novocure®

Novocure (NVCR) q1 2019 results

Thursday, May 2, 2019

patientforward

forward-looking statements

This presentation contains certain forward-looking statements with respect to the business of Novocure and certain of its plans and objectives, including with respect to the development and commercialization of its lead product candidate, Optune, for a number of oncology indications. These forward-looking statements can be identified in this presentation by the fact that they do not relate only to historical or current facts. Forward-looking statements often use words "expect", "intend", "anticipate", "plan", "may", "should", "would", "could" or other words of similar meaning. These statements are based on assumptions and assessments made by Novocure in light of industry experience and perception of historical trends, current conditions, expected future developments and other appropriate factors. By their nature, forward-looking statements involve risk and uncertainty, and Novocure's performance and financial results could differ materially from those expressed or implied in these forward-looking statements due to general financial, economic, regulatory and political conditions as well as more specific risks and uncertainties facing Novocure such as those set forth in its Annual Report on Form 10-K filed on February 28, 2019, or in subsequent quarterly filings with the U.S. Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this presentation. Novocure assumes no obligation to update or correct the information contained in this presentation, whether as a result of new information, future events or otherwise, except to the extent legally required.

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As of the date of this presentation, Optune is only FDA-approved for the treatment of adults with supratentorial glioblastoma, or GBM, and its approval for other indications is not certain. Novocure can provide no assurances regarding market acceptance of Optune or its successful commercialization, and can provide no assurances regarding the company's results of operations or financial condition in the future. This presentation is for informational purposes only and may not be relied upon in connection with the purchase or sale of any security.

key messages

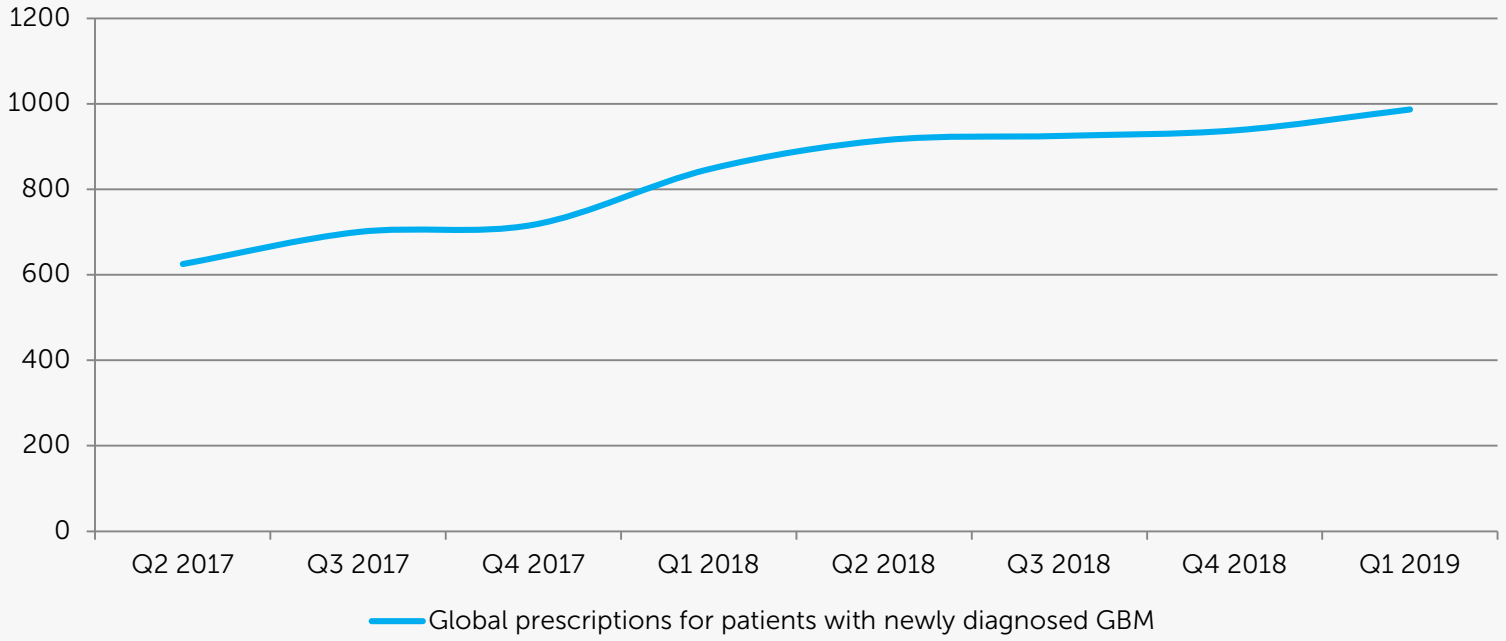
Q1 2019 ACCOMPLISHMENTS

- **More than 2,600 active patients** on Optune as of March 31, 2019
- **$73.3 million in net revenues**, 41% growth versus q1 2018
- **INNOVATE-3 open and enrolling,** our fourth ongoing phase 3 pivotal trial

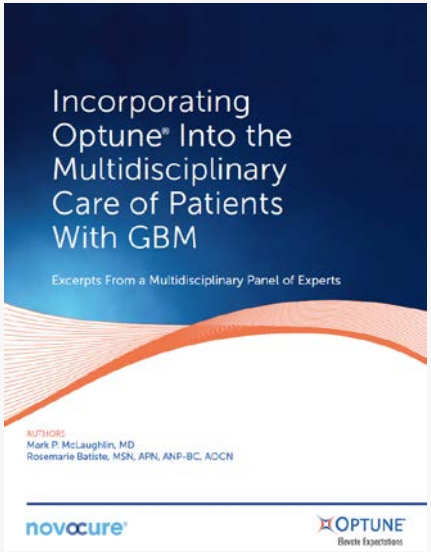
ANTICIPATED 2019 CATALYSTS

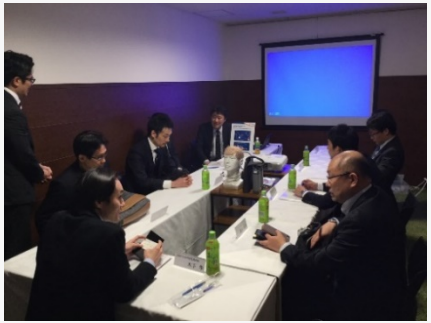
- **CMS decision** regarding coverage request for newly diagnosed GBM
- **HDE approval for malignant pleural mesothelioma** from FDA
- Potential launch of **Optune in China**
- **Positive cash flow from operations**

continued growth in newly diagnosed GBM



marketing resources encourage multidisciplinary communication and physician confidence





EF-14 dose density data published in Red Journal

Article in Press

Correlation of Tumor Treating Fields dosimetry to survival outcomes in newly diagnosed glioblastoma: A large-scale numerical simulation-based analysis of data from the Phase 3 EF-14 randomized trial

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Open Access
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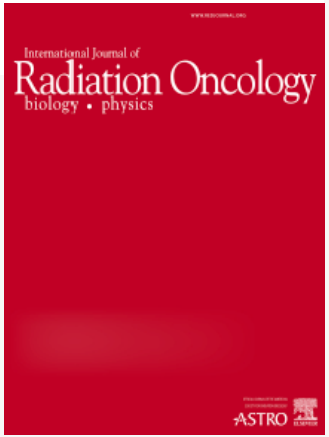


Abstract

Abstract

Introduction

Tumor Treating Fields (TTFields) are approved for glioblastoma (GBM) based on improved overall survival (OS) and progression-free survival (PFS) in the Phase 3 EF-14 trial of newly diagnosed GBM. To test the hypothesis that increasing TTFields dose at the tumor site improves patient outcomes, we performed a simulation-based study investigating the association between TTFields dose and survival (OS and PFS) in EF-14 TTFields-treated patients.

Methods

EF-14 patient cases (N=340) were included. Realistic head models were derived from T1-contrast images captured at baseline. The transducer array layout on each patient was obtained from EF-14 records; average compliance (fraction of time patient was on active treatment), and average electrical current delivered to the patient were derived from log files of the TTFields devices used by patients. TTFields intensity distributions and power densities were calculated using a Finite Elements Method. Local Minimum Dose Density (LMiDD) was defined as the product of TTFields intensity, tissue specific conductivities, and patient compliance. The average LMiDD within a tumor bed comprising the Gross Tumor Volume and the Peritumoral Boundary Zone 3 mm wide was calculated.

Results

The median OS and PFS were significantly longer when the average LMiDD in the tumor bed was $\geq$0.77 mW/cm^3: OS (25.2 vs. 20.4 months, p=0.003, HR=0.611) and PFS (8.5 vs 6.7 months, p=0.02, HR=0.699). The median OS and PFS were longer when the average TTFields intensity was >1.06 V/cm: OS (24.3 vs. 21.6 months, p=0.03, HR=0.705) and PFS (8.1 vs 7.9 months, p=0.03, HR=0.721).

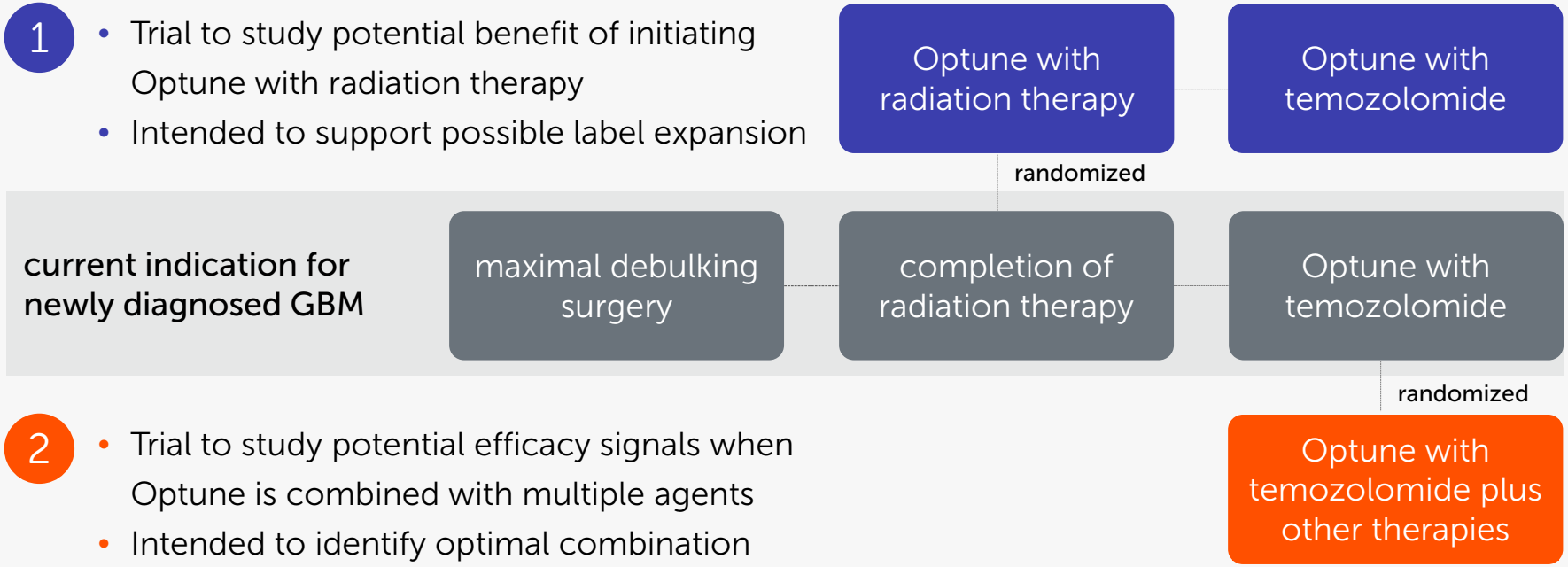
Conclusions

In this study we present the first reported analysis demonstrating patient-level dose responses to TTFields. We provide a rigorous definition for TTFields dose and set a conceptual framework for future work on TTFields dosimetry and treatment planning.

two additional randomized trials in GBM planned

1

- Trial to study potential benefit of initiating Optune with radiation therapy
- Intended to support possible label expansion



2

- Trial to study potential efficacy signals when Optune is combined with multiple agents
- Intended to identify optimal combination treatments

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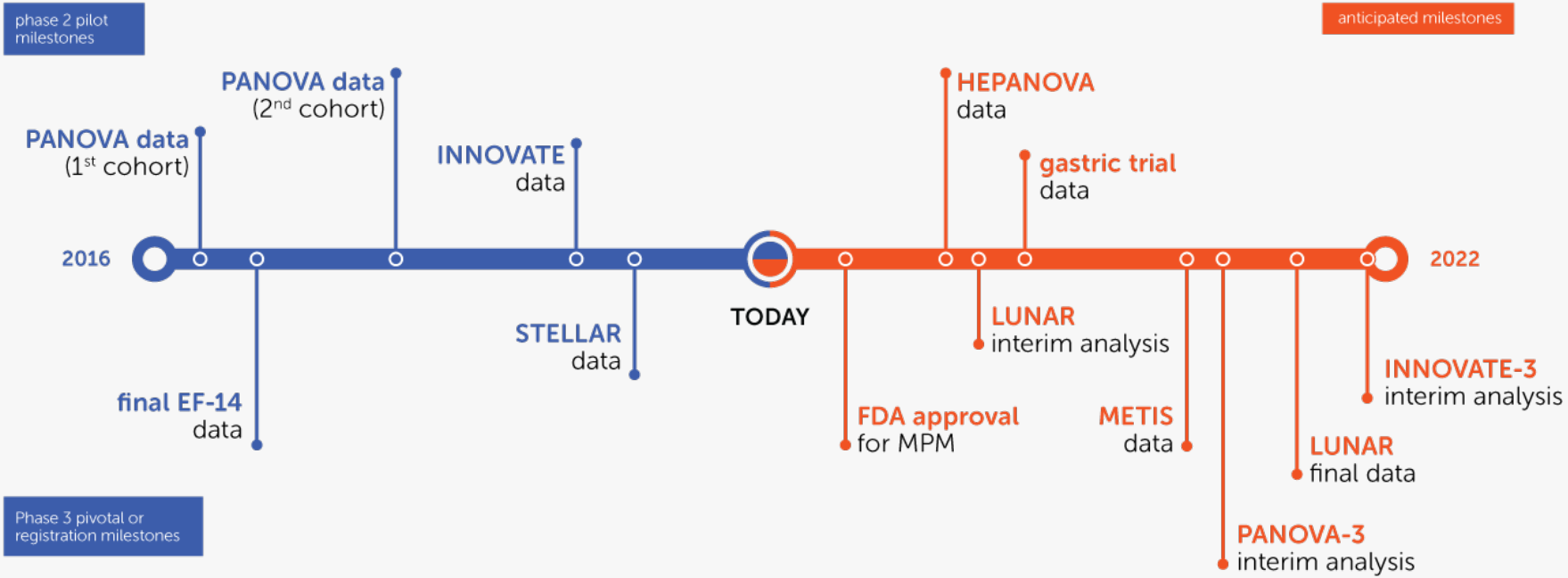
drumbeat of clinical and regulatory milestones

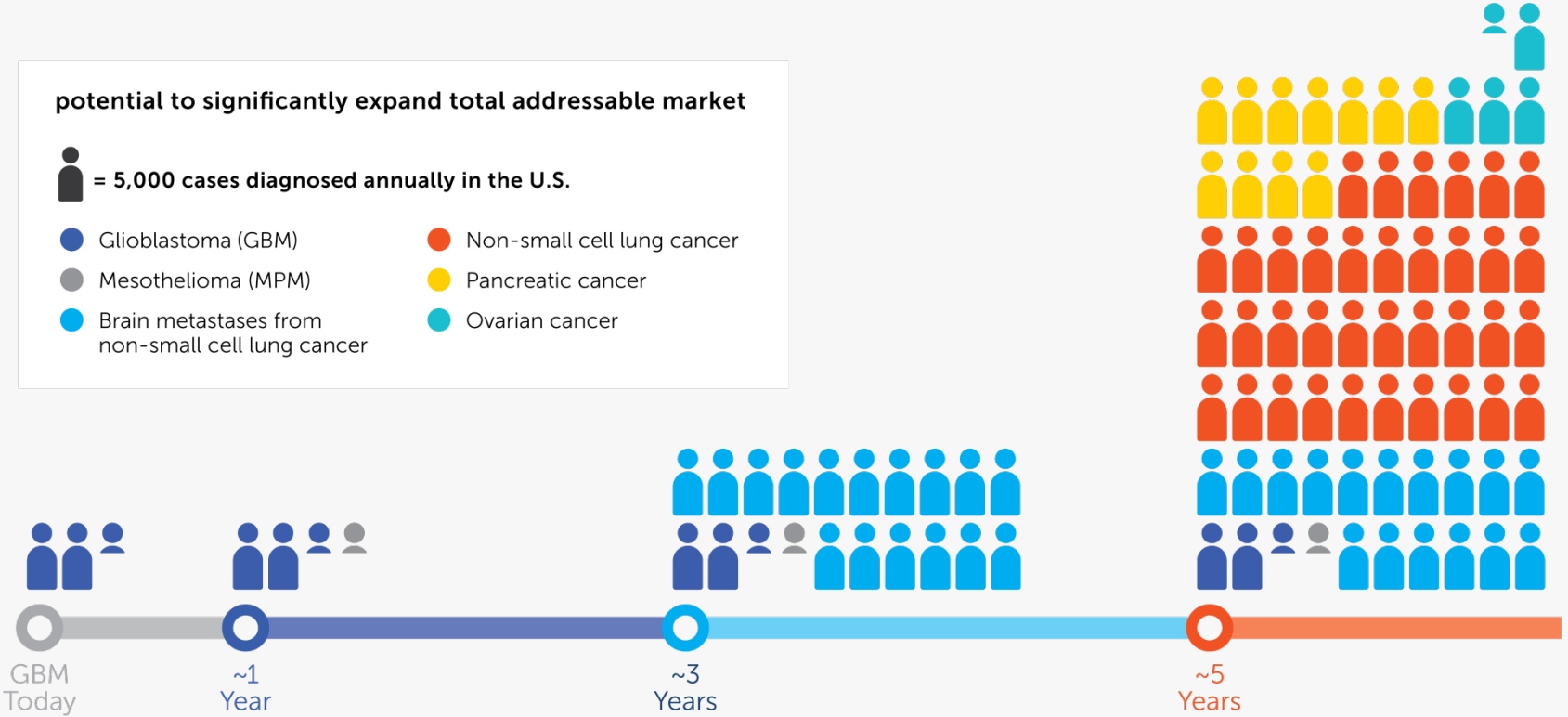


glioblastoma represents tip of the iceberg

potential to significantly expand total addressable market

= 5,000 cases diagnosed annually in the U.S.

- Glioblastoma (GBM)
- Mesothelioma (MPM)
- Brain metastases from non-small cell lung cancer
- Non-small cell lung cancer
- Pancreatic cancer
- Ovarian cancer



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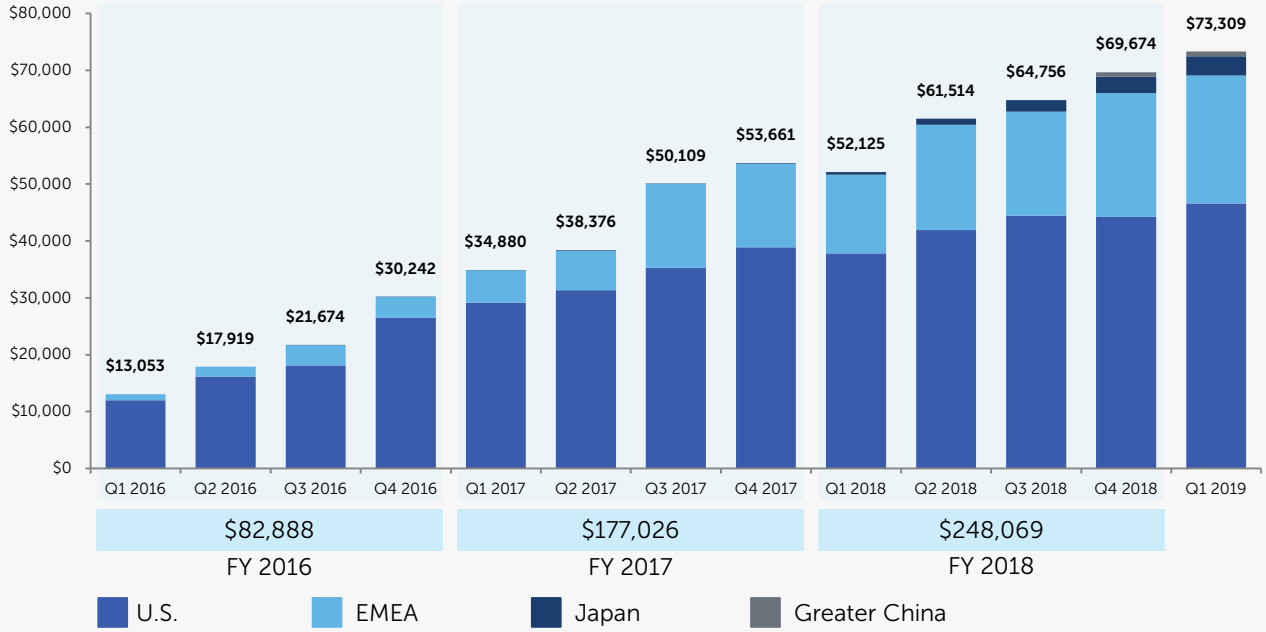
record quarterly revenue of $73.3 million

global net revenues (USD in thousands)



>2,600

ACTIVE PATIENTS
AS OF MARCH 31, 2018

41%

REVENUE GROWTH
Q1 2019 VS. Q1 2018

q1 2019 selected financial highlights

U.S. DOLLARS IN THOUSANDS	Q1 2019	Q1 2018	% CHANGE
Net revenues	$ 73,309	$ 52,125	41%
Cost of revenues	19,814	18,238	9%
Gross profit	53,495	33,887	58%
Research, development and clinical trials	17,042	11,104	53%
Sales and marketing	22,333	18,135	23%
General and administrative	20,238	17,325	17%
Total operating costs and expenses	59,613	46,564	28%
Operating income (loss)	(6,118)	(12,677)	52%
Financial expenses, net	2,371	4,853	-49%
Income (loss) before income taxes	(8,489)	(17,530)	52%
Income taxes	3,661	3,194	15%
Net income (loss)	$ (12,150)	$ (20,724)	41%
Cash and cash equivalents	$ 152,067	$ 111,603	
Short-term investments	104,535	104,712	

73%

GROSS MARGIN
Q1 2019

$257m

CASH AND CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS AS OF MARCH 31, 2019

a global oncology company with a proprietary platform

novocure™
patientforward

2 FDA-APPROVED INDICATIONS	5 INDICATIONS IN LATE-STAGE PIPELINE	140+ ISSUED PATENTS GLOBALLY
$269M TRAILING 12 MONTHS NET REVENUES	41% REVENUE GROWTH Q1 2019 VS. Q1 2018	$257M CASH ON HAND AS OF MARCH 31, 2018

Optune® indications for use and important safety information for GBM

INDICATIONS

- Optune is intended as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM).
- Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery, and completion of radiation therapy together with concomitant standard of care chemotherapy.
- For the treatment of recurrent GBM, Optune is indicated following histologically-or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

CONTRAINDICATIONS

- Do not use Optune in patients with an active implanted medical device, a skull defect (such as, missing bone with no replacement), or bullet fragments. Use of Optune together with implanted electronic devices has not been tested and may theoretically lead to malfunctioning of the implanted device. Use of Optune together with skull defects or bullet fragments has not been tested and may possibly lead to tissue damage or render Optune ineffective.
- Do not use Optune in patients that are known to be sensitive to conductive hydrogels. In this case, skin contact with the gel used with Optune may commonly cause increased redness and itching, and rarely may even lead to severe allergic reactions such as shock and respiratory failure.

Optune® indications for use and important safety information for GBM

WARNINGS AND PRECAUTIONS

- Optune can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure (the device manufacturer).
- Do not prescribe Optune for patients that are pregnant, you think might be pregnant or are trying to get pregnant, as the safety and effectiveness of Optune in these populations have not been established.
- The most common (≥10%) adverse events involving Optune in combination with temozolomide were thrombocytopenia, nausea, constipation, vomiting, fatigue, medical device site reaction, headache, convulsions, and depression.
- The most common (≥10%) adverse events seen with Optune monotherapy were medical device site reaction and headache.
- The following adverse reactions were considered related to Optune when used as monotherapy: medical device site reaction, headache, malaise, muscle twitching, fall and skin ulcer.
- Use of Optune in patients with an inactive implanted medical device in the brain has not been studied for safety and effectiveness, and use of Optune in these patients could lead to tissue damage or lower the chance of Optune being effective.
- If the patient has an underlying serious skin condition on the scalp, evaluate whether this may prevent or temporarily interfere with Optune treatment.

