



## Advicenne reports its First Half financial results as of June 30, 2024, and updates on its activities

- *Sibnaya<sup>®</sup> gross sales up 28% to €1.25 million including royalties paid by commercial partners (16% excluding royalties)*
- *Continued progress towards current operating breakeven*
- *Cash position of €2.0 million with unchanged financial visibility in the first quarter of 2025*
- *Favorable regulatory and partnership outlooks in the U.S for the future commercialization of ADV7103.*

**Paris, France, September 18, 2024 – 6:00 PM (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, today reports its semi-annual financial results as of June 30, 2024, as approved on September 18, 2024, by the Board of Directors. The first half financial report is available on the Company's website: [www.advicenne.com](http://www.advicenne.com).

**Didier Laurens, Chief Executive Officer of Advicenne, commented:** *"The first half of the year saw a steady increase in sales of Sibnaya<sup>®</sup> across Europe. Month after month, sales growth confirms the excellent uptake of our treatment by patients and healthcare professionals. These favorable market trends combined with our strict control of expenses, enable us to confirm our objective of achieving operating profitability by the end of 2024-early 2025. Finally, for the second half of the year, our teams remain committed to our strategic plan in the U.S, with further progress in our discussions with the FDA in the two indications for ADV7103, and concrete prospects for structuring commercial partnerships."*

### Half-yearly results to June 30, 2024

The key financial data for the first half of 2024 are presented in the table below. They come from the financial statements drawn up in accordance with IFRS and approved by the Board of Directors. The audit work has been carried out by the Statutory Auditors who, after limited review, have not identified any significant accounting anomalies or presentation. All financial statements and notes are available in the First Half Financial Report.

In K€	2024/06/30	2023/06/30
<b>Gross sales<sup>1</sup></b>	<b>2 462</b>	<b>2 231</b>
<i>Sibnaya<sup>®</sup> gross sales and royalties</i>	<i>1 249</i>	<i>975</i>
<b>Revenues</b>	<b>1 914</b>	<b>1 723</b>
<b>Current Operating expenses</b>	<b>4 757</b>	<b>4 668</b>
<i>R&amp;D costs</i>	<i>1 759</i>	<i>1 947</i>
<i>Sales &amp; Marketing costs</i>	<i>603</i>	<i>510</i>
<i>G&amp;A costs</i>	<i>1 360</i>	<i>1 641</i>
<b>Current Operating Result</b>	<b>-2 843</b>	<b>-2 945</b>
Non-currents assets	-1 836	0
<b>Operating Income</b>	<b>-4 679</b>	<b>-2 945</b>
Net financial income	-860	-788
<b>Net Income</b>	<b>-5 533</b>	<b>-3 734</b>
Earnings per share (€/share)	-0,45	-0,38
<b>Opening cash &amp; cash equivalent</b>	<b>5 250</b>	<b>8 322</b>
<i>Operating cashflow</i>	<i>-2 647</i>	<i>-3 709</i>
<i>Investing cashflow</i>	<i>-35</i>	<i>-623</i>
<i>Financing cashflow</i>	<i>-600</i>	<i>-568</i>
<b>Closing cash &amp; cash equivalent</b>	<b>1 968</b>	<b>3 417</b>

- **Gross sales** came to €2.46 million in the first half of the current financial year, up 10% on the first six months of 2023. These sales were driven by the steady growth of Sibnaya<sup>®</sup>, up 16% to 1.13 million euros over the period. Including royalties received from distributors in Europe and the Middle East, total gross revenues for Sibnaya<sup>®</sup> amounted to €1.25 million for the first half of 2024, up 28% on the first half of 2023.
- **Revenue from ordinary activities** amounted to 1.91 million euros, up 11% on the first half of 2023. This increase was mainly due to higher royalties on sales by Sibnaya<sup>®</sup> distributors in Europe and the Middle East, partly offset by a slight decline in the Research Tax Credit (CIR) and the negative impact of taxes and rebates on gross sales.
- **Operating loss before non-recurring items** improved to €2.84 million, compared with a loss of €2.95 million a year earlier. This improvement was driven by lower R&D expenses and a significant reduction in overheads, partly offset by higher selling expenses and cost of sales, mainly due to inventory effects.

<sup>1</sup> **Gross sales** represent the gross amount invoiced to customers for the quantities of products delivered during the year. In countries where the price or reimbursement terms have not yet been set by the authorities, annual sales correspond to gross sales less taxes and rebates set by the regulatory authorities. These taxes and rebates are recognized based on the company's best estimates, or based on assessments received from the authorities. They represented €0.77 million in H1 2024, on total gross sales of €2.46 million.

- **Non-current items**, mainly comprising an impairment charge on a primary packaging machine (bagging machine), were recognized over the period. The latest development work has confirmed the technical quality of the machine, but economic operating conditions justify the write-down of this asset, without calling into question the trajectory of Sibnaya<sup>®</sup> production cost reduction. These charges include part of the acquisition costs of the machine and its pharmaceutical development. These items have no impact on Advicenne's cash position.
- The half-year **financial result** was a loss of €0.86 million on June 30, 2024 (vs. a loss of €0.79 million in H1 2023). Interest expenses on the two tranches of the EIB loan of €7.5 million and €5 million, and the State Guaranteed Loans represent €0.88 million, including €0.70 million of non-cash expenses. These expenses comprise cash interest, capitalized interest and royalties. The balance of the financial result is made up of gains on cash investments, partially offset by foreign exchange losses.
- **Net loss** for the first half of 2024 came to €5.5 million, significantly impacted by non-recurring items. Excluding these items, the current net loss came to €3.7 million, stable compared with H1 2023.
- **Net cash outflow from operations** reached €2.65 million in the first half of 2024 (vs. €3.71 million in H1 2023), reflecting sales growth, control of operating expenses and working capital requirements.
- **Net cash outflow from investments** was virtually nil over the period. In 2023, capital expenditure represented scheduled payments for the deployment of the bagging machine.
- **Financing cash outflow** amounted to €0.60 million over the period (vs. €0.57 million in H1 2023). Amounts paid reflect the ongoing repayment of state-guaranteed loans (PGE) and the cash portion of financial expenses.
- At June 30, 2024, Advicenne had a **cash position** of €1.98 million. At the date of this document, Advicenne has financial visibility until the first quarter of 2025.

## H1 2024 Operating Highlights

### Continued commercial development of Sibnaya<sup>®</sup> in Europe

- Gross sales and royalties received from commercial partners continued to grow to €1.25 million (+28%), contributing to the Company's overall revenue growth.
- In France, the strengthening of the commercial structure is helping to sustain growth, and the number of patients treated continued to increase month-on-month over the period, despite persistent difficulties in obtaining reimbursement prices.
- Some partnerships are showing excellent results, with significant progress in Greece and certain Eastern European countries. In the Middle East, several patients are now benefiting from early access programs pending marketing authorization. The rise in royalties in H1 2024 reflects growth in our partners' end-markets.



- While some reimbursement and pricing discussions are complicated, our partners have achieved recent success in Slovakia and are leading the way in other European countries.

In the United States, the Company continued its discussions with the FDA with a view to optimizing the development plan for ADV7103 :

- In April 2024, ADV7103 was granted orphan drug designation in the cystinuria indication. Advicenne continues to work with the US FDA to clarify the clinical development plan for this indication.
- In distal Renal Tubular Acidosis (dRTA), following a very positive first round of exchanges, Advicenne continued to interact with the FDA in the first half of 2024. The aim is to optimize the development plan in the dRTA indication.
- In its discussions with the FDA, Advicenne enjoys the strong support of several opinion leaders, both American and European, as well as patient associations.

Continuation of the scientific communication program for ADV7103 in the treatment of distal Renal Tubular Acidosis (dRTA).

After an initial presentation of clinical results in 2023, based on the follow-up of patients treated for an average of 6 years, in-depth analysis of the large mass of data continued. This has led to multiple presentations of the results at several French and European congresses. These presentations are helping to improve understanding of dRTA and its treatment with ADV7103. At the same time, the Company and the principal clinical investigators finalized the preparation of the manuscript for submission for publication.

Update on discussions with Primex International AG

As announced on July 18, Primex International AG is not in a position to honor the full royalty payment due in 2025. Both companies are therefore continuing their discussions to find solutions that will best protect Advicenne's interests. Among these, the sale of the product to a third party would allow Advicenne to secure a majority share of the proceeds. Advicenne and Primex are working towards to reach a final agreement by the end of 2024.

- **Outlook for the second half of 2024**

In addition to pursuing partnership and commercial activities for Sibnaya<sup>®</sup> in Europe, Advicenne is currently focusing its efforts on regulatory approvals and clinical plans to enhance the potential value of ADV7103 in its two indications (dRTA and cystinuria). These efforts are bolstered by recent positive developments in discussion with the FDA and North American industrial and commercial partners

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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 Sibnaya<sup>®</sup> 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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### 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 2023 Universal Registration Document filed with the French financial market authority on April 5, 2024 (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.*