

Advicenne reports its financial results for the year ended December 31, 2022

- First European commercial launches of Sibnayal® (potassium citrate and potassium hydrogen carbonate)
- ADV7103 secured Orphan Drug Designation for distal Renal Tubular Acidosis (dRTA) in the US
- Optimized management of operational expenses and improved cash allocation toward value-creating operations
- Closing cash position at €8.3 million and cash runway extended into Q1 2024

Paris (France), March 30, 2023 – 6:00 pm (CET) – Advicenne (Euronext Growth Paris ALDVI - FR0013296746), a specialty pharmaceutical company dedicated to the development and commercialization of innovative treatments for patients suffering from rare renal diseases, today announces its financial results for the year ended December 31, 2022, and provides an update on its activities.

The financial statements for the year 2022 were approved by the Board of Directors at its meeting on March 30, 2023. The audit procedures are being finalized and the auditors shall issue their audit report by the end of April 2023.

Didier Laurens, Chief Executive Officer of Advicenne, commented: "2022 has undoubtedly marked a turning point for Advicenne as we shifted to the commercial phase of our main product, Sibnayal®. This has been possible thanks to the fully operational Advicenne team which has been instrumental to deliver results in line with our plans and strategy. In particular, we achieved a significant landmark as all major European countries are now commercially covered either directly or with great partners. Together we already achieved significant successes such as the reimbursements granted in Denmark and in Scotland. In the meantime, we are working on the ongoing improvement of our manufacturing processes and a cost of goods reduction roadmap. 2022 has been concluded with ADV7103 being designated Orphan Drug for dRTA in the US. This major milestone is helping us in our discussions with potential partners in the US.

In 2023, we are now focused on making Sibnayal® a commercial success throughout Europe, combined with an improved manufacturing process while pursuing a strict control of resources allocation. These clear objectives should pave the way to the Company's value creation. In parallel, we will continue to enhance the value of ADV7103 in the US by identifying the most effective regulatory and clinical pathways towards marketing authorization."



(€ thousands)	December 31, 2022	December 31, 2021
Total Gross sales ¹	3 715	3 261
of which Sibnayal	1 410	981
Total revenue and other income	3 008	3 766
of which Sibnayal revenue	1 053	880
of which other revenue	1 288	1 790
of which other income	667	1 097
Operating expenses	13 067	16 210
of which R&D expenses	7 077	8 964
of which marketing and sales expenses	1 066	1 569
of which structural and general expenses	3 807	4 703
Operating loss	-10 059	-12 444
Financial result	-1 374	5
of which financial interests	-762	-658
Net loss	-11 470	-12 427
Basic and Diluted loss per share (€/share)	-1,16	-1,34
Opening cash	12 685	16 771
Cash flows from/(used in) operations	-9 147	-12 525
Cash flows from/(used in) investing activities	-2	-451
Cash flows from /(used in) financing activities	4 783	8 909
Closing cash	8 322	12 685

2022 key financial highlights

Total Gross sales amounted €3.7 million in 2022 up 14% compared to 2021. Gross sales from Sibnayal® were €1.4 million (vs. €1.0 million in 2021) and drove the overall growth of Advicenne. Unit sales of Sibnayal® more than doubled (+110%), mainly fueled by the growth in France and the first orders from distributors. The latter impacted the average selling price upfront and will be later compensated by the expected increase in royalties' stream.

¹ Gross sales correspond to the gross amount invoiced to customers for products that were delivered during the year. For countries where the price has not yet been agreed with Health Administration, the revenue for the year represents the Gross sales less rebates owed to Health Administrations. Such rebates are accrued based on the company's best estimate and/or claims received from the administration. They represented €1 315 thousands in 2022 and €544 thousands in 2021 for total Gross sales of respectively € 3 715 thousands and € 3 261 thousands and total revenue of respectively €2 341 thousands and €2 670 thousands.



The Company recorded **operating losses of** €10.1 million (vs. €12.4 million in 2021). This improvement of almost 20% resulted from a significant reduction of **Operating expenses**, lowered by more than €3 million to €13.1 million (€16.2 million in 2021), highlighting the allocation of expenses to value-accretive activities. This strong performance has been partly offset by a reduced **Total revenue and other income** to €3.0 million which decreased by €0.9 million, due to increased rebates claimed by the French Health Administration including a one-off effect from additional rebates on 2021 Gross sales, and the drop in Research Tax Credit ("Crédit Impôt Recherche") to €0.6 million (vs. €1.1 million in 2021), explained by the end of the clinical development of ADV7103 in Europe. The Cost of Goods Sold (CoGS) in 2022 was flat as a percentage of Product Invoicing compared to 2021.

Operating expenses were mainly dedicated to R&D, for which expenses reached €7.1 million, focused on the US clinical development and improvement of the manufacturing processes. Marketing and sales expenses continued to be tightened as the need for promotional efforts are still low and are partially borne by commercial partners. General and administrative expenses were further reduced to €3.8 million, compared with €4.7 million in 2021 and benefited from the reorganization of the Company (single headquarters in Paris and concomitant reduction of sites, management reinforcement, delisting from Brussels), which will have a lasting impact on the cost structure, partly offset by some one-offs.

Financial losses reached € 1.4 million, impacted by non-cash items. The interest charges related to the EIB loan and the French state-guaranteed loan (EMP / PGE) amounted €0.7 million, up 9% compared to 2021 and include the interest from the drawdown of the second tranche of the EIB loan in December 2022. Applying IFRS standards, the revised valuation of the royalties attached to the EIB debt, generated a non-cash charge of €0.6 million (vs. a gain of €0.7 million in 2021).

The Company did not record any corporate income tax expense for fiscal year 2022.

Overall, **net loss was** €11.5 million (compared with €-12.4 million in 2021). This loss represents €1.16 per share in 2022 compared to €1.34 per share in 2021.

Net cash flow used in operating activities amounted to €-9.1 million in 2022, compared to €-12.5 million in 2021. It improved significantly thanks to the growth of Product Invoicing and control of expenses.

Net cash flow used in investing activities was close to zero as the capital expenditures were almost totally offset by the positive impact of regrouping all activities in a single location.

Net cash flow from financing activities amounted to €4.8 million in 2022 from the drawdown of the second tranche of the EIB loan.

Finally, Advicenne closed the year 2022 with a **net cash position** of €8.3 million.

In 2022, the Company was profoundly reorganized aiming to reduce its operating cash burn. With the expected revenue growth in 2023 and the full-year impact of the cash preservation measures, the runway has been extended into Q1 2024. The Company is pursuing efforts to partner the development of ADV7103 in the US and worldwide and optimize its value creation model.



2022 operational highlights

First commercial launches and deployment of strategic alliances. In 2022, Advicenne signed several exclusive distribution partnerships covering the Benelux, Central and Eastern European countries (CEE), and the Nordic countries, completing its direct presence in France and the United Kingdom. Since then, as expected, the Company completed its European commercial coverage in early 2023. The Company also signed an exclusive distribution agreement covering the MENA region. This extended commercial network has already achieved successes with commercial launches of Sibnayal® in the UK and in some Nordic countries, and the implementation of Early Access Program in CEE. In France, Advicenne has started to build up its commercial operations to be fully operational in 2023. To support its expected sales growth, Advicenne has worked with its contracted manufacturer to improve its manufacturing process, which should lead in the mid-term to a significant reduction of manufacturing costs.

ADV7103 was granted Orphan Drug Designation (ODD) for dRTA in the US, a major value enhancer. Advicenne has reached a significant milestone in the US following ODD of ADV7103 in dRTA. The ODD status provides a 7-year market exclusivity from the date of the marketing authorization and significantly enhances the potential value of ADV7103. Since Advicenne is looking for a partner in the US, this achievement should facilitate discussions. In the meantime, Advicenne pursued its strategy to further reduce development and regulatory risks and has been able to improve its compliance with the FDA's requirements on the path to marketing authorization.

Financial strengthening and management successes. In December 2022, the Company strengthened its financial position with the drawdown of the second tranche of the EIB loan for a total of €5 million. This financing will allow the Company to pursue its commercial development in Europe and further strengthen ADV7103 value in the US. This clear operational roadmap is supported by a seasoned management team which was totally renewed in 2021 and 2022.

2023 outlook

In fiscal year 2023, Advicenne expects to accelerate sales growth of its main product, Sibnayal®, in Europe directly and through the signed partnerships. The Company also intends to enter new commercial agreements in other geographic areas. In the US, Advicenne will pursue regulatory and clinical works to build up the potential value of ADV7103 in dTRA and in cystinuria.



About Advicenne

Advicenne (Euronext Growth Paris ALDVI - FR0013296746) is a specialty pharmaceutical company founded in 2007, specializing in the development of innovative treatments in Nephrology. Its lead product Sibnayal® (ADV7103) has received its Marketing Approval for distal renal tubular acidosis in EU and GB. ADV7103 is currently in late-stage development in North America. 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 2021 Universal Registration Document filed with the French financial market authority on April 29, 2022 (a copy of which is available on 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.



Appendices

IFRS consolidated financial statements for the year ended December 31, 2022

Balance sheet

ASSETS (in thousands of euros)	December 31, 2022	December 31, 2021
Intangible assets	135	167
Property, Plant and Equipment	1 908	1 836
Other financial assets	133	263
Non-current assets	2 176	2 265
Inventory	982	717
Accounts receivable	1 088	802
Tax credit	602	1 126
Financial asset	2	-
Other current assets	1 087	1 286
Cash and cash equivalents	8 322	12 685
Current assets	12 083	16 616
Total assets	14 259	18 881

LIABILITIES and CAPITAL (in thousands of euros)	December 31, 2022	December 31, 2021
Capital stock Capital-related premiums Reserves Net income	1 991 1 490 -2 627 -11 470	1 990 24 469 -13 723 -12 427
Total equity capital	-10 616	309
Provisions Long-term debt	64 17 218	96 12 <u>3</u> 71
Non-current liabilities	17 282	12 467
Financial liabilities Accounts payable Other current liabilities	1 536 1 390 4 668	165 2 929 3 012
Current liabilities	7 593	6 105
Total liabilities	14 259	18 881



Income statement

CONSOLIDATED INCOME STATEMENT (in thousands of euros)	December 31, 2022	December 31, 2021
Revenues Income from partnerships	2 341 56	2 670 19
Other operating income	611	1 078
Total revenue and other income	3 008	3 766
Cost of goods sold Research and development expenses Sales and marketing expenses Overhead and general expenses	-1 117 -7 077 -1 066 -3 807	-973 -8 964 -1 569 -4 703
Operating income	-10 059	-12 444
Net financing costs Other financial expenses Other financial income	-1 373 -3 1	139 -148 14
Income before taxes	-11 434	-12 438
Income taxes	-37	11
Consolidated net profit / loss	-11 470	-12 427
- Attributable to shareholders of Advicenne SA - Attributable to non-controlling interests	-11 470 -	-12 427 -
Earnings per share (€/share) Diluted earnings per share (€/share)	- 1,16 - 1,16	- 1,34 - 1,34



Cashflow statement

CASH FLOW	December 31, 2022	December 31, 2021
(in thousands of euros)		
Net result (loss)	-11 470	-12 427
Amortisation, depreciation and provisions	334	426
Share-based payments	480	347
Other calculated income and expenses	24	3
Net financial costs	1 146	-139
Sale of PPE and intangible assets	52	9
Self-financing capacity	-9 434	-11 782
Changes in inventory	-265	18
Changes in trade and other receivables	435	296
Changes in trade and other payables	118	-1 057
Cash flow from operations	-9 147	-12 525
Acquisition of PPE and intangible assets	-115	-297
Acquisition of financial assets	-	-
Sale of financial assets	113	-98
Cash flow from investing activities	-2	-451
Capital increase (net)	23	9 088
Own shares held in treasury	-17	-56
Net borrowings and refundable advances	5 000	45
Repayment of borrowings and refundable advances	-222	-225
Cash flow from financing activities	4 783	8 909
Changes in value of local currencies	2	-18
Change in cash	-4 363	-4 085
Opening cash position	12 685	16 771
Closing cash position	8 322	12 685