

sequana medical

2021 Full Year Results & Business Update

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Innovators in the treatment of diuretic-resistant fluid overload

liver disease 🔵 malignant ascites 🔵



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Today's presenters





Ian Crosbie Chief Executive Officer **Kirsten Van Bockstaele** Chief Financial Officer

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- The alfapump[®] system has not yet received regulatory approval in the United States and Canada. Any statement in this presentation about safety and efficacy of the alfapump[®] system does not apply to the United States and Canada. In the United States and Canada, the alfapump[®] system is currently under clinical investigation (POSEIDON Study) and is being studied in adult patients with refractory or recurrent ascites due to cirrhosis. For more information regarding the POSEIDON clinical study visit <u>www.poseidonstudy.com</u>.
- DSR[®] therapy is still under development and it should be noted that any statements regarding safety and efficacy
 arise from ongoing pre-clinical and clinical investigations which have yet to be completed. DSR[®] therapy is currently
 not approved for clinical research in the United States or Canada. There is no link between DSR[®] therapy and
 ongoing investigations with the alfapump[®] system in Europe, the United States or Canada.

COVID-19 disclaimer:

- Sequana Medical is closely following the evolution of the COVID-19 global health crisis and is in constant dialogue with its partners to assess the impact and adapt operations accordingly.
- Sequana Medical has put in place mitigation plans to minimise delays. The impact of increased demands on the healthcare systems, limitations on non-essential hospital visits and procedures, social-distancing and travel restrictions may result in further delays to execution of clinical studies and impact sales.
- Sequana Medical will continue to update the market as needed and whenever possible.

Note:

alfapump[®] is a registered trademark. DSR[®] and alfapump DSR[®] are registered trademarks in the Benelux, China, the EU, United Kingdom, and Hong Kong.

2021 & YTD Highlights

alfapump $^{\mbox{\tiny B}}$ in liver disease / NASH

- Positive results from second interim analysis of POSEIDON pivotal study; encouraging survival data at 12 months vs. published literature
- ✓ Patient enrolment and implants completed; primary endpoint on track for Q4 2022
 - ✓ FDA regulatory submission planned for mid-2023

DSR[®] in heart failure



- RED DESERT study demonstrated safety, cardio-renal benefit and long-term improvement in diuretic response
- ✓ SAHARA DESERT study interim data shows ability to remove fluid overload in decompensated patients; top-line data expected in H2 2022
- CMC and pre-clinical development of proprietary DSR Infusate 2.0 on track to start US MOJAVE DESERT study in H2 2022

Corporate



- ✓ MDSAP and European MDR certification for QMS and alfapump system
- ✓ Equity placement of €28.4 million in March 2022 extending cash runway into Q2 2023

Year in Review: alfapump® in liver disease / NASH



Interim POSEIDON: Positive for primary endpoints

Data from 26 Roll-In patients

EFFICACY

- ✓ Over 90% reduction in mean Therapeutic Paracentesis (TP) frequency (primary endpoint >50% reduction)
- ✓ 100% patients with > 50% reduction in mean TP frequency per month (primary endpoint >50% of patients)

SAFETY

 \checkmark In line with expectations – 3 composite primary safety events

QUALITY OF LIFE

✓ Clinically important improvement maintained for up to 12 months post-implantation

Interim POSEIDON: 70% survival at 12 months

Preliminary survival rate analysis of Roll-In Cohort (25 March 2022)



Mean survival probability of 70% at 12 months compares favourably to published literature reporting a survival rate for refractory ascites patients of only 50% at 12 months¹

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North American alfapump® approval on track for 2024



NTAP for breakthrough devices de-risks reimbursement in key Medicare population*



*On the basis of existing ICD-10 codes issued for the alfapump, the likely DRG coding will be 423, 424 and 425 "OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES"

PMA: Pre-Market Approval; NTAP: New Technology Add-On Payment

US – Go direct to 140 liver transplant centres

Highly efficient approach to target doctors and patients – driven by treatment guidelines



Year in Review: DSR[®] in heart failure



DSR[®] – Encouraging phase 2a heart failure data

Clearing congestion while preserving renal function is a key objective of heart failure therapy

RED DESERT – Completed (8 Euvolemic heart failure patients)	SAHARA DESERT – Ongoing (Interim data) (6 Decompensated heart failure patients)
Clinical proof-of-concept	Safely, effectively & rapidly decongest & restore euvolemia
Clear improvement in cardio-renal status	
 30% decrease in NT-proBNP* 22% increase in eGFR* and creatinine* 	 >30% decrease in NT-proBNP* Stable eGFR* and creatinine*
Dramatic and durable improvement in diuretic response	
 40-96% reduction in diuretic dose 9-19 months after study completion 	 >90% reduction in diuretic dose 3 months* after intensive DSR therapy
* 14	

* Mean value

HF: Heart Failure; NT-proBNP: N-terminal-pro hormone B-type Natriuretic Peptide (analysed in local lab); eGFR: estimated glomerular filtration rate

Proprietary DSR® drug development

Driver of high margin recurring revenue stream leveraging extensive clinical experience

1st Generation Infusate

- ✓ Sodium-free D10% (off-the-shelf)
- ✓ Rapid clinical path: Red Desert; Sahara Desert
- ✓ Clinical proof of concept

2nd Generation Infusate

- ✓ Sodium-free dextrose / icodextrin (proprietary)
- Improved therapeutic & safety profile
- ✓ IP protection drives recurring revenue from high gross margin consumable
- Animal GLP & CMC development ongoing



DSR® – plan to partner after US efficacy study

Step-by-step approach to introduction of breakthrough heart failure therapy



Key Financial Results FY 2021

Revenue:

€371K

• Limited European commercial activities due to reduced supply of **alfa**pump (up to August) and impact of COVID-19

Operating expenses: - €22.9M

- Preparation of submissions for marketing approval in US and Canada
- Pre-clinical and clinical development of proprietary DSR Infusate

Net result:

- €23.6M

Cash position of €9.6M at December 31, 2021

Post period: Equity Offering of €28.4MM

Cash runway extended into Q2 2023

Strong outlook for value drivers



Strongly positioned for growth in both our markets

- alfapump[®] in liver disease / NASH over €3 Bn / year ⁽¹⁾
 - NASH is changing liver cirrhosis market and driving growth
 - FDA breakthrough device status / Strong IP portfolio
 - North American pivotal study de-risked Fully implanted / Positive interim data
 - North American approval on track for 2024 / Go direct to 140 liver transplant centres
- DSR® In I
 Clearing
- DSR[®] in heart failure over €5 Bn / year ⁽²⁾
 - Clearing congestion while preserving renal function is a key objective of heart failure therapy
 - Clinical proof-of-concept with 1st Gen. drug Encouraging phase 2a data
 - Development of proprietary 2nd Gen. drug Strong IP / Driver of high margin recurring revenue
 - Establish partnership after US efficacy study mid-2023



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