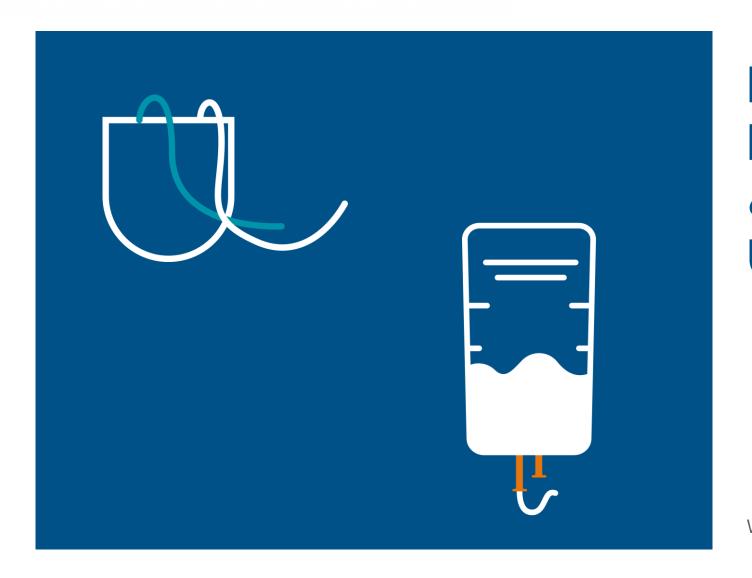
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# H1 2022 Financial Results & Business Update

Webcast presentation – 8 September 2022

## **Today's presenters**



lan 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 <a href="www.poseidonstudy.com">www.poseidonstudy.com</a>.
- 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.

#### **2022 YTD highlights**

Important progress in both our liver disease and heart failure programs

#### alfapump® – towards approval in North America





- ✓ Interim analysis<sup>(1)</sup> shows 70% survival rate at one year post implantation
- ✓ European MDR certification proves that our quality management system and **alfa**pump are compliant with latest regulatory standards for medical devices

#### DSR® – disease-modifying heart failure drug therapy



- ✓ No congestion related re-hospitalizations during study follow-up
- ✓ Clinical outcomes from proof-of-concept studies result in a 75% reduction in predicted one-year mortality based on Seattle Heart Failure model<sup>(2)</sup>
- ✓ Preparations for US IND filing of DSR 2.0 ongoing; plan to start US phase 1b/2a MOJAVE study in H1 2023

#### Total liquidity position of €23.8 million at end June 2022 and cash runway into Q3 2023<sup>(3)</sup>

- ✓ Equity placement of €28.4 million in March 2022
- ✓ Kreos loan facility of €10 million post period (drawdown before end of September 2022)

<sup>(1)</sup> Preliminary survival rate analysis of Roll-In Cohort (25 March 2022), as part of a general safety assessment

<sup>(2)</sup> Predicted one-year survival analysis using Seattle Heart Failure Model with seven patients from RED DESERT and eight patients from SAHARA I pre- and post-intensive DSR therapy. Analysis includes physician-assessed data collected post hoc.

<sup>(3)</sup> Including €10 million drawdown from Kreos loan facility before end of September 2022

## POSEIDON on track to report top-line data in Q4 2022

North American pivotal study of alfapump in patients with recurrent and refractory ascites due to liver cirrhosis

All patients implanted with the **alfa**pump

• Roll-In Cohort: 29 implants

• Pivotal Cohort: 40 implants

- ✓ Strong interim data reported in Roll-In Cohort clinically de-risks the study
  - Efficacy data outperformed primary endpoint requirements as defined for Pivotal Cohort(1)
  - Safety profile in line with expectations
  - Clinically important improvement in quality of life maintained even up to 12 months post implantation
  - 70% survival at 12 months post implantation compares favourably to literature (AASLD practice guidelines cite 50% survival rate at 12 months for refractory ascites patients)<sup>(2)</sup>

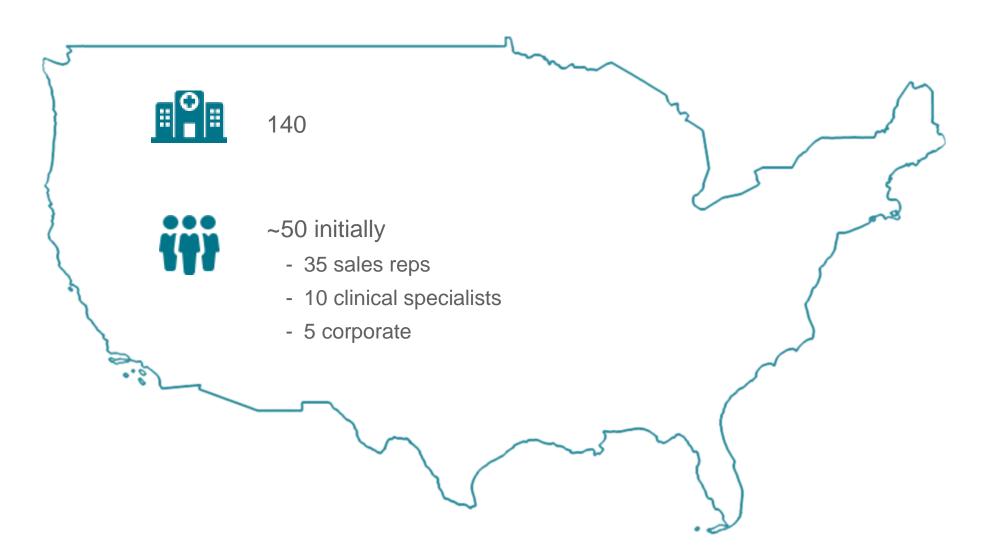
Reporting primary endpoint of Pivotal cohort in Q4 2022; Submission of PMA to US FDA planned for H2 2023

<sup>(1)</sup> Pre- and post-implant periods for this analysis of the Roll-In Cohort (N=26) differ from those that will be used for the Pivotal Cohort analysis

<sup>(2)</sup> Preliminary survival rate analysis of Roll-In Cohort (N=29, 25 March 2022); Biggins et al., Hepatology, Vol. 74, No. 2, 2021, AASLD Practice Guidance; Moreau R et al., Liver International 2004: 24: 457-464

## **Preparing for direct US commercialization**

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



## **SAHARA** reports strong interim data

Phase 2a study of DSR therapy in diuretic-resistant heart failure patients with persistent congestion

- ✓ Interim data<sup>(1)</sup> show dramatic and durable improvements in validated clinical measures
  - Safe, rapid and effective decongestion
  - Clear improvements in cardio-renal health
  - Large and long-lasting reduction in the need for diuretic drugs
  - No congestion-related re-hospitalizations during follow-up
- ✓ Completion of enrollment with first-generation DSR product ("DSR 1.0")
- Study will be extended with second-generation DSR product ("DSR 2.0") to support US IND filing

DSR therapy tackles the key clinical need of sodium overload in patients in whom loop diuretics are no longer effective

## **DSR – A Disease-Modifying Heart Failure Drug Therapy**

RED DESERT and SAHARA I deliver clinical proof-of-concept – addressing key unmet clinical needs

- Long-term & major reduction in loop diuretic dosing
  - up to 23 months in RED DESERT and up to 11 months in SAHARA I
- No heart failure congestion-related re-hospitalizations during study follow-up
- Clinical benefits result in a 75% reduction in predicted one-year mortality pre- vs. post-intensive DSR therapy based on the Seattle Heart Failure Model<sup>(1)</sup>

3 to 4 weeks of intensive DSR therapy delivers clinical benefits lasting 6 – 12 months

<sup>(1)</sup> Predicted one-year survival analysis using Seattle Heart Failure Model with seven patients from RED DESERT and eight patients from SAHARA pre- and post-intensive DSR therapy. Analysis includes physician-assessed data collected post hoc.

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#### **Moving to Proprietary DSR 2.0**

Improved clinical and safety profile driving high margin recurring revenue stream

## DSR 1.0 Sodium-free D10% (off-the-shelf)

- ✓ Clinical proof-of-concept
- ✓ Rapid clinical path
- Therapeutic profile / Ease of use
- Safety profile

**RED DESERT & SAHARA I** 

## DSR 2.0 Sodium-free dextrose / icodextrin (proprietary)

- ✓ Improved therapeutic profile
- ✓ Favorable safety profile
- ✓ Strong granted IP position in US & Europe
  - "Low or no sodium drug for the treatment of heart failure"
  - IP protection drives recurring revenue from high gross margin consumable
- ✓ Good progress in product development and GLP animal studies

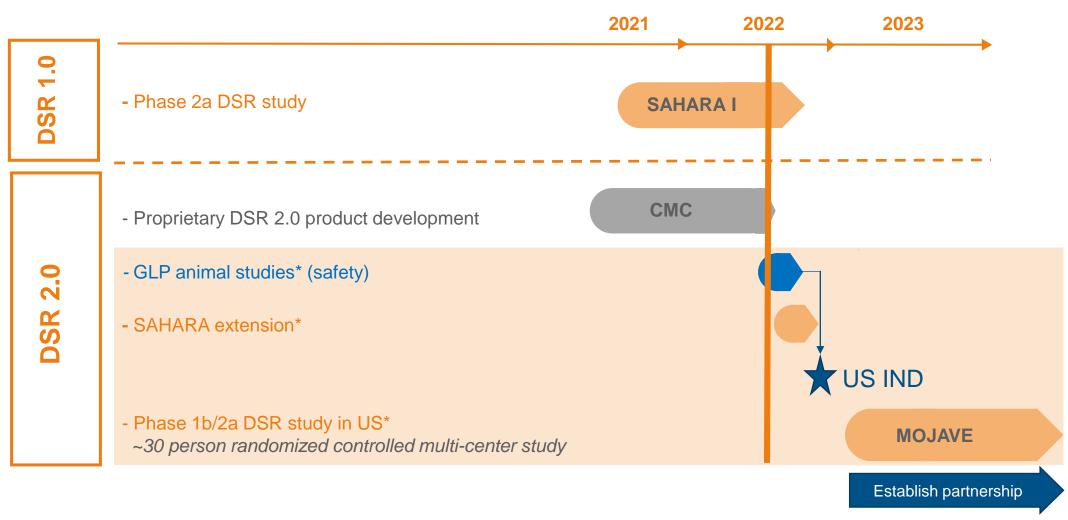
SAHARA EXTENSION & MOJAVE

**Note:** SAHARA I = SAHARA study using DSR 1.0

GLP: Good Laboratory Practice

#### Planning to kick-off US Ph. 1b/2a MOJAVE in H1 2023

Randomized, controlled, multi-center study



Timelines subject to further developments related to the ongoing COVID-19 pandemic

<sup>\*</sup> Description and timing of these studies are subject to change and/or feedback from applicable regulatory authorities

#### **Key Financial Results H1 2022**

Revenue: €464K

Resumed commercial activity in Europe as the impact of COVID declines

Operating expenses: - €13.6M

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

Net result: - €14.9M

Cash position of €23.8M at June 30, 2022

Post period: €10M loan facility with Kreos Capital<sup>(1)</sup>

Cash runway extended into Q3 2023

# Two highly experienced medtech leaders from the US appointed to our Board of Directors



- CEO of Responsive Arthroscopy
- >40 years in medical device industry
- Founder and CEO of leading medtech companies:
  - Tornier NV
  - American Medical Systems
  - Spine Tech
- Board member of Cerapedics, Lima
   Orthopedics, Osteal Therapeutics,
   UroTronic, Vergent Bioscience



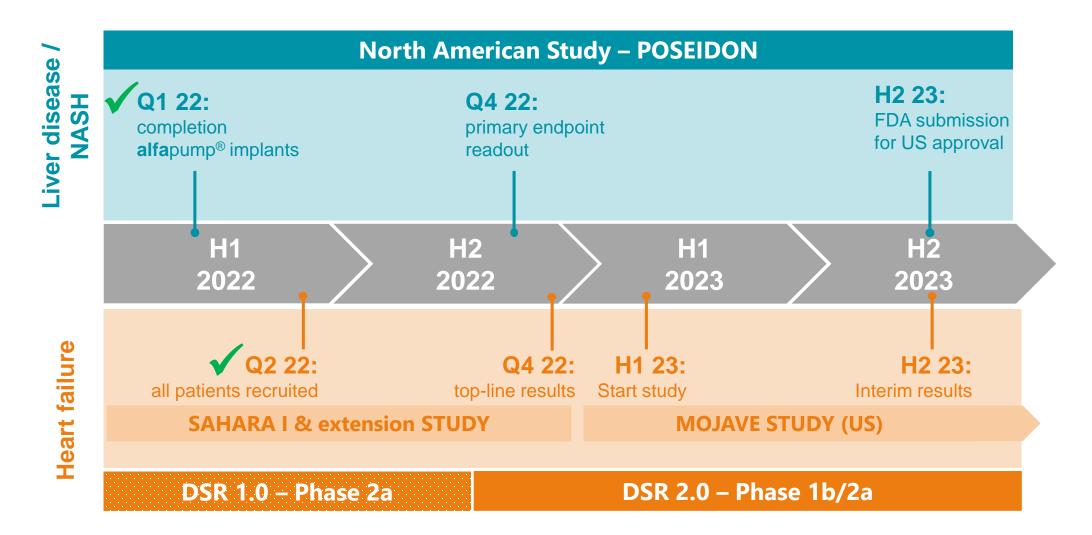
- Senior VP Global Health Economics,
   Policy & Reimbursement at Medtronic
- >30 years healthcare experience
- Member of global health economics and reimbursement organizations:
  - Duke Margolis Value-Based
     Payment and Innovative
     Technology Consortium
  - HTAi Policy Forum
  - CEVR at Tufts Medical Center

**Doug Kohrs**Non-Executive Director

Alex Clyde

Non-Executive Director

#### **Strong Outlook for Value Drivers**



#### Notes:

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