



## Advicenne Reports its Financial Results for the Year ended 31 December 2021

- **Significant regulatory and commercial progress for SibnayaI™**
- **Control of expenses with a net loss reduced to €12.4 million (vs. €14.8 million)**
- **Closing cash position at €12.7 million.**
- **Commercial launch of SibnayaI™ in Europe expected in 2022.**

**Paris, 31 March 2022** – 6.00 pm CET – Advicenne (Euronext: ALDVI), a pharmaceutical company specializing in the development and commercialization of innovative treatments for those suffering from rare renal diseases, today announces the publication of its financial results for the year ended 31 December 2021 and provides an update on its activities.

The audited financial statements for the year 2021 were approved by the Board of Directors at its meeting on March 31, 2021.

**Didier Laurens, Chief Executive Officer of Advicenne, commented:** *"We are very pleased with the achievements in 2021, which will no doubt be a springboard for our future success. During the past year, SibnayaI™ became the first treatment to obtain marketing authorization in Europe and the United Kingdom for the treatment of distal renal tubular acidosis (dRTA). In line with our timetable, we signed our first commercial agreements at the end of 2021 in Europe, covering one-third of the European patients affected with dRTA. In parallel we have made good progress with the British and French health authorities (NHS and HAS) to market SibnayaI™ in optimal conditions for Advicenne. On the financial front, our sales have increased by 20% while controlling our expenses.*

*The year 2022 is indeed shaping up positively. We remain focused on preparing for the commercial launch of SibnayaI™ and to record our first sales outside of any early availability regulatory process. In parallel with the gradual ramp-up of SibnayaI™ sales through our distribution agreements with Frost Pharma, ExCEED Orphan and TwinPharma, we intend to continue the search for partners in target areas both in and outside Europe. With the appointment of a strong management team, we are confident that we will be able to continue delivering on our strategy. Our objectives remain clear and unchanged: continuing the launch of SibnayaI™, pursuing its clinical development for the treatment of dRTA in the United States, and for the treatment of cystinuria, while also extending its indications to other renal diseases for which there is no effective therapeutic solution."*



(€ thousands)	December 31, 2021	December 31, 2020
<b>Total revenue and other income</b>	<b>3 766</b>	<b>3 564</b>
<b>Operating expenses</b>	<b>16 210</b>	<b>17 700</b>
<i>of which R&amp;D expenses</i>	8 964	8 146
<i>of which marketing and sales expenses</i>	1 569	3 827
<i>of which structural and general expenses</i>	4 703	4 841
<b>Operating loss</b>	<b>-12 444</b>	<b>-14 136</b>
<b>Net loss</b>	<b>-12 427</b>	<b>-14 846</b>
Diluted loss per share (€/share)	-1,34	-1,76
<b>Opening cash</b>	<b>16 771</b>	<b>16 629</b>
<i>Cash flows from operations</i>	-12 525	-11 694
<i>Cash flows from investing activities</i>	-451	-694
<i>Cash flows from financing activities</i>	8 909	12 529
<b>Closing cash</b>	<b>12 685</b>	<b>16 771</b>

- **Key financial Highlights (31/12/2021)**

**Operating income** amounted to €3.8 million in 2021, slightly higher (+5.7%) compared to previous year. Sales generated by Sibnaya™, LikoZam and Levidcen reached €3.3 million, up 20% year-on-year. After considering rebates and provisions, accounting revenues for 2021 were up nearly 30% to €2.7 million. In detail, operating revenues also include the Research Tax Credit (“Crédit Impôt Recherche”) for an amount of €1.1 million vs. €1.4 million in 2020. This decrease is explained by the transition of Sibnaya™ clinical development in Europe and the increase in R&D expenses in the United States, which are not eligible for the CIR.

**Current operating expenses** were down 8.4% to €16.2 million (€17.7 million in 2020). R&D expenses increased to reach about €9 million. During the year, Advicenne continued the clinical development of ADV7103 and pursued the implementation of Phase III studies in dRTA in the United States and in cystinuria in Europe. Marketing and sales expenses were significantly reduced in line with the promotion needs of Levidcen and LikoZam. Finally, general expenses amounted to €4.7 million, compared with €4.8 million in 2020. This decrease is the result of stronger control of expenses incurred by the new management, offset by one-offs following the implementation of the new management.

As a result, the Company recorded **an operating loss of €-12.4 million** (€-14.1 million in 2020). In 2021, the Company recorded a net financial product of €0.1 million, of which mostly an interest charge of €1.0 million from both the €7.5 million tranche of its loan from the EIB (European Investment Bank) and the implementation of the French state-guaranteed loan (EMP). This has been offset by revised valuation of the EIB debt of €1.2 million according to IFRS standards. The Company did not record any corporate income tax expense for fiscal year 2021.



Overall, **net income** showed a loss of €12.4 million (compared with €-14.8 million euro in 2020). This loss represents €1.34 euro per share in 2021 compared to €1.76 per share in 2020.

**Net cash flow from operating activities** amounts to €-12.5 million in 2021, compared to €-11.7 million in 2020. Cash flow from operations improved significantly to €-11.8 million (vs. €-13.6 million in 2020). The sharp reduction in trade payables impacts the WCR and consumes operating cash flow.

**Net cash flow from investing activities** amounts to €0.5 million and corresponds mainly to investments in production operations.

**Net cash flow from financing activities** amounts to €8.9 million in 2021 of which €9.4 million gross proceeds from a capital increase in June 2021.

Finally, Advicenne closed the year 2021 with a **net cash position** of €12.7 million.

- **Operational Highlights 2021**

**Registration and regulatory advances in Europe.** Advicenne has achieved important milestones during the year 2021. Last May, Sibnaya<sup>™</sup> (ADV 7103), Advicenne's most advanced drug candidate, was granted marketing authorization by the European Commission for the treatment of distal renal tubular acidosis (dRTA) in adults, adolescents and children aged one year and older. This was quickly followed by the approval of Sibnaya<sup>™</sup> by the Medicines & Healthcare products Regulatory Agency (MHRA) in the United Kingdom in July 2021 for the treatment of dRTA in the same indication. These authorizations have opened discussions with the health authorities with a view to setting the price and conditions for reimbursement of the drug. Thus, in France, the Haute Autorité de Santé (HAS) validated last December the reimbursement of Sibnaya<sup>™</sup> in its indication and assigned a level IV ASMR. Discussions are underway to set the reimbursement price. In the United Kingdom, after obtaining a list price from the National Health Service (NHS) in December 2021, discussions are continuing to set the conditions for reimbursement.

**Strategic alliances.** As expected, last year Advicenne initiated the implementation of its strategy to commercialize Sibnaya<sup>™</sup> in Europe. The Company signed several exclusive distribution partnerships covering the Benelux, Central and Eastern European countries, and the Nordic countries. The three selected partners (TwinPharma, ExCEED Orphan, and FrostPharma AB) all work within the exclusive European network, "Your Pharma Partner," whose role is to make innovative therapies available to patients in 25 European countries. In total, these agreements cover approximately one third of the European dRTA population. The Company is continuing discussions with potential partners to cover other geographical areas in Europe and beyond. Partners conduct local negotiations with health authorities regarding pricing and reimbursement. Sibnaya<sup>™</sup> is available in post-ATU in France and 4 other European countries and approximately 100 patients are being treated.

**Clinical developments in the United States and Europe.** Advicenne continued the development of ADV7103 in dRTA in 2021 with the initiation of a pivotal Phase III trial in the U.S. The primary endpoints of the study have been validated by the U.S. Food and Drug Administration (FDA). Advicenne is also pursuing the development of ADV7103 in cystinuria. In this indication, urine alkalization remains the main objective of the treatment and explains the interest of ADV7103 in twice-daily administration to improve compliance.



**Financial and managerial strengthening.** In June 2021, the Company strengthened its financial position through the completion of a reserved capital increase of €9.4 million. This financing will allow the Company to pursue the commercial, regulatory, and clinical development of its lead drug. Advicenne's management team has also been strengthened with the appointment of Didier Laurens as Chief Executive Officer, as well as several high-level executives in the areas of production, quality, and regulatory affairs.

- **2022 Outlook**

In fiscal year 2022, Advicenne expects to commercialize Sibnaya<sup>™</sup> in Europe and achieve its first sales outside the early access setting. The Company also intends to enter new partnerships in selected geographic areas. Advicenne plans to pursue the clinical development of ADV7103 in the U.S in dRTA and in cystinuria in 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 Sibnaya<sup>™</sup> (ADV 7103) has received its Marketing Approval for distal renal tubular acidosis in EU and the UK. ADV 7103 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 has been listed on the Euronext Paris stock exchange since 2017.

**For additional information see:** <https://advicenne.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 2020 universal registration document filed with the French Financial market authority on December 6, 2021 under number D.21-0962 (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.*



## Appendices

### IFRS consolidated financial statements for the year ended December 31, 2021

#### Balance Sheet

<b>ASSETS</b>	<b>December 31, 2021</b>	<b>December 31, 2020</b>
<i>(in thousands of euros)</i>		
Intangible assets	167	38
Property, Plant and Equipment	1 836	2 785
Other financial assets	263	392
<b>Non-current assets</b>	<b>2 265</b>	<b>3 215</b>
Inventory	717	735
Accounts receivable	802	818
Tax credit	1 126	1 406
Other current assets	1 286	1 059
Cash and cash equivalents	12 685	16 771
<b>Current assets</b>	<b>16 616</b>	<b>20 789</b>
<b>Total Assets</b>	<b>18 881</b>	<b>24 004</b>

<b>LIABILITIES and CAPITAL</b>	<b>December 30, 2021</b>	<b>December 31, 2020</b>
<i>(in thousands of euros)</i>		
Capital stock	1 990	1 724
Capital-related premiums	24 469	29 799
Reserves	-13 723	-13 404
Net Income	-12 427	-14 846
<b>Total equity capital</b>	<b>309</b>	<b>3 272</b>
Provisions	96	118
Long-term debt	12 371	9 247
<b>Non-current liabilities</b>	<b>12 467</b>	<b>9 366</b>
Financial liabilities	165	4 550
Accounts payable	2 929	4 434
Other current liabilities	3 012	2 383
<b>Current liabilities</b>	<b>6 105</b>	<b>11 366</b>
<b>Total Liabilities</b>	<b>18 881</b>	<b>24 004</b>



## Income Statement

<b>CONSOLIDATED INCOME STATEMENT</b> <i>(in thousands of euros)</i>	<b>December 30, 2021</b>	<b>December 31, 2020</b>
Revenues	2 670	2 062
Income from partnerships	19	73
Other operating income	1 078	1 430
<b>Total revenue and other income</b>	<b>3 766</b>	<b>3 564</b>
Cost of goods sold	-973	-886
Research and development expenses	-8 964	-8 146
Sales and marketing expenses	-1 569	-3 827
Overhead and general expenses	-4 703	-4 841
<b>Operating Income</b>	<b>-12 444</b>	<b>-14 136</b>
Net financing costs	139	-553
Other financial expenses	-148	-260
Other financial income	14	133
<b>Income before taxes</b>	<b>-12 438</b>	<b>-14 136</b>
Income taxes	11	-29
<b>Consolidated net profit / loss</b>	<b>-12 427</b>	<b>-14 846</b>
- Attributable to shareholders of Advicenne SA	-12 427	-14 846
- Attributable to non-controlling interests	-	-
Earnings per share (€/share)	-1,34	-1,76
Diluted earnings per share (€/share)	- 1,34	-1,76



## Cash Flow Statement

<b>CASH FLOW (in thousands of EUR)</b>	<b>December 31, 2021</b>	<b>December 31, 2020</b>
Net result (loss)	-12 427	-14 846
Amortisation, depreciation and provisions	426	217
Share-based payments	347	605
Other calculated income and expenses	3	-122
Net financial costs	-139	553
<b>Self-financing capacity</b>	<b>-11 782</b>	<b>-13 592</b>
Changes in inventory	18	-239
Changes in trade and other receivables	296	1 035
Changes in trade and other payables	-1 057	1 102
<b>Cash flow from operations</b>	<b>-12 525</b>	<b>-11 694</b>
Acquisition of PPE and intangible assets	-297	-575
Treasury shares	-56	-41
Acquisition of financial assets		-78
Disposal of financial assets	-98	
<b>Cash flow from investing activities</b>	<b>-451</b>	<b>-694</b>
Capital increase	9 088	662
Net borrowings and refundable advances	45	12 121
Repayment of borrowings and refundable advances	-225	-254
<b>Cash flow from financing activities</b>	<b>8 909</b>	<b>12 529</b>
<b>Impact of changes in foreign exchange rates</b>	<b>-18</b>	
<b>Change in cash</b>	<b>142</b>	<b>142</b>
Opening cash position	16 771	16 629
Closing cash position	12 685	16 771