

sequana**medical**



Innovators in the management
of **fluid overload**

liver disease – malignant ascites – heart failure

Investor presentation – October 2020

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.
- 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.

Company Overview

- Founded in 2006
- Gent, Belgium (HQ): corporate, clinical, commercial
- Zurich, Switzerland: manufacturing, engineering, QA/RA
- ~50 employees
- Euronext Brussels: SEQUA



alfapump[®] platform

Using the bladder to manage fluid overload



Fully implanted



Automatic operation



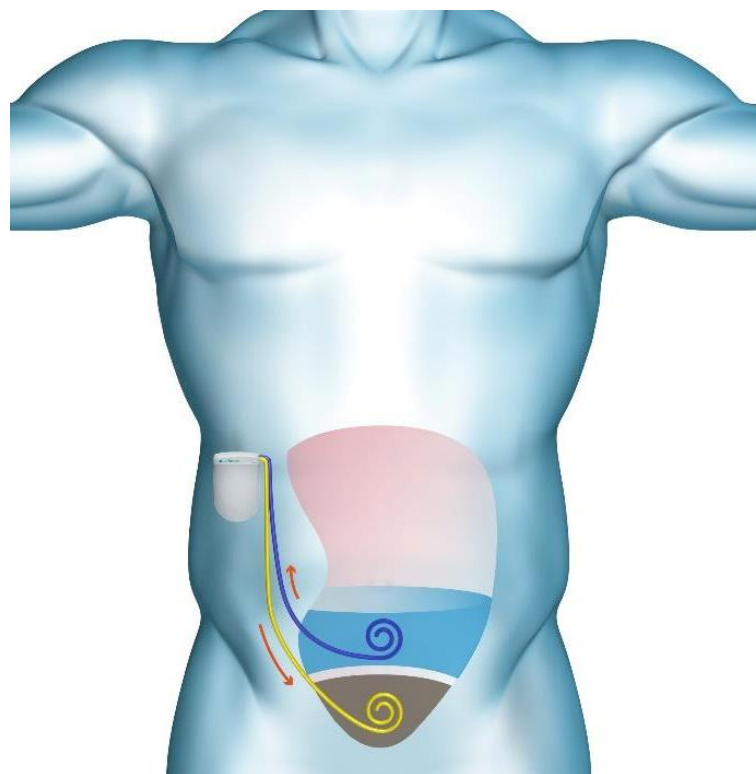
Wireless battery charging



Settings wirelessly adjusted



Remote data monitoring



Easy implantation



Long-term implantation & catheter patency



Moves up to 4 litres / day



Virtually non-clogging



No significant heating during charging and operation

Strong IP barriers through extensive patent portfolio & know-how

One platform – two products



alfapump®

Liver Disease (NASH)

Proven step change in liver refractory ascites
and malignant ascites

Over 800 devices implanted



~145 K

patients / year with refractory ascites due to
NASH within next 10-20y⁽¹⁾

> €3 Bn / year
market opportunity



alfapump® DSR

Heart Failure

Breakthrough approach to fluid overload in
heart failure

Clinical proof-of-concept of
Direct Sodium Removal (DSR)



~400 K

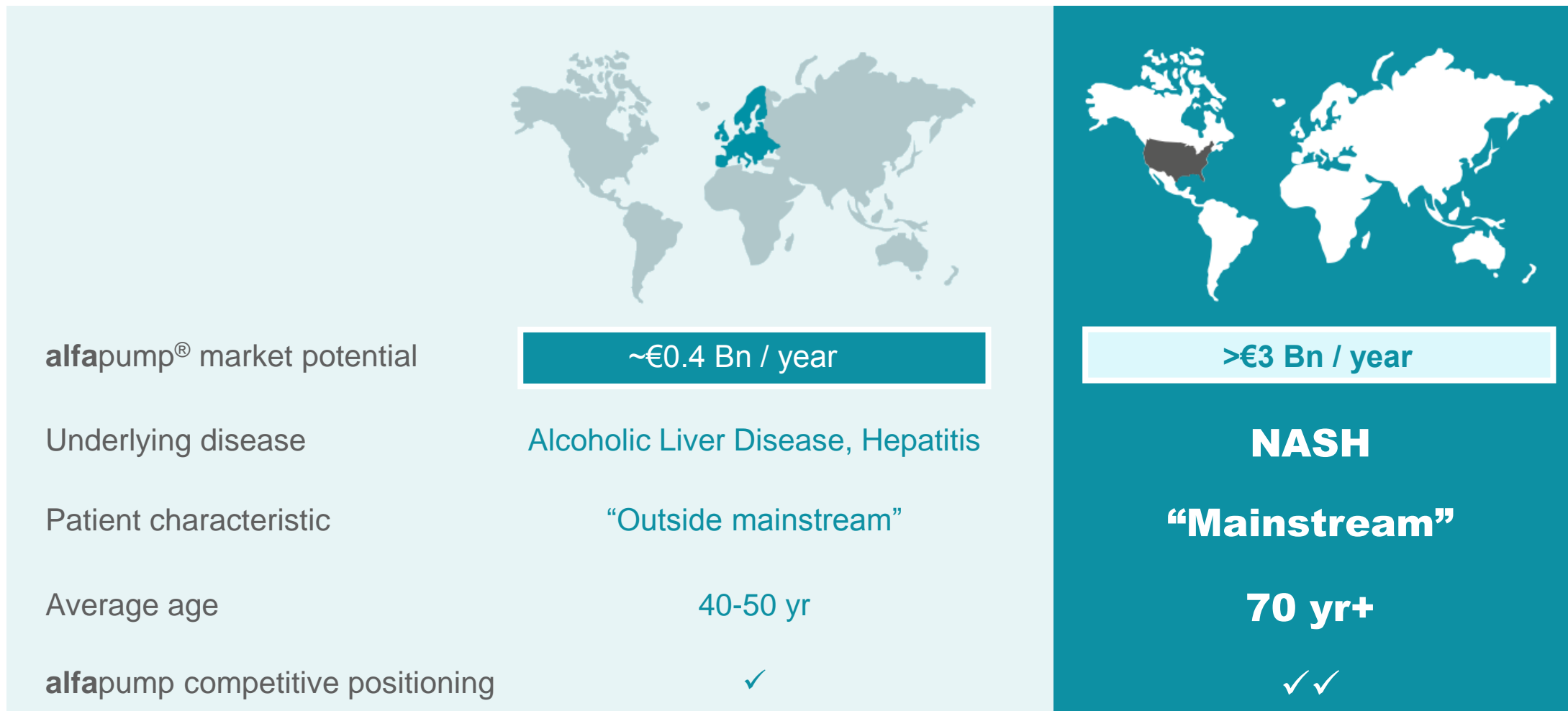
patients / year hospitalised for volume
overload due to heart failure by 2026⁽²⁾

> €5 Bn / year
market opportunity

Built upon proven European clinical & commercial experience

NASH drives US market attractiveness

Stronger competitive position in a much larger and dynamic market





alfapump®

Proven step change in the management of liver refractory ascites and malignant ascites

Liver cirrhosis and refractory ascites

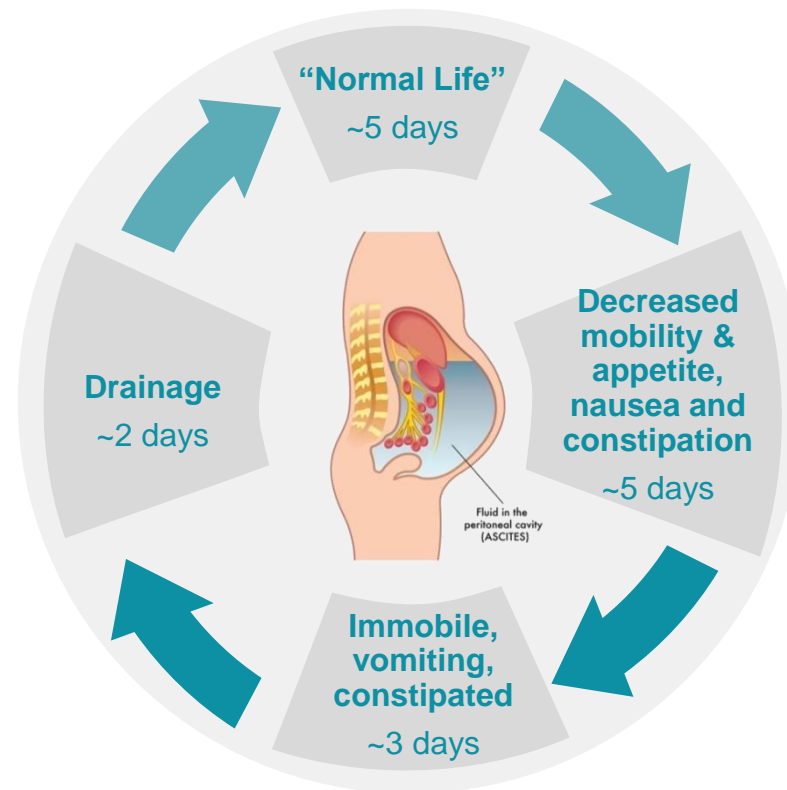
A key complication of liver cirrhosis, with a dramatic impact on quality of life

- 

Viral infections
(Hepatitis B & C)
- 


Alcoholic Liver Disease
- 


Non-Alcoholic Steatohepatitis (NASH)




Typical patient life⁽⁴⁾

US forecast

- 

Liver cirrhosis
~3-4M⁽¹⁾
- 

Ascites
~1.5M⁽²⁾
- 

Refractory Ascites
~150K⁽³⁾

Note : Prevalence of NASH in US is expected to increase by 63% between 2015-2030; Estes et al., 2018

Source 1 Management estimate in US based on Estes et al; GlobalData Nash Epidemiology Forecast to 2026; Noureddin et al., 2013

Source 2: Runyon 2009: approximately 50% of cirrhotic patients develop ascites within 10 years of diagnosis of cirrhosis

Source 3: Ginès et al., NEJM 2004: refractory ascites occurs in 5-10% patients with ascites

Source 4: Presentation of Dr. Rajiv Jalan at EASL in 2018, Large Volume Paracentesis (LVP) treatment cycle for refractory ascites

Cancer and malignant ascites

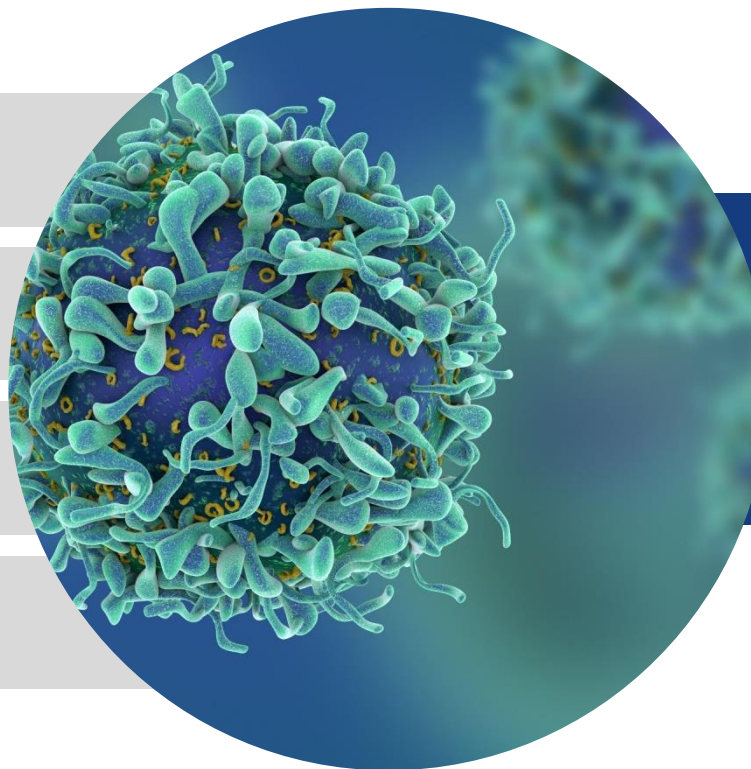
Severe complication of late-stage cancers

Fluid accumulation in the abdomen due to **drainage of lymph system**

Breast and ovarian cancer have longest survival with ascites⁽¹⁾

Severe impact on **quality of life**

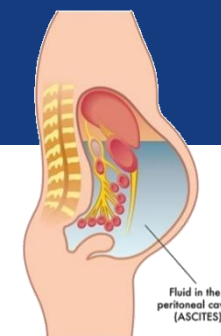
Reduces ability to undergo **anti-cancer treatment**



Malignant ascites due to breast and ovarian cancer⁽²⁾:

EU5: ~18K

US: ~16K



Clear unmet need for improving Quality of Life and the ability to increase cancer treatment intensity

Source 1: Ayantunde & S. L. Parsons. Annals of Oncology 2007

Source 2: Management estimate based on WHO cancer incidence rates (2018) and Ayantunde & S. L. Parsons. Annals of Oncology 2007.

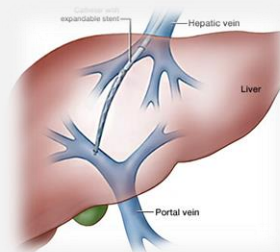
Severe limitations of existing therapies

Diet / Diuretics



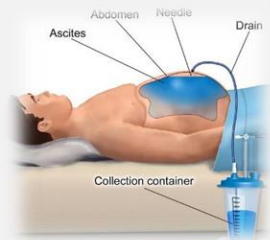
Resistance,
Complications

Transjugular Intrahepatic Portosystemic Shunt (TIPS)



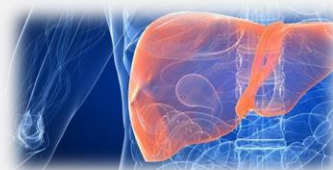
Complications,
Contraindications

Drainage (“Large Volume Paracentesis / LVP”)



Painful, Poor Quality of
Life, Short Term Benefit

Liver transplantation



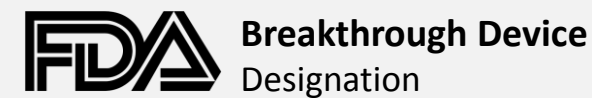
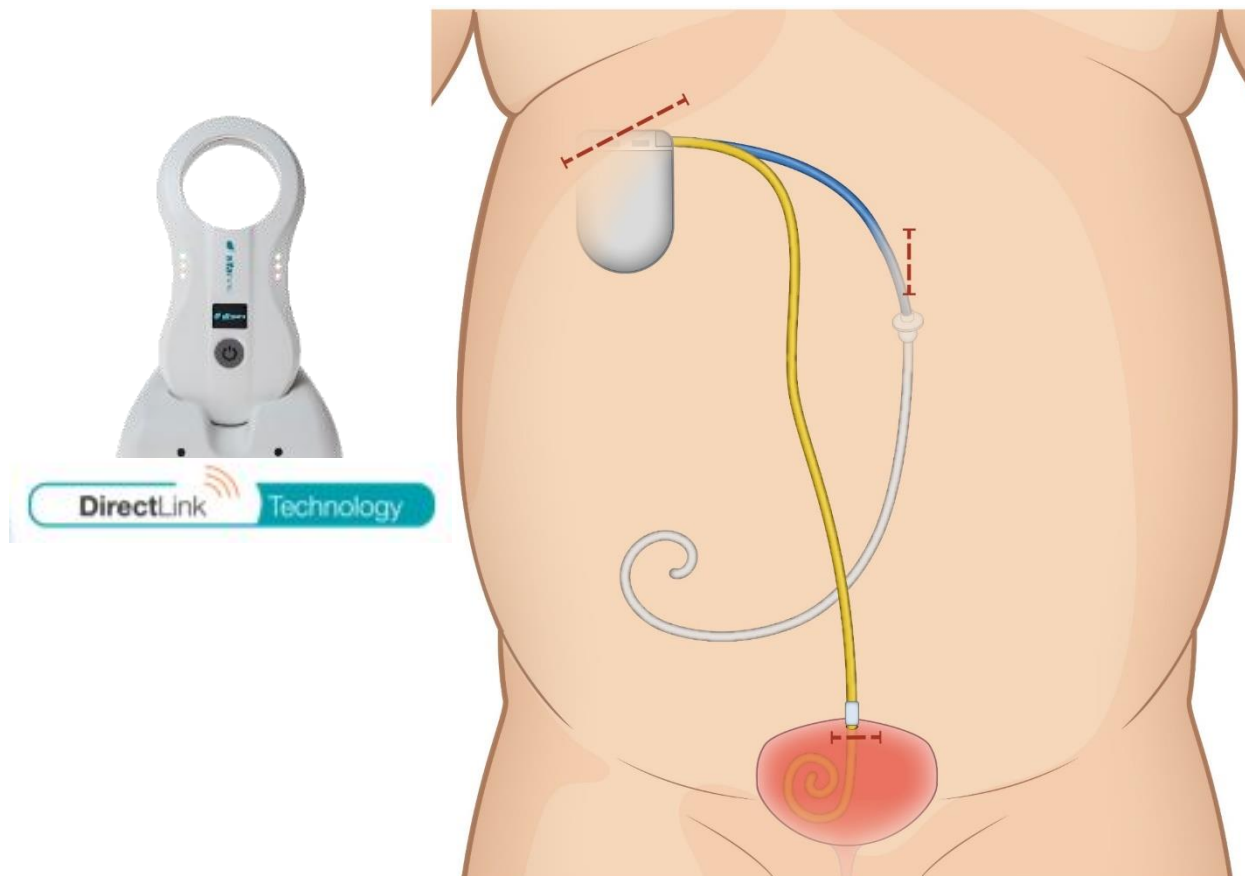
High Cost,
Limited Availability

alfapump®






alfapump® for long-term treatment

Over 800 implants and hundreds of years of patient experience



Strong health economics rationale

Significant reduction in regular drainage leads to:

-  Reduced burden of disease
-  Improved patient QoL
-  Cost savings for hospitals and payers

Estimated treatment cost / patient*:

LVP: ~\$54K ↔ **alfapump®: ~\$35K**

~\$1,8K / LVP⁽¹⁾

2 LVP / month

15 months

~\$25K / alfapump

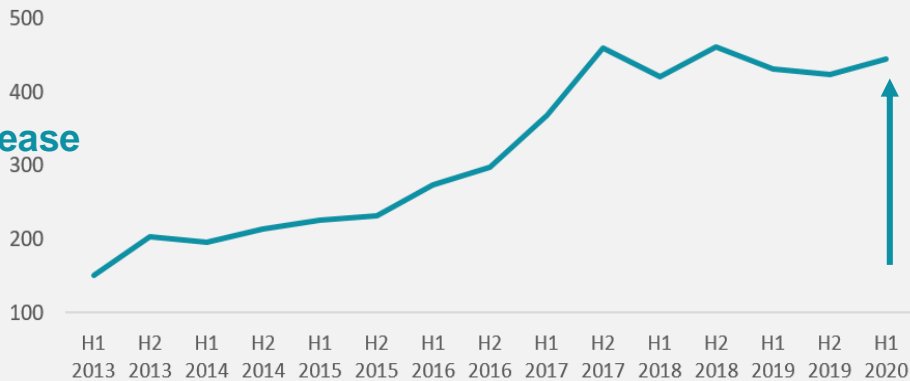
~\$10K / implantation

Strong clinical validation



Clear increase in clinical outcomes

Avg days of alfapump therapy / patient

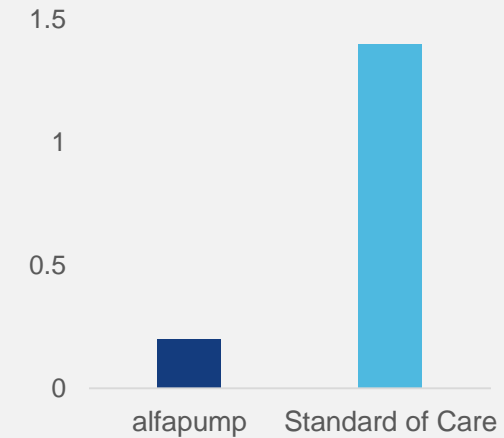


Sequana Medical data



Drastically reduced need for drainage

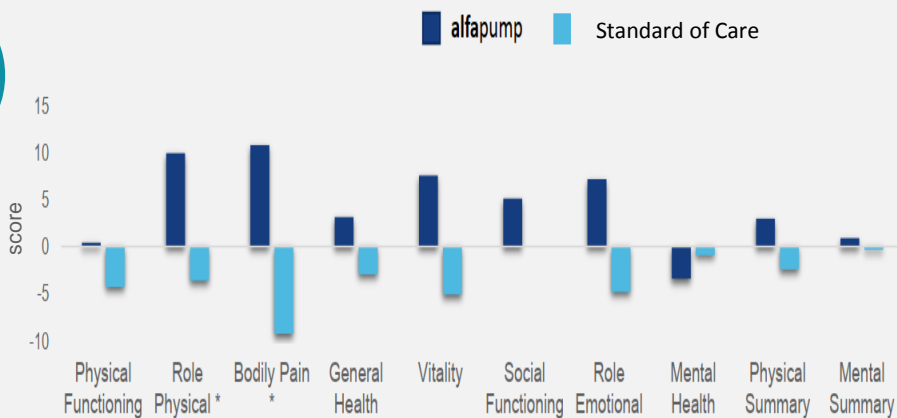
Mean # drainages / patient / 28 days



Results RCT study



Improved quality of life



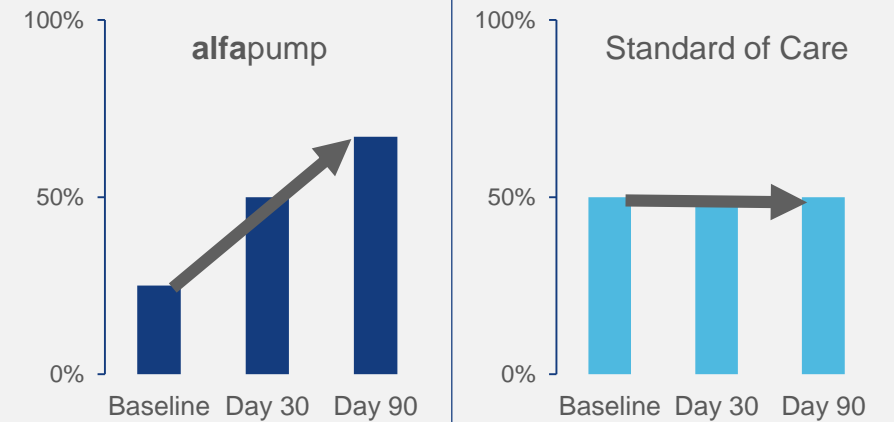
Results RCT study

* p<0.05



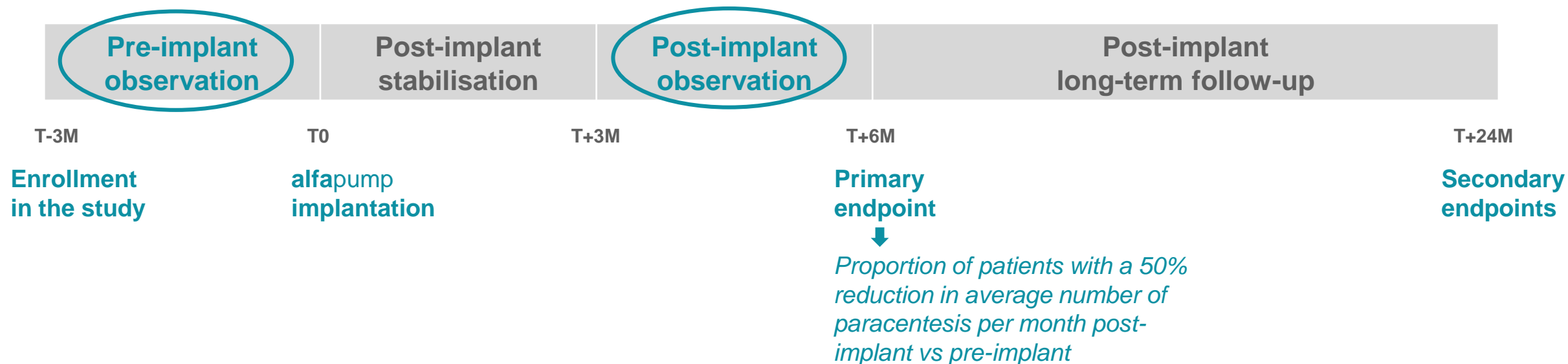
Improved nutrition

% patients adequately nourished



Results RCT study

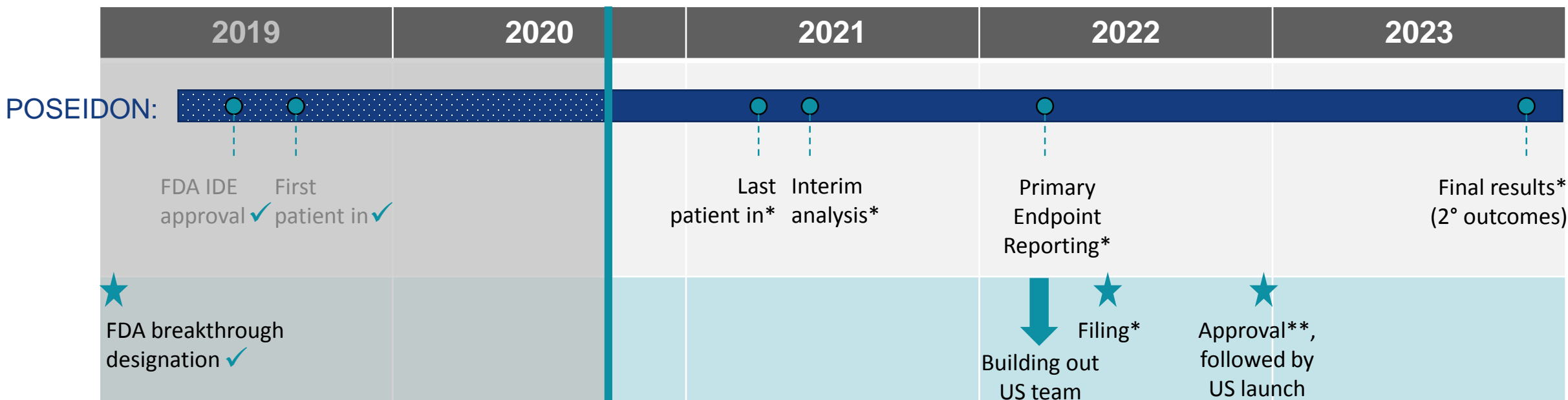
North American Pivotal Study (POSEIDON) underway



- 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

alfapump® US approval roadmap

Key anticipated milestones*



Final CMS rule on reimbursement for breakthrough devices (NTAP)

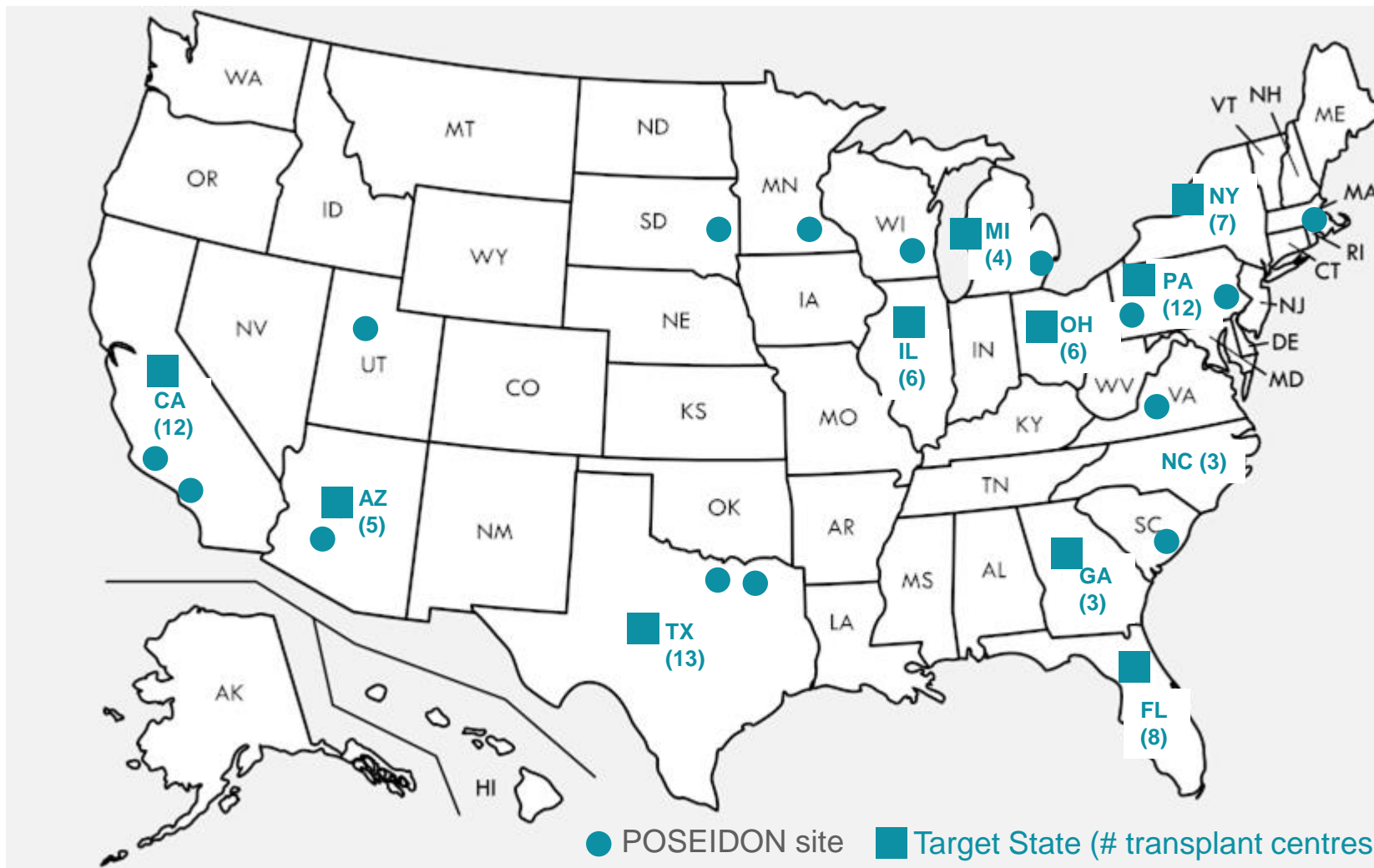
*expected to further support reimbursement for the **alfapump***

* Subject to further developments related to the ongoing COVID-19 pandemic

** Subject to FDA review timelines

FDA: Food and Drug Administration (US); IDE: Investigational Device Exemption; NTAP: New Technology Add-on Payment

Self-commercialisation in US through specialty salesforce



Initial focus on key transplant centres

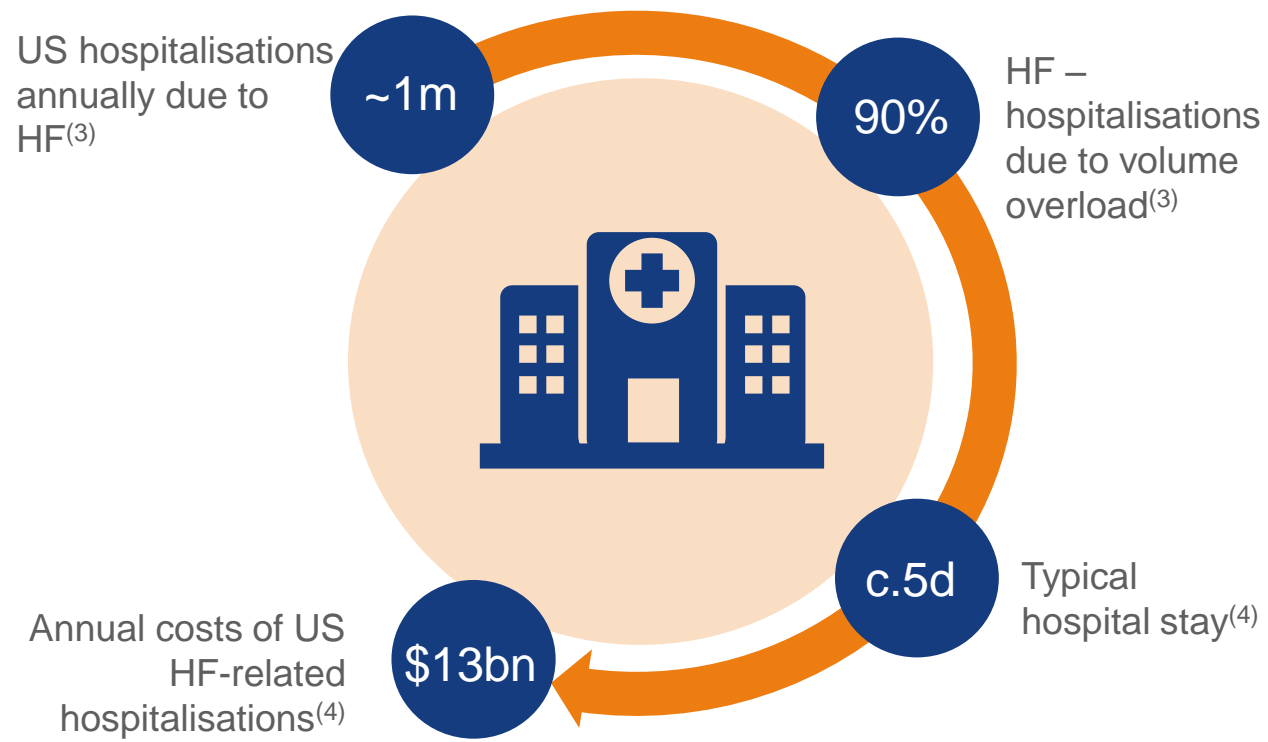
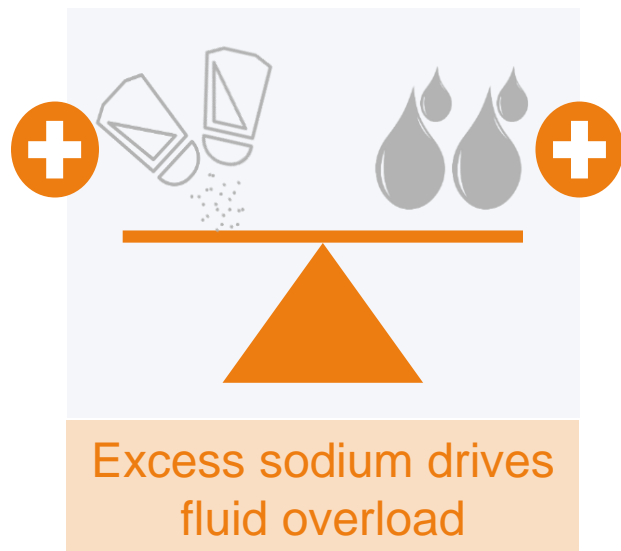
~50-person team:
35 sales reps, 10 clinical,
5 corporate



alfapump[®] DSR

Breakthrough approach to
volume overload in heart failure
built on proven **alfapump** platform

Volume overload in heart failure – major clinical problem and key driver of costs



- 40% of heart failure patients on IV loop diuretics have a poor response⁽¹⁾
- 24% re-admission rate at 30 days⁽²⁾

Direct sodium removal (DSR)

Remove the sodium and the body will eliminate the excess fluid



Administer
infusate to
peritoneal
cavity

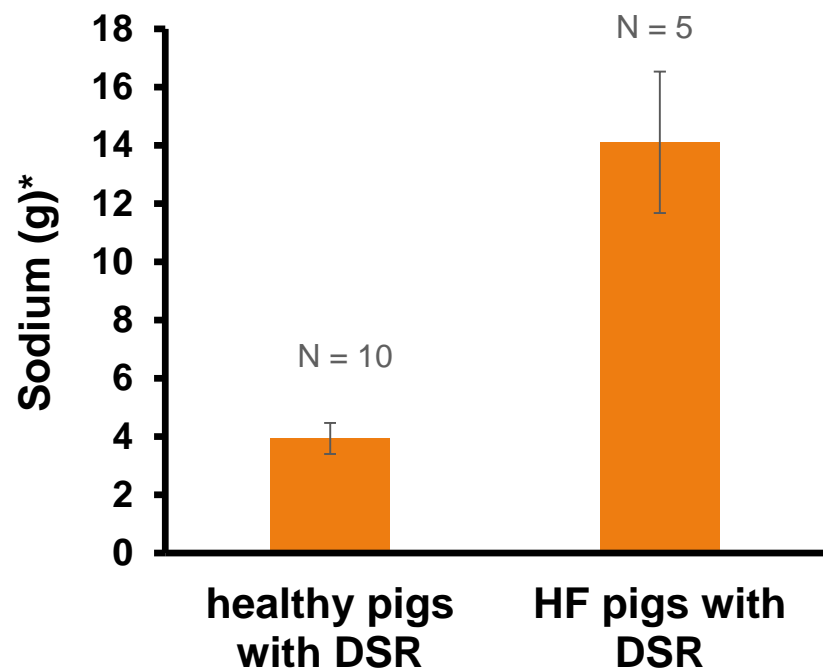
Infusate
extracts sodium
from the body

alfapump[®]
removes
extracted sodium
from peritoneal
cavity via
bladder

Body restores
balance by
eliminating
excess fluid

DSR pre-clinical and clinical Proof-of-Concept

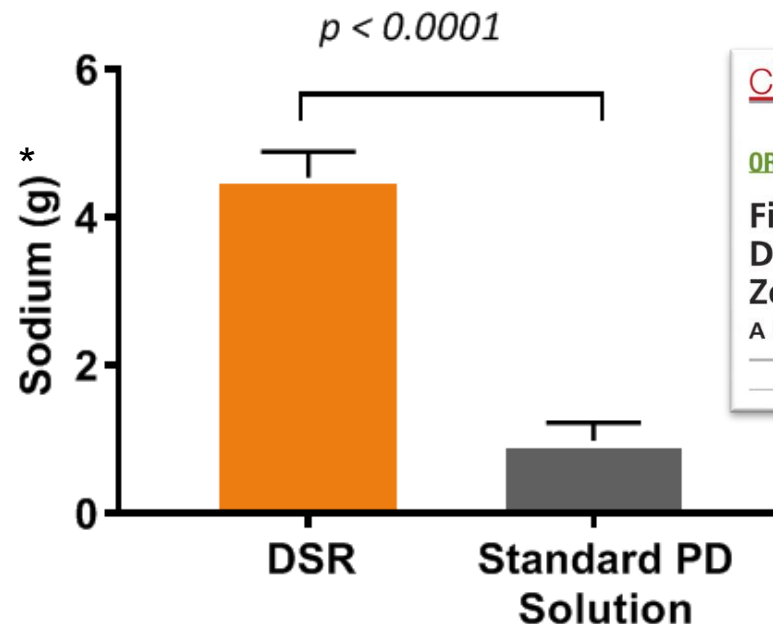
Pre-clinical studies¹



1: administration of 1 litre DSR infusate, with 2 hour dwell

* Weekly recommended intake for humans equals 14 grams (www.cdc.gov)

First-in-human study² (N=10)



2: Cross-over study: administration of 1 litre DSR infusate (D10) vs. standard PD solution, with 2 hour dwell

[Circulation](#)

ORIGINAL RESEARCH ARTICLE

First-in-Human Experience With Peritoneal Direct Sodium Removal Using a Zero-Sodium Solution

A New Candidate Therapy for Volume Overload

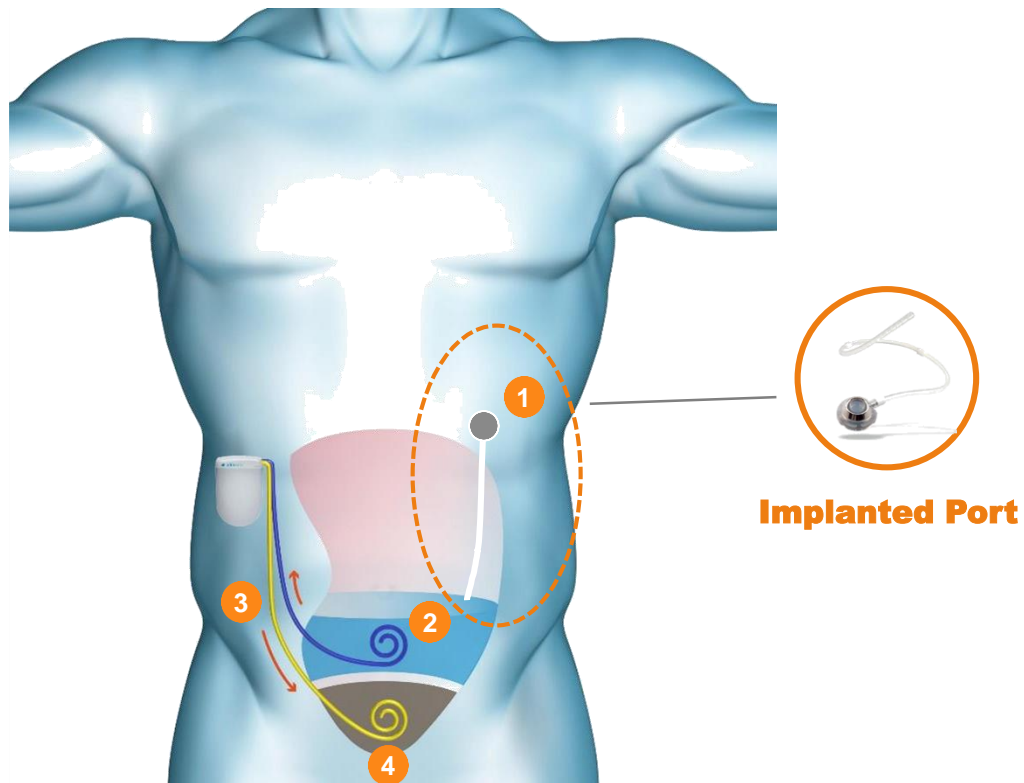
Editorial, see p 1054

Veena S. Rao, PhD

DSR therapy is capable of removing large quantities of sodium in a safe, tolerable and consistent manner

alfapump[®] DSR

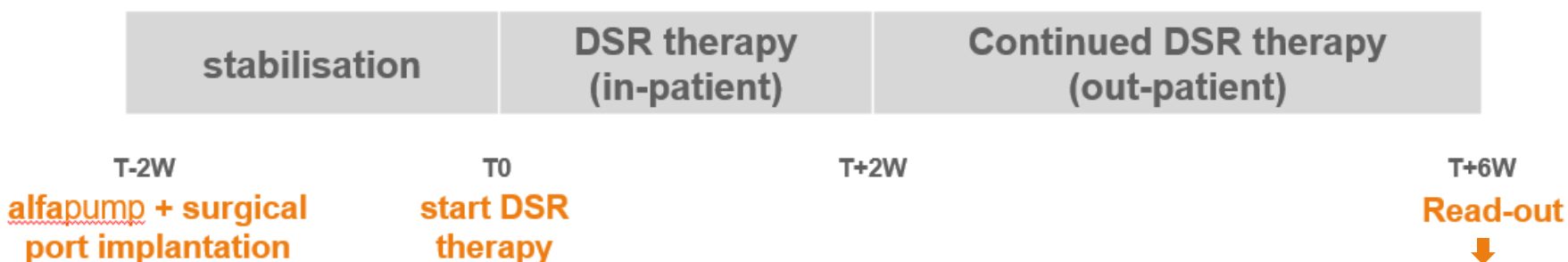
Potential chronic therapy for heart failure patients that are not well controlled on diuretics



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

Fundamental patents to reduce fluid overload in heart failure allowed in US and Europe

RED DESERT – Repeated dose alfapump® DSR study for treatment of diuretic-resistant heart failure patients



- **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

- Interim results (up to 5 patients) expected in Q4 2020
- Top-line results (up to 10 patients) expected in H1 2021

Leading experts as Heart Failure Scientific Advisors



Dr. Maria Rosa Costanzo

Medical Director of the Edward Center for Advanced Heart Failure
Medical Director Heart Failure Research for the Advocate Heart Institute



Dr. Wilson Tang

Professor of Medicine at Cleveland Clinic Lerner College of Medicine at Case Western Reserve University



Dr. Javed Butler

Professor and Chairman of the Department of Medicine at the University of Mississippi Medical Center

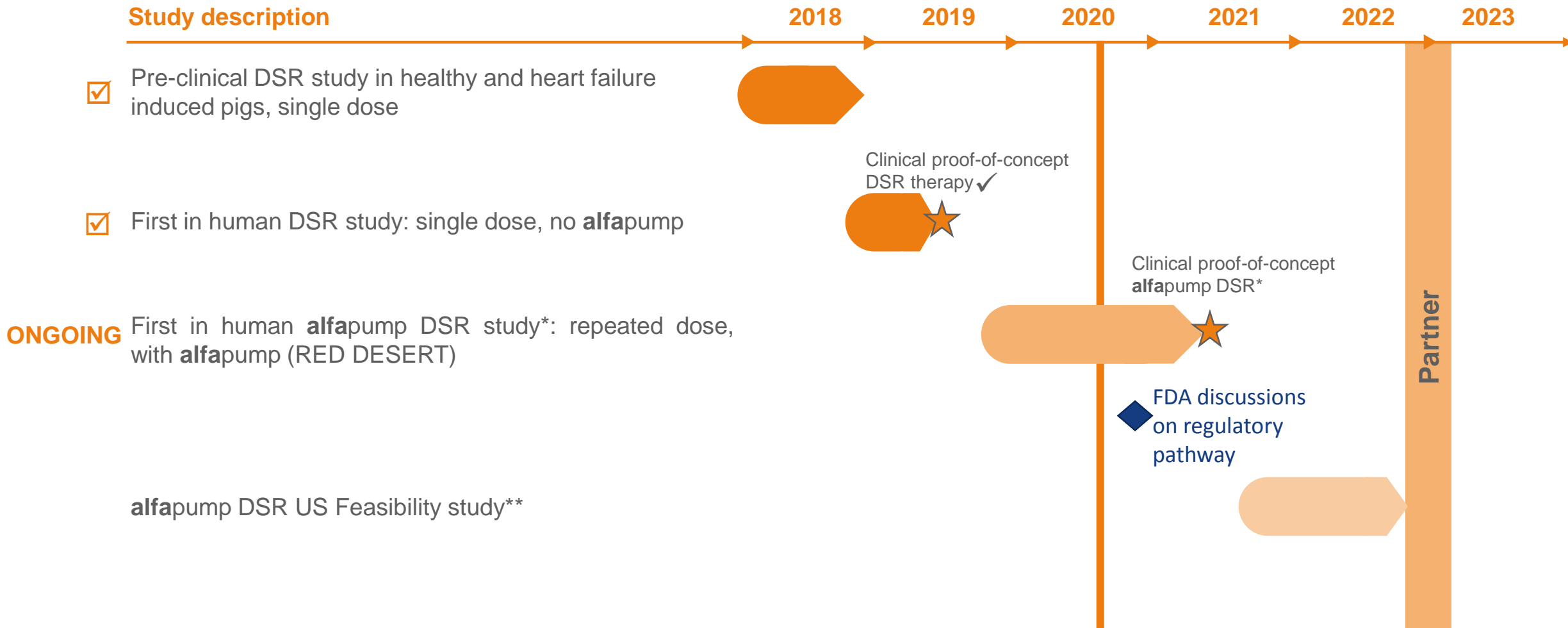


Dr. Jeffrey Testani

Associate Professor of Medicine and Director of Heart Failure Research at Yale University School of Medicine

alfapump[®] DSR development strategy

Study description



* Subject to further developments related to the ongoing COVID-19 pandemic

** Subject to change and/or feedback from applicable regulatory authorities



Conclusion

Experienced **leadership team**

Value creation in the short term

Strong organisation

Highly experienced leadership team supported by committed and well-reputed shareholders

Executive team:



Ian Crosbie
Chief Executive Officer



Kirsten Van Bockstaele
Chief Financial Officer



Oliver Gødje
Chief Medical Officer



Martijn Blom
Chief Commercial Officer



Gijs Klarenbeek
Senior Medical Advisor



Dirk Fengels
VP Engineering & Manufacturing



Timur Resch
Global VP QM/QA/RA

Board of Directors:



Pierre Chauvineau
Board Chairman



Ian Crosbie
Chief Executive Officer



Wim Ottevaere
Director



Jason Hannon
Director

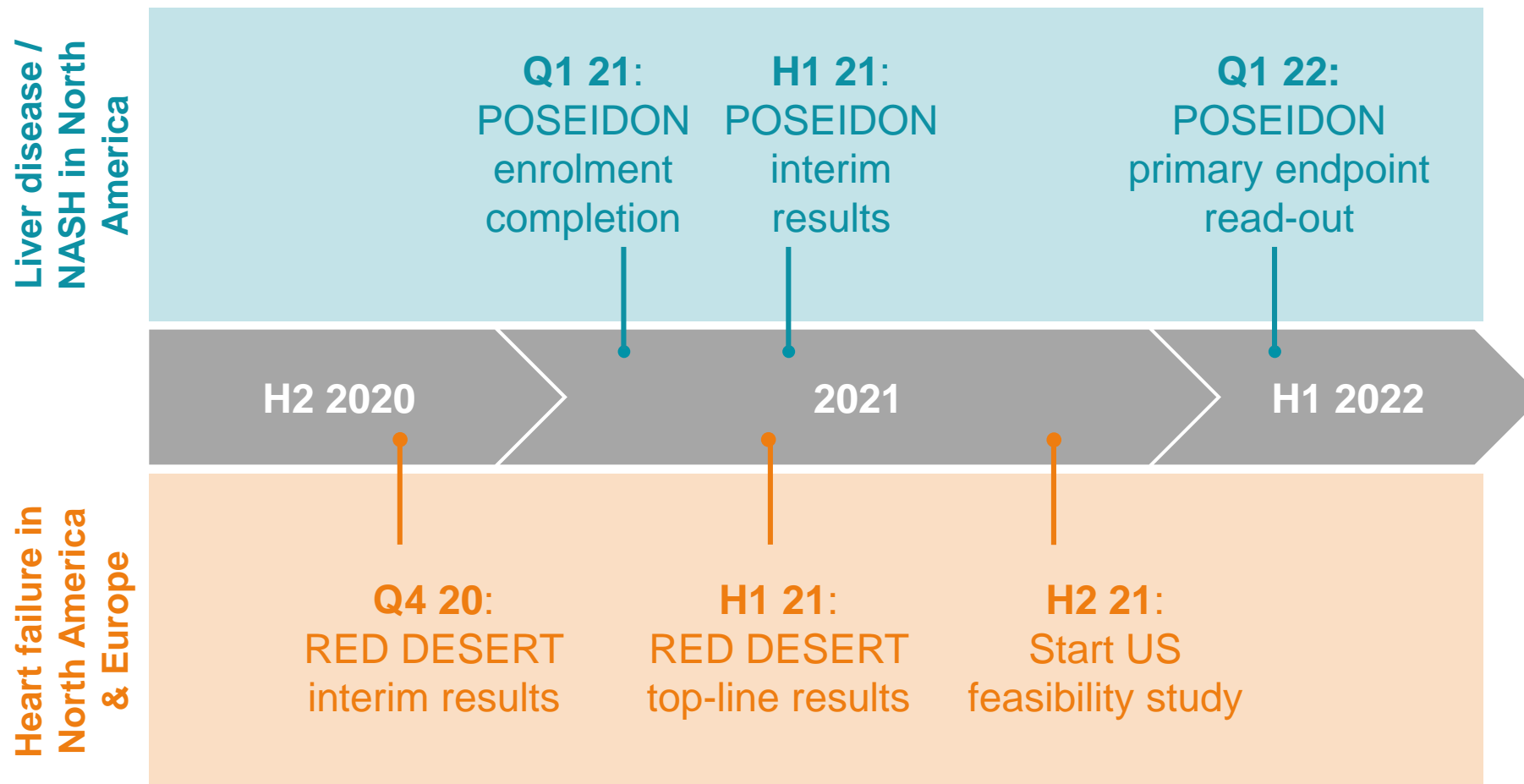


Rudy Dekeyser
Director



Erik Amble
Director

Expected Core Value Drivers & Outlook



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

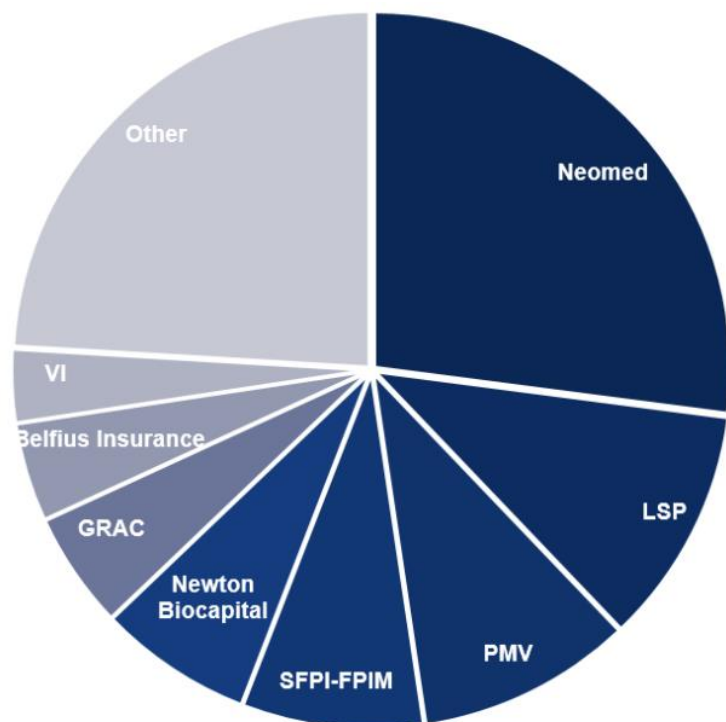
Back-up



Shareholders base and financial overview

Ticker: SEQUA – Euronext Brussels

- Outstanding shares: 15.8M
- Outstanding share options & warrants: 1.9M authorised of which 0.9M granted



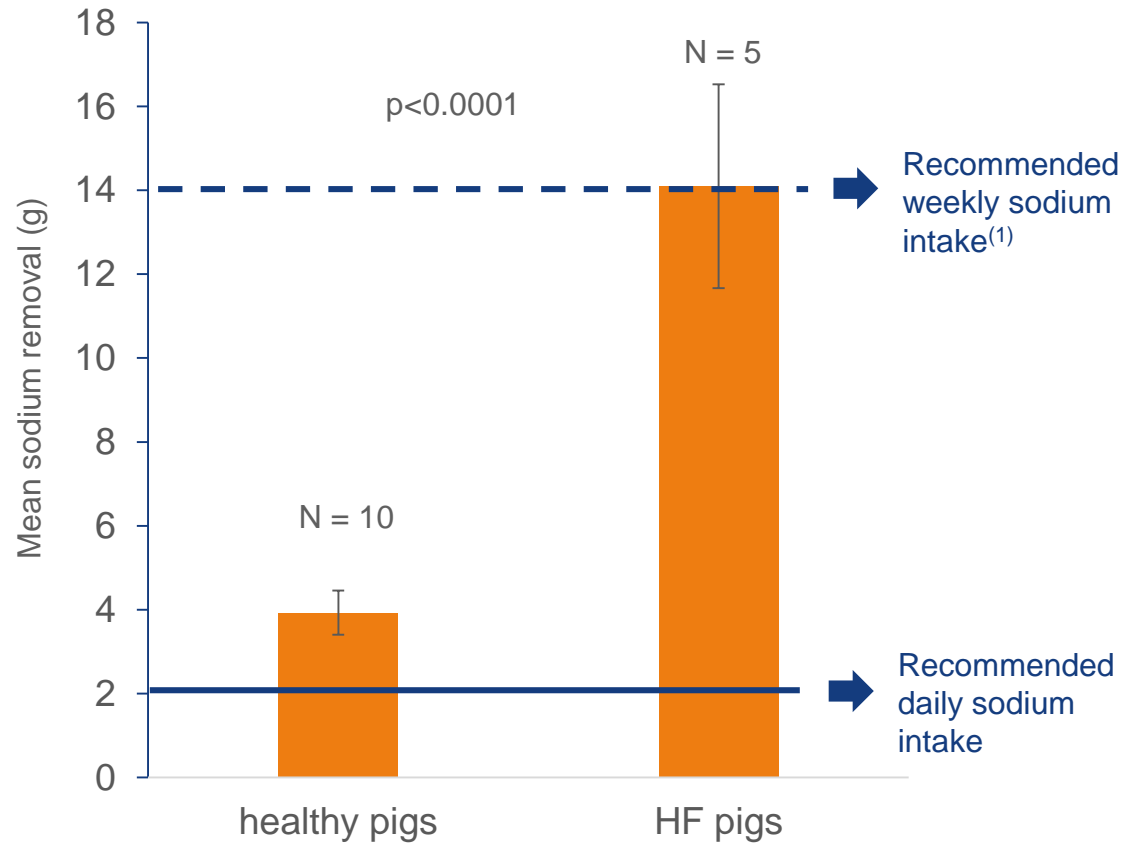
- Analysts:
 - KBC Securities – Sandra Cauwenberghs & Lenny Van Steenhuyse
 - Kempen – Ingrid Gafanhão
 - Kepler Cheuvreux – Matthias Maenhaut
 - Mirabaud – Daniel Jelovcan
- Cash (30 June 2020): €14.9M
- Debt financing in July 2020: €7.3M
- Cash runway into H2 2021



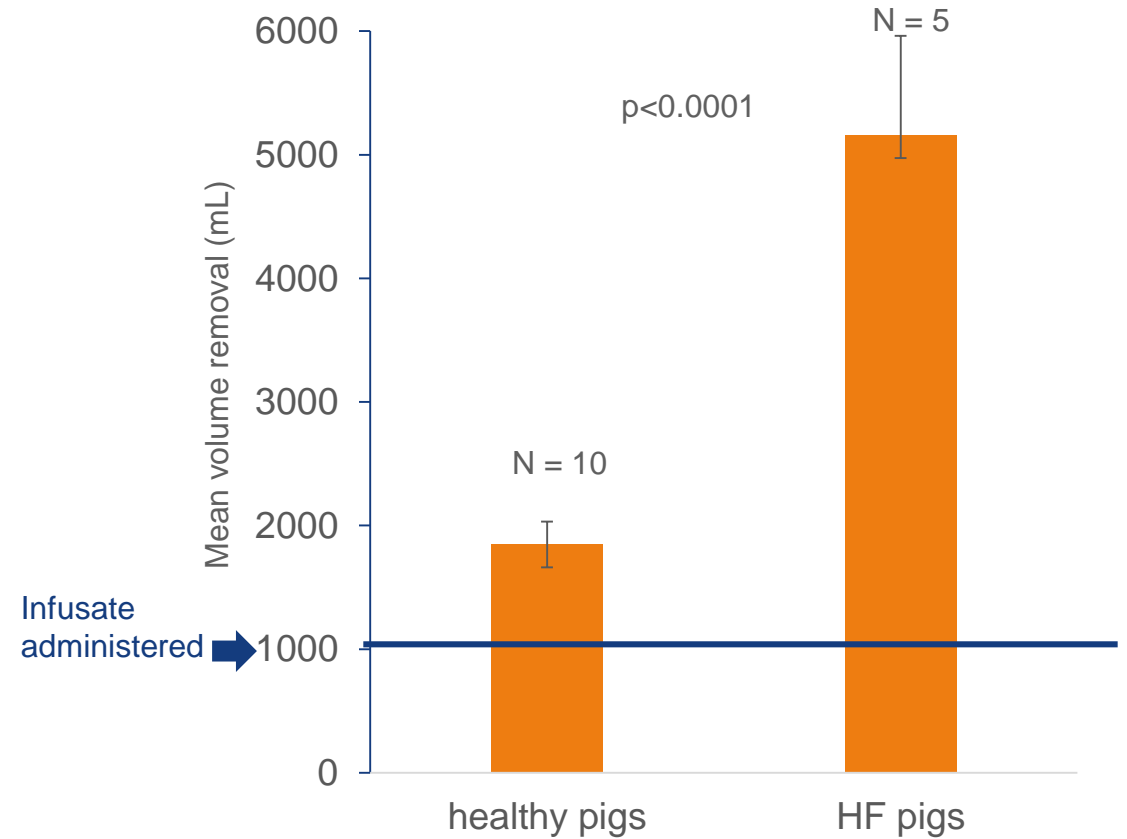
DSR pre-clinical Proof-of-Concept

Clinically relevant sodium and fluid removal

Clinically relevant removal of sodium



Effective fluid removal

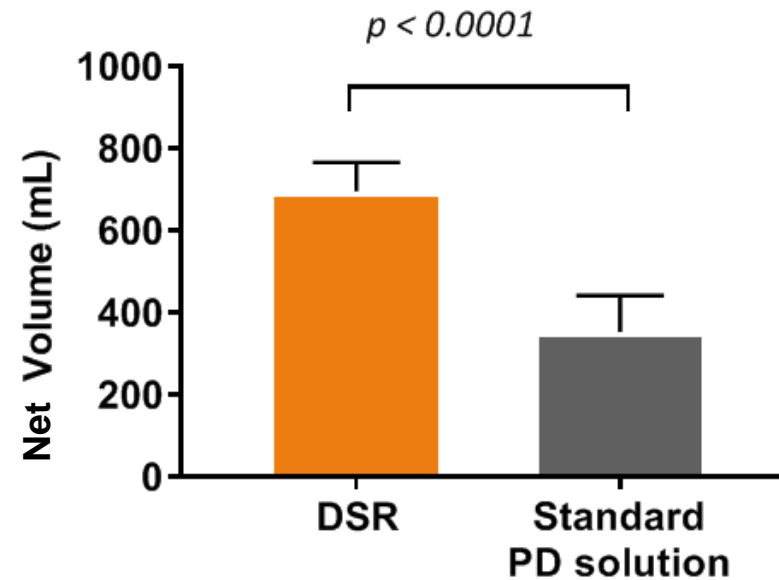
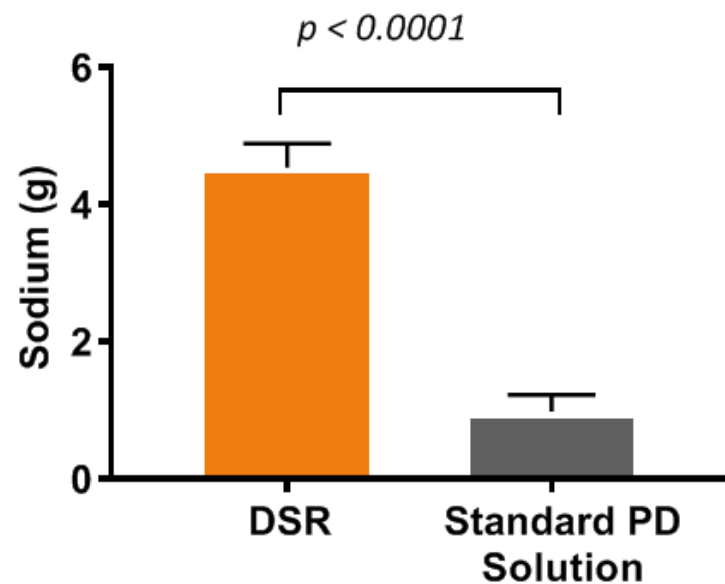


Source 1: Weekly recommended intake for humans equals 14 grams (www.cdc.gov)



DSR first-in-human study met primary and secondary endpoints

- ✓ DSR therapy was safe & well-tolerated with no adverse events or significant discomfort
- ✓ Substantially higher sodium removal with DSR vs standard Peritoneal Dialysis (PD) solution
- ✓ Minimal inter-patient variability



**Results presented at
key Cardiac
Conferences and
published in
Circulation**



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