Advicenne: Fiscal year 2024 marked by the satisfactory commercial performance of Sibnayal® in Europe and development in the United States

- Total product sales of Advicenne up 9.4% to €4.9m
- Operating cash consumption below €1M by 2025 and significant improvement in cash flow
- Cash position of €3.2 million on December 31, 2024, with a financing horizon of end-June 2025
- European in-market sales of Sibnayal® up over 130% to €6.0M and royalties received in excess of €0.5M
- Major regulatory advances for ADV7103 / Sibnayal® in the United States in its two indications (dRTA and cystinuria)
- Favorable outlook with the filing of ADV7103 in dRTA in the United States, expected in Q3 2025

Paris, France, March 27, 2025 – 6.30PM (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 2024 financial results, and provides an update on its activities.

The financial statements for the year 2024 were approved by the Board of Directors at its meeting on March 27, 2025. The audit procedures are being finalized, and the auditors shall issue their audit report by mid-April 2025. It will include a section on the significant going concern uncertainty related to the financing of the Company's activities beyond June 2025. Advicenne has chosen to publish its financial statements under French GAAP. As the company no longer publishes consolidated financial statements since the closing of its US subsidiary in 2023, publication under IFRS is no longer relevant for Advicenne SA's statutory financial statements. The 2024 financial statements under French GAAP will be available in full in the Universal Registration Document 2024.

Didier Laurens, Chief Executive Officer of Advicenne, commented: "*We are particularly pleased with the performance of Sibnayal® in Europe, with in-market sales in excess of €6.0M, thanks to the remarkable work of our team, our partners and the first patients treated outside Europe. Thanks to these results, and to the appropriate allocation of our expenses, we were able to reduce our cash consumption to less than €1 million for the year as a whole. Nevertheless, the year was marked by a still restrictive pricing environment in Europe in general and in France in particular, which prevented us from achieving our operating profitability target. Another positive result comes from the United States, with the expected filing of the Nex Drug Application (NDA) for ADV7103 in dRTA in the third quarter of 2025, and the expected approval of the final development plan for cystinuria. These highly favorable factors give us confidence in our ability to pursue and accelerate discussions with potential partners. Finally, we are actively working to strengthen our financial resources, notably with our lenders, to extend our cash horizon beyond the end of June 2025.*"

(€ thousands)	December 31, 2024	December 31, 2023
Total product sales	**4 877**	**4 458**
Of which Sibnayal®	*2 290*	*1 965*
Revenue from partnerships	**545**	**209**
Current operating expenses	**9 367**	**9 626**
Of which Cost of Goods sold	*2 699*	*1 725*
of which R&D expenses	*2 997*	*3 643*
of which marketing and sales expenses	*1 095*	*1 083*
of which structural and general expenses	*2 576*	*3 175*
Current operating results	**-3 289**	**-4 628**
of which pharmaceutical taxes [1]	*-2 878*	*-1 516*
Impairment and other non-current items	*-2 537*	*0*
Operating results	**-9 057**	**-6 473**
Exceptional product	*3 500*	*0*
Financial results	**-1 266**	**-1 384**
of which financial interests	*-1 289*	*-1 387*
Net results	**-6 464**	**-7 528**
Basic and Diluted loss per share (€/share)	*-0.53*	*-0.72*
Opening cash	**5 251**	**8 322**
Cash flows from/(used in) operations	*-762*	*-6 041*
Cash flows from/(used in) investing activities	*-108*	*-1 265*
Cash flows from/(used in) financing activities	*-1 132*	*4 233*
Closing cash	**3 248**	**5 251**

- **2024 key Financial highlights**

Product sales reached 4.88 million euros in 2024, up 9.4% on 2023. Growth in gross sales was driven mainly by Sibnayal®, which rose by almost 17% to 2.29 million euros. In France, performance was solid, with an increase of 40% over the full year, and a marked acceleration in sales in the second half of 2024. In-market sales from partners in their respective markets reached 4.1 million in 2024. Thus, sales of Sibnayal® in Europe and the Middle East totaled over 6.0 million euros, up by more than 130% on 2023. In addition to gross sales, Advicenne receives income from partnerships, based on the sales generated by its partners. In 2024, Advicenne received 0.54 million euros from partnerships, compared with 0.21 million euros in 2023.

[1] *In France, where the price has not yet been mutually agreed with the administration, taxes set by the supervisory authorities are paid to collecting bodies. These taxes are recorded based on the Company's best estimates or collections received from the administration*

In-market sales Sibnayal® (m€)	2024	2023	Growth
France	1.82	1.30	40%
Europe & Middle-East	4.19	1.27	230%
Total	**6.01**	**2.57**	**134%**

In addition to gross sales, Advicenne receives income from partnerships, based on the sales generated by its partners. In 2024, Advicenne received 0.54 million euros from partnerships, compared with 0.21 million euros in 2023.

The current operating loss for 2024 was reduced by almost 30% to -3.29 million euros, despite a step-up in the cost of goods sold, marked by inventory effects. Current operating expenses, ex-COGS, fell by more than 15% to 6.67 million euros (vs. 7.90 million euros in 2023). This improvement reflects the ongoing strict allocation of resources to R&D and sales. R&D expenditure in 2024 was mainly allocated to the development of ADV7103 in the United States.

In 2024, Advicenne recorded non-current charges of €5.31 million, including:

- a €2.88 million charge for pharmaceutical taxes set by the French health authorities in the absence of an agreement on the health insurance reimbursement price for Sibnayal® and Likozam®. This amount includes a catch-up on 2023 taxes,
- a charge of 2.53 million euros relating mostly to the total depreciation of a primary packaging machine (bagging machine). The latest development work has confirmed the technical quality of the machine, but the economic operating conditions justify the depreciation of this asset, without calling into question the trajectory of Sibnayal® production cost reduction. These charges include part of the acquisition costs of the machine and its pharmaceutical development. This items has no impact on Advicenne's cash position.

Furthermore, Advicenne booked an exceptional product of 3.50 million euros linked to the conclusion of the agreement with Primex Pharmaceuticals AG, a Swiss biopharmaceutical company, announced in December 2024. Under this agreement, Advicenne received 1.75 million euros in December 2024, with the balance to be received by mid-2026.

Financial losses came to €1.23 million, almost entirely represented by interest on the EIB loan and the French State Guaranteed Loan (PGE), down slightly on 2023 due to lower royalties paid to the EIB.

The Company recorded a research tax credit of 0.38 million euros in 2024, compared with 0.32 million euros in 2023.

Overall, net income showed a loss of 6.46 million euros, compared with 7.53 million euros in 2023.

Cash consumption from operations is 0.76 million euros in 2024, compared with 6.04 million euros in 2023, thanks to the agreement with Primex Pharmaceuticals AG. This agreement has also favored cash flow, which continues its significant improvement to -2.97 million euros (vs. -6.46 million euros in 2023), by a factor of 3 in 3 years.

Investments in 2024 fell significantly following the decision to halt the development of the primary packaging machine.

In 2024, Advicenne has repaid 1.13 million euros of state guaranteed loan (PGE) principal to its lending banks.

Finally, Advicenne ended 2024 with a net cash position of 3.25 million euros, compared with 5.25 million a year earlier. Excluding non-recurring items, this amount gives a cash horizon at the end of the second quarter of 2025.

- **2024 highlights**

Major regulatory progress for ADV7103 in the United States. The year 2024 was marked by significant progress in the development of ADV7103 in the United States for both distal renal tubular acidosis (dRTA) and cystinuria.

In dRTA, the Food and Drug Administration (FDA) has judged the European clinical data satisfactory for an NDA without additional specific clinical studies in the United States. The FDA's positive opinion was based on all the clinical data available in Europe, especially the one from the European pivotal study (B21CS) and the long-term follow-up study (B22CS). Both provide clinical efficacy and safety data on patients followed for over 6 years. Advicenne is actively working on finalizing the marketing authorization application, including additional analyses of the natural history of patients and the disease. Advicenne expects to file the NDA in the third quarter of 2025. ADV7103 has orphan drug status in the dRTA indication in the United States.

In cystinuria, Advicenne has reached a key milestone with the FDA on the development plan for ADV7103, as part of a renewed round of exchanges. Backed by preliminary clinical data, the support of several American and European opinion leaders, and the *International Cystinuria Foundation*, the leading cystinuria patient association, Advicenne has convinced the FDA to select a surrogate marker that is easier to measure and more predictive of disease progression than a clinical endpoint such as stones in the evaluation of ADV7103 in cystinuria. Advicenne is preparing to submit the final draft of the pivotal study in this indication to the FDA. The choice of a biological primary endpoint should make it possible to recruit patients in both the United States and Europe, and to consider filing applications simultaneously in both regions.

In cystinuria, 2024 was also marked by the granting of orphan drug status for ADV7103 in the United States.

Finalization of an agreement with Primex Pharmaceuticals AG. Advicenne has signed an agreement with Primex Pharmaceuticals AG, a Swiss biopharmaceutical company. This agreement finalizes the restructuring of contracts signed in 2016. Under this agreement, Advicenne will receive 3.5 million euros, half of which already paid in December 2024; the balance will be received over the next 18 months. Advicenne is also eligible for additional amounts for commercial rights outside Europe.

- **2025 outlook: a pivotal year**

Further growth in Sibnayal® sales. Advicenne expects sales of its main product, Sibnayal®, to grow in Europe in 2025. Advicenne and its partners are committed to the continued commercial success of Sibnayal®, which meets an important medical need.

Filing of ADV7103 in the United States. The major objective is to file ADV7103 in the dRTA in the United States during the third quarter. This will be a major step in creating value for the product and for Advicenne. In parallel, Advicenne plans to finalize the development plan for ADV7103 in cystinuria.

Extending the cash horizon. Advicenne is actively working to extend its cash horizon beyond the first half of 2025. Discussions with the Company's lenders, including the European Investment Bank, are ongoing. The Company is also pursuing its efforts to finalize additional sources of financing through the signature of a partnership around ADV7103 in the USA and outside Europe.

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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 Sibnayal® has received Marketing Approval for distal renal tubular acidosis (dRTA) in EU and GB. ADV7103 is currently in late stage development in cystinuria in Europe and in dRTA and cystinuria in the US and 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/.

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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.