

sequana**medical**



Innovators in the management
of **fluid overload**

liver disease – malignant ascites – heart failure

Investor presentation – January 2020

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Regulatory disclaimers:

- The **alfapump**[®] has not yet received regulatory approval in the US and Canada. Any statement in this presentation about safety and efficacy of the **alfapump** does not apply to the US and Canada because the device is currently undergoing clinical investigation in these territories.
- Sequana Medical's proprietary DSR therapy is under development and Sequana Medical is developing **alfapump** DSR (Direct Sodium Removal) to deliver a convenient and fully implanted system for DSR therapy. DSR therapy is still in development and it should be noted that any statements in this presentation regarding safety and efficacy arise from pre-clinical and clinical studies and ongoing clinical investigations which have yet to be completed. There is no link between DSR therapy and ongoing investigations with the **alfapump** system in Europe, the US and Canada.

Company Overview

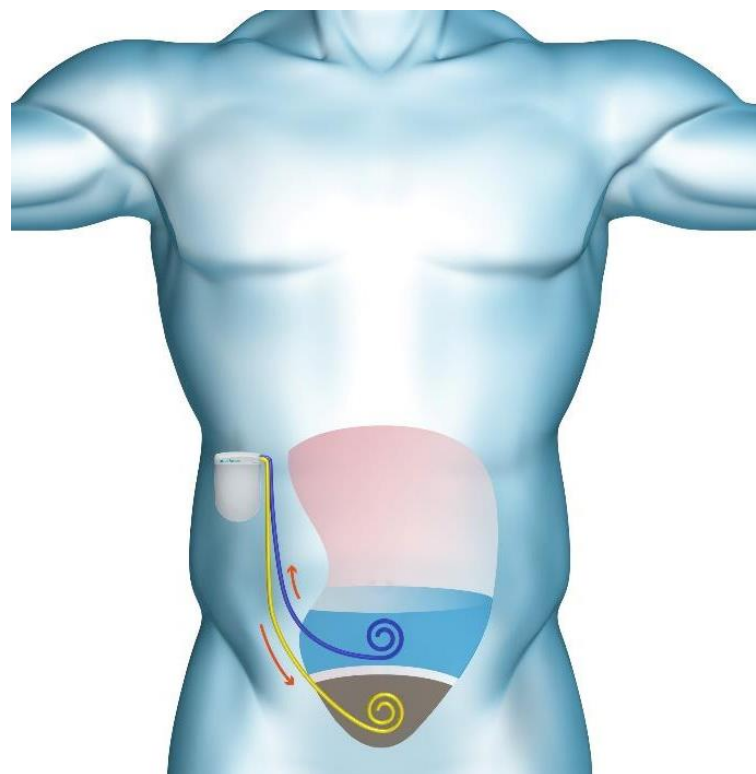
- Founded in 2006
- Gent, Belgium (HQ): corporate, clinical, commercial
- Zurich, Switzerland: manufacturing, engineering, QA/RA
- ~45 employees
- Euronext Brussels: SEQUA
– market cap: ~€80 M



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

alfa^{pump} platform

 **alfapump[®]**

proven step change in liver refractory ascites and malignant ascites;

over 700 devices implanted

 **alfapump[®] DSR**

breakthrough approach to fluid overload in heart failure;

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



Breakthrough Device Designation



NICE
National Institute for Health and Care Excellence



1913 DGVS
Deutsche Gesellschaft für Gastroenterologie, Verdauungs- und Stoffwechselkrankheiten



Focus on US NASH and global heart failure markets

Large market opportunities with high unmet medical need



Liver (NASH) in US

~145 K patients / year

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

> €3 Bn / year
market opportunity



Heart Failure in EU+US

~400 K patients hospitalised / year

for volume overload due to heart failure by 2026⁽²⁾

> €5 Bn / year
market opportunity

Built upon proven European clinical & commercial experience

NASH: non-alcoholic steatohepatitis

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

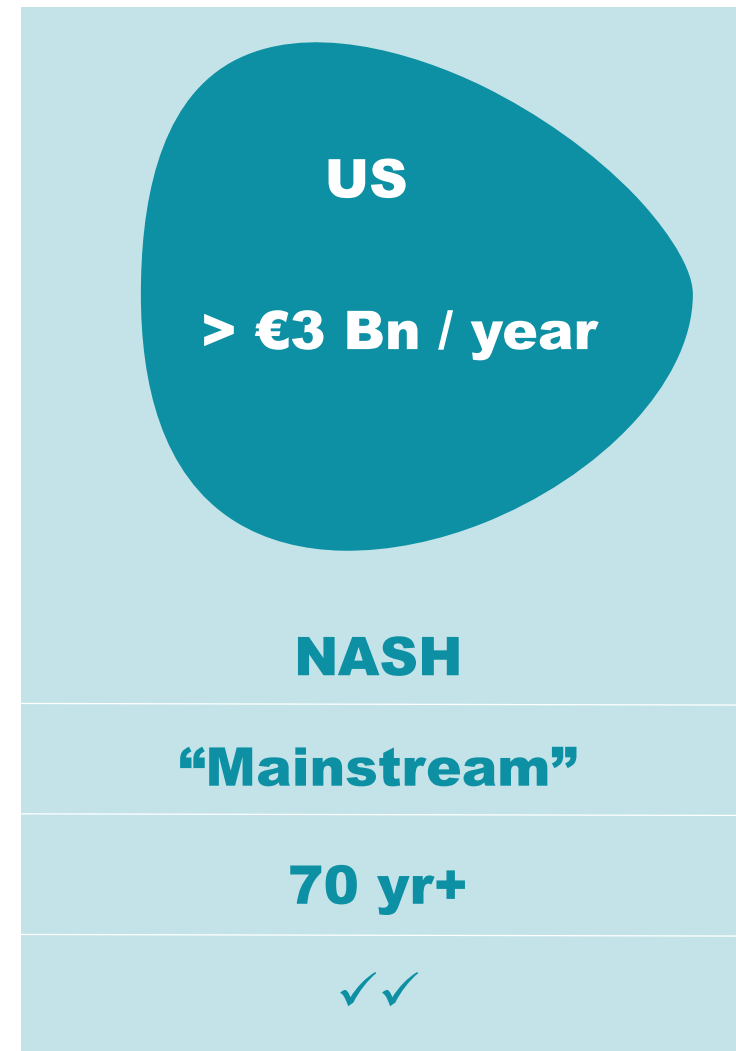
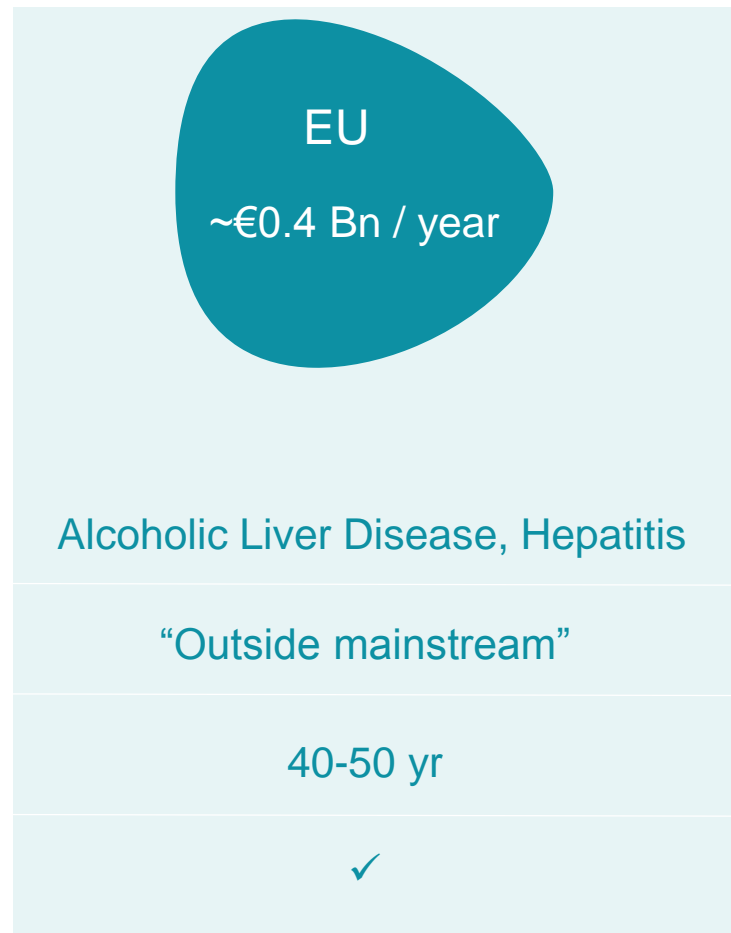
| **alfapump**[®] market potential |

| Underlying disease |

| Patient characteristic |

| Average age |

| **alfapump** competitive positioning |



Notes: 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.
 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

Liver cirrhosis and refractory ascites

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

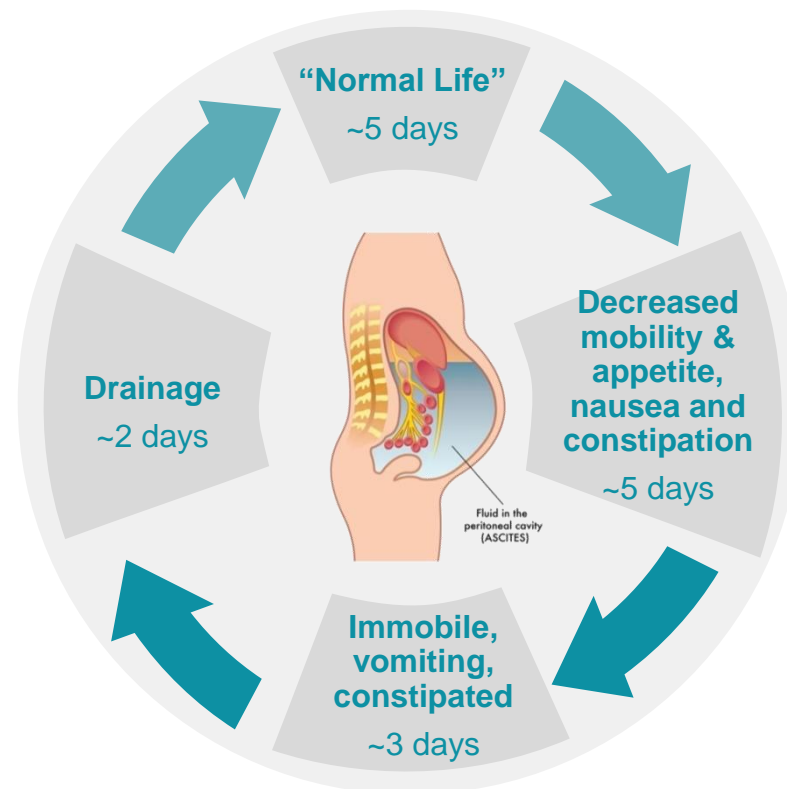
Viral infections
(Hepatitis B & C)



Alcoholic Liver Disease



Non-Alcoholic Steatohepatitis (NASH)



Typical patient life⁽⁴⁾

US forecast

~3-4M
(1)

Liver cirrhosis



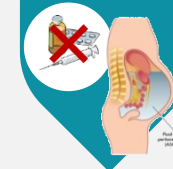
~1.5M
(2)

Ascites



~150K
(3)

Refractory Ascites



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

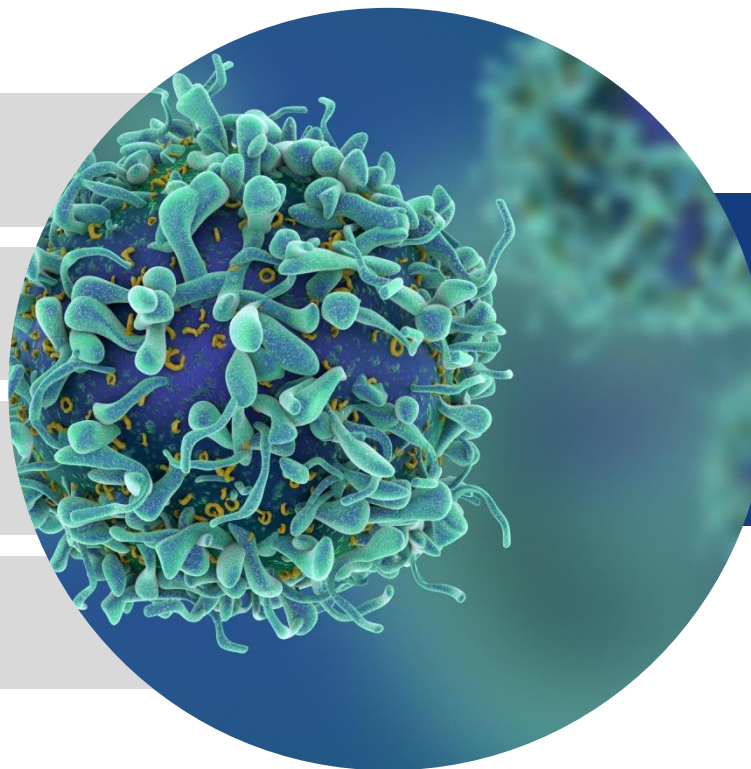
Severe complication of late-stage cancers

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**

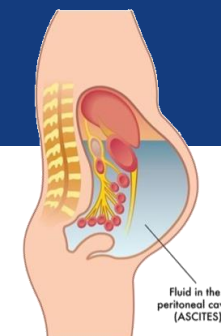
Reduces ability to undergo **anti-cancer treatment**



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.

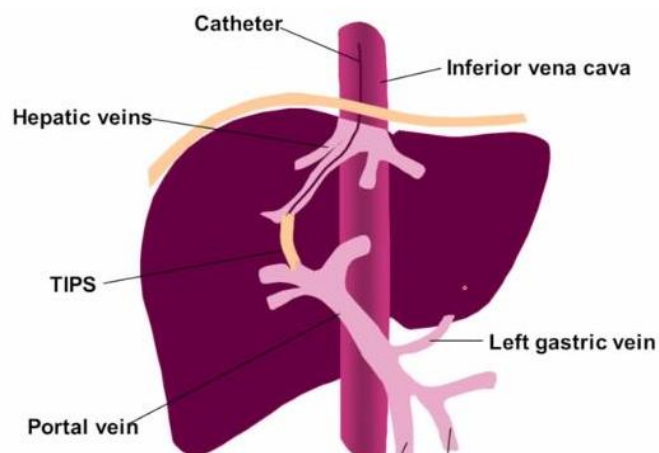
Severe limitations of existing therapies

Large Volume Paracentesis (“drainage”)



Dramatically reduces quality of life

Transjugular Intrahepatic Portosystemic Shunt (TIPS)



Increases risk of hepatic encephalopathy above age of 65 (typical age of NASH ascites patients)

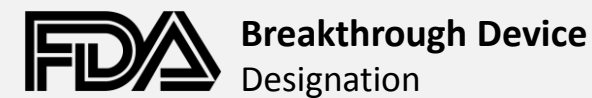
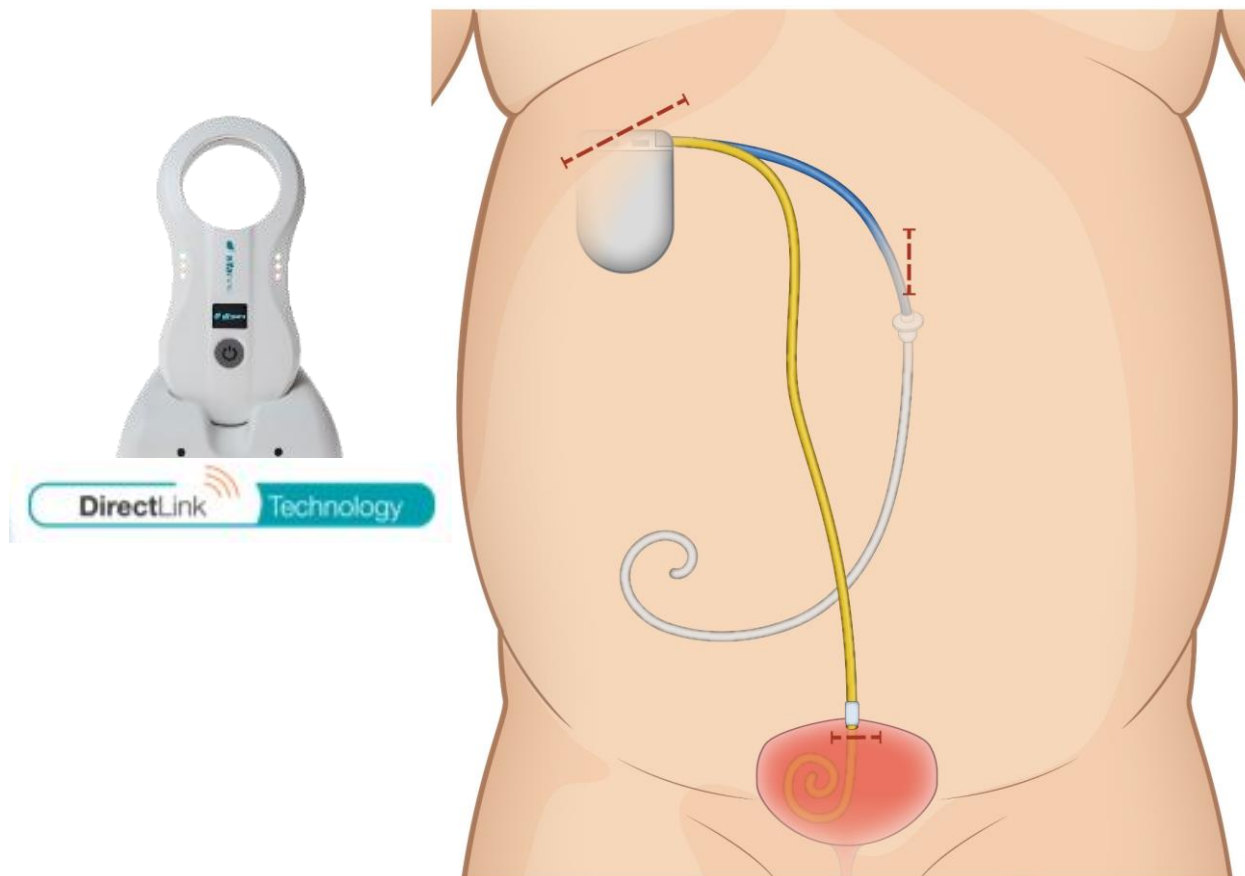
Liver transplant



Limited availability and high costs

alfapump® for long-term treatment

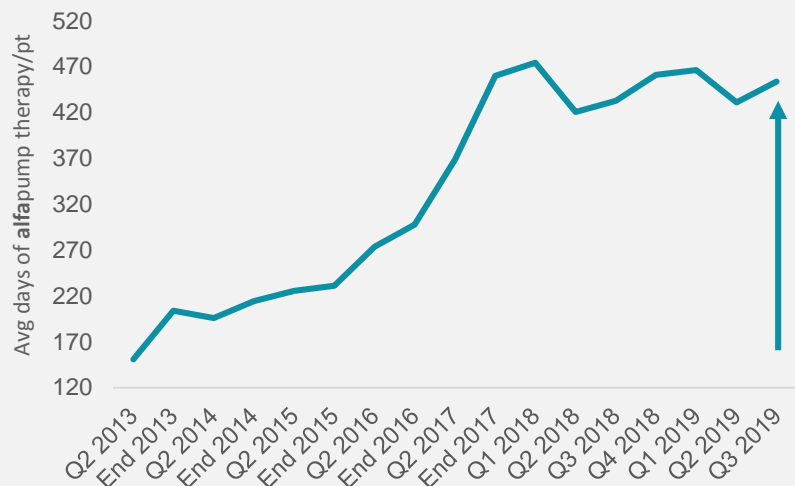
Over 700 implants and hundreds of years of patient experience



Strong clinical validation



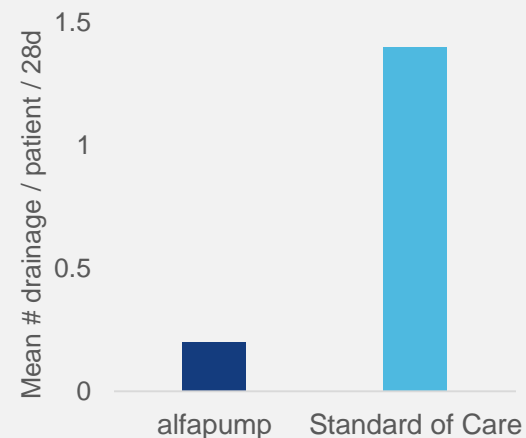
Clear increase in clinical outcomes



Sequana Medical data



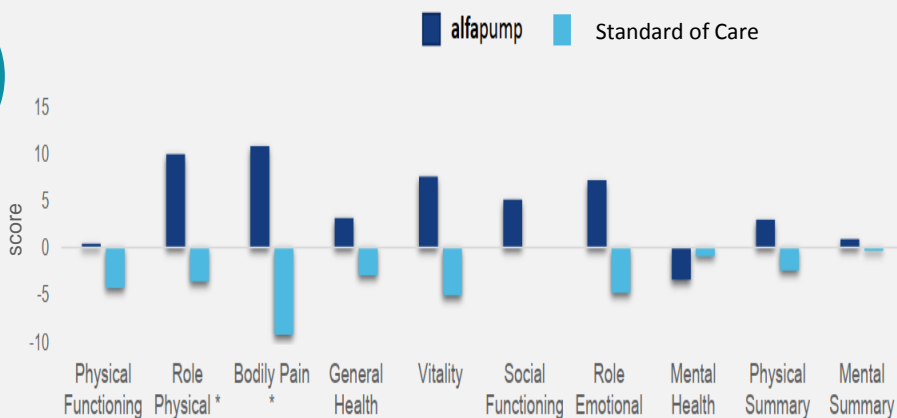
Drastically reduced need for drainage



Results RCT study



Improved quality of life



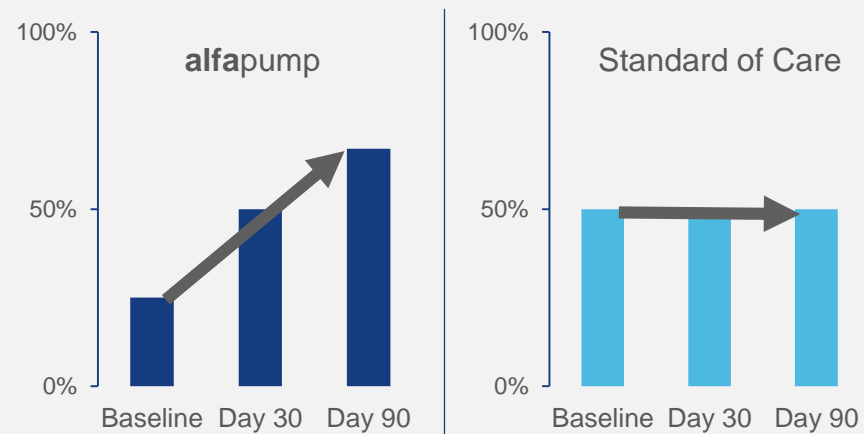
Results RCT study

* p<0.05



Improved nutrition




% patients adequately nourished

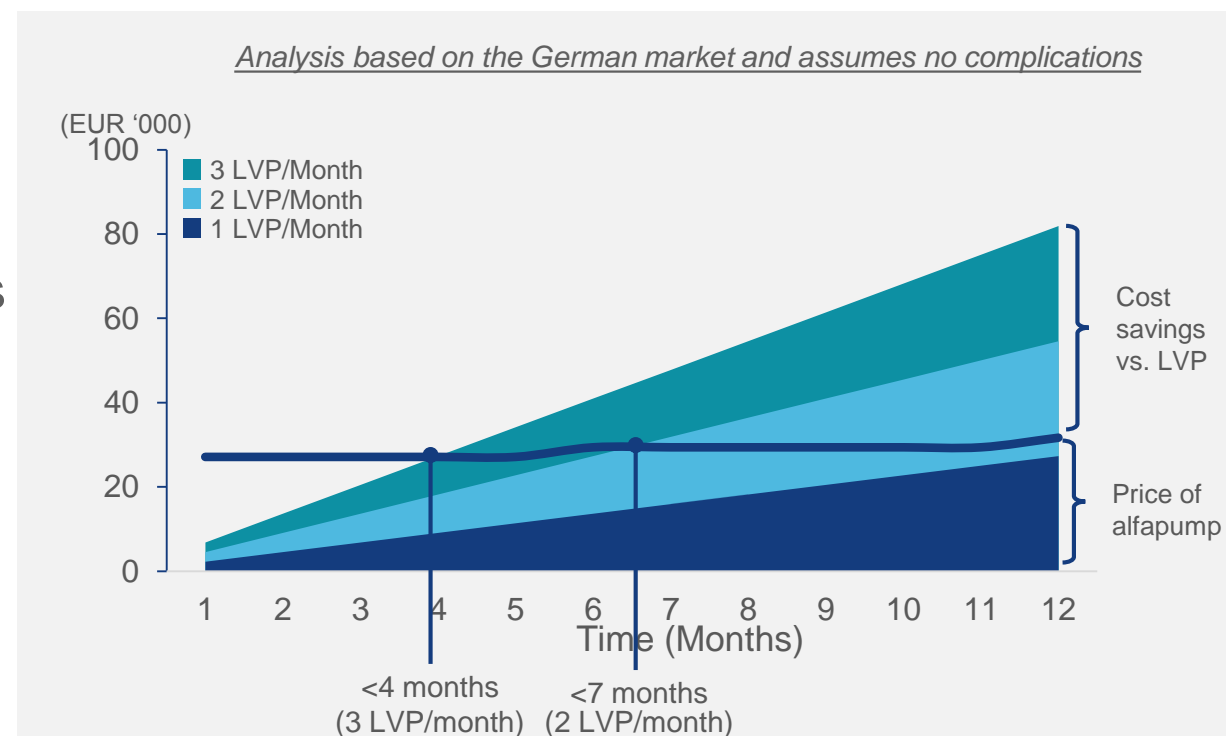


Results RCT study

Strong health economics rationale

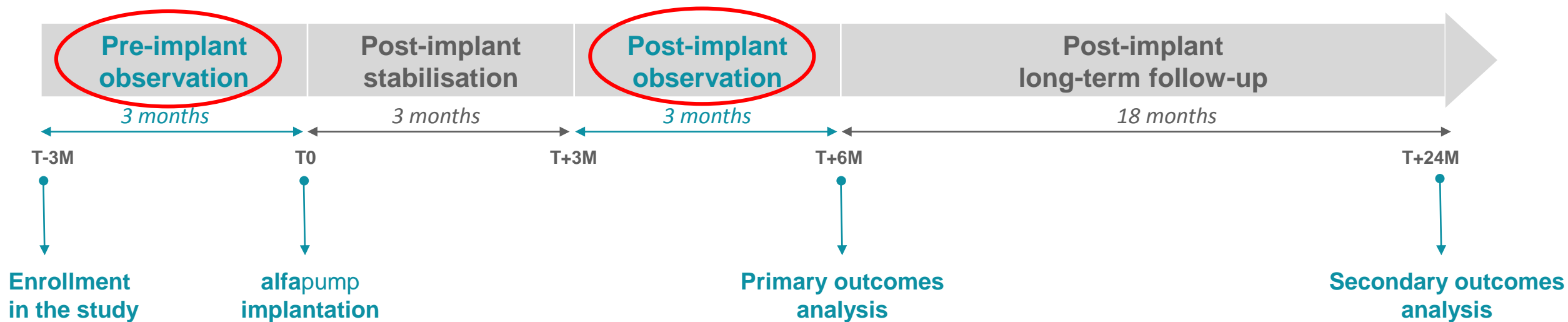
Significant reduction in regular drainage leads to:

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



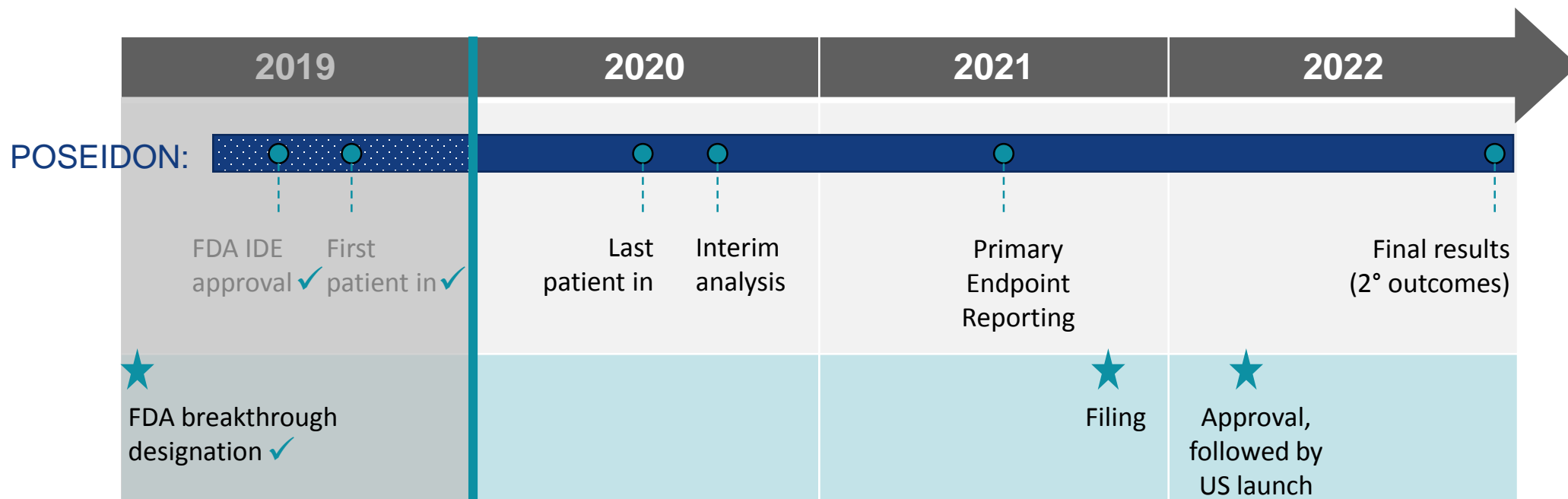
North American Pivotal Study (POSEIDON) underway

- Up to **50 patients** with recurrent or refractory ascites due to liver cirrhosis implanted with the **alfapump**⁽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



alfapump[®] US approval roadmap

Key anticipated milestones

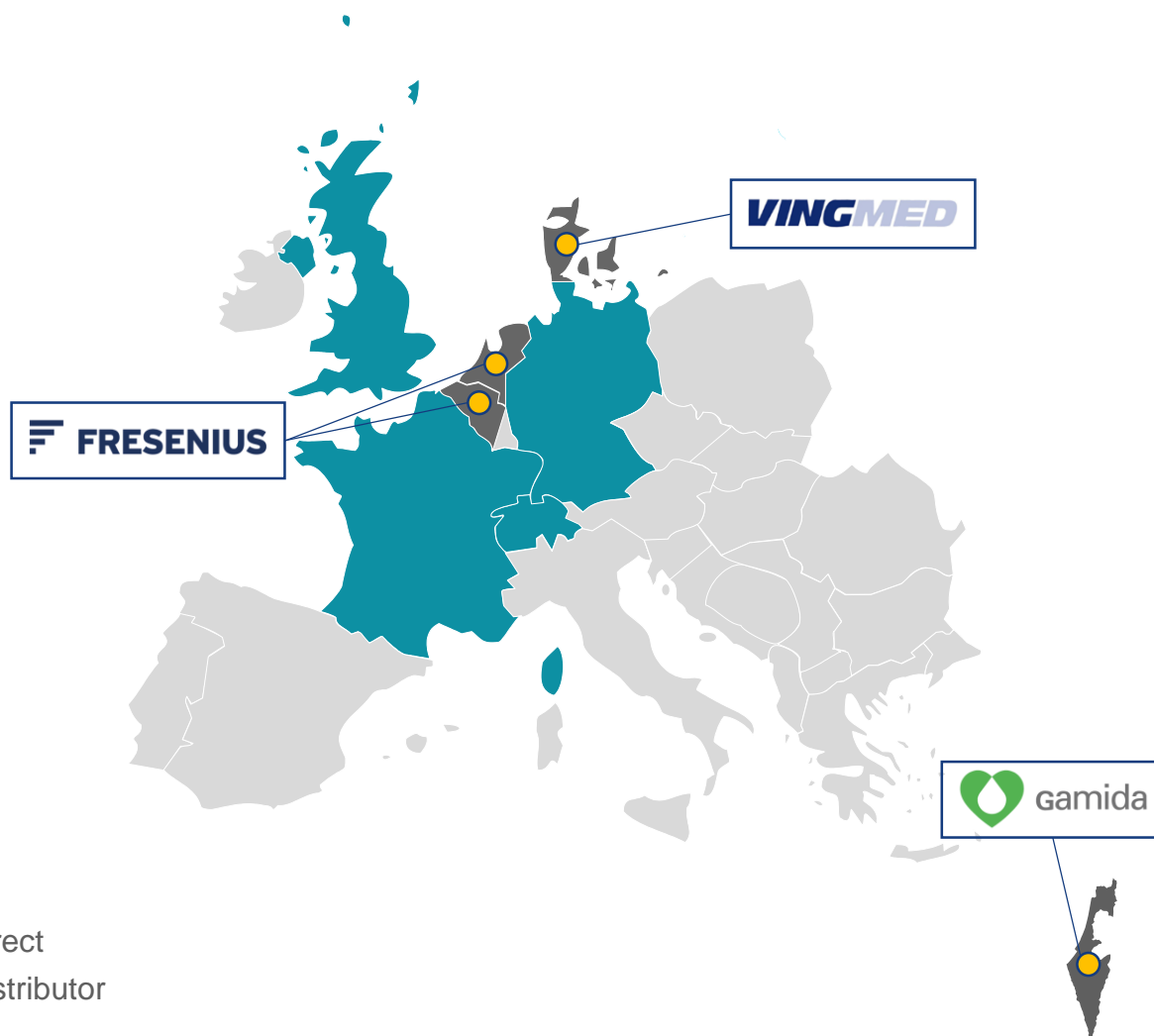


Proposed CMS rule on reimbursement for breakthrough devices (NTAP)

*Positive development for the **alfapump***

Focused European commercial activities

Building real world clinical experience and awareness



Direct
 Distributor

14 person team

Focus on specialist centers

Raise awareness at community hospital level

- Current reimbursement:**
- ✓ **Switzerland:** DRG
 - ✓ **Germany:** DRG (NUB program⁽¹⁾)
 - ✓ **UK:** local reimbursement – NICE guidance “use with special arrangements”

Note 1 NUB: “Neue Untersuchungs- und Behandlungsmethode” = add-on payment to DRG for new diagnostic and treatment methods

Strong support from patients and KOLs

Creating awareness amongst key stakeholders

Patients



“ My lifestyle has changed 100%. I was able to sleep better, eat better [...] making me feel that much better.

Family



“ I've got my freedom back. I can go shopping without having to be worried. It's amazing, he's actually dancing with me again.

Clinicians



“ The **alfapump** is an exciting new technique. Patient doesn't need to go to the hospital so often. It allows for the patient to be free, mobile and self-caring.

Building clinical evidence

Received: 22 March 2017 | First decision: 17 April 2017 | Accepted: 30 August 2017
DOI: 10.1111/apt.14331

WILEY | **AP&T** Alimentary Pharmacology & Therapeutics

Treatment of refractory ascites with an automated low-flow ascites pump in patients with cirrhosis

G. Stirnimann¹ | T. Berg² | L. Spahr³ | S. Zeuzem⁴ | S. McPherson⁵ | F. Lammert⁶ | F. Storni¹ | V. Banz¹ | J. Babatz⁷ | V. Vargas⁸ | A. Geier⁹ | A. Stallmach¹⁰ | C. Engelmann² | C. Trepte¹¹ | J. Capel¹¹ | A. De Gottardi¹



Improvement in Quality of Life and Reduction in Large Volume Paracentesis Requirement from the MOSAIC Study: a Multicenter, Open-Label, Prospective 3-Month Study of the **ALFA** pump System in Refractory Ascites

Targeting patients through print & social media

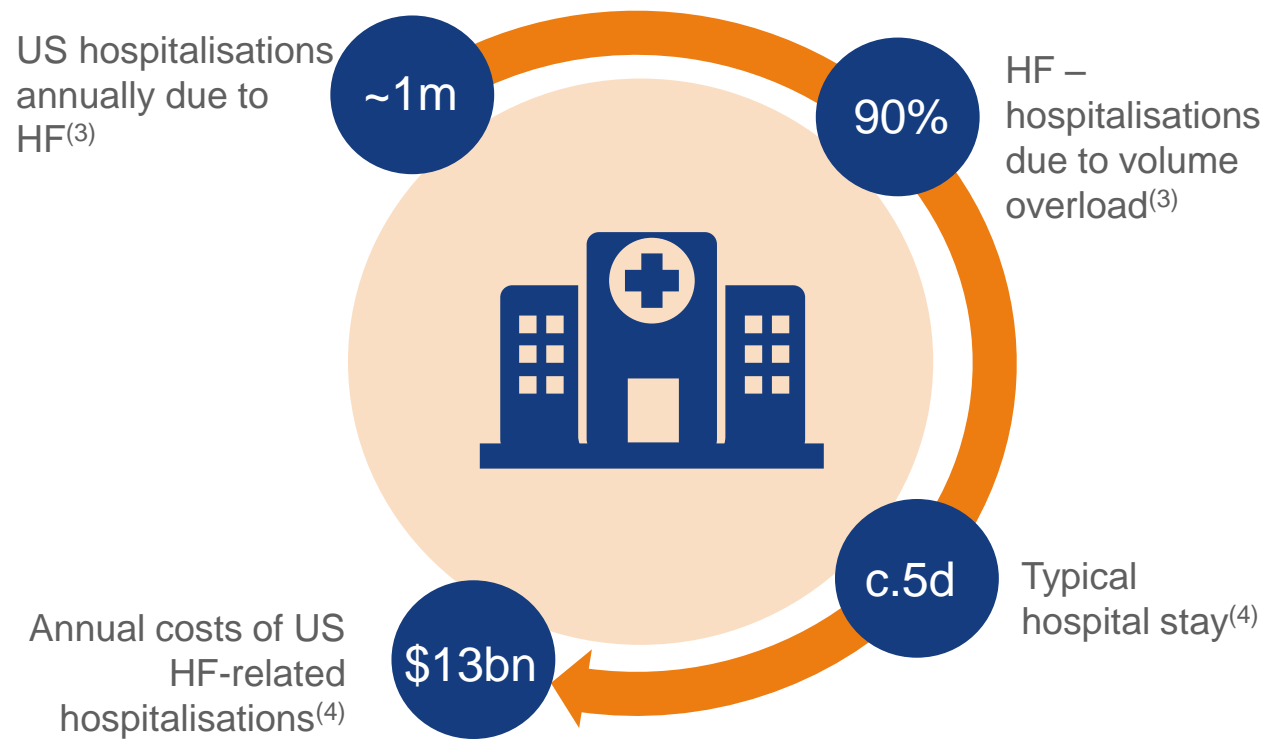
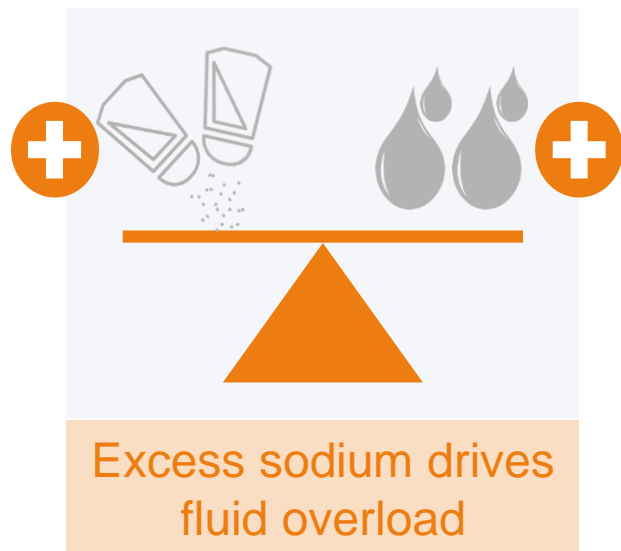




alfapump[®] DSR

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

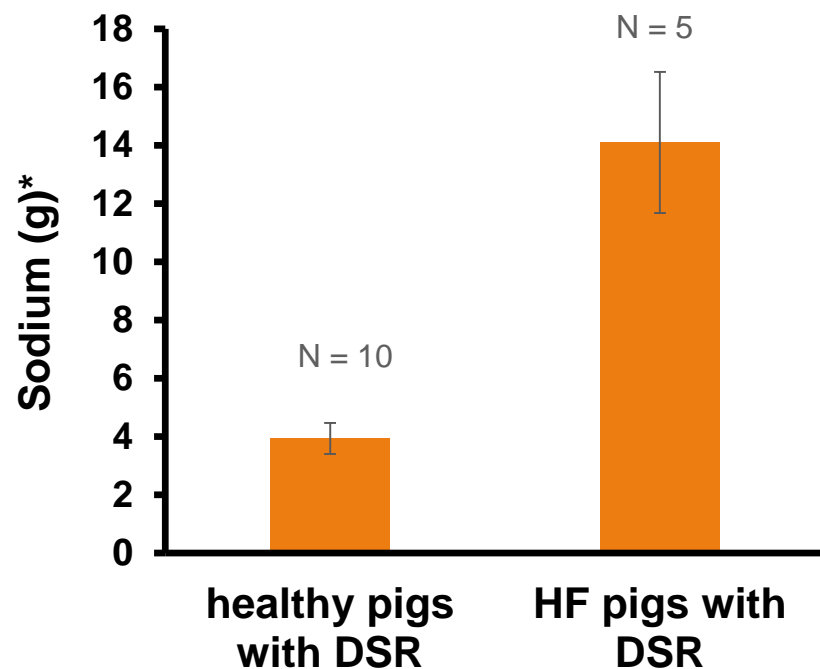
Infusate extracts sodium from the body

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

Body restores balance by eliminating excess fluid

DSR pre-clinical and clinical Proof-of-Concept

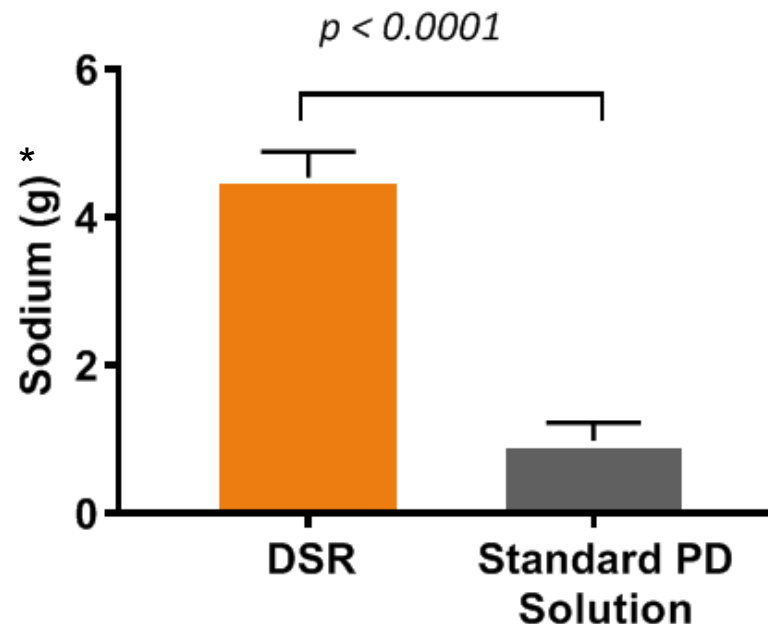
Pre-clinical studies¹



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

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

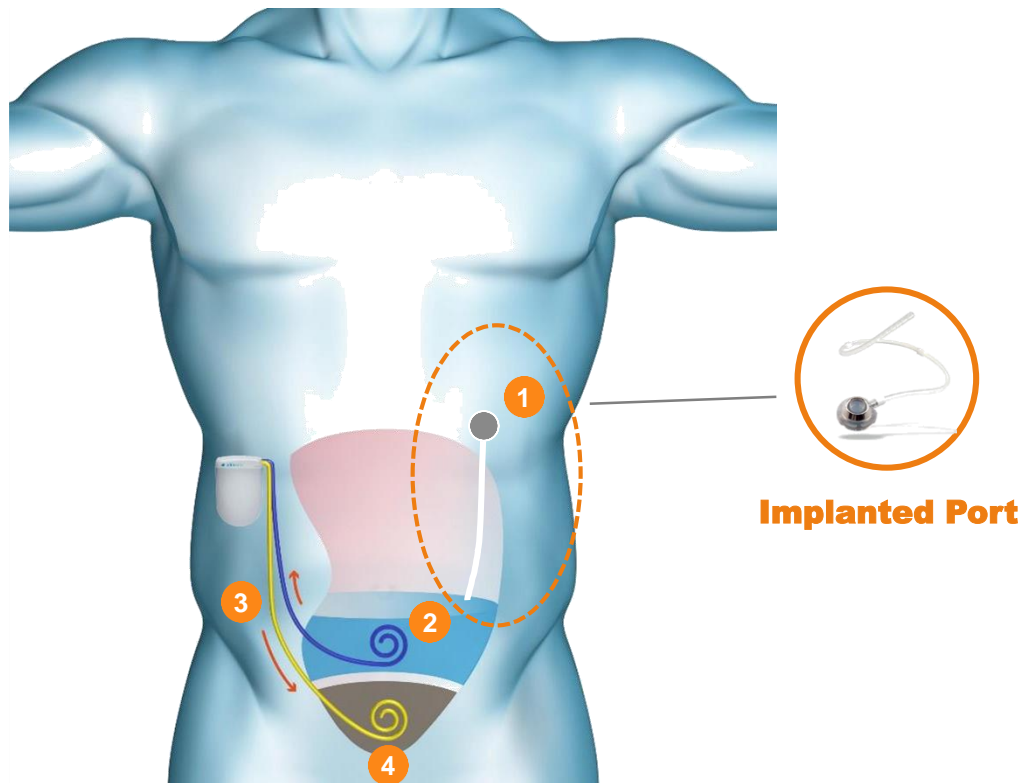
Veena S. Rao, Jeffrey M. Turner, Matthew Griffin, Devin Mahoney, Jennifer Asher, Sangchoon Jeon, Peter S. Yoo, Nabil Boutagy, Attila Feher, Albert Sinusas, F. Perry Wilson, ... [Show all Authors](#)

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

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



✓ DSR

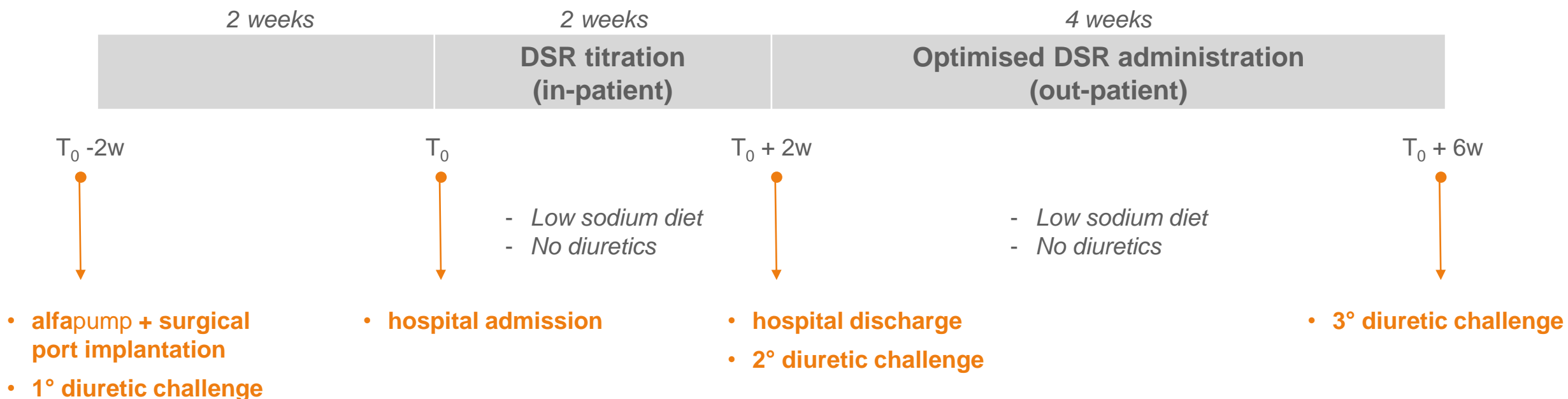
✓ alfapump

✓ 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 alfapump DSR to maintain a neutral sodium balance and maintain euvoemia
- Exploratory endpoint: impact of DSR to **restore response to diuretics**



Initial results expected in Q2 2020 and final results expected in Q3 2020

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

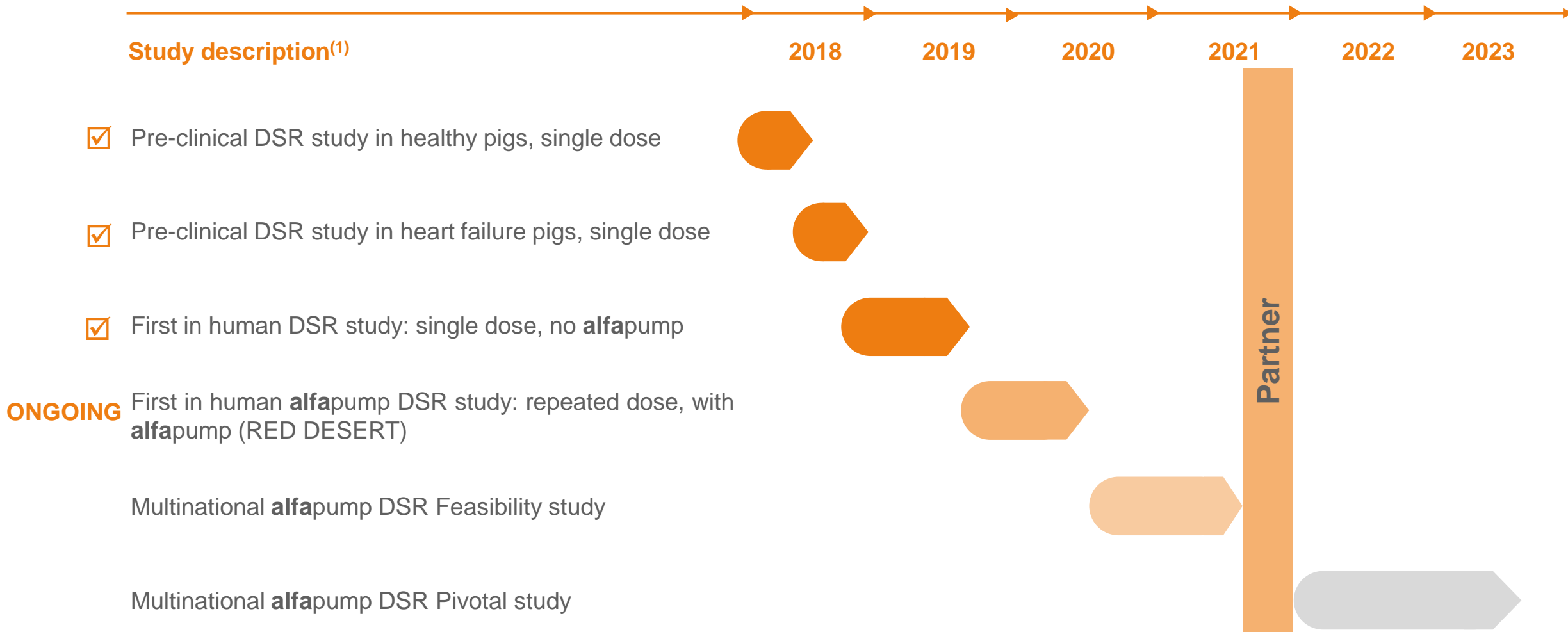
Professor and Chairman of the Department of Medicine at the University of Mississippi Medical Center



Dr. Jeffrey Testani

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

alfapump[®] DSR development overview



Note 1: study design and timelines subject to change



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



Martijn Blom
Chief Commercial Officer



Gijs Klarenbeek
Chief Medical Officer



Dirk Fengels
Vice President Engineering
& Manufacturing



Timur Resch
Global VP QM/QA/RA

Board of Directors:



Pierre Chauvineau
Board Chairman



Ian Crosbie
Chief Executive Officer



Rudy Dekeyser
Director



Wim Ottevaere
Director



Erik Amble
Director



Jason Hannon
Director

Expected near-term value drivers

H1 2020

- Initial results of RED DESERT study in heart failure patients with volume overload
- Completion of enrolment of POSEIDON study in recurrent and refractory liver ascites patients
- Initiation of Prospective Malignant Ascites Study (ProMAS)
- Initiation of Step Counter study in refractory liver ascites patients
- Expected final German⁽¹⁾ reimbursement of **alfapump**[®]

H2 2020

- Presentation of final results of RED DESERT study in heart failure patients with volume overload
- Interim results of POSEIDON study in recurrent and refractory liver ascites patients
- Completion of enrolment of ProMAS study in patients with malignant ascites
- Initiation of **alfapump** DSR feasibility study in patients with volume overload due to heart failure

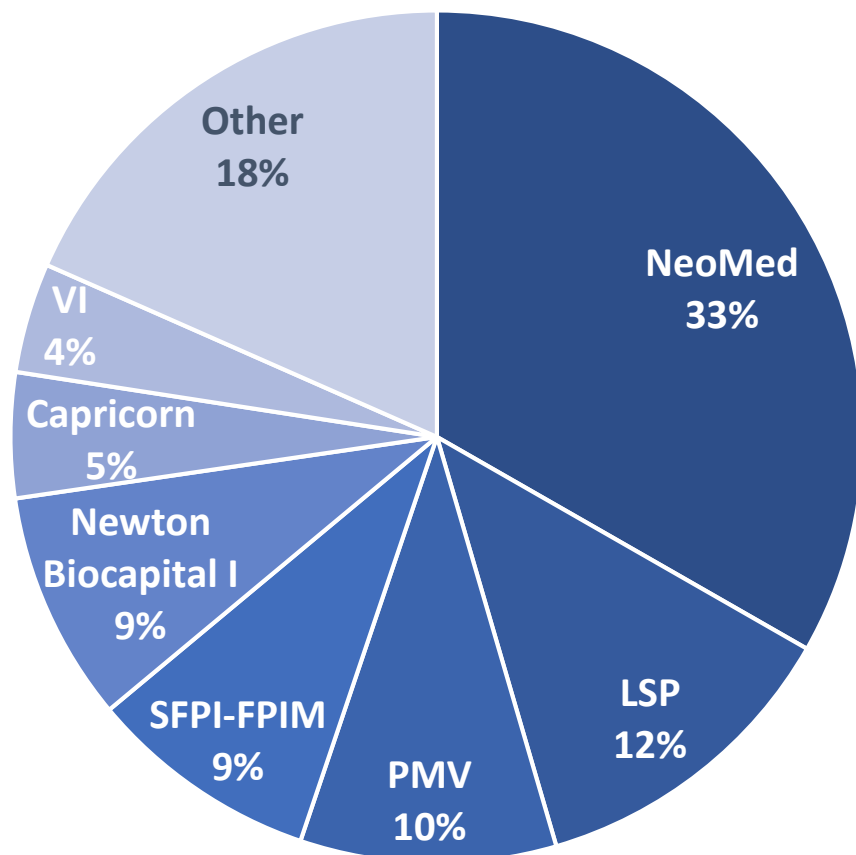
Back-up



Shareholders base and financial overview

Ticker: SEQUA – Euronext Brussels

- Outstanding shares: 12,6M
- Outstanding share options & warrants: 1,9M authorised of which 0,9M granted



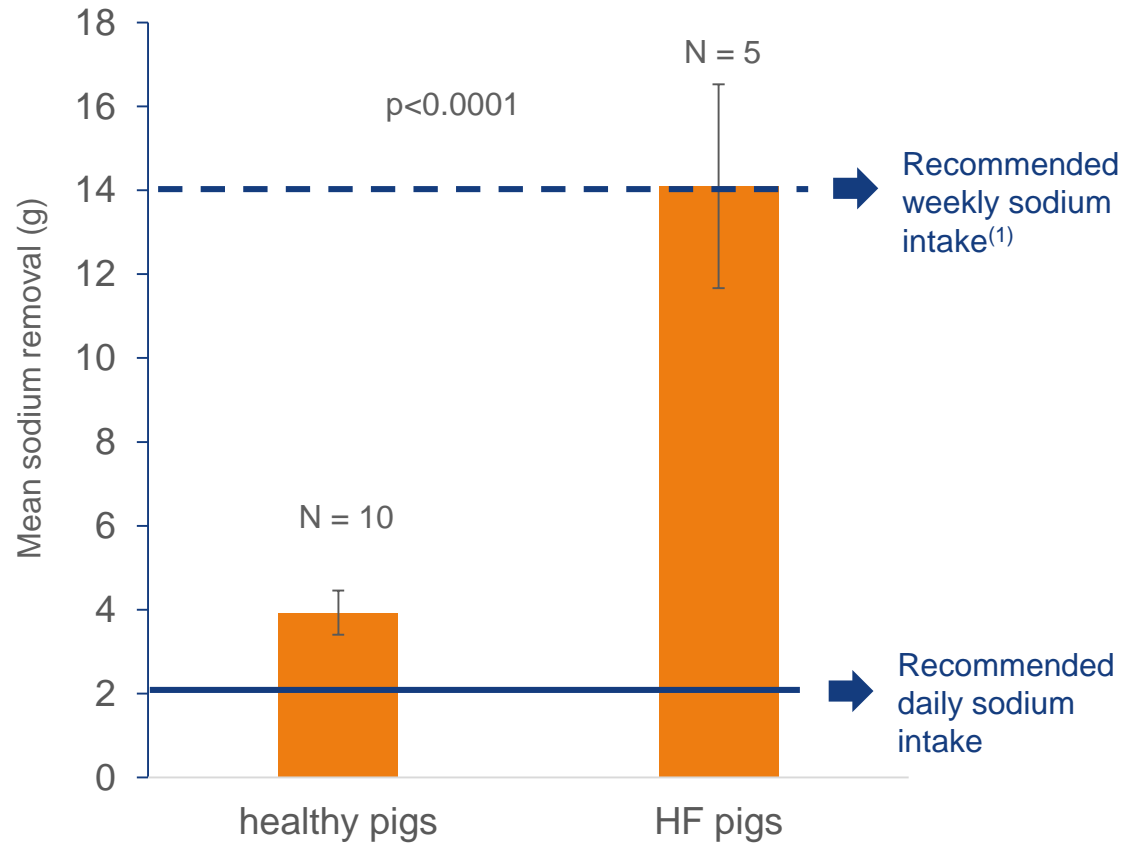
- Analysts:
 - KBC Securities – Sandra Cauwenberghs & Lenny Van Steenhuyse
 - Kempen – Ingrid Gafanhão
 - Kepler Cheuvreux – Matthias Maenhaut & Kris Kippers
 - Mirabaud – Daniel Jelovcan
- Cash (30 June 2019): €12,9M
- Financial calendar
 - 2019 full year results: 19 March 2020
 - Publication annual report: 28 April 2020



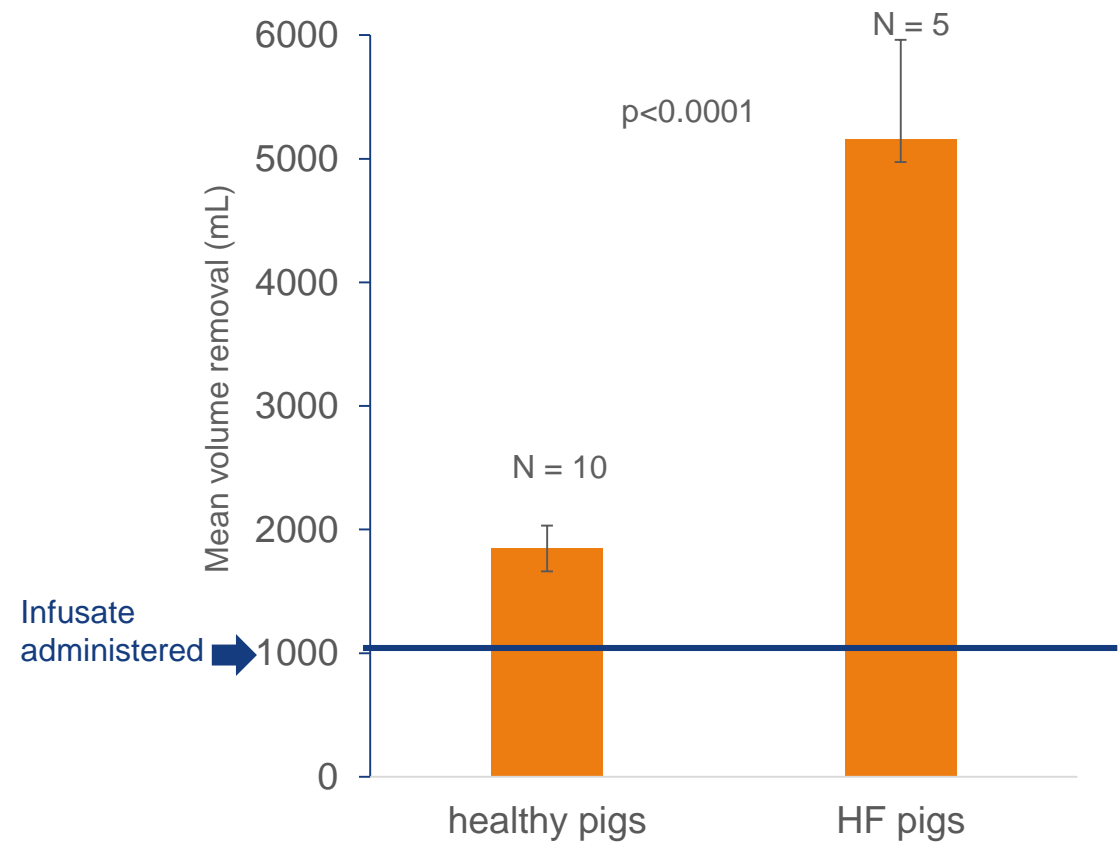
DSR pre-clinical Proof-of-Concept

Clinically relevant sodium and fluid removal

Clinically relevant removal of sodium



Effective fluid removal

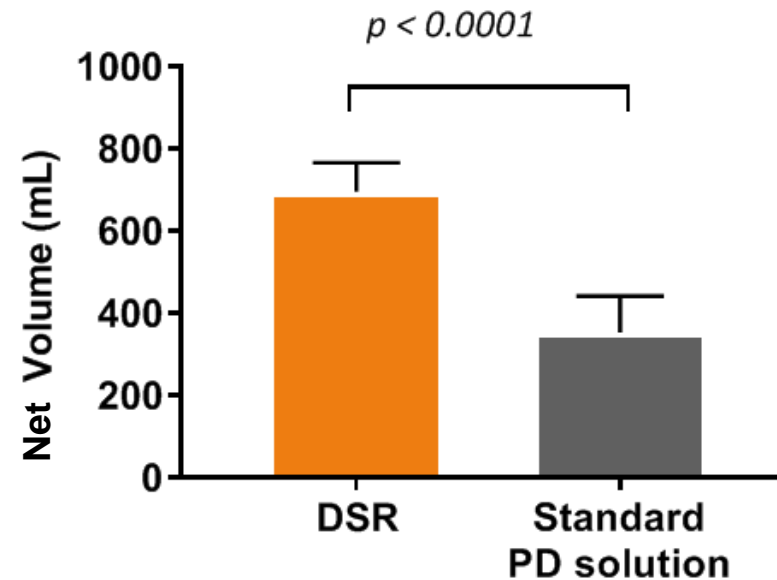
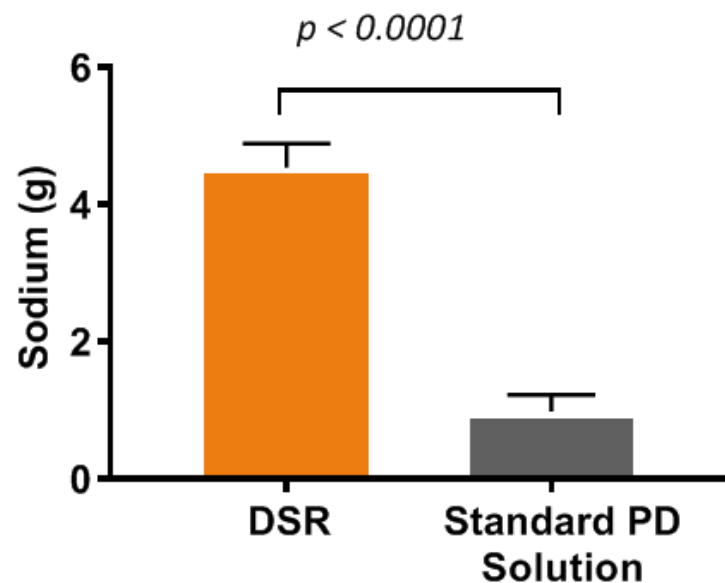


Source 1: Weekly recommended intake for humans equals 14 grams (www.cdc.gov)



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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