



## Strong improvement of 2023 results thanks to sustained commercial activity on Sibnaya<sup>®</sup>

- Sibnaya<sup>®</sup> volume up 84%.
- Gross sales exceed €4 million for the first time.
- Sharp decrease in net loss to -7.03 M€ vs. -11.47 M€ in 2022.
- Year-end cash position at €5.25 million and cash runway extended to Q2 2025.
- Major announcement post-closing: US Orphan Drug Designation of ADV7103 in cystinuria.

**Paris (France), March 28, 2024 – 7.30am CET** – Advicenne (Euronext Growth Paris ALDVI - FR0013296746), a specialty pharmaceutical company dedicated to the development and commercialization of innovative treatments for those suffering from rare renal diseases, announces today its 2023 financial results, and provides an update on its activities.

The financial statements for the year 2023 were approved by the Board of Directors at its meeting on March 27, 2024. The audit procedures are being finalized and the auditors shall issue their audit report by mid-April 2024.

**Didier Laurens, Chief Executive Officer of Advicenne, commented:** *“In 2023, Advicenne has benefited fully from the growth sales momentum, driven by the continuing increase in Sibnaya sales. In a regulatory environment that remains highly complex in terms both of pricing and reimbursement, Sibnaya's performance was remarkable in terms of both volume (+84%) and value (+40%). Combined with an optimized resources allocation towards commercial development, these key accomplishments made it possible to significantly reduce our losses, which almost halved in two years. This general dynamic should accelerate further this year with the objective of reaching operational profitability at the end of 2024. This ambition will be achieved thanks to the expected price agreement in several countries covered by our partners. At the same time, we are intensifying our actions to improve the profile of ADV7103 in the USA with the ambition of finalizing a partnership with a biopharmaceutical company. The recent announcement of orphan drug status for ADV7103 in cystinuria, following the ODD obtained in dRTA, is a major milestone in this respect.”*

(€ thousands)	December 31, 2023	December 31, 2022
<b>Total Gross Sales<sup>1</sup></b>	<b>4 458</b>	<b>3 715</b>
<i>of which Sibnaya<sup>®</sup></i>	<i>1 965</i>	<i>1 410</i>
<b>Total revenue and other income</b>	<b>3 483</b>	<b>3 008</b>
<i>of which Sibnaya<sup>®</sup> revenue</i>	<i>1 707</i>	<i>1 053</i>
<i>of which other revenue</i>	<i>1 235</i>	<i>1 288</i>
<i>of which other income</i>	<i>541</i>	<i>667</i>
<b>Operating expenses</b>	<b>9 940</b>	<b>13 067</b>
<i>of which R&amp;D expenses</i>	<i>3 752</i>	<i>7 077</i>
<i>of which marketing and sales expenses</i>	<i>1 083</i>	<i>1 066</i>
<i>of which structural and general expenses</i>	<i>3 380</i>	<i>3 807</i>
<b>Operating loss</b>	<b>-6 457</b>	<b>-10 059</b>
<b>Financial result</b>	<b>-575</b>	<b>-1 374</b>
<i>of which financial interests</i>	<i>-1 334</i>	<i>-762</i>
<b>Net Loss</b>	<b>-7 031</b>	<b>-11 470</b>
<i>Basic and Diluted loss per share (€/share)</i>	<i>-0,67</i>	<i>-1,16</i>
<b>Opening cash</b>	<b>8 322</b>	<b>12 685</b>
<i>Cash flows from/(used in) operations</i>	<i>-5 989</i>	<i>-9 147</i>
<i>Cash flows from/(used in) investing activities</i>	<i>-1 318</i>	<i>-2</i>
<i>Cash flows from/(used in) financing activities</i>	<i>4 233</i>	<i>4 783</i>
<b>Closing cash</b>	<b>5 250</b>	<b>8 322</b>

- **2023 key financial highlights**

**Total Gross sales** amounted €4.4 million in 2023 up 20% compared to 2022. Gross sales of Sibnaya<sup>®</sup> were €1.9 million (vs. €1.4 million in 2022) and drove the overall growth of Advicenne. Unit sales of Sibnaya<sup>®</sup> increased by 84% fueled by growth in France and the deployment of distribution partners in Europe and the Middle East. As anticipated, Advicenne received the first royalties on Sibnaya<sup>®</sup> amounting €0.16 million in 2023.

<sup>1</sup> **Gross sales** represent the gross amount billed to customers for the quantities of products delivered during the fiscal year. In countries where the price, or the reimbursement conditions, have not yet been decided by the administration, the annual turnover corresponds to gross sales less taxes and discounts set by the supervisory authorities. These taxes and discounts are recorded based on the Company's best estimates or collections received from the administration. They represent 1,387 thousand euros in 2023 and 1,225 thousand euros in 2022 for total gross sales of respectively 4,458 thousand euros and 3,715 thousand euros and a total income of respectively 3,071 thousand euros and 2,490 thousand euros.

The Company recorded a significant drop in **operating losses** to €6.5 million euros (compared to €10.1 million in 2022). This improvement of almost 40% is mainly linked to the increase in **total revenue and other income** to €3.5 million, an increase of almost 16% despite the drop in the Research Tax Credit (“Crédit Impôt Recherche”) to €0.3 million (compared to €0.6 million in 2022).

This solid performance also results from a significant reduction in **operating expenses**, reduced by more than €3 million to €9.9 million (vs. €13.1 million in 2022), highlighting the allocation of spending on value-creating activities. Excluding cost of products sold, the reduction in operating expenses is even more marked, at almost €4 million. The cost of sales in 2023 increased slightly as a percentage of product sales compared to 2022 due to inventory building to meet and anticipate growth in sales.

**Operating expenses** were still mainly dedicated to R&D, for which expenses reached €3.8 million, focused on activities in the USA and the improvement of manufacturing processes. Marketing and sales expenses increased slightly, but remained contained because they were mainly borne by commercial partners. General expenses were further reduced to €3.4 million, compared to €3.8 million in 2022, and reflect the full impact of the reorganizations carried out in 2021 and 2022.

**Operating losses** were almost halved over the period 2021 - 2023 under the combined effect of a continued increase in revenue and optimized control of operating expenses. Overhead costs were thus reduced by nearly €1.5 million in two financial years.

**Financial losses** amounted €0.6 million last year. Interest charges related to the EIB loan and the French State Guaranteed Loan (“PGE”) reached €1.3 million (compared to €0.7 million in 2022) and reflect the full-year impact of the drawing of the second tranche of the EIB loan in December 2022. They are partially offset by a non-cash gain of €0.8 million (vs. a charge of €0.6 million in 2022) from the revised evaluation of royalties linked to the EIB debt under IFRS rules.

The Company did not record any corporate tax expense for the 2023 financial year.

Overall, **net loss** was €7 million, compared to €11.5 million in 2022. This level reflects the significant improvement in operating profit. This loss represents €0.67 per share in 2023, compared to €1.16 per share in 2022.

**Net cash flow used in operating activities** amounted to €6.0 million in 2023, compared to €9.1 million in 2022, directly linked to operating income. Operational cash consumption was halved over the last two financial years. The cash flow improved significantly to €-6.3 million (compared to €-9.4 million in 2022) thanks to the control of outstanding invoices and despite an unfavorable inventory effect.

**Net cash flow used in investing activities** increased significantly due to a significant investment in manufacturing equipment.

**Net cash flow from financing activities** amounted to €4.2 million in 2023. The Company carried out a capital increase of €5.4 million net in October 2023. In return, the Company repaid €1.1 million of principal for EMPs (“PGE”) from lending banks.



Finally, Advicenne closes the year 2023 with a **net cash position** of €5.3 million compared to €8.3 million a year previously.

Given the expected growth in turnover in 2024, the Company extends its cash runway to the beginning of the second quarter of 2025, excluding exceptional items. The Company continues its efforts to partner with a partner in the development of ADV7103 in the USA and other regions with the objective of optimizing its value creation model.

- **2023 operational highlights**

**First commercial launches and deployment of strategic alliances.** 2023 was the year of the first significant commercial deployments in France and Great Britain.

In France, a clearly favorable trend is being observed from the second half of the year thanks to the structuring of the sales forces. Sibnaya sales recorded record monthly sales over several consecutive months until the end of 2023. A trend confirmed in the first months of 2024.

In Great Britain, although 2023 was less dynamic than expected, the signings of several hospitals in the second half of the year signal an acceleration in business trends which seem to materialize since the beginning of 2024.

In the rest of Europe, all Advicenne partners are now recording sales in their respective geographic areas with strong dynamics, particularly in Germany, Greece, Denmark, and several Eastern European countries. The first sales were also recorded in the Middle East thanks to the implementation of early access programs.

**Regulatory progress with FDA for ADV7103 in dTRA and cystinuria in the U.S.** Following on from obtaining orphan designation in December 2022, Advicenne continued its discussions with the FDA to optimize the development of ADV7103 in dTRA.

Advicenne presented long-term data (72 months) from the B22 study and pharmacovigilance data. The meeting, which took place in Q3 2023, provided an opportunity to discuss efficacy and safety data of ADV7103. Initial discussions led to a significant revision of the development plan in dTRA, both in terms of timing and costs. A complementary dossier is currently being prepared to finalize the on-going discussions.

At the same time, Advicenne recently announced orphan drug status for ADV7103 in cystinuria. This status significantly reinforces the value of ADV7103 in a pathology with significant unmet medical need. Not all these activities require a legal presence in the United States. Advicenne has therefore decided to dissolve Advicenne Inc. This decision has no impact on the continuation of American regulatory and clinical activities.

**Strengthening equity.** In October 2023, the Company strengthened its financial position with the success of its capital increase for a gross amount of €5.7 million (€5.4 million net). This financing allows the Company to continue its commercial development in Europe and to strengthen the value of ADV7103 in the U.S while extending its cash runway.



- **Promising outlook for 2024**

**Sustained growth in sales of Sibnaya<sup>®</sup>.** In fiscal 2024, Advicenne anticipates sustained growth in sales of its main product, Sibnaya<sup>®</sup>, in Europe, both directly and through partnerships. Our partners' teams are stepping up their efforts with the health authorities in their respective regions, which should result in Sibnaya obtaining acceptable pricing and reimbursement in some of these territories.

**Optimization of ADV7103 development plan in the United States.** Advicenne is continuing its discussions with the FDA on the registration strategy for ADV7103 in dRTA. The company recently completed its responses to the FDA's remaining questions. These additional data, currently being evaluated, should lead to concrete decisions by the end of the first half of the year.

These conclusions and the orphan designation for ADV7103 in cystinuria and dRTA should enable the company to enter a partnership in the United States with biopharmaceutical company responsible for the development and marketing of ADV7103 in both indications.

Based on all these favorable prospects, particularly the sales of Sibnaya<sup>®</sup> in Europe, the Company plans to achieve operational profitability during Q4 2024.

\*\*\*

## **ABOUT ADVICENNE**

Advicenne (Euronext: ALDVI) is a specialty pharmaceutical company founded in 2007, specializing in the development of innovative treatments in Nephrology. Its lead product Sibnaya<sup>®</sup> has received its Marketing Approval for distal renal tubular acidosis in EU and GB. ADV7103 is currently in late-stage development in cystinuria in Europe and in dRTA and cystinuria in the US and in Canada. Headquartered in Paris, Advicenne, listed on the Euronext Paris stock exchange since 2017, has now been listed on Euronext Growth Paris since its transfer on March 30, 2022. **For additional information, see: <https://advicenne.com/>.**

## **CONTACTS**

### **Advicenne**

Didier Laurens, CEO

+33 (0) 1 87 44 40 17

Email: [investors@advicenne.com](mailto:investors@advicenne.com)

### **Ulysses Communication**

Media relations

Bruno Arabian

+33 (0)6 87 88 47 26

Email: [advicenne@ulysses-communication.com](mailto:advicenne@ulysses-communication.com)



## **Disclaimer**

*This press release contains certain forward-looking statements concerning Advicenne group and its business, including its prospects and product candidate development. Such forward-looking statements are based on assumptions that Advicenne 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 2022 Universal Registration Document filed with the French financial market authority on April 28, 2023 (a copy of which is available on [www.advicenne.com](http://www.advicenne.com)) and to the development of economic conditions, financial markets and the markets in which Advicenne operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Advicenne or not currently considered material by Advicenne. The occurrence of all or part of such risks could cause actual results, financial conditions, performance, or achievements of Advicenne to be materially different from such forward-looking statements. Advicenne expressly declines any obligation to update such forward-looking statements.*