



## Full-year 2015 results

- Revenues up 6% and LISA TRACKER® kit sales up by a factor of 2.4
- Five major partnerships signed
- Net results in line with expectations
- Cash position strengthened to €3.5 million

**Croissy-Beaubourg and Montpellier, March 10, 2016** – Theradiag (ISIN: FR0004197747, Ticker: ALTER), a company specializing in *in vitro* diagnostics and theranostics, announced today its consolidated full-year results for the year ended December 31, 2015, as approved by its Board of Directors on March 10, 2016.

*“In 2015, we entered into five international partnerships in the United States, China and Europe, and strengthened our marketing and R&D efforts to support the development of the theranostics business. Our 2015 revenues grew by 6% for the second year in a row. The signing of major partnerships will be a crucial factor in driving the growth of our theranostics business unit in 2016 and reflect the growing interest in biotherapy monitoring”*, commented Michel Finance, Theradiag’s Chief Executive Officer.

### Full-year 2015 results

<i>In thousands of euros</i>	FY 2015	FY 2014	
<b>Revenues</b>	<b>7,563</b>	<b>7,113</b>	<b>+6%</b>
<i>Incl. in-house revenues</i>	4,881	4,326	+13%
<i>Incl. distribution revenues</i>	2,682	2,787	
<b>Operating profit/loss</b>	<b>-3,411</b>	<b>-3,193</b>	
<b>Net financial income</b>	<b>-109</b>	<b>-67</b>	
<b>Pre-tax profit/loss</b>	<b>-3,520</b>	<b>-3,260</b>	
<b>Exceptional items</b>	<b>25</b>	<b>-154</b>	
<b>Net profit/loss</b>	<b>-2,965</b>	<b>-2,964</b>	

Consolidated financial statements including the accounts of Prestizia, a wholly-owned subsidiary of Theradiag

- **Revenues up 6% and strong increase in sales of LISA TRACKER® kits**

In the financial year to December 31, 2015, Theradiag recorded an increase of 6% in its consolidated revenues to €7.6 million. The pace of revenue growth accelerated to 11% in the second half.

The full-year revenues recorded by the theranostics business unit came to €2.3 million, compared to €1.4 million the previous year. This increase reflected sales under the various partnerships signed during the year with Miraca Life Sciences (initial license payments), UCB (kit purchases) and Hospira (start-up of sales in the fourth quarter of 2015). Adjusted for the revenues specific to partnerships in 2014 and 2015, sales of LISA TRACKER® kits recorded a strong increase, rising by a factor of 2.4 in 2015 from their 2014 level. Consequently, largely as a result of the agreements with Miraca, Hospira and HOB, trends in 2015 revenues point to potential substantial growth in 2016.



The share of sales deriving from products developed in-house continued to rise (up 13%), reaching 65% of the Company's total revenues in 2015, up from 61% in 2014. In addition, revenues from the distribution of innovative molecular biology products grew by 20%.

The shift in the product mix towards in-house products paved the way for the improvement in the gross margin to continue. Despite the adverse impact of fluctuations in the euro/dollar exchange rate, the gross margin reached over 69% in 2015.

- **Full-year 2015 results**

Operating costs were 4% higher than in 2014 owing to expansion of the workforce (especially the number of employees assigned to production of LISA TRACKER® kits), marketing initiatives in support of the theranostics business development and non-recurring costs caused by the Company's move at the beginning of 2015.

Focusing mainly on further development work on LISA TRACKER® kits and development projects conducted on the microRNA technology platform, direct R&D costs (excluding grants) rose by 13% to €1.7 million during the year ended December 31, 2015, which corresponds to 22% of total revenue.

As a result, the Company recorded a net loss of €2.96 million in the year to December 31, 2015, on a par with its 2014 loss, after taking into account the €0.6 million research tax credit.

- **Cash position**

At December 31, 2015, Theradiag's had €3.53 million in available net cash, up from €3.28 million at December 31, 2014.

### **Five partnerships signed and LISA TRACKER® range extended in 2015**

- **Theranostics/LISA TRACKER®**

#### Partnerships

- Framework agreement with **pharmaceutical group UCB** under which Theradiag is to provide UCB with anti-TNF $\alpha$  certolizumab monitoring services.
- Partnership agreement with **pharmaceutical company Hospira** covering use of LISA TRACKER® kits to monitor the Inflectra® biosimilar (molecule: *infliximab*). Hospira will supply its customers in Europe, Canada and Australia with LISA TRACKER® monitoring kits to optimize patient treatment. Theradiag has become Hospira's exclusive supplier of Inflectra® monitoring kits.
- Exclusive distribution agreement with Canadian company **Somagen Diagnostics Inc.** to distribute the LISA TRACKER® biotherapy monitoring range in Canada.
- License agreement with **Miraca Life Sciences** in the form of an exclusive technology license for the approval, marketing and promotion in the United States of monitoring tests for patients treated by biotherapies. Under the terms of the agreement, Theradiag received an initial payment likely to be followed by additional payments if future tests are licensed. Theradiag will sell Miraca the requisite raw materials and earn royalties on the sales realized by Miraca in the United States.



- Cross-distribution agreement with **HOB Biotech** under which:
  - o HOB will handle the registration of LISA TRACKER® with the Chinese authorities and become its exclusive distributor in China and Asia;
  - o Theradiag and HOB have agreed to launch joint R&D projects to develop new allergy, autoimmunity and monitoring solutions based on a new innovative technology platform, sharing their experience and expertise in their respective fields. These research projects are ongoing and the new products are scheduled to be launched in 2017.

#### New CE marks

During 2015, Theradiag secured **CE marking for three new kits** in the LISA TRACKER® range:

- the monitoring test for **Herceptin®**, a humanized monoclonal antibody targeting and blocking growth in tumors controlled by the HER2 protein, used mainly in the treatment of metastatic breast cancer and metastatic gastric cancer.
- the monitoring test for **Stelara®**, a human monoclonal antibody blocking the action of immune system proteins IL-12 and IL-23, indicated in the treatment of moderate to severe chronic psoriasis and psoriatic arthritis.
- the monitoring test for **Entyvio®**, a humanized monoclonal antibody directed against  $\alpha 4\text{-}\beta 7$  integrin, indicated in the treatment of Crohn's disease and moderately to severely active ulcerative colitis in adult patients presenting with insufficient response, loss of response or intolerance to a conventional treatment or by anti-TNFs. This molecule, which belongs to a new therapeutic class with a different mechanism of action from the anti-TNFs, is the fourth available in the United States and the third in Europe for inflammatory bowel disease.
- ***In vitro* diagnostics**
  - Theradiag will be HOB's exclusive distributor in the major European countries for its innovative existing allergy and auto-immunity immunoassays.
  - The development of new solutions by **Theradiag and HOB in the allergy and auto-immune franchises** using an innovative new technology platform will be a very important growth factor for the IVD business unit. This growth may be on a par with the growth anticipated for the Theranostics business unit.
- **Theranostics/MicroARN**
  - **Rectal cancer (miCRA project):** under the **miCRA project**, a collaborative research and development program established in 2013 and awarded the Worldwide Innovation Challenge (CMI) prize, Theradiag has entered into collaboration agreements with two excellence-led rectal cancer research partners – Unicancer and Bordeaux University Hospital. These agreements will give Theradiag access to around 440 samples used in the multi-centric biological validation phase of the two theranostics tests in the miCRA project – i.e. predicting patient response to conventional radiochemotherapy treatment and to metastatic recurrences of rectal cancer.



### **About Theradiag**

Capitalizing on its expertise in the distribution, development and manufacturing of in vitro diagnostic tests, Theradiag innovates and develops theranostics tests (combining treatment and diagnosis) that measure the efficiency of biotherapies in the treatment of autoimmune diseases, cancer and AIDS. Theradiag notably markets the Lisa Tracker® range (CE marked), which is a comprehensive multiparameter theranostic solution for patients with autoimmune diseases treated with biotherapies. With its subsidiary Prestizia, Theradiag is developing new biomarkers based on microRNAs for the diagnosis and monitoring of rectal cancer, auto-immune and inflammatory diseases and HIV/AIDS. Theradiag is thus participating in the development of customized treatment, which favors the individualization of treatments, the evaluation of their efficacy and the prevention of drug resistance. The Company is based in Marne-la-Vallée, near Paris, and in Montpellier, and has over 75 employees.

For more information about Theradiag, please visit our website: [www.theradiag.com](http://www.theradiag.com)



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