



FINANCIAL AND OPERATIONAL RESULTS

FOR THE FIRST HALF OF 2015

Strong increase in revenues and theranostics sales and signature of two partnership agreements with pharmaceutical companies

- Product sales rise to 3.4 M€
- Doubling of theranostic sales
- Signature of collaborative agreements with two pharmaceutical companies

Croissy-Beaubourg and Montpellier, September 30, 2015 – Theradiag (ISIN: FR0004197747, Ticker: ALTER), a company specializing in theranostics and *in vitro* diagnostics, reported today consolidated half-year results for the first half of 2015, as approved by the Board of Directors on September 30, 2015.

Professor Gérard Tobelem, Ph.D., Chairman of Theradiag, comments: *“The two agreements signed with UCB Pharma and Hospira confirm the relevance of our theranostics kits and the growing interest of pharmaceutical companies for the monitoring of biotherapies, especially as biosimilars reach the market.”*

Biotherapy monitoring measures, for every patient, the circulating level of medication and detects potential resistance to treatment. These biological parameters enable physicians to provide patients with the right treatment, at the right time, thereby making treatments more effective.

Michel Finance, CEO of Theradiag, continues: *“Sales revenues from our theranostics operations doubled over the first half of 2015. The international expansion of our LISA TRACKER portfolio continued, notably in North America, where we signed an exclusive distribution agreement earlier in the year. Collaboration agreements with pharmaceutical companies are key catalysts for the development of our LISA TRACKER portfolio and we are actively engaging with other potential pharmaceutical partners.”*

<i>in €K</i>	HY 2015	HY 2014
Sales	3,416	3,374
<i>incl. in house sales</i>	<i>2,070</i>	<i>1,861</i>
<i>incl. distribution sales</i>	<i>1,346</i>	<i>1,513</i>
Operating profit/loss	-2,180	-1,630
Financial Income	-67	-18
Pre-tax profit/loss	-2,247	-1,648
Exceptional items	-41	27
Research tax credit	292	235
Net profit/loss	-2,043	-1,432

**consolidated accounts including Prestizia, a wholly-owned subsidiary of Theradiag*



Results for the first Half of 2015

Revenues increased to €3,416K over the first half of 2015, pulled by the increase in theranostics operations. Sales of in-house products were €2,070K, making up 60.6% of company revenues compared to 55.2% over the first half of 2014. This increase offsets the anticipated decrease in sales revenues of distribution products. The gross profit margin increased to 68.6% from 68.3% of revenues in June 2014, despite an unfavorable impact of the euro-dollar exchange rate.

Theradiag continued to open new markets for its LISA TRACKER range in the first half of 2015. Export sales totaled €1,307K, making up 38% of total revenue compared to 32% over the same period in 2014.

Sustained investments to promote the adoption of theranostics kits resulted in an increase in operating costs:

- Operating external costs were up 6%, mostly comprising costs linked to the move into the new Company headquarters in March 2015 ;
- Salary expenses were up 10%, reflecting an increase in staff to support the growth of theranostics operations.

As of June 2015, Theradiag's team counts 77 employees, compared to 73 as of June, 2014.

R&D expenditures increased to €822K as of June 2015, compared to 791K€ in the same period last year.

After taking into account €292K in research tax credit (*Crédit d'Impôt Recherche, CIR*), the net loss for the six months ended June, 2015 was €2,043K compared to €1,432 in the same period in 2014.

Cash Position

Theradiag's available cash balance as of June 30, 2015 was €2.4 million compared to €2.2 million as of June 30, 2014.

In January 2015, Theradiag set up a Standby Equity Facility (SEF[®]) with Société Générale. As of June 30, 2015, this SEF[®] has been fully drawn-down.

Partnership and Distribution agreements create momentum around theranostics

- **Master Services Agreement with UCB.** Theradiag will perform services for UCB on a project basis. Results of a first performance study confirm the suitability of Theradiag's theranostic kits for monitoring patients treated with Cimzia[®] (*certolizumab pegol*).
- **Partnership Agreement with Hospira** for the supply of LISA TRACKER's CE-marked *infliximab* monitoring kit. Hospira will be providing LISA TRACKER's infliximab assays and anti-infliximab antibodies assays in tenders awarded in Europe, Canada and Australia. Hospira has selected Theradiag as its exclusive provider of *infliximab* monitoring kits.
- **Exclusive Distribution Agreement with Somagen Diagnostics Inc. (Somagen) for the launch of LISA TRACKER in Canada.** Somagen will manage the promotion, marketing and installation



of LISA TRACKER kits in the country through a dedicated salesforce. It will also convey recent scientific developments regarding biotherapy monitoring with Canadian KOLs¹.

Increased focus on high-value diagnostics and theranostics products

- **New state-of-the-art facility to strengthen Theradiag's R&D and production capacities**
Theradiag gained 60% in floor space by moving to a new location. Two thirds of the new space are dedicated to R&D and production facilities. This will allow the Company to increase the volume of production and automation of its proprietary products, and anticipate future growth.
- **CE-marking of 2 new LISA TRACKER monitoring kits**, bringing to 10 the number of available tests - LISA TRACKER is the market's most comprehensive range of biotherapy monitoring tools:
 - o Theradiag strengthened its oncology positioning with a new CE-marked kit for the monitoring of Herceptin®. Herceptin® is the 3rd most-used treatment in oncology, in the treatment of metastatic breast cancer and metastatic gastric cancer.
 - o CE-marking of a monitoring kits of Stelara®, approved for use in moderate to severe plaque psoriasis and psoriatic arthritis.

Growing scientific consensus around the benefits of biotherapy monitoring

- **A study published in the Journal of Crohn's and Colitis sustains the predictive role of biotherapy monitoring and recommends regular monitoring of Inflammatory Bowel Disease (IBD) patients treated with biotherapies².** The study, conducted by Professor Xavier Roblin, M.D., of Saint-Etienne University Hospital, shows that monitoring of trough levels of infliximab, stable antibodies to infliximab and C-Reactive Protein (CRP) can predict loss of response in IBD patients.
- **A study published in Alimentary Pharmacology and Therapeutics (AP&T) reasserts the predictive role of biotherapy monitoring** in the clinical management of IBD patients. The study³, conducted by Prof. Ben-Horin, M.D., of the Sheba Medical Center in Israel and Prof. Roblin, M.D., of Saint-Etienne Medical Center in France, shows that undetectable levels of anti-TNF at drug cessation in patients in long-term remission are associated with low risk of relapse for 12 months after interruption of the treatment.

Recent events and perspectives

- **Two partnership agreements with UNICANCER and Bordeaux University Hospital, two leading cancer research partners signed in July**, allow Theradiag to secure access to multi-center&patient cohorts for its microRNA project in rectal cancer. Theradiag is developing, via its subsidiary Prestizia and in partnership with the Cancer Institute of Montpellier, a member of UNICANCER, two simple, fast and non-invasive theranostics tests in

¹ Key Opinion Leaders

² X. Roblin et al., Combination of C-reactive Protein, *infliximab trough levels and stable but not transient antibodies to infliximab are associated with loss of response to infliximab in inflammatory bowel disease*, Journal of Crohn's and Colitis, April 19, 2015 available at <http://ecco-icc.oxfordjournals.org/content/early/2015/04/17/ecco-icc.jiv061>

³ S. Ben Horin et al. *Undetectable anti-TNF drug levels in patients with long term remission predict successful drug withdrawal*, AP&T, 2015.



this pathology: one for early prediction of response to standard radiochemotherapy treatment; the other for anticipation of metastatic recurrences.

- **LISA TRACKER's portfolio will be strengthened in the second half of 2015** with the CE-marking of a new monitoring kit.
- **Strong increase theranostics sales revenue expected over the full year**, based on Company expectations, and as observed in previous years.

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



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