

# sequana**medical**

## H1 2020 Financial Results & Business Update

3 September 2020



# Today's presenters



**Ian Crosbie**  
Chief Executive Officer



**Kirsten Van Bockstaele**  
Chief Financial Officer

# Forward-Looking Statements

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# Disclaimers

## Regulatory disclaimer:

- The **alfapump**® system is not currently approved in the United States or 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 see [www.poseidonstudy.com](http://www.poseidonstudy.com).
- The DSR therapy is still in 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. The DSR therapy is not currently approved for clinical research in the United States or Canada. There is no link between the DSR therapy and ongoing investigations with the **alfapump**® system in Europe.

## 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 its operations as necessary.
- Sequana Medical has put in place mitigation plans to minimise delays. The impact of increased demands on the healthcare systems, restrictions 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.

# Agenda

- ✔ YTD 2020 Highlights
- ✔ Business Update
- ✔ Key Financial Results H1 2020
- ✔ Core Value Drivers & Outlook
- ✔ Q&A

# YTD 2020 Highlights

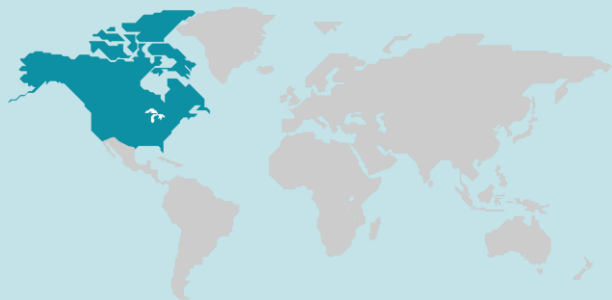
- POSEIDON – implants in Canada continue, interim results expected in H1 2021
- RED DESERT – implants continue, interim results expected in Q4 2020
- DSR – fundamental patents allowed in US and Europe
- Continued growth in European commercial implants
- Positive data published in two leading peer-reviewed publications
- Appointment of Dr Oliver Gödje as Chief Medical Officer
- Cash runway extended into H2 2021 through
  - ✓ €19M equity financing (January 2020)
  - ✓ €7.3M debt financing (July 2020)

# Strategic Focus



**alfapump®**

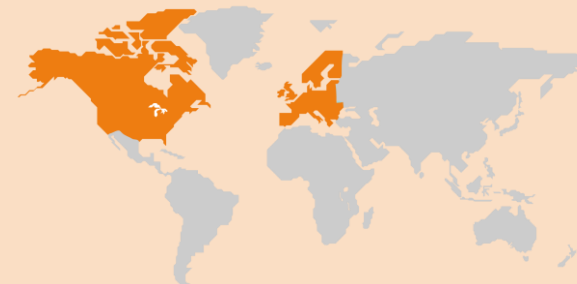
## Liver Disease (NASH)



- POSEIDON pivotal study ongoing
- Self-commercialisation

**alfapump® DSR**

## Heart Failure



- RED DESERT repeated dose study ongoing
- Partnering after US feasibility study

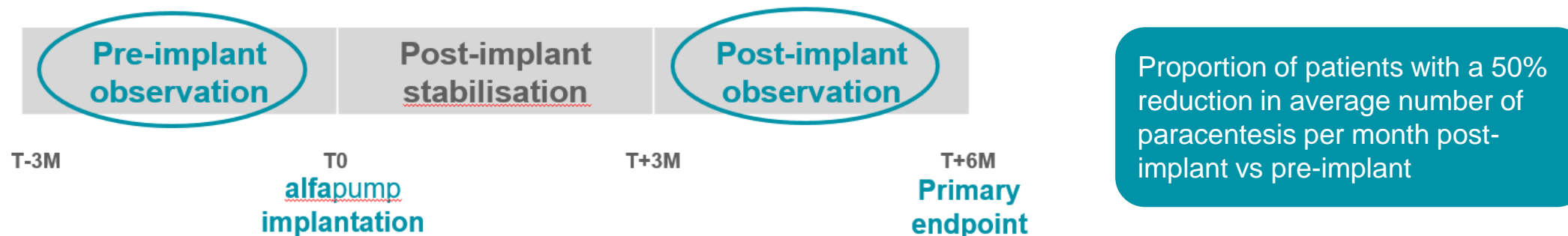


**Built upon proven European clinical & commercial experience**



# POSEIDON – to support approval in US and Canada

North American pivotal study of the alfapump® in recurrent and refractory ascites due to liver cirrhosis



- Delay due to COVID-19 restrictions on travel and non-essential hospital visits and procedures
  - Canadian sites resumed implants in patients
  - US sites continued patient screening. Patient enrolment expected to resume in [Q4 2020](#)
  - Completion of patient enrolment expected in [Q1 2021](#)
- Roll-in cohort: up to 30 patients ⇒ interim results expected in [H1 2021](#)
- Study cohort: up to 50 patients ⇒ primary endpoint read-out expected in [Q1 2022](#)
- FDA regulatory submission expected in [H1 2022](#)

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





# Limitations of Diuretic Therapy in Heart Failure

High unmet need for safe and effective chronic treatment solution to treat volume overload

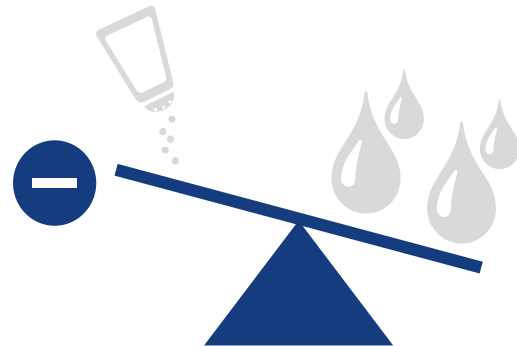


- *40% of heart failure patients on IV loop diuretics have a poor response*
- *24% hospital re-admission rate at 30 days*

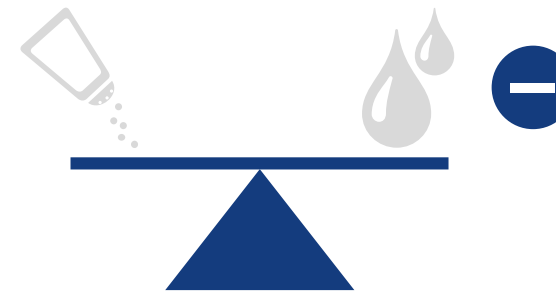


# Direct Sodium Removal (DSR)

Sequana Medical's breakthrough approach to volume overload in heart failure



DSR therapy directly removes the sodium



Body eliminates excess fluid

**“DSR represents a new potential therapy for non-renal sodium and fluid removal in edematous disorders such as heart failure”**

Circulation

**First in Human Experience with Peritoneal Direct Sodium Removal Using a Zero Sodium Solution: A New Candidate Therapy for Volume Overload**

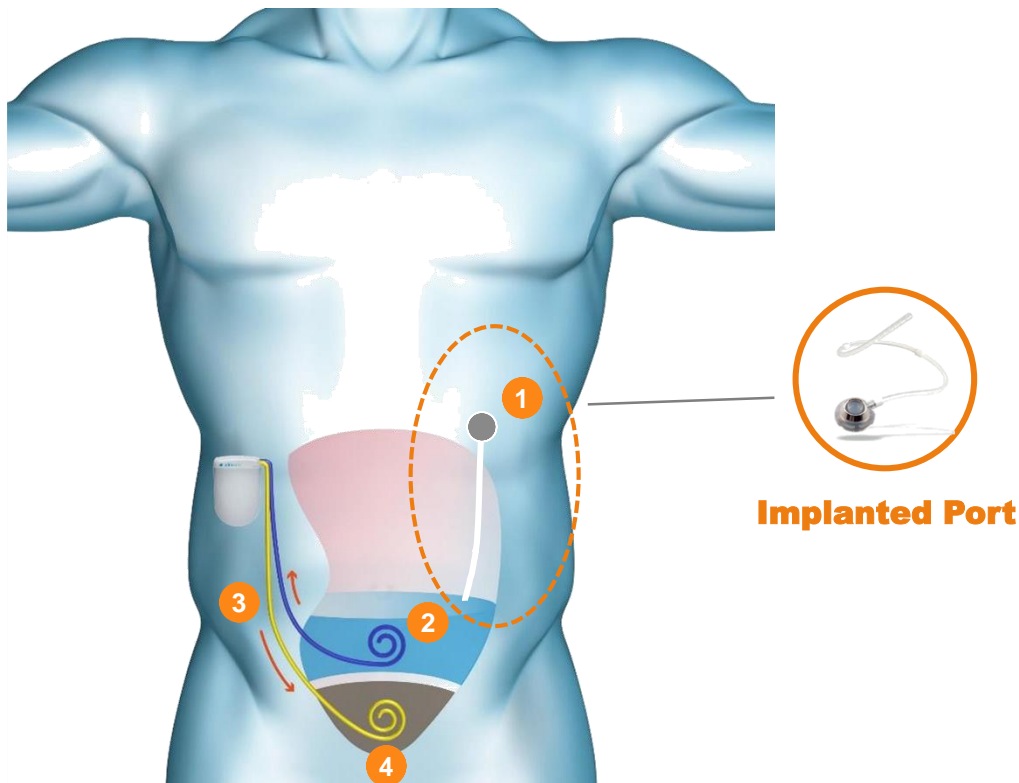
Veena S. Rao, Jeffrey M. Turner, Matthew Griffin, Devin Mahoney, Jennifer Asher, Sangchoon Jeon, Peter S. Yoo, Nabil Boutagy, Attila Feher, Albert Sinusas, F. Perry Wilson, ... [Show all Authors](#) ▾

Originally published 8 Jan 2020 | <https://doi.org/10.1161/CIRCULATIONAHA.119.043062> | Circulation. ;0:null



# alfapump<sup>®</sup> DSR

Potential chronic therapy for heart failure patients that are not well controlled on diuretics

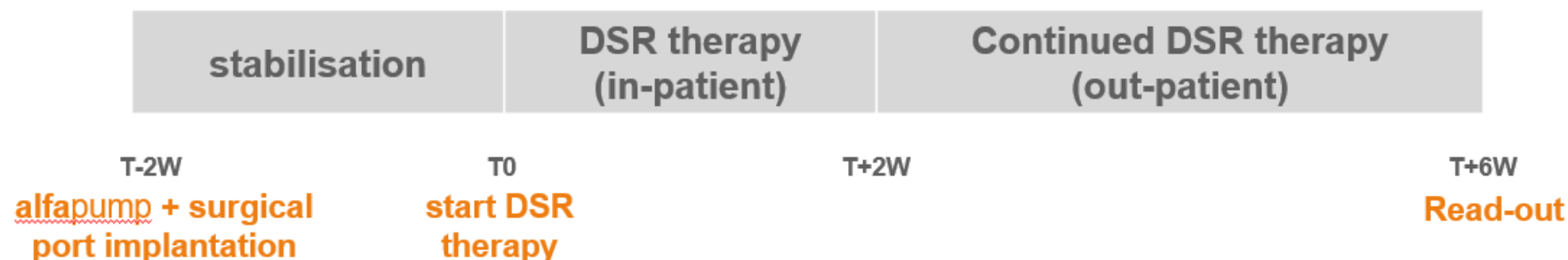


- ✓ Direct Sodium Removal
- ✓ alfapump system
- ✓ Implanted port



# RED DESERT

Repeated dose proof-of-concept study of the alfapump<sup>®</sup> DSR in diuretic-resistant heart failure patients



- Patient enrolment resumed
- Interim results (up to 5 patients) expected in Q4 2020
- Top-line results (up to 10 patients) expected in H1 2021
- Key Opinion Leader (KOL) event planned in Q4 2020

**Safety:** absence/rate of device, procedure and/or therapy related serious adverse events

**Feasibility:** ability of the alfapump DSR to maintain a neutral sodium balance and maintain euvolemia

**Exploratory:** impact of DSR to restore response to diuretics

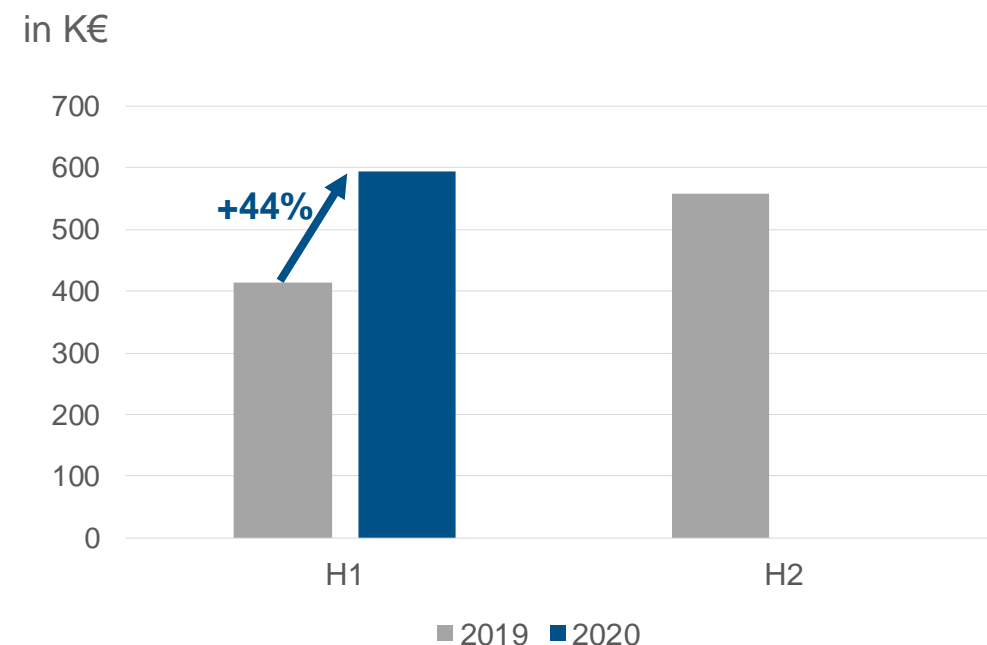


# Continued growth in European commercial sales

Refined focus on key markets



H1 2020 revenue up +44% vs H1 2019



# Key Financial Results H1 2020

**Revenue:** €595K (+ 44%)

- Strong growth in Germany and France

**Operating expenses:** - €9,397K (+ 31%)

- Ongoing Clinical studies and associated Supply Chain costs

**Net result:** - €9,554K

**Cash position of €14.9M at end of H1 2020**

**Post period:**

- Repayment Bootstrap loan (€3.2M)
- Debt financing (€7.3M)

**Cash runway extended  
into H2 2021**

# €7.3M Debt Financing in July 2020

- Three-year subordinated unsecured loan
- Straight loan of €5.9M (6% interest)
- Convertible part of €1.4M (5% interest)
  - in the event of an equity financing or sale of the Company
  - at 75% of the price of the Company's shares as will be reflected in the equity financing or sale
- Repayable in full (principal and interest) upon expiry of the term (July 2023)

# Expected Core Value Drivers & Outlook

## Outlook:

## Objectives:

Liver disease / NASH in NA

Q1 21:  
POSEIDON  
enrolment  
completion

H1 21:  
POSEIDON  
interim  
results

Q1 22:  
POSEIDON  
primary endpoint  
read-out

Obtain regulatory approval of the **alfapump**<sup>®</sup> for treatment of recurrent and refractory ascites and commercialise through our **own specialty salesforce**

H2 2020

2021

H1 2022

Heart failure in NA & EU

Q4 20:  
RED DESERT  
interim results

H1 21:  
RED DESERT  
top-line results

H2 21:  
Start US  
feasibility study

Advance clinical development of the **alfapump** DSR for treatment of volume overload and establish a **strategic partnership** for development and commercialisation post US feasibility study

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



# Q&A

