

# **PRESS RELEASE**

## Adocia Announces First Half 2020 Financial Results

- Cash position of approximately €36 million as of June 30, 2020
- The promising results obtained on M1Pram project lead to the intensification of its clinical development
- A reglementary filing by our partner Tonghua Dongbao to launch a study of a Phase 3 in China

**Lyon, France July 20<sup>th</sup>, 2020** – 6:00 pm CEST – Adocia (Euronext Paris: FR0011184241 – ADOC), the clinical-stage biopharmaceutical company focused on the treatment of diabetes and other metabolic diseases with innovative formulations of proteins and peptides, announces today its financial results for the first six months ending on June  $30^{th}$ , 2020.

Half-year consolidated financial statements, expressed according to IFRS, underwent limited review by the statutory auditors and subsequently approved at the Board of Director's meeting held today.

"During this first semester, we achieved the objectives set despite the difficult environment due to the COVID-19 pandemic." comments Gérard Soula, Chairman and CEO of Adocia.

"More precisely, we were able to finalize our M1Pram clinical study, which we obtained promising results. An additional clinical study was immediately launched on obese type 1 diabetic patients in order to confirm weight loss, which was observed on this type of patient during the first part of the study; obesity remains a major issue today, including for people with type 1 diabetes. The results of this second part are expected during this second semester. The data validates our strategic pathway for a bi-hormonal treatment which meets the deep need to improve the treatment of type 1 diabetic patients.

We are also delighted that during this period, our partner Tonghua Dongbao successfully finalized and filed the BC Lispro Phase 3 clinical development plan for the Chinese market by the Chinese regulatory authorities. In parallel, we obtained authorization from the German authorities (BfArM) to perform a BC Lispro bridging study with the THDB insulin lispro, which would enable Adocia to validate lispro insulin from THDB and thus start a Phase 3 in the US and Europe.

Finally, we have intensified our discussions with potential partners despite the difficult conditions due to travel restrictions."

#### **Key financial results**

The table below summarizes the condensed consolidated interim financial statements prepared for the sixmonth periods ended June 30, 2020 and June 30, 2019, respectively:

In ( $\in$ ) thousand, Consolidated financial statements, IAS/IFRS	06/30/2020 (6 months)	06/30/2019 (6 months)
Revenue	622	1710
Grants, research tax credits and others	2 950	3 044
Operating revenue	3 572	4754
Operating expenses	(14713)	(18 142)
OPERATING INCOME	(11 140)	(13 388)
FINANCIAL INCOME (LOSS)	(773)	404
Tax expenses	(23)	(9)
NET INCOME (LOSS)	(11 936)	(12 994)

### Key Company Results for the First Half 2020:

- Revenue of €0.6 million from the licensing agreements with Tonghua Dongbao Pharmaceuticals Co.
  Ltd, signed in April 2018, reflects the R&D services provided by Adocia for the transfer and development of licensed products.
- Operating expenses of €6 million for the first six months of 2020 totaling €14.7 million. This decrease of €3.4 million compared to 2019 resulted from:
  - o €2 million for legal proceedings against Eli Lilly which had impacted 2019
  - €0.8 million reduction in external R&D expenses (production of clinical batches realized in 2019 and lower patent fees)
- Net loss before tax of €11.9 million.
- Cash position of approximately €36 million as of June 30, 2020 compared to €43.7 million as of January 1, 2020. Cash consumption in the first six months of the year amounted to €7.8 million compared to €19.1 million over the same period in 2019. This decrease is primarily due to: (i) the receipt of the 2019 Research Tax Credit for €5.9 million in April 2020, following government measures linked to the COVID-19 epidemic, and (ii) legal proceedings against Eli Lilly which had impacted the cash position by €3.5 million in the first half of 2019.

Restated for these two elements, cash consumption for the first half of 2020 is down by  $\in$  2.2 million compared to the same period last year, primarily due to the decrease in R&D subcontracting expenses of  $\in$  1.4 million.

**Financial debts** amounted to €20.8 million as of June 30, 2020 and mainly consisted of the compulsory loan of €15 million subscribed with IPF Fund II in 2019 and bank loans to finance the acquisition and renovation of the Company's research center and corporate office.

"In this particular context our cash position allows us to finance the development of our pipeline. Thus, we are maintaining our ambitious policy while accelerating the clinical development of our combinations of prandial insulin and pramlintide, and the preparation of Phase 3 trials for BC Lispro in Europe and the US," commented Valérie Danaguezian, CFO of Adocia.

### Key events and perspectives for 2020:

The first half of 2020 was impacted by the COVID-19 pandemic and the containment measures implemented in France. In the challenging environment, Adocia quickly organized to manage the pandemic with a priority to limit the spread of the virus and ensure the safety of our employees, while maintaining the continuity of our research activities. Adocia prioritized timeline critical projects at the start of the health crisis, then gradually returned to a normal environment for all research and development activities in early May.

Subcontracting activities were also decreased due to limited resources at our subcontractors. However, most of the clinical and preclinical studies have been maintained and expected results were only slightly delayed.

The first half of 2020 was marked by significant technical and clinical advances on the bi-hormonal product M1Pram (ADO09), a combination of prandial insulin and pramlintide (an amylin analog).

In April 2020, the clinical results obtained on type 1 diabetic patients treated for three weeks showed that M1Pram restored some essential physiological functions during the digestion phase, such as the restoration of gastric emptying time, abnormally short in people with type 1 diabetes, the inhibition of the glucagon secretion (trigger of endogenous glucose synthesis) and a feeling of satiety. This restoration of normal metabolism results in improved control of post-prandial glycemia levels, with a significant reduction in insulin consumption and weight loss in overweight / obese patients.

Based on these results, Adocia plans to continue the clinical development of M1Pram with the launch of a Phase 2 clinical study with type 1 diabetic patients treated over a longer period (3 months). The results of this study should help to define the Phase 3 clinical development plan for the use of M1Pram in pen applications for type 1 diabetics.

Given the promising results obtained with this type of medical device during exploratory studies by universities, Adocia will plan a pump study of its two products M1Pram and BioChaperone® Pram associated with Lispro or Aspart in order to select the best formulation for the function of an artificial pancreas.

During this first half of 2020, Adocia continued its collaboration with partner Tonghua Dongbao (THDB), in China. An important step has been taken with the ultra-fast BioChaperone® Lispro insulin (BC Lispro) for the Chinese market, with the submission of the clinical dossier to the Chinese regulatory authorities (Center for Drug Evaluation). Regarding BioChaperone® Combo, a co-formulation of glargine (basal insulin) and lispro (meal insulin), the technology transfer to our partner is complete and the industrialization of the manufacturing process is underway. Adocia is currently collaborating with Tonghua Dongbao on the clinical development and preparation of a regulatory filing for its commercialization in China, which is proving to be a high-potential market.

In July 2020, the regulatory authorities in Germany approved the launch of a "bridging study" which enables Adocia to validate the THDB insulin lispro API. Upon validation Adocia will launch **BC Lispro** Phase 3 clinical trials **in Europe and the United States**. Adocia is actively pursuing a partnership to secure funding for the Phase 3 trials and commercialization of BC Lispro.

The **BioChaperone® Glucagon** "ready-to-use" formulation for intramuscular injectable is still unique in its mode of administration. It is generally accepted that the intramuscular route is the safest and quickest route of administration when life-threatening conditions exist. Adocia is searching for a partner to develop and market this product.

In financial terms, in the context of the COVID-19 pandemic, the Company has approached its banking and regional partners to benefit from the measures announced by the French government in order to support

businesses in this difficult environment. As such, Adocia received reimbursements for partial unemployment, commercial banks postponed the short-term payments for 6 months and a 2019 Research Tax Credit amounting to €6.5 million was paid earlier (received in April 2020).

### **About Adocia**

Adocia is a clinical-stage biotechnology company that specializes in the development of innovative formulations of therapeutic proteins and peptides for the treatment of diabetes and metabolic diseases. In the diabetes field, Adocia's portfolio of injectable treatments is among the largest and most differentiated of the industry, featuring five clinical-stage products and three preclinical-stage products. The proprietary BioChaperone® technological platform is designed to enhance the effectiveness and/or safety of therapeutic proteins while making them easier for patients to use. Adocia customizes BioChaperone to each protein for a given application.

Adocia's clinical pipeline includes four novel insulin formulations for prandial treatment of diabetes: two ultra-rapid formulations of insulin analog lispro (BioChaperone® Lispro U100 and U200), a combination of basal insulin glargine and rapid-acting insulin lispro (BioChaperone® Combo) and one combination of a prandial insulin with amylin analog pramlintide M1Pram (ADO09). The clinical pipeline also includes an aqueous formulation of human glucagon (BioChaperone® Glucagon) for the treatment of hypoglycemia.

Adocia preclinical pipeline includes three products: a combination of rapid human insulin analogues and Pramlintide (BioChaperone® LisPram), a combination of insulin glargine with GLP-1 receptor agonists (BioChaperone® Glargine GLP-1) for the treatment of diabetes and a ready-to-use combination of glucagon and a GLP-1 receptor agonist (BioChaperone® Glucagon GLP1) for the treatment of obesity.

Adocia aims to deliver "Innovative medicine for everyone, everywhere."

To learn more about Adocia, please visit us at www.adocia.com







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