



advicenne

BIOTECH AGORA
October 20th, 2022



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Agenda

- Business Update
- H1 2022 financial statement
- Q&A



Business Update

Management Team with Proven Track Record

Adrian Hepner
Interim CMO

Maxime Laugier
Manufacturing
Director

Didier Laurens
CEO

Laurent Cassedanne
Quality Director

Robbie McCarthy
GM Advicenne Inc. USA



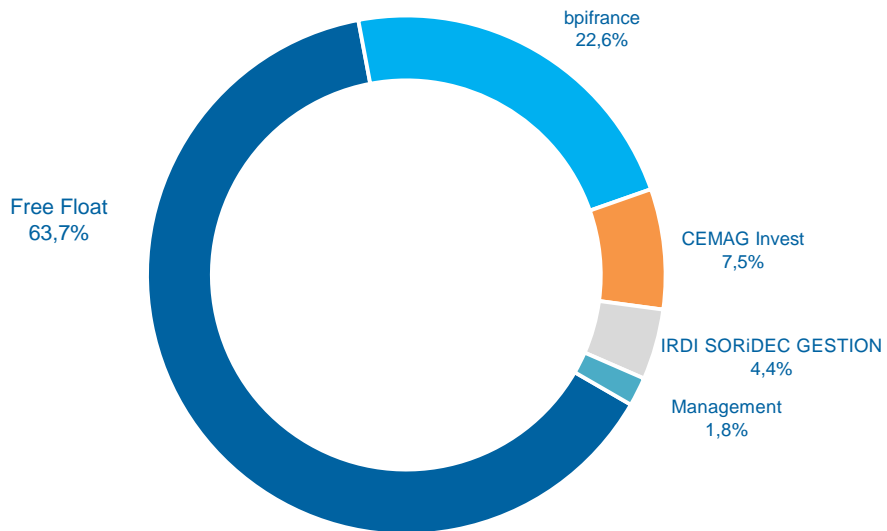
Catherine Guittet
EU Clinical Director

Isabelle Kervella
Deputy CFO

Sabrina Chekroun
Head of Regulatory
Affairs

Hege Hellstrom
CCO

Company's Governance



- 5 Board members + 1 observer
 - 2 Bpifrance representatives
 - 1 Cemag Invest representative
 - 1 Independent
 - CEO
-
- Chairman: P. Boucheron (bpifrance)

Commercial stage Specialty Pharma

Ozalin

- Oral suspension / Midazolam
- Licenced out to Primex
- EU MA in 2017
- Europe launch

Likozam

- Clobazam oral suspension
- Rare form of Epilepsy
- Marketing rights from Rosemont (UK)

**2021 Sales
>3M€**






Levidcen

- Rare form of Epilepsy
- MAH
- Marketing rights from Desitin (Ger)

Sibnaya / ADV7103

- Lead product
- EU / UK MA in 2021
- Launch in progress

Product portfolio: 2 European Market Approvals

Product	Indication	Preclinical / Phase 1	Phase 2/3	Registration
 Ozalin	Neurology	COMPLETED		EMA approved 2018
 Sibnaya [®]	dRTA	COMPLETED		EMA approved 2021
 ADV 7103	dRTA	ARENA 2 PROGRAM		
 Sibnaya [®]	Cystinuria	CORAL 1 PROGRAM		
 ADV 7103	Cystinuria	CORAL 2 PROGRAM		
ADV 6769	Neurology			

ARENA: Alkalinisation for RENal Acidosis; CORAL: Cystine – ORnithine – Arginine – Lysine (4 dibasic amino-acids for which gastro-intestinal absorption and renal reabsorption are defective in cystinuria patients)

OZALIN®: First product being approved

- Oral formulation of midazolam (2mg/ml)
- Market Approval in Europe in sedation for children from 6 months to 17 years old
- Addressing a significant unmet need to improve child surgical conditions
- Licensed-out to Primex Pharmaceuticals AG
- Licensing scheme: Upfront, Milestones and Royalties
- 7M€ already received in upfront and milestones
- 33M€ Royalties to be received in 2025 at the latest

SIBNAYAL® – Presentation

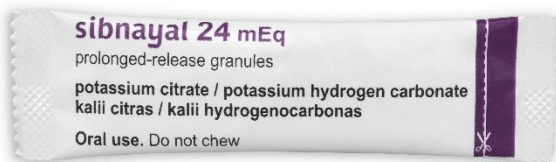
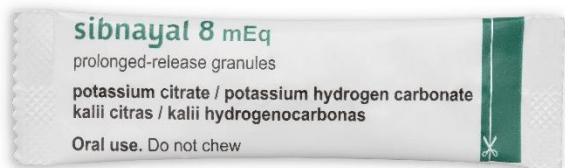
- Fixed combination: prolonged-release granules of Potassium Citrate (CK) & prolonged-release granules of Potassium Bicarbonate (BK) in ratio 1/3:2/3
- Two strengths: 8 mEq and 24 mEq in sachets
- For oral use. The total daily dose is administered twice daily, typically twelve hours apart.



SIBNAYAL®: leverage its European MA value

- EMA approval in distal Renal Tubular Acidosis (dRTA) in April 2021
- Granted MHRA approval in July 2021 (UK)
- dRTA is a rare disease affecting around 30,000 patients in Europe
- Prepare and execute European launch of Sibnaya[®] **mainly** through partnerships

Sibnaya[®], market ready for Europe



Sibnaya[®]: a unique and advanced manufacturing process



Manufacture at industrial batch size



High speed tableting with multi-tip toolings



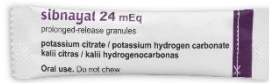
Coating technology designed for mini-tablets



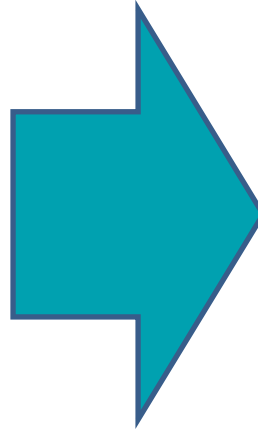
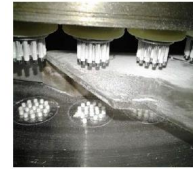
High speed dual filling stick packaging

Sibnaya[®]: an improving manufacturing flow

2022

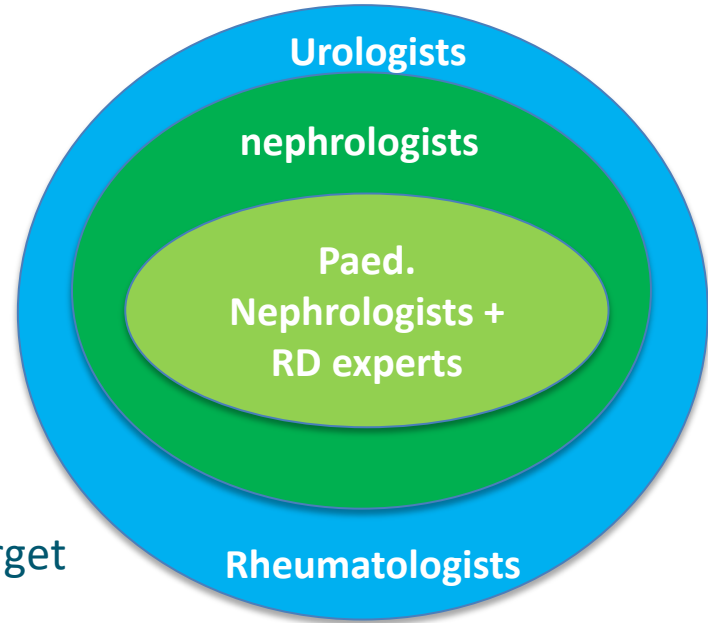


2023



Sibnaya[®] prescribers: a limited target

- **Special Tier: 20 WW** KOLs /stakeholders
- **Tier 1: Hospital Paediatric nephrologists: 100%**
 - 400 in US, 500 in EU (350 in EU5)
- **Tier 2: Adult nephrologists: target 20%**
 - 1000 in US, 2 000 in EU (800 in EU5)
- **Tier 3:**
 - Rheumatologists: to be adjusted
 - Urologists (cystinuria): 100% hospital then reduced target
 - Others: internal medicine, functional exploration...



Sibnaya[®] commercial strategy



Pricing discussion with CEPS on going

OPERATIONS

- Optimal sales 5 reps focusing on University Hospital Centers
- Around 70 hospital already ordering Sibnaya
- Medical Affairs
- Supportive KOL network

→ Carte de France des CHU



Sibnaya[®] commercial strategy



List price: c.11,000€ / patient / year

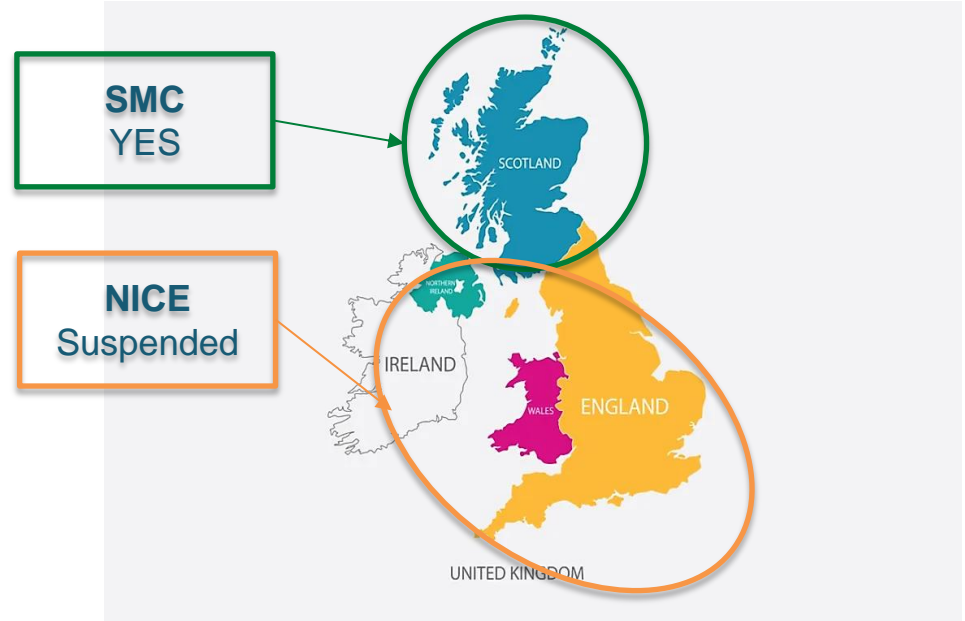
SMC: approved Sibnaya[®] for NHS Scotland

NICE: application withdrawn

- Local discussion with prescriber / pharmacy
- No economic impact

OPERATIONS

- GB-based Wholesaler
- QPPV : Compliance / Quality in place
- 2 Sales rep recruited
- 1 Medical support
- 10 core targets centers identified



Sibnaya[®] commercial strategy: about partners

Germany
Under discussion

Nordics & Baltics
Frost Pharma

CEE
ExCEED Orphan

Benelux
TwinPharma

South Europe
Under discussion



ADV 7103: Complete the US NDA pathway

- Filing through 505(b)2 (Potassium Citrate as reference substance)
- FDA agreed on the pivotal trial design in dRTA (ARENA-2):
 - Ready to start a short-term study (B23) and a follow-up trial (B24)
 - B23 will support the NDA filing
- FDA pending questions reviewed and agreed:
 - **Combination rule**
 - Urinary pH

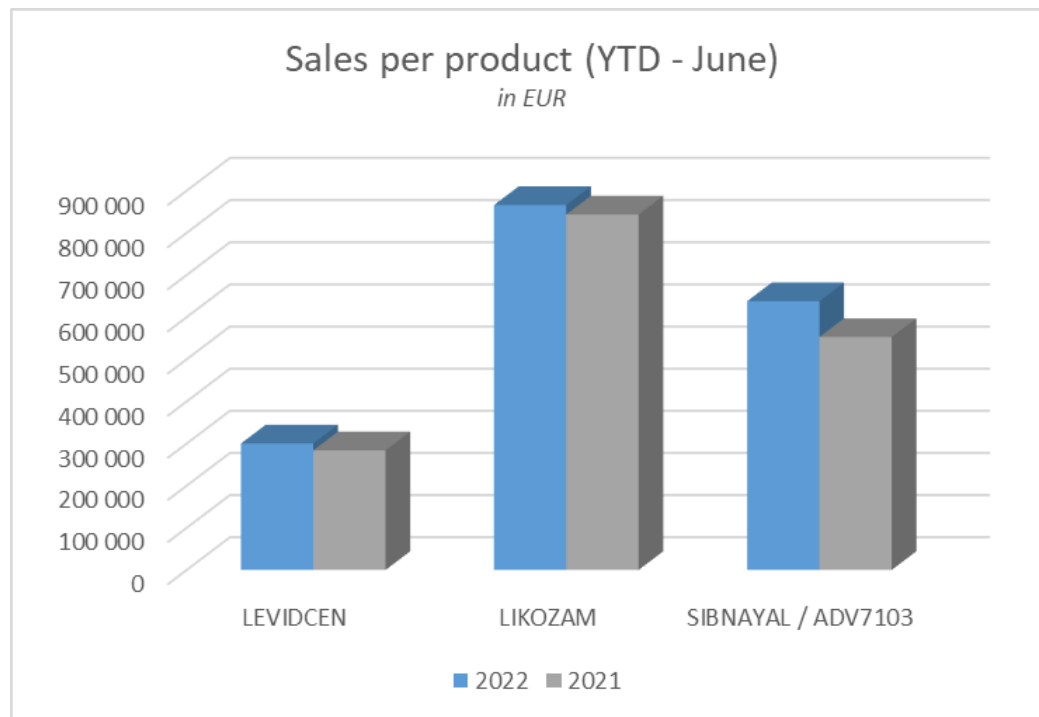
ADV 7103: Enlarge indications

- **Complete the development in Cystinuria**
 - Rationale: Need for urine alkalinization
 - Orphan designation in Europe
 - US ODD: in preparation
- Explore other indications where alkalinizing agents are needed



H1 2022 Financial Statement

Revenue by product – H1 2022



- June YTD sales:
 - 1.80 m€ vs 1.68 m€ LY (+7%)
- Sibnaya[®] :
 - 638 k€ vs 553 k€ in 2021 (+15%)
- Liko zam and Levidcen:
 - 1 166 k€ vs 1 127 k€ in 2021 (+3.4%)

P&L IFRS HY22-HY21

CONSOLIDATED INCOME STATEMENT <i>(in thousands of euros)</i>	June 30, 2022	June 30, 2021
Revenues	1 555	1 364
Income from partnerships	28	10
Other operating income	351	372
Total revenue and other income	1 934	1 746
Cost of goods sold	-616	-540
Research and development expenses	-3 090	-4 713
Sales and marketing expenses	-635	-1 631
Overhead and general expenses	-1 989	-2 409
Operating income	-4 396	-7 547
Net financing costs	-671	-538
Other financial expenses	-445	
Other financial income	700	82
Income before taxes	-4 813	-8 003
Income taxes	-	14
Consolidated net profit / loss	-4 813	-7 990
- Attributable to shareholders of Advicenne SA	-4 813	-7 990
- Attributable to non-controlling interests	-	-
Earnings per share (€/share)	-0,48	-0,93
Diluted earnings per share (€/share)	-0,48	-0,93

- **Revenue from partnerships**
 - Royalties received based on sales from Primex and 1st sales from new commercial partners
- **Other income**
 - Research Tax Credit
- **Operational costs: 6.3 MEUR (-34%)**
 - **R&D:** 3.1 MEUR vs 4.7 in HY21: main allocation of expenses, slight decrease notably due to the end of trials in Europe
 - **G&A:** 2.0 MEUR vs 2.4 MEUR in HY21: global effort of costs cutting since mid 2021
 - **Exceptional items** related to restructuring
- **Financial result: -0.4 MEUR (vs.-0.5 MEUR)**
 - Interests charge of 0.7 MEUR (1st tranche of EIB loan)
 - Favorable FX effect (0.3 MEUR)

Balance sheet IFRS HY22-FY21

ASSETS <i>(in thousands of euros)</i>	June 30, 2022	December 31, 2021
Intangible assets	152	167
Property, plant and equipment	2 004	1 836
Other financial assets	166	263
Non-current assets	2 323	2 265
Inventory	694	717
Accounts receivable	1 056	802
Tax credit	1 482	1 126
Other current assets	877	1 286
Cash and cash equivalents	7 288	12 685
Current assets	11 397	16 616
Total assets	13 720	18 881

LIABILITIES and CAPITAL <i>(in thousands of euros)</i>	June 30, 2022	December 31, 2021
Capital stock	1 991	1 990
Capital-related premiums	1 490	24 469
Reserves	-2 978	-13 723
Net income / loss	-4 813	-12 427
Total equity capital	-4 311	309
Provisions	34	96
Long-term debt	12 906	12 371
Non-current liabilities	12 940	12 467
Financial liabilities	403	165
Accounts payable	1 573	2 929
Other current liabilities	3 115	3 012
Current liabilities	5 091	6 105
Total liabilities and capital	13 720	18 881

1. Research Tax Credit

- 0.35 MEUR as at June 30, 2022 and 1.1 MEUR for FY21

2. Other current assets

- mainly tax receivables (VAT)

3. Cash position as at June 30, 2022: 7.3 MEUR

- tight expenses control by management
- payment terms strictly controlled

4. Net equity: -4.3 MEUR

- prior years tax losses (23 MEUR) allocated on capital premium (decision of the GA on June 9, 2022)

5. Other current liabilities

- ATU provision by 2.2 MEUR vs 1.9 MEUR as at Dec 31, 2021

6. Financial debt: 13.3 MEUR

- increase in capitalized interests related to the 1st tranche of EIB loan

Cash-flow statement IFRS HY22-HY21

CASH FLOW <i>(in thousands of euros)</i>	June 30, 2022	June 30, 2021
Net income (loss)	-4 813	-7 990
Amortisation, depreciation and provisions	205	206
Share-based payments	179	164
Other calculated income and expenses	10	-50
Net financial costs	671	477
Disposal of PPE and intangibles assets	50	8
Self-financing capacity	-3 698	-7 185
Changes in inventory	23	360
Changes in trade and other receivables	-201	-331
Changes in trade and other payables	-1 252	-1 371
Cash flow from operations	-5 128	-8 527
Acquisition of PPE and intangibles assets	-121	-256
Treasury shares	-	-99
Disposal of financial assets	-97	-104
Cash flow from investing activities	-218	-459
Capital increase	23	9 089
Repayment of borrowings and refundables advances	-73	-140
Cash flow from financing activities	-51	8 948
Change in cash	-5 397	-38
Opening cash position	12 685	16 771
Closing cash position	7 288	16 733

Net cash flow from operating activities

- Significant improvement linked to the net result of the period
- WCR control

Net cash flow from investing activities

- Mainly investments in production operations
- Disposals related to the combination of our 3 sites in 1 unique site "FSH"

Net cash flow from financing activities

- No specific operation on H1 2022 vs 9.4 MEUR capital increase in June 2021

Advicenne's main takeaways

- Execute the commercial ramp-up of Sibnaya[®] in Europe
- Progress in the development of our main asset in the US and in other indications
- Finalize EIB 2nd tranche drawdown



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Contact: Didier Laurens - CEO
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