



Corporate presentation Q2 2025

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# Advicenne's value proposition

- **A revenue generating specialty pharma**
  - A proprietary asset, Sibnaya<sup>®</sup> (ADV7103), marketed in Europe in rare renal disease
  - Significant US & EU market potential in two orphan indications
- **Major steps forward to market ADV7103 in the USA**
  - Regulatory clarity for NDA in dRTA; direct filing prepared
  - Major step forward in regulatory pathway in cystinuria
  - ADV7103 Orphan Drug Designation in both indications
- **Significantly reduced operating and financial risk**

# Sibnaya<sup>®</sup> / ADV7103 commercially available

- **Commercial launch in EU and UK for the treatment of dRTA** (distal Renal Tubular Acidosis) in pediatric (from one year of age) and adult patients
- **European End-Market 2024 sales: €6.0m up 135%.** Strong performance in **France** and **Germany**
- **More than 450 patients** treated in EU - An average **gain of 10 patients** per month. First patients treated in **GCC**
- **Distribution partnerships** covering Europe and MENA with **on-going pricing discussions** in most of European countries



# ADV7103: a breakthrough alkalinizing asset for rare renal diseases

- **Patented** prolonged release **combination** of potassium citrate (CK) and potassium hydrogen carbonate (bicarbonate - BK) enabling **twice-daily dosing**
- **Only convenient chronic oral treatment (>6-year European follow-up data):**
  - **Sustained efficacy**
  - **Strong treatment compliance**
  - **Very good safety profile**



## dRTA<sup>(1)</sup>

- ✓ **Centralized market approval** in EU and the UK (Commercial name: **SibnayaI®**)
- ✓ **Orphan Drug Designation** in the US
- ✓ **NDA approval process** on-going in the US

## Cystinuria

- ✓ **Phase III clinical plan** to be agreed with EU and US agencies
- ✓ **Orphan Drug Designation** in the US

<sup>(1)</sup> distal Renal Tubular Acidosis is a rare but serious chronic disease characterized by the increase of acid ions in the blood

# ADV 7103: designed to change patient's lives

## Current therapeutic options <sup>(1)</sup>

## ADV7103

Requires 3-6 intake per day	●	✓	1	x	●	Twice daily dosing (12h)
Frequent gastrointestinal intolerance	●	✓	3	x	●	Satisfactory gastrointestinal tolerance
Bad taste and less adapted to pediatric patients	●	✓	4	x	●	Tasteless and well adapted to pediatric patients
In several countries need for pharmacy compounding	●	✓	5	x	●	Ready to use pharmaceutical product
<sup>1</sup> Current treatments are not standardized	●	✓	6	x	●	Approved drug in rare renal disease

## ADV7103: compelling treatment opportunity for rare renal patients

<sup>(1)</sup> Mainly intake of high doses of alkalinizing agents, no approved SoC in the EU and the US before Sibnaya®

# dRTA: a rare disease with life-long complications

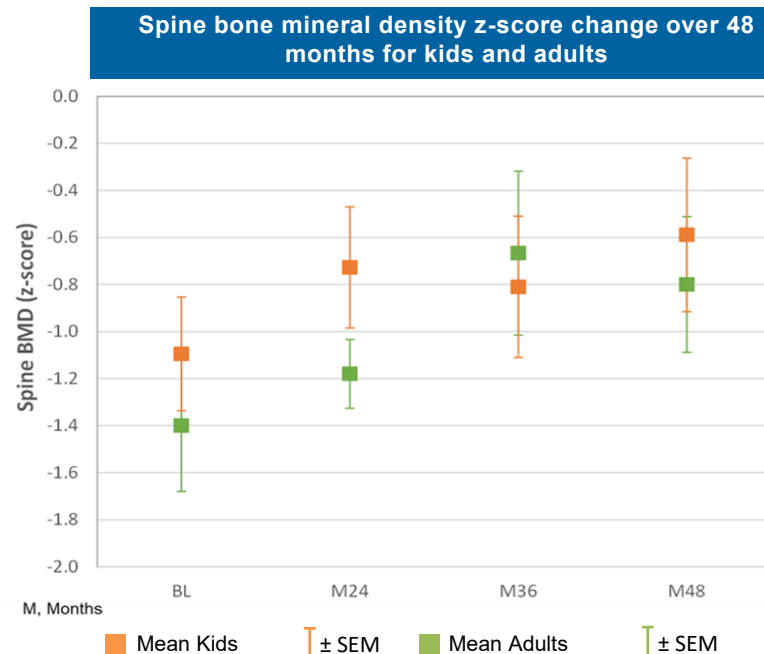
- **distal Renal Tubular Acidosis (dRTA)** is a rare and chronic serious renal disorder characterized by the increase of acid ions in the blood leading to decreased bone mineral density
- **2 identified forms:**
  - **Genetic** (or inherited) form (usually identified in infancy)
  - **Acquired** form
- An **underdiagnosed** and **undertreated** disease:
  - **c.20,000** clearly identified cases in Europe and **c.20,000** in the US
- Potential **c.150,000** RTA treatable population in the US

- Failure to thrive
- Muscle weakness / paralysis
- Rickets / Osteomalacia / soft bones / Fractures
- Cardiac dysfunctions / arrhythmia
- Nephrocalcinosis
- Lithiasis
- Chronic Kidney Disease (CKD)



Sources: Lopez-Garcia et al 2019, Rodriguez-Soriano et al 1982, Domrongkitchaiporn et al. 2002a, Domrongkitchaiporn et al. 2002b, MacSherry et al. 1978, Caldas et al. 1992

# ADV7103: impact on LT bone growth consequences of dRTA



## Analysis of covariance of z-score

### Statistically significant incremental improvement

- Significant increase of z-score in spine BMD compared to baseline (ANCOVA) for both kids and adults (24 patients)
- At month 24: LS mean difference estimate [95% CI] of 0.22 [-0.01, 0.44] units (p=0.0573)
- At month 36: LS mean difference estimate [95% CI] of 0.31 [0.08, 0.54] units (p=0.0103\*)
- At month 48: LS mean difference estimate [95% CI] of 0.36 [0.13, 0.60] units (p=0.0038\*)

\*Statistically significant

source: Bertholet-Thomas et al. Efficacy and safety of an innovative prolonged-release combination drug in patients with distal renal tubular acidosis: an open-label comparative trial versus standard of care treatments. *Paediatric Nephrol.* 2021 Jan;36(1):83-91.

source: Safety, efficacy, and acceptability of ADV7103 during 24 months of treatment: an open-label study in paediatric and adult patients with distal renal tubular acidosis. *Paediatric Nephrol.* 2021 Jul;36(1):1765-1774.

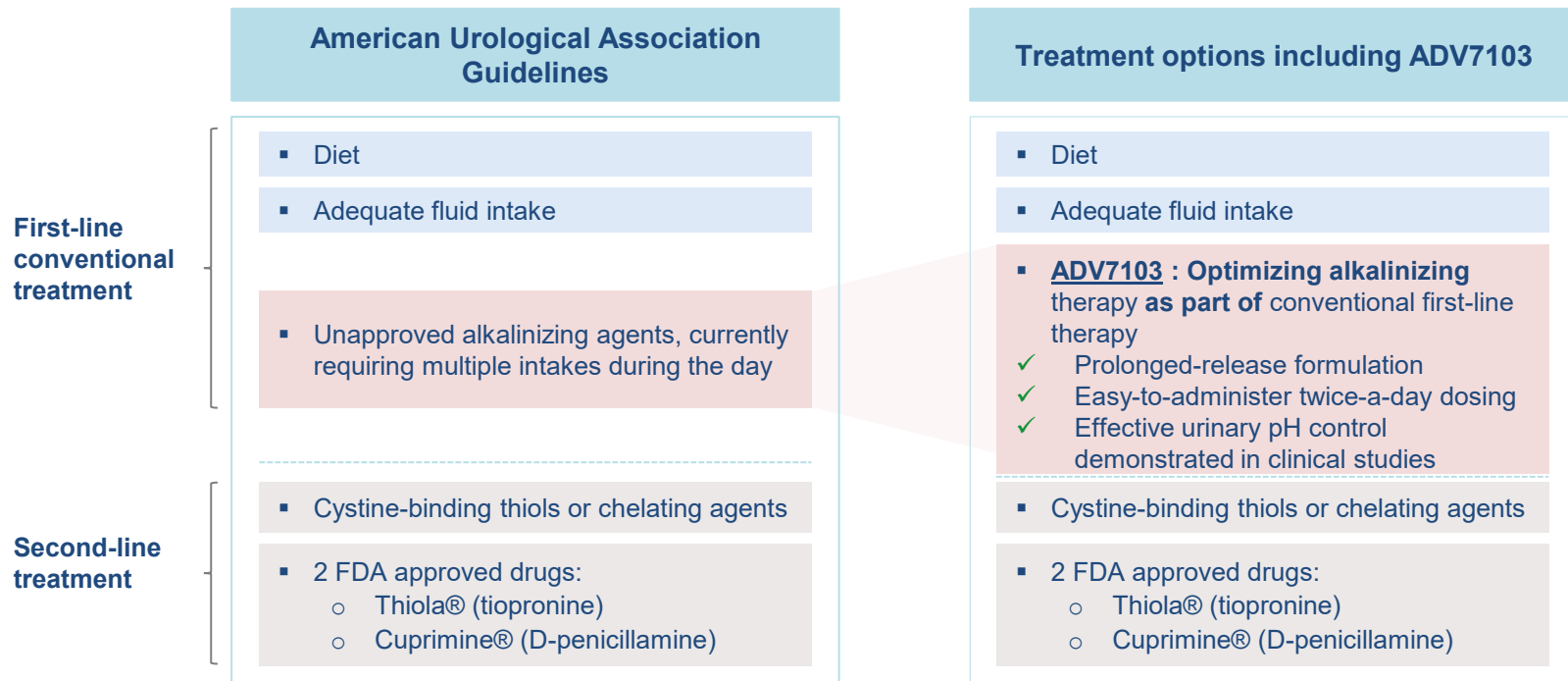


# Cystinuria: a rare and well documented genetic disease

- **Cystinuria** is a rare genetic disease characterized by a build-up of undissolved cystine in the kidneys and bladder, leading to the formation of cystine crystals and/or stones which may block the urinary tract
- Cystine stones are challenging and often require expensive, invasive surgical removal
- Cystinuria often leads to **chronic kidney disease (CKD)**, **nephrectomy**, **kidney atrophy**, recurrent **urinary tract infections** and **hypertension**
- **Estimated prevalence of c.40,000 cases in Europe/UK, c.30,000 cases in the US**
- **US ICD-10 code** for easier diagnosis and reimbursement processes

Source: Orphanet

# Cystinuria: a significant market opportunity



# Regulatory strategy leading to early NDA filing in dRTA



**Advicenne has convinced FDA of a possible filing by leveraging EU clinical data and KOL support**

## **Well established safety and efficacy as approved by EMA**

- B21: demonstrated control of metabolic acidosis with very good safety and tolerability profiles
- B22: long term follow-up, up to 72 months with supportive data on growth and renal function preservation
- No unexpected safety or pharmaco-vigilance event since European commercial launch

## **FDA convinced by long term safety and efficacy data from EU**

- No further US clinical study required for NDA filing
- A pathway now exists to submit EU data for an NDA filing

# Update on dRTA 2025 regulatory activity



## Current situation

### Advicenne actively preparing for NDA submission

- Pre NDA meeting executed Q2 2025 – feedback from FDA positive, clarity provided on submission details
- All additional research projects completed on time, delivering data required for NDA; Gastric pH, retrospective data from B21, GOSH ADV7103 patient clinical audit
- Major focus for organization. Project is on track

### Timelines

- Submit NDA Q4 2025
- Estimated PDUFA action date H2 2026

# Update on Cystinuria regulatory activity



Advicenne has agreed a pathway to approval via a PIII study with a biomarker endpoint

## Importance of achieving ODD

- Agreement from FDA that this drug has a role in cystinuria treatment

## Strategy in cystinuria

- Type C meeting Q4 2024 – FDA agreed PIII registration study design with a biomarker primary endpoint for cystine solubility in urine
- Meeting supported by Advicenne partners: patient advocates and global experts
- Agreed cystine solubility as endpoint – FDA requested Advicenne propose assay

# Advicenne regulatory strategy for Cystinuria



Advicenne strategy in cystinuria validated by grant of ODD

- Next Type C meeting planned to finalize the pivotal study design
- In partnership with KOLs, Advicenne is identifying the right measure for cystine solubility to use in the study

## Timelines

- Contract in place with Mayo Clinic Lab for cystine solubility assay – results due Q3 2025
- Type C meeting to review protocol and assay for endpoint – Q4 2025
- PIII study FPI could be as early as Q4 25/ Q1 26 – resource dependent

# ADV7103: strong business protection

- **ADV7103** is protected by **3 family patents** covering formulation, including the patent that covers the combination of potassium citrate and potassium bicarbonate in a delayed-release formulation
- **Initial patents expiration date: November 2031 in USA and Europe**



- Since the approval of ADV7103 in EU and the UK, **relevant patent terms have been extended** through **Supplementary Protection Certificate (SPC)** by **5 years (until 2036)** in **France, GB, Italy and Spain**
- **6-month Pediatric exclusivity extension**



- **ADV7103 eligible for Patent Term Extension (PTE)**

# ADV7103: strong business protection

## Orphan Drug Designation (ODD)



- **ADV7103** ODD for dRTA achieved December 2022
- **Exclusivity period:** 2033 in USA
- **ADV7103** ODD for Cystinuria achieved April 2024
- **Exclusivity period:** 2034 in USA
- **Reduced research costs due to tax breaks for all US R&D at higher level (25%)**



# P&L – French GAAP

FR GAAP INCOME STATEMENT <i>(in thousands of euros)</i>	December 31, 2024	December 31, 2023
Revenues	4 877	4 458
Income from partnerships	545	209
Other operating income	4 156	332
<b>Total revenue and other income</b>	<b>9 578</b>	<b>4 999</b>
Cost of goods sold	-2 731	-1 725
Research and development expenses	-5 501	-3 643
Sales and marketing expenses	-3 974	-2 599
Overhead and general expenses	-2 576	-3 175
		-
<b>Operating income</b>	<b>-5 204</b>	<b>-6 144</b>
Net financing costs	-1 289	-1 387
Other financial expenses	-13	-30
Other financial income	36	33
		-
<b>Income before taxes</b>	<b>-6 470</b>	<b>-7 528</b>
Income taxes	6	- 1
<b>Net profit / loss</b>	<b>-6 464</b>	<b>-7 528</b>

- **Revenue and other income: €9.6m** (vs. €5.0m in 2023, +92%)
  - Sibnaya<sup>®</sup> +14%, +40% in France
  - Partnership income: mostly royalties from Sibnaya<sup>®</sup> sales
  - Other operating income: €3.5m from the Primex deal end of 2024 + CIR: €0.3m in 2024
- **Operating expenses: €14.8m vs. €11.1m in 2023**, impacted by non-current items (see next slide) :
  - CoGS: stock building combined with the absence of capitalization of costs (notably pharmaceutical development costs) in 2024 vs. 2023
  - R&D costs: expenses allocated to the development of ADV7103 in the US (dRTA and cystinuria), impairment of the Stickpack
  - Marketing & sales expenses: sales efforts focused on Sibnaya<sup>®</sup>. Impacted by €2.9m in taxes and rebates set by French regulatory bodies (€1.5m in 2023)
  - Overheads down 19% vs 2023: strict cost control policy maintained
- **Net financial expense: €1.3m vs. €1.4m in 2023**
  - mainly interest on borrowings 2023

# P&L – Current / non current – French GAAP

FR GAAP INCOME STATEMENT (in thousands of euros)	December 31, 2024	December 31, 2023	Variance
Revenues	4 877	4 458	419
Income from partnerships	545	209	336
Other operating income	656	332	324
<b>Total revenue and other income</b>	<b>6 078</b>	<b>4 999</b>	<b>1 079</b>
Cost of goods sold	-2 699	-1 725	-974
Research and development expenses	-2 997	-3 643	646
Sales and marketing expenses	-1 095	-1 083	-12
Overhead and general expenses	-2 576	-3 175	599
<b>Current operating income</b>	<b>-3 289</b>	<b>-4 628</b>	<b>1 338</b>
Other operating income - non current	3 500	-	3 500
Pharmaceuticals taxes	-2 878	-1 516	-1 362
Cost of goods sold - non current	-33	-	-33
Research and development expenses - non current	-2 504	-	-2 504
<b>Non current operating items</b>	<b>-1 914</b>	<b>-1 516</b>	<b>-398</b>
<b>Operating income</b>	<b>-5 204</b>	<b>-6 144</b>	<b>940</b>

## 2024 non current items

- Revenue from Primex deal (€3.5m)
- Clawback: €2.3m for 2024 **AND** €0.6m additional for 2023 = €2.9m
- Stickack impairment: €2.3m (€1.6m already in H1)
- Improved organization: €0.3m (booked in H1)

Ex CoGS, current op. charges 2024 down 15% to €6.7m (vs. €7.9m in 2023).

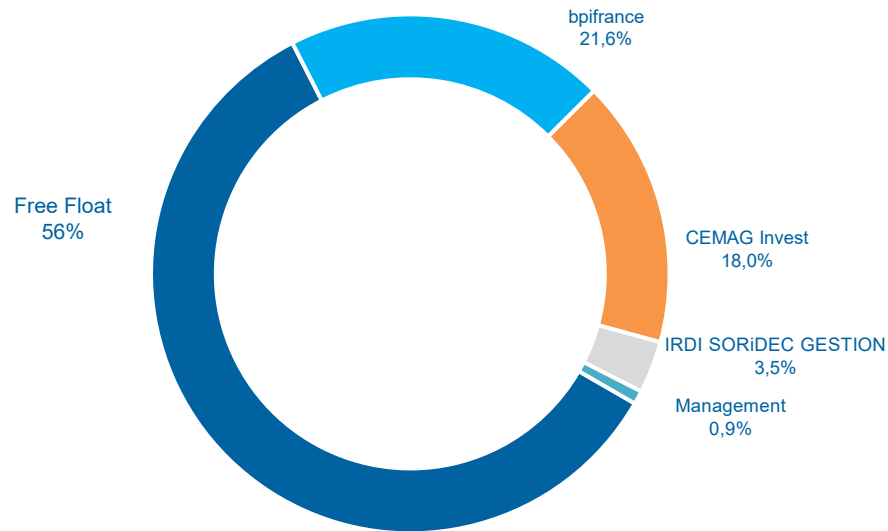
Current operating losses lowered by 29% to -€3.3m (vs. -€4.6m in 2023)

# Cash-flow statement

<b>CASH FLOW</b> <i>(in thousands of euros)</i>	<b>December 31, 2024</b>	<b>December 31, 2023</b>
Net result (loss)	-6 464	-7 528
Amortisation, depreciation and provisions	2 584	73
Net financial costs	900	997
Sale of PPE and intangible assets	9	-
<b>Self-financing capacity</b>	<b>-2 971</b>	<b>-6 457</b>
Changes in inventory	59	-758
Changes in trade and other receivables	-1 604	263
Changes in trade and other payables	3 754	912
<b>Cash flow from operations</b>	<b>-762</b>	<b>-6 041</b>
Acquisition of PPE and intangible assets	-91	-1 229
Scope variations	-	-
Sale of financial assets	-17	6
<b>Cash flow from investing activities</b>	<b>-108</b>	<b>-1 265</b>
Capital increase (net)	-	5 417
Own shares held in treasury	-17	-26
Net borrowings and refundable advances	-	42
Repayment of borrowings and refundable advances	-1 115	-1 200
<b>Cash flow from financing activities</b>	<b>-1 132</b>	<b>4 233</b>
<b>Changes in value of local currencies</b>	<b>-</b>	<b>3</b>
<b>Change in cash</b>	<b>-2 003</b>	<b>-3 070</b>
Opening cash position	5 251	8 322
Closing cash position	3 248	5 251

- **Cash consumption from operations: €0.8m vs €6.0m in 2023**
  - Sustained improvement thanks to revenue growth (including the positive impact of Primex) and strict cash allocation control
  - WCR also benefiting from the Primex deal
- **Cash consumption from investments**
  - Almost nil in 2024
  - Capex for the stickpack booked in 2023
- **Cash consumption from financing**
  - PGE repayment started in 2023

# Shareholding structure



Source: Company information



Contact: Didier Laurens - CEO  
[dlaurens@advicenne.com](mailto:dlaurens@advicenne.com)