

# **Press Release**

# Adocia: Activity and results for the first half of 2013

- Intensification of R&D activity ahead of the launch of three clinical trials for insulin projects, starting in the second half of 2013
- Net result of EUR -4.6 million as a result of step-up in R&D spending
- Sound financial position: EUR 22.8 million in cash

**Lyon (France), September 5, 2013 -** Adocia (NYSE Euronext Paris: FR0011184241 - ADOC), a biotechnology company specializing in the development of 'best-in-class' medicines from already approved therapeutic proteins, announces today its financial results for the first six months of 2013.

IFRS half year financial results for the period from January 1<sup>st</sup> to June 30, 2013 have been submitted to a limited review by our Financial auditors and validated by our Board Meeting held on September 4, 2013 and authorized for publication. The 2013 half year report is available on Adocia's website, in French only, Investors/Regulated Information/Financial report (<u>http://www.adocia.com/Investors.en,52.html</u>).

## Significant events of the first half of 2013:

- Intensification of research activity in order to gather clinical data for the three planned clinical trials on type I diabetes patients. These trials are expected to take place during the second half of 2013 for the insulin combo, the fast-acting human insulin Hinsbet® and the ultra fast-acting insulin analog projects.
- A strengthened patent portfolio, with the approval of three new patents in the USA. These include one major patent covering BioChaperone<sup>®</sup> projects in clinical development, and the filing of two new patents covering innovations in the field of insulin.
- A positive scientific opinion from the European Medicines Agency (EMA), confirming only one European phase III clinical trial for the diabetic foot ulcer treatment would be required in order to receive marketing authorization. In India, reorganization in the regulatory authorities structure has resulted in delays in the approval of our application, meaning that authorization of our phase III clinical trial is, at time of publication, still pending.

#### Post June 2013 events:

- July 9, 2013: payment of EUR 3.1 million granted under the French research and development tax credit (*Crédit d'Impôt Recherche*) in respect to expenditure generated in 2012, bringing our cash flow to EUR 23.5 million at the end of August 2013.
- July 29, 2013: end of collaboration with Eli Lilly following a mutual decision not to continue further joint research as outlined in the December 2011 license agreement that granted Lilly access to Adocia's BioChaperone® technology for the formulation of a fast-acting insulin analog. Consequently, Adocia reacquired its exclusive development rights for an ultra fast-acting insulin analog and intends to pursue this project actively. This event will impact the third-quarter accounts that will benefit from the upturn in revenue steaming from the balance of the up-front payment (equal to EUR 4.6 million in revenue with no cash impact).

"Before year end, we intend to launch a phase II clinical trial for the development of our ultra fast-acting insulin analog, following the termination of the Lilly partnership. We believe that this trial will increase the value of this project, and consequently attract potential collaborations," said Gérard Soula, President and CEO of Adocia. "Adocia is currently developing three complementary insulin therapy products and owns a wide and coherent portfolio of key products, likely to draw interest from current actors in the insulin field or from new market players. Our strong financial position of EUR 23.5 million enables us to finance our projects for the next two years."

## Financial highlights as of June 30, 2013:

- **Sound financial position with EUR 22.8 million in cash**, with a burn rate of EUR 7.7 million for the first six months of the year.
- An operational loss of EUR 4.6 million for the first half compared with EUR 1.7 million for the six-month period ending June 30, 2012. These results are in line with previsions made and reflect the investment in research and development carried out in this first half.

Operational expenses are therefore up EUR 1.5 million (+26%) compared to the report for the first six months for the year 2012, while operational revenue has decreased compared to the first semester of 2012, which saw a EUR 1.4 million payment arising from research services.

"Our cash-flow is in line with our operational plan, and our priority is to continue to manage it rigorously," said Valérie Danaguezian, Chief Financial Officer of Adocia. "Our solid financial situation allows us to continue to develop our portfolio of products, including the ultra fastacting insulin analog project".

## Upcoming events:

- SFAF (French Society of Financial Analysts): Presentation of first half financial results September 6, 2013
- Large & Midcap Event October 2 and 3, 2013 in Paris.

## Financial Results as of June 30, 2013:

The following table summarizes the half-year financial statements established in accordance with IRFS standards for the six-month period until June 30, 2013 and 2012.

In thousands of Euros – IFRS Standards	June 30, 2013	June 30, 2012
Operating Revenue	2 739	4 107
Research and development expenses	(6 460)	(5 094)
General Expenses	(926)	(776)
Operating Expenses	(7 386)	(5 870)
Operational Results (loss)	(4 647)	(1 762)
Net financial Income	25	13
Net Result (loss)	(4 622)	(1 749)
Average number of shares outstanding (in thousands)	6 203	5 739
Net loss per share (in €)	(0.7)	(0.3)

## **Operational Products:**

The following table shows details of operational products for each period:

	30/06/2013	30/06/2012
In thousands of Euros – IFRS Standards		
Research Contracts and collaborative development contracts	-47	1 398
Licenses Revenue	953	1 151
Turnover (a)	905	2 549
Grants, public funding and tax credit research (b)	1 834	1 558
<b>Operating revenues</b> (a)+(b)	2 739	4 107

- Operating revenues on June 30, 2013 have decreased by 33% compared with those registered over the same period in 2012.
- Licenses revenue amounts to nearly EUR 1 million, in line with the six months of 2012. These revenues relate essentially to the amortization of the up-front payment of EUR 7.6 million received under the contract signed with Eli Lilly for the development of a new formulation of a fast acting insulin analog.
- For the first six months of 2013 no research contract and collaborative contracts revenue has been registered due to the stage of current projects and activities by Adocia. For the same period in 2012, an amount of EUR 1.4 million has been recognized.
- The other operating revenues products are mainly constituted by the tax credit research for a total amount of EUR 1.8 million compared with EUR 1.6 million as of June 30, 2012. This increase is mainly explained by the increase of research and development expenses eligible over the period concerned.

### **Operating expenses:**

In thousands of Euros - IFRS	June 30, 2013	June 30, 2012
Research and Development expenses	(6 460)	(5 094)
General and administrative expenses	(926)	(776)
Operating Expenses	(7 386)	(5 870)

- Operating expenses increased by 26%, or EUR +1.5 million rising from EUR 5.9 million for the first six months of 2012 to EUR 7.4 million for the first six months of 2013.
- Close to 87% of operational expenses are accounted for by research and development expenses. They reflect the increasing efforts made on the various projects in the portfolio.
- The main types of operating expenses are:
  - External expenses represent more than 53% in total operational expenses and are up +28% compared to the first six months of 2012. These expenses consist mainly of subcontracting costs relating to pre-clinical and clinical studies.
  - Wage and salaries represent the second main area of expenses with more than 38% of the total. The increase of 29% compared to the same period of 2012 reflects new hires in 2012 to support the growth of the company and support its projects.

## Balance sheet items

In thousands of Euro – IFRS Standards	June 30, 2013	June 30, 2012
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Cash and Cash equivalent	22 814	33 705
Total asset	30 378	40 308
Owner's equity	18 852	27 325
Financial debts	2 086	2 442

- As of June 30, 2013, the amount of cash and cash equivalents held by the company amounts to EUR 22.8 million, compared with EUR 30.5 million as of December 31, 2012.
- Shareholder's equity has decreased from EUR 23 million at the end of December 2012 to EUR 18.8 million at the end of June 2013, mainly reflecting capital increases due to the loss during the six first months of 2013.
- Financial debts, amounting to EUR 2.1 million at the end of June 2013, mainly concern the repayment of advances received from the French Agency Oséo innovation.

On the first half year, the company reimbursed an amount of EUR 0.4 million for the advance received for the osteoporosis project; this reimbursement was planned in the contract signed in 2007.

#### About Adocia

#### "Innovative medicine for everyone, everywhere"

Adocia is a biotech company specialized in the development of best-in-class drugs from the innovative formulation of certain already-approved therapeutic proteins.

Adocia is specialized in insulin therapy and the treatment of the diabetic foot, one of the main complications of diabetes. Worldwide, more than 366 million individuals are currently suffering from diabetes (with a forecast of 552 million individuals by 2030, i.e. a 51% increase, reaching 70% in emerging countries). 15% of these patients will develop a foot ulcer during their lifetime. The markets targeted by Adocia represent more than USD20 billion (USD17 billion for insulin therapy and USD3 billion for diabetic foot ulcer healing).

Through its BioChaperone® state-of-the-art technological platform, Adocia intends to enhance the effectiveness and safety of therapeutic proteins and their ease of use for patients, with the aim of making these medicines accessible to the broadest public.

Adocia successfully completed two phases I and II studies on the formulation of a fast-acting human insulin and obtained promising phase I/II results on a diabetic foot ulcer-healing product. Furthermore, Adocia is developing a unique combination of fast-acting insulin and slow-acting insulin, for an optimal insulin therapy with one single product.

#### To be a global leader for the formulation of therapeutic proteins

Based on its experience and recognized know-how, Adocia has extended its activities to the formulation of monoclonal antibodies, which are gold standard molecules for the treatment of numerous chronic pathologies (oncology, inflammation, etc.). In this field, Adocia is engaged in collaborative programs with two major pharmaceutical companies.

Adocia's therapeutic innovations aim at bringing solutions to a profoundly changing global pharmaceutical and economic context, characterized in particular by the increased prevalence and impact of the targeted pathologies, population growth and ageing, the need to control public health expenditures and increasing demand from emerging countries.

Adocia is listed on the regulated market of NYSE Euronext in Paris (ISIN: FR0011184241, mnemo / Reuters / Bloomberg: ADOC, ADOC.PA, ADOC.FP) and its share included in the Next Biotech index. For more information: www.adocia.com

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#### Disclaimer

This press release contains certain forward-looking statements concerning Adocia and its business. Such forward-looking statements are based on assumptions that Adocia considers to be reasonable. However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the "Risk Factors" section of the Reference Document registered by the Autorité des marchés financiers on April 25, 2013 under number R13-017 (a copy of which is available on www.adocia.com) and to the development of economic conditions, financial markets and the markets in which Adocia operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Adocia or not currently considered material by Adocia. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Adocia to be materially different from such forward-looking statements.