

## PRESS RELEASE

Lyon, February 27<sup>th</sup>, 2024

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# ADOCIA Reports Fourth Quarter 2023 Financial Results and Provides a Business Update

- Cash of €13.0 million as of December 31, 2023, with cash burn of €3.8 million in Q4 2023
- Indebtedness reduced to a €5.6 million state-guaranteed loan
- Continued discussions with Sanofi on M1Pram and progress in development with the manufacturing of clinical batches for Phase 2b in the United States
- Consolidated preclinical efficacy data on AdoShell® Islets in preparation for first-in-human study, and interest expressed by major pharmaceutical companies in in-licensing the technology
- Positive results on three BioChaperone® Combo clinical trials enabled Adocia's partner Tonghua Dongbao to prepare next development steps with Chinese regulatory authorities

Adocia's management will hold a web conference at 6:00 pm CET on February 28, 2024, to discuss fourth quarter 2023 financial results. Access the live webcast [by following this link](#).

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 obesity, today reports financial results for its fourth quarter of 2023 and provides a business update.

*"We are emerging from an eventful 2023 as a strengthened company and we enter 2024 with active discussions underway with Sanofi on M1Pram, and also with key players on AdoShell Islets", said Olivier Soula, Adocia CEO and co-founder. "I would like to extend my warmest thanks to Adocia's employees for their loyalty and constant dedication during this difficult year, so that we can continue to create and to develop high-value innovations, that have captured the interest of the largest pharmaceutical companies. Looking ahead, we are preparing to make 2024 a transformative year for Adocia."*

## Fourth quarter 2023 financial results

"During the fourth quarter 2023, we maintained focus on advancing M1Pram and AdoShell Islets, as well as developing BC Lispro and BC Combo in support of our Chinese partner. Adocia is now in a simple and clear financial situation with debt limited to a state-guaranteed loan of 5,6m€ with a maturity date at the end of August 2026, and all warrants and convertible bonds have been redeemed" said Valérie Danaguezian, Chief Financial and Administrative Officer. "Our cash position of €13 million as of December 31, 2023, enables us to fund planned activities until the end of August 2024, not taking into account any payments from existing or future partnerships. Our priority is to strengthen the company's financial position, primarily through partnerships, while evaluating various financing options."

Full year audited financial results for 2023 will be published in April 2024.

The main financial figures for the quarter are as follows:

### Detail of the revenue

<i>In thousands of euros, IFRS standards (unaudited)</i>	12/31/2023 (3 months)	12/31/2022 (3 months)	12/31/2023 (12 months)	12/31/2022 (12 months)
Licensing revenues	75	88	313	5 088
Research and collaboration agreements	128	1 608	1 837	6 359
<b>Revenue</b>	<b>203</b>	<b>1 696</b>	<b>2 150</b>	<b>11 447</b>

The Company's revenues are mainly derived from the licensing and collaboration agreements signed with Tonghua Dongbao (THDB) for the development, manufacturing and marketing of BioChaperone® (BC) Lispro and BioChaperone® Combo in China and other Asian territories.

**Revenue for the fourth quarter of 2023** of €0.2 million consists of services provided by Adocia's teams on BC Combo and the completion of three clinical trials in Europe, with positive results announced on October 23.

**Annual revenues for 2023** of €2.2 million consists of €1.5 million from THDB related to BC Combo activities and €0.6 million from an ongoing feasibility study on the AdOral® project.

For comparison, revenue in 2022 of €11.5 million represented (i) services performed for THDB on BC Combo, and (ii) a €4.8 million milestone payment received in May 2022 for the recruitment and dosing of the first patient in the Phase 3 program of BC Lispro initiated by THDB in China.

Finally, and marginally now, 2023 licensing revenue included the impact of the application of IFRS 15 on the treatment of the upfront payment received from THDB in 2018, upon signature of the licensing agreements. This represents an amount of €238,000 in 2023, compared with €262,000 in 2022. Amortization was complete as of the end of December 2023.

### Net Cash Position

The company's cash position stood at €13.0 million as of December 31, 2023, compared with €17.4 million as of December 31, 2022. The cash position as of end of December 2023 takes notably into account the following major receipts and disbursements in the second half of 2023:

- Sanofi's payment of €10 million in July 2023 under the M1Pram exclusivity agreement;
- The completion of a €10 million financing consisting of a €5 million private placement and the issuance of €5 million in convertible bonds. All convertible bonds issued by the company have been converted as of the end of September 2023, and Vester Finance declared that it had exceeded the threshold of 10% of the Company's capital, positioning itself as a significant shareholder in the Company;
- Repayment of IPF Partners debt in the amount of €10.2 million;
- The receipt of €2.5 million following the full exercise of IPF Partners warrants.

Cash outflows from operating activities for 2023 were €14.5 million, down from last year's outflow of €23 million (with both periods excluding financing operations).

Net financial debt (excluding IFRS 16 impacts and derivative instruments) was €5.7 million as of December 31, 2023, compared with €24.1 million as of December 31, 2022. The significant decrease in debt of €18.4 million was primarily due to (i) the repayment of the IPF Partners loan in full, (ii) the conversion of all convertible bonds into shares issued (i.e., -€6,8 million compared with year-end 2022) (iii) the payment of PGE loan maturities (state guaranteed loan) for €0.8 million and (iv) Bpifrance's waiver of €0.5 million on the Hinsbet program initiated in 2012 and subsequently discontinued.

## 4<sup>th</sup> Quarter Highlights

### M1PRAM: toward a global partnership to address a serious unmet medical need

As a reminder, on July 5, 2023<sup>1</sup>, Sanofi and Adocia signed an option agreement giving Sanofi the exclusive right to negotiate a worldwide partnership for M1Pram (and other insulin-pramlintide combinations developed by Adocia). This agreement is still in force today. Sanofi paid Adocia €10 million to acquire this right.

In December 2023, Adocia's Board of Directors approved the creation of Pramulin Therapeutics, a 100%-owned subsidiary of Adocia, with a view to structuring a future partnership. Pramulin Therapeutics will be dedicated exclusively to the development of M1Pram.

- **Clinical development**

The M1Pram Medical Advisory Board met in December 2023 to finalize the protocol for the Phase 2b study. Preparations are underway for this clinical program, including 140 patients with type 1 diabetes and a BMI > 30kg/m<sup>2</sup>, in the United States.

Manufacturing of clinical batches is underway, to ensure the launch of the Phase 2b study during the third quarter of 2024.

- **Medical need**

In the United States alone, there are nearly 2 million insulin-dependent people who are affected by obesity and overweight (approximately 1 million with type 1 diabetes, and 1 million with type 2 diabetes). Worldwide, this population is estimated at nearly 40 million. M1Pram could address an important unmet medical need for these people by enabling weight loss while maintaining glycemic control. It is estimated that M1Pram could generate annual sales of several billion dollars in the United States.

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<sup>1</sup>Press Release, July 5, 2023, ADOCIA Grants Sanofi an Exclusive Right to Negotiate a Partnership on M1Pram for 10 Million Euros and Obtains Commitment from Investors to Provide 10 Million Euros in Financing

## ADOSHELL® ISLETS: a strategic priority

New data on AdoShell® Islets, an immunoprotective biomaterial containing islets for the treatment of diabetes by cell therapy, were revealed at the prestigious international congresses of the ADA, EASD and IPITA-IXA-CTRMS<sup>2</sup>.

The data support AdoShell® Islets as a biocompatible immunoprotective material for islet transplantation, without immunosuppression. *In vivo*, in rodent diabetic models, the survival of encapsulated islets was maintained after a 7-month study without immunosuppression, and efficacy was established with the ability to control hyperglycemia. Designed for minimally invasive surgery, AdoShell® Islet has demonstrated exceptional biocompatibility.

Adocia is actively preparing a first clinical trial to bring this technology to patients as quickly and safely as possible. Adocia is preparing interactions with the EMA to validate the proposed development plan. AdoShell® Islets could then be tested in the clinic as early as 2025.

The preclinical data generated to date are attracting the interest of major industry players, and discussions have been initiated.

The AdoShell® matrix, as a technological platform, is also being considered for applications with stem cells and in other therapeutic fields (e.g., Parkinson's disease, hemophilia, oncology, etc.). Deployment of the platform will depend on the interest of future partners.

## BC COMBO & BC LISPRO: capitalizing on our strong partnership with THDB

- **BioChaperone® Combo**

Positive results from three clinical studies conducted with BC Combo (CT046 - 47 and 48) were announced in October 2023<sup>3</sup>. Conducted by Adocia in Germany, these studies were fully funded by Tonghua Dongbao, to which BC Combo was licensed in 2018.

The studies enrolled people with type 1 and type 2 diabetes, and healthy Chinese volunteers, and demonstrated BC Combo efficacy, with a good safety and tolerance profile.

The different clinical studies conducted confirm the potential of BC Combo to reduce postprandial hyperglycemia and lower the risk of hypoglycemia, while providing 24-hour basal control. The data generated support the goal of effective once- or twice-daily dosing.

The overall findings showed that BC Combo had a good benefit/risk ratio, supporting its clinical development in the next phase. Tonghua Dongbao is currently preparing the next stages of development with the Chinese regulatory authorities. Treatment of the first patient in the first Phase 3 of BC Combo, expected in 2024, would trigger a \$10 million milestone payment to Adocia.

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<sup>2</sup> ADA: American Diabetes Association 83<sup>rd</sup> Scientific Sessions, EASD: 59<sup>th</sup> Annual Meeting of the European Association for the Study of Diabetes, IPITA-IXA-CTRMS: International Pancreas and Islet Transplant Association, International Xenotransplantation Association, and Cell Transplant and Regenerative Medicine Society joint congress

<sup>3</sup> October 23, 2023, ADOCIA's Partner Tonghua Dongbao Announces Positive Results of Three Clinical Trials on BioChaperone® Combo

- **BioChaperone® Lispro**

The pivotal Phase 3 program with BioChaperone Lispro, conducted in China by Adocia's partner Tonghua Dongbao, continues its course. The study involves 1,300 type 1 and type 2 diabetic patients recruited from over 100 centers across China, and the last patient last visit (LPLV), expected in the second half of 2024, would trigger the payment process of \$10 million to Adocia.

### ADORAL®: the promise of oral delivery of peptides

Aiming to overcome the challenge of oral peptide administration, AdOral is attracting the interest of several biopharmaceutical companies. The AdOral technology is currently being tested on peptides from two pharmaceutical partners.

## 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 an initial application in pancreatic cells transplantation; and 4) AdoGel®, a long-acting drug delivery platform.

Adocia holds more than 25 patent families. Based in Lyon, the company has about 80 employees. Adocia is listed on the regulated market of Euronext™ Paris (Euronext: ADOC; ISIN: FR0011184241).

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for everyone, everywhere



# 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 26, 2023 updated by the amendment of 26 July 2023 (D.23-0346-A01) and amendment of 13 September 2023 (D.23-0346-A02), available at [www.adocia.com](http://www.adocia.com), in particular uncertainties inherent in research and*

*development, future clinical data, analyses, and the evolution of the economic context, the financial markets and the markets in which Adocia operates, which could impact the Company's short-term financing requirements and its ability to raise additional funds.*

*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.*