sequanamedical

Innovators in the management of fluid overload

liver disease – malignant ascites – heart failure

Investor presentation – September 2020

Forward-Looking Statements

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Disclaimers

Regulatory disclaimer:

- The **alfa**pump® system is not currently approved in the United States or 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 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 **alfa**pump® 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.

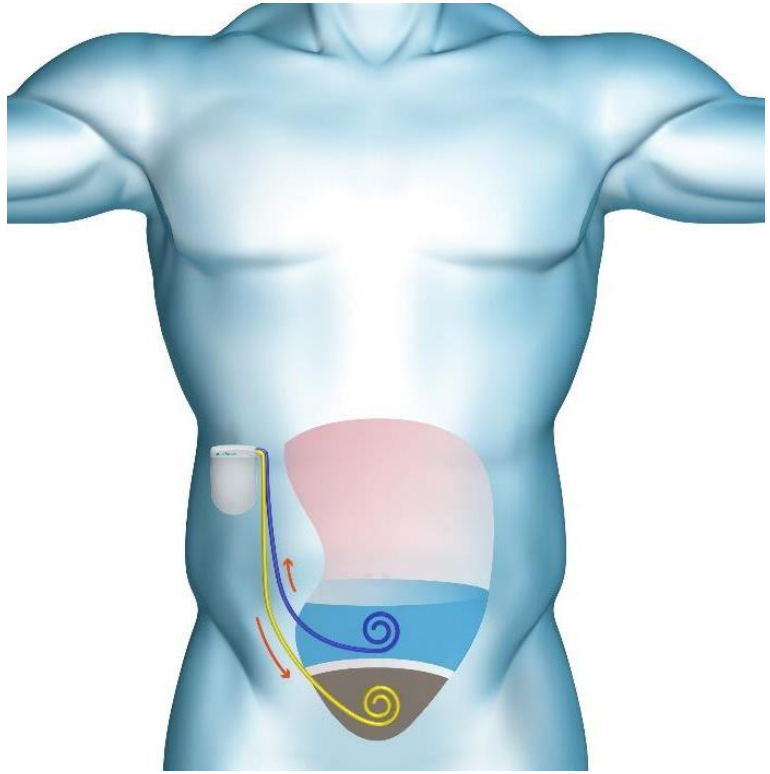
Company Overview

- 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

Source 1: Management estimate that is inclusive of estimated growth in prevalence of NASH for the US based on GlobalData Epidemiology Forecast to 2026
Source 2: Management estimate based on GlobalData Heart Failure Epidemiology Forecast to 2026; Costanzo et al. (2007). Kiglore et al (2017)

NASH drives US market attractiveness

Stronger competitive position in a much larger and dynamic market

alfapump® market potential	~€0.4 Bn / year	>€3 Bn / year
Underlying disease	Alcoholic Liver Disease, Hepatitis	**NASH**
Patient characteristic	“Outside mainstream”	**“Mainstream”**
Average age	40-50 yr	**70 yr+**
alfapump competitive positioning	✓	✓✓

Notes: current estimated EU Liver market: Data from 1980-2010, death rates between 9-12.4 per 100,000; Mokdad et al., 2014, Management estimates of 7.5% cirrhosis patients that die per year based on experts feedback.
forecast US Liver market: Management estimate that is inclusive of estimated growth in prevalence of NASH for the US based on GlobalData Epidemiology Forecast to 2026.

alfapump®

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

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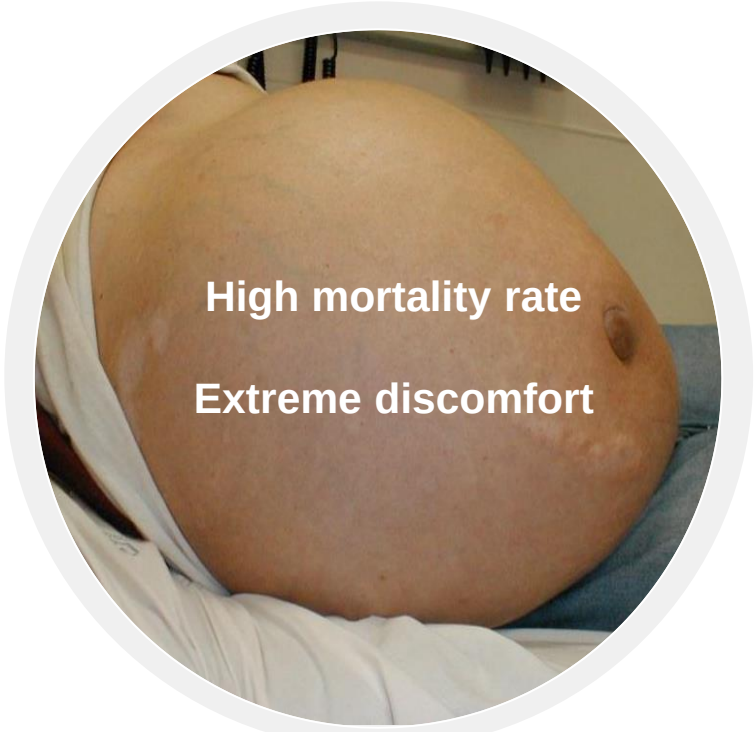
Liver cirrhosis and refractory ascites

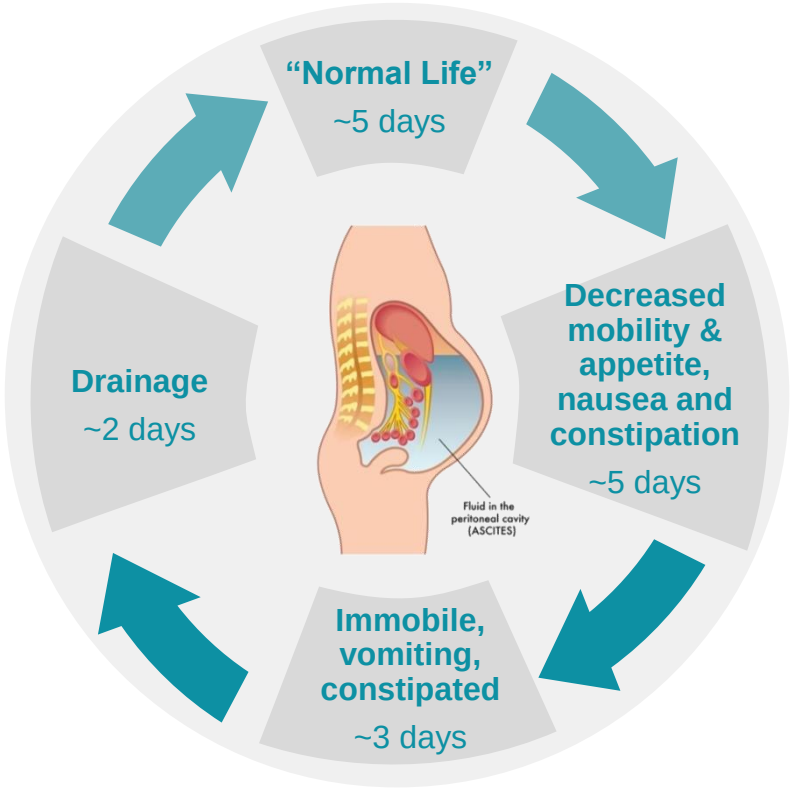
A key complication of liver cirrhosis, with a dramatic impact on quality of life

Viral infections (Hepatitis B & C)

Alcoholic Liver Disease

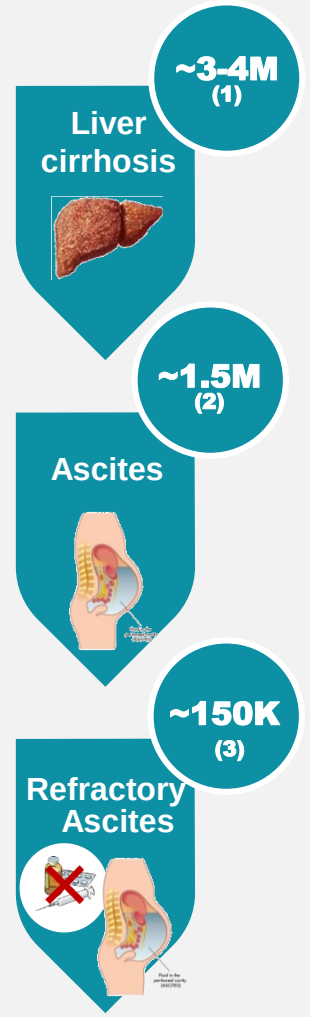
Non-Alcoholic Steatohepatitis (NASH)





Typical patient life(4)

US forecast



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

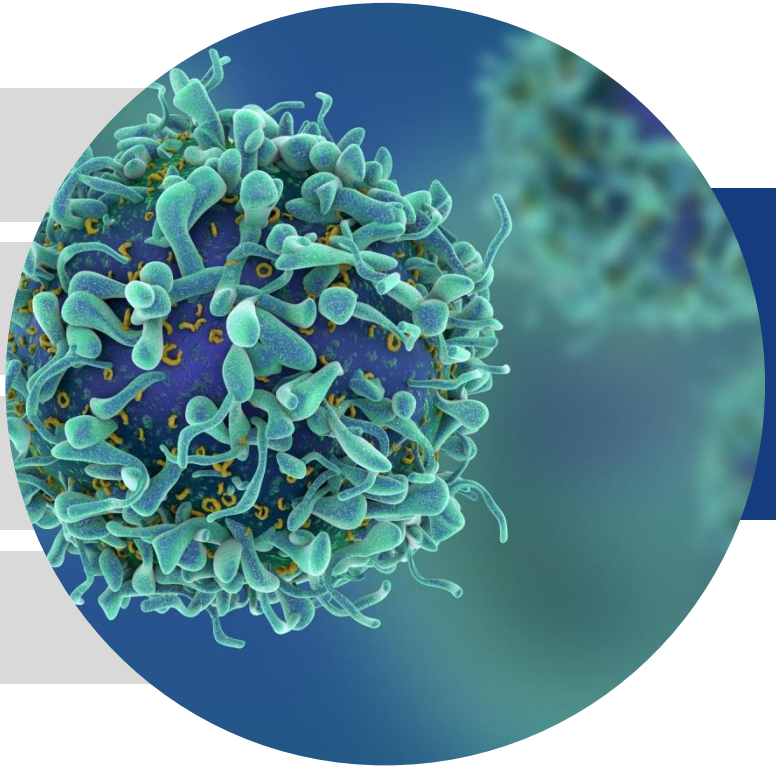
Severe complication of late-stage cancers

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**

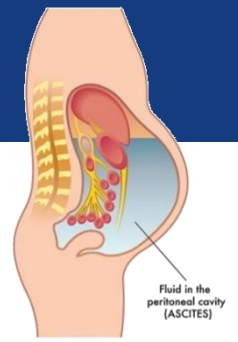
Reduces ability to undergo **anti-cancer treatment**



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

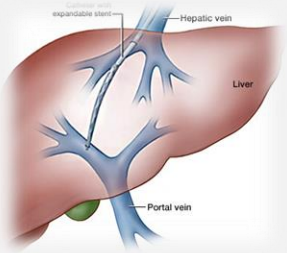
Source 1: Ayantunde & S. L. Parsons. Annals of Oncology 2007
Source 2: Management estimate based on WHO cancer incidence rates (2018) and Ayantunde & S. L. Parsons. Annals of Oncology 2007.

Severe limitations of existing therapies

Diet / Diuretics

Resistance,
Complications

Transjugular Intrahepatic Portosystemic Shunt (TIPS)

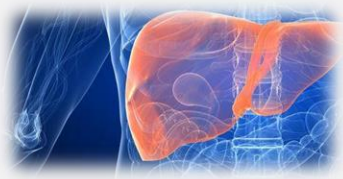


Complications,
Contraindications

Drainage (“Large Volume Paracentesis / LVP”)

Painful, Poor Quality of Life, Short Term Benefit

Liver transplantation



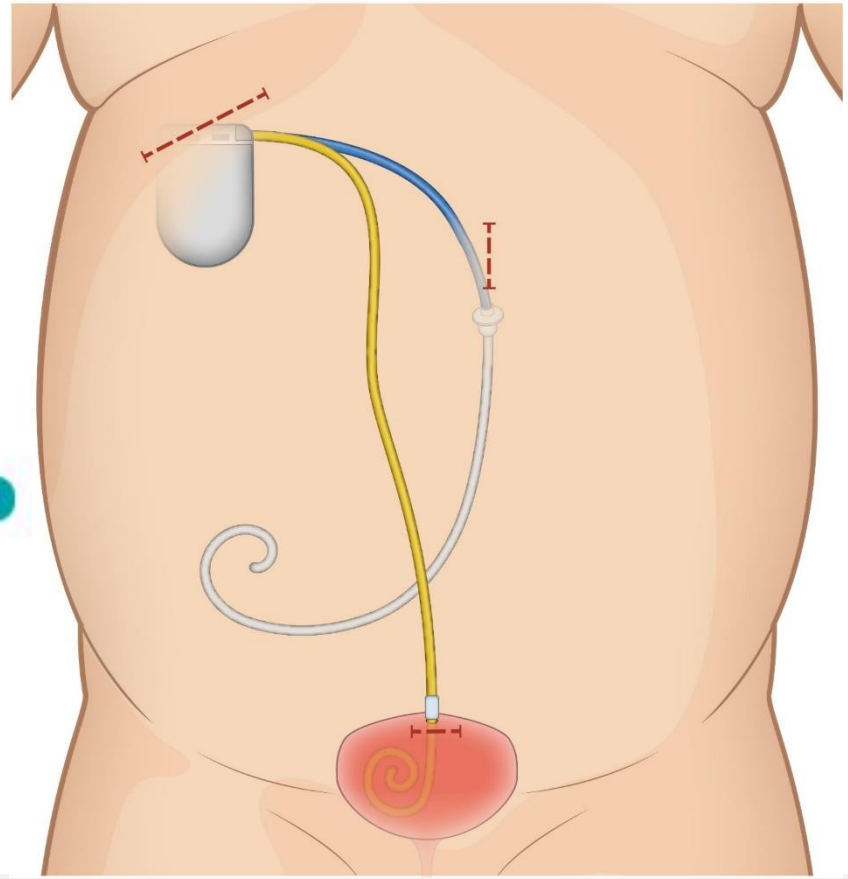
High Cost,
Limited Availability

alfapump®

alfapump® for long-term treatment

Over 800 implants and hundreds of years of patient experience

DirectLink Technology



CE

EASL The Home of Hepatology

NICE National Institute for Health and Care Excellence

1913 DGVS Deutsche Gesellschaft für Gastroenterologie, Verdauungs- und Stoffwechselkrankheiten

FDA **Breakthrough Device** Designation

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	**alfa**pump®**: ~$35K**
~$1,8K / LVP(1)	~$25K / **alfa**pump
2 LVP / month	~$10K / implantation
15 months	

** Management estimate of US treatment costs, assuming no complications*

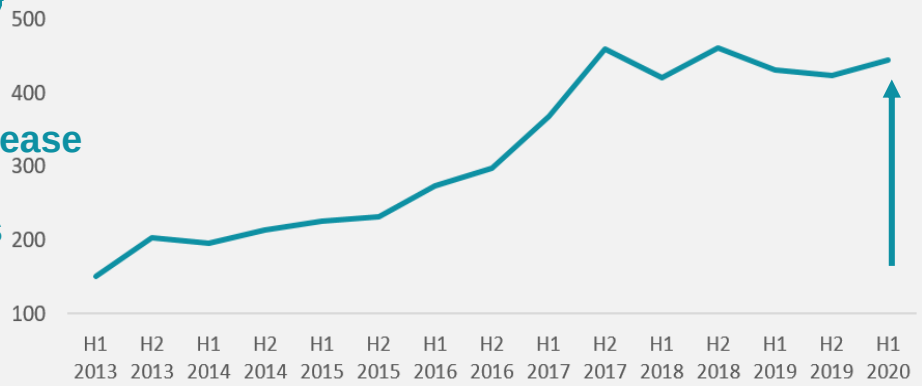
QoL: Quality of Life; LVP: Large Volume Paracentesis

Source 1: Kwan et al., J Vasc Interv Radiol 2018

Strong clinical validation

Clear increase in clinical outcomes

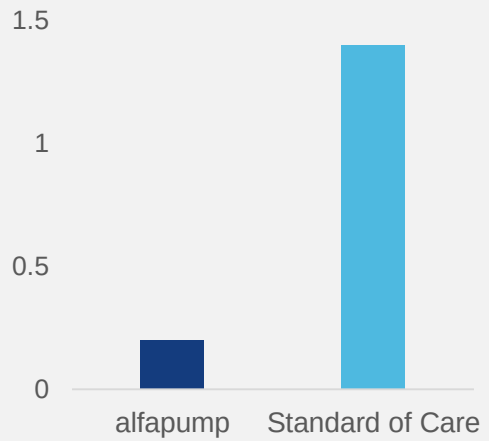
Avg days of alfapump therapy / patient



Sequana Medical data

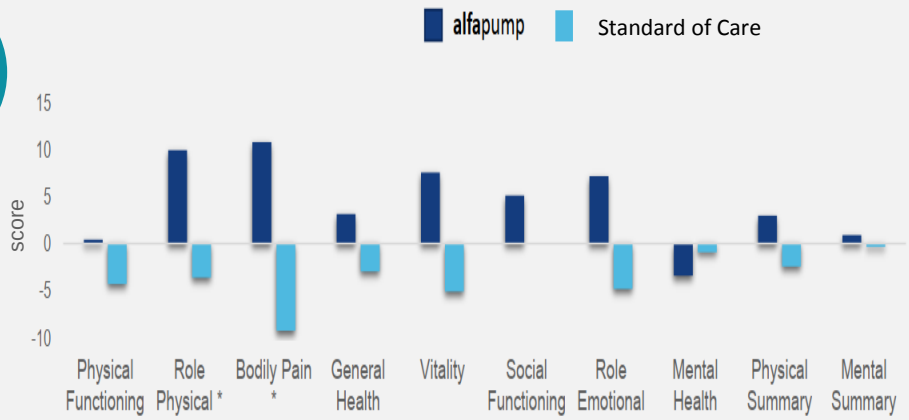
Drastically reduced need for drainage

Mean # drainages / patient / 28 days



Results RCT study

Improved quality of life

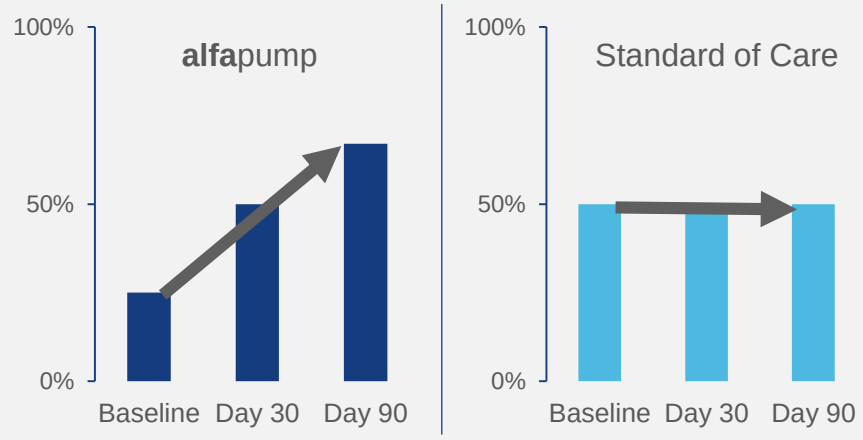


Results RCT study

** p<0.05*

Improved nutrition

% patients adequately nourished



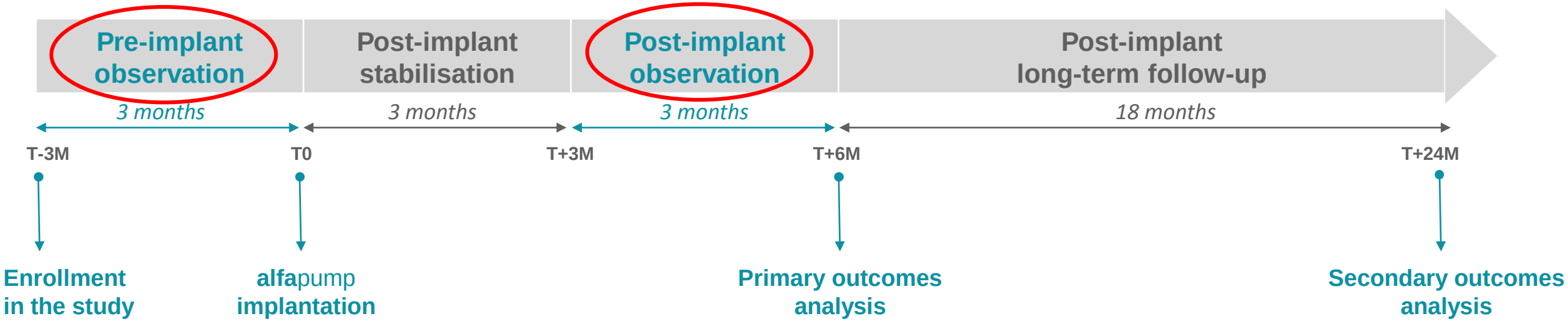
Results RCT study

RCT: Randomised Controlled Trial (2013-2016)

North American Pivotal Study (POSEIDON) underway

- Up to **50 patients** with recurrent or refractory ascites due to liver cirrhosis implanted with the **alfa**pump[(1)]
- Primary endpoint at **9 months after enrollment**:

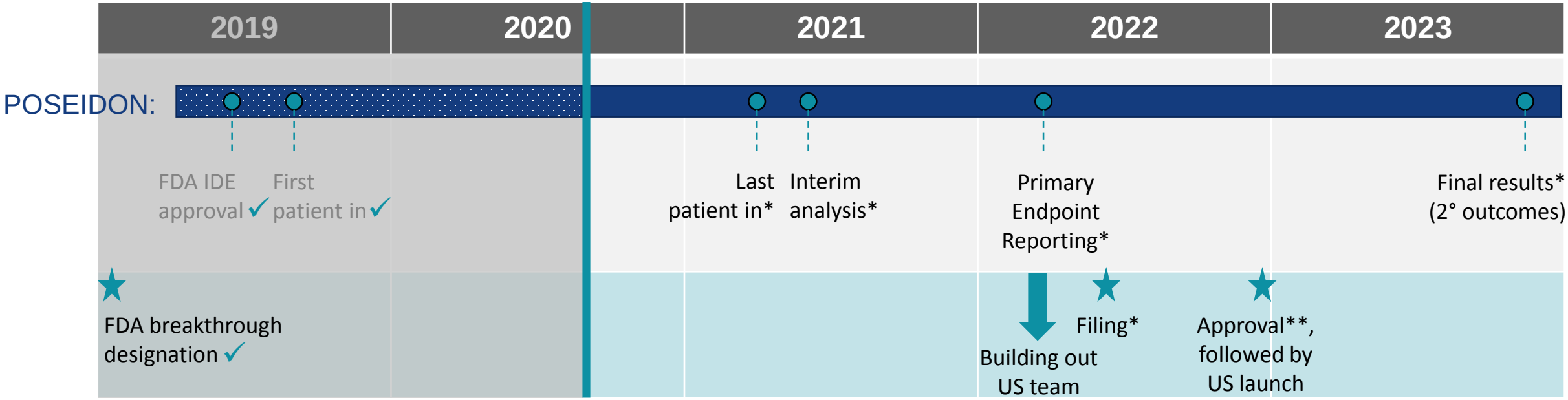
  ⇨ proportion of patients with a 50% reduction in average number of paracentesis per month post-implant vs pre-implant



Note 1: in Study Cohort

alfapump® US approval roadmap

Key anticipated milestones*

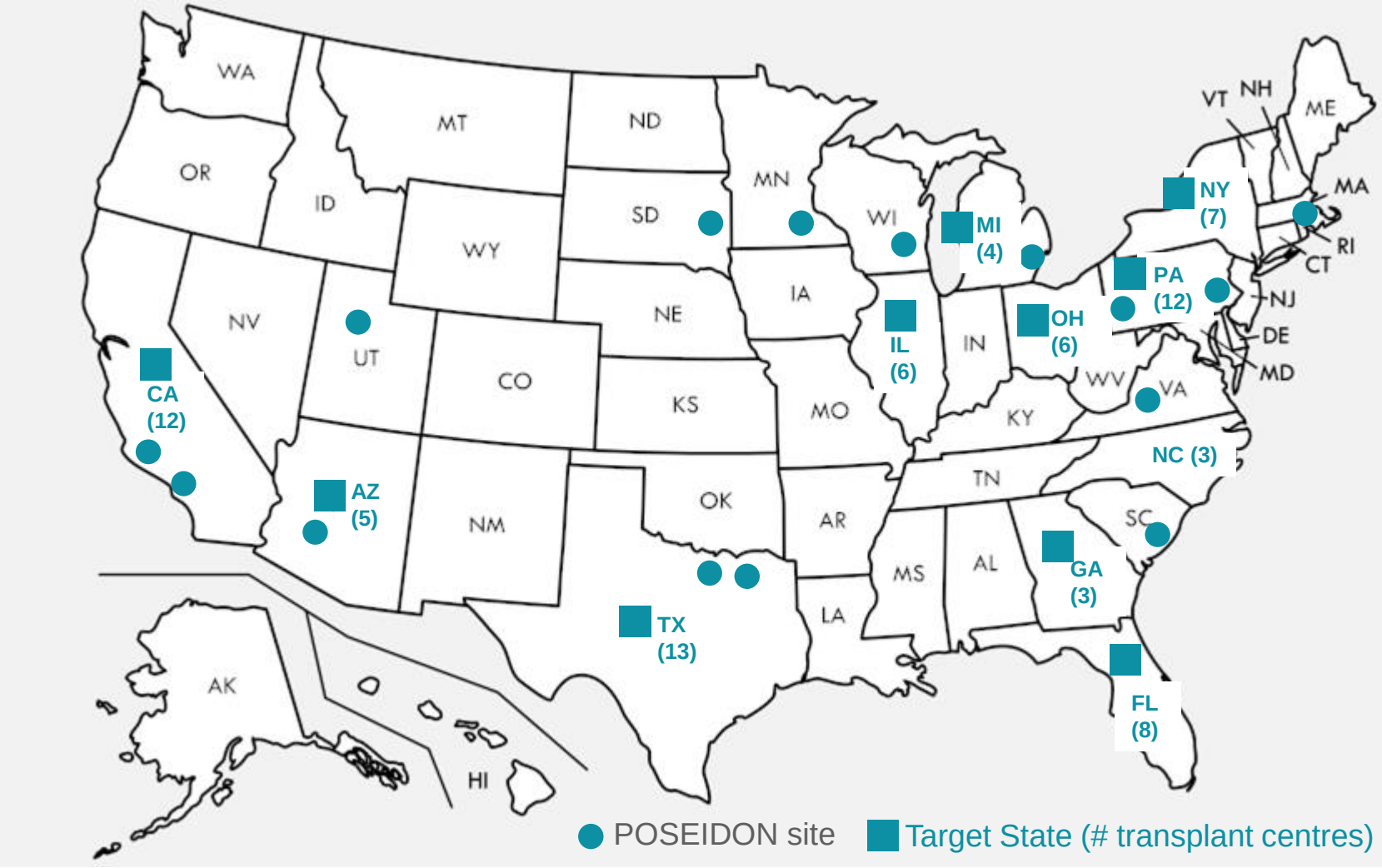


*Final CMS rule on reimbursement for breakthrough devices (NTAP) expected to further support reimbursement for the **alfa**pump*

* *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 **alfa**pump platform

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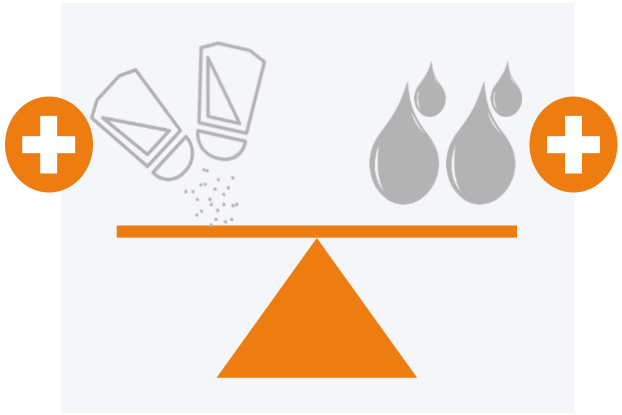
Volume overload in heart failure – major clinical problem and key driver of costs



Excess sodium drives fluid overload

US hospitalisations annually due to HF[3]

~1m

90%

HF – hospitalisations due to volume overload[3]

c.5d

Typical hospital stay[4]

$13bn

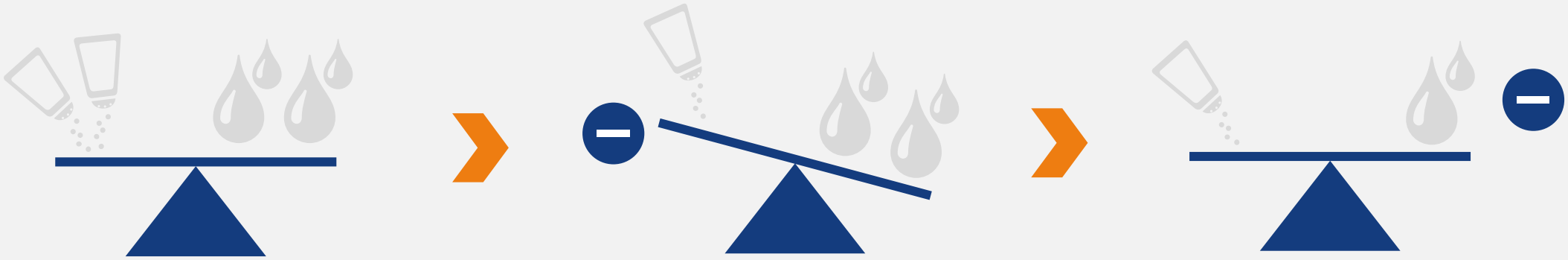
Annual costs of US HF-related hospitalisations[4]

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

Source 1: Testani, Circ Heart Failure, 2014 & 2016; Source 2: Ross et al. (2010); Source 3: Costanzo et al., J. Am. Coll., 2007; Source 4: Kilgore et al. (2017)

Direct sodium removal (DSR)

Remove the sodium and the body will eliminate the excess fluid



Too much sodium drives fluid overload

Removing the sodium (DSR)

Elimination of excess fluid

Administer infusate to peritoneal cavity

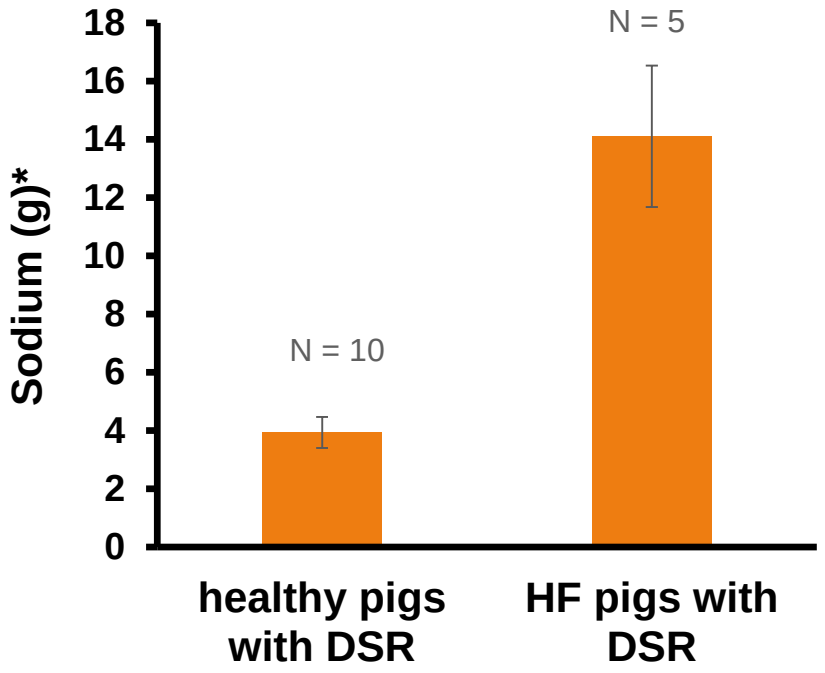
Infusate extracts sodium from the body

alfapump® **removes extracted sodium from peritoneal cavity via bladder**

Body restores balance by eliminating excess fluid

DSR pre-clinical and clinical Proof-of-Concept

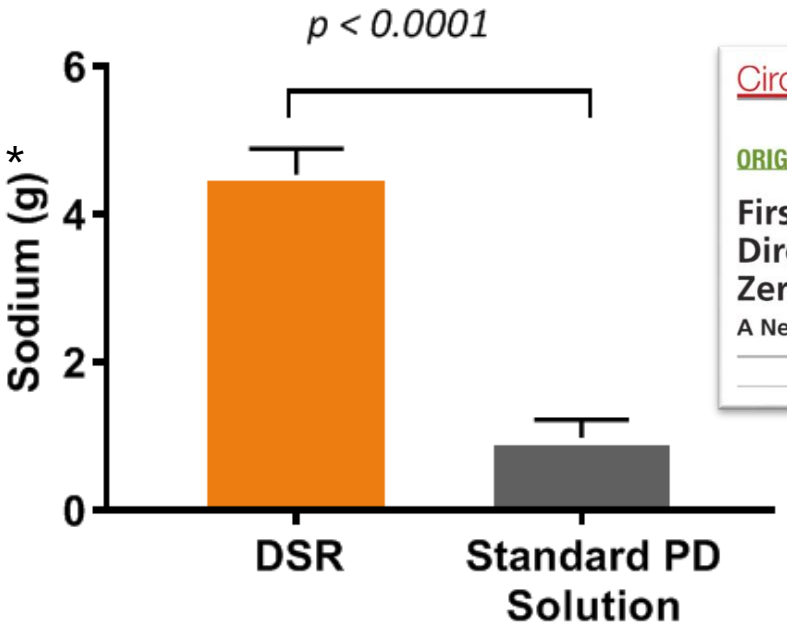
Pre-clinical studies[1]



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 study[2] (N=10)




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

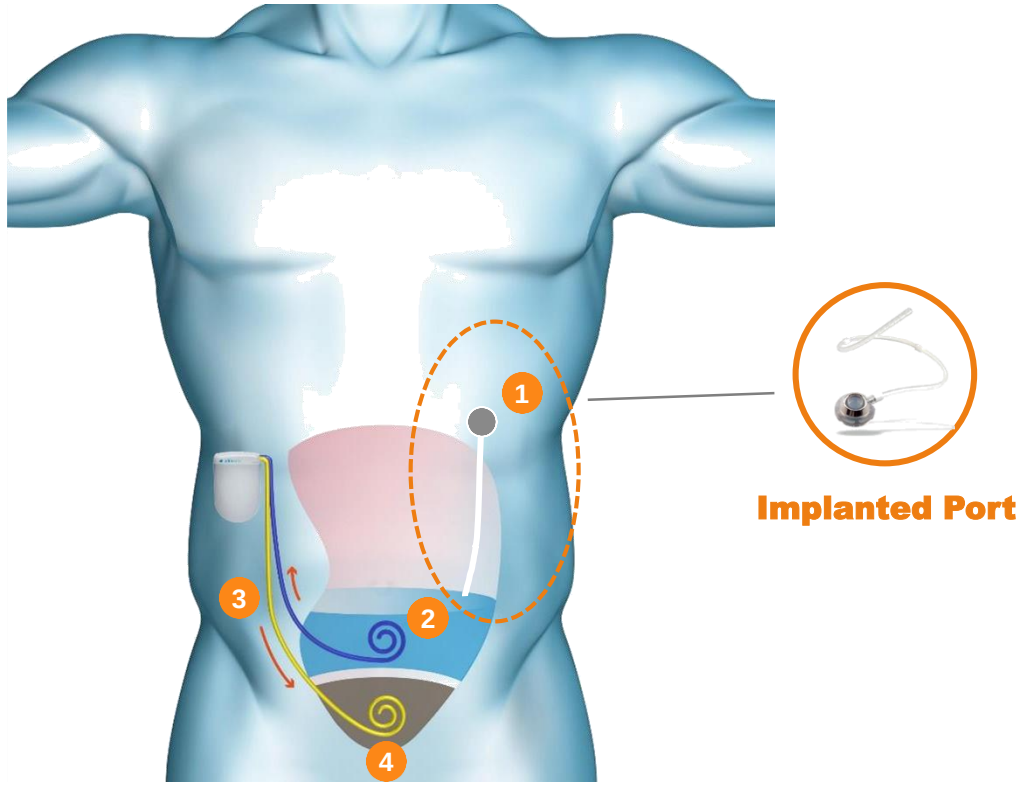
Veena S. Rao, PhD

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

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

alfapump® DSR

Fully implanted and convenient system for DSR therapy leveraging proven elements

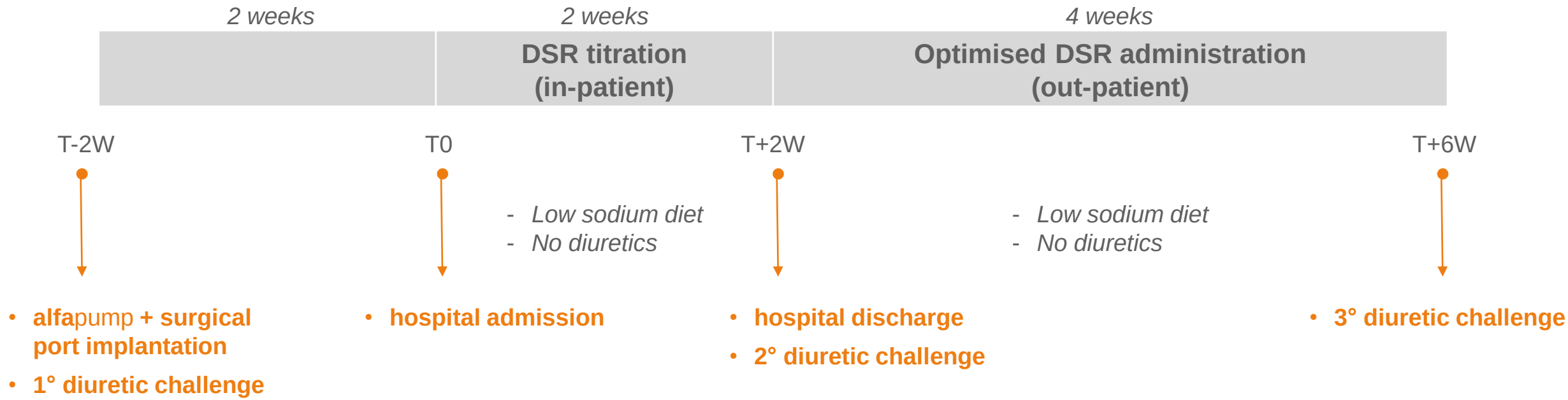


- ✓ Direct Sodium Removal
- ✓ alfapump
- ✓ Implanted port

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

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

- Up to **10 patients** with heart failure on high dose diuretics across two centres (Belgium and Georgia)
- Primary **safety** endpoint: absence/rate of device, procedure and/or therapy related serious adverse events
- Secondary **feasibility** endpoint: ability of **alfa**pump DSR to maintain a neutral sodium balance and maintain euvolemia
- Exploratory endpoint: impact of DSR to **restore response to diuretics**



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

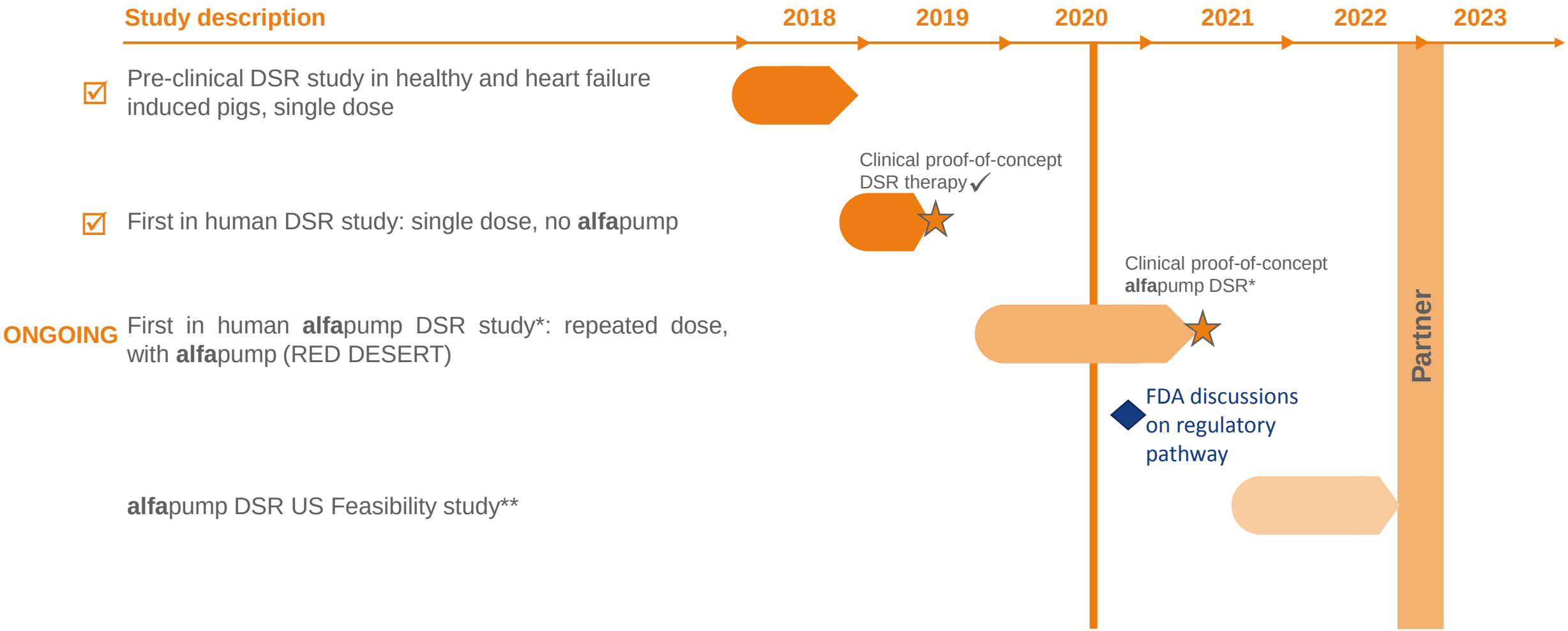
Dr. Javed Butler

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



** 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

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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 Gödje
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

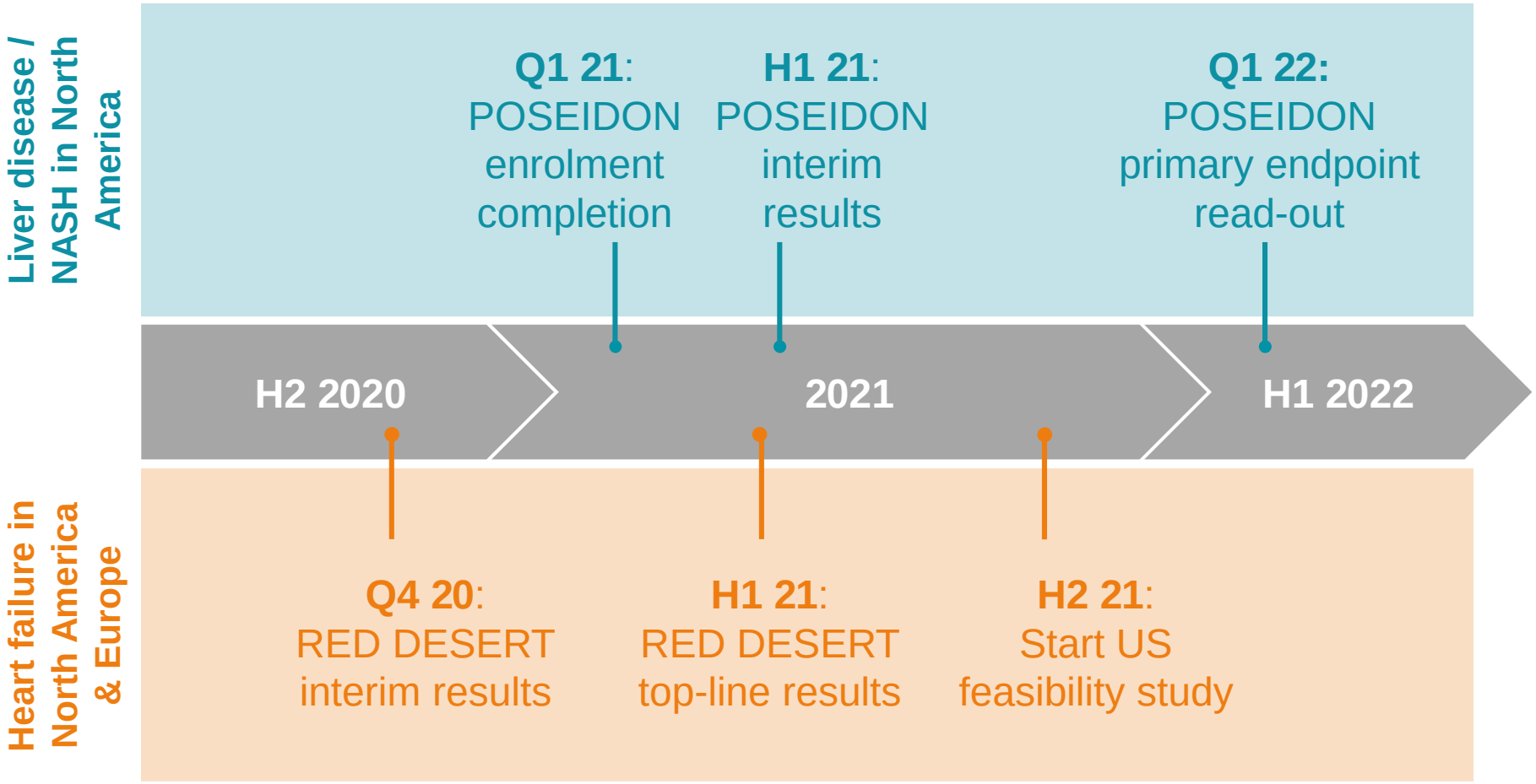
Wim Ottevaere
Director

Jason Hannon
Director

Rudy Dekeyser
Director

Erik Amble
Director

Expected Core Value Drivers & Outlook



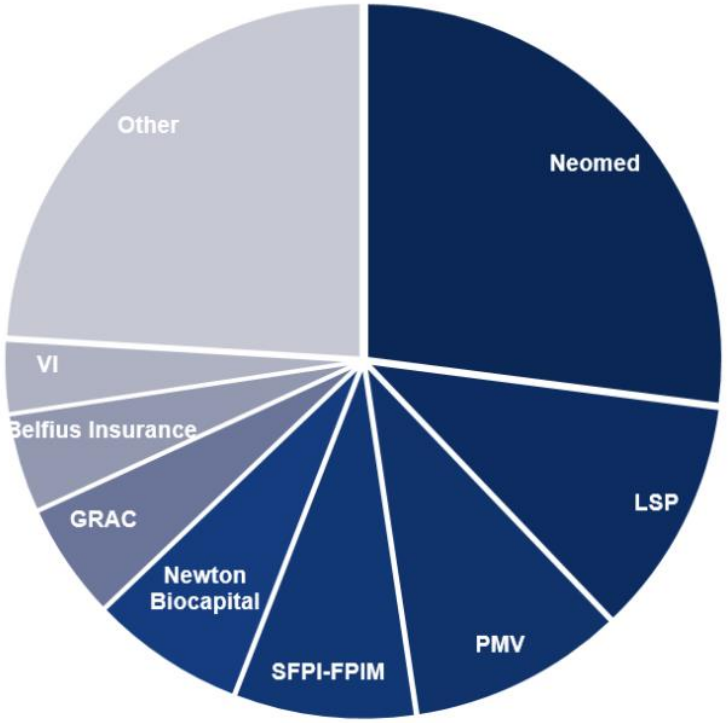
Note: Presented timelines are subject to further developments related to the COVID-19 pandemic

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

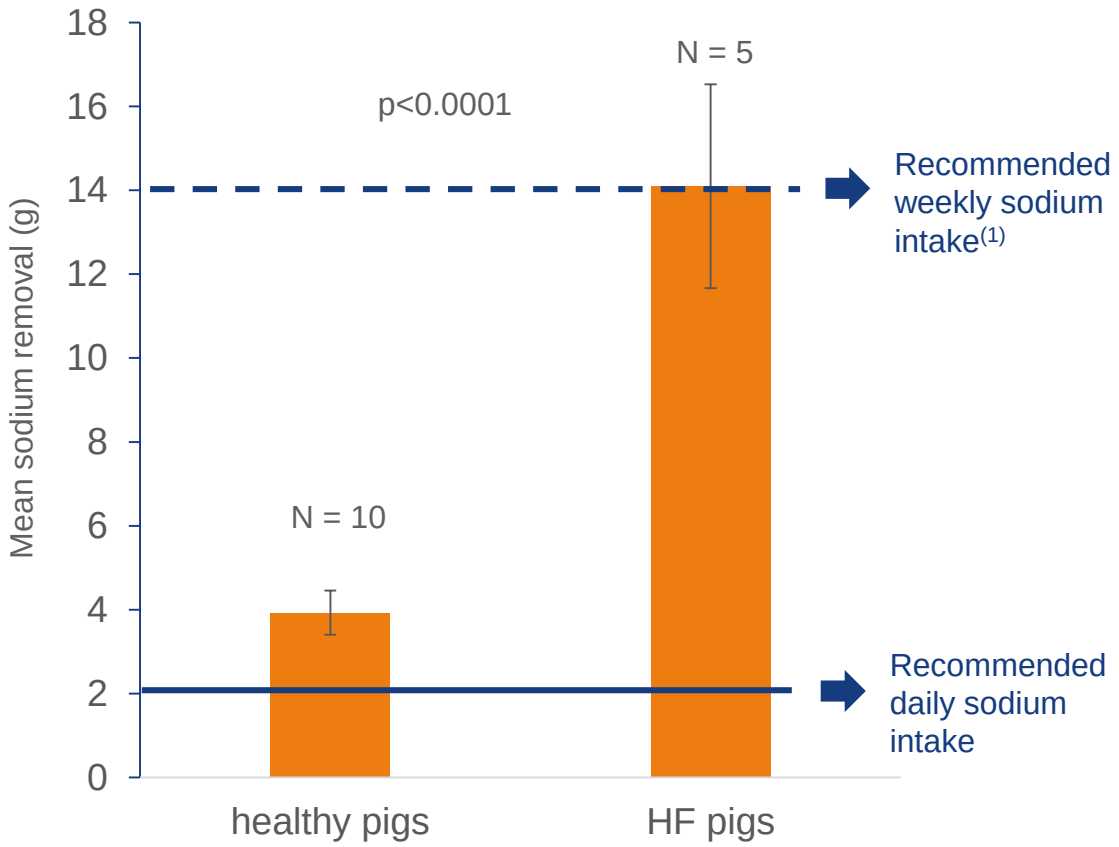


- Analysts:
  - KBC Securities – Sandra Cauwenberghs & Lenny Van Steenhuyse
  - Kempen – Ingrid Gafanhão
  - Kepler Cheuvreux – Matthias Maenhaut
  - Mirabaud – Daniel Jelovcan
- Cash (30 June 2020): €14.9M
- Debt financing in July 2020: €7.3M
- Cash runway into H2 2021

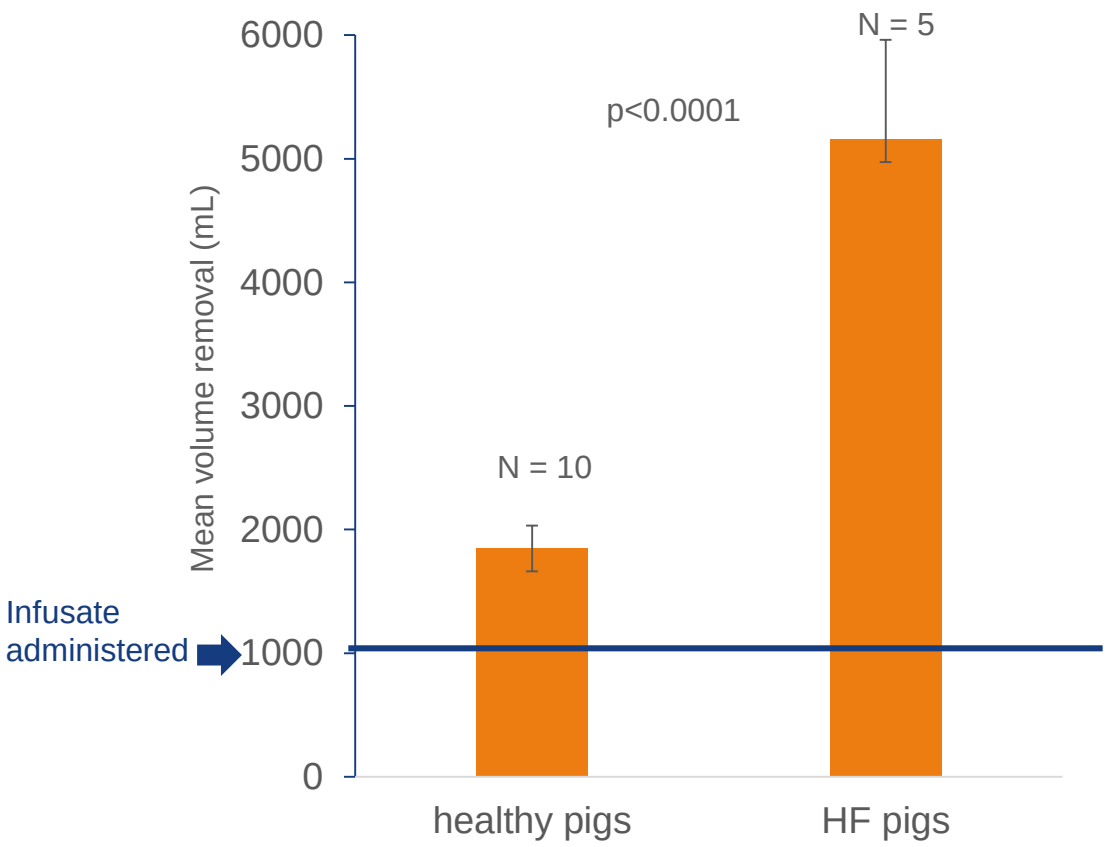
DSR pre-clinical Proof-of-Concept

Clinically relevant sodium and fluid removal

Clinically relevant removal of sodium



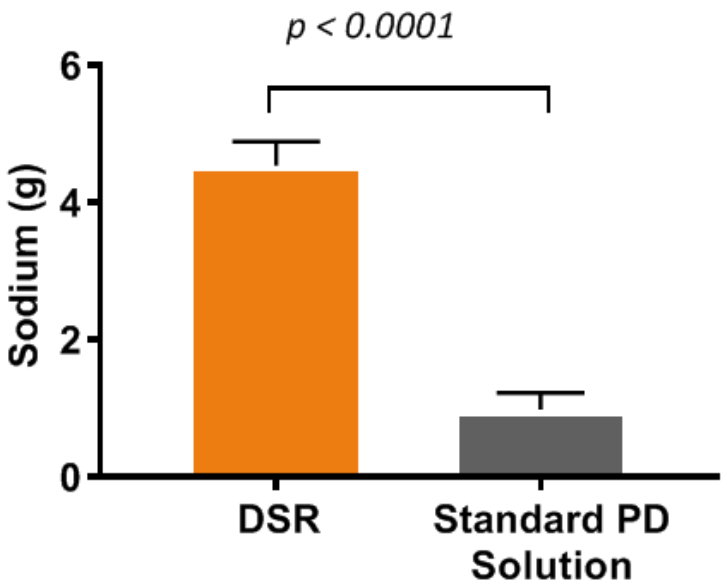
Effective fluid removal

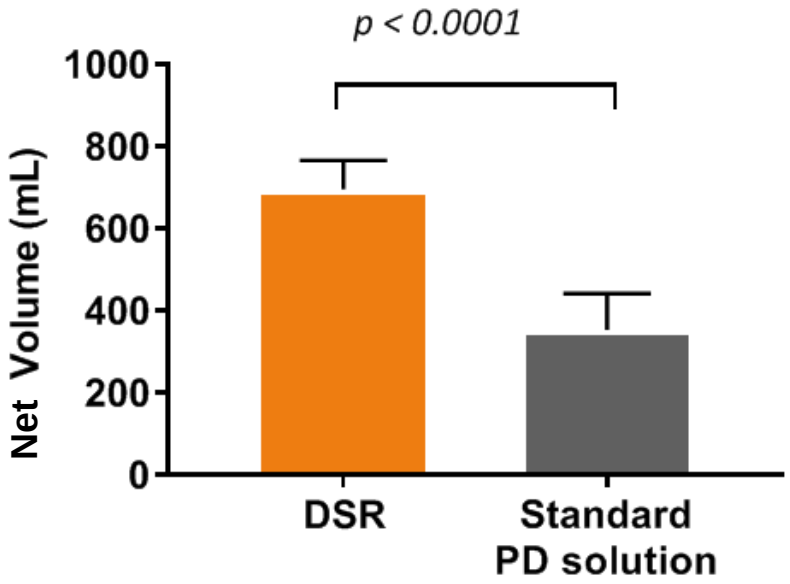


Source 1: Weekly recommended intake for humans equals 14 grams (www.cdc.gov)

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

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

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