

Theraclion announces its 2014 full-year results in line with expectations

- Year of major achievements to step up growth
- First reimbursements in Germany
- Numerous scientific publications validating the medical efficacy of Echopulse®
- Tight control of operating expenses

Malakoff – France, 19 March 2015 – THERACLION (Alternext, FR0010120402 – ALTHE, PEA-PME eligible), a company specialized in leading-edge medical equipment for echotherapy, today announced its 2014 full-year results to December 31, 2014, as approved by the Board of Directors in its meeting held on March 17th, 2015. The statutory accounts for fiscal 2014 have been audited and the auditor's report is pending

David Caumartin, Chief Executive Officer of Theraclion, comments: "2014 was an important year for Theraclion, during which we entered the marketing phase. We therefore generated our first revenues relating to sales of our Echopulse® solution and maintained our investment efforts while also controlling our operating expenses. Our pro-active strategy of obtaining reimbursement is under way, with three initial agreements signed with insurance companies in Germany that should lead to others in the short and medium term. We expect significant acceleration in our installed base in 2015. Our priority is to offer our innovative, non-invasive and effective treatment to patients while also offering unique benefits to all users."

New management team in place

In order to maximise its commercial development, the company's management team has been strengthened with the arrival of David Caumartin as Chief Executive Officer and Anja Kleber as Vice-President, Marketing/Market Access. Theraclion has also appointed Jose Abellan-Martinez, Mike Leach and Sylvain Yon as Business Development Directors for Germany, the United Kingdom and Asia respectively. Theraclion is focusing its efforts on the largest European markets, including Germany, and emerging markets, particularly in Asia.

Continuing commercial roll-out and first agreement with a radiology centre

In 2014, Theraclion continued its roll-out in Europe with the installation of Echopulse® at the American Hospital of Paris and at the HELIOS Klinik of Schkeuditz. A first commercial agreement was also signed with a private medical imaging centre, SELAS du Nedon in Istres.

First reimbursement agreement in Germany

A first reimbursement agreement for the Echopulse® system has been signed between the German health insurance company Continentale BKK, the Northern Germany Healthcare Association and the Marienhospital in Bottrop. Obtaining reimbursement from healthcare systems is a major growth driver for the company.

Efficacy and tolerance of Echopulse® validated in numerous scientific publications

2014 saw increased momentum in publications of high-level scientific studies validating the efficacy and tolerance of Echopulse®. Three publications - two on thyroid nodules and one on breast fibroadenomas - were published:

- Journal of Therapeutic Ultrasound Early assessment of high-intensity focused ultrasound treatment of benign thyroid nodules by scintigraphic, Dr Korkusuz (Frankfurt);
- International Journal of Hyperthermia Local thyroid tissue ablation by High-Intensity Focused Ultrasound: Effects on thyroid function and first human feasibility study with hot and cold thyroid nodules, Dr Korkusuz (Frankfurt);
- Expert Review Of Medical Devices High-intensity focused ultrasound in breast pathology: non-invasive treatment of benign and malignant lesions, Dr Cavallo Marincola (Roma).

First clinical trials in the United States

Theraclion carried out its first treatments of breast fibroadenoma with the Echopulse® device in the United States in a collaborative effort with the University of Virginia, U.S. The study relates to 20 patients and was conducted after Investigational Device Exemption (IDE) was obtained in February. This constitutes the first phase of the Premarket Approval (PMA) process in the United States.

2014 full-year results

In €′000	2014	2013	Var. %
Revenues	800	15	>100%
Operating subsidies	14	60	(77%)
Other income	6	2	>100%
Total income	820	76	>100%
Purchasing goods and Inventory change	(391)	(43)	>(100%)
Other purchasing and External costs	(2,395)	(2,152)	(11%)
Other operating expenses	(2,981)	(2,428)	(23%)
Operating income /(loss)	(4,948)	(4,547)	(9%)
Net financial items	(183)	(125)	(46%)
Exceptional items	(18)	183	>(100%)
Tax credit	526	378	39%
Net income/(loss)	(4,623)	(4,111)	(12%)

Start of volume marketing of Echopulse®

In 2014, Theraclion generated its first revenues of €800 thousand, marking the effective start of the commercial launch. These sales account for 97% of total revenues and correspond to the sale of three systems to a well-known radiology centre (the SELAS du Nedon private medical imaging centre in Istres), to the HELIOS Klinik of Schkeuditz in Eastern Germany and to the Turkish distributor Penta.

Income from sales of consumables totalled €26 thousand, an increase of +73% year-on-year.

At 31 December 2014, Theraclion had an installed base of 11 Echopulse® systems worldwide: eight at healthcare facilities and three within the framework of clinical trials. The company is focusing its efforts on the largest European markets, namely Germany, France, the United Kingdom and Italy.

Tight control of costs despite an increase in the average number of employees

Theraclion is continuing with its R&D efforts while also controlling its costs and operating expenses despite strengthening its workforce. The average number of employees for the year was 22 as of 31 December 2014, compared with 16 as of 31 December 2013.

Purchasing goods and other purchasing rose by 27% to K€2,787 compared with K€2,195 in 2013. Other operating expenses came to K€2,981 compared with K€2,428 in 2013, an increase of 23%. The company maintained its policy of solid investment, with total R&D costs of €M2.1 (compared with €M 2.2 in 2013) representing nearly 3 times the total revenue.

After net financial items – representing an expense of K€183 over the year, impacted by the increase in financial expenses, particularly related to interest on repayable advance TUCE (for K€ 105) – the company sustained a net loss of K€4,623 in 2014 compared with a loss of K€4,111 in 2013.

Cash position

At 31 December 2014, Theraclion's net cash position amounted to K€4,272 compared with K€407 at 31 December 2013.

Subsequent events

Further publications, including one in the prestigious review Radiology

- Journal of Therapeutic Ultrasound Ultrasound-guided high-intensity focused ultrasound treatment of breast fibroadenoma a multicenter experience, Dr Kovatcheva (Sofia)
- Journal of Therapeutic Ultrasound Volume reduction of benign thyroid nodules three months after a single treatment with High Intensity Focused Ultrasound (HIFU), Dr Korkusuz (Frankfurt)
- Radiology US-guided High-Intensity Focused Ultrasound Ablation of Benign Solid Thyroid Nodules: Initial Clinical Outcomes, Dr Kovatcheva (Sofia)

Installation of Echopulse® at the Institut de Radiologie in Paris

The Institut de Radiologie in Paris, France's largest radiology centre, chose the Echopulse® system to add to the imaging methods it currently offers.

Continuing international expansion

In order to step up its international roll-out, particularly in Asia, Theraclion has opened a subsidiary in Hong Kong. In addition, it has signed partnership agreements with two agents in charge of sales in Switzerland and Finland, and hired Giuliano Laghi as Business Development Director in Italy, thereby further strengthening the company's presence in Europe.

Further reimbursement in Germany

After obtaining reimbursement from German health insurance company Continentale BKK, further insurance companies, including BKK Schleswig-Holstein and BKK VBU, have agreed to offer

echotherapy to their members, covering more than half a million individuals at present. This will enable Theraclion to strengthen and boost its presence and growth in Germany.

Signing of an equity line financing with Kepler Cheuvreux

Kepler Cheuvreux has committed to subscribe to successive capital increases, issued by tranches over the next 36 months, within the global limit of 400,000 new Theraclion shares, which could allow Theraclion to receive approximately €4.3 million¹ at the current stock price. This agreement with Kepler Cheuvreux will strengthen the cash perspective and on Theraclion's financing plan.

About Theraclion

Based in Malakoff, near Paris, Theraclion is a French company specialized in leading-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 52% of its 25-strong team are dedicated to R&D and clinical trials. For more information, visit http://www.theraclion.com.

Theraclion is listed on Alternext Paris

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¹ Based on the closing price on March 17, 2015 (€10.72)