

## PRESS RELEASE

Lyon, March 15<sup>th</sup>, 2023



**ADOCIA**

innovative medicine  
for everyone, everywhere

# ADOCIA announces its annual results for 2022 and provides corporate and financial update

Adocia management will hold a Webcast (in French) on Thursday, March 16, 2023, at 6:30 pm CEST

TEAMS Link: <https://zoom.us/j/96854749555>

ID meeting: 968 5474 9555

- Net loss of €6.9m (€22.8m in 2021)
  - Revenues increased to €11.4m (€1.4m in 2021) reflecting milestone achievements on the two projects licensed to Tonghua Dongbao
  - Operating expenses of €30.2m (€25.4m in 2021)
  - A capital gain of €11.2m on the sale and lease-back of Adocia's Lyon facility
- A cash position of €17.4m as of December 31, 2022 (€15.2m in 2021)
  - A cash position which enables to finance activities through September 2023
  - Partnership discussions which could significantly extend the cash horizon
  - Discussions also ongoing with the Company's lenders to restructure the financial covenants and satisfy them beyond March 31st, 2023
- Major clinical and preclinical advances:
  - Entry into phase 3 of BioChaperone<sup>®</sup> Lispro in China, triggering \$5m milestone payment received from Tonghua Dongbao
  - Outstanding phase 2 clinical results for M1Pram achieving weight loss of more than 5kg after 4 months of treatment, and
  - Preclinical proof-of-concept achieved for AdoShell<sup>®</sup> Islets in cell therapy

6:00 pm CET - 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 annual financial results as of December 31, 2022. The consolidated financial statements were approved by the board of directors on March 14, 2023 and the audit of the accounts is being finalized. These statements will be presented to shareholders for approval at the next annual general meeting on May 11, 2023.

Gérard Soula, Chairman and CEO of Adocia states: " The company is actively working to increase its cash position with non-dilutive options to ensure longer-term financing of operations and to meet commitments made to its lenders.

M1Pram's outstanding results have attracted the interest of several companies involved in the treatment of obesity and diabetes and advanced discussions are ongoing. Objective of these discussions is to sign a licensing agreement that would not only allow to cover its expenses but even more to ensure a worldwide development of this product whose properties are recognized as unique and exceptional by the endocrinology community.

The fight against obesity, a major societal issue, is a new paradigm for the pharmaceutical industry, which is targeting tens of billions of dollars in sales in this field in the near future.

Aware of time needed to sign such an agreement, we are also in discussions with investors who may wish to buy a portion of the future revenues generated by our BioChaperone® Lispro product for which we expect to receive a total of \$30m in milestone payments, followed by double-digit royalties on sales from our partner in China. This product is currently in phase 3 in China and aims to be commercialized in the world's largest insulin market.

Finally, we will also continue to work with our primary lender to restructure our debt and have the time required to achieve both of these objectives.

We are confident in Adocia's pipeline of strong assets to benefit patients with diabetes and obesity worldwide, anticipated to ensure our long-term success".

## Financial highlights

The following table summarizes the financial statements under IFRS for the year ended December 31, 2022 with a comparison to the year 2021:

<i>In (€) thousands - unaudited</i>	<b>FY 2022 (12 months)</b>	<b>FY 2021 (12 months)</b>
Revenue	11 447	1 444
Research Tax Credit	5 914	4 611
<b>Operating revenue</b>	<b>17 361</b>	<b>6 055</b>
Research and development expenses	(25 898)	(20 016)
General and administrative expenses	(4 359)	(5 404)
<b>Operating expenses</b>	<b>(30 257)</b>	<b>(25 421)</b>
<b>OPERATING INCOME (LOSS)</b>	<b>(12 896)</b>	<b>(19 366)</b>
Other non-recurring operating income and expenses	11 199	0
<b>OPERATING INCOME</b>	<b>(1 698)</b>	<b>(19 366)</b>
<b>FINANCIAL INCOME</b>	<b>(4 727)</b>	<b>(3 388)</b>
Tax	(476)	0
<b>NET INCOME (LOSS)</b>	<b>(6 901)</b>	<b>(22 754)</b>

Company's results for the year 2022 are characterized by:

- **Net loss of €6.9m in 2022**, compared to a loss of €22.8m in 2021, mainly consisted of:
  - **Revenue** of €11.4m in 2022 (compared to €1.4m in 2021), mainly driven from the two license agreements signed with Tonghua Dongbao ("THDB") for the development, production and commercialization of BioChaperone® Lispro and BioChaperone® Combo in China and other Asian territories.

In 2022, the revenue includes \$5m of licensing revenues triggered by the first patient dosed in the pivotal phase 3 clinical study conducted by THDB in China with BioChaperone Lispro. It also includes €6.1m from collaboration signed with THDB for services provided by Adocia's team on the BioChaperone Combo program to conduct three clinical studies in Europe. These activities, launched in 2021, have generated close to €1m in revenues last year.
  - **Other operating income** of €5.9m, mainly consisting of the research tax credit generated on the 2022 expenses, up compared to last year amount (€4.6m), reflecting the increase in eligible operating expenses.
  - **Current operating expenses** of €30.2m, up by €4.8m compared to last year. This increase, which concerns R&D expenses (general expenses are down), is related to the significant clinical activities conducted on behalf of THDB on BioChaperone Combo in Europe.
  - **A non-recurring operating income** of €11.2m recognized following the sale and leaseback of the building in March 2022. This transaction resulted in a net cash receipt of €18.9m and generated an accounting gain of €16.6m. This gain has been restated in accordance with IFRS 16, and only the portion constituting the rights transferred to the purchaser-lessor appears under other non-recurring operating income.
  - **A negative financial result** of €4.7m reflecting the financial interest paid on the loan contracted with IPF Partner and on the PGE (State guaranteed loans) granted to the Company by several financial institutions (for a total of €2.9m) as well as the fair value revaluation (non-cash IFR impact) of the convertible bonds (OCA1023 and OCA1124 issued by the company in October 2021 and December 2022 respectively for a total amount of €1.3m) and the IPF warrants (for €0.7m).
  - **The net loss** for the year amounted to €6.9m, with a significant improvement compared to fiscal year 2021 (loss of €22.7m) due to the increase in revenues and the completion of the sale and leaseback of the building.
- **A cash position of €17.4m as of December 31, 2022** (compared to €15.2m as of December 31, 2021).
  - The increase of €2.2m in cash over the year is explained by the sale of the building in March 2022, which resulted in a net cash receipt of €18.9m by the €4.2m cash inflow related to the milestone payment received from THDB on BioChaperone Lispro and the issuance of convertible bonds called OC1124 in December for an amount of €6m to European investors.
  - Cash burn for the year was nearly €15m, down from previous year (€19m), due to the receipt of the milestone payment from Tonghua Dongbao in mid-2022.
  - The positive net cash flow from investing activities of €21.8m mainly reflects the sale and leaseback of the building.
  - Cash flows from financing activities include the repayment of the loan related to the building sold (€4.4m) and the repayment of the IPF partner and PGE loans (€6.2m), partially offset by the financing transaction of €6m carried out in December, relating to the issue OC1124.

- **Net financial debt (excluding IFRS 16 impacts and derivatives) of €24.1m at the end of December 2022**, compared with €33.3m at December 31, 2021, i.e. a net decrease of €9.1m
  - The decrease in debt by €15.7m is due to (i) the repayment of the IPF Partners loan (€5.8m), including €2m of early repayment following the exercise of a contractual option, (ii) the conversion of the convertible bonds into shares known as "OC1023" issued by the company in October 2021, leading to a decrease in debt of €5.7m, and (iii) the early repayment of the loans (€4.2m) attached to the building as a result of the lease-back operation.
  - The decrease in debt is partially offset by the increase linked to the convertible bond financing transaction (OC1124) carried out in 2022 (€6.6m).

The annual accounts were approved by the Board of Directors on the basis of the going concern principle and with mention of a significant uncertainty about this going concern principle in the notes to the accounts. The audit of the company's annual accounts is currently being finalized.

## Cash forecast and perspectives

In February 2023, the Company received €4.5m from BNP Paribas Factor following the mobilization of its receivable related to the 2022 research tax credit (CIR). As a result, the Company had a cash position of €17m at the end of February 2023.

Financial debts at the end of February 2023 amounted to €22.7, down €1.4m compared to December 31, 2022, following the repayment of the PGE loans at the end of February, the conversion of the convertible bonds over the first two months of the year, and the waiver by BPI france (formerly OSEO) of the €0.5m repayable advance.

The cash position of €17m allows the company to finance its activities until September 2023, but does not allow it to respect the financial commitments (covenants) made to its lenders, beyond March 2023. The company is in discussions with its lenders to restructure its debt in order to extend its cash flow horizon and thus enable it to pursue the discussions initiated in recent months.

Indeed, Adocia is actively pursuing several options that would allow it, if they proved to be successful, to significantly strengthen its cash position: signing a partnership, monetizing future royalties, raising funds. If none of these options were to succeed, and if no new agreement were to be reached with its lenders, the company's cash flow horizon would be shortened to the end of May 2023.

Management is actively pursuing all of these options in parallel and remains confident that it can extend its cash horizon.

## Highlights of the year 2022

Year 2022 was marked by progress on our flagship products, which attracted the interest of potential partners with a view to establishing licensing agreements for our specialty products. At the same time, Adocia has established *in vivo* proofs of concept on its AdOral, AdoShell and AdoGel technology platforms. The business team is looking for partnerships on these three technology platforms.

- Major clinical progress and deployment of technological platforms

### BioChaperone<sup>®</sup> Lispro: start of phase 3 in China

In May 2022, Adocia announced the dosing of the first patient in the phase 3 program of BioChaperone<sup>®</sup> Lispro with its partner Tonghua Dongbao. This large-scale program will include 1,300 people with Type 1 or Type 2 diabetes in 100 clinical research centers in China. This major development milestone has triggered a \$5m payment from Tonghua Dongbao to Adocia. Additional payments of up to \$30m are contingent upon the achievement of future development milestones until marketing authorization. Royalties payments on future sales of Tonghua Dongbao are also planned.

In parallel, a phase 1 study was completed in December 2022 and the preparatory work for the Phase 3 studies in the United States and Europe has been finalized, with positive opinions received from the FDA and the EMA. The company is searching for a partner capable of financing the pivotal program until marketing authorization is obtained for these territories.

### M1Pram: exceptional clinical results obtained in phase 2

Adocia has intensified the clinical development of its two candidates, M1Pram and BioChaperone LisPram, which are positioned for the auto-injector pen and pump markets respectively. These fixed-dose combinations of insulin and amylin analogues are expected to provide improved medical benefits compared to rapid insulins administered alone, by achieving weight loss in obese or overweight diabetic patients. In the United States, 65% of type 1 diabetic patients and 85% of type 2 diabetic patients are overweight or obese.

The results of the Phase 2 study (CT041) with M1Pram autoinjector pen were disclosed on June 21, 2022. The primary endpoint was met, with a weight loss in overweight people (BMI > 25 kg/m<sup>2</sup>) with Type 1 diabetes demonstrated over 4 months compared to Humalog<sup>®</sup> (-2.13 kg). The treatment was well tolerated and good overall glycemic control was maintained. Better appetite control was expressed in the patient satisfaction survey (82.4% with M1Pram vs. 43.2% with Humalog<sup>®</sup>). In a post-hoc analysis, M1Pram showed exceptional weight loss in the subpopulation of obese patients (BMI >30 kg/m<sup>2</sup>). Weight loss was -5.56 kg in the M1Pram group versus -0.57 kg in the Humalog group (p=0.03) at 16 weeks of treatment, and weight loss did not plateau at the end of the study. These results were presented at EASD 2022.

In parallel, a proof-of-concept study in humans was initiated with BioChaperone LisPram. This combination was specifically designed for automated pump administration using an algorithm. The clinical part of this study, conducted in collaboration with Dr. Ahmad Haidar of McGill University (Canada), has been completed and results are expected in the first quarter of 2023.

### AdoShell<sup>®</sup> Islets: first preclinical proof-of-concept for the treatment of type 1 diabetes by cell therapy

The function of AdoShell Islets is to maintain the secretory activity of transplanted pancreatic cells, while protecting them from the immune system. In September 2022, Adocia announced the first preclinical proof of concept for AdoShell Islets for the treatment of Type 1 diabetes by cell therapy. AdoShell Islets restored glycemic

control in immunocompetent diabetic animals, without insulin or immunosuppressants, until the end of the 132-day trial. These results were presented at the PODD 2022 cell therapy session in Boston in October 2022. A new series of trials on diabetic rats confirm these promising results with 80 days of glycemic control (study still in progress). Studies are also underway on pig models, in order to prepare the first in human trials. An academic collaboration has been established with several teams, including Inserm with Professor François Pattou, a world-recognized specialist in islet transplantation.

- New proprietary technology platforms opening up promising markets

#### AdOral®: oral delivery of peptides to replace injections

Adocia has developed a technology that can enable the oral delivery of peptides, which would make it possible to switch from injectable to oral forms. In addition to improving patient quality of life and compliance, oral forms of peptides may be of interest for product life cycle management and would avoid the difficulties associated with large-scale production of sterile injectables. Initial preclinical results have shown an increase in the absorption efficiency of peptides by the digestive tract.

A first application to semaglutide, a GLP-1 receptor agonist used in the treatment of diabetes and obesity, has validated this technology in preclinical studies by demonstrating improved bioavailability. This technological platform opens up numerous applications in various therapeutic areas.

#### AdoGel®: a technology for the long-term delivery of peptides and small molecules

AdoGel has been designed to enable the long-term delivery of therapeutic solutions, in order to compensate for repeated drug administration and improve compliance. Designed for release from one month to several years, AdoGel also avoids an initial concentration peak and improves the time in the therapeutic window.

A first application to a contraceptive treatment has demonstrated in vivo a release without initial burst and a zero-order release profile up to 6 months.

These three technological platforms invented by Adocia open up numerous potential applications in various therapeutic areas.

- Change in the governance

At the beginning of December 2022, the Company was informed that Bpifrance Investissement had resigned from its position as director. Bpifrance Investissement was represented by Mr. Olivier Martinez who had been a member of Adocia's Board of Directors since BioAm's investment in 2007.

The Board of Directors meeting held on December 14, 2022 appointed Mr. Mads Dall as a provisional director, replacing Bpifrance Investissement for the remaining term of the latter's mandate, i.e. until the General Meeting to be held in May 2023. Mr. Mads Dall is internationally recognized for his expertise in the field of diabetes. He had a long career at Novo Nordisk which included development of the commercial activities in China.

## Post-period events

At the beginning of January 2023, the Company received a letter from Bpifrance (formerly OSEO) certifying the effective termination of the Hinsbet program initiated in 2012. This decision leads to the waiver of the outstanding debt of 520,000 euros and consequently to the recognition, in 2023, of a grant for the same amount.

## Agenda for 2023

- Continuation of BioChaperone® Lispro Phase 3 program in China.
- Release of results from three phase 1 studies of BioChaperone® Combo, financed by Tonghua Dongbao and conducted by Adocia in the first half of 2023. The data generated will be used to support the application for direct entry into phase 3 in China.
- Release of BioChaperone® LisPram pump study results, conducted in partnership with McGill University, in the first half of the year.
- Continued deployment of technology platforms.

## About Adocia

Adocia 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 four 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; 4) AdoGel®, a long-acting drug delivery platform.

Adocia holds more than 25 patent families.

Based in Lyon, the company has about 100 employees. Adocia is listed on the regulated market of Euronext™ Paris (Euronext: ADOC; ISIN: FR0011184241).

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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 [www.adocia.com](http://www.adocia.com)), 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 forward-looking statements.

This press release and the information contained herein do not constitute an offer to sell or the solicitation of an offer to buy Adocia's shares in any jurisdiction.