

2014 INTERIM RESULTS

- **Confirmation of clinical results in first half:**
 - Publication of the results on the treatment of thyroid nodules in the *Journal of Therapeutic Ultrasound*
 - First trial in the USA for the breast fibroadenoma
- **First health insurance reimbursement approved in Germany with health insurance fund BKK for breast fibroadenoma with Echopulse therapy**
- **First equipment sales**
- **A strong financial position with €7.5 million of cash and cash equivalent as of June 30th, 2014**

Malakoff – FRANCE, 2 October 2014 – THERACLION (Alternext, FR0010120402 – ALTHE, PEA PME eligible), a company specialized in cutting-edge medical equipment for Echotherapy, announced today its interim results for the period ending June 30, 2014, which were approved by the Board of Directors on September 30, 2014.

David Caumartin, Chief Executive Officer of Theraclion, said: *“We are actively pursuing our development efforts and our goal of radically transforming the treatment of breast and thyroid benign tumors with our Echopulse® device using high-intensity focused ultrasound (HIFU), a breakthrough technology. Our IPO in April gave us the resources to set up our commercial organization and finance our growth. We expect to establish our own sales force in key countries such as Germany, Italy, Great Britain and France. In addition, our interim results, in line with our forecasts, illustrate our careful expenditure management while speeding-up our commercial development.”*

Half-year with promising clinical trials and launch of new studies

During the first half of 2014, Theraclion obtained excellent results with Echopulse® in their clinical studies of breast fibroadenoma (France and Bulgaria) and thyroid nodule (Bulgaria), with more than 70% reduction of the tumor volume and an excellent safety. Theraclion will present the detailed results at the Congress of FUS (Focused UltraSound) Foundation next October. The results of the thyroid nodule study were published September 30th in the “Journal of Therapeutic Ultrasound” (<http://www.jtulasound.com/content/2/1/18>) (see today’s specific Press Release).

Meanwhile, several clinical trials have started in several countries:

- **United States:** following the FDA study clearance, obtained in February 2014, the first feasibility trial on fibroadenoma started with the first 5 patient treatments. This study is being conducted under an IDE (Investigational Device Exemption) with the University of Virginia and will enroll 20 patients. The broad media coverage in the United States (television, web and press), draws lot of attention to Echopulse® and its potential benefits for American women.
- **Germany:** at the Frankfurt University Medical Center, 10 patients were treated for thyroid nodules by Dr Marco Etzel. The patients are now being monitored. Two articles were submitted to the international journal “Nuclear Medicine”.

- **Germany:** at the University of Tübingen, Dr Hahn treated 20 patients with Echopulse®, using a new treatment procedure for breast fibroadenoma to treat the entire tumor. The patient enrollment is now completed.
- **England:** the controlled clinical trial of Pr Douek at the Guy's & St Thomas Hospital started in January. The study enrolls 50 patients and evaluates a new treatment procedure that burns only the tumor peripheral area. To date, 22 patients have been treated.

The academic clinical teams and Theraclion are very pleased with the various results, demonstrating medical benefits of Echopulse®.

Increasing adoption of Echopulse and first reimbursement approved

Theraclion has initiated commercial launch of Echopulse® in countries where CE marking is recognized. The strategy has already proven successful, with significant initial achievements such as:

- signing of an initial reimbursement agreement with the German health insurance fundmutual BKK;
- signing of a distribution agreement in Poland and the set-up of the first equipment in a diagnostic and cancer treatment center in Katowice, which is planned for the second half of the year;
- completion of the first five non-invasive benign breast tumor treatments in the United States as part of a first US study to support Echopulse® FDA market approval.

2014 Interim results

First equipment sales

During the first half of 2014, Theraclion recorded its first equipment sales, which were recognized in turnover for k€483. The Company also booked k€11 in other revenue, consisting primarily of operating subsidies.

<i>Currency: € 000</i>	H1 2014	H1 2013
Revenue	483	0
Other products	11	46
Operating income	495	46
External charges	(1 392)	(977)
Other operating expenses	(1 502)	(1 337)
Net operating income	(2 400)	(2 269)
Financial income	(122)	(31)
Extraordinary income	(2)	183
Research tax credit	242	119
Net result	(2 282)	(1 997)

Limited review of half-year results

Controlling costs and operating expenses

Theraclion continued its investments while controlling costs and operating expenses, in line with the Company's development strategy.

Cost of goods sold amounted to k€1,392, up 42% compared with the same period in 2013. This increase is partly due to the ramp up of Echopulse® production, with merchandise purchases up k€219 compared with 2013. Other operating expenses totaled k€1,502 over the first half of the year, up 12%. Operating losses were quite stable with k€2,400 as of June 30th, 2014, versus k€2,269 as of June 30th, 2013.

Research and Development and Clinical development expenditures represented the majority of operating expenses and totaled k€1,209 over the first half of 2014. Operating expenses for Marketing and Sales amount to k€427 for the period.

Taking into account financial income and expenses, a loss of k€122 during the half year impacted by setting up convertible bonds and interest on current accounts (both put in place during the second half of 2013) for k€76, net income for the half year stood at -k€2,282, compared with -k€1,997 last year.

A strong cash position: €7.5 million as of June 30th, 2014

As of the end of June 2014, available cash totaled €7.5 million, after taking into account the capital increase in cash of €9.4 million carried out in April 2014. The Company's monthly cash consumption was stable at around €0.5 million.

Theraclion's average workforce was 18 employees as of June 30, 2014, versus 16 as of June 30, 2013.

First half highlights and events after the reporting period:

Successful IPO

In April, Theraclion successfully completed its IPO on the Alternext Paris exchange and raised €10.9 million (consisting of €9.4 million in cash and €1.5 million by offsetting debts). The Company's shares started trading on April 25, 2014 and the IPO proceeds will finance operations and the acceleration of the Company's commercial development.

Strengthening the Company

Theraclion reinforced its management team with David Caumartin joining as Chief Executive Officer and Anja Kleber as Vice-President of Marketing/Market Access. These two key appointments are an important step for Theraclion, which should accelerate the Company's commercial development.

In July, Theraclion also obtained k€900 from Bpifrance (repayable advance, subject to project success), as part of the R&D TUCE project.

About Theraclion

Based in Malakoff, near Paris, Theraclion is a French company specialized in cutting-edge medical devices for echotherapy. Theraclion designs, develops and markets a medical device (Echopulse®) that combines advanced ultrasound imaging and HIFU therapy. Theraclion is ISO 13485 certified and has received the CE mark for non-invasive ablation of breast fibroadenomas and thyroid nodules. A full 70% of its 19-strong team are dedicated to R&D and clinical trials. For more information, visit <http://www.theraclion.com>.

Theraclion is listed on Alternext Paris

PEA-PME Eligible

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