

## YEAR END REPORT 2019

### Fourth quarter (1 October – 31 December 2019)

- Other income amounted to TSEK 1 243 (TSEK 197).
- Profit after tax amounted to TSEK -3 706 (-3 242).
- Corresponding to SEK -0,04 (-0,05) per share before and after diluted earnings.
- Operating cash flow was TSEK -3 407 (-3 806).

### Full year 2019

- Other income amounted to TSEK 3 248 (1 099) TSEK.
- Profit after tax amounted to TSEK -13 685 (-11 814) TSEK.
- Corresponding to SEK -0,16 (-0,16) per share before and after diluted earnings.
- Operating cash flow was TSEK -10 055 (-10 864).
- Cash as of 31 December amounted to TSEK 54 206 (45 025).
- Equity ratio in parent company: 94 (94) percent.

### CEO's statement.

## Focus on technology and system development, and on the conduct of clinical trials

Throughout the fall, our focus has been on the technology and product development of our medical technology system, as well as on the conduct of our clinical trial.

Our treatment system is a combination product comprising the medtech system and the already registered drug Visudyne. The development of the system is progressing in two parallel tracks. First, after consultation with our reference physicians, we have been able to replace the system's previous software with a novel and more modern and user-friendly interface, which communicates with our dose platform (IDOSE®) to control the hardware. The improved graphics provides physicians with higher resolution pictures and a more natural workflow. In addition, it facilitates the creation of treatment plans within the system, and gives physicians improved feedback during treatment. The new software also provides us with an updated platform in view of future IDOSE® developments.

At the same time as the software platform has been developed, the hardware platform has undergone a root and branch reform; the new design, for which a patent is pending, is more compact, easier to maintain, quicker to manufacture and reduces the cost of components by 80 percent. The treatment system now fits on an instrument stand and it can easily be integrated with the rest of the equipment in the operating theatre. The first units are built and tested in

SpectraCure's own laboratory. The plan is to offer four complete and approved systems in the third quarter of 2020.

The clinical trials aim to demonstrate that our treatment method is safe to use and to verify the clinical efficacy. All patients will be monitored for 12 months post treatment, with follow-ups that include blood samples, biopsies and MRI scans (magnetic resonance imaging). The result of the phase 2 study will be presented when all follow-ups of finished treatments have been concluded.

In the fourth quarter it was disclosed that our expert advisers had recommended us to apply for accelerated approval; the effort to prepare the extensive application commenced immediately. A consent and obtainment of accelerated approval from the FDA (Food and Drug Administration) may entail changes in the endpoint requirements for the ongoing clinical trial and accelerated product launch.

A future FDA approval would mean both that our system is approved and that the indication for Visudyne, which is presently registered for a different indication, is extended. It would likely entail that we could obtain accelerated approval directly on the basis of a phase 2 study instead of having to conduct a phase 3 study first. If this were to be the case, we would conduct a phase 3 study with a longer follow-up period, but this is already included in the plan. It is up to the FDA to decide whether to provide accelerated approval according to the current statutory provisions. The clinical trial must be considered "adequate and well controlled", which, simply put, means that accelerated approval can be given provided that the study protocol has been prepared in consultation with the FDA and that the trial has been conducted in accordance with Good Clinical Practice (GCP), which is the established quality system for clinical trials. SpectraCure's trials meet these requirements.

We have met our business objectives during the period. In the fourth quarter, Nasdaq approved our application to move the trade of our share to First North Premier. The successful new share issue carried out in November provided the Company MSEK 36.8 in proceeds. The proceeds from the issue thus ensures the estimated capital requirements for the continuation of the clinical trial, and we are looking forward to the result.

**For further information, please contact:**

SpectraCure AB publ, CEO, Masoud Khayyami, phone: +46 (0) 70 815 21 90

Certified Adviser is G&W Fondkommission, e-mail: [ca@gwkapital.se](mailto:ca@gwkapital.se), phone: +46(0) 8 503 000 50

This information is information that SpectraCure AB is required to disclose under the EU Market Abuse Regulation. The information was provided, through the contact of the above contact person, for publication on February 25th, 2020 at 12 noon.

**SpectraCure** was founded in 2003 as a spin off from Lund University departments for medical laser applications and physics. The company focuses on cancer treatments using medical systems with laser light sources and reactive drugs, which is referred to as "Interstitial Photodynamic Therapy", PDT, a treatment methodology suitable for internal solid tumours of various kind, e.g. prostate and abdominal salivary glands, but also other indications such as cancer tumours in the head and neck region. [www.spectracure.com](http://www.spectracure.com)