

2015 annual results

- **More than doubled full-year sales to €1.7 million (119% growth)**
- **Tripled number of commercial sites: presence extended to six new countries**
- **Tripled number of routine treatments in the thyroid indication**
- **Extended reimbursement in Germany and submitted application for early reimbursement in France**
- **Firm grip on operating expenses**

Malakoff – France, 29 March 2016 – Theraclion (Alternext, FR0010120402 – ALTHE, eligible for PEA-PME plans), a company specialising in leading-edge medical equipment for echotherapy, today announced its results for the financial year ended 31 December 2015, approved by the Board of Directors on 24 March 2016. The 2015 consolidated financial statements have been audited and the auditors' report will be issued after validation of the Management Report.

David Caumartin, Chief Executive Officer of Theraclion, said: *"2015 was a transformative year for Theraclion. We expanded our commercial presence at a faster pace, tripling our active sites and signing 12 commercial agreements¹. Germany is a strategic market for the company. By increasing the number of contracts with insurance companies and opening up reimbursement for Echopulse as a thyroid treatment, we are increasing the number of German patients with access to echotherapy. Theraclion intends to step up its efforts to achieve an ongoing increase in patient access to this non-invasive alternative treatment. We expect growth to accelerate in 2016."*

Further international expansion

To step up its international expansion, particularly in Asia, Theraclion set up a subsidiary in Hong Kong in March, 2015 and appointed Dennis Guo as its Head of Business Development. Theraclion now also operates directly in the United Kingdom, Italy, Germany and France, and through distribution agreements or agents in Finland, Spain, Poland, the Czech Republic, the Balkan states, Turkey, Egypt, Tunisia, Kuwait, South Korea, Taiwan, Singapore and Russia.

Tripling in the number of routine clinical treatment sites

Theraclion now provides echotherapy to patients across 16 sites, as opposed to five in 2014: six in Germany, three in France, one in the United Kingdom, one in Spain, one in Turkey, one in Switzerland, one in Hong Kong, one in South Korea and one in Taiwan.

Start of reimbursement for thyroid treatment and creation of a strong business hub in Germany

More than 1.5 million German patients are now covered by health insurance policies, and nine public-sector insurance companies reimburse Echopulse treatments. In 2015, the first reimbursement agreements for thyroid treatments were obtained and five sites were opened. Availability of reimbursement is enabling Theraclion to increase its presence and accelerate its growth in Germany.

¹Commercial agreements cover equipment sales and loans, for which Theraclion invoices customers on either a rental or pay-as-you-go basis.

Reduction in treatment time with the new BEAMOTION procedure

To further its aim of meeting the needs of customers and clinicians ever more effectively and to make treatment as comfortable as possible, Theraclion has developed its CE-marked BEAMOTION procedure. Clinical trials involving BEAMOTION show a significant reduction in treatment time of up to 5 times in some cases. With this new technology, which requires just a local anaesthetic, Theraclion is offering the fastest treatment in the industry.

2015 consolidated results

<i>In thousands of euros</i>	2015	2014	Change
Revenue	1,531	800	91%
Equipment sales	1,412	774	83%
Equipment rental	75		
Consumables	40	26	54%
Services	4		
Subsidies	61	14	337%
Other revenue	5	6	-10%
Total operating revenue	1,597	820	95%
Purchasing and external costs	(4,815)	(2,787)	73%
Other operating expenses	(4,023)	(2,992)	34%
Operating income/(loss)	(7,241)	(4,959)	46%
Net financial items	(178)	(183)	-3%
Net non-recurring items	180	(18)	1,098%
Tax credit	826	526	57%
Net income/(loss)	(6,412)	(4,634)	38%
Average headcount (FTE)	30	22	36%

Faster growth in commercial agreements

Theraclion's 2015 revenue rose 91% to €1,531 thousand, and there was €217 thousand of non-recurring revenue from the sale of a previously installed system to a private clinic, as part of clinical trials in a European university. Overall 2015 sales rose 119% to €1,748 thousand.

Revenue from sales of consumables totalled €40 thousand, up 54% year-on-year.

In 2015, Theraclion signed 12 commercial agreements² as opposed to only two in 2014, and extended its commercial presence to six new countries.

Theraclion tripled its number of routine clinical treatment sites in 2015 to 16 by the end of the year.

Disciplined cost control

Theraclion is continuing its commercial and R&D efforts, while keeping a firm grip on costs and operating expenses. Those costs are rising in line with average annual headcount, which went from 22 in 2014 to 30 in 2015.

Purchases of goods and other purchasing and external expenses rose 73% to €4,815 thousand from €2,787 thousand in 2014. Other operating expenses increased 34% from €2,992 thousand in 2014 to €4,023 thousand in 2015. The company maintained its policy of sustained investment, with R&D expenditure rising from €2.1 million in 2014 to €2.6 million, representing almost 1.7 times total revenue.

²Commercial agreements cover equipment sales and loans, for which Theraclion invoices customers on either a rental or pay-as-you-go basis.

After including net financial expense of €178 thousand – mainly consisting of €164 thousand of interest on the TUCE repayable advance – the company made a net loss of €6,412 thousand as opposed to a net loss of €4,634 thousand in 2014.

Cash

At 31 December 2015, Theraclion had available cash of €3,753 thousand versus €4,272 thousand at 31 December 2014.

Subsequent events

Application for the Forfait Innovation in France

On 26 January 2016, Theraclion filed an application with France's health ministry and national health authority for the Forfait Innovation, a new early reimbursement mechanism for innovative medical devices designed to accelerate market adoption of novel technologies. The application requires a clinical trial or a cost effectiveness study to generate the missing data necessary to compare the innovative approach with standard treatment. If successful, the Forfait Innovation determines the criteria for flat-rate reimbursement.

Ongoing lesion volume reduction in patients treated for breast tumours after three years

Follow-up data collected three years after the start of a clinical trial at the University of Sofia in Bulgaria showed an ongoing reduction of benign breast tumors. Patients saw an 80% reduction in volume between one and three years after treatment with Echopulse, with no relapses.

Strong patient demand for the thyroid indication

Having initially focused on developing its treatment for breast fibroadenoma, Theraclion decided in late 2014 to step up its work on treating thyroid nodules. Following that decision, it has opened seven sites since the start of 2015, including six in the last few months of 2015. Those sites are offering patients routine clinical treatment of thyroid nodules using Echopulse.

In the last six months, the number of routine clinical thyroid treatments using Echopulse has been three times the total number of treatments, excluding clinical trials, carried out before that period. Sites opened since the end of 2015 have treated 3.5 patients per month on average. That figure is likely to increase rapidly in the next few months. Overall, more than 180 thyroid treatments (including clinical trials) have been carried out using the Echopulse system to date.

About Theraclion

Theraclion is a French company specializing in high-tech medical equipment using therapeutic ultrasound. Drawing on leading-edge technologies, Theraclion has designed and manufactured an innovative solution for echotherapy, the Echopulse®, allowing non-invasive tumor treatment through ultrasound-guided high-intensity focused ultrasound.

Theraclion is ISO 13485 certified and has received the CE mark for non-invasive ablation of breast fibroadenomas and thyroid nodules. Based in Malakoff, near Paris, France Theraclion has brought together a team of 34 people, 50% of whom are dedicated to R&D and clinical trials. For more information, please visit Theraclion's website: www.theraclion.com.

Theraclion is listed on Alternext Paris

PEA-PME eligible

Mnemonic: ALTHE - ISIN Code: FR0010120402



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