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H1 2021 Financial Results & Business Update

2 September 2021

Today's presenters

Ian Crosbie
Chief Executive Officer

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Chief Financial Officer

Disclaimers

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Disclaimers

Regulatory disclaimer:

- The **alfa**pump® system has not yet received regulatory approval in the United States and Canada. Any statement in this presentation about safety and efficacy of the **alfa**pump® system does not apply to the United States and Canada. In the United States and Canada, the **alfa**pump® 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 www.poseidonstudy.com.
- 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 **alfa**pump® 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:

- **alfa**pump® is a registered trademark. DSR® and **alfa**pump DSR® are registered trademarks in Benelux.

YTD 2021 Highlights

- **alfa**pump® – results from 2nd interim analysis of POSEIDON in recurrent / refractory liver ascites re-confirm positive outcomes against all primary endpoints; awaiting FDA approval on POSEIDON pivotal study expansion

- **alfa**pump® – FDA regulatory submission now expected in mid-2023 due to worldwide supply shortage of electronic components; European commercial activities and clinical studies unaffected

- **alfa**pump DSR® – Strong top-line results from RED DESERT in stable heart failure patients; initiated SAHARA DESERT in decompensated heart failure patients

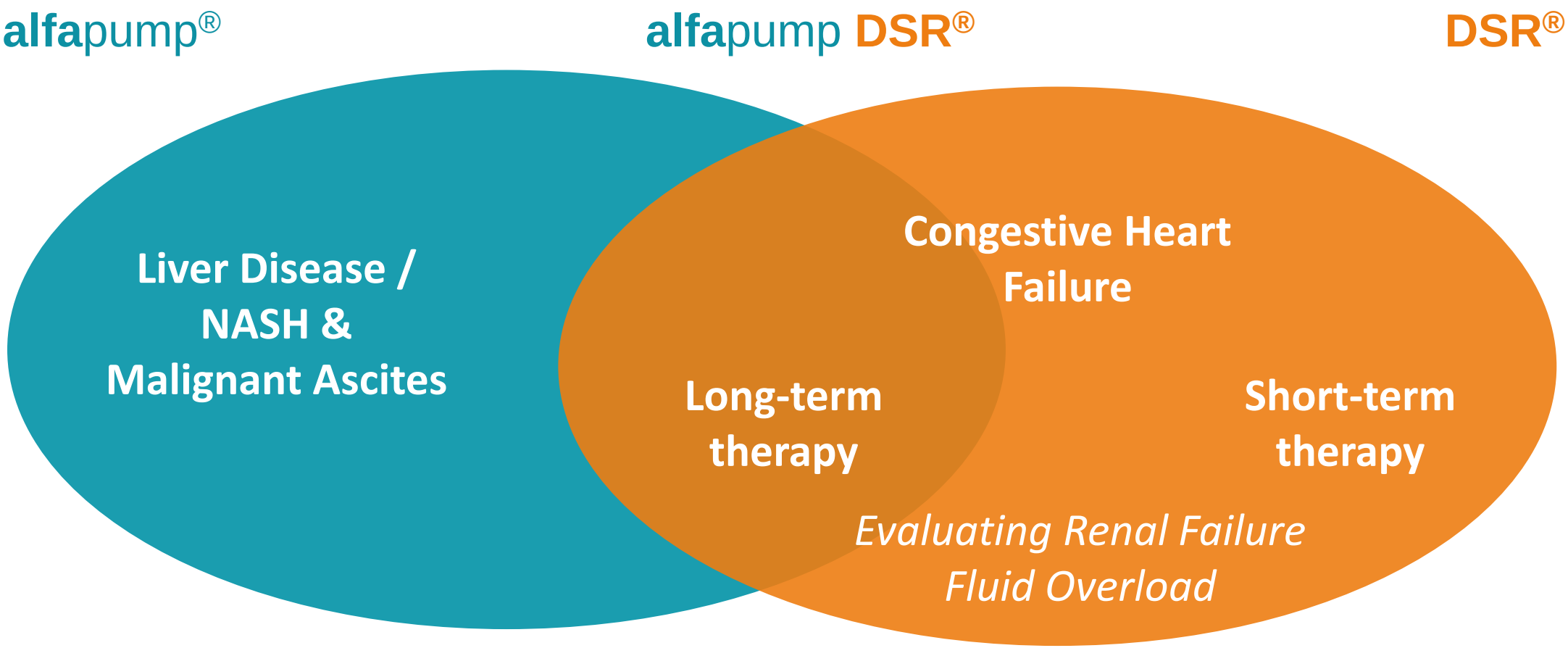
- DSR® – Key patents granted in US and Europe; expansion of DSR development programme with Short-Term DSR therapy; proprietary DSR Infusate 2.0 development ongoing

- Appointment of Ms. Jackie Fielding as Non-Executive Director

- Cash runway extended into Q2 2022 through €22.5M equity financing

Building Sequana Medical on two platforms

Complementary approaches to diuretic-resistant fluid overload



2nd interim POSEIDON: Positive for primary endpoints

Data from 26 Roll-In patients with recurrent or refractory liver ascites implanted with the alfapump®

- ✓ Substantial and durable reduction in need for Therapeutic Paracentesis (TP)
  - Over 90% reduction in mean frequency of TP post- vs. pre-implant[1] (primary endpoint of >50% reduction)
  - All patients experienced at least a 50% reduction in the mean frequency of TP per month[1] (primary endpoint of >50% of patients)
- ✓ Safety profile in line with expectations – 3 out of 26 patients experienced a composite primary safety event
- ✓ Clinically important improvement in quality of life maintained for up to 12 months post-implantation

Note 1: Pre- and post-implant periods for this analysis of the Roll-In Cohort differ from those that will be used for the Pivotal Cohort analysis

Key Takeaways from KOL webinar with Dr. Vargas and Dr. Knuttinen from Mayo Clinic, Arizona

High Burden	• Ascites has a significant negative impact on patients and may lead to serious complications
Increasing prevalence	• Net effect of NASH becoming very prevalent is that we will see an increased incidence of cirrhosis with the complication of ascites
Patient support	• **alfa**pump is very well accepted with strong interest from the patient community
Easy implantation	• Implantation of **alfa**pump is a minimally invasive procedure under local anaesthesia / moderate sedation and recommends the use of ultrasound for ascites localisation and catheter placement
Solid benefit on patients	• Reported outcomes of POSEIDON are solid and shows that **alfa**pump has a positive impact on patients

replay available on our investors webpage "Events & Presentations"

N. American Liver Programme Update

- POSEIDON – Submitted protocol amendment to the US FDA to extend patient enrolment due to the higher attrition rate prior to implantation
  - Discussions with the FDA ongoing
  - Update on timelines for completion of patient enrolment and subsequent primary endpoint read-out once we have clarity on study expansion from the FDA
- PMA – Submission for regulatory approval now expected in mid-2023
  - Detailed planning and discussions with suppliers on verification and validation activities supporting the PMA made clear that worldwide shortage of electronic components will lead to a delay in delivery of subcomponents and result in an expected 6 months delay of the PMA submission
  - European commercial activities and clinical studies unaffected
- Sponsored patient registry (NACSELD) and FDA patient preference study ongoing

PMA: *Pre-Market Approval;* ***NACSELD:*** *North American Consortium for the Study of End Stage Liver Disease*

Resumed commercial activity in Europe in H2 2021

H1 2021

- Reduced supply of **alfa**pump systems to European commercial markets
- Resolved low manufacturing yield of **alfa**pump systems

H2 2021

- Resumed commercial activities in Germany and France in August
- 2021 revenues expected, on a *pro rata* basis, in line with periods before reduced manufacturing supply

RED DESERT: Strong clinical proof-of-concept

Data from 8 euvolemic heart failure patients on high-dose diuretics treated with DSR 3x per week up to 6 weeks

- ✓ Highly effective replacement of high-dose loop diuretics
- ✓ Generally safe and well tolerated; no clinically relevant hyponatremia
- ✓ Dramatic and long-term improvement in diuretic response
  - Over 150% increase in diuretic response**
  - 79% reduction in diuretic dose** 10 months after study completion***
- ✓ Significant improvement in cardio-renal function
  - 30% decrease* in NT-proBNP** (p<0.001)
  - 22% increase* in eGFR** (p<0.001)
  - 22% decrease* in creatinine** (p<0.001)

Presented as Late-Breaker and Highlight at Heart Failure 2021

"Simultaneous normalisation of diuretic response and improvement in cardio-renal status is a never before seen treatment effect" – Dr. Testani, Yale

** Paired statistical analysis of patients with baseline and D42 value (N=7); ** mean value ***median follow-up*

ESC: *European Society of Cardiology*

Heart Failure – Continued progress in SAHARA DESERT and DSR® development programme

- First patients enrolled in SAHARA DESERT
  - Plan for 20 decompensated heart failure patients with persistent congestion despite high doses of diuretics
  - Evaluate ability of **alfa**pump DSR® to eliminate persistent congestion, restore correct fluid status (euvolemia) and improve cardio-renal condition for up to 22 weeks
  - Interim data expected in Q4 2021 / Top-line data expected in H2 2022

- DSR development progressing
  - Key patents for **alfa**pump DSR granted in US and EU
  - Continued pre-clinical development of proprietary DSR Infusate 2.0
  - Introduced Short-Term DSR therapy complementing **alfa**pump DSR therapy

Key Financial Results H1 2021

Revenue: **€23K**

- Reduced supply of **alfa**pump to European commercial markets
- Impact of COVID-19 on **alfa**pump procedures in Germany and France

Operating expenses: **- €11,501K**

- Preparations for submissions for marketing approval in US and Canada
- DSR pre-clinical and clinical development

Net result: **- €11,890K**

- **Cash position of €21.8M at end of June 2021**
  - Q1 2021: ABB Equity Offering (€22.5M)
- **Cash runway extended into Q2 2022**

Highly experienced leadership team

Appointment of Jackie Fielding, replacing Jason Hanon as Non-Executive Director

Executive team:

Ian Crosbie
Chief Executive Officer

Kirsten Van Bockstaele
Chief Financial Officer

Oliver Gödje
Chief Medical Officer

Dragomir Lakic
VP Manufacturing

Gijs Klarenbeek
Senior Medical Advisor

Martijn Blom
Chief Commercial Officer

Timur Resch
Global VP QM/QA/RA

Andreas Wirth
VP Engineering

Board of Directors:

Pierre Chauvineau
Board Chairman

Ian Crosbie
Chief Executive Officer

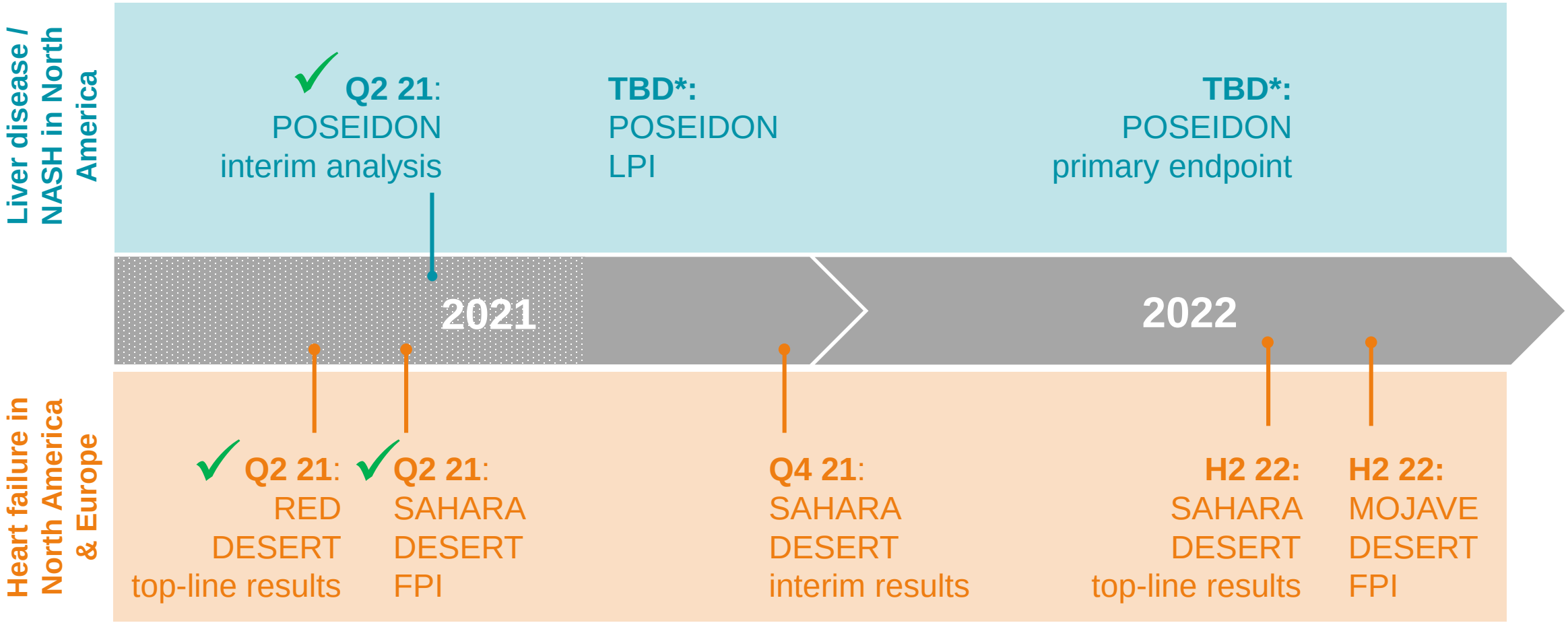
Wim Ottevaere
Director

Jackie Fielding
Director

Rudy Dekeyser
Director

Erik Amble
Director

Expected core value drivers & outlook



** Pending further clarity from the FDA on study expansion – the Company will update the market as soon as possible*

Note: Presented timelines are subject to further developments related to the COVID-19 pandemic

***FPI:** First Patient In; **LPI:** Last Patient In*

Q&A