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 June 30, 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 July 18, 2019**
Ordinary shares, no par value	98,176,183 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," 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 research and development related to our Tumor Treating Fields delivery systems marketed under various brand names, including Optune, the NovoTTF-100L System ("NovoTTF-100L") and software and systems to support and optimize the delivery of Tumor Treating Fields (collectively, the "Products"). 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 our Products 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 our Products 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 our Products for the treatment of solid tumor cancers other than glioblastoma ("GBM") and malignant pleural mesothelioma ("MPM");
- our estimates regarding revenues, expenses, capital requirements and needs for additional financing;
- our ability to obtain regulatory approvals for the use of our Products in cancers other than GBM and MPM;
- our ability to acquire from third-party suppliers the supplies needed to manufacture our Products ;
- our ability to manufacture adequate supply;
- our ability to secure and maintain adequate coverage from third-party payers to reimburse us for our Products for current and future indications;
- our ability to receive payment from third-party payers for use of our Products 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.

NovoCure Limited
Quarterly Report on Form 10-Q
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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

NOVOCURE LIMITED AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	June 30, 2019 Unaudited	December 31, 2018 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 180,073	$ 140,622
Short-term investments	104,511	105,256
Restricted cash	2,110	2,134
Trade receivables	42,533	36,523
Receivables and prepaid expenses	15,302	14,279
Inventories	25,454	22,555
Total current assets	369,983	321,369
LONG-TERM ASSETS:		
Property and equipment, net	8,399	8,442
Field equipment, net	7,466	6,924
Right-of-use assets, net	14,659	-
Other long-term assets	5,682	3,058
Total long-term assets	36,206	18,424
TOTAL ASSETS	$ 406,189	$ 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)

	June 30, 2019 Unaudited	December 31, 2018 Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 30,069	$ 26,708
Other payables, lease liabilities and accrued expenses	43,498	37,852
Total current liabilities	73,567	64,560
LONG-TERM LIABILITIES:		
Long-term loan, net of discount and issuance costs	149,344	149,268
Deferred revenue	8,874	9,929
Employee benefit liabilities	3,610	2,683
Long-term lease liabilities	11,582	-
Other long-term liabilities	306	1,094
Total long-term liabilities	173,716	162,974
TOTAL LIABILITIES	247,283	227,534
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares no par value, unlimited shares authorized; issued and outstanding: 97,858,876 shares and 93,254,185 shares at June 30, 2019 (unaudited) and December 31, 2018, respectively	-	-
Additional paid-in capital	818,338	757,314
Accumulated other comprehensive income (loss)	(2,357)	(1,400)
Retained earnings (accumulated deficit)	(657,075)	(643,655)
Total shareholders' equity	158,906	112,259
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 406,189	$ 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 June 30,		Six months ended June 30,		Year ended December 31,
	2019	2018	2019	2018	2018
	Unaudited		Unaudited		Audited
Net revenues	$ 86,713	$ 61,514	$ 160,022	$ 113,639	$ 248,069
Cost of revenues	21,106	19,833	40,920	38,071	80,048
Gross profit	65,607	41,681	119,102	75,568	168,021
Operating costs and expenses:					
Research, development and clinical trials	19,454	11,362	36,496	22,466	50,574
Sales and marketing	23,708	19,196	46,041	37,331	77,663
General and administrative	21,249	18,208	41,487	35,533	73,456
Total operating costs and expenses	64,411	48,766	124,024	95,330	201,693
Operating income (loss)	1,196	(7,085)	(4,922)	(19,762)	(33,672)
Financial expenses (income), net	1,239	2,860	3,610	7,713	12,270
Income (loss) before income taxes	(43)	(9,945)	(8,532)	(27,475)	(45,942)
Income taxes	1,227	5,565	4,888	8,759	17,617
Net income (loss)	$ (1,270)	$ (15,510)	$ (13,420)	$ (36,234)	$ (63,559)
Basic and diluted net income (loss) per ordinary share	$ (0.01)	$ (0.17)	$ (0.14)	$ (0.40)	$ (0.69)
Weighted average number of ordinary shares used in computing basic and diluted net income (loss) per share	96,356,317	91,331,862	95,583,802	90,658,735	91,828,043

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
U.S. dollars in thousands

	Three months ended June 30,		Six months ended June 30,		Year ended December 31,
	2019	2018	2019	2018	2018
	Unaudited		Unaudited		Audited
Net income (loss)	$ (1,270)	$ (15,510)	$ (13,420)	$ (36,234)	$ (63,559)
Other comprehensive income (loss), net of tax:					
Change in foreign currency translation adjustments	47	11	(214)	21	27
Pension benefit plan	(662)	44	(743)	49	(84)
Total comprehensive income (loss)	$ (1,885)	$ (15,455)	$ (14,377)	$ (36,164)	$ (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
Share-based compensation to employees	-	13,732	-	-	13,732
Proceeds from issuance of shares	43,421	1,208	-	-	1,208
Exercise of options and warrants and vested RSUs	2,122,658	19,457	-	-	19,457
Other comprehensive income (loss), net of tax benefit of $69	-	-	(615)	-	(615)
Net income (loss)	-	-	-	(1,270)	(1,270)
Balance as of June 30, 2019 (Unaudited)	97,858,876	$ 818,338	$ (2,357)	$ (657,075)	$ 158,906

	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
Share-based compensation to employees	-	10,206	-	-	10,206
Proceeds from issuance of shares	54,386	938	-	-	938
Exercise of options and warrants and vested RSUs	2,049,986	10,274	-	-	10,274
Other comprehensive income (loss), net of tax benefit of $3	-	-	55	-	55
Net income (loss)	-	-	-	(15,510)	(15,510)
Balance as of June 30, 2018 (Unaudited)	92,503,273	$ 729,684	$ (1,273)	$ (616,330)	$ 112,081

(*) 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 June 30,		Six months ended June 30,		Year ended December 31,
	2019	2018	2019	2018	2018
	Unaudited		Unaudited		Audited
Cash flows from operating activities:					
Net income (loss)	$ (1,270)	$ (15,510)	$ (13,420)	$ (36,234)	$ (63,559)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:					
Depreciation and amortization	2,132	2,287	4,061	4,490	9,006
Asset write-downs and impairment of field equipment	86	93	161	142	407
Share-based compensation to employees	13,732	10,206	23,381	18,726	39,846
Decrease (increase) in trade receivables	(3,313)	(3,599)	(6,010)	(5,271)	(4,151)
Amortization of discount (premium)	(587)	(370)	(1,165)	2,057	1,022
Decrease (increase) in receivables and prepaid expenses	(1,685)	(1,277)	(1,024)	(3,111)	(6,174)
Decrease (increase) in inventories	(1,316)	482	(2,899)	2,120	(529)
Decrease (increase) in other long-term assets	(632)	(278)	(2,531)	(898)	(949)
Decrease (increase) in right of use assets, net	800	-	2,613	-	-
Increase (decrease) in trade payables	126	1,016	3,361	3,229	9,503
Increase (decrease) in other payables and accrued expenses	2,097	(528)	1,108	(8,828)	4,210
Increase (decrease) in employee benefit liabilities, net	50	1	93	77	133
Increase (decrease) in long-term lease liability	(575)	-	(1,152)	-	-
Increase (decrease) in other long-term liabilities	(579)	(16)	(1,826)	(816)	9,370
Net cash provided by (used in) operating activities	$ 9,066	$ (7,493)	$ 4,751	$ (24,317)	$ (1,865)
Cash flows from investing activities:					
Purchase of property and equipment	$ (892)	$ (854)	$ (1,752)	$ (1,591)	$ (2,916)
Purchase of field equipment	(1,505)	(604)	(2,970)	(1,974)	(3,795)
Proceeds from maturity of short-term investments	105,000	60,000	210,661	105,000	255,000
Purchase of short-term investments	(104,351)	(59,384)	(208,676)	(104,134)	(253,782)
Net cash provided by (used in) investing activities	$ (1,748)	$ (842)	$ (2,737)	$ (2,699)	$ (5,493)
Cash flows from financing activities:					
Proceeds from issuance of shares, net	$ 1,208	$ 938	$ 1,208	$ 938	$ 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)	(24)	(16)	(41)	(84)
Exercise of options and warrants	19,457	10,274	36,435	12,855	18,468
Net cash provided by (used in) financing activities	$ 20,657	$ 11,188	$ 37,627	$ 62,902	$ 69,369
Effect of exchange rate changes on cash and cash equivalents	$ 47	$ 11	$ (214)	$ 21	$ 27
Increase (decrease) in cash, cash equivalents and restricted cash	28,022	2,864	39,427	35,907	62,038
Cash, cash equivalents and restricted cash at beginning of period	154,161	113,761	142,756	80,718	80,718
Cash, cash equivalents and restricted cash at the end of the period	$ 182,183	$ 116,625	$ 182,183	$ 116,625	$ 142,756
Supplemental cash flow activities:					
Cash paid during the period for:					
Income taxes	$ 4,358	$ 8,256	$ 7,391	$ 12,014	$ 20,350
Interest	$ 3,415	$ 3,416	$ 6,794	$ 6,425	$ 13,334
Non-cash activities upon implementation of ASC-842:					
Right of use assets obtained in exchange for lease obligations	$ 1,539	$ -	$ 17,273	$ -	$ -

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

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 delivery systems, including Optune and NovoTTF-100L , for the treatment of solid tumors. The Company has received regulatory approval from the U.S. Food and Drug Administration ("FDA") under the Premarket Approval pathway and regulatory approvals and clearances in certain other countries for Optune to treat adult patients with GBM. The Company also has received FDA approval under the Humanitarian Device Exemption pathway to market NovoTTF-100L for unresectable, locally advanced or metastatic MPM in combination with standard chemotherapies.

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 amendments in ASU 2018-11 provide lessors with a practical expedient, by class of underlying asset, not to separate non-lease components from the associated lease component and, instead, to account for those components as a single component if the non-lease components otherwise would be accounted for under the new revenue guidance (Topic 606) and both of the following are met:

1. The timing and pattern of transfer of the non-lease component(s) and associated lease component are the same.
2. The lease component, if accounted for separately, would be classified as an operating lease.

As the non-lease component(s) associated with the lease component is the predominant component of the combined component, the Company accounts for the combined component in accordance with Topic 606.

The consolidated financial statements for the three and six months ended June 30, 2019 are presented under the new standard, while comparative year and other 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.

	June 30, 2019 Unaudited	December 31, 2018 Audited
Cash	$ 8,896	$ 9,197
Money market funds	171,177	131,425
Total cash and cash equivalents	$ 180,073	$ 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.

	June 30, 2019 Unaudited	December 31, 2018 Audited
Short-term investments	$ 104,511	$ 105,256

The estimated fair value of the Company's short-term investments as of June 30, 2019 and December 31, 2018 was $ 104,564 and $ 105,266 , respectively.

We use quoted market prices to determine the fair value of cash equivalents and short-term investments, therefore they are categorized as level 1.

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 June 30, 2019 and December 31, 2018, the Company's inventories were composed of:

	June 30, 2019 Unaudited	December 31, 2018 Audited
Raw materials	$ 3,431	$ 870
Work in progress	9,116	8,667
Finished products	12,907	13,018
Total	$ 25,454	$ 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 six months ended June 30, 2019, totaled $2,374. Future minimum lease payments under non-cancelable operating leases as of June 30, 2019, are as follows:

	June 30, 2019 Unaudited
Future minimum lease payments:	
2019 (excluding the six months ended June 30, 2019)	$ 2,265
2020	4,116
2021	3,826
2022	2,927
2023	1,899
Thereafter	3,695
Total future minimum lease payments	$ 18,728
Less imputed interest	(3,198)
Net present value of future minimum lease payments	$ 15,530
Presented as of June 30, 2019:	
Short-term lease liabilities	$ 3,948
Long-term lease liabilities	11,582
Net present value of future minimum lease payments	$ 15,530
Weighted average of remaining operating lease term	5.24
Weighted average of operating lease discount rate	7.44%

The right-of-use assets are presented net of $684 in deferred rents.

Pledged deposits and bank guarantees. As of June 30, 2019 and December 31, 2018, the Company pledged bank deposits of $ 1,143 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 $ 1,307 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 June 30, 2019, 11,986,679 ordinary shares were available for grant under the 2015 Plan.

A summary of the status of the Company's option plans as of June 30, 2019 and changes during the period then ended is presented below:

	Six months ended June 30, 2019 Unaudited	
	Number of options	Weighted average exercise price
Outstanding at beginning of year	14,438,215	$ 13.56
Granted	1,411,781	47.40
Exercised	(3,837,716)	9.91
Forfeited and cancelled	(86,223)	16.87
Outstanding as of June 30, 2019	11,926,057	$ 18.72
Exercisable options	4,348,026	$ 13.82

For the six months, ended June 30, 2019, options to purchase 3,837,716 ordinary shares were exercised, resulting in the issuance of 3,837,716 ordinary shares.

A summary of the status of the Company's RSUs as of June 30, 2019 and changes during the period then ended is presented below:

	Six months ended June 30, 2019 Unaudited	
	Number of RSUs	Weighted average grant date fair value price
Unvested at beginning of year	1,613,197	$ 14.04
Granted	540,294	47.26
Vested	(723,554)	12.99
Forfeited and cancelled	(9,427)	29.18
Unvested as of June 30, 2019	1,420,510	$ 27.11

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 June 30, 2019 , 3,078,989 ordinary shares were available to be purchased by eligible employees under the ESPP and 390,614 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:

	Six months ended June 30,		Year ended December 31,
	2019	2018	2018
	Unaudited		Audited
Stock Option Plans			
Expected term (years)	5.50-6.50	5.50-6.25	5.50-6.25
Expected volatility	55%-57%	52%-55%	52%-55%
Risk-free interest rate	2.21%-2.40%	2.70%-2.89%	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 and six months ended June 30, 2019 and 2018 and the year ended December 31, 2018 was:

	Three months ended June 30,		Six months ended June 30,		Year ended December 31,
	2019	2018	2019	2018	2018
	Unaudited		Unaudited		Audited
Cost of revenues	$ 595	$ 263	$ 1,021	$ 428	$ 1,261
Research, development and clinical trials	1,813	1,286	3,001	2,192	4,709
Sales and marketing	3,255	1,893	5,217	3,329	7,393
General and administrative	8,069	6,764	14,142	12,777	26,483
Total share-based compensation expense	$ 13,732	$ 10,206	$ 23,381	$ 18,726	$ 39,846

NOTE 6: SUPPLEMENTAL INFORMATION

The Company operates in a single reportable segment.

The following table presents long-lived assets by location:

	June 30, 2019	December 31, 2018
	Unaudited	Audited
United States	$ 8,152	$ 8,289
Switzerland	2,852	2,513
Israel	2,473	2,236
Germany	871	1,054
Others	1,517	1,274
Total	$ 15,865	$ 15,366

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

	Three months ended June 30,		Six months ended June 30,		Year ended December 31,
	2019	2018	2019	2018	2018
	Unaudited		Unaudited		Audited
United States	$ 58,934	$ 41,935	$ 105,538	$ 79,738	$ 168,414
EMEA (*)	22,505	18,522	45,025	32,396	72,485
Japan	4,185	1,057	7,555	1,505	6,351
Greater China (1)	1,089	-	1,904	-	819
Total	$ 86,713	$ 61,514	$ 160,022	$ 113,639	$ 248,069
(*) including Germany	$ 22,139	$ 17,651	$ 42,377	$ 31,009	$ 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 (referred to in this table as "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 June 30, 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 adoption of Optune and the NovoTTF-100L System ("NovoTTF-100L"), our commercial Tumor Treating Fields delivery systems, and to advance programs testing the efficacy and safety of Optune and NovoTTF-100L in multiple solid tumor indications through our clinical pipeline.

We have built a commercial organization in the United States, Austria, Germany, Israel, Japan, Sweden and Switzerland, which we refer to as our currently active markets. Optune is approved by the U.S. Food and Drug Administration ("FDA") under the Premarket Approval ("PMA") pathway for the treatment of adult patients with newly diagnosed glioblastoma ("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.

In May 2019, NovoTTF-100L received approval by the FDA under the Humanitarian Device Exemption ("HDE") pathway to treat unresectable, locally advanced or metastatic malignant pleural mesothelioma ("MPM") in combination with standard chemotherapies. We have initiated a phased launch for MPM shaped by our learnings from our GBM rollout. In 2019, we will focus on certifying radiation oncologists and driving adoption at the approximately 30 centers that we believe see the majority of U.S. MPM patients. We certified our first MPM prescribers in early June. Certifications are ongoing and information has been requested by multiple sites to support the required institutional review board approval. We expect our first MPM patient to start therapy in the third quarter. We are currently exploring the appropriate regulatory pathway for MPM in our currently active markets outside of the U.S.

We continue to work with payers to expand access to Optune for patients with GBM. As of June 30, 2019, more than 246 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 accepted our local coverage determination ("LCD") reconsideration request for the treatment of newly diagnosed GBM and planned to take steps to publish a final LCD for newly diagnosed GBM. In March 2019, the DME MACs met with a contractor advisory committee, 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).

In May 2019, the DME MACs issued a proposed LCD that provides coverage of Optune for newly diagnosed GBM, subject to certain restrictions. The proposed LCD was subject to a 45-day public comment period which closed in June 2019. The DME MACs released a final LCD and fee schedule amount in July 2019 which provides coverage and pricing of Optune for newly diagnosed GBM, effective September 1, 2019. In response to public comments, the final coverage criteria eliminated or revised many of the restrictions originally proposed.

In June 2019, the German Institute for Quality and Efficiency in Healthcare ("IQWiG"), published its rapid report concluding that, based on a review of our EF-14 phase 3 pivotal trial, patients with newly diagnosed GBM lived longer when treated with Optune in addition to standard chemotherapy, without affecting quality of life. According to the published timeline, we now expect a national reimbursement decision in Germany no later than October 2020.

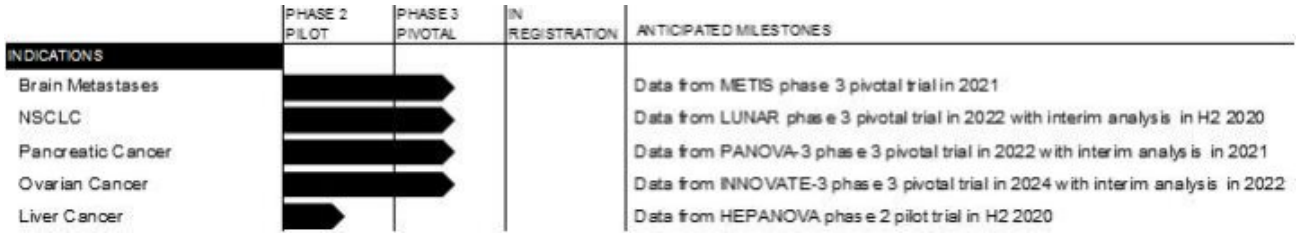
We expect to begin a dialogue with payers around access to NovoTTF-100L for patients with MPM in future quarters. We anticipate MPM claims during the early launch phase will go through an appeal process with payers, similar to our early experience with GBM.

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. The first trial, which we plan to begin as early as 2019, 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, which we plan to begin in 2020, 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. 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 now expect the LUNAR interim analysis in the second half of 2020, with final data from LUNAR in 2022.



We believe we have a robust patent and intellectual property portfolio, with over 145 issued patents and numerous patent applications pending worldwide covering global commercialization rights to Optune in oncology.

In 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 submitted to the Chinese regulatory authorities an application to designate Optune as an Innovative Medical Device and is pursuing a clinical trial waiver for the GBM indication in China. Should a clinical trial waiver be granted, Zai intends to launch Optune in China before the end 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 and six months ended June 30, 2019, our net revenues were $86.7 million and $160.0 million, respectively, and our net loss was $1.3 million and $13.4 million, respectively. As of June 30, 2019, we had an accumulated deficit of $657.1 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 and NovoTTF-100L 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 and second quarters 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 and NovoTTF-100L. 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.

Operating statistics	June 30, 2019	June 30, 2018
Active patients at period end (1)		
United States	1,846	1,575
EMEA (*)	737	557
Japan	143	37
Total	2,726	2,169
(*) including Germany	496	387

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Gross billings (in millions)	$ 170.1	$ 135.6	$ 328.0	$ 261.8
Prescriptions received in period (2)				
United States	989	947	1,914	1,893
EMEA (*)	299	265	629	547
Japan	74	32	129	62
Total	1,362	1,244	2,672	2,502
(*) including Germany	224	190	478	400

(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 June 30, 2019 compared to three months ended June 30, 2018

	Three months ended June 30,			
	2019	2018	Change	% Change
Net revenues	$ 86,713	$ 61,514	$ 25,199	41%

Net revenues. Net revenues increased $25.2 million, or 41%, to $86.7 million for the three months ended June 30, 2019 from $61.5 million for the three months ended June 30, 2018. This was primarily due to an increase of 557 active patients in our currently active markets, representing 26% growth, and an increase in net revenues per active patient. The increase in net revenues per active patient was primarily driven by improved reimbursement rates, which we believe are sustainable. The improved reimbursement rates also resulted in an additional benefit of approximately $5 million to second quarter net revenues, which we do not expect to be as significant in future quarters.

	Three months ended June 30,			
	2019	2018	Change	% Change
Cost of revenues	$ 21,106	$ 19,833	$ 1,273	6%

Cost of revenues. Our cost of revenues increased by $ 1.3 million, or 6 %, to $ 21.1 million for the three months ended June 30, 2019 from $ 19.8 million for the three months ended June 30, 2018 . The increase in cost of revenues was primarily due to the cost of shipping transducer arrays to a higher volume of commercial patients partially offset by a reduction in the cost of goods per active patient driven by ongoing efficiency initiatives and scale . Gross margin was 76 % for the three months ended June 30 , 2019 and 68 % for the three months ended June 30 , 2018.

Operating Expenses.

	Three months ended June 30,			
	2019	2018	Change	% Change
Research, development and clinical trials	$ 19,454	$ 11,362	$ 8,092	71%
Sales and marketing	23,708	19,196	4,512	24%
General and administrative	21,249	18,208	3,041	17%
Total operating expenses	$ 64,411	$ 48,766	$ 15,645	32%

Research, development and clinical trials expenses. Research, development and clinical trials expenses increased $8.1 million, or 71%, to $19.5 million for the three months ended June 30, 2019 from $11.4 million for the three months ended June 30, 2018. The change is primarily due to an increase in clinical trial and personnel expenses for our phase 3 pivotal trials and an increase in costs associated with medical affairs, regulatory matters and engineering.

Sales and marketing expenses. Sales and marketing expenses increased $4.5 million, or 24%, to $23.7 million for the three months ended June 30, 2019 from $19.2 million for the three months ended June 30, 2018. The change was primarily due to increased marketing expenses related to the launch of NovoTTF-100L for MPM and increased personnel costs.

General and administrative expenses. General and administrative expenses increased $3.0 million, or 17%, to $21.2 million for the three months ended June 30, 2019 from $18.2 million for the three months ended June 30, 2018. The change was primarily due to an increase in personnel costs and an increase in professional services.

	Three months ended June 30,			
	2019	2018	Change	% Change
Financial expenses (income), net	$ 1,239	$ 2,860	$ (1,621)	(57%)

Financial expenses, net. Financial expenses decreased $1.6 million, or 57%, to $1.2 million for the three months ended June 30, 2019 from $2.9 million for the three months ended June 30, 2018. The change was primarily due to interest income and the favorable impact of foreign exchange.

	Three months ended June 30,			
	2019	2018	Change	% Change
Income taxes	$ 1,227	$ 5,565	$ (4,338)	(78%)

Income taxes. Income taxes decreased $4.3 million, or 78%, to $1.2 million for the three months ended June 30, 2019 from $5.6 million for the three months ended June 30, 2018. The change was primarily a result of the mix of applicable statutory tax rates in certain active jurisdictions.

Six months ended June 30, 2019 compared to six months ended June 30, 2018

	Six months ended June 30,			
	2019	2018	Change	% Change
Net revenues	$ 160,022	$ 113,639	$ 46,383	41%

Net revenues. Net revenues increased $ 46.4 million, or 41 %, to $ 160.0 million for the six months ended June 30, 2019 from $ 113.6 million for the six months ended June 30, 2018 . This was primarily due to an increase of 557 active patients in our currently active markets, representing 26 % growth, and an increase in net revenues per active patient driven by a n improvement in reimbursement performance , which we believe is sustainable .

	Six months ended June 30,			
	2019	2018	Change	% Change
Cost of revenues	$ 40,920	$ 38,071	$ 2,849	7%

Cost of revenues. Our cost of revenues increased by $2.8 million, or 7%, to $40.9 million for the six months ended June 30, 2019 from $38.1 million for the six months ended June 30, 2018. The increase in cost of revenues was primarily due to the cost of shipping transducer arrays to a higher volume of commercial patients partially offset by a reduction in the cost of goods per active patient driven by ongoing efficiency initiatives and scale. Gross margin was 74% for the six months ended June 30, 2019 and 66% for the six months ended June 30, 2018.

Operating Expenses.

	Six months ended June 30,			
	2019	2018	Change	% Change
Research, development and clinical trials	$ 36,496	$ 22,466	$ 14,030	62%
Sales and marketing	46,041	37,331	8,710	23%
General and administrative	41,487	35,533	5,954	17%
Total operating expenses	$ 124,024	$ 95,330	$ 28,694	30%

Research, development and clinical trials expenses. Research, development and clinical trials expenses increased $14.0 million, or 62%, to $36.5 million for the six months ended June 30, 2019 from $22.5 million for the six months ended June 30, 2018. The change is primarily due to an increase in clinical trial and personnel expenses for our phase 3 pivotal trials and an increase in costs associated with medical affairs, regulatory matters and engineering.

Sales and marketing expenses. Sales and marketing expenses increased $8.7 million, or 23%, to $46.0 million for the six months ended June 30, 2019 from $37.3 million for the six months ended June 30, 2018. The change was primarily due to increased marketing expenses related to the launch of NovoTTF-100L for MPM and increases in our personnel costs associated with a larger sales force globally.

General and administrative expenses. General and administrative expenses increased $6.0 million, or 17%, to $41.5 million for the six months ended June 30, 2019 from $35.5 million for the six months ended June 30, 2018. The change was primarily due to an increase in personnel costs and an increase in professional services.

	Six months ended June 30,			
	2019	2018	Change	% Change
Financial expenses (income), net	$ 3,610	$ 7,713	$ (4,103)	(53%)

Financial expenses, net. Financial expenses decreased $4.1 million, or 53%, to $3.6 million for the six months ended June 30, 2019 from $7.7 million for the six months ended June 30, 2018. The change was primarily due to the 2018 accelerated amortization costs triggered by the repayment of our 2015 term loan credit facility, interest income and the favorable impact of foreign exchange, 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 .

	Six months ended June 30,			
	2019	2018	Change	% Change
Income taxes	$ 4,888	$ 8,759	$ (3,871)	(44%)

Income taxes. Income taxes de creased $ 3.9 million, or 44 %, to $ 4.9 million for the six months ended June 30, 2019 from $ 8.8 million for the six months ended June 30, 2018 . The change was primarily a result 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 June 30, 2019, we had an accumulated deficit of $657.1 million. To date, we have primarily financed our operations through the issuance and sale of equity and the proceeds from long-term loans. At June 30, 2019, we had $284.6 million in cash, cash equivalents and short-term investments, an increase of $38.7 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 cash flow from operations and the exercise of options .

We believe our cash, cash equivalents and short-term investments as of June 30, 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 our products 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 June 30, 2019, we had received a total of $824.3 million from these activities.

	Six Months Ended June 30,			
	2019	2018	Change	% Change
Net cash provided by (used in) operating activities	$ 4,751	$ (24,317)	$ 29,068	(120%)

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 provided by operating activities was $4.8 million for the six months ended June 30, 2019, as compared to $24.3 million used in operating activities for the six months ended June 30, 2018. Gross profit increased by $43.5 million for the six months ended June 30, 2019 versus the six months ended June 30, 2018, fully funding incremental investments of $14.0 million in research and development and $14.7 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, an increase in payables, and an increase in share-based compensation partially offset by an increase in inventories.

	Six Months Ended June 30,			
	2019	2018	Change	% Change
Net cash provided by (used in) investing activities	(2,737)	(2,699)	$ (38)	1%

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 $ 2.7 million for the six months ended June 30, 2019 , essentially flat compared to $ 2.7 million for the six months ended June 30, 2018 .

	Six Months Ended June 30,			
	2019	2018	Change	% Change
Net cash provided by (used in) financing activities	37,627	62,902	$ (25,275)	(40%)

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 $37.6 million for the six months ended June 30, 2019, as compared to $62.9 million for the six months ended June 30, 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 June 30, 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 have been no material changes from the information disclosed in our 2018 10-K.

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 June 30, 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 June 30, 2019, our Chief Executive Officer and Chief Financial Officer have concluded that, as of June 30, 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 June 30, 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.

In February 2019, a civil claim was filed in the District Court in Haifa, Israel (the "Court"), 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.

In May 2019, we filed a motion to dismiss the claim and the Plaintiff responded to our motion in June 2019. In July 2019, a preliminary hearing took place and the Plaintiff was given 30 days to advise the Court as to how it wishes to proceed. 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 we believe liability is not probable and the amount of any potential liability cannot be reasonably estimated.

Item 1A. Risk Factors

Any of the following risks could have a material adverse effect on our business, prospects, financial condition and results of operations. In any such case, the trading price of our ordinary shares could decline, and you could lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in our Annual Report on Form 10-K for the year ended December 31, 2018, including our consolidated financial statements and the related notes thereto, our quarterly reports on Form 10-Q, as well as our other filings with the SEC.

Risks relating to our business, our Tumor Treating Fields delivery systems, and our software and systems to support and optimize the delivery of Tumor Treating Fields (collectively, our "Products")

Our business and prospects depend heavily on Optune, which is currently approved only for the treatment of GBM, and NovoTTF-100L which is approved for the treatment of MPM. If we are unable to increase sales of our Products, obtain further regulatory approvals for and further commercialize our Products for the treatment of additional indications or are significantly delayed or limited in doing so, our business and prospects will be materially harmed.

To date we have received FDA regulatory approval under the PMA pathway and certain approvals in other jurisdictions for the use of Optune for treatment of adult patients with newly diagnosed GBM in combination with temozolomide (a form of chemotherapy and for treatment of adult patients with recurrent GBM. We have also affixed a CE mark to Optune for certain indications in the EU. We have also received FDA approval under the HDE pathway to market NovoTTF-100L for unresectable, locally advanced or metastatic, malignant pleural mesothelioma in combination with standard chemotherapies. However, such approvals and the CE mark affixed to Optune do not guarantee future revenues for these indications. Further, until we receive FDA and analogous approval in other jurisdictions for the use of our Products for other indications, almost all of our revenues will derive from sales of Optune for the treatment of newly diagnosed and recurrent GBM or NovoTTF-100L for MPM. The commercial success of our Products and our ability to generate and maintain revenues from the use of our Products will depend on a number of factors, including:

- our ability to obtain additional regulatory approvals for and further commercialize our Products;
- our ability to develop, obtain regulatory approval for and commercialize our Products for additional indications;
- the acceptance of our Products by patients and the healthcare community, including physicians and third-party payers (both private and public), as therapeutically effective and safe;
- the relative cost, safety and efficacy of alternative therapies;
- our ability to obtain and maintain sufficient coverage or reimbursement by private and public third-party payers;

- the ability of our third-party manufacturers to manufacture our Products in sufficient quantities with acceptable quality;
- our ability to provide marketing, distribution and customer support for our Products;
- results of future clinical studies relating to our Products or other competitor products for similar indications;
- compliance with applicable health care and cybersecurity laws and regulations;
- the maintenance of our existing regulatory approvals in the U.S., the EU, Japan and other jurisdictions; and
- the consequences of any reportable adverse events involving our Products occurring in the U.S., the EU, Switzerland, Israel, Japan or other jurisdictions.

In addition, the promotion of our Products is limited to approved indications, which vary by geography, and the FDA label for Optune is limited in certain respects (for example, it is not approved for use in the brain stem, is not approved for use as monotherapy in newly diagnosed GBM and is limited for use by adults ages 22 and older), which may reduce the number of patients to whom it may be prescribed. Similarly, the label for NovoTTF-100L also contains certain limitations which may adversely affect adoption, including the requirement to display on all marketing materials that the efficacy of the product has not been established, and a limitation on use by adults ages 22 and older only.

In addition to our Products, our ability to generate future revenues will depend on achieving regulatory approval of, and eventual commercialization of, our Products for additional indications. However, obtaining regulatory approval of our Products for additional indications is not guaranteed. Our near-term prospects are substantially dependent on our ability to obtain regulatory approvals on the timetable we have anticipated, and thereafter to further successfully commercialize our Products for additional indications. Regulatory changes or actions in which we operate or propose to operate may further affect our ability to obtain regulatory approvals on the anticipated timetable. If we are not able to receive such approvals or to further commercialize our Products, or are significantly delayed or limited in doing so, our business and prospects will be materially harmed and we may need to delay our initiatives or even significantly curtail operations.

To date, we have incurred substantial operating losses.

We were founded in 2000 and have incurred substantial operating losses to date. In assessing our prospects, you must consider the risks and difficulties frequently encountered by companies in new and rapidly evolving markets, particularly companies engaged in the development and sales of oncology products. These risks include our ability to:

- continue to develop and enhance our Products;
- obtain regulatory approval to commercialize our Products for additional indications and enhance or modify our Products;
- increase our sales, marketing and distribution organization to commercialize our Products;
- perform pre-clinical and clinical research, engineering research and development and clinical trials on our Products and Tumor Treating Fields;
- establish and increase awareness and acceptance of our Products;
- implement and successfully execute our business and marketing strategy;
- respond effectively to competitive pressures and developments;
- maintain, protect and expand our intellectual property portfolio;
- operate in compliance with applicable health care and cybersecurity laws and regulations;
- expand our presence in our key markets;
- attract, retain and motivate qualified personnel; and
- grow our organization to support our operations and our clinical pipeline and expand commercialization efforts.

We anticipate continuing to incur significant costs associated with commercializing our Products for approved indications including product sales, marketing, manufacturing and distribution expenses . 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 . Our expenses could increase beyond expectations if, for example, we are required by the FDA, or other regulatory agencies to change manufacturing processes for our Products, or to perform clinical, nonclinical or other types of studies in addition to those that we currently anticipate. Our revenues are dependent, in part, upon the size of the markets in the jurisdictions in which we receive regulatory approval, the accepted price for our Products and the ability to obtain reimbursement at such price. If the number of addressable patients is not as significant as we estimate, the indications approved by regulatory authorities is narrower than we expect or the eligible population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenues. If we are not able to generate significant revenues, we may never become profitable.

If we do not achieve our projected research and development and commercialization goals in the timeframes we announce or expect, our results of operations would be adversely affected and we may need to raise additional capital to fund our operations.

For planning purposes, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings in the U.S. and other jurisdictions and the receipt of regulatory approvals in such jurisdictions. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of the achievement of these milestones can vary dramatically from our estimates, in many cases for reasons beyond our control, depending on numerous factors, including:

- the rate of progress, costs and results of our research and development activities and clinical trials;
- our ability to identify and engage appropriate health care professionals to conduct our clinical trials;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- the extent of scheduling conflicts with participating clinicians and clinical institutions;
- the occurrence of adverse events during clinical trials;
- the occurrence of adverse events due to a cybersecurity breach involving our Products;
- the receipt of approvals by our competitors of competing products and by us of our Products for additional indications;
- our ability to achieve coverage and reimbursement milestones with private and governmental third-party payers;
- our ability to access sufficient, reliable and cost-effective supplies of components used in the manufacture of our Products, including the batteries, transducer arrays and other materials;
- our ability to develop and maintain a sales and marketing organization and/or enter into sales and marketing collaborations for our Products; and
- changes in regulations and other actions by regulators.

For example, our key milestones include clinical development and regulatory milestones for the use of our Products to treat brain metastases, non-small cell lung cancer, pancreatic cancer and ovarian cancer. We can provide no assurance that we will achieve these milestones on our expected timetable, or at all.

If we do not achieve these milestones in the timeframes we expect and generate substantial revenues, and/or if we are unable to obtain sufficient additional funds through financings, the proceeds from long-term loans, strategic collaborations or the license or sale of certain of our assets on a timely basis when necessary, we may be required to reduce expenses by delaying, reducing or curtailing the development of our Products and we may need to raise additional capital to fund our operations, which we may not be able to obtain on favorable terms, if at all. If we fail to commence or complete, or experience delays in or are forced to curtail, our proposed clinical programs or otherwise fail to adhere to our projected development milestones in the timeframes we announce or expect (or within the timeframes expected by analysts or investors), or we fail to raise any required additional capital, any of such events could have a

material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. We will need to generate significant revenues to achieve profitability, and we may never do so.

We may not be successful in our efforts to create a pipeline of future indications for our Products and successfully commercialize them.

We are pursuing clinical development of our Products to treat a variety of solid tumors. For these future indications, we are at varying stages of development and we generally do not have relevant regulatory approvals to market our Products for these indications. Further, we do not currently intend to pursue indications involving solid tumors of the throat or extremities, and we do not believe our Products would be efficacious for non-solid tumor cancers like lymphoma or other blood cancers.

Even if we are successful in continuing to build our pipeline, obtaining regulatory approvals and commercializing our Products for additional indications are susceptible to risks of failure, including the significant risk that the development of our Products for any potential indications will fail to demonstrate adequate efficacy or an acceptable safety profile, to gain regulatory approval and/or to become commercially viable. We cannot provide any assurance that we will be able to advance any of these additional indications through the development and commercialization process. Our research programs may initially show promise in addressing additional indications, yet fail to yield approvals or commercialization for many reasons, including the following:

- we may not be able to assemble sufficient resources to pursue clinical trials for additional indications;
- our Products may not succeed in preclinical or clinical testing for additional indications;
- our Products may, on further study be shown to have harmful side effects for other indications or other characteristics that indicate they are unlikely to be effective or otherwise do not meet applicable regulatory criteria for such indications;
- competitors may develop alternative treatments that render our Products obsolete or less attractive;
- the market for our Products may change so that the continued development of our pipeline as currently contemplated is no longer appropriate;
- we may not be able to produce our Products for current and future indications in commercial quantities at an acceptable cost, or at all;
- our Products may not meet standards set by applicable regulatory authorities to obtain approval or clearance to market our Products for additional indications;
- our Products may not be accepted as safe, effective, convenient, cost-effective or otherwise desirable by patients, the medical community, regulatory authorities or third-party payers.

If any of these events occur, we may be forced to delay or abandon our development efforts for our anticipated pipeline, which would have a material adverse effect on our business and prospects and could potentially cause our stock price to decline and cause us to cease operations. Moreover, any such events regarding the use of our Products in any particular indication may have a negative effect on the approval process for other indications and/or result in losing or delaying approval of our Products for other indications, which may exacerbate the harm to our business and prospects.

If we encounter difficulties enrolling patients in our clinical trials, our clinical trials could be delayed or otherwise adversely affected.

The timely completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the severity of the disease under investigation;
- the limited size and nature of the patient population;
- the patient eligibility criteria defined in our protocol and other clinical trial protocols;

- the nature of the trial protocol, including the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects;
- clinicians' and patients' perceptions as to the potential advantages and side effects of our Products in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are pursuing;
- availability of other clinical trials that exclude use of our Products;
- the possibility or perception that enrolling in a Product's clinical trial may limit the patient's ability to enroll in future clinical trials for other therapies due to protocol restrictions;
- the possibility or perception that our software is not secure enough to maintain patient privacy;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the availability of appropriate clinical trial investigators, support staff and proximity of patients to clinical sites;
- physicians' or our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will choose to withdraw from or otherwise not be able to complete a clinical trial.

Patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive follow-up to assess the safety and effectiveness of our Products, or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competing products. In addition, the inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events for reasons that may not be related to our Products, or, in those trials where our Products are being tested in combination with one or more other therapies, for reasons that may be attributable to the other therapies, but which can nevertheless negatively affect clinical trial results. If we have difficulty enrolling a sufficient number or diversity of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business.

If we are unable to continue the development of an adequate sales and marketing organization or contract with third parties to assist us, we may not be able to successfully commercialize our Products for current and future indications .

To achieve commercial success for our Products, we must continue to develop and grow our sales and marketing organization and, as necessary, enter into sales and distribution relationships with third parties to market and sell our Products. Developing and managing a sales and marketing organization is a difficult, expensive and time consuming process. To be successful we must:

- recruit and retain adequate numbers of effective and experienced sales personnel;
- effectively train our sales personnel in the benefits and risks of our Products;
- establish and maintain successful sales, marketing and education programs that educate health care providers so they can appropriately inform their patients about our Products; and
- manage geographically disbursed sales functions and marketing campaigns.

We may not be able to successfully develop adequate sales and marketing capabilities to achieve our growth objectives. We will have to compete with other medical device, pharmaceutical and life sciences companies to recruit, hire, train and retain the sales and marketing personnel that we anticipate we will need. In addition, because some of our current Products require, and we anticipate our future Products will require, physician training and education, our sales and marketing organization must grow substantially as we expand our approved indications and markets. As a consequence, our expenses associated with building up and maintaining our sales force and marketing capabilities may be disproportionate to the revenues we may be able to generate on sales of our Products.

If we are unable to establish adequate sales and marketing capabilities or successful sales and distribution relationships, we may fail to realize the full revenue potential of our Products for current and future indications, and we may not be able to achieve the necessary

growth in a cost-effective manner or realize a positive return on our investment. If we establish sales and distribution agreements with other companies, we may not have control over the resources or degree of effort that any of these third parties may devote to Optune, and if they fail to devote sufficient time and resources to the marketing of Optune, or if their performance is substandard, it will adversely affect our revenues.

The success of our business may be dependent on the actions of our collaborative partners.

Our global business strategy includes, in part, the consummation of collaborative arrangements with companies who will support the development and commercialization of our products and technology in return for royalties on commercial sales and milestone payments for progress in clinical development, regulatory approval and sales targets. For example, we have exclusively licensed rights to commercialize our Products in the field of oncology in Greater China to Zai pursuant to an agreement that also establishes a development partnership for Tumor Treating Fields in multiple solid tumor indications. Zai is responsible for the development and commercialization of our Products in Greater China at its sole cost with certain assistance from us.

When we collaborate with a third party for development and commercialization of a Product in a particular territory, we can expect to relinquish some or all of the control over the future success of that Product to the third party in such territory. In addition, our collaborative partners may have the right to abandon research or development projects and terminate applicable agreements, including payment obligations, prior to or upon the expiration of the agreed upon terms. We may not be successful in establishing or maintaining collaborative arrangements on acceptable terms or at all, collaborative partners may terminate funding before completion of projects, our Products may not achieve the criteria for milestone payments, our collaborative arrangements may not result in successful product commercialization and we may not derive any revenue from such arrangements. To the extent that we are not able to develop and maintain collaborative arrangements, we would need to devote substantial capital to undertake development and commercialization activities on our own in order to further expand our global reach, and we may be forced to limit the territories in which we commercialize our Products.

Reliance on collaborative relationships poses a number of risks, including the following:

- our collaborators may not perform their obligations as expected or in compliance with applicable laws;
- the prioritization, amount and timing of resources dedicated by our collaborators to their respective collaborations with us is not under our control;
- some Products with respect to which we collaborate may be viewed by our collaborators as competitive with their own product candidates or products;
- our collaborators may elect not to proceed with the development of Products that we believe to be promising;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development or commercialization, might cause delays or termination of the research, development or commercialization of Products, might lead to additional responsibilities for us with respect to Products, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- some of our collaborators might develop independently, or with others, products that could compete with our Products;
- a delay in the development or regulatory approval timelines for our Products in the Zai Territory would result in a potential delay or loss of milestone payments and future royalties (if any) from the partnership under the collaboration agreement with Zai; and
- if the Zai Agreement is terminated for any reason, then we may need to establish a new development and commercialization partnership to further our Products in Greater China. There can be no assurance that we would be able to find such a partner.

We may not be successful in achieving market acceptance of our Products by healthcare professionals, patients and/or third-party payers in the timeframes we anticipate, or at all, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

Our business model is predicated on achieving market acceptance of our Products as a monotherapy or in combination with well-established cancer treatment modalities like surgery, radiation and pharmacological therapies. We may not achieve market acceptance of our Products for current or future indications in the amount of time that we have anticipated, or at all, for a number of different reasons, including the following factors:

- it may be difficult to gain broad acceptance of our Products because it is a new technology and involves a novel mechanism of action, and as such physicians may be reluctant to prescribe our Products without prior experience or additional data or training;
- physicians may be reluctant to prescribe our Products due to their perception that the clinical trials are not appropriately designed as they are, for example, unblinded;
- physicians at large academic universities may prefer to enroll patients into clinical trials instead of prescribing our Products;
- it may be difficult to gain broad acceptance at community hospitals where the number of patients seeking cancer treatment may be more limited than at larger medical centers, and such community hospitals may not be willing to invest in the resources necessary for their physicians to become trained to use our Products, which could lead to reluctance to prescribe our Products;
- patients may be reluctant to elect to use our Products for various reasons, including a perception that the treatment is untested or difficult to use (for example, they will need to shave the areas on their bodies where the arrays are applied) or a perception that our software is not secure;
- our Products may have side effects (for example, dermatitis where the transducer arrays are placed) and our Products cannot be worn in all circumstances (for example, they cannot get wet and are difficult to wear in high temperatures); and
- the price of our Products includes a monthly fee for use of the delivery system; therefore, as the duration of the treatment course increases, the overall price will increase correspondingly, and, when used in combination with other treatments, the overall cost of treatment will be greater than using a single type of treatment.

In particular, our Products may not achieve market acceptance for current or future indications because of the following additional factors:

- achieving patient acceptance is difficult because GBM and MPM are devastating diseases with poor prognoses, and not all patients with potentially short lifespans are willing to comply with requirements of treatment with our Products, such as the need to use our Products for at least 18 hours per day, carrying around a device and shaving the area where the arrays are worn (which, for GBM is the head, and may be of particular concern), and other patients may forego our Products for privacy, cosmetic visibility or mobility reasons;
- achieving patient compliance is difficult because the recommended average daily use of our Products is at least 18 hours a day, requiring patients to wear the delivery system nearly continuously, which to some extent restricts physical mobility because the battery must be frequently exchanged and recharged, and the patient or a caregiver must ensure that it remains continuously operable;
- certain patients are not advised to use our Products, including patients who have an active electronic medical device, which include deep brain stimulators, spinal cord stimulators, vagus nerve stimulators, pacemakers, defibrillators and programmable shunts, because the use of our Products with these devices has not been tested and may lead to malfunctioning of these devices; patients who have a skull defect or bullet fragments are also not advised to use our Products because the use of our Products with these conditions has not been tested and may lead to tissue damage or render our Products ineffective; and patients who are sensitive to conductive hydrogels because skin contact with the gel used in our Products for patients that are sensitive to conductive hydrogels may commonly cause increased redness and itching, and in rare instances may lead to severe allergic reactions, such as shock or respiratory failure;

- the need to wear our Products nearly continuously (recommended at least 18 hours per day) in order to achieve maximum efficacy of our Products may also impact the pool of patients to whom physicians may be willing to prescribe treatment, as physicians may be reluctant to prescribe our Products for patients who are physically frail or lack caregiver support. Efficacy may also be limited in instances where patients take a break from the delivery system when experiencing skin rashes, while bathing or swimming (because our Products cannot get wet), or while traveling; and
- adverse events reported in clinical trials by GBM and MPM patients treated with our Products as monotherapy include medical device site reaction, headache, malaise, muscle twitching, fall and skin ulcer; additional adverse events reported in clinical trials by GBM and MPM patients treated with our Products in combination with chemotherapies in addition to the above, were thrombocytopenia, nausea, constipation, vomiting, fatigue and other side effects consistent with treatment with chemotherapies.

In addition, even if we are successful in achieving market acceptance of our Products for GBM or MPM, we may be unsuccessful in achieving market acceptance of our Products as a treatment for other solid tumor cancers, such as brain metastases, NSCLC, pancreatic cancer, ovarian cancer and other solid tumor cancers, because certain radiation, chemotherapies and/or systemic medical therapies may become or remain the preferred standard of care for these indications.

There may be other factors that are presently unknown to us that also may negatively impact our ability to achieve market acceptance of our Products. If we do not achieve market acceptance of our Products in the timeframes we anticipate, or are unable to achieve market acceptance at all, our business, prospects, financial condition and results of operations could be materially adversely affected, and our stock price could decline.

Failure to secure and maintain adequate coverage and reimbursement from third-party payers could adversely affect acceptance of our Products and reduce our revenues.

We expect that the vast majority of our revenues will come from third-party payers either directly to us in markets where we provide our Products or plan to provide our delivery system candidates to patients or indirectly via payments made to hospitals or other entities providing our Products or which may in the future provide our delivery system candidates to patients.

In the U.S., private payers cover the largest segment of the population, with the remainder either uninsured or covered by governmental payers. We anticipate that the majority of the third-party payers outside the U.S. will be government agencies, government sponsored entities or other payers operating under significant regulatory requirements from national or regional governments.

Third-party payers may decline to reimburse for procedures, supplies or services not under coverage policies. Additionally, some third-party payers may decline to reimburse us for a particular patient even with the existence of a coverage policy. Additionally, private commercial and government payers may be permitted to consider the cost of a treatment in approving coverage or in setting payment for the treatment.

Private and government payers around the world are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of governments around the world. Adoption of additional price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our revenues and operating results. If third-party payers do not consider our Products or the combination of our Products with additional treatments to be cost-justified under a required cost-testing model, they may not cover our Products for their populations or, if they do, the level of payment may not be sufficient to allow us to sell our Products on a profitable basis.

Reimbursement for the treatment of patients with medical devices around the world is governed by complex mechanisms established on a national or sub-national level in each country. These mechanisms vary widely among countries and evolve constantly, reflecting the efforts of these countries to reduce public spending on healthcare. As a result, obtaining and maintaining reimbursement for the treatment of patients with medical devices has become more challenging globally. We cannot, therefore, guarantee that the treatment of patients with our Products or the use of software and systems to support and optimize the delivery of treatment with our Products would receive reimbursement approvals and cannot guarantee that our existing reimbursement approvals will be maintained in any country.

We provide financial assistance to patients in certain markets who qualify based on established financial criteria. Primarily, we provide financial assistance to patients where we have or are actively pursuing reimbursement coverage. This financial assistance is intended to defray out-of-pocket costs for our Products for patients who begin treatment but who are unable to pay for the costs of their treatment not covered by insurance. Our costs associated with this program could increase if payers increase the cost-sharing burden of patients or we do not obtain reimbursement coverage and we elect to continue providing financial assistance in those markets. Additionally we provide charitable donations to foundations that can then provide financial assistance to those receiving health care coverage from federal or state funded programs. Changes to government regulations related to manufacturer-sponsored patient assistance programs that could reduce our ability to support patients financially could ultimately reduce clinical use of our Products.

Our failure to secure or maintain adequate coverage or reimbursement for our Products or the use of software and systems to support and optimize the delivery of treatment with our Products by third-party payers in the U.S. or in the other jurisdictions in which we market our Products could have a material adverse effect on our business, revenues and results of operations and cause our stock price to decline.

We may not be successful in securing and maintaining reimbursement codes necessary to facilitate accurate and timely billing for our Products or physician services attendant to our Products.

Third-party payers, healthcare systems, government agencies or other groups often issue reimbursement codes to facilitate billing for products and physician services used in the delivery of medicine. Within the U.S., the billing codes most directly related to our Products are contained in the Healthcare Common Procedure Coding System ("HCPCS code set"). The HCPCS code set contains Level I codes that describe physician services, also known as Common Procedural Terminology codes ("CPT codes") and Level II codes that primarily describe products. The CMS is responsible for issuing the HCPCS Level II codes. The American Medical Association issues HCPCS Level I codes.

We have secured unique HCPCS Level II codes that describe Optune and we are able to use these codes in the U.S. to bill third-party payers. Loss of these codes or any alteration in the payment attached to these codes would materially impact our operating results. We do not have a unique HCPCS Level II code for NovoTTF-100L at this time.

Although we are attempting to secure CPT codes, no CPT codes currently exist to describe physician services related to the delivery of our Products therapy. We may not be able to secure CPT codes for physician services related to our Products based on the relatively low incidence of GBM. Our future revenues and results may be affected by the absence of CPT codes, as physicians may be less likely to adopt the therapy when not adequately reimbursed for the time, effort, skill, practice expense and malpractice costs required to provide the therapy to patients.

We have not secured codes to describe our Products, the use of software and systems to support and optimize the delivery of treatment with our Products or to document physician services related to the delivery of our Products in markets outside the U.S. The absence of these codes may affect the future growth of our business.

There is no assurance that Medicare or the Medicare Administrative Contractors will provide coverage or adequate payment rates for our Products.

To date, approximately 20-25% of patients using Optune in the U.S. were beneficiaries under the Medicare fee-for-service program. We anticipate the majority of patients with mesothelioma will be beneficiaries under the Medicare fee-for-service program. Failure to secure coverage and adequate payment from Medicare would reduce our revenues and may also affect the coverage and payment decisions of other third-party payers in the U.S.

Medicare has the authority to issue national coverage determinations or to defer coverage decisions to its regional Medicare Administrative Contractors ("MACs"). Medicare has not issued a national coverage determination for any of our Products. Medicare classifies Optune and NovoTTF-100L as durable medical equipment ("DME"). The fact that only two MACs administer the entire DME program may negatively affect our ability to petition individual medical policy decision-makers at the MACs for coverage. The absence of a positive coverage determination from Medicare or the DME MACs would materially affect our future revenues.

Additionally, Medicare has the authority to publish the price of durable medical equipment products. Medicare may publish prices for our Products that do not reflect then-current prices for our Products. Medicare price schedules are frequently referenced by private payers in the U.S. and around the world. Medicare could materially reduce our revenues and operating results by publishing prices for our Products below established prices of our Products with non-Medicare payers in the U.S. and our other active markets .

Medicare has assigned the billing codes describing Optune to the DME category for products that require frequent and substantial servicing. DME items in this billing category are billed monthly and payment is not capped after a time period. Medicare could materially reduce our revenues and operating results by revising its payment category classifications for our Products.

CMS implemented a demonstration project in 2012 to require prior authorization for certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies items. Claims for services that did not receive prior authorization before they were rendered will be automatically denied. In the event Medicare adds one of our Products to the list of items requiring prior authorization that may reduce our ability to bill and secure payment for patients who would otherwise be covered to use our Product under the Medicare fee-for-service program.

Medicare issued a revised Program Integrity Manual, specifically chapter 13, in 2018 with new guidance to the MACs on the development of local coverage determinations ("LCD") policies. The Medicare guidance imposes a series of requirements on the MACs, including a requirement to form contractor advisory committees to review new LCDs and to subject almost all LCD revisions to a public comment period. These requirements will likely slow the process for LCD revisions, and may delay coverage for our Products in future indications.

The Medicare fee-for-service program has denied coverage for our claims to date. Although we are actively appealing these coverage denials, we are unable to bill our existing Medicare fee-for-service patients for amounts not paid by Medicare. Therefore, we are absorbing and may continue to absorb the costs of treatment for amounts not paid by Medicare.

We appeal Medicare coverage denials through the Medicare appeals process: redetermination by a MAC, reconsideration by a Qualified Independent Contractor, hearing before an Administrative Law Judge, or ALJ, at the Office of Medicare Hearings and Appeals, review by the Medicare Appeals Council, and judicial review in U.S. District Court. Currently, there is a considerable backlog of appeals at the ALJ level and there are significant delays in the assignment of ALJ cases. Thus, we anticipate that, even if we are successful in winning our appeals, we will experience a significant delay in securing payment for Medicare patients when Medicare's DME MACs deny coverage for patients who start therapy.

We depend on single-source suppliers for some of our components. The loss of these suppliers could prevent or delay shipments of our Products, delay our clinical trials or otherwise adversely affect our business.

In certain jurisdictions, we source some of the key components of our Products from only a single vendor. If any one of these single-source suppliers were to fail to continue to provide components to us on a timely basis, or at all, our business and reputation could be harmed. Our policy is to seek second-source suppliers, but we can provide no assurance we will secure or maintain such suppliers. We are in the process of developing and obtaining regulatory approval for second sources for critical materials in all jurisdiction s. Various steps must be taken before securing these suppliers, including qualifying these suppliers in accordance with regulatory requirements , but we may never receive such approvals.

Establishing additional or replacement suppliers for any components of our Products, and obtaining any additional regulatory approvals required to add or replace suppliers, will take a substantial amount of time and could result in increased costs and impair our ability to produce our Products, which would have a material adverse effect on our business, prospects, financial condition and results of operations. We may have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or other regulatory authorities, or to comply with the Essential Requirements laid down in Annex I to the Directive 93/42/EEC concerning medical devices, commonly known as the Medical Devices Directive, which are the minimum requirements governing design and manufacturing in the EU. The risks associated with the failure of our suppliers to comply with strictly enforced regulatory requirements as described below are exacerbated by our dependence on single-source suppliers. Furthermore, since some of these suppliers are located outside of the U.S., we are subject to export laws in other jurisdictions and U.S. import and customs regulations, which complicate and could delay shipments of components to us. Changes in U.S. social, political, regulatory and economic conditions or in laws and policies governing foreign trade, manufacturing, development and investment in the territories and countries where we may develop and sell products, and any negative sentiments towards the U.S. as a result of such changes, could adversely affect our business.

If we experience any deficiency in the quality of, delay in or loss of availability of any components supplied to us by third-party suppliers, or if we have to switch to replacement suppliers, we may face additional regulatory delays and the manufacture and delivery of our Products would be interrupted for an extended period of time, which could materially adversely affect our business, prospects, financial condition and results of operations. In addition, we may be required to obtain prior regulatory approval if we use different suppliers or components. Such changes could affect our FDA regulatory approvals and the compliance of our Products with the Essential Requirements laid down in Annex I to the Medical Devices Directive and the validity of our current CE Certificates of Conformity. If we are required to obtain prior regulatory approval from the FDA or regulatory authorities in other jurisdictions or to conduct a new conformity assessment procedure and obtain new CE Certificates of Conformity in the EU to use different suppliers or components for our Products, regulatory approval or the CE Certificates of Conformity for our Products may not be received on a timely basis, or at all, which would have a material adverse effect on our business, prospects, financial condition and results of operations.

Quality control problems with respect to delivery systems and components supplied by third-party vendors could have a material adverse effect on our reputation, our clinical trials or the commercialization of our Products and, as a result, a material adverse effect on our business, prospects, financial condition and results of operations.

Our Products, which are manufactured by third parties, are highly technical and are required to meet exacting specifications. Any quality control problems that we experience with respect to the delivery systems and components supplied by third-party vendors could have a material adverse effect on our reputation, our attempts to complete our clinical trials, our operating expenses or the commercialization of our Products. The failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action, including warning letters, product recalls, suspension or termination of distribution, product seizures or civil penalties. If we experience any delay or deficiency in the quality of products supplied to us by third-party suppliers, or if we have to switch to replacement suppliers, we may face additional regulatory delays and the manufacture and delivery of our Products would be interrupted for an extended period of time, which would materially adversely affect our business, prospects, financial condition and results of operations.

If the third parties on which we rely to conduct our clinical trials and to assist us with preclinical research and development do not perform as contractually required or expected, we may not be able to obtain regulatory approvals for or commercialize our Products.

We do not have the ability to independently conduct some of our preclinical and all of our clinical trials for our Products and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators, contract laboratories and collaborative partners, to conduct such trials. We and these third parties are required to comply with current good clinical practices ("cGCPs") which are regulations and guidelines enforced by the FDA and comparable regulatory authorities in other jurisdictions for clinical development. We and these third parties are also required to comply with current good laboratory practices ("cGLPs") which are regulations and guidelines enforced by the FDA and comparable regulatory authorities in other jurisdictions for nonclinical laboratory studies. Regulatory authorities enforce these cGLPs and cGCPs through periodic inspections of trial sponsors, laboratories, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGLP and cGCP regulations, the

clinical data generated in our nonclinical studies and clinical trials may be deemed unreliable and the FDA or regulatory authorities in other jurisdictions may require us to perform additional nonclinical or clinical trials before approving our approved applications. We cannot be certain that, upon inspection or review of our files, such regulatory authorities will determine that any of our nonclinical studies or clinical trials comply with the applicable cGLP or cGCP regulations.

Any third parties conducting our nonclinical studies and clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting nonclinical studies, clinical studies or other cancer treatment development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our Products or successfully commercialize our Products on a timely basis, if at all, and our business, prospects and results of operations may be adversely affected.

Continued testing of our Products may not yield successful results and could reveal currently unknown safety hazards associated with our Products.

Our research and development programs are designed to test the safety and efficacy of our Products and Tumor Treating Fields through extensive preclinical and clinical testing. Even if our ongoing and future clinical trials are completed as planned, we cannot be certain that their results will support our claims or that the FDA and other regulatory authorities will agree with our conclusions. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and preclinical studies. The clinical trial process may fail to demonstrate that our delivery system candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a delivery system candidate and may delay development of others. It is also possible that patients enrolled in clinical trials will experience adverse side effects that have not been previously observed. In addition, our preclinical studies and clinical trials for our delivery system candidates involve a relatively small patient population and, as a result, these studies and trials may not be indicative of future results.

We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent further commercialization of our Products, including the following:

- safety and efficacy results for our Products obtained in our preclinical and clinical testing may be inconclusive or may not be predictive of results obtained in future clinical trials, following long-term use or in much larger populations;
- unanticipated adverse events may occur during our clinical trials;
- the data collected from our clinical trials may not reach statistical significance due to limited sample size or otherwise not be sufficient to support FDA or other regulatory approval; and
- our Products and software and systems to support and optimize the delivery of treatment with our Products may not produce the desired effect or may result in adverse health effects or other characteristics that are not currently known that may preclude additional regulatory approval or result in additional limitations to commercial use if approved.

To date, patients treated with our Products in our clinical trials have experienced treatment-related side effects, including dermatitis (including mild to moderate skin irritation) where the transducer arrays are placed, headaches, weakness, falls, fatigue, muscle twitching and skin ulcers, along with traditional side-effects associated with the chemotherapeutic agents often co-administered with our Products. There may be additional side effects observed in future clinical trials and/or through real-world experience with patients using our Products. Undesirable side effects caused by our Products could cause us or regulatory authorities to interrupt, delay or terminate clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects.

If unacceptable side effects arise in the development of our Products for future indications, we could suspend or terminate our clinical trials or the FDA or other regulatory authorities could order us to cease clinical trials or deny approval of our delivery system candidates for any or all targeted indications, narrow the approved indications for use or otherwise require restrictive product labeling or marketing or require further clinical trials, which may be time-consuming and expensive and may not produce results supporting FDA or other regulatory approval of our Products in a specific indication. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our delivery system candidates to understand the side effect profiles for our clinical trials and upon any commercialization of our Products for future indications. Inadequate training in recognizing or managing the potential side effects of our Products could result in patient injury or death. Any of these occurrences may harm our business, prospects and financial condition significantly.

Any delay or termination of our clinical trials will delay the filing of our Products submissions for regulatory approvals and ultimately our ability to commercialize our Products and generate revenues. Furthermore, we may abandon our Products for indications that we previously believed to be promising. Any of these events could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

We face competition from numerous competitors, most of whom have far greater resources than we have, which may make it more difficult for us to achieve significant market penetration and which may allow our competitors to develop additional oncology treatments to compete with our Products.

The oncology market is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. Our Products primarily compete with radiation and pharmacological therapies. We may face additional competition as advancements are made in the field of anti-cancer therapies and as we enter additional oncological markets. To date, we have conducted clinical trials where our Products are used in combination with a certain subset of other anti-cancer therapies. Many of our competitors are large, well-capitalized companies with significantly greater market share and resources than we have. As a consequence, they are able to spend more aggressively on product development, marketing, sales and other initiatives than we can. Many of these competitors have:

- significantly greater name recognition and experience;
- established relations with healthcare professionals, patients and third-party payers;
- established distribution networks;
- additional product lines, and the ability to offer rebates or bundle products to offer higher discounts or more competitive pricing or other incentives to gain a competitive advantage; and/or
- greater financial and human resources for research and development, sales and marketing, patent litigation and/or acquisitions.

Although we believe our Products represents a treatment modality that can be used in combination with other cancer treatment modalities, our current competitors or other companies may at any time develop additional drugs and devices for the treatment of GBM, MPM, and other solid tumors that could be more effective than using our Products. If an existing or future competitor develops a product that proves to be superior or comparable to our Products, our revenues may decline. In addition, some of our competitors may compete by changing the price of their cancer treatments. If these competitors' products were to gain acceptance by healthcare professionals, patients or third-party payers, a downward pressure on prices could result. If prices were to fall, we may not be able to improve our gross margins or sales growth sufficiently to achieve profitability.

As we expand, we may experience difficulties managing our growth.

Our anticipated growth will place a significant strain on our management and on our operational and financial resources and systems. Failure to manage our growth effectively could materially adversely affect our business. Additionally, our anticipated growth will increase the demands placed on our suppliers, resulting in an increased need to carefully monitor the available supply of components and quality assurance. There is no guarantee that our suppliers will be able to support our growth. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

Because of the specialized nature of our business, the termination of relationships with our key employees, consultants and advisors may prevent us from developing our Products, conducting clinical trials, commercializing our Products and obtaining any necessary financing. Further, the inability to recruit and retain additional personnel may have an adverse effect on our ability to successfully operate our business.

We are highly dependent on members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements with each of our executive officers, any of them could leave our employment at any time. We do not have "key person" insurance on any of our employees. The loss of the services of one or more of our current employees might impede the achievement of our business objectives.

The competition for qualified personnel in the oncology field is intense, and we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. Our future success depends upon our ability to attract, retain and motivate highly skilled employees. In order to commercialize our Products successfully, we will be required to expand our workforce, particularly in the areas of research and development and clinical trials, sales and marketing and supply chain management. These activities will require the addition of new personnel and the development of additional expertise by existing management personnel. We face intense competition for qualified individuals from numerous pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions. We may not be able to attract and retain these individuals on acceptable terms or at all. Failure to do so would materially harm our business.

Changes in tax or other laws, regulations or treaties, changes in our status under U.S. or non-U.S. laws or adverse determinations by taxing or other governmental authorities could increase our tax burden or otherwise affect our financial condition or results of operations, as well as subject our shareholders to additional taxes.

The amount of taxes we pay is subject to a variety of tax laws in the various jurisdictions in which we and our subsidiaries are organized and operate. Our domestic and international tax liabilities are dependent on the location of earnings among these various jurisdictions. Such tax liabilities could be affected by changes in tax or other laws, treaties and regulations, as well as the interpretation or enforcement thereof by tax or other governmental entities in any relevant jurisdiction. The amount we pay in tax to any particular jurisdiction depends, in part, on the correct interpretation of the tax laws in such jurisdiction, and we have made a number of determinations as to the effect of such tax laws in our particular circumstances. In some cases, the determinations we have made as to the effect of the tax laws in a particular jurisdiction depend on the continuing effectiveness of administrative rulings we have received from the tax authorities in that jurisdiction, while in other cases, our determinations are based on the reasoned judgment of our tax advisors. Although we believe that we are in compliance with the administrative rulings we have received, that the assumptions made by our tax advisors in rendering their advice remain correct, and that as a result we are in compliance with applicable tax laws in the jurisdictions where we and our subsidiaries are organized and operate, a taxing authority in any such jurisdiction may challenge our interpretation of those laws and assess us or any of our subsidiaries with additional taxes.

Additionally, from time to time, proposals can be made and legislation can be introduced to change the tax laws, regulations or interpretations thereof (possibly with retroactive effect) of various jurisdictions or limit tax treaty benefits that, if enacted, could materially increase our tax burden, increase our effective tax rate or otherwise have a material adverse impact on our financial condition and results of operations. It is possible that these changes could adversely affect our business. While we monitor proposals and other developments that would materially impact our tax burden and effective tax rate and investigate our options accordingly, we could still be subject to increased taxation on a going forward and retroactive basis no matter what action we undertake if certain legislative proposals or regulatory changes are enacted, certain tax treaties are amended and/or our interpretation of applicable tax or other laws is challenged and determined to be incorrect. Any alternative interpretations of applicable tax laws asserted by a tax authority or changes in tax laws, regulations or accounting principles that limit our ability to take advantage of tax treaties between

jurisdictions, modify or eliminate the deductibility of various currently deductible payments, increase the tax burden of operating or being resident in a particular country, result in transfer pricing adjustments or otherwise require the payment of additional taxes, may have a material adverse effect on our cash flows, financial condition and results of operations

The termination or revision of any of our tax rulings or indirect tax exemptions that we have or may have in the future may have a material adverse effect on our cash flows, financial condition and results of operations.

We believe our ordinary shares should not be treated as stock of a passive foreign investment company, or PFIC, for U.S. federal income tax purposes in the current taxable year or in a future taxable year, but this conclusion is a factual determination that is made annually and thus may be subject to change. If we were to be treated as a PFIC, this could result in adverse U.S. federal income tax consequences to U.S. persons that hold our ordinary shares.

Based on the composition of our assets and the nature of our income, we believe that our shares should not be treated as stock of a PFIC for U.S. federal income tax purposes, but this conclusion is a factual determination that is made annually and thus may be subject to change.

A non-U.S. corporation will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which a specified percentage of its gross income is "passive income" or a specified percentage of its assets produce or are held for the production of passive income ("passive assets"), including cash. If we are treated as a PFIC, and a U.S. person that holds our ordinary shares, either directly or indirectly, did not make one of the applicable available elections, such U.S. person would be subject to adverse U.S. federal income tax consequences on distributions with respect to the ordinary shares to the extent the distributions are "excess distributions," which are generally distributions in excess of a normal rate of distribution as calculated for PFIC purposes. Gain realized on the sale or other disposition of the ordinary shares would generally not be treated as capital gain, but rather would be treated as if such U.S. person had realized such gain and certain "excess distributions" ratably over the holding period for the ordinary shares and would be taxed at the highest tax rate in effect for each such year to which the gain was allocated, together with an interest charge in respect of the tax attributable to each such year. Partial redemptions would also be treated as excess distributions. We will, upon request from any shareholder, prepare and provide information as necessary for "qualified electing fund" elections but we make no representation as to the availability of "mark to market" elections that may mitigate the consequences of our being a PFIC to any U.S. investor. Prospective U.S. investors should consult their own U.S. tax advisors regarding the potential application of the PFIC rules.

Product liability suits, whether or not meritorious, could be brought against us due to alleged defective delivery systems or for the misuse of our Products. These suits could result in expensive and time-consuming litigation, payment of substantial damages and an increase in our insurance rates.

If our current or future delivery systems are defectively designed or manufactured, contain defective components or are misused, or if someone claims any of the foregoing, whether or not meritorious, we may become subject to substantial and costly litigation. For example, we may be sued if our Products causes or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. This may occur if our Products are misused or damaged, has a sudden failure or malfunction (including with respect to safety features) or is otherwise impaired due to wear and tear. Even absent a product liability suit, malfunctions of the device or misuse by the physician or patient would need to be remedied swiftly in order to maintain continuous use and ensure efficacy of our Products.

Any product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the delivery system, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our Products. Even successful defense may require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our Products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;

- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any delivery system candidate; and
- a decline in our share price.

Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us. We may not have sufficient insurance coverage for all claims. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and could reduce revenues. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, if any, which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Even if our agreements with our manufacturers and suppliers entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Other future litigation and regulatory actions could have a material adverse impact on the Company.

From time to time, we may be subject to litigation and other legal and regulatory proceedings relating to our business or investigations or other actions by governmental agencies, including as described in Part I, Item 3 "Legal Proceedings" of this Annual Report on Form 10-K. No assurances can be given that the results of these or new matters will be favorable to us. An adverse resolution of lawsuits, arbitrations, investigations or other proceedings or actions could have a material adverse effect on our financial condition and results of operations, including as a result of non-monetary remedies. Defending ourselves in these matters may be time-consuming, expensive and disruptive to normal business operations and may result in significant expense and a diversion of management's time and attention from the operation of our business, which could impede our ability to achieve our business objectives. Additionally, any amount that we may be required to pay to satisfy a judgment, settlement, fine or penalty may not be covered by insurance. Subject to the Jersey Companies Law, our articles of association permit us to indemnify any director against any liability, to purchase and maintain insurance against any liability for any director and to provide any director with funds (whether by loan or otherwise) to meet expenditures incurred or to be incurred by such director in defending any criminal, regulatory or civil proceedings or in connection with an application for relief (or to enable any such director to avoid incurring such expenditure). In addition, we have entered into indemnification agreements with each of our directors, and we anticipate entering into indemnification agreements with each of our officers, to indemnify them against certain liabilities and expenses arising from their being a director to the maximum extent permitted by Jersey law. In the event we are required to make such payments to our directors, there can be no assurance that any of these payments will not be material.

Global economic, political and industry conditions constantly change and unfavorable conditions, particularly in Israel, may have a material adverse effect on our business and results of operations.

We are a global oncology treatment company with worldwide operations. Volatile economic, political and market conditions, such as political or economic instability, majority hostilities or acts of terrorism, in the regions in which we operate may have a negative impact on our operating results and our ability to achieve our business objectives. We may not have insight into economic and political trends that could emerge and negatively affect our business. In addition, significant or volatile changes in exchange rates between the U.S. dollar and other currencies may have a material adverse impact upon our liquidity, revenues, costs and operating results.

In particular, we have research facilities located in Israel, and certain key suppliers manufacture their goods in one physical location in Israel. Due to the high-conflict nature of this area, Israel could be subject to additional political, economic and military confines, which could result in a material adverse effect on our operations. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in the agreements.

The vote by the United Kingdom electorate in favor of the United Kingdom's exit from the EU could adversely impact our business, results of operations and financial condition.

The passage of the referendum on the United Kingdom's membership in the EU, referred to as "Brexit," in favor of the exit of the United Kingdom from the EU, could cause disruption to and create uncertainty surrounding our business, which could have an adverse effect on our business, financial results and operations. The timing of the proposed exit was initially scheduled for March 29, 2019. That deadline has been extended to October 31, 2019 to allow the parties to negotiate a withdrawal agreement, which has proven to be difficult. Discussions between the United Kingdom and the EU will continue to focus on withdrawal issues and transition agreements. However, limited progress to date in these negotiations and ongoing uncertainty within the government of the United Kingdom sustains the possibility of the United Kingdom leaving the EU without a withdrawal agreement and associated transition period in place, which is likely to cause significant market and economic disruption.

The ultimate effects of Brexit will depend on any agreements the United Kingdom makes to retain access to markets in the EU, either during a transitional period or more permanently.

Depending on the outcome of these negotiations, we could face new challenges in our operations, such as instability in global financial and foreign exchange markets, including volatility in the value of the British pound and European euro, and increased trade barriers, all of which could result in restrictions on the movement of capital within our organization, the mobility of our personnel and the potential future commercialization of our Products and could change our tax benefits or liabilities, any of which could have a material adverse effect on our business, results of operations or financial condition. At this time, we cannot predict the impact that an actual exit from the EU will have on our business generally and our UK and European operations more specifically, and no assurance can be given that our operating results, financial condition and prospects would not be adversely impacted by the result.

We are increasingly dependent on information technology systems and subject to privacy and security laws., Our software and systems to support and optimize the delivery of treatment with our Products, and our systems and infrastructure face certain risks, including from cyber security breaches and data leakage.

We increasingly rely upon technology systems and infrastructure. Our technology systems, including our Products, are potentially vulnerable to breakdown or other interruption by fire, power loss, system malfunction, unauthorized access and other events. Likewise, data privacy breaches by employees and others with both permitted and unauthorized access to our Products and our systems may pose a risk that PI may be exposed to unauthorized persons or to the public, or may be permanently lost. The increasing use and evolution of technology, including cloud-based computing, creates additional opportunities for the unintentional dissemination of information, intentional destruction of confidential information stored in our systems or in non-encrypted portable media or storage devices. We could also experience a business interruption, information theft of confidential information, or reputational damage from

industrial espionage attacks, malware or other cyber incidents, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party service providers or other business partners.

Additionally, we must comply with numerous laws and regulations governing the processing, collection, dissemination, access, use, sharing and security of protected patient information ("PI"). In the U.S., the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations (collectively, "HIPAA") provide data privacy and security provisions for safeguarding medical information. Additionally, states in the U.S. are enacting local privacy laws (e.g., California) In the EU, the GDPR has recently been enacted and is designed to harmonize data privacy laws for both patient and employee data across Europe and which replaced Directive 95/46/EC of the European Parliament and of the Council of October 24, 1995, and applicable national laws. The GDPR has added a number of strict data protection and security requirements for companies processing data of EU residents. In Israel, the Privacy Protection (Data Security) Regulations 5777-2017 were recently enacted which impose mandatory comprehensive data security and breach notification requirements on anyone who owns, manages or maintains a database containing personal data in Israel. Additionally, privacy laws are evolving in Japan.

While we have invested heavily in the protection of data and information technology and in related training, there can be no assurance that our efforts will prevent significant breakdowns, breaches in our systems or other cyber incidents or ensure compliance with all applicable security and privacy laws, regulations and standards, including with respect to third-party service providers that utilize sensitive personal information, including PI, on our behalf. Any such breakdown, breach, incident or failure to comply could expose us to a risk of loss of information, litigation, penalties, remediation costs and potentially significant liability to customers, employees, business partners and regulatory authorities, including, for example, under HIPAA in the United States and the GDPR in the European Union, and may ultimately have a material adverse effect upon our reputation, business, operations or financial condition. In addition, significant implementation issues may arise as we continue to consolidate and outsource certain computer operations and application support activities.

Disruption of critical information systems or material security breaches in our products may adversely affect our business and customer relations

Information technology helps us operate efficiently, develop and commercialize our products, interface with and support our customers, maintain financial accuracy and efficiency and produce our financial statements. The size and complexity of our computer systems, and scope of our geographic reach, make us potentially vulnerable to IT system breakdowns, internal and external malicious intrusion, cyberattacks and computer viruses. Because the techniques used to obtain unauthorized access, or to sabotage systems, change frequently and generally are not recognized until launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology infrastructure, then a security breach could subject us to, among other things, transaction errors, business process inefficiencies, the loss of customers, damage to our reputation, business disruptions or the loss of or damage to intellectual property. Such security breaches could expose us to a risk of loss of information, litigation, penalties, remediation costs and potentially significant liability to customers, employees, business partners and regulatory authorities, including, for example, under HIPAA in the United States and the GDPR in the European Union. If our data management systems do not effectively collect, secure, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, or human error, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations will be impaired. Any such impairment could materially and adversely affect our financial condition and results of operations.

We develop and commercialize hardware products that rely upon software to operate properly and software products that produce treatment data and confidential patient information. Additionally, we process sensitive personal data, including patient health information, in the normal course of operating our business. While we have implemented security measures to protect our hardware and software products and systems from unauthorized access, these measures may not be effective. A security breach, whether of our products, systems or third-party hosting services we utilize, could disrupt treatments being provided by our products, disrupt access to our customers' stored information, such as patient treatment data and health information, and could lead to the loss of, damage to or public disclosure of such data and information, including patient health information. Such an event could have serious negative consequences, including possible patient injury, regulatory action, fines, penalties and damages, reduced demand for our products, an

unwillingness of customers to use our products, harm to our reputation and brand and time-consuming and expensive litigation, any of which could have a material adverse effect on our financial results.

If we were to experience a significant security breach of our information systems or data, the cost associated with the investigation, remediation and potential notification of the breach to customers, including patients, and counterparties could be material. We carry a limited amount of insurance for cybersecurity liability, and our insurance coverage may be inadequate. In the future, our insurance coverage may be expensive or not be available on acceptable terms or in sufficient amounts, if at all.

Changes in our technology could result in impairment charges in future periods.

U.S. generally accepted accounting principles ("GAAP") require annual (or more frequently if events or changes in circumstances warrant) impairment tests of goodwill, intangible assets and other long-lived assets. Generally speaking, if the carrying value of the asset is in excess of the estimated fair value of the asset, the carrying value will be adjusted to fair value through an impairment charge. Circumstances such as changes in technology or in the way an asset is being used may trigger an impairment review. Any negative perception of such a deficit could have an adverse effect on the price of our ordinary shares and could impair our ability to obtain new financing or refinance existing indebtedness.

If any of our or our suppliers' or manufacturers' facilities are damaged or our clinical, research and development or other business processes interrupted, our business could be seriously harmed.

We conduct our business in a limited number of facilities in the U.S., Germany, Switzerland, the Netherlands, Israel and Japan. Damage or extended periods of interruption to our or our suppliers' or manufacturers' corporate, development or research facilities or delays in the transportation, import or export of finished goods or components due to fire, natural disaster, power loss, communications failure, unauthorized entry, terrorist attacks or other events could cause us to cease or delay development and/or delivery of our Products. Our internal computer systems may fail or suffer security breaches, which could result in a material disruption of our business. Our business may be seriously harmed by such delays and interruption.

Our research facilities are located in Israel, and certain key suppliers manufacture goods in physical locations in Israel. One of our key suppliers manufactures its goods in one physical location in Israel. Although our facilities have not sustained any damage from such attacks, this is a high conflict area and any future attacks and resulting damage could adversely affect our operations. In addition, our business insurance only covers certain specified events associated with war or terrorism in the Middle East, and may not cover all such events. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, this government coverage may not be maintained, or may be insufficient to cover all losses we incur, even if available. Any losses or damages incurred by us could have a material adverse effect on our business.

We have significant debt service obligations and may incur additional indebtedness in the future, which could adversely affect our financial condition and results of operations and our ability to react to changes in our business.

We currently have $150.0 million of principal indebtedness outstanding under our Loan and Security Agreement dated as of February 7, 2018, between us, as borrower, and BioPharma Credit PLC, as lender ("2018 Credit Facility"). We may incur additional indebtedness in the future. Our existing indebtedness and any additional indebtedness we may incur could require us to divert funds identified for other purposes for debt service and impair our liquidity position.

The fact that a substantial portion of our cash flow from operations could be needed to make payments on our indebtedness could have important consequences, including the following:

- increasing our vulnerability to general adverse economic and industry conditions or increased interests rates;
- reducing the availability of our cash flow for other purposes;
- limiting our flexibility in planning for or reacting to changes in our business and the markets in which we operate, which would place us at a competitive disadvantage compared to our competitors that may have less debt;

- limiting our ability to borrow additional funds for working capital, capital expenditures and other investments; and
- failing to comply with the covenants in our debt agreements could result in all of our indebtedness becoming immediately due and payable.

Our ability to obtain necessary funds through borrowing, as well as our ability to service our indebtedness, will depend on our ability to generate cash flow from operations. Our ability to generate cash is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control. If our business does not generate sufficient cash flow from operations or if future borrowings are not available to us under our 2018 Credit Facility or otherwise in amounts sufficient to enable us to fund our liquidity needs, our financial condition and results of operations may be adversely affected. Our inability to make scheduled payments on our debt obligations in the future would require us to refinance all or a portion of our indebtedness on or before maturity, sell assets or seek additional equity investment. We may not be able to take any of such actions on a timely basis, on terms satisfactory to us or at all.

Covenants in our debt agreements restrict our operational flexibility.

Our 2018 Credit Facility contains usual and customary restrictive covenants relating to the operation of our business, including restrictions on our ability:

- to incur or guarantee additional indebtedness;
- to incur or permit to exist certain liens;
- to enter into certain sale and lease-back transactions;
- to make certain investments, loans and advances;
- to effect certain mergers, consolidations, asset sales and acquisitions;
- to pay dividends on, or redeem or repurchase, capital stock, enter into transactions with affiliates or materially change our business; and
- to repay or modify certain other agreements with respect to other material indebtedness or modify our organizational documents.

Risks relating to regulation

Our delivery system candidates must undergo rigorous preclinical and clinical testing and we must obtain regulatory approvals, which could be costly and time-consuming and subject us to unanticipated delays or prevent us from marketing any delivery systems.

Our research and development activities, as well as the manufacturing and marketing of our Products and software and systems to support and optimize the delivery of treatment with our Products, are subject to regulation, including regulation for safety, efficacy and quality, by the FDA in the U.S. and comparable authorities in other countries. FDA regulations and the regulations of comparable regulatory authorities in other jurisdictions are wide-ranging and govern, among other things:

- the conduct of preclinical and clinical studies;
- product design, development, manufacturing and testing;
- product labeling;
- product storage and shipping;
- premarket clearance, approval and conformity assessment procedures;
- premarket clearance, approval and conformity assessment procedures for modifications introduced in marketed products;

- post-approval market surveillance and monitoring;
- reporting of adverse events or incidents and implementation of corrective actions, including product recalls;
- pricing and reimbursement;
- interactions with healthcare professionals;
- interactions with patients;
- advertising and promotion; and
- product sales and distribution.

Clinical testing can be costly and take many years, and the outcome is uncertain and susceptible to varying interpretations. Moreover, success in preclinical and early clinical trials does not ensure that large-scale trials will be successful or predict final results. Acceptable results in early trials may not be replicable in later trials. A number of companies in the oncology industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Negative or inconclusive results or adverse medical events during a clinical trial could cause it to be redone or terminated. In addition, failure to construct appropriate clinical trial protocols could result in the test or control group experiencing a disproportionate number of adverse events and could cause a clinical trial to be suspended, redone or terminated. We cannot be certain if or when the FDA, a regulatory agency in another jurisdiction or our notified body (a private organization designated in an EU member state to conduct conformity assessment procedures under the Medical Devices Directive) might request additional studies, under what conditions such studies might be requested, or what the size or length of any such studies might be. The clinical trials of our delivery system candidates may not be completed on schedule, the FDA, regulatory agencies in other jurisdictions or our notified body may order us to stop or modify our research, or these agencies or our notified body may not ultimately approve or issue a CE Certificate of Conformity for any of our delivery system candidates for commercial sale. While we have received regulatory approval for Optune for treatment of adult patients with recurrent GBM in the U.S., the FDA required us to initiate a post-approval study and we have met this requirement. The data collected from our clinical trials may not be sufficient to support regulatory approval in the U.S., Japan and other countries or to obtain CE Certificate of Conformity in the EU for our various future delivery system candidates. Even if we believe the data collected from our clinical trials are sufficient, the FDA, equivalent regulatory bodies in other jurisdictions and notified bodies have substantial discretion in the assessment and approval or conformity assessment processes and may disagree with our interpretation of the data. Our failure to adequately demonstrate the safety and efficacy of any of our delivery system candidates would delay or prevent regulatory approval in the U.S., Japan and other countries or the CE marking in the EU of our delivery system candidates, which could prevent us from achieving profitability.

We currently market Optune in the U.S., as well as the EU, Switzerland, Israel and Japan. We currently market NovoTTF-100L in the U.S. only. We intend to market Optune in a number of additional international markets. Although Optune has been approved for commercialization in Australia, Switzerland and Israel and is CE marked in the EU, in order to market Optune in other jurisdictions and for other indications, we must obtain separate regulatory approvals and CE Certificates of Conformity, as applicable. The requirements governing the conduct of clinical trials and manufacturing and marketing of our delivery system candidates outside the U.S. vary widely from country to country. CE Certificates of Conformity and regulatory approvals in other jurisdictions may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical trial designs. CE marking processes and regulatory approvals in other jurisdictions include essentially all of the risks associated with the FDA approval processes. Some regulatory agencies in other jurisdictions must also approve prices of the delivery systems. Approval of a product by the FDA does not ensure approval of the same product by the health authorities of other countries or CE marking of Optune in the EU and vice versa. In addition, changes in regulatory policy in the U.S. or in other countries for the approval or CE marking of a medical device during the period of product development and regulatory agency review or notified body review of each submitted new application may cause delays or rejections.

Upcoming changes in the EU rules governing the placing on the market of medical devices will have an impact on the CE marking of Optune and our delivery system candidates in the EU. In April 2017, the EU adopted the new Medical Devices Regulation, replacing the two existing directives, the Medical Devices Directive and the Active Implantable Medical Devices Directive. The new regulation will enter into force after a three-year transition period ending in spring 2020. When applicable, the regulations will change the

regulatory system for medical devices in the EU, which may prevent or delay the CE marking of our delivery system candidates or impact our ability to modify Optune for CE marking purposes on a timely basis.

We may choose to, or may be required to, suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's cGCPs and the equivalent laws and regulations applicable in other jurisdictions in which the clinical trials are conducted. The clinical trials are subject to oversight by the FDA, regulatory agencies in other jurisdictions, ethics committees and institutional review boards at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with delivery system candidates produced under the FDA's Quality System Regulation ("QSR") and in accordance with the applicable regulatory requirements in the other jurisdictions in which the clinical trials are conducted. The conduct of clinical trials may require large numbers of test patients. Patient enrollment is a function of many factors, including the size of the patient population for the target indication, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. Clinical trials may be suspended by the FDA or by a regulatory agency in another jurisdiction at any time if the FDA or the regulatory agency finds deficiencies in the conduct of these trials or it is believed that these trials expose patients to unacceptable health risks.

We, the FDA or regulatory agencies in other jurisdictions might delay or terminate our clinical trials of a delivery system candidate for various reasons, including:

- the delivery system candidate may have unforeseen adverse side effects;
- the time required to determine whether the delivery system candidate is effective may be longer than expected;
- we may not agree with the FDA, a regulatory authority in another jurisdiction or an ethics committee regarding the protocol for the conduct of a clinical trial;
- new therapies may become the standard of care while we are conducting our clinical trials, which may require us to revise or amend our clinical trial protocols or terminate a clinical trial;
- fatalities may occur during a clinical trial due to medical problems that may or may not be related to clinical trial treatments;
- the delivery system candidate may not appear to be more effective than current therapies;
- there may be insufficient patient enrollment in the clinical trials; or
- we may not be able to produce sufficient quantities of the delivery system candidate to complete the trials.

Furthermore, the process of obtaining and maintaining regulatory approvals in the U.S. and other jurisdictions and CE Certificates of Conformity in the EU for new therapeutic products is lengthy, expensive and uncertain. It can vary substantially, based on the type, complexity and novelty of the product involved. Accordingly, any of our delivery system candidates could take a significantly longer time than we expect to, or may never, gain regulatory approval or obtain CE Certificates of Conformity in the EU, which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

Healthcare reform and other legislative and regulatory changes in the U.S. and in other countries may adversely affect our business and financial results.

In response to perceived increases in healthcare costs in recent years, there have been and continue to be proposals by the U.S. federal government, state governments, regulators and third-party payers to control these costs and, more generally, to reform the U.S. healthcare system. In the U.S., the Patient Protection and Affordable Care Act (the "PPACA"), was enacted in 2010 with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers.

The current U.S. Administration and members of the U.S. Congress have stated that they will seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the PPACA. Since January 2017, the U.S. President has signed several executive orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements mandated by the PPACA, including directing executive departments and federal agencies to waive, defer, grant

exemptions from, or delay the implementation of the provisions of the PPACA to the maximum extent permitted by law. In December 2017, the U.S. President signed the Tax Cuts and Jobs Act, which, among numerous other actions, repealed the individual mandate of the PPACA, effective January 1, 2019. In December 2018, a federal district court in Texas ruled the individual mandate was unconstitutional and could not be severed from the PPACA. As a result, the court ruled the remaining provisions of the PPACA were also invalid, though the court declined to issue a preliminary injunction with respect to the PPACA. However, it remains unclear whether the court's ruling will be upheld by appellate courts. Additionally, while the House and Senate attempted, but failed, to pass legislation to comprehensively repeal the PPACA, these efforts may be resumed. Further legislative changes to and regulatory changes under PPACA also remain possible.

There is uncertainty with respect to the impact the U.S. Administration and any attempted legislation may have, if any, and any changes will likely take time to unfold and could have an impact on coverage and reimbursement for healthcare items and services, including our Products and our delivery system candidates. For example, PPACA requires that health insurance plans sold to individuals and small businesses provide coverage for "essential health benefits" ("EHBs"), which are defined according to state-specific benchmark plans. The Department of Health and Human Services issued a final rule that provides states with greater flexibility in how they select their EHB-benchmark plan, including providing states with substantially more options in what they can select as an EHB-benchmark plan and allowing states to build their own set of benefits as part of their EHB-benchmark plan, subject to certain requirements. Providing the states with this increased flexibility to define EHBs may have the effect of decreasing coverage for anti-cancer devices such as our Products.

In addition, other legislative changes have been proposed and adopted in the U.S. since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent statutory amendments, will continue through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act, was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals.

In June 2018 CMS updated language in the Medicare Claims Processing Manual that revised the manner in which CMS sets reimbursement rates for new DME devices not assigned to an existing HCPCS code. CMS previously set such reimbursement rates by using fees for comparable equipment or, if comparable equipment was not available, the supplier's list or retail price. Beginning in October 2018, when comparable equipment is not available, in addition to the supplier's list or retail price, CMS has also considered "verifiable information from supplier invoices and non-Medicare payer data" when setting reimbursement rates for new DME devices not assigned to an existing HCPCS code. In addition, in July 2018, CMS issued a request for information ("RFI") requesting stakeholder comments regarding potential additional changes to the manner in which CMS sets reimbursement rates for new DME devices not assigned to an existing HCPCS code. In November 2018, CMS published the comments it received in response to the RFI. It is not clear what additional changes, if any, CMS may institute to its DME reimbursement rates. To the extent Medicare makes a negative decision regarding the fees for our Products or declines to cover our Products, our business would be subject to material damage.

In 2017, CMS published the Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures final rule. This final rule aims to streamline the Medicare appeals process and includes changes such as permitting the designation of Medicare Appeals Council decisions as precedential, expanding the Office of Medicare Hearings and Appeals' available adjudicator pool, and simplifying proceedings when CMS or CMS contractors are involved, among others. The final rule became effective on March 20, 2017. We are monitoring the implementation of this final rule and cannot predict to what extent CMS may or may not use this final rule in denying coverage for our Products.

The process governing Medicare appeals and the significant backlog of appeals at the ALJ level was the subject of multi-year litigation. The litigation was adjudicated in November 2018 with the court ordering the Department of Health and Human Services to clear the backlog by 2022, and reach compliance with the 90-day timeline to decide ALJ cases by this time. We cannot provide any assurance that our outstanding ALJ appeals will be favorably decided, or that the Department of Health and Human Services will meet this deadline.

We believe that substantial uncertainty remains regarding the net effect of the PPACA, or its repeal and potential replacement, on our business, including uncertainty over how benefit plans purchased on exchanges will cover our Products, how the expansion or contraction of the Medicaid program will affect access to our Products, the effect of risk-sharing payment models such as Accountable Care Organizations and other value-based purchasing programs on coverage for our Products, and the effect of the general increase or decrease in Federal oversight of healthcare payers. The taxes imposed and the expansion in government's role in the U.S. healthcare industry under the PPACA, if unchanged, may result in decreased revenues, lower reimbursements by payers for our Products and reduced medical procedure volumes, all of which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Specifically, beginning in January 2013, PPACA imposed a 2.3% excise tax on the constructive sale price in the U.S. of certain medical devices by a manufacturer, producer or importer of such devices. This tax was initially suspended for two years beginning January 1, 2016 and ending December 31, 2017. New legislation was passed such that this tax will continue to be suspended until January 1, 2020.

Finally, in the U.S., there is increased focus on drug pricing, and the U.S. President, policy officials and lawmakers have expressed a clear interest in efforts to reduce prices for drugs and biologicals, further increase transparency around prices and price increases, lower out-of-pocket costs for consumers, and decrease spending on drugs by government programs. We expect regulatory changes and continued Congressional investigations and negative media attention in the coming months with respect to drugs reimbursed by federal healthcare programs. While the current focus is on pharmaceutical products, the scrutiny and concern with respect to rising healthcare costs could have a negative impact on our operations as well.

In the future, the U.S. Congress could also pass additional healthcare laws and CMS could implement regulatory changes. Further, various healthcare reform proposals have emerged at the state level. These laws and regulations could potentially affect coverage and reimbursement for our Products and our delivery system candidates. However, we cannot predict the ultimate content, timing or effect of any future federal or state healthcare initiatives or the impact any future legislation or regulation will have on us. The competent authorities in the EU member states, Switzerland, Israel, Japan, and other jurisdictions are increasingly active in their goal of reducing public spending on healthcare. We cannot, therefore, guarantee that the treatment of patients with our Products would be reimbursed in any particular country or, if successfully included on reimbursement lists will remain thereon. In May 2017, new rules governing medical devices in the EU were adopted which will take effect in May 2020 and will impose additional requirements on manufacturers of medical devices placed on the market in the EU. Failure to comply with these new requirements may affect our ability to market Optune in the EU.

We are subject to extensive regulation by the FDA and equivalent authorities in other jurisdictions, which could restrict the sales and marketing of our Products and could cause us to incur significant costs. In addition, we may become subject to additional regulation in other jurisdictions as we increase our efforts to market and sell Optune and future Products outside of the U.S.

We market and sell our Products, and expect to market and sell future Products, subject to extensive regulation by the FDA and numerous other federal, state and governmental authorities in other jurisdictions. These regulations are broad and relate to, among other things, the conduct of preclinical and clinical studies, product design, development, manufacturing, labeling, testing, product storage and shipping, premarket clearance and approval, conformity assessment procedures, premarket clearance and approval of modifications introduced in marketed products, post-market surveillance and monitoring, reporting of adverse events and incidents, pricing and reimbursement, interactions with healthcare professionals, interactions with patients, advertising and promotion and product sales and distribution. Although we have received FDA approval to market Optune in the U.S. for the treatment of adult patients with newly diagnosed GBM (in combination with temozolomide) and recurrent GBM and approval to market NovoTTF-100L for MPM, we will require additional FDA approval to market our Products for other indications. We may be required to obtain approval of a new PMA, HDE or PMA supplement application for modifications made to our Products. This approval process is costly and uncertain, and it could take one to three years, or longer, from the time the application is filed with the FDA. We may make modifications in the future that we believe do not or will not require additional approvals. If the FDA disagrees, and requires

new PMAs, HDEs, or PMA supplements for the modifications, we may be required to recall and to stop marketing the modified versions of our Products.

In addition, before our Products can be marketed in the EU, they must obtain a CE Certificate of Conformity from a notified body. New therapeutic uses of CE marked medical devices falling outside the scope of the current CE Certificate of Conformity require a completely new conformity assessment before the device can be CE marked and marketed in the EU for the new intended purpose.

These processes can be expensive and lengthy and entail significant fees. The process preceding CE marking of a medical device in the EU could also be expensive and lengthy and its outcome would be uncertain. We may make modifications in the future that we believe do not or will not require additional approvals or the notification of our notified body and potentially additional conformity assessment to permit the maintenance of our current CE Certificate of Conformity. If the competent authorities of the EU member states or our notified body disagree and require the conduct of a new conformity assessment procedure and the modification of the existing CE Certificate of Conformity or the issuance of a new certificate, we may be required to recall or suspend the marketing of the modified versions of Optune.

In Japan, new medical devices or new therapeutic uses of medical devices falling outside the scope of the existing approval by the MHLW require a new assessment and approval for each such new device or use. Accordingly, we may be required to obtain a new approval from MHLW before we launch a modified version of our Products or the use of our Products for additional indications. Approval time frames from the MHLW vary from simple notifications to review periods of one or more years, depending on the complexity and risk level of the device. In addition, importation into Japan of medical devices is subject to "Quality Management System (QMS) Ordinance," which includes the equivalent of "Good Import Practices" regulations in the U.S. As with any highly regulated market, significant changes in the regulatory environment could adversely affect our ability to commercialize Optune in Japan.

In the U.S. and other jurisdictions, we also are subject to numerous post-marketing regulatory requirements, which include regulations under the QSR related to the manufacturing of our Products, labeling regulations and medical device reporting regulations, which require us to report to the FDA or other regulatory authorities in other jurisdictions and notified bodies if our Products cause or contributes to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. In addition, these regulatory requirements may change in the future in a way that adversely affects us. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by the FDA or other regulatory authorities in other jurisdictions and notified bodies, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- patient notification, or orders for repair, replacement or refunds;
- voluntary or mandatory recall or seizure of our current or future delivery systems;
- administrative detention by the FDA or other regulatory authority in another jurisdiction of medical devices believed to be adulterated or misbranded;
- operating restrictions, suspension or shutdown of production;
- refusal or delay of our requests for PMA or analogous approval for new intended uses for or modifications to our Products;
- refusal or delay of our requests for PMA or analogous approval of new delivery systems;
- refusal or delay in obtaining CE Certificates of Conformity for new intended uses for or modifications to our Products;
- suspension, variation or withdrawal of the CE Certificates of Conformity granted by our notified body in the EU member states;
- operating restrictions;
- suspension or withdrawal of PMA or analogous approvals that have already been granted;

- refusal to grant export approval for our Products or any delivery system candidates; or
- criminal prosecution.

The occurrence of any of these events could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

Modifications to our Products may require approvals of new PMAs, HDEs, or PMA supplement applications, modified or new CE Certificates of Conformity and analogous regulatory approvals in other jurisdictions or even require us to cease promoting or to recall the modified versions of our Products until such clearances, approvals or modified or new CE Certificates of Conformity are obtained, and the FDA, regulatory authorities in other jurisdictions or our notified body may not agree with our conclusions regarding whether new approvals are required.

Any modification to a device approved through the PMA pathway that impacts the safety or effectiveness of the device requires submission to the FDA and FDA approval of a PMA supplement application or even a new PMA application, as the case may be. Likewise, substantial modifications to a device approved under an HDE may require further regulatory filings. The FDA requires a company to make the determination as to whether a new PMA, HDE or PMA supplement application is to be filed, but the FDA may review the company's decision. For example, in the past, we have made initial determinations that certain modifications did not require the filing of a new PMA or PMA supplement application and have notified the FDA of these changes in our PMA Annual Report, but after its review of our PMA Annual Report, the FDA requested that we submit these modifications to the FDA as a PMA supplement application. From time to time, we may make other changes to the delivery systems, software, packaging, manufacturing facilities and manufacturing processes and may submit additional PMA supplement applications for these changes. FDA may conduct a facility inspection as part of its review and approval process. In addition, it is possible that the FDA will require a human factors (user interface) study. It is also possible that the FDA may require additional clinical data. We can provide no assurance that we will receive FDA approval for these changes on a timely basis, or at all. We also may make additional changes in the future that we may determine do not require the filing of a new PMA or PMA supplement application. The FDA may not agree with our decisions regarding whether the filing of new PMAs or PMA supplement applications are required.

In addition, any substantial change introduced to a medical device CE marked in the EU or to the quality system review by our notified body requires a new conformity assessment of the device and can lead to changes to the CE Certificates of Conformity or the preparation of a new CE Certificate of Conformity. Substantial changes include, among others, the introduction of a new intended purpose of the device, a change in its design or a change in the company's suppliers. Responsibility for determination that a modification constitutes a substantial change lies with the manufacturer of the medical device. We must inform the notified body that conducted the conformity assessment of the Products we market or sell in the EU of any planned substantial changes to our quality system or changes to our Products which could affect compliance with the Essential Requirements laid down in Annex I to the Medical Devices Directive or the devices' intended purpose. The notified body will then assess the changes and verify whether they affect the Product's conformity with the Essential Requirements laid down in Annex I to the Medical Devices Directive or the conditions for the use of the device. If the assessment is favorable, the notified body will issue a new CE Certificate of Conformity or an addendum to the existing CE Certificate of Conformity attesting compliance with the Essential Requirements laid down in Annex I to the Medical Devices Directive. There is a risk that the competent authorities of the EU member states or our notified body may disagree with our assessment of the changes introduced to our Products. The competent authorities of the EU member states or our notified body also may come to a different conclusion than the FDA on any given product modification.

If the FDA disagrees with us and requires us to submit a new PMA or PMA supplement application for then-existing modifications and/or the competent authorities of the EU member states or our notified body disagree with our assessment of the change introduced in a product, we may be required to cease promoting or to recall the modified product until we obtain approval and/or until a new conformity assessment has been conducted in relation to the product, as applicable. In addition, we could be subject to significant regulatory fines or other penalties. Furthermore, our Products could be subject to recall if the FDA, analogous regulatory authorities in other jurisdictions, or the competent authorities of the EU member states or our notified body determine, for any reason, that our Products are not safe or effective or that appropriate regulatory submissions were not made. Any recall or requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenues and potential operating restrictions imposed by the FDA, analogous foreign regulatory authorities, or the competent

authorities of the EU member states or our notified body. Delays in receipt or failure to receive approvals, the loss of previously received approvals, the failure to conduct appropriate conformity assessments prior to CE marking of Optune, or the failure to comply with any other existing or future regulatory requirements, could reduce our sales, profitability and future growth prospects.

We will spend considerable time and money complying with federal, state and local rules, regulations and guidance in other jurisdictions in addition to FDA regulations, and, if we are unable to fully comply with such rules, regulations and guidance, we could face substantial penalties.

We are subject to extensive regulation by the U.S. federal government and the states and other countries in which we conduct our business. U.S. federal government healthcare laws apply when we submit a claim on behalf of a U.S. federal healthcare program beneficiary, or when a customer submits a claim for an item or service that is reimbursed under a U.S. federal government-funded healthcare program, such as Medicare or Medicaid. The laws that affect our ability to operate our business in addition to the Federal Food, Drug, and Cosmetic Act and FDA regulations include, but are not limited to, the following:

- the Federal Anti-Kickback Statute, which prohibits offering or providing remuneration of any kind with the intent to induce or reward referrals for items or services reimbursable by a federal healthcare program;
- the U.S. Federal False Claims Act which prohibits submitting false claims or causing the submission of false claims to the federal government;
- Medicare laws and regulations that prescribe requirements for coverage and payment, including the conditions of participation for DME suppliers, and laws prohibiting false claims or unduly influencing selection of products for reimbursement under Medicare and Medicaid;
- healthcare fraud statutes that prohibit false statements and improper claims to any third-party payer;
- the federal physician self-referral prohibition, commonly known as the Stark law, which prohibits physicians from referring Medicare patients to an entity for the provision of certain designated health services (including DME) if the physician (or a member of the physician's immediate family) has an impermissible financial relationship with that entity;
- the Federal Beneficiary Anti-Inducement Statute, which prohibits the offering of any remuneration to a beneficiary of Medicare, Medicaid or any other U.S. federally financed healthcare program that is likely to influence that beneficiary's choice of provider or supplier. This can include, but is not limited to, inappropriate provision of patient services including financial assistance. Recent government investigations have focused on this particular prohibition. There are established exceptions from liability, but we cannot guarantee that all of our practices will fall squarely within those safe harbors;
- similar state anti-kickback, false claims, insurance fraud and self-referral laws, which may not be limited to government-reimbursed items, as well as state laws that require us to maintain permits or licenses to distribute durable medical equipment;
- federal and state accreditation and licensing requirements applicable to DME providers and equivalent requirements in other jurisdictions;
- the U.S. Foreign Corrupt Practices Act, which can be used to prosecute companies in the U.S. for arrangements with physicians or other parties outside the U.S. if the physician or party is a government official of another country and the arrangement violates the law of that country;
- the Federal Trade Commission Act, the Lanham Act and similar federal and state laws regulating truthfulness in advertising and consumer protection;
- the federal Physician Payments Sunshine Act (the "Sunshine Act") and similar state and foreign laws, which require periodic reporting of payments and other transfers of value made to U.S.-licensed physicians, teaching hospitals, and other health care practitioners; and
- the laws and codes of practices applicable in the EU member states, Switzerland, Japan, Israel and other jurisdictions concerning the marketing and promotion of medical devices, interactions with healthcare professionals, interactions with patients and consumer protection, comparative advertising and unfair commercial practices, data protection (as outlined above), anti-corruption, bribery and reimbursement of medical devices.

The laws and codes of practices applicable to us are subject to evolving interpretations. Moreover, certain federal and state laws regarding healthcare fraud and abuse and certain laws in other jurisdictions regarding interactions with healthcare professionals and patients are broad and we may be required to restrict certain of our practices to be in compliance with these laws. Similar law exists in the EU, individual EU member states and other countries. These laws are complemented by EU or national profession al codes of practices. Healthcare fraud and abuse laws also are complex and even minor, inadvertent irregularities can potentially give rise to claims that a statute has been violated. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil penalties, including, for example, exclusion from participation as a supplier of delivery systems to beneficiaries covered by federal healthcare programs. For example, most states require us to maintain a license as a DME provider. The Medicare program requires that we maintain accreditation with an independent quality body. Loss of this accreditation would result in loss of our billing privileges to Medicare.

Federal and state governmental agencies and their agents, including DME MACs, may conduct audits of our operations, relating to covered items and services including those furnished to beneficiaries and health care providers. Private and government-funded managed care payors may conduct similar post-payment audits, in addition to our internal audits and monitoring. Depending on the nature of the conduct found in such audits and whether the underlying conduct could be considered systemic, the resolution of these audits could have a material adverse effect on our financial position and results of operations.

CMS contracts with Recovery Audit Contractors (RACs) on a contingency fee basis to conduct post-payment reviews to detect and correct improper payments in the Medicare fee-for-service program. The RAC program's scope includes managed Medicare plans and Medicaid claims. RAC denials are appealable; however, there currently are significant delays in the ALJ process, which could negatively impact our ability to appeal RAC payment denials. In addition, CMS employs various other program integrity contractors to perform post-payment audits of claims and identify overpayments, and state Medicaid agencies and other contractors have increased their review activities.

Any violation of these laws or equivalent laws and codes of practices in other jurisdictions regarding interactions with healthcare professionals and patients and bribery could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline. Similarly, if there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which likewise could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

In addition, although we believe that we have the required licenses, permits and accreditation to dispense our Products in the future, a regulator could find that we need to obtain additional licenses or permits. We also may be subject to audits, mandatory reaccreditation and other requirements in order to maintain our billing privileges. Failure to satisfy those requirements or successfully address any issues identified in an audit could cause us to lose our privileges to bill public and private payers. If we are required to obtain permits or licenses that we do not already possess, we also may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business, our prospects and our financial results. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

Because of the specialized nature of our business and unique legal and regulatory requirements in the medical device industry, a fully staffed regionally based health care compliance program is critical to ensure proactive risk identification and remediation.

An effective healthcare compliance program must be based on the seven elements of compliance (as outlined in the Office of Inspector General Guidance for Pharmaceutical Manufacturers 2013, which applies equally to medical device manufacturers) including: compliance oversight, auditing and monitoring, reporting and communications, investigations, corrective actions, standards and training. Compliance programs must be overseen by a Chief Compliance Officer and sufficient regional staff to operationalize the seven elements of compliance.

Our Chief Compliance Officer is also our General Counsel who works out of the U.S. office, with a staff of two other compliance professionals who also work out of the U.S. office. The Chief Compliance Officer and these compliance professionals have global

accountability for healthcare compliance in the U.S., Europe, Japan and Israel. Despite the strong compliance foundation that we have built, without regional compliance support in the regions in which we do business, risk could go undetected and we could be liable under the various laws as outlined above .

If we, our collaborative partners, our contract manufacturers or our component suppliers fail to comply with the FDA's QSR or equivalent regulations established in other countries, the manufacturing and distribution of our Products could be interrupted, and our Product sales and results of operations could suffer.

We, our collaborative partners, our contract manufacturers and our component suppliers are required to comply with the FDA's QSR and the equivalent quality system requirements imposed by the laws and regulations in other jurisdictions, which are a complex regulatory framework that covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our Products. All aspects of our supply chain are subject to periodic inspections and audits by the FDA, notified bodies and other regulatory authorities to ensure continuing compliance. We cannot assure you that our facilities or our contract manufacturers' or component suppliers' facilities would pass any future quality system inspection. If our or any of our contract manufacturers' or component suppliers' facilities fails a quality system inspection, the manufacturing or distribution of our Products could be interrupted and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse quality system inspection could force a suspension or shutdown of our packaging and labeling operations or the manufacturing operations of our contract manufacturers, and lead to suspension, variation or withdrawal of our regulatory approvals or a recall of our Products. If any of these events occurs, we may not be able to provide our customers with our Products on a timely basis, our reputation could be harmed and we could lose customers, any or all of which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

Our Products may in the future be subject to recalls that could harm our reputation, business and financial results.

The FDA and similar governmental authorities in other jurisdictions have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, governmental bodies in other jurisdictions have the authority to require the recall of our Products in the event of material deficiencies or defects in design or manufacture. Distributors and manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our manufacturers could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. Requirements for the reporting of product recalls to the competent authorities are imposed in other jurisdictions in which our Products are or would be marketed in the future. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or to the competent authorities of other countries. In the future, we may initiate voluntary recalls involving our Products that we determine do not require notification of the FDA or to other equivalent non-U.S. authorities. If the FDA or the equivalent non-U.S. authorities disagree with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA and the equivalent non-U.S. authorities could take enforcement action if we fail to report the recalls when they were conducted. Recalls of our Products would divert managerial and financial resources and could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

If our Products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA Medical Device Reporting regulations and the equivalent regulations applicable in other jurisdictions in which our Products are or may be marketed in the future, medical device manufacturers are required to report to the FDA and to the equivalent non-U.S. authorities information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA or to the equivalent authorities in other jurisdictions within the required timeframes, or at all, the FDA or the equivalent authorities in other jurisdictions could take enforcement action against us. Any such adverse event involving our Products also could result in future voluntary corrective actions, such as recalls or customer notifications,

or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our Products for unapproved or off-label uses.

Medical devices may be marketed only for the indications for which they are approved. Our promotional materials and training materials must comply with FDA regulations and other applicable laws and regulations governing the promotion of our Products in the U.S. and other jurisdictions. Currently, Optune is approved for treatment of adult patients with newly diagnosed GBM (in combination with temozolomide) and recurrent GBM in the U.S. and is approved for treatment of adult patients with GBM in Japan. In the EU and Switzerland, we have CE marked the Optune delivery system for the treatment of newly diagnosed GBM (in combination with temozolomide), recurrent GBM, and advanced NSCLC (in combination with standard-of-care chemotherapy). Optune is also approved in Israel and in Australia for the treatment of recurrent GBM and newly diagnosed GBM (in combination with temozolomide). The NovoTTF-100L System is only approved in the U.S. for the treatment of unresectable, locally advanced or metastatic MPM.

If the FDA or the competent authorities in other jurisdictions, including the EU member states, determine that our promotional materials or training constitutes promotion of an unapproved use, they could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled or warning letter, an injunction, seizure, civil fines and criminal penalties. It is also possible that authorities in other federal, state or national enforcement in other jurisdictions might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and the commercialization of our Products and future delivery systems would be impaired.

U.S. legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our delivery system candidates and to manufacture, market and distribute our Products after approval is obtained.

From time to time, legislation is drafted and introduced in the U.S. Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our Products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future delivery system candidates. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our Products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future delivery systems could make it more difficult and costly to obtain clearance or approval for new delivery systems, or to produce, market and distribute our Products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new delivery systems would have an adverse effect on our ability to expand our business in the U.S.

As a DME supplier, if we are found to have violated laws protecting the confidentiality of patient information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of federal and state laws protecting the confidentiality of certain PI and restricting the use and disclosure of PI, as well as data protection laws applicable in other jurisdictions, such as the EU member states.

In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under HIPAA. These privacy rules protect medical records and other personal information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose.

The collection and use of personal health data in the EU is governed by the GDPR, which is designed to harmonize data privacy laws for both patient and employee data across Europe, and national laws. The enactment of the GDPR requires us to make operational changes relating to our receipt and processing of personal data of EU residents . Important components of the new regulation include, but are not limited to, increased territorial scope; increased penalties up to 4% of annual gross revenue; stricter requirements for written privacy consent and notification language and specific and documented processes related to breach notification; right to be forgotten and right to access data; and assignment of a Data Protection Officer.

In Israel, the Privacy Protection (Data Security) Regulations 5777-2017 were recently enacted which impose mandatory comprehensive data security and breach notification requirements on anyone who owns, manages or maintains a database containing personal data in Israel. Additionally, privacy laws are evolving in Japan.

The protection of personal data is becoming increasingly securitized throughout the world. We have established a data privacy compliance program to comply with the various laws; however, the laws are constantly evolving as are the different enforcement landscapes. If we are found to be in violation of the privacy rules, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

We are affected by and subject to environmental laws and regulations that could be costly to comply with or that may result in costly liabilities.

We are subject to environmental laws and regulations, including those that impose various environmental controls on the manufacturing, transportation, storage, use and disposal of batteries and hazardous chemicals and other materials used in, and hazardous waste produced by, the manufacturing of our Products. We incur and expect to continue to incur costs to comply with these environmental laws and regulations. Additional or modified environmental laws and regulations, including those relating to the manufacture, transportation, storage, use and disposal of materials used to manufacture our Products or restricting disposal or transportation of batteries, may be imposed that may result in higher costs.

In addition, we cannot predict the effect that additional or modified environmental laws and regulations may have on us, our third-party suppliers of equipment, batteries and our Products or our customers. For example, we and our suppliers rely on an exemption from the European Directive 2011/65/EU relating to the restriction of the use of certain hazardous substances in electrical and electronic equipment relating to lead content in our transducer arrays. To the extent this exemption is revoked, it may have a material impact on our business and results of operations.

Regulations on the transportation of lithium ion batteries may affect our business.

Our Products uses lithium ion batteries. The transportation of lithium and lithium-ion batteries is regulated worldwide. Laws regulating the transportation of batteries have been and may be enacted which could impose additional costs that could harm our ability to be profitable.

Under recommendations adopted by the International Air Transport Association ("IATA"), our batteries currently require a Class 9 designation for transportation. Our larger first generation delivery system batteries must be properly packaged and labeled in order to be shipped by air transport as cargo. Our smaller second generation delivery system batteries can be shipped without the class 9 sticker if shipped with the device but require the class 9 sticker if shipped by air separately. The larger batteries are not allowed on passenger aircraft according to the IATA standards. The smaller batteries are allowed as carry on only and cannot be checked as luggage. Consequently, we offer to ship batteries for patients who are traveling by air.

If additional restrictions are put in place that limit our ability to ship our Products by air freight or on water borne cargo, it could have an adverse effect on our supply chain, our inventory management procedures and processes and our ability to fill prescriptions and service patients in a timely manner, which could have a material adverse effect on our business, prospects, financial condition and results of operations. In addition, compliance with future worldwide or IATA approval process and regulations could require significant time and resources from our technical staff and, if redesign were necessary, could delay the introduction of new products.

Risks relating to intellectual property

If we fail to protect, sustain, further build and enforce our intellectual property rights, including to our proprietary technology, trade secrets or know how, competitors may be able to develop competing therapies.

Our success depends, in part, on our ability to obtain and maintain protection for our Products and technologies under the patent laws or other intellectual property laws of the U.S. and other countries. The standards that the U.S. Patent and Trademark Office ("USPTO") and its counterparts in other jurisdictions use to grant patents are not always applied predictably or uniformly and can change. Consequently, we cannot be certain as to whether pending patent applications will result in issued patents, and we cannot be certain as to the type and extent of patent claims that may be issued to us in the future. Any issued patents may not contain claims that will permit us to stop competitors from using similar technology.

Our current intellectual property portfolio consists of over 140 issued patents. In the U.S. the patents have expected expiration dates between 2021 and 2037. As our patents expire we will be subject to additional risks. Patent expiration could adversely affect our ability to protect future product development and our competitors may develop and market competing products. We have also filed additional patent applications worldwide that may never be issued. Consequently, our operating results and financial position could be materially adversely affected. In addition, due to the extensive time needed to develop, test and obtain regulatory approval for our treatment therapies, any patents that protect our product candidates may expire early during commercialization. This may reduce or eliminate any market advantages that such patents may give us and harm our financial position. If we fail to develop and successfully launch new products prior to the expiration of patents for our existing products, our sales and achieving patient acceptance with respect to those products could decline significantly. We may not be able to develop and successfully launch more advanced replacement products before these and other patents expire.

Our existing and future patent portfolio also may be vulnerable to legal challenges. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. On September 16, 2011, President Obama signed into law the Leahy-Smith America Invents Act ("AIA") a significant patent law reform. The AIA implements a first-inventor-to-file standard for patent approval, changes the legal standards for patentability and creates a post-grant review system. As a result of the uncertainties of patent law in general, and surrounding the interpretation of the AIA in particular, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Any attempt to enforce our intellectual property rights may also be time-consuming and costly, may divert the attention of management from our business, may ultimately be unsuccessful or may result in a remedy that is not commercially valuable. Such attempts may also provoke third parties to assert claims against us or result in our intellectual property being narrowed in scope or declared to be invalid or unenforceable.

In addition, we rely on certain proprietary trade secrets, know-how and other confidential information. We have taken measures to protect our unpatented trade secrets, know-how and other confidential information, including the use of confidentiality and assignment of inventions agreements with our employees, consultants and certain contractors. It is possible, however, that these persons may breach or challenge the agreements, that our trade secrets may otherwise be misappropriated or that competitors may independently develop or otherwise discover our trade secrets. There is therefore no guarantee that we will be able to obtain, maintain and enforce the intellectual property rights that may be necessary to protect and grow our business and to provide us with a meaningful competitive advantage, and our failure to do so could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

The oncology industry is characterized by patent and other intellectual property litigation and disputes, and any litigation, dispute or claim against us may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our business, harm our reputation and require us to remove certain delivery systems from the market.

Whether a product infringes a patent or violates other intellectual property rights involves complex legal and factual issues, the determination of which is often uncertain. Any intellectual property dispute, even a meritless or unsuccessful one, would be time consuming and expensive to defend and could result in the diversion of our management's attention from our business and result in adverse publicity, the disruption of research and development and marketing efforts, injury to our reputation and loss of revenues. Any of these events could negatively affect our business, prospects, financial condition and results of operations.

Third parties may assert that Tumor Treating Fields, our Products, the methods employed in the use of our Products or other activities infringe on their patents. Such claims may be made by competitors seeking to obtain a competitive advantage or by other parties, many of whom have significantly larger intellectual property portfolios than we have. Additionally, in recent years, individuals and groups have begun purchasing intellectual property assets for the purpose of making claims of infringement and attempting to extract settlements from companies like ours. The risk of infringement claims is exacerbated by the fact that there are numerous issued and pending patents relating to the treatment of cancer. Because patent applications can take many years to issue, and in many cases remain unpublished for many months after filing, there may be applications now pending of which we are unaware that may later result in issued patents that our Products may infringe. There could also be existing patents that one or more components of our Products may inadvertently infringe. As the number of competitors in the market for the treatment of cancer grows, the possibility of inadvertent patent infringement by us or a patent infringement claim against us increases. To the extent we gain greater market visibility, our risk of being subject to such claims is also likely to increase.

If a third party's patent was upheld as valid and enforceable and we were found to be infringing, we could be prevented from making, using, selling, offering to sell or importing our Products or other delivery system candidates, unless we were able to obtain a license under that patent or to redesign our systems to avoid infringement. A license may not be available at all or on terms acceptable to us, and we may not be able to redesign our Products to avoid any infringement. Modification of our Products or development of delivery system candidates to avoid infringement could require us to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. If we are not successful in obtaining a license or redesigning our delivery systems, we may be unable to make, use, sell, offer to sell or import our delivery systems and our business could suffer. We may also be required to pay substantial damages and undertake remedial activities, which could cause our business to suffer.

We may also be subject to claims alleging that we infringe or violate other intellectual property rights, such as copyrights or trademarks, may have to defend against allegations that we misappropriated trade secrets, and may face claims based on competing claims of ownership of our intellectual property. The confidentiality and assignment of inventions agreements that our employees, consultants and other third parties sign may not in all cases be enforceable or sufficient to protect our intellectual property rights. In addition, we may face claims from third parties based on competing claims to ownership of our intellectual property.

We also employ individuals who were previously employed at other medical device companies, and as such we may be subject to claims that such employees have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of their former employers. Any such litigation, dispute or claim could be costly to defend and could subject us to substantial damages, injunctions or other remedies, which could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

The patent rights on which we rely to protect the intellectual property underlying our Products may not be adequate, which could enable third parties to use our technology or market competing products, which would harm our continued ability to compete in the market.

Our success will depend in part on our continued ability to develop or acquire commercially valuable patent rights and to protect these rights adequately. The scope of some of our patents is limited to certain ranges. For example, some of our patents protect low-intensity (1-3 V/cm) and intermediate frequency (100-300 kHz) alternating electric fields, but do not cover intensities and frequencies for electric fields that are outside of these ranges. While intensities and frequencies of electric fields outside of these ranges have not yet proven to be effective treatment modalities, that may not be the case in the future. Our patent position is generally uncertain and involves complex legal and factual questions. The risks and uncertainties that we face with respect to our patents and other related rights include the following:

- the pending patent applications we have filed may not result in issued patents or may take longer than we expect to result in issued patents;
- the pending patent applications and patents we own may be subject to interference proceedings or similar disputes over the priority of the inventions claimed;
- the claims of any patents that are issued may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;

- changes in patent laws or their interpretation in the U.S. and other countries (including the recently enacted AIA) could diminish the value of our patents, narrow the scope of our patent protection or adversely affect our ability to obtain new patents;
- obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements;
- other parties may challenge patents, patent claims or patent applications licensed or issued to us, and such patents, patent claims or patent applications may be narrowed or found to be invalid or unenforceable; and
- other companies may design around or expand upon technologies we have patented or developed.

We also may fail to apply for or be unable to obtain patent rights in some other countries. In addition, the legal systems of certain countries may not protect our rights to the same extent as the laws of the U.S., which could affect our ability to enforce patent rights effectively in such other countries. For a variety of reasons, we may decide not to file for patent protection for certain of our intellectual property. Our patent rights underlying Tumor Treating Fields and our Products may not be adequate, and our competitors or customers may design around our proprietary technologies or independently develop similar or alternative technologies or products that are equal or superior to ours without infringing on any of our patent rights. In addition, the patents licensed or issued to us may not provide a competitive advantage, and may be insufficient to prevent others from commercializing products similar or identical to ours. The occurrence of any of these events could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

We have limited intellectual property rights in other jurisdictions outside of our key markets and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside of our key markets. In some countries outside the U.S., we do not have any intellectual property rights, and our intellectual property rights in other countries outside the U.S. have a different scope and strength compared to our intellectual property rights in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement rights are not as strong as those in the U.S. These products may compete with our delivery systems, and our patents or other intellectual property rights may not be effective or adequate to prevent such competition.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our delivery systems.

As is the case with other medical device companies, our success is heavily dependent on our intellectual property rights, and particularly on our patent rights. Obtaining and enforcing patents in the medical device industry involves both technological and legal complexity, and is therefore costly, time consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could further negatively impact the value of our patents, narrow the scope of available patent protection or weaken the rights of patent owners.

Risks relating to our ordinary shares

The market price for our ordinary shares may be volatile, which could result in substantial losses to you.

The market price for our ordinary shares may be volatile and subject to wide fluctuations in response to factors such as publication of clinical studies relating to our Products, our other delivery system candidates or a competitor’s product, actual or anticipated fluctuations in our quarterly results of operations, changes in financial estimates by securities research analysts, negative publicity, studies or reports, changes in the economic performance or market valuations of other companies that operate in our industry, changes

in the availability of third-party reimbursement in the U.S. or other countries, changes in governmental regulations or in the status of our regulatory approvals or applications, announcements by us or our competitors of material acquisitions, strategic partnerships, joint ventures or capital commitments, intellectual property litigation, release of lock-up or other transfer restrictions on our outstanding ordinary shares, and economic or political conditions in the U.S., Israel or elsewhere. In addition, the performance, and fluctuation in market prices, of companies in other jurisdictions that have listed their securities in the U.S. may affect the volatility in the price of and trading volumes of our ordinary shares. Volatility in global capital markets, as was experienced during the global financial crisis beginning in 2008 and during the recent European sovereign debt crisis, as well as volatility resulting from the recent economic slowdown in Asia, could also have an adverse effect on the market price of our ordinary shares. Furthermore, the securities market has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price and liquidity of our ordinary shares.

Our ordinary shares are issued under the laws of Jersey, which may not provide the level of legal certainty and transparency afforded by incorporation in a U.S. state.

We are incorporated under the laws of the Bailiwick of Jersey, Channel Islands. Jersey legislation regarding companies is largely based on English corporate law principles. However, there can be no assurance that Jersey law will not change in the future or that it will serve to protect investors in a similar fashion afforded under corporate law principles in the U.S., which could adversely affect the rights of investors.

U.S. shareholders may not be able to enforce civil liabilities against us.

We are a Jersey entity with most of our assets located outside of the U.S. Although we have appointed an agent for service of process in the U.S. for purposes of U.S. federal securities laws, a number of our directors and executive officers and a number of directors of each of our subsidiaries are not residents of the U.S., and all or a substantial portion of the assets of such persons are located outside the U.S. As a result, it may not be possible for investors to effect service of process within the U.S. upon such persons or to enforce against them judgments obtained in U.S. courts predicated upon the civil liability provisions of the federal securities laws of the U.S.

We have been advised by our Jersey lawyers that the courts of Jersey would recognize any final and conclusive judgment under which a sum of money is payable (not being a sum payable in respect of taxes or other charges of a like nature or in respect of a fine or other penalty) obtained against us in the courts of any other territory in respect of certain enforceable obligations in accordance with the principles of private international law as applied by Jersey law (which are broadly similar to the principles accepted under English common law) and such judgment would be sufficient to form the basis of proceedings in the Jersey courts for a claim for liquidated damages in the amount of such judgment. In such proceedings, the Jersey courts would not re-hear the case on its merits save in accordance with such principles of private international law. Obligations may not necessarily be enforceable in Jersey in all circumstances or in accordance with their terms; and in particular, but without limitation: (i) any agreement purporting to provide for a payment to be made in the event of a breach of such agreement would not be enforceable to the extent that the Jersey courts were to construe such payment to be a penalty that was excessive, in that it unreasonably exceeds the maximum damages that an obligee could have suffered as a result of the breach of an obligation; (ii) the Jersey courts may refuse to give effect to any provision in an agreement that would involve the enforcement of any revenue or penal laws in other jurisdictions; and (ii) the Jersey courts may refuse to allow unjust enrichment or to give effect to any provisions of an agreement (including provisions relating to contractual interest on a judgment debt) that it considers usurious.

Our annual and quarterly results may fluctuate due to a number of factors and, as a result, could fall below investor expectations or estimates by securities research analysts, which may cause the trading price of our ordinary shares to decline.

Our revenues and results of operations are difficult to predict, and potentially may vary significantly from period to period. As a result of a number of factors, many of which are beyond our control, it is possible that results of operations for future periods may be below the expectations of public market analysts and investors, which could cause our stock price to decline. Factors that may affect our quarterly results include, but are not limited to:

- failure to obtain regulatory approval for our delivery systems;
- failure to effectively commercialize our delivery systems;

- competition; and
- changes in the laws and regulations that affect our operations.

As a result, investors should not rely on year-to-year or quarter-to-quarter comparisons of results of operations as an indication of future performance.

Substantial future sales of our ordinary shares in the public market, or the perception that such sales may occur, could cause the price of our ordinary shares to decline.

Sales of our ordinary shares in the public market, or the perception that these sales may occur, could cause the market price of our ordinary shares to decline. All ordinary shares sold in our IPO (other than any shares acquired by our affiliates) are freely transferable without restriction or additional registration under the Securities Act of 1933, as amended, or the Securities Act.

Our memorandum and articles of association contain anti-takeover provisions that could adversely affect the rights of holders of our ordinary shares.

Our amended and restated memorandum and articles of association, referred to as the memorandum and articles of association, contain certain provisions that could limit the ability of third parties to acquire control of our company, including a provision for a classified board of directors and a provision that grants authority to our board of directors to issue from time to time one or more classes of preferred shares without action by our shareholders and to determine, with respect to any class of preferred shares, the terms and rights of that class. The provisions could have the effect of depriving our shareholders of the opportunity to sell their ordinary shares at a premium over the prevailing market price by discouraging third parties from seeking to obtain control of our company in a tender offer or similar transactions.

If securities or industry analysts do not publish research or publish unfavorable or inaccurate research about our business, our share price and trading volume could decline.

The trading market for our ordinary shares will continue to depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We may be unable to sustain coverage by well-regarded securities and industry analysts. If either none or only a limited number of securities or industry analysts maintain coverage of our company, or if these securities or industry analysts are not widely respected within the general investment community, the trading price for our ordinary shares would be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who cover us downgrade our ordinary shares or publish inaccurate or unfavorable research about our business, the price of our ordinary shares would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our ordinary shares could decrease, which might cause the price of our ordinary shares and trading volume to decline.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired and investors' views of us could be harmed.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. We have spent considerable resources since our IPO designing, implementing and testing our internal controls over financial reporting and developing our internal audit function. If we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our ordinary shares could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

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

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.1#	Non-Employee Director Compensation Program				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: July 25, 2019

/s/ Wilco Groenhuysen

Wilco Groenhuysen
Chief Financial Officer
(principal financial and accounting officer
and duly authorized officer)

Exhibit 10.1

NOVOCURE LIMITED

Non-Employee Director Compensation Program

1. General . This Non-Employee Director Compensation Program (this " Program ") is adopted by the Board of Directors (the " Board ") of NovoCure Limited, a public limited company incorporated under the laws of Jersey, Channel Islands (the " Company "). For purposes of this Program, a " Non-Employee Director " shall mean a director of the Company who is not an employee of, or compensated consultant to, the Company or any of its subsidiaries.

2. Annual Cash Compensation . Each Non-Employee Director shall be entitled to an annual cash retainer fee of $45,000 (the " Annual Retainer "). In addition to the Annual Retainer payments, Non-Employee Directors will be entitled to an annual cash retainer of (a) $25,000 for serving as the chairperson of the Board's Audit Committee (the " Audit Committee "), (b) $15,000 for serving as the chairperson of the Board's Compensation Committee (the " Compensation Committee "), (c) $10,000 for serving as the chairperson of the Board's Nominating and Governance Committee (the " Nominating Committee "), and (d) $25,000 for serving as the lead independent director of the Board. In addition to the Annual Retainer payments, Non-Employee Directors will be entitled to an annual cash retainer of (a) $15,000 for serving as a member of the Board's Audit Committee, (b) $7,500 for serving as a member of the Compensation Committee, and (c) $5,000 for serving as a member of the Nominating Committee. The Annual Retainer, any annual retainer for serving as the chairperson of a committee and any annual retaining for serving as a member of a committee shall be pro-rated for any partial period of service. All cash compensation payable to Non-Employee Directors shall be payable in arrears on a quarterly basis within thirty days following the end of each fiscal quarter.

3. Equity Awards to Non-Employee Directors . On the date of each annual meeting of the Company's shareholders (" Annual Meeting ") or such other date duly authorized by the Compensation Committee or the Board, the Compensation Committee or the Board may consider a grant of equity award(s) under the Company's 2015 Omnibus Incentive Plan or any other applicable Company equity incentive plan then-maintained by the Company (the " Plan ") consistent with the terms below.

Initial Awards . Each Non-Employee Director who is initially elected or appointed to the Board on or after the Effective Date shall be granted on (a) in case of appointment between the Annual Meetings, the last trading day of the month following such election or appointment or, if such date falls during a companywide closed trading window, then on the first day on which such trading window opens and (b) in case of election by shareholders at an Annual Meeting, the date of such Annual Meeting, a non-qualified share option (an " Initial Award ") under the Plan to purchase that number of shares to the Company's ordinary shares such that the award has an aggregate Grant Date Fair Value of $667,000 (subject to rounding of shares to the nearest whole number). No Non-Employee Director shall be granted more than one Initial Award. For purposes of this Program, "Grant Date Fair Value" shall mean the fair value of an award as of the date of grant as determined in accordance with ASC Topic 718, "Share-Based Payment", using the Black-Scholes pricing model (or other acceptable valuation model as in use from time to time) and the valuation assumptions used by the Company in accounting for options as of such date of grant.

An Initial Award shall vest annually in equal installments over three years on the anniversary of the date of grant of such Initial Award (the " Grant Anniversary Date "), subject to the Non-Employee Director's continued service to the Company; provided, however, that in the case of Initial Awards granted on the date of the Company's Annual Meeting if a subsequent Annual Meeting is held prior to the Grant Anniversary Date, the annual vesting for such year shall occur the day immediately preceding the date of the Annual Meeting Date in such year , subject to the Non-Employee Director's continued service to the Company on such date.

Annual Awards. A Non-Employee Director who has served as a member of the Board for at least six months prior to the date of the Company's annual meeting of shareholders shall be granted equity award(s) under the Plan consisting of non-qualified share options and/or restricted share units (collectively, the " Annual Awards "). The Compensation Committee or the Board shall allocate 50% of the Grant Date Fair Value of the equity award to restricted share units and the remainder to non-qualified share options. The total aggregate Grant Date Fair Value of the equity award(s) shall equal $345,000 (subject to rounding of shares to the nearest whole number).

Each Annual Award shall vest in full on the earlier of (a) Grant Anniversary Date or (b) the day immediately preceding the date of the next Annual Meeting, subject to the Non-Employee Director's continued service to the Company.

Any equity awards made pursuant to this Program and then-outstanding shall vest in full immediately prior to a Change in Control (as defined in the Plan), subject to Non-Employee Director's continued service to the Company on such date.

4. Effective Date . This Program shall be effective as of April 30, 2019 (the " Effective Date "). The terms of this Program shall supersede any prior compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors.

5. Expense Reimbursements . Each Non-Employee Director will be entitled to reimbursement for all reasonable and documented expenses incurred in the performance of his or her duties as a director of the Company pursuant to the terms of any applicable Company expense reimbursement policy that is in effect from time to time.

6. Program Subject to Amendment, Modification and Termination . This Program may be amended, modified or terminated by the Board or Compensation Committee at any time, or from time to time, in their sole discretion. No Non-Employee Director shall have any rights hereunder unless and until an Award (as defined in the Plan) is actually granted under the Plan. Without limiting the generality of the foregoing, the Board and Compensation Committee hereby expressly reserve the authority to terminate this Program during any year up and until the election of directors at a given Annual Meeting.

7. Taxes . The Company is not responsible for the tax consequences under federal, foreign, provincial, state or local law with respect to any compensation, fees, equity awards or other payments made pursuant to this Program.

Exhibit 31.1

CERTIFICATIONS

I, Asaf Danziger, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NovoCure Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: July 25, 2019

/s/ Asaf Danziger
Asaf Danziger
Chief Executive Officer and Director

Exhibit 31.2

CERTIFICATIONS

I, Wilco Groenhuysen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NovoCure Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: July 25, 2019

/s/ Wilco Groenhuysen
Wilco Groenhuysen
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

NOVOCURE LIMITED
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of NovoCure Limited (the "Company") on Form 10-Q for the quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Asaf Danziger, Chief Executive Officer (Principal Executive Officer) of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Asaf Danziger
Asaf Danziger
Chief Executive Officer
(Principal Executive Officer)

Date: July 25, 2019

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff on request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is 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 the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

NOVOCURE LIMITED
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of NovoCure Limited (the "Company") on Form 10-Q for the quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Wilco Groenhuysen, Chief Financial Officer (Principal Financial and Accounting Officer) of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Wilco Groenhuysen
Wilco Groenhuysen
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: July 25, 2019

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff on request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is 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 the Report), irrespective of any general incorporation language contained in such filing.