

Theraclion reports 2018 half-year results

- 89% growth in the number of treatments
- Half-year losses of € 3.6 million including € 0.5 million of non-recurring items
- Reorganization of the company and reduction of 20% of expenses on an annual basis
- Cash of € 1.5 million as of June 30, 2018
- Completion of the study on treatment of varicose veins by echotherapy

Malakoff – 24 September 2018 – THERACLION (Euronext Growth, FR0010120402 – ALTHE), a company specialized in leading-edge medical equipment for echotherapy, announces today its half-year results for 2018 ended June 30, 2018, and approved by the Board of Directors on September 18, 2018, which have been subject to a limited review by the statutory auditors. The certification report is being processed and will be issued after reading the half-yearly financial report.

David Caumartin, CEO of Theraclion, says: "Theraclion continues to grow: the number of treatments has almost doubled compared to the first half of 2017, as well as the recurring revenues from the sale of consumables and services. Theraclion recorded losses of € 3.6 million in the first half of the year, including € 0.5 million of non-recurring costs mainly related to the reorganization of the company, that will reduce its annualized costs by 20%, excluding purchases of merchandise. *Theraclion is focusing on the development of Echopulse for the treatment of varicose veins and is accelerating access to the most important markets: the countries with the greatest commercial potential in the short term and the strategic markets of the United States and China.*"

Half year results of Theraclion SA 2018

<i>In thousands of euros</i>	30 June 2018	30 June 2017	Var. %
Revenue	862	753	14%
<i>Equipment sales</i>	653	656	0%
<i>Equipment rental</i>	72	24	203%
<i>Consumables</i>	70	46	52%
<i>Services</i>	67	28	139%
Subsidies	4	42	-90%
Other revenues	2	0	NA
Total operating revenue	868	795	9%
External costs	2 571	2 526	2%
Other operating expenses	2 473	2 210	12%
Operating income/(loss)	-4 176	-3 940	6%
Net financial items	-121	-110	10%
Net non-recurring items	-24	-4	505%
Research tax credit	710	652	9%
Net income/(loss)	-3 611	-3 402	6%
Average headcount (FTE)	32	35	-9%

Growth in sales to non-Group customers: + 61%



In accordance with the changes in the reporting entity for the Theraclion financial statements decided in 2017, the figures published today are those of the legal entity Theraclion SA. They do not consolidate the contributions of Theraclion APAC Ltd (Hong Kong) and Theraclion China Co., Ltd. (Shenzhen). Sales to these subsidiaries are accounted for as sales to third parties. The addition of sales by Theraclion SA and its subsidiaries to third parties amounted to € 899,000, up 61% from € 559,000 in 2017. Sales by

Theraclion SA alone amounted to € 862,000, up 14% year-on-year.

The K€ 653 in equipment sales for the first half of 2018 correspond to the sales of three Echopulse systems, the sale of consumables is up 52% in line with the increase in the number of treatments, the increase in sales of services of 139 % reflects the underwriting of maintenance contracts for systems that are outside the warranty period. In total, recurring revenues - consumables and maintenance services - doubled compared to the first half of 2017.

K€	June 2018	June 2017	% vs 2017
Sales Theraclion SA	862	753	+14%
Inc External Sales	680	549	+24%
Inc Sales to Theraclion SA branches	183	204	-11%
Externales Sales from branches ¹	220	11	+1 962%
External sales Theraclion SA + branches	899	559	+61%

Theraclion is reorganizing itself by concentrating its salesforce on immediately exploitable markets and on the development of strategic markets for varicose veins (the United States and China), which allows a 20% reduction in expenses on an annual basis.

Merchandise purchases and external expenses amounted to € 2.6 million and increased by 2% as a result of clinical research expenditures related to the multicentric pivotal trial conducted to obtain authorization to treat benign breast nodules by echotherapy in the United States and the feasibility test in varicose veins. The veins feasibility study completed recruitment in June. Other operating expenses rose by 12% to € 2.5 million, including € 0.5 million of non-recurring items mainly related to the reorganization of Theraclion. Excluding non-recurring items, these charges would decrease by 10%.

Theraclion focuses on the rapid launch of a varicose vein treatment solution. Theraclion has completed its feasibility study and regulatory approval to allow a registration filing is scheduled for late 2018. The Company is continuing its commercial efforts in Germany and neighboring countries and Hong Kong, markets with significant commercial potential in the short term. Theraclion is making progress on access to the strategic markets of the United States and China.

This strategic refocusing reduces the annual payroll by 25%, from 33 employees in December 2017 to 23 employees at the end of September, which reduces the annual payroll by around 25%.

¹ Non audited numbers



After taking into account the financial result, a loss of € 121,000 for the half-year, mainly related to interest on the repayable advance TUCE and a research tax credit of € 710,000, up 9%, the result of the first semester 2018 came to a loss of € 3,611 thousand, an increase of 6% compared to a loss of € 3,402 thousand in the first half of 2017.

Major events of 2018 and post-closing

Completion of the study on the treatment of varicose veins by echotherapy

Final results: safety and efficiency

The study was conducted by Dr. Alfred Obermayer Surgeon at St. Joseph's Hospital in Vienna and Director of the Karl Landsteiner Institute for Functional Phlebology in Melk. He says, "We performed echotherapy on patients who had already been treated with other techniques but remained symptomatic. The encouraging results we have obtained with echotherapy suggest that we have identified a relevant alternative to current solutions; we are satisfied with these clinical results »

Benefits of echotherapy on existing methods

Existing methods, even if some are minimally invasive, have disadvantages, mainly related to the fact that they require incisions: a sterile surgical block and anesthesia - or even general anesthesia. These acts are delicate to perform, a large surgical experience is required, which makes them extremely dependent on the experience of operators. Side effects such as pigmentation, inflammation, nerve damage or induration are also sometimes observed. The patient who has just been treated is absolutely not autonomous and requires postoperative assistance. Echotherapy has the potential to respond to the shortcomings of these existing methods.

Dr. Michel Nuta, Chief Medical Officer and Vice President Veins Theraclion, adds: "The end results are far beyond our expectations. Given the profile of treated patients who had mostly recurred after initial treatment with traditional methods, we are very confident about the benefits and effectiveness of this new technique. "

The treatment of varicose veins by echotherapy represents a substantial market opportunity that can be quickly accessed

The health costs of treating varicose veins are \$ 9 billion a year. This figure excludes the treatment of telangiectasia, or so-called spider veins. The venous medical device market has grown by 12% per year over the last 10 years, from approximately \$ 160 million to over \$ 500 million through the rapid adoption of minimally invasive methods such as radio frequency and laser devices. Minimally invasive techniques have paved the way for reimbursement in some markets. In other markets, patients commonly opt for out of pocket payment to avoid invasive surgery.

"With this study, we will be able to file the registration application simultaneously in Europe and the United States at the end of 2018. Subject to the completion of the regulatory steps, Theraclion could start selling its echotherapy solutions in 2019. We focused our research, development and clinical studies to transform this huge market. We will address it by addressing unmet medical needs and by deriving many benefits from our echotherapy technology. We bring a revolutionary, non-invasive,



accurate and safe approach that addresses the shortcomings of current options. The whole project looks extremely promising," says David Caumartin.

Reorganization of the company and reduction of expenses

Theraclion aligns its organization with its objectives of commercial and strategic development. The industrialization program of its Echopulse in France ended at the end of 2017 with the delivery of the first devices that were sold to China. The end of this program results in a reduction of 10 employees between December 2017 and September 2018, representing a 25% decrease in the annual payroll.

Advanced in the Investigational Device Exemption (IDE) study for market access in the United States for the treatment of breast adenofibromas.

Of the planned 100 patients, 80 have already been treated in the pivotal clinical trial evaluating the safety and efficacy of Echopulse® echotherapy as a non-invasive treatment for breast fibroadenoma (FA). Recruitment is conducted in four US centers, the University of Virginia Medical School (UVA), three prestigious New York sites: Langone Bellevue, Montefiore Medical Center, and New York Presbyterian / Columbia. and in two centers in Europe: the Tübingen University Hospital in Germany and the Sofia University Hospital in Bulgaria. Patients receive a single high-intensity focused ultrasound treatment with Echopulse®. The primary endpoint is a reduction in fibroadenoma volume, pain, and anxiety.

In France: inclusion in July 2018 of the first patient in the framework of the "Forfait Innovation" study

The "Forfait Innovation" consists of a derogatory and transitional treatment of the cost of treatments performed with the new technique. This reimbursement makes it possible to partially finance the study which aims to demonstrate that the treatment of fibroadenomas (benign tumors) of the breast by ultrasound (ultrasound focused high intensity ultrasound) is less expensive and as effective as surgery.

This study provides for the recruitment of 300 patients in 12 centers in France (150 patients will be treated with HIFU and 150 patients will be treated by surgery). After completion of the inclusion of the patients in the study, and waiting for the final reimbursement of the echo therapy treatment, the patients of the investigating centers will be able to continue to benefit from the treatment and its reimbursement "Forfait Innovation".

Theraclion realizes several key projects with German Universities

In August 2018, a project submitted by Theraclion was selected under the Eurostars program. Theraclion will develop a solution that will combine High Intensity Focused Ultrasound (HIFU) and radiation therapy for the treatment of cancer. This project will be developed over 3 years in collaboration with the Fraunhofer Institute for Medical Image Computing (MEVIS), the Innovation Center Computer Assisted Surgery (ICCAS - Universität Leipzig) and the SME Mediri Theraclion will receive grants up to 40% expenditure to be committed, valued at 1.7 M Euros.

Theraclion also announces the signing of a commercial agreement with the University Hospital "Klinikum rechts der Isar" of the "Technical University of Munich" (TUM) for the use of Echopulse® in the treatment of patients with thyroid nodules. The system will be installed at TUM hospital "Rechts der Isar" in the nuclear medicine department.



Evolution of cash flow and continuity of operations

In June 2018, Theraclion set up financing through the issuance of 120 redeemable share warrants (BSARs) divided into 12 equal monthly tranches for a total amount of € 3.6 million provided by NICE & GREEN, a company specializing in providing financing solutions tailored to listed companies. NICE & GREEN is committed to purchase a tranche of 0,3 M€ every month in exchange for the right to subscribe new Theraclion shares for a price based on listed price adjusted for a 7% discount. As of today, 198.623 shares have been issued as part of this contract, representing 2.5% of Theraclion's capital.

At June 30, 2018, Theraclion's available cash position amounted to € 1.5 million. Given its sales prospects (including those resulting from orders received), reductions in expenses incurred and in view of its cash flow projections, the Company has carried out a specific review of its liquidity risk and has implemented actions to ensure the continuity of operations until June 30, 2019. In this regard, it is currently studying several financing options in the next 6 months amounting to approximately € 4 million.

About Theraclion

Theraclion is a French company specialized in high technology medical equipment using therapeutic ultrasound. Based on the most advanced technologies, Theraclion designs and markets an innovative Echopulse® echo-therapy solution, which allows the treatment of tumors using Ultrasound Focused under ultrasound guidance. Theraclion is ISO 13485 certified and CE marked for noninvasive ablation of breast adenofibromas and thyroid nodules. Located in Malakoff, near Paris, Theraclion brings together a team of 25 people, more than 50% of whom are dedicated to R & D and clinical trials.

For more information, do not hesitate to visit the Theraclion website:
www.theraclion.com

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