	-	-	9,649
Exercise of options and warrants and vested RSUs	2,438,612	16,978	-	-	16,978
Other comprehensive income (loss), net of tax benefit of $11	-	-	(342)	-	(342)
Net income (loss)	-	-	-	(12,150)	(12,150)
Balance as of March 31, 2019 (Unaudited)	95,692,797	$ 783,941	$ (1,742)	$ (655,805)	$ 126,394

	Ordinary shares Shares	Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings (accumulated deficit)	Total shareholders' equity
Balance as of December 31, 2017 (audited)	89,478,032	$ 697,165	$ (1,343)	$ (582,258)	$ 113,564
Share-based compensation to employees	-	8,520	-	-	8,520
Exercise of options and warrants and vested RSUs	920,869	2,581	-	-	2,581
Cumulative effect adjustment on retained earnings (*)	-		-	2,162	2,162
Other comprehensive income (loss), net of tax benefit of $5	-	-	15	-	15
Net income (loss)	-	-	-	(20,724)	(20,724)
Balance as of March 31, 2018 (Unaudited)	90,398,901	$ 708,266	$ (1,328)	$ (600,820)	$ 106,118

(*)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 March 31,		Year ended December 31,
	2019	2018	2018
	Unaudited		Audited
Cash flows from operating activities:			
Net income (loss)	$(12,150)	$(20,724)	$(63,559)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	1,929	2,203	9,006
Asset write-downs and impairment of field equipment	75	49	407
Share-based compensation to employees	9,649	8,520	39,846
Decrease (increase) in trade receivables	(2,697)	(1,672)	(4,151)
Amortization of discount (premium)	(578)	2,427	1,022
Decrease (increase) in receivables and prepaid expenses	661	(1,834)	(6,174)
Decrease (increase) in inventories	(1,583)	1,638	(529)
Decrease (increase) in other long-term assets	(1,899)	(620)	(949)
Decrease (increase) in right of use assets, net	1,813	-	-
Increase (decrease) in trade payables	3,235	2,213	9,503
Increase (decrease) in other payables and accrued expenses	(989)	(8,300)	4,210
Increase (decrease) in employee benefit liabilities, net	43	76	133
Increase (decrease) in long-term lease liability	(577)	-	-
Increase (decrease) in other long-term liabilities	(1,247)	(800)	9,370
Net cash provided by (used in) operating activities	$(4,315)	$(16,824)	$(1,865)
Cash flows from investing activities:			
Purchase of property and equipment	$(860)	$(737)	$(2,916)
Purchase of field equipment	(1,465)	(1,370)	(3,795)
Proceeds from maturity of short-term investments	105,661	45,000	255,000
Purchase of short-term investments	(104,325)	(44,750)	(253,782)
Net cash provided by (used in) investing activities	$(989)	$(1,857)	$(5,493)
Cash flows from financing activities:			
Proceeds from issuance of shares, net	$-	$-	$1,835
Proceeds from long-term loan, net	-	149,150	149,150
Repayment of long-term loan	-	(100,000)	(100,000)
Repayment of other long-term loan	(8)	(17)	(84)
Exercise of options and warrants	16,978	2,581	18,468
Net cash provided by (used in) financing activities	$16,970	$51,714	$69,369

Effect of exchange rate changes on cash and cash equivalents	$(261)	$10	$27
Increase (decrease) in cash, cash equivalents and restricted cash	11,405	33,043	62,038
Cash, cash equivalents and restricted cash at beginning of period	142,756	80,718	80,718
Cash, cash equivalents and restricted cash at the end of the period	$154,161	$113,761	$142,756
Supplemental cash flow activities:			
Cash paid during the period for:			
Income taxes	$3,033	$3,758	$20,350
Interest	$3,379	$3,009	$13,334
Non-cash activities upon implementation of ASC-842:			
Right of use assets obtained in exchange for lease obligations:	$15,733	$-	$-

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 Optune for the treatment of solid tumors. The Company has regulatory approvals and clearances in certain countries for Optune 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 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, 2018 (the "2018 10-K") filed with the Securities and Exchange Commission on February 28, 2019.

The significant accounting policies applied in the audited annual consolidated financial statements of the Company as disclosed in the 2018 10-K are applied consistently in these unaudited interim consolidated financial statements, except as noted below:

Recently Adopted Accounting Pronouncements. In 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)", which amends the existing standards for lease accounting, requiring lessees to recognize most leases on their balance sheets. The new standard establishes a right-of-use model that requires a lessee to recognize a right-of-use asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating. The standard is effective for interim and annual reporting periods beginning after December 15, 2018.

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 additional (and optional) transition method to adopt the new leases standard. Under this method, an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Consequently, the prior comparative period's financials will remain the same as those previously presented. The Company adopted the new standard as of January 1, 2019 and it has also elected to adopt the package of practical expedients permitted in ASC 842.

The consolidated financial statements for the three months ended March 31, 2019 are presented under the new standard, while comparative year and periods presented are not adjusted and continue to be reported in accordance

with Topic 840, Leases.

NOTE 2: CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

Cash equivalents include items almost as liquid as cash, such as certificates of deposit and time deposits with maturity periods of three months or less when purchased.

	March 31, 2019 Unaudited	December 31, 2018 Audited
Cash	$9,104	$9,197
Money market funds	142,963	131,425
Total cash and cash equivalents	$152,067	$140,622

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.

	March 31, 2019 Unaudited	December 31, 2018 Audited
Short-term investments	$104,535	$105,256

The estimated fair value of the Company's short-term investments as of March 31, 2019 and December 31, 2018 was $104,547 and $105,266, respectively.

NOTE 3: INVENTORIES

Inventories are stated at the lower of cost or net realizable value. The weighted average methodology is applied to determine cost. As of March 31, 2019 and December 31, 2018, the Company's inventories were composed of:

	March 31, 2019 Unaudited	December 31, 2018 Audited
Raw materials	$ 1,526	$ 870
Work in progress	8,176	8,667
Finished products	14,436	13,018
Total	$ 24,138	$ 22,555

NOTE 4: COMMITMENTS, RIGHTS OF USE AND CONTINGENT LIABILITIES

Operating Leases and Rights of Use. The facilities of the Company are leased under various operating lease agreements for periods, including options for extensions, ending no later than 2029. The Company also leases motor vehicles under various operating leases, which expire on various dates, the latest of which is in 2022.

Under ASU No. 2016-02, "Leases (Topic 842), all leases with durations greater than 12 months, including non-cancelable operating leases, are now recognized on the balance sheet. The aggregated present value of lease agreements, net of deferred rent, are recorded as a long-term asset titled right-of-use assets. The corresponding lease liabilities are split between other payables within current liabilities and long-term lease liabilities within long-term liabilities. The lease liabilities are presented without consideration for deferred rent.

Upon implementation of ASC-842, effective January 1, 2019, the Company recorded an increase in right-of-use assets obtained in exchange for lease obligations of $15,733 on our opening balance sheet. Lease and rental payments for the three months ended March 31, 2019, totaled $1,740. Future minimum lease payments under non-cancelable operating leases as of March 31, 2019, are as follows:

	March 31, 2019 Unaudited
Future minimum lease payments:	
2019 (excluding the three months ended March 31, 2019)	$ 3,216
2020	3,766
2021	3,475
2022	2,503
2023	1,655
Thereafter	3,258

Total future minimum lease payments	$ 17,873	
Less imputed interest	(3,090	)
Net present value of future minimum lease payments	$ 14,783	
Presented as of March 31, 2019:		
Short-term lease liabilities	$ 3,768	
Long-term lease liabilities	11,015	
Net present value of future minimum lease payments	$ 14,783	
Weighted average of remaining operating lease term	6.38	
Weighted average of operating lease discount rate	7.46	%

The right-of-use assets are presented net of $863 in deferred rents.

Pledged deposits and bank guarantees. As of March 31, 2019 and December 31, 2018, the Company pledged bank deposits of $1,134 and $1,143, 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 $1,294 and $1,299, respectively.

NOTE 5: SHARE CAPITAL

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 generally vest over a three-year period. RSUs granted under the 2015 Plan that are cancelled before expiration become available for future grants. As of March 31, 2019, 12,649,222 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, 2019 and changes during the period then ended is presented below:

	Three months ended March 31, 2019 Unaudited	
	Number of options	Weighted average exercise price
Outstanding at beginning of year	14,438,215	$ 13.56
Granted	751,471	47.04
Exercised	(2,047,421)	8.38
Forfeited and cancelled	(40,258)	14.47
Outstanding as of March 31, 2019	13,102,007	$ 16.29
Exercisable options	5,852,344	$ 12.79

For the three months, ended March 31, 2019, options to purchase 2,047,421 ordinary shares were exercised, resulting in the issuance of 2,047,421 ordinary shares.

A summary of the status of the Company's RSUs as of March 31, 2019 and changes during the period then ended is presented below:

	Three months ended March 31, 2019 Unaudited	
	Number of RSUs	Weighted average grant date fair value price
Unvested at beginning of year	1,613,197	$ 14.04
Granted	486,506	47.04
Vested	(391,191)	12.09
Forfeited and cancelled	(3,837)	21.15
Unvested as of March 31, 2019	1,704,675	$ 23.89

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 March 31, 2019, 3,122,410 ordinary shares were available to be purchased by eligible employees under the ESPP and 347,193 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:

	Three months ended March 31,		Year ended December 31,
	2019	2018	2018
	Unaudited		Audited
Stock Option Plans			
Expected term (years)	6.23	6.25	5.50-6.25
Expected volatility	55%	55%	52%-55%
Risk-free interest rate	2.40%	2.77%	2.70%-2.99%
Dividend yield	0.00%	0.00%	0.00%
ESPP			
Expected term (years)	0.50	0.50	0.50
Expected volatility	62%	53%	45%-53%
Risk-free interest rate	2.51%	1.61%	1.61%-2.14%
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 months ended March 31, 2019 and 2018 and the year ended December 31, 2018 was:

	Three months ended March 31,		Year ended December 31,
	2019	2018	2018
	Unaudited		Audited
Cost of revenues	$426	$164	$ 1,261
Research, development and clinical trials	1,188	906	4,709
Sales and marketing	1,962	1,436	7,393
General and administrative	6,073	6,014	26,483
Total share-based compensation expense	$9,649	$8,520	$ 39,846

NOTE 6: SUPPLEMENTAL INFORMATION

The Company operates in a single reportable segment.

The following table presents long-lived assets by location:

	March 31, 2019 Unaudited	December 31, 2018 Audited
United States	$ 7,973	$ 8,289
Switzerland	2,939	2,513
Israel	2,428	2,236
Germany	958	1,054
Others	1,389	1,274
Total	$ 15,687	$ 15,366

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

	Three months ended March 31,		Year ended December 31,
	2019	2018	2018
	Unaudited		Audited
United States	$46,604	$37,802	$168,414
EMEA (*)	22,520	13,874	72,485
Japan	3,370	449	6,351
Greater China (1)	815	-	819
Total	$73,309	$52,125	$248,069
(*) including Germany	$21,287	$13,358	$67,849

(1) Reflects revenue recognized in accordance with a License and Collaboration Agreement between us and Zai Lab (Shanghai) Co., Ltd. (“Zai”), dated September 10, 2018, pursuant to which Zai is commercializing Optune in China, Hong Kong, Macau and Taiwan (“Greater China”). For additional information, see Note 12 to the Consolidated Financial Statements in our 2018 10-K.

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 March 31, 2019 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. Please refer to the information under the heading "Cautionary Note Regarding Forward-Looking Statements" elsewhere in this report. 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 with 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 Tumor Treating Fields delivery system, for the treatment of glioblastoma ("GBM") and to advance programs testing the efficacy and safety of Optune in multiple solid tumor indications through our clinical pipeline.

Optune is approved by the U.S. Food and Drug Administration ("FDA") for the treatment of adult patients with newly diagnosed GBM in combination with temozolomide, a chemotherapy drug, and for use as monotherapy treatment for adult patients with GBM following confirmed recurrence after chemotherapy. We also have approval to market Optune for the treatment of GBM in the European Union, Japan and certain other countries. We have built a commercial organization and launched Optune for the treatment of GBM in the United States, Austria, Germany, Israel, Japan, Sweden and Switzerland, which we refer to as our currently active markets.

We continue to work with payers to expand access to Optune for patients with GBM. As of March 31, 2019, more than 245 million Americans had coverage of Optune for newly diagnosed and/or recurrent GBM. 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. We are actively appealing Medicare fee-for-service coverage denials through the Administrative Law Judge ("ALJ") process with Centers for Medicare and Medicaid Services ("CMS").

In 2018, the Medicare durable medical equipment Medicare Administrative Contractors ("DME MACs") confirmed that they have accepted our local coverage determination ("LCD") reconsideration request for the treatment of newly diagnosed GBM and plan to take steps to publish a final LCD for newly diagnosed GBM. In March 2019, the DME MACs met with a contractor advisory committee ("CAC"), a formal mechanism for healthcare professionals to be informed of the evidence used in developing the LCD and to promote communications between the DME MACs and the healthcare community. The panel expressed their confidence that there is sufficient evidence to determine that Optune provides net positive health outcomes in the Medicare-eligible population (3.82 on a scale of 1 to 5). The timing of the publication of the proposed LCD following the CAC meeting is unclear at this time. Once published, the proposed LCD will be subject to a 45-day public comment period and, following that public comment period, a final LCD will be published.

In order to further advance the scientific evidence supporting the use of Optune in GBM and gather additional information about Optune's optimal use, we plan to initiate two additional randomized trials in GBM as early as 2019. The first trial will be designed to study the potential benefit of earlier initiation of Optune, concurrent with radiation therapy, versus initiation post radiation and is intended to support possible label expansion. The second trial will be designed to identify potential efficacy signals when Optune is combined with temozolomide and several other

therapeutic agents in a multifactorial trial design and is intended to identify optimal combination treatments.

Currently, we are conducting phase 3 pivotal trials evaluating the use of Optune in brain metastases, non-small-cell lung cancer, pancreatic cancer and ovarian cancer. We are also conducting a phase 2 pilot trial evaluating the use of Optune in liver cancer. In 2018, we successfully completed a phase 2 pilot trial in malignant pleural mesothelioma ("MPM") and, based on those trial results, have since submitted a humanitarian device exemption application to the FDA for approval in MPM. We anticipate expanding our clinical pipeline over time to study the safety and efficacy of Optune for additional solid tumor indications.

In March 2019, we enrolled the first patient in our INNOVATE-3 /ENGOT-ov50 trial, a phase 3 pivotal trial testing the effectiveness of Optune with paclitaxel in patients with recurrent, platinum-resistant ovarian cancer. The protocol specifies overall survival as primary endpoint and an event-driven interim analysis, which we anticipate will occur in 2022. The European Network for Gynaecological Oncological Trial groups ("ENGOT") and The GOG Foundation, Inc. ("GOG"), third-party clinical trial networks, are collaborating with us on the trial. ENGOT and GOG were involved in the development of the trial and the collaborations are intended to facilitate enrollment of INNOVATE-3 at leading cancer centers in Europe and the United States.

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

We believe we have a robust patent and intellectual property portfolio, with over 140 issued patents and numerous patent applications pending worldwide covering global commercialization rights to Optune in oncology.

In September 2018, we granted Zai Lab (Shanghai) Co., Ltd. ("Zai") a license to commercialize Optune in China, Hong Kong, Macau and Taiwan under a License and Collaboration Agreement (the "Zai Agreement"). Zai has begun the process for regulatory approval of Optune in China. Zai is seeking a trial waiver from the Chinese regulatory authorities enabling a potential launch in China as early as the fourth quarter of 2019. On the clinical development front, Zai is working to finalize the protocol for a phase 2 pilot trial in gastric cancer and is collaborating closely with our clinical teams to initiate trials in other key indications in China.

Financial Overview. We view our operations and manage our business in one operating segment. For the three months ended March 31, 2019, our net revenues were $73.3 million, and our net loss was $12.2 million. Our net loss for the three months ended March 31, 2019 included $9.6 million, in non-cash share-based compensation expense. As of March 31, 2019, we had an accumulated deficit of $655.8 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 Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (the "2018 10-K"). 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 2018 10-K.

Commentary on Results of Operations

Net revenues. Our revenues are primarily derived from patients using Optune in our currently active markets. We charge for treatment with Optune on a monthly basis. Our potential net revenues per patient are determined by our ability to secure payment, the monthly fee we collect and the number of months that the patient remains on therapy.

We also recognized revenue pursuant to the Zai Agreement in the first quarter of 2019. For additional information regarding the Zai Agreement, see Note 12 to the Consolidated Financial Statements in our 2018 10-K.

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;
- 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.

	Three Months Ended March 31,	
Operating statistics	2019	2018
Gross billings (in millions)	$158.0	$126.3
Active patients at period end (1)		
United States	1,778	1,445
EMEA (*)	735	544
Japan	118	20
Total	2,631	2,009
(*) including Germany	510	377

	Three months ended March 31,	
	2019	2018
Prescriptions received in period (2)		
United States	925	946
EMEA (*)	330	282
Japan	55	30
Total	1,310	1,258

(*) including Germany	254	210

(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.

Three months ended March 31, 2019 compared to three months ended March 31, 2018

	Three months ended March 31,			
	2019	2018	Change	% Change
Net revenues	$73,309	$52,125	$21,184	41 %

Net revenues. Net revenues increased $21.2 million, or 41%, to $73.3 million for the three months ended March 31, 2019 from $52.1 million for the three months ended March 31, 2018. This was primarily due to an increase of 622 active patients in our currently active markets, representing 31% growth, and an increase in net revenues per active patient. The increase in net revenues per active patient was primarily driven by improving reimbursement approval rates in Germany and by growth in Austria and Japan.

	Three months ended March 31,			
	2019	2018	Change	% Change
Cost of revenues	$19,814	$18,238	$1,576	9 %
Non-cash expenses:				
Share-based compensation expense	$426	$164	$262	160 %
Depreciation	1,384	1,516	(132)	(9 %)
Total non-cash expenses	$1,810	$1,680	$130	8 %
Total cost of revenues, net of non-cash expenses (**)	$18,004	$16,558	$1,446	9 %

** 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 $1.6 million, or 9%, to $19.8 million for the three months ended March 31, 2019 from $18.2 million for the three months ended March 31, 2018. The increase in cost of revenues was primarily due to the cost of shipping transducer arrays to a higher volume of commercial patients. Gross margin was 73% for the three months ended March 31, 2019 and 65% for the three months ended March 31, 2018. Our gross margin continues to benefit from ongoing efficiency initiatives and scale.

Operating Expenses.

	Three months ended March 31,				
	2019	2018	Change	% Change	
Research, development and clinical trials	$17,042	$11,104	$5,938	53	%
Sales and marketing	22,333	18,135	4,198	23	%
General and administrative	20,238	17,325	2,913	17	%
Total operating expenses	$59,613	$46,564	$13,049	28	%
Non-cash expenses:					
Share-based compensation expense	$9,223	$8,356	$867	10	%
Other non-cash expenses	697	687	10	1	%
Total non-cash expenses	$9,920	$9,043	$877	10	%
Total operating expenses, net of non-cash expenses (**)	$49,693	$37,521	$12,172	32	%

Research, development and clinical trials expenses. Research, development and clinical trials expenses increased $5.9 million, or 53%, to $17.0 million for the three months ended March 31, 2019 from $11.1 million for the three months ended March 31, 2018. The change is primarily due to an increase in clinical trial and personnel expenses for our INNOVATE-3, LUNAR, METIS and PANOVA-3 trials and an increase in costs associated with medical affairs and regulatory matters.

Sales and marketing expenses. Sales and marketing expenses increased $4.2 million, or 23%, to $22.3 million for the three months ended March 31, 2019 from $18.1 million for the three months ended March 31, 2018. The change was primarily due to increased marketing expenses and increases in our personnel costs associated with a larger sales force globally.

General and administrative expenses. General and administrative expenses increased $2.9 million, or 17%, to $20.2 million for the three months ended March 31, 2019 from $17.3 million for the three months ended March 31, 2018. The change was primarily due to an increase in personnel costs and an increase in professional services.

	Three months ended March 31,				
	2019	2018	Change	% Change	
Financial expenses (income), net	$2,371	$4,853	$(2,482)	(51	%)

Financial expenses, net. Financial expenses decreased $2.5 million, or 51%, to $2.4 million for the three months ended March 31, 2019 from $4.9 million for the three months ended March 31, 2018. The change was primarily due to the 2018 accelerated amortization costs triggered by the repayment of our 2015 term loan credit facility, partially offset

by interest expenses on our new $150 million term loan credit facility. For additional information, see Note 10 to our Consolidated Financial Statements in our 2018 10-K.

	Three months ended March 31,			
	2019	2018	Change	% Change
Income taxes	$3,661	$3,194	$ 467	15 %

Income taxes. Income taxes increased $0.5 million, or 15%, to $3.7 million for the three months ended March 31, 2019 from $3.2 million for the three months ended March 31, 2018. The change was primarily a result of a higher number of active patients and 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. As of March 31, 2019, we had an accumulated deficit of $655.8 million. To date, we have primarily financed our operations through the issuance and

sale of equity and the proceeds from long-term loans. At March 31, 2019, we had $152.1 million in cash and cash equivalents and $104.5 million in short-term investments. At March 31, 2019, our cash, cash equivalents and short-term investments totaled $256.6 million, an increase of $10.7 million compared to $245.9 million at December 31, 2018. The increase in our cash, cash equivalents and short-term investments was primarily due to the exercise of options.

We believe our cash, cash equivalents and short-term investments as of March 31, 2019 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 anticipate continuing to incur significant costs associated with commercializing Optune 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. Such expenses may outpace our gross profit. As a result, we may need to raise additional capital to fund our operations.

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, 2019, we had received a total of $803.6 million from these activities.

	Three Months Ended March 31,	
	2019	2018
Net cash provided by (used in) operating activities	$(4,315)	$(16,824)
Net cash provided by (used in) investing activities	(989)	(1,857)
Net cash provided by (used in) financing activities	16,970	51,714
Net increase (decrease) in cash, cash equivalents, short-term investments and restricted cash	$11,666	$33,033

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.

Net cash used in operating activities was $4.3 million for the three months ended March 31, 2019, as compared to $16.8 million for the three months ended March 31, 2018. Gross profit increased by $19.6 million for the three months ended March 31, 2019 versus the three months ended March 31, 2018, fully funding incremental investments of $5.9 million in research and development and $7.1 million in sales, marketing, general and administrative expenses. The year-over-year reduction in cash used in operating activities was primarily driven by a decrease in net loss, as well as an increase in share-based compensation, a decrease in right of use assets and an increase in working capital.

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 $1.0 million for the three months ended March 31, 2019, compared to $1.9 million for the three months ended March 31, 2018. The year-over-year reduction in cash used in investing activities was primarily driven by the roll-over of our short-term investments.

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 $17.0 million for the three months ended March 31, 2019, as compared to $51.7 million for the three months ended March 31, 2018. The year-over-year decrease in cash provided by financing activities was primarily related to the 2018 principal amount of our credit facility and partially offset by proceeds from the exercise of options.

Our material outstanding indebtedness consists of our term loan credit facility. As of March 31, 2019, 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. If we prepay outstanding loan amounts prior to August 7, 2020, we must pay a make-whole amount equal to the amount of interest that would have accrued on the amount of all principal we prepaid from the date of such prepayment through February 7, 2021.

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

There were no material changes in our commitments under contractual obligations during the three months ended March 31, 2019.

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 U.S. Securities and Exchange Commission (“SEC”) rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There have been no material changes from the information disclosed in our 2018 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 March 31, 2019. 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, 2019, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2019, 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, 2019, 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 2018 10-K except as noted below.

On February 3, 2019, a civil claim was filed in the District Court in Haifa, Israel, by Ofir Paz ("Paz"), a former member of our Board of Directors, and EES Investments Ltd., a company wholly owned by Paz (together with Paz, "Plaintiff") against us and Prof. Yoram Palti. Plaintiff claims that he is entitled to 210,000 ordinary shares pursuant to an alleged 2003 verbal agreement between Plaintiff and Prof. Palti, who was also a member of our Board of Directors at that time, for Plaintiff's contribution to the advancement of our business and the consummation of a third party investment in our company. Plaintiff is asking the court to issue an order (x) providing that he is the holder of 210,000 ordinary shares, or alternatively (y) providing that he is entitled to receive from us and Prof. Palti 210,000 ordinary shares, and also ordering that our register of shareholders be amended to reflect his ownership of such shares.

A response to the claim was filed on behalf of Yoram Palti in April 2019 and we are preparing our response to the claim. We believe that the complaint is without merit and plan to defend against this claim vigorously. We have not accrued any amounts in respect of these claims, as a liability is not probable and the amount of any potential liability cannot be reasonably estimated.

Item 1A. Risk Factors

There have been no material changes to our risk factors disclosed in Part I, Item 1A "Risk Factors to our 2018 10-K.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On April 30, 2019, the Company's Board of Directors adopted a revised Non-Employee Director Compensation Plan containing certain administrative updates.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
10.1	Form of Restricted Share Unit Award Notice for Employees in Austria#				X
10.2	Form of Non-Qualified Stock Option Agreement for Employees in Austria#				X
10.3	Form of Restricted Share Unit Award Notice for Employees in Sweden#				X
10.4	Form of Non-Qualified Stock Option Agreement for Employees in Sweden#				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 2, 2019 /s/ Wilco Groenhuysen
Wilco Groenhuysen
Chief Financial Officer
(principal financial and accounting officer

and duly authorized officer)