

## Theraclion's half year results 2016

- Sales up sharply and dynamic business development in the first half 2016
- Effective control of operating costs along with strengthened cash-position
- New clinical data and tripling of thyroid treatments in Germany and Asia
- Extension of reimbursement in Germany (AOK)
- FDA clearance to start a prospective multicentric clinical study in USA (Investigational Device Exemption) on 100 patients

**Malakoff - France, October 18, 2016 - THERACLION** (Alternext FR0010120402 - ALTHE), a company specializing in leading-edge medical equipment for echotherapy, today announces its consolidated half year results ended June 30, 2016, approved by the Board of Directors on October 13, 2016 and having undergone a limited review by the auditors. The certification report will be issued after verification of the interim financial report.

David Caumartin, Theraclion CEO, said: *"After an exceptional 2015's year end, Theraclion continues to grow in the first half of 2016 with the signing of 5 trade agreements. Germany, thanks to coverage agreements obtained from several health insurance companies, has transformed into Theraclion's lead market. The first half has set the stage for a sharp acceleration in sales while controlling our operating expenses. The success of our capital increase in August supports our goal of further development of our existing markets and expansion to new territories and new therapeutic indications. "*

### Consolidated results - First half 2016

| In K€                                    | 30/06/2016    | 30/06/2015    | Var. %      |
|--|---------------|---------------|-------------|
| Revenues                                 | 463           | 38            | 1 119%      |
| from equipment sales                     | 294           | 0             | na          |
| from equipment rent                      | 101           | 32            | 212%        |
| from consumables                         | 56            | 6             | 880%        |
| from services                            | 13            | 0             |             |
| Subventions                              | 51            | 14            | 264%        |
| Other products                           | 8             | 4             | 50%         |
| <b>Operating income</b>                  | <b>523</b>    | <b>56</b>     | <b>834%</b> |
| External changes                         | -1 979        | -1 747        | 13%         |
| Other operating expenses                 | -2 368        | -1 743        | 36%         |
| <b>Net operating income</b>              | <b>-3 825</b> | <b>-3 434</b> | <b>11%</b>  |
| Financial income                         | -135          | -94           | 44%         |
| Extraordinary income                     | -2            | -6            | -67%        |
| Research tax credit                      | 470           | 360           | 31%         |
| <b>Net result</b>                        | <b>-3 492</b> | <b>-3 175</b> | <b>10%</b>  |
| <b>Average number of employees (FTE)</b> | <b>35</b>     | <b>31</b>     | <b>13%</b>  |



## **Theraclion achieves € 0.5 million sales in the first half 2016, a multiplication by 12 compared to the first half 2015**

In the first half 2016, Theraclion achieved sales of K€ 463, an increase of 1 119%. Over the same period, the company generated a sharp increase in rental equipment income (+ 212%) and consumables sales (+ 880%) driven by the tripling of the number of care centers utilizing Echotherapy in routine clinical practice. The number of treatments carried out in those sites also tripled over the period to 125 treatments.

In the first half 2016, the company registered 5 trade agreements: 2 Echopulse® sales in Germany, (including one which was transferred in third quarter) and 3 contracts for the provision of equipment against pay per use (2 in Germany and one in Italy). Theraclion's echotherapy solution is available in 20 sites (against 16 in 2015): 9 in Germany, three in France, one in the United Kingdom, one in Spain, one in Turkey, one in Switzerland, one in Italy, one in Hong Kong, one in Korea and one in Taiwan.

### **Effective cost control**

Theraclion continues its marketing and R & D efforts while rigorously controlling its costs and operating expenses which grew in proportion with the company's growth in head count from 31 employees at 30 June 2015, to 35 at 30 June 2016. It is to be noted that the operating expenses of first half 2016 decreased by 9% over the second half of 2015 excluding cost of sales.

Comparing H1 2016 versus H1 2015, purchases of goods and other purchases and external expenses rose 13% to K€ 1,979 versus K€ 1,747. Other operating expenses amounted to K€ 2,368 versus K€ 1,743 in 2015, an increase of 36%. The company maintained its sustained investment policy with total R & D costs amounting to € 1.8 million versus € 2.6 million for the full year 2015.

After taking into account the financial result in loss of K€ 135 over the year, in particular linked to the financial interests of a repayable advance from BPI, the consolidated result for the first half 2016 was a loss of K€ 3,492 compared to a loss of K€ 3,175 for the same period in 2015.

### **Cash position**

At June 30, 2016, Theraclion's available cash totaled K€ 2,017 versus K€ 3,753 on 31 December 2015. Excluding the impact of capital increases in cash in the first half totaling € 2.1 million, the monthly cash burn of the company is up to around K€ 870 , which is due to significant working capital effects (around K€ 700) related to advance payments and purchasing of equipment for sale in the second half.

## Post first half 2016 closing events

**Successful capital increase with preferential subscription rights (9.6 million euros, or 100% of the target), with over 80% of exercise of the subscription rights.**

The Company has successfully conducted a capital increase with preferential subscription rights which took place from 26 July to 5 August 2016. This has raised a total gross amount of € 9,629,337 through the issue of 1,610,257 new shares at a price of 5.98 euros.

This has empowered the company to pursue its development within existing markets, especially in Germany, to continue conducting its clinical studies, including access to the two largest markets of the United States and China and to initiate extension of indications to breast and thyroid cancers.

By subscribing 51.6% of the securities offered to the capital increase, the Chinese health group Furui, now Theraclion's second largest shareholder, holds 19% of the company.

In the same process, the funds managed by Truffle Capital, founder & historic shareholder, now hold less than 50% of Theraclion shares. Truffle, whose mission is to support the creation of innovative companies, decided to give up its seat on the Board of Directors of the Company. *"We are delighted to see Theraclion's commercial progress and growth to maturity",* commented Dr. Philippe Pouletty, MD, partner and co-founder of Truffle Capital. *"Truffle Capital aims to accompany younger companies. This is why we wanted, after 12 years, to no longer be part of the board. We are also convinced of the promising future of Theraclion and are proud to remain the reference shareholder."*

**Extension of reimbursement in Germany to a member of the largest German insurance group health and continuation of the process to obtain an early repayment in France**

In the first half, the Company signed four trade agreements in Germany: two sales, one delivered in the third quarter, and two contracts for provision of equipment against pay per use. These successes resonate with an increasing number of people for whom echotherapy is reimbursed. Theraclion is pleased to announce the signing by the German insurance company, Allgemeine Ortskrankenkasse (AOK) Bremen / Bremerhaven of a reimbursement agreement for echotherapy treatment of thyroid nodules and breast fibroadenomas. AOK Bremen / Bremerhaven is part of the AOK group, Germany's largest health insurer with 25 million members.

On 25th January 2016, Theraclion announced that it filed its application to Forfait Innovation which is a path to reimbursement by special dispensation for treatments and innovative medical devices intended to expedite market access for new technologies. Funding is distributed to collect clinical and health economics data to provide the missing information needed to compare the innovation with the standard of care.

On June 21st 2016, the Company received a request for clarification from the High Authority for Health (HAS) to which it replied on 5th September. On October 7th, the company received confirmation of the continuing review of its application for Forfait Innovation by DGOS after validation from HAS of the required criteria. A final decision is expected by the end of the year.



**Echopulse® demonstrates positive clinical results in 5 studies in the United States, Europe and Asia for the treatment of breast fibroadenomas and symptomatic benign thyroid nodules.**

At the 5th International Symposium on focused ultrasound (FUS Symposium), the presentation of data from 5 studies demonstrated even more promising clinical results from echotherapy. The symposium was held from 28th August to 1st September 2016 in Bethesda, USA. Organized by the Focused Ultrasound Foundation, the international symposium on focused ultrasound is the largest international conference dedicated to therapies using High Intensity Focused Ultrasound (HIFU), bringing together each year the most accomplished experts, researchers and practitioners in the field, alongside key industry players.

**FDA approves the start of an IDE study (Investigational Device Exemption) on 100 patients with breast fibroadenoma.**

On August 31st, 2016, Theraclion announced the receipt from US health authorities (FDA) of an approval for its IDE application ("Investigational Device Exemption"), and therefore the approval to proceed with a clinical investigation of the Echopulse device in breast fibroadenoma patients, conducted through the 513 (f) (2) process.

**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 35 people, 50% of whom are dedicated to R&D and clinical trials. For more information, please visit Theraclion's website: [www.theraclion.com](http://www.theraclion.com).

**Theraclion is listed on Alternext Paris  
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