Novocure Ltd
Form 10-Q
October 27, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2015

or

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

Commission File Number 001-37565

NovoCure Limited

(Exact Name of Registrant as Specified in Its Charter)

Jersey (Channel Islands)	Not Applicable
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

Le Masurier House

La Rue Le Masurier

St. Helier, Jersey JE2 4YE

(Address of principal executive offices)

+44 (0) 15 3475 6700

(Registrant's Telephone Number, Including Area Code)

Not Applicable

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

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

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

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

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

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

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

Class	Outstanding as of October 22, 2015
Ordinary shares, no par value	83,618,701 Shares

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our research and development, clinical trial and commercialization activities and projected expenditures;
- the further commercialization of Optune and our delivery system candidates;
- our business strategies and the expansion of our sales and marketing efforts in the United States and in other countries;
- the market acceptance of Optune and our other delivery systems by patients, physicians, third-party payers and others in the healthcare and scientific community;
- our plans to pursue the use of TTFields delivery systems for the treatment of other solid tumor cancers;
- our estimates regarding revenues, expenses, capital requirements and needs for additional financing;
- our ability to obtain regulatory approvals for additional indications and any future delivery systems;
- our ability to acquire the supplies needed to manufacture our delivery systems from third-party suppliers;
- our ability to manufacture adequate supply;
- our ability to secure adequate coverage from third-party payers to reimburse us for our delivery systems;
- our ability to 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. Some of these factors are described in Part II, Item IA, Risk Factors, of this Quarterly Report on Form 10-Q. 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.

NovoCure Limited

Quarterly Report on Form 10-Q

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NOVOCURE LIMITED AND SUBSIDIARIES

CONDENSED INTERIM CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	September 30, 2015 Unaudited	December 31, 2014 Audited
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 110,324	$ 57,613
Short-term investments	26,999	44,999
Restricted cash	166	61
Receivables and prepaid expenses	10,164	5,711
Inventories	11,149	3,446
Total current assets	158,802	111,830
LONG-TERM ASSETS:		
Property and equipment, net	6,106	3,732
Field equipment, net	4,516	2,017
Severance pay fund	75	70
Deferred IPO costs	2,577	-
Other long-term assets	1,705	227
Total long-term assets	14,979	6,046
TOTAL ASSETS	$ 173,781	$ 117,876

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

NOVOCURE LIMITED AND SUBSIDIARIES

CONDENSED INTERIM CONSOLIDATED BALANCE SHEETS

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

	September 30, 2015 Unaudited	December 31, 2014 Audited
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$15,235	$10,033
Other payables and accrued expenses	10,680	7,636
Total current liabilities	25,915	17,669
LONG-TERM LIABILITIES:		
Long-term loan, net of discount	24,554	-
Accrued severance pay	248	246
Other long-term liabilities	1,840	2,086
Total long-term liabilities	26,642	2,332
TOTAL LIABILITIES	$52,557	$20,001
COMMITMENTS AND CONTINGENCIES	-	-
SHAREHOLDERS' EQUITY:		
Share capital -		
Ordinary shares—unlimited no par value shares authorized; Issued and outstanding: 12,432,293 shares and 13,431,414 shares at September 30, 2015 (unaudited), and December 31, 2014, respectively;	-	-
Preferred shares—unlimited no par value shares authorized; Issued and outstanding: 62,744,517 shares and 58,676,017 shares at September 30, 2015 (unaudited), and December 31, 2014, respectively;	-	-
Additional paid-in capital	476,377	374,375
Accumulated deficit	(355,153)	(276,500)
Total shareholders' equity	121,224	97,875
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$173,781	$117,876

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

NOVOCURE LIMITED AND SUBSIDIARIES

CONDENSED INTERIM CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2015	2014	2015	2014
	Unaudited		Unaudited	
Net revenues	$8,953	$4,374	$20,704	$11,689
Cost of revenues	5,659	2,586	14,306	7,406
Gross profit	3,294	1,788	6,398	4,283
Operating costs and expenses:				
Research, development and clinical trials	10,211	9,276	32,903	29,191
Sales and marketing	8,916	5,384	24,137	16,439
General and administrative	8,405	5,033	22,748	15,800
Total operating costs and expenses	27,532	19,693	79,788	61,430
Operating loss	(24,238)	(17,905)	(73,390)	(57,147)
Financial expenses, net	(809)	(53)	(2,277)	(91)
Loss before income tax expense	(25,047)	(17,958)	(75,667)	(57,238)
Income tax expense	976	362	2,986	528
Net loss	$(26,023)	$(18,320)	$(78,653)	$(57,766)
Basic and diluted net loss per Ordinary share	$(2.09)	$(1.45)	$(6.21)	$(4.67)
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share	12,431,586	12,594,483	12,666,455	12,377,832

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

NOVOCURE LIMITED AND SUBSIDIARIES

CONDENSED INTERIM STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

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

	Ordinary shares Shares	Preferred shares Shares	Additional paid-in capital	Accumulated deficit	Total shareholders' equity
Balance as of January 1, 2014	11,891,421	58,676,017	$ 367,597	$ (195,818)	$ 171,779
Share-based compensation to employees	-	-	4,624	-	4,624
Exercise of options and warrants	1,539,993	-	2,154	-	2,154
Net loss	-	-	-	(80,682)	(80,682)
Balance as of December 31, 2014	13,431,414	58,676,017	374,375	(276,500)	97,875
Share-based compensation to employees	-	-	7,372	-	7,372
Exercise of options and warrants	6,089	-	31	-	31
Issuance of Series J preferred shares, net *)	-	4,068,500	94,599	-	94,599
Issuance of shares and options in respect of settlement, net of fair value of shares provided as indemnification	(1,005,210)	-	-	-	-
Net loss	-	-	-	(78,653)	(78,653)
Balance as of September 30, 2015 (unaudited)	12,432,293	62,744,517	$ 476,377	$ (355,153)	$ 121,224

*) Net of issuance expenses of $319

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

NOVOCURE LIMITED AND SUBSIDIARIES

CONDENSED INTERIM CONSOLIDATED CASH FLOWS

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

	Nine months ended September 30,	
	2015	2014
	Unaudited	
Cash flows from operating activities:		
Net loss	$(78,653)	$(57,766)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,005	1,464
Asset write-downs and impairment	42	19
Accrued interest expense	154	-
Share-based compensation to employees	7,372	3,354
Amortization of discount (premium)	231	(17)
Increase in receivables and prepaid expenses	(4,453)	(73)
Increase in inventories	(7,703)	(804)
Decrease in other long-term assets	79	20
Increase (decrease) in trade payables	4,597	(3,395)
Increase in other payables and accrued expenses	2,892	462
Increase (decrease) in severance pay, net	(3)	49
Increase (decrease) in other long-term liabilities	(323)	59
Net cash used in operating activities	(73,763)	(56,628)
Cash flows from investing activities:		
Purchase of property and equipment	(3,613)	(443)
Purchase of field equipment	(3,547)	(891)
Decrease (increase) in restricted cash	(105)	1,035
Proceeds from maturity of short-term investments	77,000	69,000
Purchase of short-term investments	(58,992)	(107,981)
Net cash provided by (used in) investing activities	10,743	(39,280)
Cash flows from financing activities:		
Proceeds from issuance of preferred shares, net	94,599	-
Proceeds from issuance of long-term loan, net	22,886	-
Proceeds from issuance of other long-term loans	-	54
Repayment of other long-term loan	(47)	(64)
Deferred IPO costs	(1,733)	-
Purchase of shares	(5)	-
Exercise of options and warrants	31	1
Net cash provided by (used in) financing activities	115,731	(9)

Increase (decrease) in cash and cash equivalents	52,711	(95,917)
Cash and cash equivalents at the beginning of the period	57,613	175,894
Cash and cash equivalents at the end of the period	$110,324	$79,977
Supplemental cash flow data		
Cash paid during the period for:		
Interest	$1,683	$21
Income taxes, net	$823	$230
Non-cash financing activities:		
Deferred IPO costs	$844	$-

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

NOVOCURE LIMITED AND SUBSIDIARIES

Notes to Condensed Interim Consolidated Financial Statements (unaudited)

NOTE 1:- GENERAL

NovoCure Limited (including its consolidated subsidiaries, the "Company") was incorporated in Jersey (Channel Islands) and is principally engaged in the development, manufacture and commercialization of tumor treating fields ("TTFields") for the treatment of solid tumors. Since inception, the Company has devoted substantially all of its efforts to developing a family of products to deliver TTFields for a variety of solid tumor indications, raising capital and recruiting personnel. The Company commenced selling and marketing activities for Optune, its first approved delivery system, in the United States at the end of 2011, and began commercial launch in Europe during 2014 and in Japan during the second half of 2015.

NovoCure Limited wholly owns the following subsidiaries: Novocure Luxembourg Sarl ("Novocure Luxembourg") and Novocure (Israel) Ltd. ("Ltd."). Novocure Luxembourg wholly owns Novocure GmbH, NovoCure Limited's Swiss subsidiary ("Novocure Switzerland") and Novocure GmbH, the German subsidiary of NovoCure Limited ("Novocure Germany"). Novocure Switzerland wholly owns Novocure Inc. ("Inc."), the U.S. subsidiary, and Novocure KK, the Japanese subsidiary. Inc. wholly owns Novocure (USA) LLC.

The Company's research and development activity is conducted by Ltd. and clinical trials are managed on behalf of the Company mainly by Ltd., Novocure Switzerland and Inc. Novocure KK markets TTFields and will conduct clinical trials in Japan. Inc. is marketing and selling TTFields in the United States Novocure Switzerland manages the global supply chain operations for the Company, manages clinical trials conducted outside the United States and Japan and manages the marketing of TTFields in Europe. Novocure Germany supports and markets TTFields in Germany.

In September 2015, the Company's shareholders approved the restructuring of the Company's share capital by converting the Company's ordinary and preferred shares to no par value shares and by effecting a sub-division of the issued and outstanding share capital of the Company based on a proportion of 1:5.913 ("Share Split Ratio"). Following this approval, each ordinary and preferred share, nominal value £0.01 per share, was divided into 5.913 shares of such applicable class of shares of the Company, each with no par value per share. The Split Ratio to the Company's outstanding options and warrants, in accordance with their terms. All share information included in these consolidated financial statements has been retroactively adjusted to reflect the conversion to no par value shares and the Share Split Ratio.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

Significant accounting policies applied in the audited annual consolidated financial statements of the Company are applied consistently in these unaudited interim financial statements

a. Use of estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company evaluates on an ongoing basis its assumptions, including those related to contingencies, deferred taxes, tax liabilities, useful-life of field equipment and share-based compensation costs. The Company's management believes that the estimates, judgment and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities at the dates of the consolidated financial statements, and the reported amounts of net revenue and expenses during the reporting period. Actual results could differ from those estimates.

b. Financial statements in U.S. dollars:

The accompanying financial statements have been prepared in U.S. dollars in thousands.

The Company finances its operations in U.S. dollars and a substantial portion of its costs and revenues from its primary markets is incurred in U.S. dollars. As such, the Company's management believes that the dollar is the currency of the primary economic environment in which the Company operates. Thus, the functional and reporting currency of the Company is the U.S. dollar.

Transactions and balances denominated in U.S. dollars are presented at their original amounts. Monetary accounts maintained in currencies other than the dollar are re-measured into dollars in accordance with Accounting Standards Codification No. 830-10, "Foreign Currency Matters." All transaction gains and losses of the re-measurement of monetary balance sheet items are reflected in the consolidated statements of operations as financial income or expenses, as appropriate.

c. Principles of consolidation:

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Intercompany transactions and balances, including profits from intercompany sales not yet realized outside the Company, have been eliminated upon consolidation.

d. Cash equivalents:

Cash equivalents are short-term, highly liquid investments that are readily convertible into cash with an original maturity of three months or less at the date acquired.

e. Short-term investments and restricted cash:

1. Short-term investments:

The Company accounts for investments in debt securities in accordance with ASC 320, “Investments-Debt and Equity Securities.” Management determines the appropriate classification of its investments in marketable debt securities at the time of purchase and reevaluates such determinations at each balance sheet date. As of September 30, 2015, all securities are classified as held-to-maturity since the Company has the intent and ability to hold the securities to maturity and, accordingly, debt securities are stated at amortized cost.

The amortized cost of held-to-maturity securities is adjusted for amortization of premiums and accretion of discounts to maturity and any other than temporary impairment losses. Such amortization and interest are included in the consolidated statement of operations as financial income or expenses, as appropriate.

For the nine-months period ended September 30, 2014 and 2015 (unaudited), no other than temporary impairment losses have been identified.

2. The Company has restricted cash as of September 30, 2015 of $166 (unaudited) used as security to cover bank guarantees in respect of use of Company credit cards in the Swiss operations.

f. Inventories:

Inventories are stated at the lower of cost or market. Cost is determined using the weighted average method. The Company regularly evaluates the ability to realize the value of inventory. If actual demand for the Company’s delivery systems deteriorates, or market conditions are less favorable than those projected, inventory write-offs may be required.

There were no inventory write-offs for the nine-month periods ended September 30, 2014 and 2015 (unaudited).

g. Property and equipment:

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets at the following rates:

	%
Computers and laboratory equipment	15 - 33

Office furniture	6-33
Leasehold improvements	Over the shorter of the term of the lease or its useful life

h. Field equipment under operating leases:

Field equipment is stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful life of the field equipment which was determined to be two years. Field equipment consists of equipment being utilized under rental agreements accounted for in accordance with ASC 840 on a monthly basis as an operating lease, as well as “service pool” equipment. Service pool equipment is equipment owned and maintained by the Company that is swapped for equipment that needs repairs or maintenance by the Company while being rented by a patient. The Company records a provision for any excess, lost or damaged equipment when warranted based on an assessment of the equipment. Write-downs for equipment are included in cost of revenues. During the nine-month periods ended September 30, 2014 and 2015 (unaudited) $12 and $32, respectively, write-downs had been identified.

i. Impairment of long-lived assets:

The Company’s long-lived assets are reviewed for impairment in accordance with ASC 360-10, “Property, Plant and Equipment”, whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Recoverability of an asset to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows

expected to be generated by the asset. If such asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. During the nine-month periods ended September 30, 2014 and 2015 (unaudited), no impairment losses have been identified.

j. Long-term lease deposits:

Long-term lease deposits in respect of office rent and vehicles under operating leases are presented in other long-term assets.

h. Revenue recognition:

The TTFields delivery system ("System") for GBM, Optune, is comprised of two main components: (1) an Electric Field Generator (the "device") and (2) Transducer Arrays and related accessories that are disposable supplies to the device ("disposables"). Title is retained by the Company for the device and the patient is provided replacement disposables for the device during the rental period. The device and disposables are always supplied and functioning together and are not sold on a standalone basis.

Revenues are recognized when persuasive evidence of an arrangement exists, delivery of the system has occurred, the price is fixed or determinable and collectability is reasonably assured. The evidence of an arrangement generally consists of a prescription, a patient service agreement and the verification of eligibility and insurance with the patient's third-party insurance company ("payer"). The Company generally bills third-party payers a monthly fee for use of the System by patients. As such, the Company takes assignment of benefits and risk of collection from the third-party payer. Patients have out-of-pocket costs for the amount not covered by their payer and the Company bills the patient directly for the amounts of their co-pays and deductible, subject to the Company's patient assistance programs.

For the reported periods, all revenues are recognized when cash is collected assuming that all other revenue recognition criteria have been met, as the price is not fixed or determinable and the collectability cannot be reasonably assured. The price is not fixed or determinable since the Company does not have sufficient history with payers to reliably estimate their individual payment patterns and as such cannot reliably estimate the amount that would be ultimately collected. Once sufficient history is established and the Company can reliably estimate the amounts that would be ultimately collected per payer/payer group and the above criteria are met, the Company will recognize revenues from the use of the System on an accrual basis ratably over the lease term.

Revenues are presented net of indirect taxes, which include excise tax of $752 and $1,446 for the nine months ended September 30, 2014 and 2015 (unaudited), respectively and sales tax of $206 and $424 for the nine months ended September 30, 2014 and 2015 (unaudited), respectively.

i. Research, development and clinical trials:

Research, development and clinical trials, including direct and allocated expenses are expensed as incurred.

j. Shipping and handling costs:

The Company does not bill its customers for shipping and handling costs associated with shipping its delivery systems to its customers. These shipping and handling costs of $405 and $891 for the nine-month period ended September 30, 2014 and 2015 (unaudited), respectively, are included in selling and marketing costs.

k. Accounting for share-based payments:

The Company accounts for share-based compensation in accordance with ASC 718, “Compensation—Stock Compensation.” ASC 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in the company’s consolidated statements of operations.

The Company recognizes compensation costs net of a forfeiture rate only for those shares expected to vest using the accelerated method over the requisite service period of the award, which is generally the option vesting term of four years. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The Company selected the Black-Scholes option-pricing model as the most appropriate fair value method for its option awards. The option-pricing model requires a number of assumptions, of which the most significant are the share price expected, expected volatility and the expected option term.

The fair value of ordinary shares underlying the options has historically been determined by management and the board of directors. Because there has been no public market for the Company’s ordinary shares, the board of directors has determined fair value of an ordinary share at the time of grant of the option by considering a number of objective and subjective factors including operating and financial performance, the lack of liquidity of share capital, general and industry specific economic outlook and valuations performed amongst other factors. The fair value of the underlying ordinary shares will be determined by the board of directors until such time as the Company’s ordinary shares are listed on an established share exchange or national market system. The Company’s board of directors determined the fair value of ordinary shares for the reported periods, among other factors, based on valuations performed

using the hybrid method, which is the hybrid between the probability weighted expected return method (PWERM) and the option pricing method, as the Company began to consider initial public offering (IPO) activities commencing in January 2012.

The computation of expected volatility is based on actual historical share price volatility of comparable companies. Expected term of options granted is calculated using the average between the vesting period and the contractual term to the expected term of the options in effect at the time of grant. The Company has historically not paid dividends and has no foreseeable plans to pay dividends and, therefore, uses an expected dividend yield of zero in the option pricing model. The risk-free interest rate is based on the yield of U.S. treasury bonds with equivalent terms.

l. Fair value of financial instruments:

The carrying amounts of cash and cash equivalents, short-term investments, restricted cash, receivables and prepaid expenses, trade payables and other accounts payable and accrued expenses approximate their fair value due to the short-term maturity of such instruments. Based upon the borrowing terms and conditions currently available to the Company, the carrying values of the long-term loans approximate fair value.

m. Basic and diluted net loss per share:

The Company applies the two class method as required by ASC 260-10, “Earnings Per Share.” ASC 260-10 requires the income or loss per share for each class of shares (ordinary and preferred shares) to be calculated assuming 100% of the Company’s earnings are distributed as dividends to each class of shares based on their contractual rights. No dividends were declared or paid during the reported periods.

According to the provisions of ASC 260-10, the Company’s preferred shares are not participating securities in losses and, therefore, are not included in the computation of net loss per share.

Basic and diluted net loss per share is computed based on the weighted average number of ordinary shares outstanding during each year. Diluted loss per share is computed based on the weighted average number of ordinary shares outstanding during the period, plus dilutive potential shares considered outstanding during the period, in accordance with ASC 260-10. Basic and diluted net loss per ordinary share was the same for each period presented as the inclusion of all potential ordinary shares (all preferred shares, options and warrants) outstanding was anti-dilutive.

n. Income taxes:

The Company accounts for income taxes in accordance with ASC 740-10, “Income Taxes.” ASC 740-10 prescribes the use of the liability method whereby deferred tax asset and liability account balances are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected reverse. The Company provides a valuation allowance, to reduce deferred tax assets to their estimated realizable value, if needed.

ASC 740 clarifies the accounting for uncertainty in income taxes by prescribing a minimum recognition threshold for a tax position taken or expected to be taken in a tax return that is required to be met before being recognized in the financial statements. ASC 740 also provides guidance on measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition.

o. Concentration of risks:

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash and cash equivalents, restricted cash and short-term investments.

Cash and cash equivalents and restricted cash are invested in major banks or financial institutions in Jersey (Channel Islands), the United States, Israel, Luxemburg, Switzerland, Japan and Germany. Such investments may be in excess of insured limits and are not insured in other jurisdictions. Generally, these investments may be redeemed upon demand and, therefore, bear minimal risk.

The Company has no off-balance sheet concentrations of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

In the nine month period ended September 30, 2015, one payer represented $3,951 or 18% of net revenues, respectively. In the nine month period ended September 30, 2014, the same payer represented $1,890 or 15% of revenues, respectively.

p. Retirement plans and severance pay:

The Company has a 401(k) retirement savings plan for its U.S. employees. Each eligible employee may elect to contribute a portion of the employee’s compensation to the plan. The Company does not make any matching contributions to the plan.

The Company has an occupational benefit plan with a private pension fund for its Swiss employees, whereby the employee and the Company contribute to the pension fund.

The pension expense for the nine months periods ended September 30, 2014 and 2015 (unaudited) was $155 and $218, respectively.

The majority of the Company's employees in Israel have subscribed to Section 14 of Israel's Severance Pay Law, 5723-1963 ("Section 14"). Pursuant to Section 14, Ltd.'s employees covered by this section are entitled to monthly deposits at a rate of 8.33% of their monthly salary, made on their behalf by the Company. Payments in accordance with Section 14 release the Company from any future severance liabilities in respect of those employees. Neither severance pay liability nor severance pay fund under Section 14 for such employees is recorded on the Company's consolidated balance sheet.

With regard to employees in Israel that are not subject to Section 14, the Company's liability for severance pay is calculated pursuant to Israeli Severance Pay Law, based on the most recent salary of the relevant employees multiplied by the number of years of employment as of the balance sheet date. These employees are entitled to one month's salary for each year of employment or a portion thereof. The Company's liability for these employees is fully provided for through monthly deposits to the employees' pension and management insurance policies and an accrual. The value of these deposits is recorded as an asset on the Company's consolidated balance sheet.

The carrying value of the deposited funds is based on the cash surrender value and includes profits accumulated up to the balance sheet date. The deposited funds may be withdrawn only upon the fulfillment of the obligation pursuant to the Israeli Severance Pay Law. Severance pay expense for the nine months periods ended September 30, 2014 and 2015 amounted to $239 and $218, respectively.

q. Contingent liabilities:

The Company accounts for its contingent liabilities in accordance with ASC 450, "Contingencies". A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter. As of September 30, 2015, the Company was not a party to any litigation that could have a material adverse effect on the Company's business, financial position, results of operations or cash flows.

Recently Issued Accounting Pronouncement

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers", an updated standard on revenue recognition. ASU 2014-09 provides enhancements to the quality and consistency of how revenue is reported while also improving comparability in the financial statements of companies reporting using IFRS and US GAAP. The core principle of the new standard is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration (that is, payment) to which the company expects to be entitled in exchange for those goods or services. The new standard also will result in enhanced disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively (for example, service revenue and contract modifications) and improve guidance for multiple-element arrangements. ASU 2014-09 was initially effective for annual and interim reporting periods beginning after December 15, 2016 and may be adopted either on a full retrospective or modified retrospective approach. On July 9, 2015, the FASB approved a one - year deferral of the effective date of the ASU. The revised effective date is for annual reporting periods beginning after December 15, 2017 and interim periods therein, with early adoption permitted as of the original effective date. The Company is evaluating the impact of implementation of this standard on its consolidated financial statements.

NOTE 3:- UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

The accompanying condensed consolidated financial statements include the accounts of the Company and its consolidated subsidiaries, intercompany accounts and transactions have been eliminated. In the opinion of the Company's management, the condensed consolidated financial statements reflect all adjustments, which are normal and recurring in nature, necessary for fair financial statement presentation. The preparation of these condensed consolidated financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in these condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

These condensed consolidated financial statements and accompanying notes should be read in conjunction with the Company's annual consolidated financial statements and the notes thereto for the fiscal year ended December 31, 2014, included in the Company's Prospectus filed pursuant to Rule 424(b)(1) of the Securities Act on October 2, 2015 with the SEC.

NOTE 4:- SHORT TERM INVESTMENTS

The Company invests in marketable US 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 and their estimated fair value as of December 31, 2014 was

$44,999.As of September 30, 2015 (unaudited), the amortized cost of the T-bills was $26,999 and the estimated fair value was $27,002.

NOTE 5:- INVENTORIES (in thousands)

	September 30, 2015 Unaudited	December 31, 2014 Audited
Raw materials	$ 3,095	$ 526
Work in progress	3,154	1,280
Finished products	4,900	1,640
Total	$ 11,149	$ 3,446

NOTE 6:- LONG - TERM LOAN, NET OF DISCOUNT

In January 2015, the Company entered into a five-year term loan agreement (the “Loan Agreement”) with a lender to draw up to $100,000. In January 2015, the Company drew $25,000 from the lender. The Company may draw the remaining $75,000. at its option at any time through June 30, 2016. Interest on the outstanding loan is 10.0% annually, payable quarterly in arrears. In addition, there is a 1.5% funding fee payable on the amount drawn on the funding date, a 0.75% pay-down fee on all principal amount repayments to be paid on the date such payments of principal are made and a pre-payment fee of 3.0%, 2.0% or 1.0% if the Company prepays outstanding loan amounts prior to the first, second or third year, respectively, from the initial funding date. The entire outstanding principal loan is due on January 2020. The loan is secured by a first - priority security interest in substantially all assets of the Company. The Loan Agreement sets forth certain affirmative and negative covenants with which the Company must comply on a quarterly basis commencing March 31, 2015 through the term of loan. As of September 30, 2015, the Company was in compliance with its debt covenants.

The total discount of $491 presented net of the loan and additional deferred issuance costs of approximately $1,739 in respect of the loan (presented in other long-term assets in the balance sheet) are amortized to interest expense over the five year term of the loan using the effective interest method.

NOTE 7:- COMMITMENTS AND CONTINGENT LIABILITIES

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

latest of which is in 2017.

As of December 31, 2014 and September 30, 2015 (unaudited), the Company pledged bank deposits of $130 and $133 respectively to cover bank guarantees in respect of its leases of operating facilities and obtained guarantees by the bank for the fulfillment of the Company's lease commitments of $281 and $283, respectively.

NOTE 8:- SHARE CAPITAL

Series J Preferred shares investment round

In June 2015, the Company issued 4,068,500 Series J convertible preferred shares at $23.33 per share to certain investors for a total consideration of $94,599 (net of issuance expenses of $319). The Series J preferred shares are senior to the other series of preferred shares on payment of the liquidation preference (equal to $23.33 per share), but otherwise have similar participating preferred rights, dividend rights and voting rights of the other series of preferred shares.

Settlement agreement

In February 2015, the Company entered into a settlement agreement (the "Agreement") with a third party with respect to a resolution of certain potential disputes regarding intellectual property developed by the Company's founder and historically assigned to the Company. In exchange for a release of potential disputes from the third party, the Company paid $1,000. on execution of the Agreement and will pay an additional $1,000. ("Additional Payment") at the earliest of (i) 18 months after signing of the Agreement, (ii) an initial public offering ("IPO") and (iii) the earlier of consummation of a merger/acquisition ("M&A") or achievement of a Cumulative Net Sales milestone of $250,000. (as defined pursuant to the Agreement), The Additional Payment was paid in October 2015from the proceeds of the Company's IPO . The Company will pay an additional $5,500 on the earlier of (i) achievement of the

Cumulative Net Sales milestone per above and (ii) consummation of an M&A. In addition, the Company agreed to issue 1,005,210 ordinary shares (the "Issued Shares") to the third party and grant options to the third party to purchase 1,005,210 ordinary shares (the "Granted Options") that are fully vested and at no cost. The options terminate at the earlier of (i) 12 months subsequent to the IPO and (ii) immediately prior to an M&A.

In February 2015, the Company contemporaneously entered into a Letter of Agreement ("Letter of Agreement") with the founder mentioned above and a related party (together, the "Founder"). Pursuant to the Letter of Agreement, in furtherance to a previous indemnification provided by the Founder in 2009, in connection with the intellectual property he assigned to the Company and the Agreement signed above, the Founder agreed to indemnify the Company for the compensation incurred to the third party by providing 2,010,420 ordinary shares which were redeemed and cancelled (the "Redeemed Shares") in March 2015 to the Company at $5, and may be obligated to pay an additional $2,000. in cash to the Company upon its request out of the net proceeds from the sale of any ordinary shares by the Founder in a private transaction or - following the consummation of the IPO in an open market transaction if the closing price of the ordinary shares is at least 80% of the price per share for which the ordinary shares were sold in the IPO (after deducting underwriting discounts and commissions and offering expenses). In March 2015, the Company issued the Issued Shares and Granted Options to the third party.

Accordingly, for the year ended December 31, 2014, the Company recorded a provision for a net settlement expense of $1,867. in general and administrative expense, in accordance with ASC 450 reflecting the present value of the cash obligation of $2,000. and the fair value of the Issued Shares and Granted Options to the third party, net of the fair value of the consideration provided by the Founder (Redeemed Shares), which amounted to nil as presented in the statement of shareholder's equity, in connection with the indemnification provided and the Letter of Agreement.

NOTE 9:- SHARE OPTIONS

In 2003, the Company and its shareholders approved and adopted the 2003 Share Option Plan (the "2003 Plan"), which provided for the grant of options to the Company's officers, directors, employees and advisors. The options granted generally have a four-year vesting period and expire ten years after the date of grant Since March 2013, when the 2003 Plan expired, the Company has made grants pursuant to the 2013 Share Option Plan (as described below) and, following completion of the IPO in October 2015, all future equity grants will be made under the 2015 Omnibus Incentive Plan (as described below). However, any awards granted under the 2003 Plan that are outstanding as of the IPO will continue to be subject to the terms and conditions of the 2003 Plan and the applicable option award agreement.

In 2013, the Company and its shareholders approved and adopted our 2013 Share Option Plan (the "2013 Plan") , which provided for the grant of options to the Company's officers, directors, employees and advisors. In February and March 2015, the Company's board of directors and its shareholders approved an increase in the number of ordinary shares reserved for grant of options pursuant to the 2013 Plan by 2,956,500 ordinary shares to 13,198,224 ordinary shares. The options granted generally have a four-year vesting period and expire ten years after the date of grant. Following completion of the IPO, no further awards will be granted under the 2013 Plan and instead, future equity grants will be made under the 2015 Omnibus Incentive Plan, but awards granted under the 2013 Plan that are outstanding as of the IPO shall continue to be subject to the terms and conditions of the 2013 Plan.

NOTE 9:- SHARE OPTIONS (Cont.)

In August 2015, the Company's board of directors adopted and established the 2015 Omnibus Incentive Plan (the " 2015 Plan"). The Company's shareholders approved the 2015 Plan in September 2015. Under the 2015 Plan, the Company can issue various types of equity compensation awards such as restricted shares, performance shares, restricted stock units, performance units, long-term cash award and other share-based awards.

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

In September 2015, the Company's compensation committee granted options to purchase 921,488 ordinary shares to certain of the Company's employees pursuant to the 2015 Plan, conditioned upon the consummation of the IPO (see Note 11). The per share exercise price of these options is equal to the price per share at which the shares were sold to the public ($22). These awards are subject to continued employment and generally vest over four years.

As of September 30, 2015 (unaudited), 11,057,024 ordinary shares are available for grant under the 2015 Plan after taking into account the grants made in September 2015 conditioned upon the consummation of the IPO (see Note 11).

A summary of the status of the Company's option plans as of September 30, 2015 (unaudited) and changes during the period then ended is presented below:

	Period ended September 30, 2015 (unaudited)		
	Number of options	Weighted average exercise price	Aggregate intrinsic value
Outstanding at beginning of period	7,426,159	$ 3.98	
Granted	2,718,127	17.02	
Exercised	(2,512)	7.36	
Forfeited and cancelled	(191,276)	8.39	
Outstanding at end of period	9,950,498	$ 7.46	$ 144,651
Exercisable options	5,163,286	$ 2.86	$ 98,819
Vested and expected to vest	8,968,053	$ 5.96	$ 143,856

NOTE 9:- SHARE OPTIONS (Cont.)

The options outstanding as of September 30, 2015 (unaudited) have been separated into ranges of exercise prices, as follows:

Exercise price	Number of options outstanding as of September 30, 2015	Weighted average remaining contractual term (years)	Number of options exercisable as of September 30, 2015	Weighted average remaining contractual term (years)
0.01	98,995	0.46	98,995	0.46
0.17	1,403,857	0.96	1,403,857	0.96
0.23	440,531	3.68	440,531	3.68
0.38	488,331	5.04	488,331	5.04
3.44	1,779,072	6.13	1,350,491	6.12
6.72	940,424	6.93	687,525	6.93
6.83	92,227	7.20	46,390	7.20
7.03	613,174	7.39	306,570	7.39
7.04	137,321	7.72	69,311	7.72
7.28	167,921	7.90	79,366	7.90
7.48	504,365	8.39	127,555	8.39
7.52	116,769	8.49	29,186	8.49
7.58	52,032	8.74	13,006	8.74
7.73	431,053	9.02	22,172	8.87
14.37	1,616,012	9.41	-	-
15.60	146,926	9.57	-	-
22.00 (1)	921,488	10.00	-	-
	9,950,498	6.62	5,163,286	4.63

(1) conditioned upon the consummation of the IPO (see above).

As of September 30, 2015 (unaudited), there was unrecognized compensation cost of $13,932, which is expected to be recognized over a weighted average period of approximately 3.15 years.

The total non – cash share-based compensation expense related to all of the Company’s equity-based awards, recognized for the three and nine months ended September 30, 2015 and 2014 (unaudited) was comprised as follows:

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2015	2014	2015	2014
	Unaudited		Unaudited	
Cost of revenues	$35	$14	$54	$31
Research, development and clinical trials	668	254	1,717	543
Sales and marketing	571	262	1,550	807
General and administrative	1,654	675	4,051	1,973
Total share-based compensation expense	$2,928	$1,205	$7,372	$3,354

NOTE 10:- SUPPLEMENTAL INFORMATION

The Company operates in a single reportable segment.

The following table presents long-lived assets by location:

	September 30, 2015 Unaudited	December 31, 2014 Audited
Europe, Middle East and Africa		
Israel	$ 1,156	$ 1,009
Switzerland	2,972	1,259
Other	425	13
Total Europe, Middle East and Africa	4,553	2,281
United States	6,069	3,468
Total	$ 10,622	$ 5,749

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2015	2014	2015	2014
	Unaudited		Unaudited	
Europe, Middle East and Africa	$407	$258	$994	$286
United States	8,546	4,116	19,710	11,403
Total	$8,953	$4,374	$20,704	$11,689

NOTE 11:- SUBSEQUENT EVENTS

IPO. On October 7, 2015, the Company completed the IPO of its ordinary shares, which resulted in the sale of 7,500,000 ordinary shares at a price of $22.00 per ordinary share. The Company received net proceeds from the IPO of approximately $150,500, net of underwriting discounts and commissions and estimated offering expenses. In connection with the closing of the IPO, all of the Company's outstanding preferred shares were converted into ordinary shares of the Company on a one-to-one basis. The underwriters for the IPO have an option, exercisable through October 31, 2015, to purchase up to 1,125,000 additional ordinary shares to cover over-allotments, if any. On October 19, 2015, following the partial exercise by the underwriters of their option, the Company sold an additional 376,195 ordinary shares at a price of $22.00 per share and received net proceeds of approximately $7,700, net of underwriting discounts and commissions.

Warrant Exercises- In October 2015, certain investors exercised warrants for an aggregate of 565,696 ordinary shares. Total purchase price received by the Company related to the warrant exercises was $2,003.

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

Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to provide information to assist you in better understanding and evaluating our financial condition and results of operations. We encourage you to read this MD&A in conjunction with our consolidated financial statements for the period ended September 30, 2015 included in Part I, Item 1 of this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under Part II, Item 1A, Risk Factors, of this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

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

We view our operations and manage our business in one operating segment. We have incurred significant losses and cumulative negative cash flows from operations since our founding in 2000. Our net losses were $80.7 million for the year ended December 31, 2014 and $78.6 million for the nine months ended September 30, 2015. As of September 30, 2015, we had an accumulated deficit of $329.1 million. Our net losses primarily resulted from costs incurred in connection with our pre-clinical and clinical trial programs, costs incurred in our commercial launch efforts, including the U.S. launch of Optune for the treatment of recurrent GBM, and general and administrative costs necessary to operate as a multi-national oncology business. To date, we have financed our operations primarily through the issuance and sale of our convertible preferred shares and the proceeds from long-term loans. As of September 30, 2015, we had received a total of $454.3 million from the sale of our convertible preferred shares that were authorized, issued and outstanding prior to the closing of our initial public offering ("IPO") on October 7, 2015. On September 16, 2015, we effected a 5.913 for 1 share split applicable to our ordinary shares and all classes of our preferred shares. On October 7, 2015, all of our convertible preferred shares were converted to our ordinary shares on a one-for-one basis upon the closing of our IPO. Our IPO closed on October 7, 2015, and we issued and sold 7.5 million ordinary shares at a per share price to the public of $22.00. We received cash proceeds of approximately $150.5 million from the IPO, net of underwriting discounts and commissions and estimated offering expenses. On October 19, 2015, following the partial exercise by the underwriters of their over-allotment option, we issued and sold an additional 376,195 ordinary shares at a per share price to the public of $22.00 and received net proceeds of approximately $7.7 million, net of underwriting discounts and commissions.

In October 2015, we received U.S. Food and Drug Administration ("FDA") approval to market and sell Optune for the treatment of adult patients with newly diagnosed glioblastoma in combination with temozolomide. We have commenced our commercial launch for that indication in the United States. In the same month, we began placing a CE mark on our newly designed second generation Optune system and began roll-out of that system to patients in Germany. We plan to initiate a broader roll-out to additional countries in Europe by the end of the year.

We expect to continue to incur significant expenses and operating losses for at least the next several years. We expect our research, development and clinical trials expenses to increase in connection with our ongoing activities,

particularly as we continue the research, development and clinical trials of TTFields and related delivery system candidates, including multiple simultaneous clinical trials for certain delivery system candidates, some of which are in, or we expect will be entering, late-stage clinical development. In addition, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We may need additional funding to support the continuation of our operating activities. Until we can generate substantial revenues (which may not occur), we expect to finance our cash needs through the proceeds of our IPO and availability under our term loan credit facility, and possibly also from collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We will need to generate significant revenues to achieve profitability, and we may never do so.

Critical accounting policies and estimates

In accordance with U.S. GAAP, in preparing our financial statements, we must make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of net revenues and expenses during the reporting period. We develop and periodically change these

estimates and assumptions based on historical experience and on various other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates.

The critical accounting policies requiring estimates, assumptions and judgments that we believe have the most significant impact on our consolidated financial statements are described below.

Revenue recognition

The TTFields delivery system, currently marketed for newly diagnosed and recurrent GBM as Optune, is comprised of two main components: (1) an electric field generator and (2) transducer arrays and related accessories that are disposable supplies to the device, or the transducer arrays. We retain title to the electric field generator, and the patient is provided replacement transducer arrays for the device during the term of treatment. The electric field generator and transducer arrays are always supplied and function together and are not sold on a standalone basis.

Revenues are recognized when persuasive evidence of an arrangement exists, delivery of the electric field generator and transducer arrays has occurred, the price is fixed or determinable and collectability is reasonably assured. The evidence of an arrangement generally consists of a prescription, a patient service agreement and the verification of eligibility and insurance with the patient's third-party insurance company. We generally bill third-party payers a monthly rental fee for use of Optune by patients. As such, we take assignment of the benefit and risk of collection from the third-party payer. Patients often have out-of-pocket costs for the amount not covered by their third-party payer and we bill the patient directly for the amounts of their co-pays and deductibles subject to our patient assistance programs.

For the reported periods, all revenues were recognized when cash was collected as the price is not fixed or determinable and the collectability cannot be reasonably assured. The price is not fixed or determinable since we do not have sufficient history with third-party payers to reliably estimate their individual payment patterns and as such cannot reliably estimate the amount that would be ultimately collected. Once sufficient history is established and we can demonstrate that we can reliably estimate the amounts that would be ultimately collected per third-party payer or payer group and the above criteria are met, we will recognize revenues ratably over the term of the patient's use of Optune.

Revenues are presented net of indirect taxes incurred in the reported period, including the U.S. medical device excise tax and sales tax, regardless of whether the revenues associated with those taxes are reported on a cash basis.

Long-lived assets

Property and equipment and field equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful life of the relevant asset. We make estimates of the useful life of our property and equipment and field equipment, based on similar assets purchased in the past and our historical experience with such similar assets, in order to determine the depreciation expense to be recorded for each reporting period.

Our field equipment consists of equipment being utilized under rental agreements accounted for on a monthly basis as an operating lease, as well as service pool equipment. Service pool equipment is equipment owned and maintained by us that is swapped for equipment that needs repair or maintenance by us while being used by a patient. We record a provision for any excess, lost or damaged equipment when warranted based on an assessment of the equipment.

We assess impairment whenever events or changes in circumstances indicate that the carrying amount of the asset is impaired or the estimated useful life is no longer appropriate. Circumstances such as changes in technology or in the

way an asset is being used may trigger an impairment review.

Inventories

Inventories are stated at the lower of cost or market. We regularly evaluate the ability to realize the value of inventory. If actual demand for our delivery systems declines or market conditions are less favorable than those projected, inventory write-offs may be required.

Income taxes

As part of the process of preparing our consolidated financial statements, we are required to calculate our income taxes based on taxable income by jurisdiction. We make certain estimates and judgments in determining our income taxes, including valuation of our

uncertain tax positions, for financial statement purposes. Significant changes to these estimates may result in an increase or decrease to our tax provision in the subsequent period when such a change in estimate occurs.

Uncertain tax positions are based on estimates and assumptions that have been deemed reasonable by management. Our estimates of unrecognized tax benefits and potential tax benefits may not be representative of actual outcomes.

Results of Operations

(Unaudited; tables in thousands, except for share and per share data, operating statistics and % change data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Net revenues	$8,953	$4,374	$20,704	$11,689
Cost of revenues	5,659	2,586	14,306	7,406
Gross profit	3,294	1,788	6,398	4,283
Operating costs and expenses:				
Research, development and clinical trials	10,211	9,276	32,903	29,191
Sales and marketing	8,916	5,384	24,137	16,439
General and administrative	8,405	5,033	22,748	15,800
Total operating costs and expenses	27,532	19,693	79,788	61,430
Operating loss	(24,238)	(17,905)	(73,390)	(57,147)
Financial expenses, net	(809)	(53)	(2,277)	(91)
Loss before income taxes	(25,047)	(17,958)	(75,667)	(57,238)
Income taxes	976	362	2,986	528
Net loss	$(26,023)	$(18,320)	$(78,653)	$(57,766)

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
Operating statistics	2015	2014	2014	2015

Prescriptions received in period (1)				
Europe, Middle East and Africa	47	9	18	111
United States	307	133	422	1,108
	354	142	440	1,219
Active patients at period end (2)				
Europe, Middle East and Africa			9	60
United States			170	408
			179	468

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

(2) An “active patient” is a patient who is on TTFields therapy under a commercial prescription order as of the measurement date, including patients who may be on a temporary break from treatment and who plan to resume treatment in less than 60 days. In the United States, total cash payments of $19.7 million, net of indirect taxes, received during the nine months ended September 30, 2015 were recorded as revenues for Optune provided to patients in the current and prior periods. These cash payments represent an average of approximately $14,500 for each month of use, net of indirect taxes. Our average fill rate in the United States (i.e. prescriptions converted to active patients) for the nine months ended September 30, 2015 was 72%.

Three Months Ended September 30, 2015 Compared to Three Months Ended September 30, 2014

	Three Months Ended September 30,			
	2015	2014	Change	% Change
Net revenues	$8,953	$4,374	$4,579	105 %

Net revenues. Substantially all of our revenues are derived from patients using our TTFields delivery system, marketed as Optune in our currently active markets. Total cash payments received during the nine months ended September 30, 2015 were recorded as revenues for Optune provided to patients in the current and prior periods. Net revenues increased by $4.6 million, or 105%, to $9.0 million for the three months ended September 30, 2015 from $4.4 million for the three months ended September 30, 2014. The increase was primarily due to an increase of $4.3 million in U.S. commercial sales of Optune, primarily driven by a 60% increase in the number of US certified centers at September 30, 2014 versus at September 30, 2015, from 135 to 215, respectively, and increased US sales and marketing efforts, and to an increase of $0.3 million in commercial sales of Optune in our currently active markets in Europe (primarily Germany and Switzerland).

Cost of revenues. Our cost of revenues is comprised primarily of (i) cost of the disposable transducer arrays purchased from third-party manufacturers, (ii) depreciation expense for the field equipment, including the electric field generator used by patients and (iii) personnel, warranty and overhead costs such as facilities, freight and depreciation of property, plant and equipment associated with managing our inventory, warehousing and order fulfillment functions. Our cost of revenues increased by $3.1 million, or 119%, to $5.7 million for the three months ended September 30, 2015 from $2.6 million for the three months ended September 30, 2014. The increase was due to the increased volume of Optune shipments to commercial patients, comprised of $1.8 million in the cost of transducer arrays shipped to patients mainly in the United States, $0.8 million in personnel, $0.4 million in facility and other costs and $0.1 million in field equipment depreciation expense. The personnel, facility and other costs reported for the three months ended September 30, 2015 were driven by our efforts to establish the infrastructure necessary to support our commercialization efforts.

Operating Expenses.

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

	Three Months Ended September 30,			
	2015	2014	Change	% Change
Research, development and clinical trials	$10,211	$9,276	$935	10 %
Sales and marketing	8,916	5,384	3,532	66 %
General and administrative	8,405	5,033	3,372	67 %
	$27,532	$19,693	$7,839	40 %

Research, development and clinical trials expenses. Research, development and clinical trials expenses increased by $0.9 million, or 10%, to $10.2 million in the three months ended September 30, 2015 from $9.3 million for the three months ended September 30, 2014. The change was primarily due to an increase of $0.2 million in personnel costs (including share-based compensation) due to increased headcount related to the expansion of research and development activity for possible future indications, an increase of $0.9 million in supported third-party research and facility expenses, offset by a decrease in clinical trials and subcontractors expenses of $0.2 million as a result of the termination of EF-14 in the fourth quarter 2014. Total non-cash share-based compensation for research, development and clinical trials personnel for the three months ended September 30, 2015 and 2014 was $0.7 million and $0.3 million, respectively.

Sales and marketing expenses. Sales and marketing expenses increased by $3.5 million, or 66%, to $8.9 million for the three months ended September 30, 2015 from $5.4 million for the three months ended September 30, 2014. The change was due to an increase of $3.0 million in advertising and other marketing expenses and an increase of $0.5 million for increased headcount to support marketing activities (including share-based compensation). Total non-cash share-based compensation for sales and marketing personnel for the three months ended September 30, 2015 and 2014 was $0.6 million and $0.3 million, respectively.

General and administrative expenses. General and administrative expenses increased by $3.4 million, or 67%, to $8.4 million for the three months ended September 30, 2015 from $5.0 million for the three months ended September 30, 2014. The change was primarily due to an increase of $1.7 million in personnel costs due to increased headcount (including share-based compensation expenses) to support the growth and operation of our business, and an increase of $1.5 million in facilities and costs associated with preparing the

company for its initial public offering. Total non-cash share-based compensation for general and administrative personnel for the three months ended September 30, 2015 and 2014 was $1.7 million and $0.7 million, respectively.

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 functional 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. Financial expenses, net increased by $0.8 million to $0.8 million for the three months ended September 30, 2015, primarily due to finance expense, including interest, amortization of discount and deferred issuance costs related to our term loan credit facility entered into in January 2015.

	Three Months Ended September 30,				
	2015	2014	Change	% Change	
Income taxes	$976	$362	$ 614	170	%

Income taxes. Income taxes increased by $0.6 million to $1.0 million for the three months ended September 30, 2015. The change was primarily attributable to an increase in the statutory tax provision for Switzerland, the United States and Japan.

Nine Months Ended September 30, 2015 Compared to Nine Months Ended September 30, 2014

	Nine Months Ended September 30,				
	2015	2014	Change	% Change	
Net revenues	$20,704	$11,689	$9,015	77	%

Net revenues. Net revenues increased by $9.0 million, or 77%, to $20.7 million for the nine months ended September 30, 2015 from $11.7 million for the nine months ended September 30, 2014. The increase was primarily due to an increase of $8.2 million in U.S. commercial sales of Optune, primarily driven by a 60% increase in the number of US certified centers at September 30, 2014 versus at September 30, 2015, from 135 to 215, respectively, and increased US sales and marketing efforts and an increase of $0.8 million in commercial sales of Optune in our currently active markets in Europe.

Cost of revenues. Our cost of revenues increased by $6.9 million, or 93%, to $14.3 million for the nine months ended September 30, 2015 from $7.4 million for the nine months ended September 30, 2014.

The increase was primarily due to an increase of $4.4 million in transducer arrays shipped to U.S. commercial patients, an increase of $0.8 million in transducer arrays shipped to patients in Europe, an increase of $0.3 million for field equipment depreciation and an increase in personnel costs of $1.2 million associated with new employees.

Operating expenses

	Nine Months Ended September 30,				
	2015	2014	Change	% Change	
Research, development and clinical trials	$32,903	$29,191	$3,712	27	%
Sales and marketing	24,137	16,439	7,698	47	%
General and administrative	22,748	15,800	6,948	44	%
	$79,788	$61,430	$18,358	30	%

Research, development and clinical trials expenses. Research, development and clinical trials expenses increased by $3.7 million, or 27%, to $32.9 million for the nine months ended September 30, 2015 from $29.2 million for the nine months ended September 30, 2014. The change is primarily due to an increase in clinical trials expenses of $0.5 million, an increase of $1.1 million of personnel costs (including share-based compensation), and an increase of $0.2 million for regulatory expenses related to the preparation of approval applications to the Japanese Ministry of Health, Labor and Welfare for the treatment of recurrent GBM and the FDA in the United States for the treatment of newly diagnosed GBM in combination with temozolomide, an increase of related supported third-party research expenses of $1.0 million and an increase of $1.0 million in facility expenses due to an increase in activity in Switzerland and Japan. Total non-cash share-based compensation for research, development and clinical trials personnel for the nine months ended September 30, 2015 and 2014 was $1.7 million and $0.5 million, respectively.

Sales and marketing expenses. Sales and marketing expenses increased by $7.7 million, or 47%, to $24.1 million for the nine months ended September 30, 2015 from $16.4 million for the nine months ended September 30, 2014. The increase was driven by an increase

of $1.8 million of personnel costs (including share-based compensation), an increase of $4.2 million in advertising and other marketing expenses and an increase of $1.7 million in advisory fees. Total non-cash share-based compensation for sales and marketing personnel for the nine months ended September 30, 2015 and 2014 was $1.6 million and $0.8 million, respectively.

General and administrative expenses. General and administrative expenses increased by $6.9 million, or 44%, to $22.7 million for the nine months ended September 30, 2015 from $15.8 million for the nine months ended September 30, 2014. The increase was primarily related to an increase in personnel costs of $4.0 million (including share-based compensation) due to increased headcount to support the growth and operation of our business, an increase of $0.6 million for costs of professional services relating to the implementation of our new SAP ERP system and legal services, and an increase of $2.3 million related to facility and costs associated with preparing the company for its initial public offering. Total non-cash share-based compensation for general and administrative personnel for the nine months ended September 30, 2015 and 2014 was $4.0 million and $2.0 million, respectively.

Financial expenses, net. Financial expenses, net increased by $2.2 million, or 2,200%, to $2.3 million for the nine months ended September 30, 2015 from $0.1 million for the nine months ended September 30, 2014. The change was primarily due to the finance expenses, including interest, amortization discount and deferred issuance costs, related to our term loan credit facility entered into in January 2015.

	Nine Months Ended September 30,				
	2015	2014	Change	% Change	
Income taxes	$2,986	$528	$2,458	465	%

Income taxes. Income taxes increase by $2.5 million, or 465%, to $3.0 million for the nine months ended September 30, 2015 from $0.5 million for the nine months ended September 30, 2014. The change was primarily attributable to an increase in the statutory tax provision related to Switzerland, the United States and Japan.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred significant losses and cumulative negative cash flows from operations since our founding in 2000. As of September 30, 2015, we had an accumulated deficit of $355.1 million. We expect to continue to incur losses until our delivery systems achieve market acceptance. To date, we have primarily financed our operations through the issuance and sale of our convertible preferred shares and the proceeds from long-term loans. As of September 30, 2015, we had received a total of $454.3 million from the sale of our convertible preferred shares, including the sale of shares of our Series J convertible preferred stock in June 2015 for net proceeds of $94.6 million, all of which converted into our ordinary shares upon consummation of our IPO.

As of September 30, 2015, we had $110.3 million of cash and cash equivalents, including short-term investments of $27.0 million. In January 2015, we entered into the Loan and Security Agreement dated as of January 7, 2015, between us, as borrower, and Biopharma Secured Investments III Holdings Cayman LP, as lender (the “Term Loan

Credit Facility"), for up to $100.0 million, of which we drew $25.0 million on entering into the facility. In June 2015, we raised $94.6 million through the issuance of our Series J convertible preferred shares. Our IPO closed on October 7, 2015 and we issued and sold 7.5 million ordinary shares. We received cash proceeds of approximately $150.5 million from the IPO, net of underwriting discounts and commissions and estimated offering expenses. We believe our cash and cash equivalents as of September 30, 2015, together with the net proceeds of the IPO and availability under our Term Loan Credit Facility, are sufficient for our operations for at least the next 12 months based on our existing business plan and our ability to control the timing of significant expense commitments. We expect that our research, development and clinical trials expenses, sales and marketing expenses and general and administrative expenses will continue to increase over the next several years. As a result, we may need to raise additional capital in the future to fund our operations.

	Nine Months Ended September 30,	
	2015	2014
	(in thousands)	
Net cash used in operating activities	$(73,763)	$(56,628)
Net cash provided by (used in) investing activities	10,743	(39,280)
Net cash provided by (used in) financing activities	115,731	(9)
Net increase in cash and cash equivalents	$52,711	$(95,917)

Operating activities

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

Net cash used in operating activities was $73.8 million for the nine months ended September 30, 2015, as compared to $56.7 million for the nine months ended September 30, 2014, reflecting a net loss of $78.7 million and a change of $4.8 million in our net operating assets and liabilities, offset by non-cash charges of $9.7 million.

The change in our net operating assets and liabilities was primarily the result of an increase in our inventories of $7.7 million necessary to meet anticipated demand and an increase in other receivables of $4.5 million, offset by an increase in trade payables of $4.6 million and other payables of $3.0 million. Non-cash charges included $7.4 million of share-based compensation, $2.0 million of depreciation and $0.2 million of amortization related to our Term Loan Credit Facility.

Investing activities

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

Net cash provided by investing activities was $10.7 million in the nine months ended September 30, 2015 attributable to our receipt of $77.0 million from the maturity of short-term investments, offset by the purchase of new short-term investments of $59.0 million, purchases of $3.6 million of property and equipment and purchases of $3.5 million of field equipment. Net cash used in investing activities for the same period in 2014 was $39.2 million, attributable to the purchase of $107.9 million of short-term investments, purchases of property and equipment of $0.4 million and purchases of field equipment of $0.9 million, offset by receipt of $69.0 million from the maturity of short-term investments and a decrease in restricted cash of $1.0 million.

Financing activities

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

Net cash provided by financing activities was $115.7 million for the nine months ended September 30, 2015, attributable to the net proceeds from the issuance of Series J preferred shares of $94.6 million and borrowings under our Term Loan Credit Facility of $22.9 million, offset by deferred IPO costs of $1.7 million. Net cash provided by financing activities was $0.1 million in the same period of 2014, attributable to a long-term loan.

Term Loan Credit Facility

Our material outstanding indebtedness consists of our Term Loan Credit Facility, which provides for up to $100.0 million of borrowings in up to four draws, the first of which was made on January 30, 2015 in the amount of $25.0 million. Interest on the outstanding loan is 10% annually, payable quarterly in arrears. As of September 30, 2015, the aggregate principal balance of amounts outstanding under the Term Loan Credit Facility was approximately $25.0 million. The commitments made by the lender to make additional term loans terminate on June 30, 2016. We may prepay the term loans, in whole, at any time, and must prepay in the event of a change of control, in each case, subject to a pay-down fee, prepayment premium and/or make-whole payment. The funding fee payable on the amount drawn

on the funding date is 1.5%, the pay-down fee on all principal payments to be paid on the date such payments are made is 0.75% and the pre-payment fee if we prepay outstanding loan amounts prior to the first, second or third year from the initial funding date is 3.0%, 2.0% or 1.0%, respectively.

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

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

Contractual Obligations and Commitments

The following summarizes our significant contractual obligations at December 31, 2014:

	Payments Due by Period						
Contractual Obligations:	2015	2016	2017	2018	2019	After	Total
	(in thousands)						
Operating leases	$1,620	$1,385	$1,241	$937	$801	$1,395	$7,379
Term Loan Credit Facility(1)	-	-	-	-	-	25,188	25,188
Other long-term loans	59	66	69	73	22	90	380
Settlement agreement	$2,000	-	-	-	-		$2,000

There were no material changes in our commitments under contractual obligations in the nine months ended September 30, 2015.

The total amount of unrecognized tax benefits for uncertain tax positions was $0.3 million and $0.4 million at December 31, 2014 and September 30, 2015, respectively. Payment of these obligations would result from settlements with taxing authorities. Due to the difficulty in determining the timing of settlements, these obligations are not included in the above table. We do not expect a significant tax payment related to these obligations within the next year.

We also have employment agreements with certain employees that require the funding of a specific level of payments, if certain events, such as a change in control or termination without cause, occur.

In the course of normal business operations, we also have agreements with contract service providers to assist in the performance of our research and development (including clinical trials) and manufacturing activities. We could also enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require up-front payments and even long-term commitments of cash.

Off-Balance Sheet Arrangements

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

JOBS Act Election

The Jumpstart our Business Startups Act of 2012, or the JOBS Act, permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have irrevocably elected to “opt out” of the exemption for the delayed adoption of certain accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates and foreign currency exchange rates. We do not hold or issue financial instruments for trading purposes.

Interest Rate Sensitivity

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. Our cash, cash equivalents and short-term investment accounts as of September 30, 2015 totaled $137.3 million, and consist primarily of cash, cash equivalents and short-term investments with maturities of less than one year from the date of purchase. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of the interest rates in the United States. However, because of the short-term nature of the instruments in our portfolio, a 10% change in market interest rates would not be expected to have a material impact on our financial condition or our results of operations.

Foreign Currency Exchange Risk

Our consolidated results of operations and cash flow are subject to fluctuations due to changes in foreign currency exchange rates. All of our revenues are generated in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are

located, which is primarily in the United States, Switzerland and Israel. Our consolidated results of operations and cash flow are, therefore, subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates. The effect of a hypothetical 10% change in foreign currency exchange rates applicable to our business would not have a material impact on our historical consolidated financial statements. We do not hedge our foreign currency exchange risk.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2015. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2015, our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2015, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2015, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

An investment in our ordinary shares involves a high degree of risk. You should carefully consider all of the information in this Quarterly Report on Form 10-Q, including the risks and uncertainties described below, before you decide to buy our ordinary shares. 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 this Quarterly Report on Form 10-Q, including our consolidated financial statements and the related notes.

Risks relating to our business, TTFields and our delivery systems

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

Although we have received the FDA regulatory approvals for Optune for treatment of adult patients with newly diagnosed GBM in combination with temozolomide and recurrent GBM and the Japanese Ministry of Health, Labour and Welfare regulatory approvals for Optune for the treatment of recurrent GBM, and have affixed a CE mark to our TTFields delivery systems for certain indications in the European Union, such approvals and the CE mark affixed to our delivery systems do not guarantee future revenues for these indications, and until we receive FDA approval for the use of TTFields delivery systems for other indications, almost all of our revenues in the United States will derive from sales of Optune for newly diagnosed and recurrent GBM. The commercial success of Optune and any other delivery systems and our ability to generate and maintain revenues from the use of these delivery systems will depend on a number of factors, including:

- our ability to develop, obtain regulatory approval for and commercialize Optune and our other TTFields delivery system candidates for additional indications;
- our ability to successfully commercialize Optune and our other delivery system candidates for approved indications in our key markets;
- the acceptance of TTFields by patients and the healthcare community, including physicians and third-party payers (both private and public), as therapeutically effective and safe relative to the cost and safety of alternative therapies;
- the ability to obtain and maintain sufficient coverage or reimbursement by private and public third-party payers;
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the ability of our third-party manufacturers to manufacture Optune and other delivery systems in sufficient quantities with acceptable quality;
- our ability to provide marketing and distribution support for Optune and our other delivery system candidates;
- results of future clinical studies relating to TTFields or our competitors' products;
- the label and promotional claims allowed by the FDA and by the applicable rules on the promotion of medical devices in other foreign jurisdictions, such as in the EU member states;
- the maintenance of our existing regulatory approvals in the United States, the European Union, Switzerland and Japan; and
- the consequences of any reportable adverse events occurring in the United States, the European Union or other foreign jurisdictions.

In addition, sales of Optune are 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, and is limited for use by adults ages 22 and older). Optune is also less efficacious in the cerebellum, which may reduce the number of GBM patients to whom it may be prescribed.

Our ability to generate future revenues will depend on achieving regulatory approval of, and eventual commercialization of, our most advanced delivery system candidates. However, obtaining regulatory approval of our delivery systems 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 delivery systems. If we are not able to receive such approvals or to further commercialize our delivery systems, 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, operated as a development stage company through December 31, 2011 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 Optune and our delivery system candidates;
- obtain regulatory clearance to commercialize new delivery systems and enhance or modify our existing delivery systems;
- increase our sales, marketing and distribution organization to commercialize our delivery systems;
- perform clinical research and trials on TTFields;
- establish and increase awareness and acceptance of our delivery systems;
- implement and successfully execute our business and marketing strategy;
- respond effectively to competitive pressures and developments;
- maintain, protect and expand our intellectual property portfolio;
- expand our presence and commence operations in our key markets;
- attract, retain and motivate qualified personnel; and
- grow our organization to support our operations and our clinical pipeline and planned commercialization efforts.

We anticipate incurring significant costs associated with commercializing our delivery systems for approved indications. Our expenses could increase beyond expectations if we are required by the FDA, or other regulatory agencies, domestic or foreign, to change manufacturing processes for our delivery systems, 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 delivery systems and the ability to obtain reimbursement at such price. If the number of our addressable patients is not as significant as we estimate, the indications approved by regulatory authorities is narrower than we expect or the 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.

We can also be negatively affected by general economic conditions. We may not have insight into trends that could emerge and negatively affect our business. As a result of these or other risks, our business strategy might not be successful.

If we do not achieve our projected research and development and commercialization goals in the timeframes we announce or expect, our business would be harmed 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 United States and other foreign 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 enroll patients who meet clinical trial eligibility criteria;
- the extent of scheduling conflicts with participating clinicians and clinical institutions;
- the occurrence of unanticipated adverse events during clinical trials;
- the receipt of approvals by our competitors and by us of our delivery systems and our competitors' products;

- 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 delivery systems and delivery system candidates, including the transducer arrays and other materials;
- our ability to develop a sales and marketing organization and/or enter into sales and marketing collaborations for Optune and, if approved, our delivery system candidates; and
- other actions by regulators.

For example, our key milestones include our FDA approval of our second-generation Optune delivery system for GBM; and other clinical development milestones for other indications. 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/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 delivery systems 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 goals 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 may not be successful in our efforts to create a pipeline of delivery system candidates for future indications for TTFields and successfully commercialize them, or we may expend our resources on indications that do not yield a successful approval and fail to capitalize on other indications that may be more profitable or for which there is a greater likelihood of success.

We are pursuing clinical development of TTFields to treat a variety of solid tumors. For these future indications, we are at an early stage of development and we do not have approvals. Further, we do not intend to pursue indications involving solid tumors of the throat or extremities, and TTFields would not 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 delivery system candidates for additional indications are prone to risks of failure, including the significant risk that the development of our delivery system candidates for any potential indications will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We cannot provide you 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 delivery system candidates may not succeed in pre-clinical or clinical testing;
- our delivery systems 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 delivery systems obsolete or less attractive;
- the market for TTFields may change so that the continued development of our pipeline as currently contemplated is no longer appropriate;
- our delivery systems may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and

- our delivery systems may not be accepted as safe, effective, convenient or otherwise desirable by patients, the medical community 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 us to cease operations. Moreover, any such events in respect of any particular indication and/or delivery system candidate may have a negative effect on the approval process for other indications and/or result in losing approval of approved delivery systems for other indications, which may exacerbate the harm to our business and prospects.

We have limited experience in commercializing Optune and, to the extent we do not successfully develop this ability or contract with a third party to assist us, we may not be able to successfully commercialize our delivery systems that may be approved for commercial sale.

We currently have a small sales and marketing organization, and we may not be able to successfully develop adequate sales and marketing capabilities to achieve our growth objectives. The growth of our sales and marketing organization will require us to commit significant additional management and other resources. We will have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain the sales and marketing personnel that we anticipate we will need. If we are unable to establish adequate sales and marketing capabilities, we will need to enter into sales and distribution agreements to market some or all of our delivery systems that may be approved for commercial sale. In addition, because Optune and future delivery systems 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 Optune and other delivery systems.

If we are unable to establish adequate sales and marketing capabilities or successful distribution relationships, we may fail to realize the full sales potential of some or all of our delivery system candidates, 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 distribution agreements with other companies, we generally would not have control over the resources or degree of effort that any of these third parties may devote to our delivery systems, and if they fail to devote sufficient time and resources to the marketing of such delivery systems, or if their performance is substandard, it will adversely affect our revenues.

We may not be successful in achieving market acceptance of TTFields 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 TTFields as a monotherapy or in combination with well established cancer treatment modalities like surgery, radiation and chemotherapy. We may not achieve market acceptance of Optune and other TTFields delivery systems we develop in the amount of time that we have anticipated, or at all, for a number of different reasons. As a general matter, we may not achieve market acceptance of TTFields because of the following factors, among others:

- it may be difficult to gain broad acceptance of TTFields because it is a new technology and involves a novel delivery system, and as such physicians may be reluctant to prescribe TTFields delivery systems without prior experience or additional data or training;
- 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 TTFields, which could lead to reluctance to prescribe our TTFields delivery systems;
- patients may be reluctant to elect to use our TTFields delivery systems, including Optune, for various reasons, including a perception that the treatment is untested;
- the delivery systems may have some side effects (for example, dermatitis where the transducer arrays are placed) and the delivery system cannot be worn in all circumstances (for example, it cannot get wet and is difficult to wear in high temperatures); and
- the price of the TTFields delivery systems includes a monthly fee for use of the delivery system (including the transducer arrays), so as the duration of the treatment course increases, the 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, Optune may not achieve market acceptance because of the following additional factors (which may apply to our future delivery systems, to varying degrees):

- achieving patient acceptance is difficult because GBM is a devastating disease with a poor prognosis, and not all patients with short lifespans are willing to comply with Optune therapy requirements, such as extended use of Optune, carrying around a battery pack and shaving their heads (which may be of particular concern to women), and other patients may forego Optune treatment for cosmetic or mobility reasons;
- achieving patient compliance is difficult because the recommended average daily use of Optune 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 recharged, and the patient or a caregiver must ensure that it remains continuously operable;

- certain patients are not advised to use Optune, 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 Optune with these devices has not been tested and may lead to malfunctioning of these devices; patients who have a skull defect, a shunt or bullet fragments because the use of Optune with these conditions has not been tested and may lead to tissue damage or render Optune ineffective; and patients who are sensitive to conductive hydrogels because skin contact with the gel used in Optune 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 Optune nearly continuously in order to achieve efficacy of TTFields may also impact the pool of patients to whom physicians may be willing to prescribe treatment, as physicians may be reluctant to treat patients who are physically frail or lack caregiver support with Optune, and 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 Optune cannot get wet, or while traveling because Optune batteries cannot be taken on airplanes, and although we ship batteries to patients, there is inevitably a disruption in continuous use; and
- side effects reported by GBM patients treated with a combination of TTFields and temozolomide, including dermatitis where the transducer arrays are placed, headaches, weakness, falls, fatigue, muscle twitching and skin ulcers (and there may be additional side effects not yet observed).

In addition, even if we are successful in achieving market acceptance of Optune for GBM, we may be unsuccessful in achieving market acceptance of TTFields as a treatment for other solid tumor cancers, such as brain metastases, NSCLC, pancreatic cancer, ovarian cancer, mesothelioma and other solid tumor cancers, because certain radiation or chemotherapies may 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 TTFields delivery systems. If we do not achieve market acceptance of our delivery systems 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 delivery systems 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 delivery systems to patients or indirectly via payments made to hospitals or other entities providing our delivery systems to patients. Private payers in the United States cover a majority of the population, with the remainder covered by governmental payers or uninsured. In 2014, United Healthcare and Aetna represented 15% and 12%, respectively, of our net revenues. We anticipate that the majority of the third-party payers outside the United States will be government agencies, government sponsored entities or other payers operating under significant regulatory requirements from national or regional governments.

Medical treatments may not be reimbursed by third-party payers based on a number of factors, such as a determination that it is experimental, not medically necessary or not appropriate for a particular patient. Currently, we are aware that seven private payers in the United States have issued policies that deny coverage for Optune on one or more of these bases. 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 in the United States and 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 U.S. federal and state governments and 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 delivery

system or the combination of our delivery system with additional treatments to be cost-justified under a required cost-testing model, they may not cover our delivery systems for their populations or, if they do, the level of payment may not be sufficient to allow us to sell our delivery systems on a profitable basis.

Reimbursement for the treatment of patients with medical devices in the EU member states, Switzerland and Japan is governed by complex mechanisms established on a national level in each country. In the European Union, these mechanisms vary widely among the EU member states and evolve constantly, reflecting the efforts of these countries to reduce public spending on healthcare. As a result, obtaining reimbursement for the treatment of patients with medical devices has become more challenging. Outside the United States, the European Union and Japan, reimbursement systems vary significantly by country. We cannot, therefore, guarantee that the treatment of patients with Optune or any of our future delivery systems would be reimbursed in any of the EU member states, Switzerland, Japan or any other country.

We provide financial assistance to patients to defray their out-of-pocket costs for Optune, and therefore, absorb any unreimbursed costs of patients who begin treatment and 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.

Our failure to secure or maintain adequate coverage or reimbursement for Optune or any of our future delivery systems by third-party payers in the United States or in the other jurisdictions in which we market Optune or any of our future delivery systems, could have a material adverse effect on our business, financial condition and results of operations and cause our stock price to decline.

We may not be successful securing and maintaining reimbursement codes necessary to facilitate accurate and timely billing for Optune, future delivery systems and physician services attendant to TTFields therapy.

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 United States, the billing codes most directly related to Optune and future delivery systems are contained in the Healthcare Common Procedure Coding System, or HCPCS code set. The HCPCS code set contains Level I codes that describe physician services, also known as Common Procedural Terminology codes, or CPT codes, and Level II codes that primarily describe products. The Centers for Medicare and Medicaid Services, or 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 United States 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.

No CPT codes exist to describe physician services related to the delivery of TTFields therapy. We may not be able to secure CPT codes for physician services related to Optune 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 delivery systems or to document physician services related to the delivery of TTFields therapy in markets outside the United States. 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 Optune or our future delivery systems.

Approximately 25% of our patients are beneficiaries under the Medicare fee-for-service program as of September 30, 2015. 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 United States.

Medicare has the authority to issue national coverage determinations or to defer coverage decisions to its regional Medicare Administrative Contractors, or MACs. Medicare has not issued a national coverage determination for Optune. The four MACs that administer the durable medical equipment benefit for Medicare, or DME MACs, have each issued local coverage determination policies stating that Optune is not reasonable and necessary for the treatment of recurrent GBM. The continuing 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 Optune or future delivery systems that do not reflect then current prices for Optune or future delivery systems. Medicare price schedules are frequently referenced by private payers in the United States and around the world. Medicare would materially reduce our revenues and operating results by publishing a price for Optune or future delivery systems that is not based on the actual price of Optune or future delivery systems within the private payer market.

We are unable to bill our existing Medicare fee-for-service patients for amounts not paid by Medicare. Therefore, we will absorb the costs of treatment for amounts not paid by Medicare.

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

We source some of the key components of Optune 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. For example, we currently have a single source for the ceramic discs used in the transducer arrays for Optune, which we source from Exelis Inc., or Exelis (formerly ITT Corporation). We currently do not have alternate suppliers for these ceramic discs, and our existing supplier

would be difficult for us to replace because the ceramic discs are manufactured with specialized electrical properties designed specifically for Optune, and as such there are few vendors available to produce these components, and those that can supply them may not be able to do so on terms that are commercially favorable to us. We are in the process of identifying a second source for the ceramic discs, but we can provide no assurance that we will secure an alternate supplier on favorable terms or in time to support our commercialization efforts, or at all. Our current agreement with Exelis continues through July 21, 2017, following which time the agreement will automatically renew for up to three successive two-year periods unless either we provide timely written notice of non-renewal (for any reason) or Exelis provides timely written notice of non-renewal (if we fail to satisfy certain minimum purchase requirements). We currently expect that this agreement will be renewed. In addition to certain other customary termination rights, Exelis can terminate this agreement with 90 days' written notice if we breach any of our material obligations under the agreement.

Agreements with our other suppliers range from terms of four years to ten years and are terminable by either party, generally between 180 days' and 12 months' written notice. Establishing additional or replacement suppliers for any components of our delivery systems, 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 Optune, 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 foreign 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 European Union. 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 United States, we are subject to foreign export laws and United States import and customs regulations, which complicate and could delay shipments of components to us.

We are currently seeking second-source suppliers, which we expect to have under contract over the next few years, but we can provide no assurance we will achieve this on this timeframe or at all. Various steps must be taken before signing up these suppliers, including qualifying these suppliers in accordance with regulatory requirements.

If we experience any delay or deficiency in the quality of 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 Optune 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 delivery systems 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 foreign regulatory authorities 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 delivery systems, regulatory approval or the CE Certificates of Conformity for our delivery systems 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 Optune and our future delivery systems and, as a result, a material adverse effect on our business, prospects, financial condition and results of operations.

Our delivery systems, 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 or the commercialization of Optune and our future delivery systems. 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 delivery systems 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 pre-clinical research and development do not perform as contractually required or expected, we may not be able to obtain regulatory approvals for our future delivery systems or commercialize our future delivery systems.

We do not have the ability to independently conduct our pre-clinical and clinical trials for our delivery systems and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to conduct such trials. We and these third parties are required to comply with current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for TTFields in clinical development. Regulatory

authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or foreign regulatory authorities 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 clinical trials comply with the cGCP regulations.

Any third parties conducting our 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 pre-clinical, 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 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 pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our delivery systems or successfully commercialize our delivery systems on a timely basis, if at all, and our business, prospects and results of operations may be adversely affected.

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 size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- 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 TTFields 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;
- 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;
- 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 TTFields 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 TTFields, or, in those trials where TTFields is 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.

Continued testing of Optune or our other delivery system candidates may not yield successful results and could reveal currently unknown safety hazards associated with TTFields.

Our research and development programs are designed to test the safety and efficacy of TTFields through extensive pre-clinical 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 regarding them. Success in pre-clinical 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 pre-clinical 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 pre-clinical 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 Optune and any of our delivery system candidates, including the following:

- safety and efficacy results for Optune and any of our delivery system candidates obtained in our pre-clinical 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 TTFields' clinical trials;
- the data collected from clinical trials of our delivery system candidates may not reach statistical significance due to limited sample size or otherwise be sufficient to support FDA or other regulatory approval; and
- our delivery system candidates may not produce the desired effects or may result in adverse health effects or other characteristics that are not currently known that preclude additional regulatory approval or limit their commercial use if approved.

To date, patients treated with Optune in our EF-11 and EF-14 clinical trials have experienced treatment-related side effects, including dermatitis where the transducer arrays are placed, headaches, weakness, falls, fatigue, muscle twitching and skin ulcers. There may be additional side effects observed in future clinical trials and/or through real-world experience with patients using Optune or our other TTFields delivery system candidates. Undesirable side effects caused by our delivery systems 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 delivery system candidates, 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 delivery system candidates 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 any of our delivery system candidates. Inadequate training in recognizing or managing the potential side effects of our delivery system candidates 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 delivery systems submissions for regulatory approvals and ultimately our ability to commercialize our delivery systems and generate revenues. Furthermore, we may abandon delivery system candidates 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 them to develop additional oncology treatments to compete with TTFields.

The oncology market is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. As a monotherapy, TTFields primarily competes with radiation and pharmacological therapies. We may face additional competition as advancements are made in the field of immuno-oncology and to date, we have not conducted any clinical trials where TTFields is used in combination with an immuno-oncological therapy. Many of our competitors are large, well capitalized companies with significantly more 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 TTFields 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 and other solid tumors that could reduce the benefits of using our TTFields delivery systems. If an existing or future competitor develops a product that proves to be superior or comparable to Optune or any of our future delivery systems, 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 us. Additionally, our anticipated growth will increase the demands placed on our suppliers, resulting in an increased need for us to carefully monitor the available supply of components and quality assurance. 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 management and scientific personnel may prevent us from developing TTFields, conducting clinical trials 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.

For the majority of our history, Asaf Danziger and Dr. Eilon Kirson have played a significant role in our research efforts. Mr. Danziger is our Chief Executive Officer and a director of our company and Dr. Kirson is our Chief Science Officer and Head of Research and Development. We are highly dependent on these individuals, and they have played a critical role in our research and development programs, clinical trials and financing. Additionally, we have several scientific personnel with significant expertise in TTFields, some of whom are critical to our research and development efforts. The loss of the services of either of these key members of our company or any of our scientific personnel may prevent us from achieving 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 TTFields 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. For example, while our U.S. operations are subject to U.S. federal income tax, we believe that a significant portion of our non-U.S. operations are generally not subject to U.S. tax other than withholding taxes in certain 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 have been made and legislation has been introduced (for example, the Swiss Corporate Tax Reform III, or CTR III) 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. As an example, recent U.S. legislative proposals would broaden the circumstances under which a foreign corporation like us would be considered a U.S. resident for U.S. federal income tax purposes, in addition to other U.S. legislative proposals that could have a material adverse impact on us by overriding certain tax treaties and limiting the treaty benefits on certain payments, which could increase our tax liability. We cannot predict whether or when any of these potential changes in law might become effective in any jurisdiction.

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. In particular, 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.

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 delivery systems. 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 delivery systems cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. This may occur if Optune is 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 TTFields.

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 Optune and our delivery system candidates. 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 TTFields delivery systems;
- 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.

Regional instability in Israel may adversely affect business conditions and may disrupt our business and negatively affect our revenues and results of operations.

We have research facilities located in Israel, and one of our key suppliers, which is both a component supplier and finished good manufacturer, manufactures its goods in one physical location in Israel. Accordingly, political, economic and military conditions in Israel may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors, as well as incidents of civil unrest. In recent years, these have included hostilities between Israel and Hezbollah in Lebanon and

Hamas in the Gaza strip, both of which resulted in rockets being fired into Israel, causing casualties and disruption of economic activities. While we did not sustain damages from the conflicts with Hezbollah or Hamas, our Israeli operations, which are located in Haifa, in northern Israel, are within range of Hezbollah missiles and we or our immediate surroundings may sustain damages in a missile attack, which could adversely affect our operations. Recent political events, including political uprisings, social unrest and regime change, in various countries in the Middle East and North Africa have weakened the stability of those countries, which could result in extremists coming to power. Any future armed conflicts or political instability in the region could have a material adverse effect on our business, prospects, financial condition and results of operations

and cause our stock price to decline. 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.

Additionally, several countries, principally in the Middle East, restrict doing business with Israeli companies, and additional countries and groups may impose similar restrictions if hostilities in Israel or political instability in the region continue or increase. If recent regime changes and civil wars in neighboring states result in the establishment of fundamentalist Islamic regimes or governments more hostile to Israel, or if Egypt or Jordan abrogates its respective peace treaty with Israel, Israel could be subject to additional political, economic and military confines, which could result in a material adverse effect on 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. Additionally, 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.

If any of our 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 United States, Switzerland, Israel and Japan. Additionally, one of our key suppliers, which is both a component supplier and finished goods manufacturer, manufactures its goods in one physical location in Israel. Damage or extended periods of interruption to our or our suppliers' or manufacturers' corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry, terrorist attacks or other events could cause us to cease or delay development of some or all of our delivery systems. 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.

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.

As of September 30, 2015, we had approximately $25.0 million of indebtedness outstanding under our Loan and Security Agreement dated as of January 7, 2015, between us, as borrower, and Biopharma Secured Investments III Holdings Cayman LP, as lender, or the Term Loan Credit Facility, and availability to borrow an additional $75.0 million thereunder. We may incur additional indebtedness in the future, including draws under our Term Loan Credit Facility. 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 Term Loan 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 Term Loan 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.

In addition, our Term Loan Credit Facility has a minimum liquidity covenant, which is tested quarterly. We must also meet certain annual pro forma net sales requirements.

Risks relating to regulation

Our delivery system candidates must undergo rigorous pre-clinical 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 Optune and our delivery system candidates, are subject to regulation, including regulation for safety, efficacy and quality, by the FDA in the United States and comparable authorities in other countries. FDA regulations and the regulations of comparable foreign regulatory authorities are wide-ranging and govern, among other things:

- the conduct of pre-clinical 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;
- 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 pre-clinical 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 foreign regulatory agency 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, foreign

regulatory agencies 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 United States, 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 United States, Japan and other countries or to obtain CE Certificate of Conformity in the European Union for our various future delivery system candidates. Even if we believe the data collected from our clinical trials are sufficient, the FDA, equivalent foreign regulatory bodies 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 United States, Japan and other countries or the CE marking in the European Union of our delivery system candidates, which could prevent us from achieving profitability.

We currently market Optune in the United States, as well as certain EU member states, Switzerland and Japan. We intend to market our TTFields delivery systems in a number of additional international markets. Although certain of our delivery systems have been approved for commercialization in Australia, Switzerland and Israel and are CE marked in the European Union, in order to market our delivery systems in other foreign jurisdictions and for other indications, we must obtain separate regulatory approvals and CE Certificates of Conformity. The requirements governing the conduct of clinical trials and manufacturing and marketing of our delivery system candidates outside the United States vary widely from country to country. Foreign regulatory approvals and CE Certificates of Conformity may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical trial designs. Foreign regulatory approval and CE marking processes include essentially all of the risks associated with the FDA approval processes. Some foreign agencies 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 European Union and vice versa. In addition, changes in regulatory policy in the United States or in foreign 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 CE marking of medical devices may also have a potential impact on the CE marking of our delivery systems in the European Union. On September 26, 2012, the European Commission adopted a package of legislative proposals designed to replace the existing regulatory framework for medical devices in the European Union. On October 22, 2013, the European Parliament voted on an amended draft of the Regulation. The proposed text is currently being discussed by the Council of the European Union, or the Council. If and when adopted, the proposed new legislation may prevent or delay the CE marking of our delivery systems under development or impact our ability to modify our currently CE marked delivery systems on a timely basis. On June 19, 2015, the Council came to a common position concerning the Council's proposed amendments to the two draft regulations intended to replace the current Medical Devices Directive, the Active Implantable Medical Devices Directive and the In Vitro Diagnostic Medical Devices Directive. Negotiations among the Council, the European Parliament and the European Commission are now expected to start in the fourth quarter of 2015. Depending on the outcome of the negotiations, the regulation on medical devices and the regulation on in vitro diagnostic medical devices could be definitively adopted in mid-2016.

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, foreign regulatory agencies, 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 Good Manufacturing Practices, or GMP, 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 foreign regulatory agency at any time if the FDA or the foreign 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 foreign regulatory agencies 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 foreign regulatory authority or an ethics committee regarding the protocol for the conduct of 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 United States and other foreign jurisdictions and CE Certificates of Conformity in the European Union 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 European Union, 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 United States 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 United States healthcare system. In the United States, the Patient Protection and Affordable Care Act, or 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.

In addition, other legislative changes have been proposed and adopted in the United States 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. On January 2, 2013, the American Taxpayer Relief Act, or the ATRA, was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals.

The U.S. Congress could pass additional healthcare laws in the future, including those that affect coverage and reimbursement for healthcare items and services, including our delivery systems. The Centers for Medicare and Medicaid Services, or CMS, also could implement regulatory changes that could affect coverage and reimbursement for our delivery systems as well. In addition, various healthcare reform proposals have also emerged at the state level. We cannot predict to what extent future healthcare initiatives will be implemented at the federal or state level or the effect any future legislation or regulation will have on us.

We continue to evaluate the impact that PPACA will have on our business. The taxes imposed by the new federal legislation and the expansion in government's role in the U.S. healthcare industry may result in decreased revenues, lower reimbursements by payers for our delivery systems 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.

The competent authorities in the EU member states are increasingly active in their goal of reducing public spending on healthcare. We cannot, therefore, guarantee that the treatment of patients with Optune would be reimbursed in any of the EU member states or, if successfully included on reimbursement lists will remain thereon. If adopted, the recent proposals of the European Commission for new rules governing medical devices in the European Union could impose additional requirements on manufacturers of medical devices placed on the market in the European Union. Failure to

comply with these new requirements may affect our ability to market our delivery systems in the European Union.

We are subject to extensive regulation by the FDA and equivalent foreign authorities, which could restrict the sales and marketing of Optune and could cause us to incur significant costs. In addition, we may become subject to additional foreign regulation as we increase our efforts to sell Optune outside of the United States.

We sell Optune, and expect to sell our delivery system candidates, subject to extensive regulation by the FDA and numerous other federal, state and foreign governmental authorities. These regulations are broad and relate to, among other things, the conduct of pre-clinical 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, advertising and promotion and product sales and distribution. Although we have received FDA approval

to market Optune in the United States for the treatment of adult patients with newly diagnosed in combination with temozolomide and recurrent GBM, we will require additional FDA approval to market Optune for other indications. We may be required to obtain approval of a new PMA or PMA supplement application for modifications made to Optune. 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 or PMA supplements for the modifications, we may be required to recall and to stop marketing the modified versions of Optune.

In addition, before our delivery systems can be marketed in the European Union, 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 European Union 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 European Union 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 maintenance of 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 the United States and other jurisdictions, we also are subject to numerous post-marketing regulatory requirements, which include quality system regulations related to the manufacturing of our delivery systems, labeling regulations and medical device reporting regulations, which require us to report to the FDA or other foreign regulatory authorities and notified bodies if our delivery systems cause or contribute 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 foreign regulatory authorities 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 of medical devices believed to be adulterated or misbranded;
- operating restrictions, suspension or shutdown of production;
- refusal or delay of our requests for PMA approval for new intended uses or modifications to Optune;
- refusal or delay of our requests for PMA approval of new delivery systems;
- refusal or delay in obtaining CE Certificates of Conformity for new intended uses or modifications to Optune;
- 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 approvals that have already been granted;
- refusal to grant export approval for Optune 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 Optune or any of our future approved delivery systems may require approvals of new PMA or PMA supplement applications, modified or new CE Certificates of Conformity or even require us to cease promoting or to recall the modified versions of Optune until such clearances, approvals or modified or new CE Certificates of Conformity are obtained, and the FDA,

foreign regulatory authorities 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. The FDA requires a company to make the determination as to whether a new PMA 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. Currently, we intend to submit a PMA supplement application for our next-generation Optune delivery system, which may require clinical data, and from time to time make other changes to the software and packaging and may submit additional PMA supplement applications for these changes. 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 European Union 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 delivery systems we market or sell in the European Union of any planned substantial changes to our quality system or changes to our devices 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 delivery system'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 delivery systems. 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 delivery systems could be subject to recall if the FDA or the competent authorities of the EU member states or our notified body determine, for any reason, that our delivery systems 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 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 our delivery systems, 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 foreign regulations in addition to FDA regulations, and, if we are unable to fully comply with such regulations, we could face substantial penalties.

We are subject to extensive regulation by the U.S. federal government and the states and foreign 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 for the purpose of inducing or rewarding referrals for items or services reimbursable by a federal healthcare program;
- the U.S. federal False Claims Act, or the 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 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;
- 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;
- state accreditation and licensing requirements applicable to DME providers;
- the U.S. Foreign Corrupt Practices Act, which can be used to prosecute companies in the United States for arrangements with physicians or other parties outside the United States 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 advertising and consumer protection;
- the Physician Payments Sunshine Act, or the Sunshine Act, and similar state and foreign laws, which require reporting of payments and other transfers of value to health care practitioners periodically; and
- the laws and codes of practices applicable in the EU member states, Switzerland and Japan concerning the marketing and promotion of medical devices, interactions with healthcare professionals, consumer protection, comparative advertising and unfair commercial practices, data protection, 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 foreign laws regarding interactions with healthcare professionals 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 European Union, individual EU member states and other foreign countries. These laws are complemented by EU or national profession 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.

Any violation of these laws or equivalent foreign laws and codes of practices regarding interactions with healthcare professionals 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 delivery systems, 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.

If we, our contract manufacturers or our component suppliers fail to comply with the FDA's quality system regulations or equivalent regulations established in foreign countries, the manufacturing and distribution of our delivery systems could be interrupted, and our delivery system sales and results of operations could suffer.

We, our contract manufacturers and our component suppliers are required to comply with the FDA's quality system regulations 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 delivery systems. 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 and the two critical finished goods manufacturers listed in our PMA were inspected by the FDA in the first half of 2012 and again in the fall of 2013. No material inspectional observations were identified and no FDA Form 483s were issued following these inspections. 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 delivery systems 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 delivery systems. If any of these events occurs, we may not be able to provide our customers with TTFields delivery systems that they require 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 delivery systems may in the future be subject to recalls that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities 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, foreign governmental bodies have the authority to require the recall of our delivery systems 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 delivery systems 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 delivery systems 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 any of our delivery systems 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 delivery systems 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 foreign jurisdictions in which our delivery systems 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 foreign authorities within the required timeframes, or at all, the FDA or the equivalent foreign authorities could take enforcement action against us. Any such adverse event involving our delivery systems 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 delivery systems 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 delivery systems in the United States and foreign jurisdictions. Currently, Optune is approved for treatment of adult patients with newly diagnosed GBM (in combination with temozolomide) and recurrent GBM in the United States. In the European Union 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 Japan for the treatment of recurrent GBM and in Australia for the treatment of recurrent GBM and newly diagnosed GBM (in combination with temozolomide).

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 letter, a warning letter, an injunction,

seizure, civil fines and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities 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 commercialization of Optune 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 delivery systems 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 delivery systems. 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 delivery systems. 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 Optune. 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 United States.

As a DME supplier, if we are found to have violated laws protecting the confidentiality of patient health 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 patient health information, including patient records, and restricting the use and disclosure of that protected information, 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 health 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 European Union is governed by the provisions of Directive 95/46/EC of the European Parliament and of the Council of October 24, 1995, on the protection of individuals with regard to the processing of personal data and on the free movement of such data, commonly known as the Data Protection Directive. The EU member states have adopted national laws and regulations transposing the EU Data Protection Directive into their national laws. The Data Protection Directive and related national laws impose a number of requirements, including an obligation to seek the consent of individuals to whom the personal data relates, the information that must be provided to the individuals, notification of data processing obligations to the competent national data protection authorities of EU member states and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict rules on the transfer of personal data out of the European Union to the United States. We are currently assessing the impact of the recent EU decision overturning the EU-United States data protection safe harbor. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of EU member states may result in fines and other administrative penalties.

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 affected by federal, state, foreign and local 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 delivery systems. 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 delivery systems 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 delivery systems 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.

The Air Line Pilots Association International has called on the U.S. government to prohibit shipments of lithium-ion batteries on cargo and passenger planes pending new regulations, in light of recent incidents involving a battery pack for an electric bicycle and more recently lithium ion batteries in a shipment of electronic cigarettes that may have been a contributing factor in a fire on a FedEx cargo plane. Rechargeable lithium-ion batteries are not as flammable and can be put out with fire extinguishers, but the National Transportation Safety Board has issued a series of recommendations calling for tighter regulation and testing of the batteries. In March 2014, the U.S. Department of Transportation and the Pipeline and Hazardous Materials Safety Administration issued new standards to strengthen safety conditions for the shipment of lithium-ion batteries and cells. The new rules enhance packaging and hazard communication requirements for lithium-ion batteries transported by air, adopt separate shipping descriptions for lithium-ion batteries, revise provisions for the transport of small and medium lithium-ion batteries packed with, or contained in, equipment, and harmonize the provisions for the transport of low production and prototype lithium cells and batteries with the International Civil Aviation Organization's Technical Instructions and the International Maritime Dangerous Goods Code. In February 2015, the U.S. Postal Service revised its policies so that shipping carriers are not permitted to ship packages solely containing lithium-ion batteries internationally. Consequently, we use vendors other than the U.S. Postal Service to ship our lithium-ion batteries.

Additionally, lithium ion batteries are classified as Class 9—Miscellaneous Dangerous Goods by the International Air Transport Association, or IATA. Our batteries have passed the UN 3480 test for transport as cargo called out in the IATA guidelines and, as such, when they are properly packaged and labeled (with a class 9 sticker) they can be shipped by air transport as cargo. However, our batteries are not allowed on passenger aircraft according to the IATA standards. 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 delivery systems 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.

Risks relating to intellectual property

If we are unable to protect our proprietary technology, trade secrets or know-how, we may not be able to operate our business profitably. Similarly, if we fail to sustain, further build and enforce our intellectual property rights, competitors may be able to develop competing therapies.

Our success depends, in part, on our ability to obtain and maintain protection for our delivery systems and technologies under the patent laws or other intellectual property laws of the United States and other countries. The standards that the U.S. Patent and Trademark Office, or USPTO, and its foreign counterparts 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 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, or 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 TTFields, Optune, our other delivery system candidates, the methods employed in the use of our delivery systems or other activities infringe on U.S. or foreign 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 delivery systems may infringe. There could also be existing patents that one or more components of our delivery systems 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 Optune 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 delivery systems to avoid any infringement. Modification of our delivery systems 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.

We entered into a settlement agreement in February 2015 with the Technion, whereby we agreed to resolve certain potential disputes among us, the Technion and Professor Yoram Palti arising out of certain intellectual property that Professor Palti developed while affiliated with the Technion and which Professor Palti has assigned to us. As part of the settlement, we have a contingent obligation to pay the Technion $5.5 million upon the earlier of our achieving $250.0 million of cumulative net sales since our inception, as defined in the Settlement Agreement, and any merger, consolidation, reorganization or sale or other disposition of all or substantially all of our assets.

The patent rights on which we rely to protect the intellectual property underlying TTFields delivery systems 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 are limited to certain ranges. For example, some of our patents protect low-intensity (1-3 V/cm), 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 United States 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 technologies we have patented or developed.

We also may fail to apply for or be unable to obtain patent rights in some foreign countries. In addition, the legal systems of certain countries may not protect our rights to the same extent as the laws of the United States, which could affect our ability to enforce patent rights effectively in such foreign 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 TTFields, Optune and our other delivery systems 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 foreign intellectual property rights 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 United States, we do not have any intellectual property rights, and our intellectual property rights in other countries outside the United States have a different scope and strength compared to our intellectual property rights in the United States. Consequently, we will not be able to prevent third parties from practicing our inventions in all countries outside the United States. 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 United States. 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 United States 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

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our ordinary shares less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including the ability to include only two years of audited financial statements and only two years of related management's discussion and analysis of financial condition and results of operations disclosure, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act or any Public Company Accounting Oversight Board requirements regarding mandatory audit firm rotation or supplemental disclosures regarding the audit, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our ordinary shares held by non-affiliates exceeds $700 million as of any June 30 before that time, in which case, we would become a large accelerated filer under SEC rules and would no longer be an emerging growth company as of the following December 31. We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

There was no public market for our ordinary shares prior to our initial public offering, and an active trading market for our ordinary shares may not develop. As a result, you may not be able to resell your ordinary shares at or above the price you paid, or at all.

Prior to our initial public offering in October 2015, there was no public market for our ordinary shares and we cannot predict the extent of investor interest in us following our initial public offering. An active trading market for our ordinary shares may not develop or be maintained after our initial public offering and the market price of our ordinary shares may decline, from time to time. The lack of an active market for our ordinary shares may impact our shareholders' ability to sell their shares at the time they wish to sell or at a price that they consider reasonable.

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 Optune, 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 United States 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 United States, Israel or elsewhere. In addition, the performance, and fluctuation in market prices, of other foreign companies that have listed their securities in the United States 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 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 United States, 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 United States. Although we have appointed an agent for service of process in the United States 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 United States, and all or a substantial portion of the assets of such persons are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States 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 United States.

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: (a) 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; (b) the Jersey courts may refuse to give effect to any provision in an agreement that would involve the enforcement of any foreign revenue or penal laws; and (c) 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 initial public offering (other than any shares acquired by our affiliates) will be freely transferable without restriction or additional registration under the Securities Act of 1933, as amended, or the Securities Act. Substantially all of the remaining ordinary shares outstanding after our initial public offering in October 2015 will be available for sale upon the expiration of the 180-day lock-up period, subject to volume, notice and manner of sale restrictions as applicable to our affiliates in the United States under Rule 144 and Rule 701 under the Securities Act. Any or all of these ordinary shares may be released prior to expiration of the lock-up period at the discretion of J.P. Morgan Securities LLC. To the extent ordinary shares are

released before the expiration of the lock-up period and these ordinary shares are sold into the market, the market price of our ordinary shares could decline.

Our executive officers, directors and principal shareholders may exert control over us and may be able to exercise influence over matters subject to shareholder approval.

Our executive officers and directors, together with their respective affiliates, beneficially owned immediately after the consummation of our initial public offering approximately 33.6% of our outstanding ordinary shares, before giving effect to any exercise of the underwriters' over-allotment option. Accordingly, these shareholders, if they act together, will be able to exercise substantial influence over all matters requiring shareholder approval, including the election of directors and approval of corporate transactions, such as a merger. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on the market value of our ordinary shares.

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.

Our management has broad discretion over the use and investment of the net proceeds we received in our initial public offering and may not apply the proceeds in ways that increase the value of your investment.

Our management has broad discretion over the use and investment of the net proceeds we received from our initial public offering, and you will be relying on, and may not agree with, the judgment of our management regarding the application of these net proceeds. Our management intends to use the net proceeds for working capital and general corporate purposes, including clinical trials, research and development and continued commercialization of Optune and future delivery systems. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business and cause the price of our ordinary shares to decline. Pending these uses, we may invest the net proceeds we receive from our initial public offering in a manner that does not produce income or loses value.

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.

We incur significant costs on an ongoing basis as a result of operating as a company whose ordinary shares are publicly traded in the United States, and our management will be required to devote substantial time to new compliance initiatives, including after we are no longer an emerging growth company.

As a company whose shares are publicly traded in the United States, we incur significant legal, accounting and other expenses on an ongoing basis. In addition, the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, and the rules of the SEC and The NASDAQ Stock Market LLC, or NASDAQ, have imposed various requirements on public companies, including requirements for the establishment and maintenance of effective disclosure controls and internal control over financial reporting. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

When the emerging growth company exemptions under the JOBS Act cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with reporting requirements. We cannot predict or estimate the amount of additional costs we may incur as a result of losing our emerging growth company status or the timing of such costs.

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 will be required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. In addition, beginning with our annual report on Form 10-K for our fiscal year ending December 31, 2016 to be filed in 2017, we will be required to furnish a report by management on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We are in the process of designing, implementing and testing the internal control over financial reporting required to comply with this obligation, which process is time-consuming, costly and complicated. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K following the date on which we are no longer an emerging growth company, which may be up to five full years following the date of our initial public offering in October 2015. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit function, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 in a timely manner, or 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 NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to implement our business plan successfully and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new, operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors when required under Section 404 of the Sarbanes-Oxley Act. Moreover, we cannot be certain that these measures would ensure that we implement and maintain adequate controls over our financial processes and reporting in the future. Even if we were to conclude, and, when required, our auditors were to concur, that our internal control over financial reporting provided reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, because of its inherent limitations, internal control over financial reporting may not prevent or detect fraud or misstatements or omissions.

We have never declared or paid cash dividends on our ordinary shares and we do not anticipate paying dividends in the foreseeable future and, as a result, you must rely on price appreciation of our ordinary shares for a return on your investment.

We have never declared or paid cash dividends on our ordinary shares. We currently intend to retain our funds and any future earnings to support the operation, growth and development of our business. Any future determination to declare cash dividends will be made at the discretion of our board of directors and subject to compliance with applicable laws and covenants under our current or any future credit facilities, which may restrict or limit our ability to pay dividends, and the form, frequency and amount of dividends will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that

our board of directors may deem relevant. We do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. As a result, a return on your investment will only occur if our share price appreciates. There is no guarantee that our ordinary shares will appreciate in value or even maintain the price at which you purchased your ordinary shares. You may not realize a return on your investment in our ordinary shares and you may even lose your entire investment in our ordinary shares.

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

(a) From January 1, 2015 to September 30, 2105, we have issued the following securities, which include convertible preferred shares and options to acquire our ordinary shares. WE believe that each of the following instances was exempt from registration under the Securities Act in reliance on Regulation S under the Securities Act, under Section 4(2) of the Securities Act regarding transactions not involving a public offering and under Rule 701 promulgated under the Securities Act:

Purchaser	Date of sale or issuance	Number of securities	Consideration in United States dollars
Ordinary shares (1)	March-15	1,005,210	-
Series J Preferred Share Purchasers	June-15	4,068,500	$94.9 million
Options to Purchase Ordinary Shares (2)	January 1, 2015 to September 30, 2015	2,801,849	-
Ordinary Share Option Exercisers	January 1, 2015 to September 30, 2015	2,512	$0.02 million

(1) Ordinary shares issued to the Technion. See Note 8 to our consolidated financial statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q.
(2) Number of securities includes an option to purchase 1,005,210 ordinary shares issued to the Technion in March 2015. See Note 8 to our consolidated financial statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q.

(b) On October 7, 2015, we closed our IPO, in which we sold an aggregate of 7,500,000 ordinary shares at a price to the public of $22.00 per share. On October 19, 2015, the underwriters to the IPO partially exercised their over-allotment option, in which we sold an aggregate of 376,195 ordinary shares at a price to the public of $22.00 per share. We received net proceeds from the IPO and the over-allotment option of approximately $158.2 million, after deducting the underwriting discounts, commissions and estimated offering expenses payable by us. The offer and sale of all of the ordinary shares in the IPO and the over-allotment option were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-206681), which was declared effective by the SEC on October 1, 2015 (the “Registration Statement”).

There has been no material change in the planned use of proceeds from our IPO as described in the Registration Statement. No amount of proceeds has been used to date, as we had sufficient cash on hand prior to the IPO to fund our near-term activities. We invested the proceeds received in short-term, interest-bearing investment-grade securities and government securities. None of the offering proceeds were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10.0% or more of any class of our equity securities or to any other affiliates.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Number	Filed Herewith
3.1	Memorandum and Articles of Association	S-1/A	9/21/15	3.5	
4.1	Form of Ordinary Shares Certificate	S-1/A	9/21/15	4.1	
4.2	Eleventh Amended and Restated Investors Rights Agreement, dated June 1, 2015	DRS	6/24/15	4.2	
4.3	Tenth Amended and Restated Registration Rights Agreement, dated June 1, 2015	DRS	6/24/15	4.3	
10.1	Loan and Security Agreement between the Company and Biopharma Secured Investments III Holdings Cayman LP, dated January 7, 2015	DRS	6/24/15	10.1	
10.2	Strategic Supplier Agreement between the Company and ITT Corporation (assigned to Exelis Inc.), dated July 21, 2011, as amended on April 29, 2014†	DRS	6/24/15	10.2	
10.3	2003 Share Option Plan#	DRS	6/24/15	10.3	
10.4	2013 Share Option Plan#	DRS	6/24/15	10.4	
10.5	2015 Omnibus Incentive Plan#	S-1/A	9/21/15	10.5	
10.6	Employment Agreement with Asaf Danziger and the Company, dated October 1, 2002#	DRS	6/24/15	10.6	
10.7	Employment Agreement with Wilhelmus C.M. Groenhuysen and the Company, dated December 23, 2011†#	DRS	6/24/15	10.7	
10.8	Employment Agreement with Kinyip Gabriel Leung and the Company, dated August 24, 2011†#	DRS	6/24/15	10.8	
10.9	Employment Agreement with Eilon Kirson and the Company, dated June 2, 2002†#	DRS	6/24/15	10.9	
10.10	Consulting Agreement with Palti Consultants Ltd. and the Company, dated May 1, 2002†#	DRS	6/24/15	10.10	
10.11	Consulting Agreement with William F. Doyle, dated June 24, 2014†#	DRS	6/24/15	10.11	
10.12	Form of Indemnification Agreement	S-1/A	9/21/15	10.12	
10.13	Settlement Agreement with the Technion, dated February 10, 2015	DRS/A	8/11/2015	10.13	
10.14	Director Compensation Plan#	S-1/A	9/21/15	10.14	
10.15	Employee Share Purchase Plan#	S-1/A	9/21/15	10.15	
10.16	Amendment to Consulting Agreement with William F. Doyle, dated September 16, 2015#	S-1/A	9/21/15	10.16	
10.17	Form of Non-Qualified Stock Option Agreement pursuant to the 2015 Omnibus Incentive Plan (U.S. individuals)#	S-1/A	9/21/15	10.17	
10.18	Form of Incentive Stock Option Agreement pursuant to the 2015 Omnibus Incentive Plan (U.S. individuals)#	S-1/A	9/21/15	10.18	
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934,				X

	as amended	
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.

** XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Exchange Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

€Confidential treatment has been granted for certain information set forth in this exhibit. Such information has been omitted and filed separately with the Securities and Exchange Commission.
#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: October 27, 2015 /S/ Wilco Groenhuysen
Wilco Groenhuysen
Chief Financial Officer
(principal financial and accounting officer)