

Theraclion announces 2015 interim results and provides update on recent corporate activities

- Continued execution of commercial development strategy
- Built a strong pipeline of orders
- New reimbursement agreements in Germany
- Managed operating costs effectively
- Strengthened cash position

Malakoff – FRANCE, October 6th, 2015 – THERACLION (Alternext, FRO010120402 – ALTHE), a company specialized in leading-edge medical equipment for echotherapy, announces today interim financial results for the period ending June 30, 2015, which were approved by the Board of Directors on September 30, 2015.

David Caumartin, Chief Executive Officer of Theraclion comments: *“During the first half of the year, we strengthened our marketing & sales teams in order to accelerate the Company’s international expansion. Theraclion now maintains offices in Germany, UK and Italy, has a strong presence in Hong-Kong through the Company’s subsidiary and leverages a significant distribution network in Egypt, Taiwan and South Korea. In addition, we obtained new reimbursement agreements for the treatment of breast fibroadenoma in Germany, which is a key commercial market for Theraclion, and recently signed an agreement for the treatment of thyroid nodules, a significant milestone for our Echopulse® solution. Collectively, these recent accomplishments support our 2015 sales objectives and enhance our market penetration. As evidence of this, we are experiencing strong growth in orders compared to 2014, with five orders to date, versus 1 order at this time last year. These systems will be installed in the different sites in Germany, Egypt, Hong-Kong, Taiwan, and South Korea during the second half of the year and will impact Theraclion’s turnover and cash position at that time.”*

A first half marked by the pursuit of international expansion

The Company recorded its first Echopulse® order in Egypt through AB Care, Theraclion’s local distributor in this area. The system will be installed during the fourth quarter of the year at EgyHiFu, a state-of-the-art medical centre in Cairo specialised in the treatment of abdominal and prostate tumours using HIFU technology. With the arrival of the Echopulse, EgyHifu will have the ability to extend its care to the non-invasive treatments of breast fibroadenoma and benign thyroid nodules.

In addition, in order to accelerate the Company’s commercial roll-out internationally, and in Asia in particular, Theraclion opened a subsidiary in Hong Kong, which was recently awarded a contract via a tender offer by the Queen Mary University Hospital in Hong Kong, China. Theraclion’s system will be used in the hospital’s treatments of breast surgery and endocrinology.

In the U.S., Theraclion made important progress on the regulatory front, meeting with the Food and Drug Administration (FDA) to determine the appropriate regulatory steps and clinical data needed to obtain approval to market the Echopulse system in the U.S. Theraclion intends to submit a De Novo pathway (513(k)) and is actively discussing potential study designs with the FDA. The FDA will publish a report on the recent meeting in the coming weeks.

New reimbursement agreements in Germany for the treatment of breast fibroadenoma

More than one million German women are now covered for the treatment of breast fibroadenoma through echotherapy. Since September 2014, five *Betriebskrankenkassen* (BKK) health insurance companies have signed the reimbursement agreement.

Important new publications, including one in top-tier journal, *Radiology*

The first half of 2015 also included multiple key publications highlighting the positive clinical results of Echopulse treatment for both breast and thyroid nodules. These results were published in the following scientific journals:

- *Radiology* – Ablation of Benign Thyroid Nodules through HIFU: Initial Clinical Results, Dr. Kovatcheva (Sofia)
- *Journal of Therapeutic Ultrasound* – Treatment of Breast Fibroadenomas by Echotherapy - Multicentre Study, Dr. Kovatcheva (Sofia)
- *Journal of Therapeutic Ultrasound* – Reduction in Volume of Benign Thyroid Nodules Three Months After a Single HIFU Treatment, Dr. Korkusuz (Frankfurt)

Key figures and 2015 Interim results

Table 1: Key figures for the First Half of 2015

	S1 2015	S1 2014
Confirmed orders* (number of systems)	3	1
Turnover (in '000 €)	38	483
Net Result (in '000 €)	(3 175)	(2 282)
Cash and cash equivalent (in '000 €)	4 717	7 521
Number of employees	31	18

(*) The 3 orders correspond to a center in Cairo in Egypt, one in Hong-Kong and another in Paderborn in Germany.

Table 2: Profit/Loss for the First Half of 2015

<i>In thousands of euros</i>	H1 2015	H1 2014
Turnover	38	483
Operating subsidies	14	7
Other income	4	4
Total Income	56	495
Purchases of goods and change in inventory	42	(219)
Other purchases and external charges	(1,789)	(1,173)
Other operating costs	(1,743)	(1,502)
Operating result	(3,434)	(2,400)
Net financial income (expense)	(94)	(122)
Net extraordinary income (expense)	(6)	(2)
Tax credits	360	242
Net income	(3,175)	(2,282)

Limited review of half-year financial statements

During the first half of 2015, Theraclion's turnover totalled €38 thousand, 85% of which related to equipment rental and 15% to sales of consumables. The Company also recognised €18 thousand in other revenue, which was primarily comprised of operating subsidies.

As of 30 June 2015, there were 12 Echopulse systems installed globally, including 9 at health care institutions and 3 in connection with clinical trials.

Operating Costs Well-Contained

Purchases of goods and other purchases and external charges totalled €1,747 thousand, an increase of 26% compared to the same period in 2014. Other operating costs increased by 16% to €1,743 thousand, compared with €1,502 thousand as of 30 June 2014. With average headcount of 31 employees as of 30 June 2015, compared to 18 as of 30 June 2014 (an increase of 72%), employee costs totalled €1,466 thousand, a 21% increase compared to the same period in 2014.

R&D charges continue to represent the majority of operating costs, totalling €1,520 thousand for the first half of 2015, versus €1,209 thousand for the first half of 2014.

After accounting for financial result (a loss of €94 thousand for the first half), extraordinary result (a loss of €6 thousand) and income relating to the research tax credit (RTC) of €360 thousand, net result for the half-year showed a loss of €3,175 thousand, as compared with a loss of €2,282 thousand in the previous period.

Enhanced Cash Position

In June 2015, the Company completed a private placement with specialised European and U.S. institutional investors. This financing transaction provided Theraclion with an additional €4 million last June. The capital increase is intended to enable Theraclion to:

- accelerate commercial development in Europe
- continue R&D efforts to develop the Echopulse in new indications
- obtain regulatory approvals in the United States and in China

Following this private placement, 16 employees of Theraclion (out of 25) invested more than €300 thousand buy purchasing existing shares, showing their trust in the development of the Echopulse and their commitment to the innovative technology that Echotherapy is.

As of 31 August 2015, Theraclion had €4.7 million in cash (compared with €4.7 million as of 30 June 2015 and €4.3 million as of 31 December 2014), following the July payment of a repayable advance of €1.1 million granted by Bpifrance in connection with the ISI-TUCE project.

Others significant events during the period and Subsequent events

Expansion of the Installed Base in Europe and Sale of a First Echopulse in Asia.

In Germany, a strategic market for Theraclion, Praxis für Nuklearmedizin, a prestigious private nuclear medicine centre in Paderborn, and BORAD, a private radiology, nuclear medicine and radiotherapy centre in Bottrop, adopted the Echopulse system for the standard treatment of their patients' benign thyroid nodules.

Theraclion was awarded a contract in a call for tenders by the Queen Mary University Hospital in Hong Kong, China, one of the top universities in the Times Higher Education ranking of Asian universities for 2015, for the treatment of breast fibroadenomas and benign thyroid nodules. Distribution agreements were also signed in South Korea and Taiwan early in the second half of the year. Two orders in connection with those agreements were finalized in August, and the corresponding installations are planned for year-end, increasing the number of orders to 5 as of today (versus 3 as of June 30, 2015).

Product Development Strategy

In line with Theraclion's strategy to develop increasingly innovative treatment solutions, in June 2015, the Company initiated a clinical trial to confirm the effectiveness of the Echopulse system's new protocol.

Primarily intended to reduce treatment time and improve patient comfort, treatments using the new protocol have already been performed on 14 patients, 3 on breast fibroadenomas and 11 on thyroid nodules. The results confirm that the treatment is not only three times as fast, but also significantly enhances patient and physician comfort level.

First Reimbursement in Germany for the Treatment of Thyroid Nodules

In addition to the already existing reimbursement for fibroadenomas, the treatment of thyroid nodules by Echopulse will now be reimbursed by one of the largest German insurance companies, BKK Novitas. This first agreement represents a significant breakthrough for patient access to echotherapy technology and an advantage for centres offering this treatment in Germany, such as the Paderborn centre and the BORAD centre in Bottrop.

New Study Confirming the Medium-Term Efficacy of Echopulse for Thyroid Nodules

The positive results of a medium-term evaluation trial of the reduction in the volume of benign thyroid nodules treated by Echopulse were published in the journal, *Röfo*. The paper demonstrates the consistency of Echopulse's postoperative results and confirms the assessment of nodule volume in the medium-term. In addition, no serious side effects from the protocol were noted after three months of follow-up, consistent with previous findings. The paper, entitled, "Localised Ablation of Thyroid Tissue by High-Intensity Focused Ultrasound: Volume Reduction, Effects on Thyroid Function and Immune Response", is available online at the following URL:

<http://www.ncbi.nlm.nih.gov/PubMed/26200565>.

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 30 people, 53 percent 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

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