

ADOCIA Announces First Half 2022 Financial Results and Provides a Business Update

Adocia management will hold a Webcast (in French) on Tuesday, September 20, 2022, at 6:00 pm CEST

- Net profit for the six months ended June 30, 2022, of EUR 4.25 million compared to a loss of EUR 10.6 million a year earlier
 - Strong increase in half-year revenues to EUR 7.3 million (vs. EUR 0.4 million in H1 2021), following the achievement of major milestones with our partner Tonghua Dongbao
 - o Income of 16 million euros capital gains realized for the sale of the building
- Cash position strengthened to 23.9 million euros as of June 30, 2022, from 15.2 million euros as of December 31, 2021.
- Achievement of key program milestones: entry into phase 3 of BC Lispro in China, start of BC Combo clinical studies and positive results from the phase II study on M1Pram.

6.00pm CEST - Adocia (Euronext Paris: FR0011184241 – ADOC), a clinical-stage biopharmaceutical company focused on the research and development of innovative therapeutic solutions for the treatment of diabetes and other metabolic diseases, announces today its financial results for the six months ended June 30th, 2022.

Half-year consolidated financial statements, expressed according to IFRS guidelines, underwent limited review by the statutory auditors and subsequently have been approved at the Board of Director's meeting held on September 16th, 2022.

"We are pleased with the progress of our programs and in particular the launch of our Phase 3 clinical trials on BC Lispro with our partner Tonghua Dongbao. We expect to receive additional development milestone payments of up to \$30 million. Regarding the 2nd project partnered with Tonghua Dongbao, the 3 studies initiated on BC Combo are expected to be the last step before entering Phase 3 and the upcoming development milestone payments amount to \$50 million. Finally, we are very pleased with the remarkable results achieved with M1Pram and AdoShell. With M1Pram, we would be the first to offer obese people with type 1 diabetes to lose weight while maintaining an effective insulin therapy. As for AdoShell Islets, we are working to achieve the grail for the type 1 diabetic patient by offering a donor cell transplantation without resorting to immunosuppressive treatment," commented Gérard Soula, Chairman and CEO of Adocia.

Key financial results

The table below compares the condensed consolidated financial statements prepared for the six-month periods ended June 30, 2022, and June 30, 2021, respectively:

In (EUR) thousands, Consolidated financial statements, IAS/IFRS	06/30/2022 6 months	06/30/2021 6 months
Revenue	7 349	402
Grants, research tax credits and others	3 0 6 9	2 126
Operating revenue	10 418	2 5 2 8
Operating expenses	(15 509)	(12 168)
CURRENT OPERATING INCOME (LOSS)	(5 090)	(9 639)
Other operating revenue and expenses	11 199	0
OPERATING INCOME (LOSS)	6 108	(9 639)
FINANCIAL INCOME (LOSS)	(1 379)	(965)
Tax expense	(478)	0
NET INCOME (LOSS)	4 2 5 2	(10 604)

The financial results of the Company as of June 30, 2022, are characterized by the following main elements:

- Revenue of EUR 7,3 million, mostly derived from the licensing agreements with Tonghua Dongbao Pharmaceuticals Co. Ltd (THDB) for the development, manufacturing and commercialization of BioChaperone® Lispro and BioChaperone® Combo in China and other territories in Asia. For the first semester of 2022, the revenue is mainly driven by licensing revenues of USD 5 million, triggered by the first patient dosed in the pivotal Phase 3 clinical study conducted by THDB in China with Ultra-Rapid Insulin BC Lispro¹. Revenue of the first semester also includes EUR 2.2 million from collaboration signed with THDB for services provided by Adocia's teams on the BioChaperone® Combo program to conduct of three clinical studies in Europe.
- **Other current operating revenues** of EUR 3 million, mainly from the research and development tax credit ("Crédit d'Impôt Recherche"), generated from expenses incurred in the first six months of 2022.
- Other non-current operating income totaling EUR 11.2 million related exclusively to the net capital gain realized on the sale of its building in Lyon in March 2022, which resulted in a net cash receipt of EUR 18.9 million².
- Operating expenses for the first six months of 2022 amounted to EUR 15.5 million, an increase of EUR 3.3 million compared to the same period in 2021. This increase is mainly due to increased external R&D expenses related to higher activities on preclinical and clinical studies, in particular the BC Combo studies performed under the collaboration agreement with THDB. This increase is partially offset by the decrease in internal expenses and in particular personnel expenses, linked to the decrease in FTE³ over the period concerned (-0.5 million euros).

¹See press release dated May 09, 2022

 $^{^2\,\}text{See}$ press release dated March 28, 2022

³FTE: Full Time Equivalent

- **Financial expenses** of almost EUR 1.4 million related mainly to interest generated on loans (including IPF for EUR 0.9 million) and early repayment indemnities for loans in the context of the sale of the building (EUR 0.2 million).
- **A profit before tax** taking into account the above items amounts to EUR 4.7 million compared to a loss of EUR 10.6 million in the same period last year. The tax charge for the period (EUR 0.5 million) relates to the 10% withholding tax on the \$5 million milestone payment received from THDB.
- **Cash position** of EUR 23.9 million as of June 30, 2022, compared to EUR 15.2 million as of December 31, 2021. The increase in cash is due to two significant events: the sale of the building in March 2022, which resulted in a net cash inflow of EUR 18.9 million, and the cash inflow of EUR 4.2 million from the milestone payment received from THDB.

Cash consumption from operations for the first six months of the year amounted to EUR 10.2 million, higher than last year (EUR 7.4 million) on a comparable basis (excluding financing transactions). This increase is mainly due to the impact of the repayment of the debts.

Financial debts (excluding IFRS 16 impacts and derivative debts) amounted to EUR 23.1 million as of June 30, 2022, compared with EUR 33.3 million as of December 31, 2021. The decrease is mainly due to (i) the early repayment of loans (EUR -4.2 million) linked to the building sale, (ii) the conversion of the "OCA 1023" bonds at the end of June 2022 (EUR -3.8 million) and (iii) the repayment of the IPF loan (EUR -1.9 million).

In order to respect the financial commitments made to its lenders, and to strengthen its cash position, Adocia has signed a letter of intent regarding the implementation of a financing operation for an amount of EUR 6 million, which could take place during the fourth quarter of 2022 and which would enable it to extend its cash horizon until March 2023. In addition, the Company is continuing to study other sources of financing while continuing to focus on ongoing discussions to conclude partnerships for its various programs.

"From a financial point of view, we have achieved a very good operation with the sale of our building. The receipt in March 2022 of EUR 19 million immediately available funds provides the cash to develop our innovations" comments Valérie Danaguezian, Adocia's Chief Financial Officer. "This first half of the year was also marked by the receipt of the first milestone payment under the contract signed in 2018 with Tonghua Dongbao for the development of BC Lispro. Beyond the significant impact on our cash position (\leq 4.2 million), this major step forward gives us better visibility on the next steps and their impact on our 3-year plan."

Program Update

The first half of 2022 was marked by significant progress in the collaboration with Tonghua Dongbao for the development of BC Lispro (ultra-fast insulin) and BC Combo (combination of basal and prandial insulins). Major progress was also made at all levels of portfolio maturity, with positive results from the phase 2 clinical study on M1Pram, a combination of a prandial insulin (M1) and an amylin analogue (Pramlintide), and the first preclinical proof of concept on AdoShell Islets for the treatment of type 1 diabetes by cell therapy.

BIOCHAPERONE[®] LISPRO

Adocia's partner in China, Tonghua Dongbao, is currently conducting its pivotal Phase III program with BioChaperone Lispro. The clinical program, fully funded by Tonghua Dongbao, enrolls more than 1,300 people with Type 1 and T2 diabetes recruited in more than 100 centers across China. The first patient was enrolled and dosed in May 2022, which resulted in Adocia receiving a milestone payment of \$5 million⁴. The studies are on schedule. A total \$30 million additional milestone payments could be triggered by future development achievements of BC Lispro until product registration. License agreement with Tonghua Dongbao also includes double-digit royalties on future sales.

BIOCHAPERONE[®] COMBO

On April 11, 2022, Tonghua Dongbao and Adocia announced having initiated 3 clinical studies in Europe (CT046 - 47 and 48) with BioChaperone Combo. Studies are on schedule and results are expected in the first quarter 2023⁵. This clinical program aims to qualify Tonghua Dongbao's insulins and should allow the latter to file the BC Combo dossier with the Chinese Drug Agency (CDE) to obtain approval to start a pivotal phase 3 program in China. Under the terms of the agreement, signed with Tonghua Dongbao Adocia is eligible for up to \$50 million in milestone payments plus double-digit royalties on future sales of the product in China and other Tonghua Dongbao territories.

M1PRAM

Phase 2 clinical study (CT041) sponsored by Adocia, comparing M1Pram (a combination of insulin analog M1 and amylin analog Pramlintide) to insulin lispro (Humalog®, Eli Lilly) in people with type 1 diabetes was completed at the end of the second quarter 2022. On June 21st, 2022, Adocia announced positive topline results: the phase 2 trial has met the primary objective by reducing weight in overweight people with type 1 diabetes⁶. Injections of M1Pram demonstrated weight loss vs. Humalog (-2.13kg) over 4 months with progressive and continuous weight loss still ongoing at the end of study period. Both treatments were well tolerated, and overall good glycemic control was maintained with each treatment. Better control of appetite was also expressed in patient satisfaction surveys after 16 weeks of treatment (82.4% with M1Pram vs. 43.2% with Humalog).

Additional analyses show greater weight loss in sub-populations with higher body mass indexes. Patients treated with M1Pram and having a BMI above 28kg/m² achieved a weight loss greater than 3kg, at the end of the study period when the BMI is greater than 30kg/m² the weight loss observed exceeds 5kg.

M1Pram is the only insulin developed to date for people with type 1 diabetes that reduces weight and improves appetite control. These results have been selected for oral presentation at the upcoming European Diabetes Congress, EASD, on September 20th, 2022.

BCLISPRAM

The pilot trial in people with type 1 diabetes, conducted in collaboration with Prof. Ahmad Haidar of McGill University, aims to evaluate the pharmacokinetic and pharmacodynamic characteristics and the efficacy of BC LisPram (a fixed combination of insulin and amylin analogues, lispro and pramlintide) when administered in closed loop compared to rapid insulin (lispro) administered by pump. The clinical part of the study is completed, and results are expected in Q4 2022.

⁴ See press release dated May 09, 2022

⁵ See press release dated May 18, 2022

⁶ See press release dated June 21, 2022

CELL THERAPY: ADOSHELL[®] ISLETS

AdoShell Islets is an immuno-protective synthetic biomaterial containing islets of Langerhans (from donor pancreases) for the treatment of type diabetes by cell therapy. The preclinical work carried out during the first half of 2022 has enabled us to establish a first proof of concept by achieving glycemic control - without insulin injections or immunosuppression - in immunocompetent diabetic rats during the 132-day study⁷. The insulin secreted by the transplanted islets was measured for 132 days and no slowing of secretion was observed during the duration of the study.

At the end of the study the graft was removed, which resulted in an observable drop of insulin secretion and rise in blood sugar levels, the animals rapidly returned to their diabetic state. At the same time, the animals in the control group (diabetic rats that did not receive AdoShell Islets) were unable to control their blood sugar levels. Additional ongoing studies in diabetic rats seem to confirm these initial results, producing insulin and normalizing the glycemia in diabetic rats for 80 days (study still on-going). AdoShell Islets will be evaluated in diabetic pigs in the 4th quarter of 2022.

In parallel with the development of AdoShell Islets using donor pancreases to primarily treat most severe cases of type 1 diabetes, Adocia also aims to develop its AdoShell technology using stem cells, which would ultimately make this technology possible to free itself from the limit of the number of donors and thus treat a much larger number of people with type 1 diabetes. Thus, Adocia has ongoing collaborations with stem cell companies.

ORAL DELIVERY: ADORAL®

Preclinical work conducted during the first quarter shows that AdOral significantly improves the absorption of peptides when administered orally compared to the reference technology used on the Rybelsus product (Novo's oral semaglutide). These unpublished results are currently being presented to pharmaceutical companies with the aim to establish collaborations.

OBESITY PROGRAMS

Adocia is currently testing several hormonal combinations administered by pump in rodents. Adocia's objective is to identify the best drug candidate for patch pump administration. As part of this project, Adocia is considering collaboration with patch-pump companies interested in reaching the obesity market and its 600 million-plus patients.

Governance

On June 28, 2022, Bpifrance Investissement decided to appoint Mr. Olivier Martinez as its representative to Adocia board of directors in replacement of Mr. Laurent Arthaud (it being specified that Mr. Olivier Martinez was previously a director of Adocia on his own name). Also, the board of directors of Adocia held on June 28, 2022 decided to modify the composition of its remuneration committee as follows: Mrs. Ekaterina Smirnyagina chairwoman and Mr. Olivier Martinez member.

⁷ See press release dated September 07, 2022

Availability of the half-year financial report

The 2022 half-year financial report of Adocia has been filed with the French Financial markets authority (Autorité des marchés financiers). It is available to the public and can be consulted on the www.adocia.com website in the Financials - Documentation section.

About Adocia

<u>Adocia</u> is a biotechnology company specializing in the discovery and development of therapeutic solutions in the field of metabolic diseases, primarily diabetes and obesity. The company has a broad portfolio of drug candidates based on three proprietary technology platforms:

1) The BioChaperone[®] technology for the development of new generation insulins and products combining insulins with other classes of hormones; 2) *AdOral*[®], an oral peptide delivery technology; 3) *AdoShell*[®], an immunoprotective biomaterial for cell transplantation with a first application in pancreatic cells transplantation for patients with "brittle" diabetes.

Adocia holds more than 25 patent families.

Based in Lyon, the company has approximately 115 employees. Adocia is listed on the EuronextTM Paris market (Euronext: ADOC; ISIN: FR0011184241).

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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 as being reasonable. However, there can be no guarantee that the estimates contained in such forward-looking statements will be achieved, as such estimates are subject to numerous risks including those which are set forth in the "Risk Factors" section of the universal registration document that was filed with the French Autorité des marchés financiers on April 21, 2022 (a copy of which is available at <u>www.adocia.com</u>, in particular uncertainties that are linked to research and development, future clinical data, analyses, and the evolution of the economic

context, the 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 considered as material by Adocia as of this day. The occurrence of all or part of such risks could cause that actual results, financial conditions, performances, or achievements of Adocia be materially different from those mentioned in the forwardlooking statements.