

sequana**medical**



Innovators in the management
of **fluid overload**

liver disease – malignant ascites – heart failure

Investor presentation – June 2020

Disclaimers

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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 and **alfapump** DSR are 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, **alfapump** DSR and ongoing investigations with the **alfapump** system in Europe, the US and Canada.

COVID-19 notice

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.

Although it is difficult to draw conclusions at this point on the systemic risk this disease could pose, the Company 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 are expected to **result in delays to execution of clinical studies and impact sales**.

Sequana Medical will **update its guidance** on the expected impact and any material change in the Company's **operations and outlook when the situation is clarified**.

Company Overview

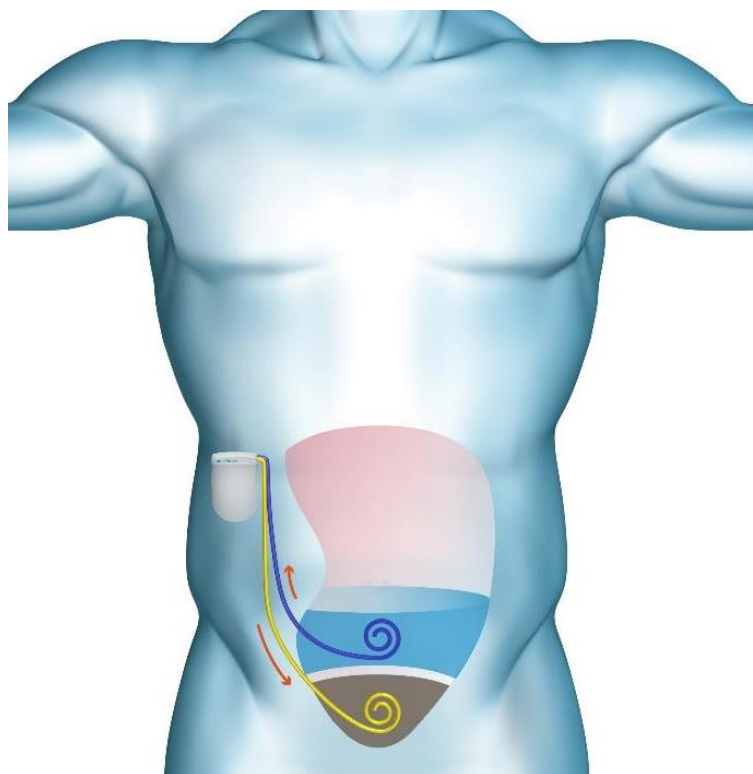
- Founded in 2006
- Gent, Belgium (HQ): corporate, clinical, commercial
- Zurich, Switzerland: manufacturing, engineering, QA/RA
- ~45 employees
- Euronext Brussels: SEQUA



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 750 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

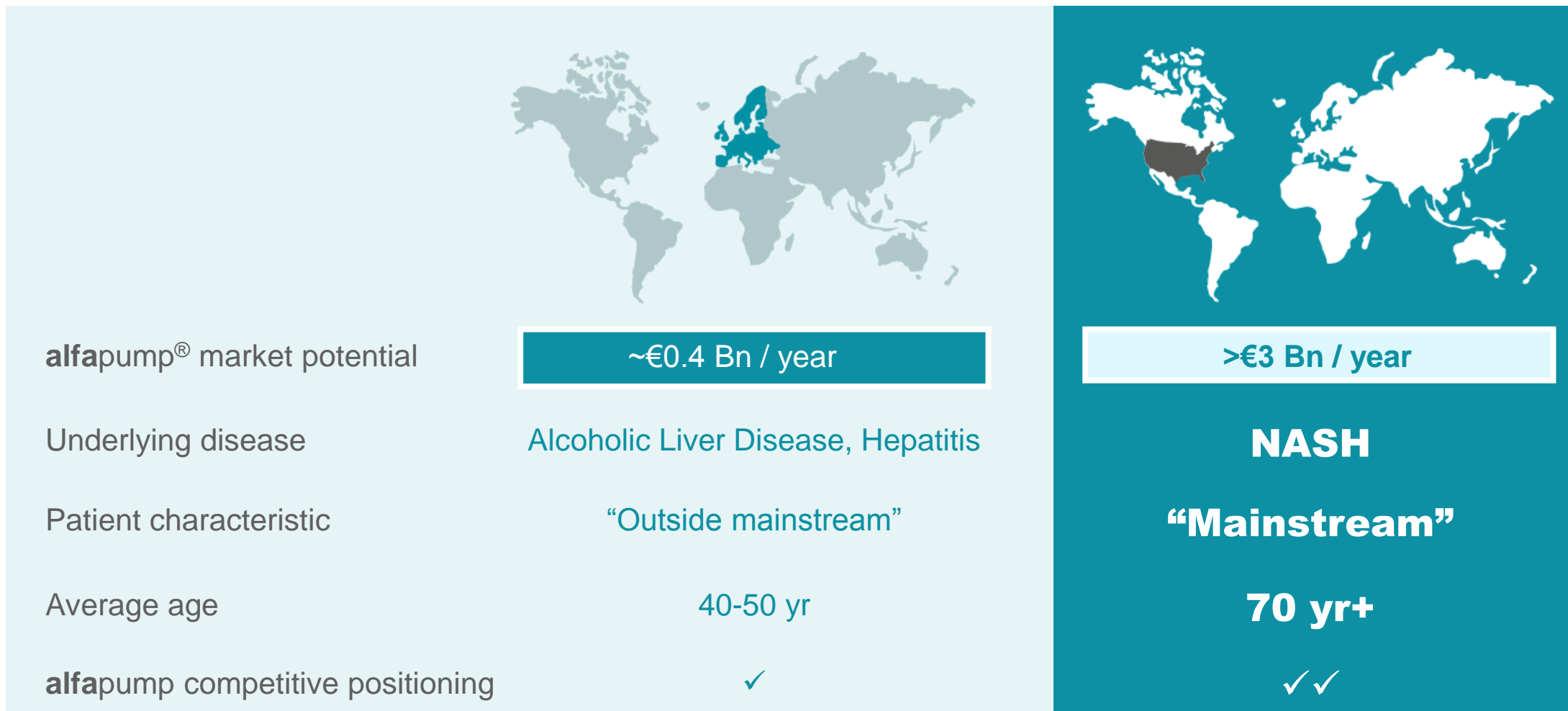
patients / year hospitalised for volume
overload due to heart failure by 2026⁽²⁾

> €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

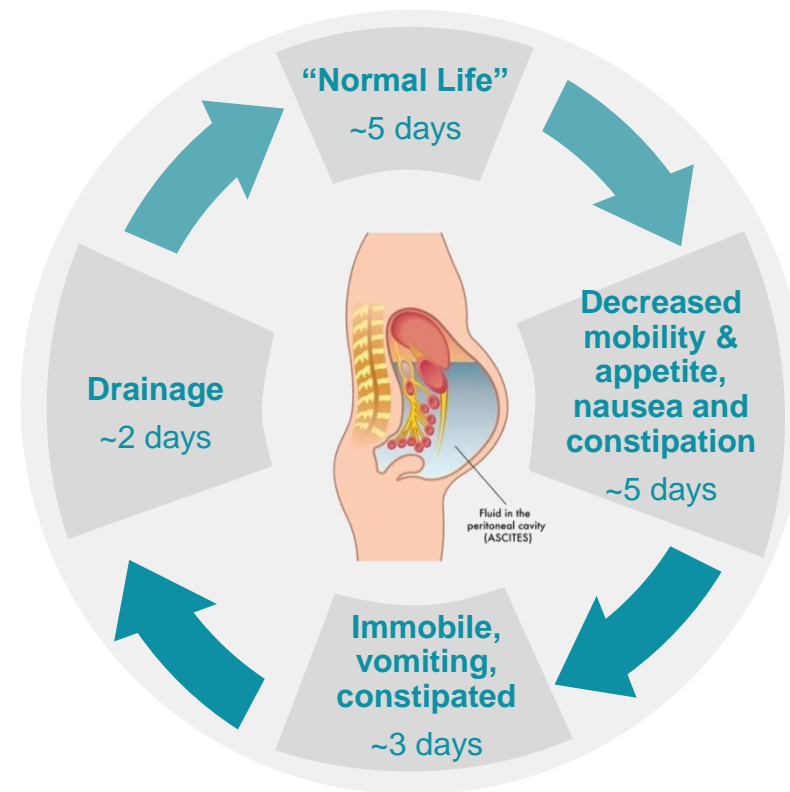
A key complication of liver cirrhosis, with a dramatic impact on quality of life

- 

Viral infections
(Hepatitis B & C)
- 


Alcoholic Liver Disease
- 

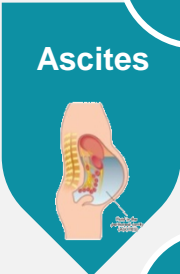
Non-Alcoholic Steatohepatitis (NASH)




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

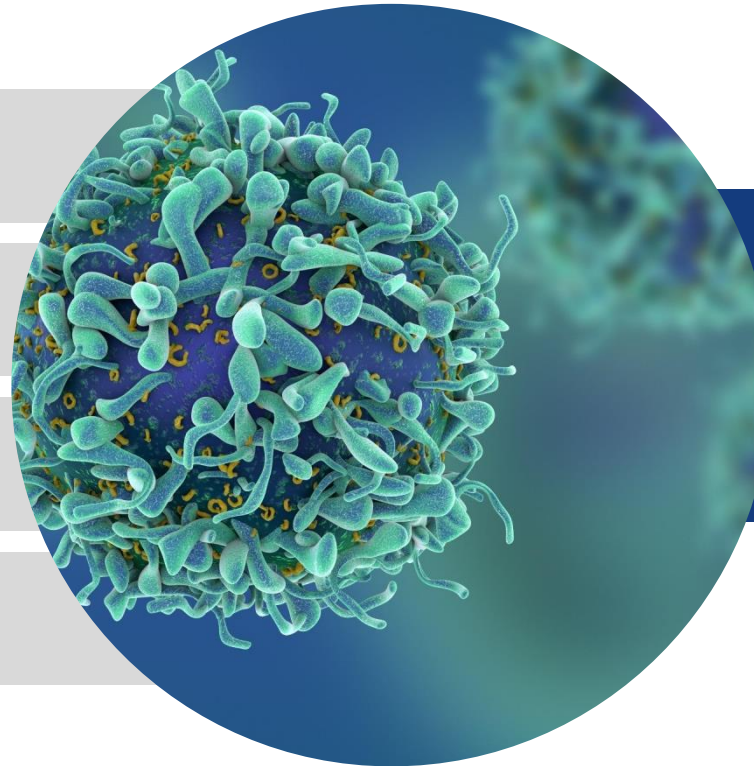
Severe complication of late-stage cancers

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**

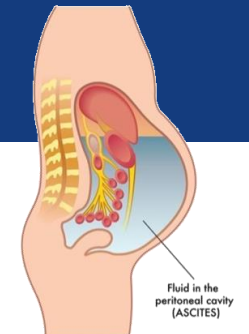
Reduces ability to undergo **anti-cancer treatment**



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.

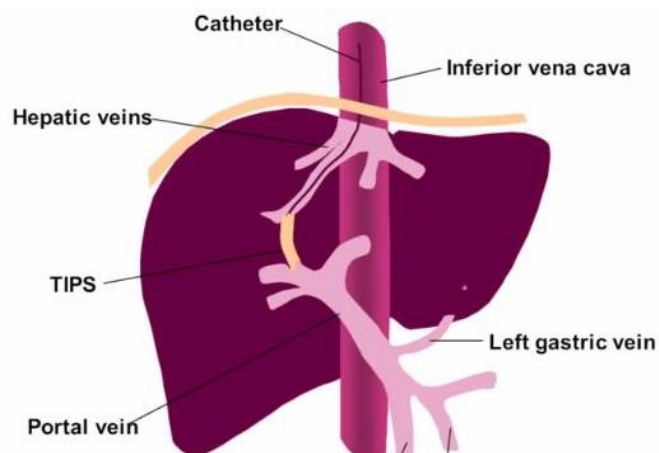
Severe limitations of existing therapies

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)

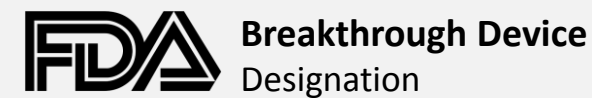
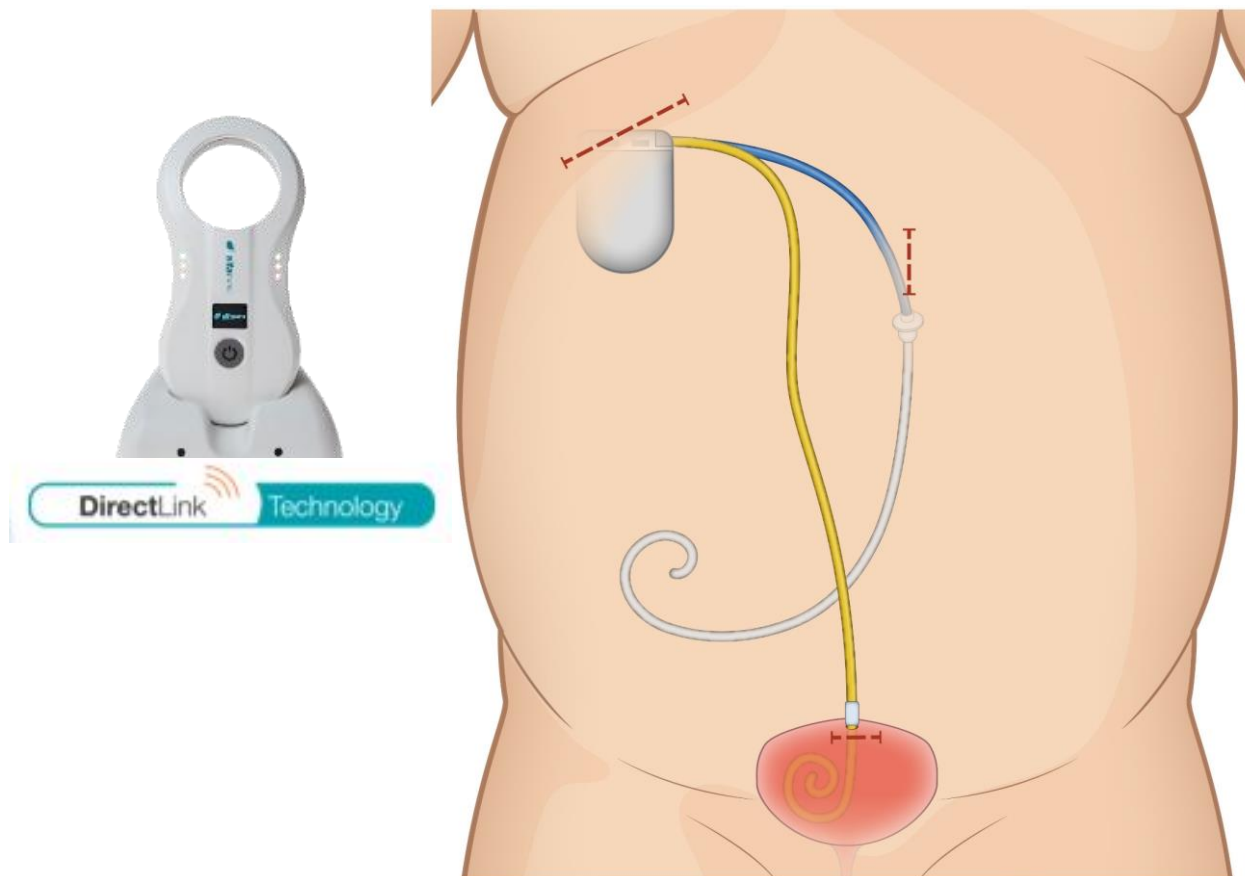
Liver transplant



Limited availability and high costs

alfapump® for long-term treatment

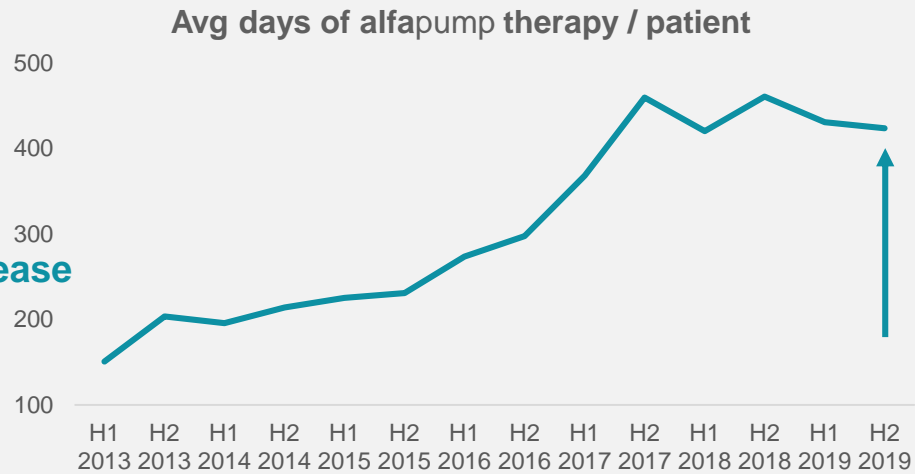
Over 750 implants and hundreds of years of patient experience



Strong clinical validation



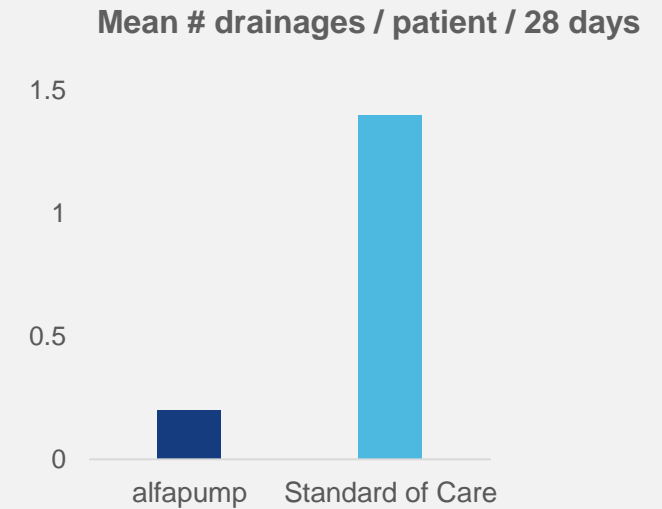
Clear increase in clinical outcomes



Sequana Medical data



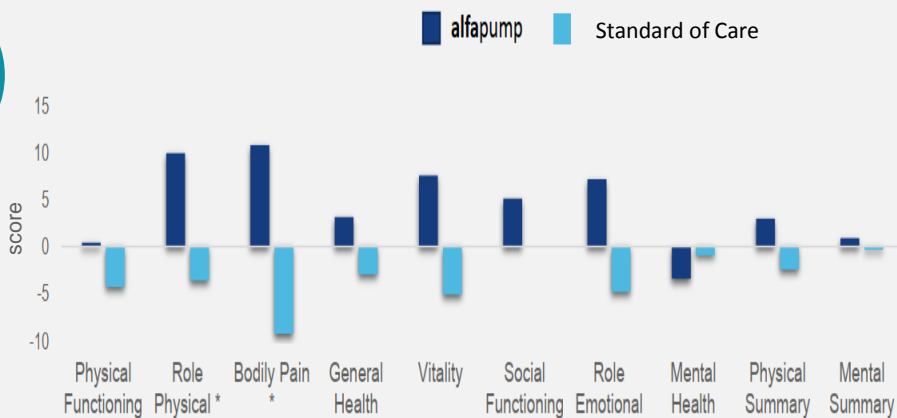
Drastically reduced need for drainage



Results RCT study

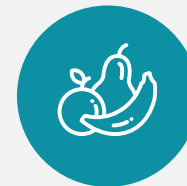


Improved quality of life

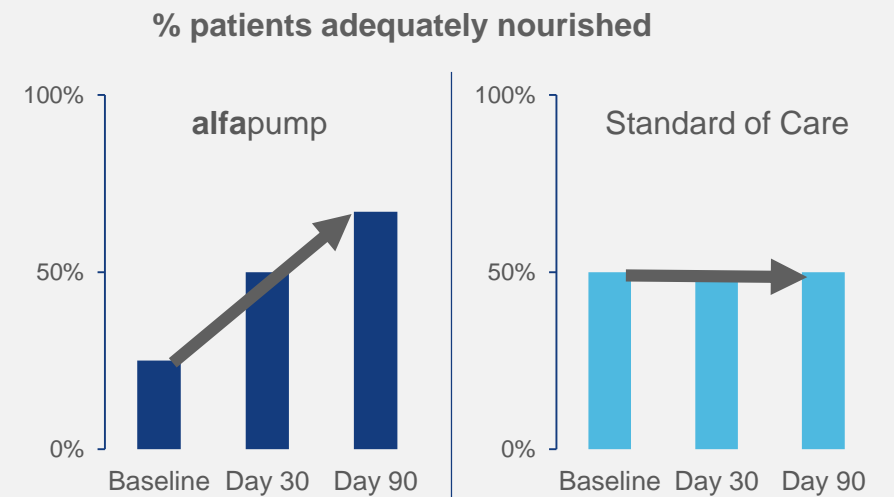


Results RCT study

* p<0.05



Improved nutrition

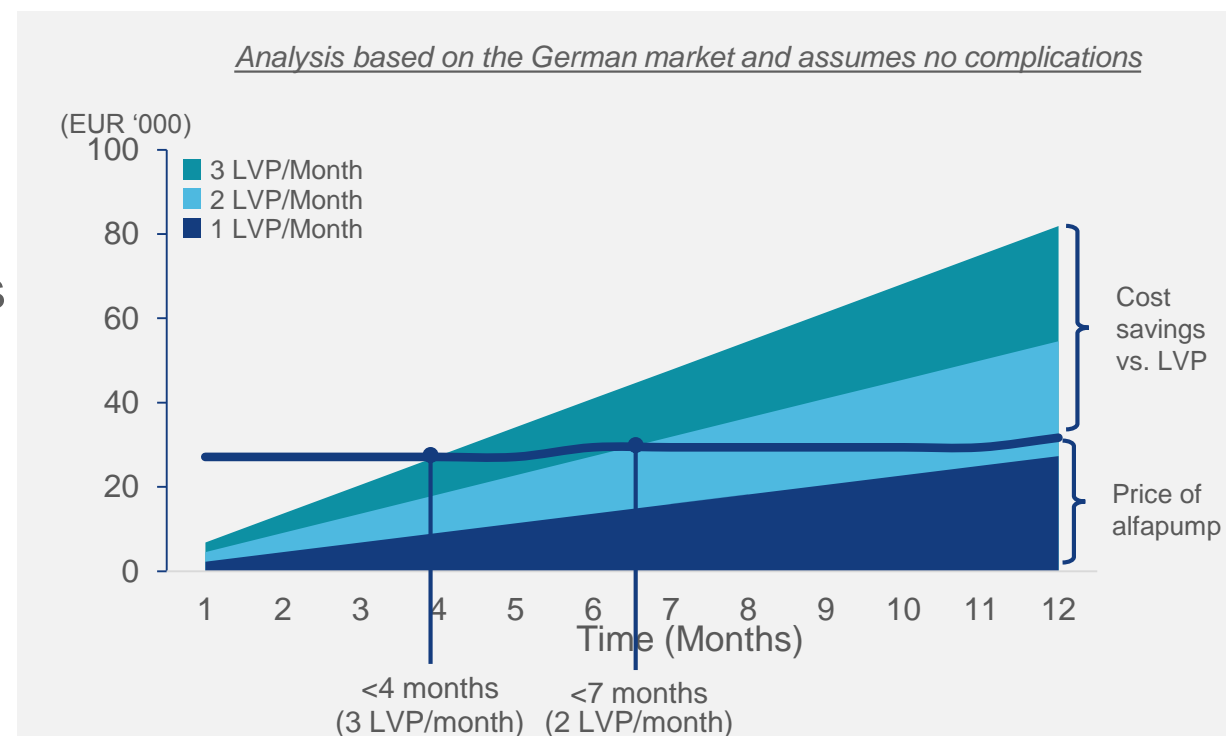


Results RCT study

Strong health economics rationale

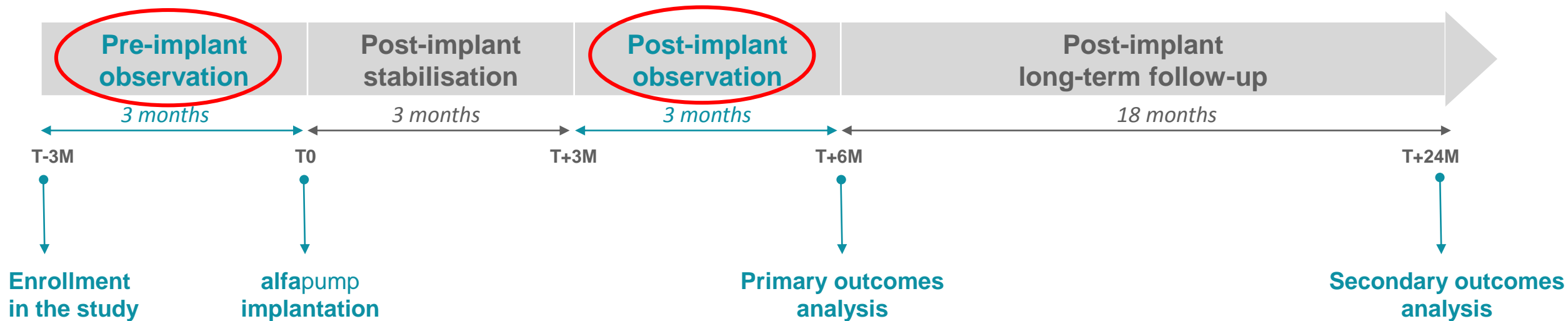
Significant reduction in regular drainage leads to:

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



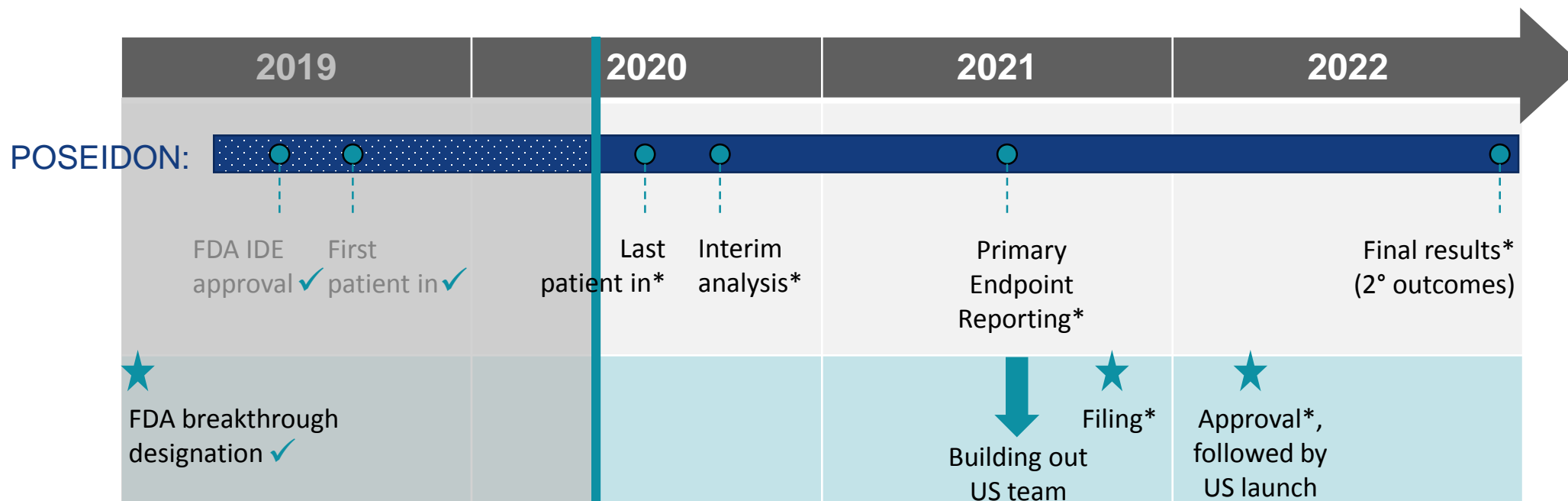
North American Pivotal Study (POSEIDON) underway

- 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

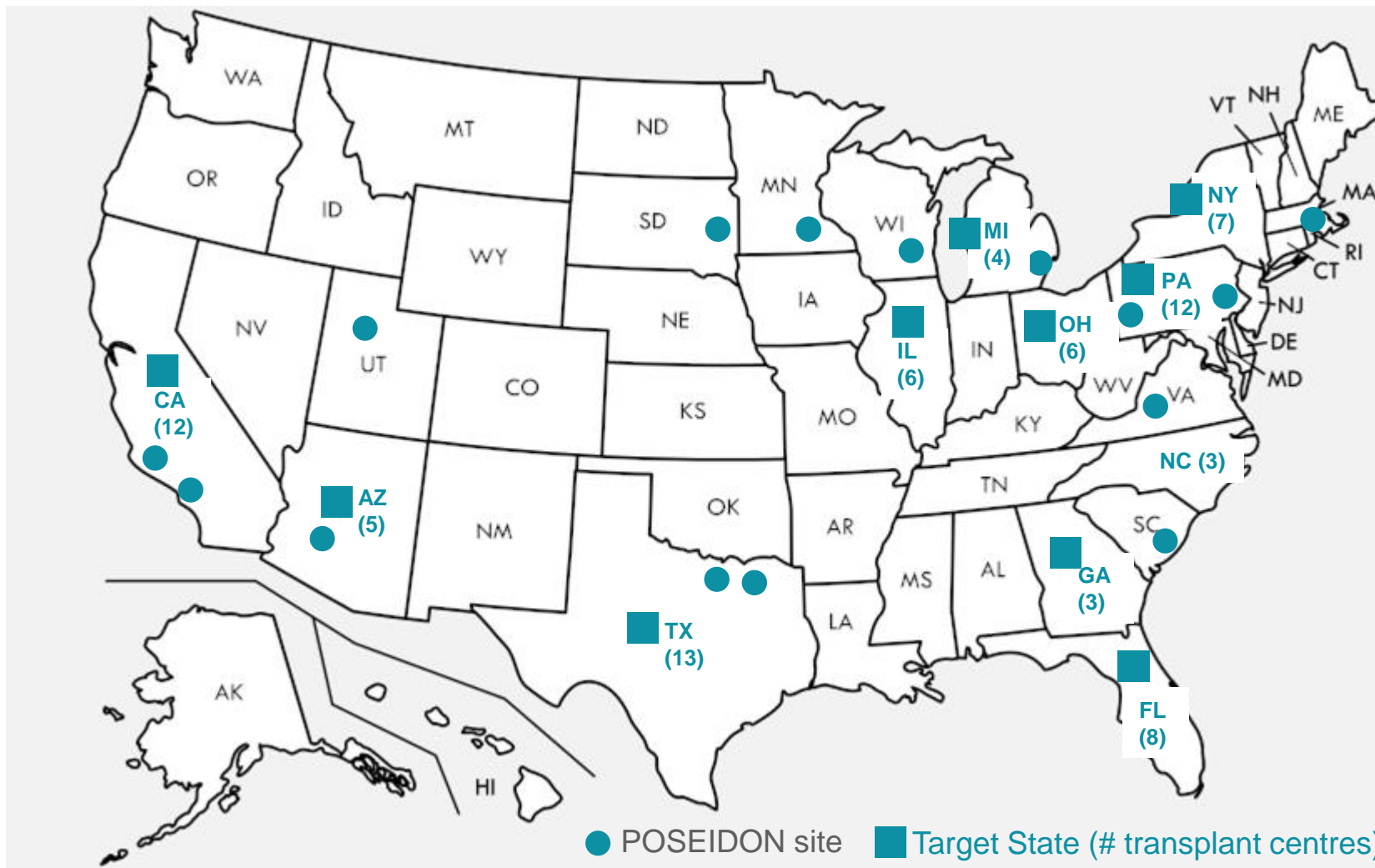


Final CMS rule on reimbursement for breakthrough devices (NTAP) expected to further support reimbursement for the alfapump

*Note: timings presented in this slide reflect pre-COVID-19 expectations and will be delayed due to the COVID-19 pandemic

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

Self-commercialisation in US through specialty salesforce

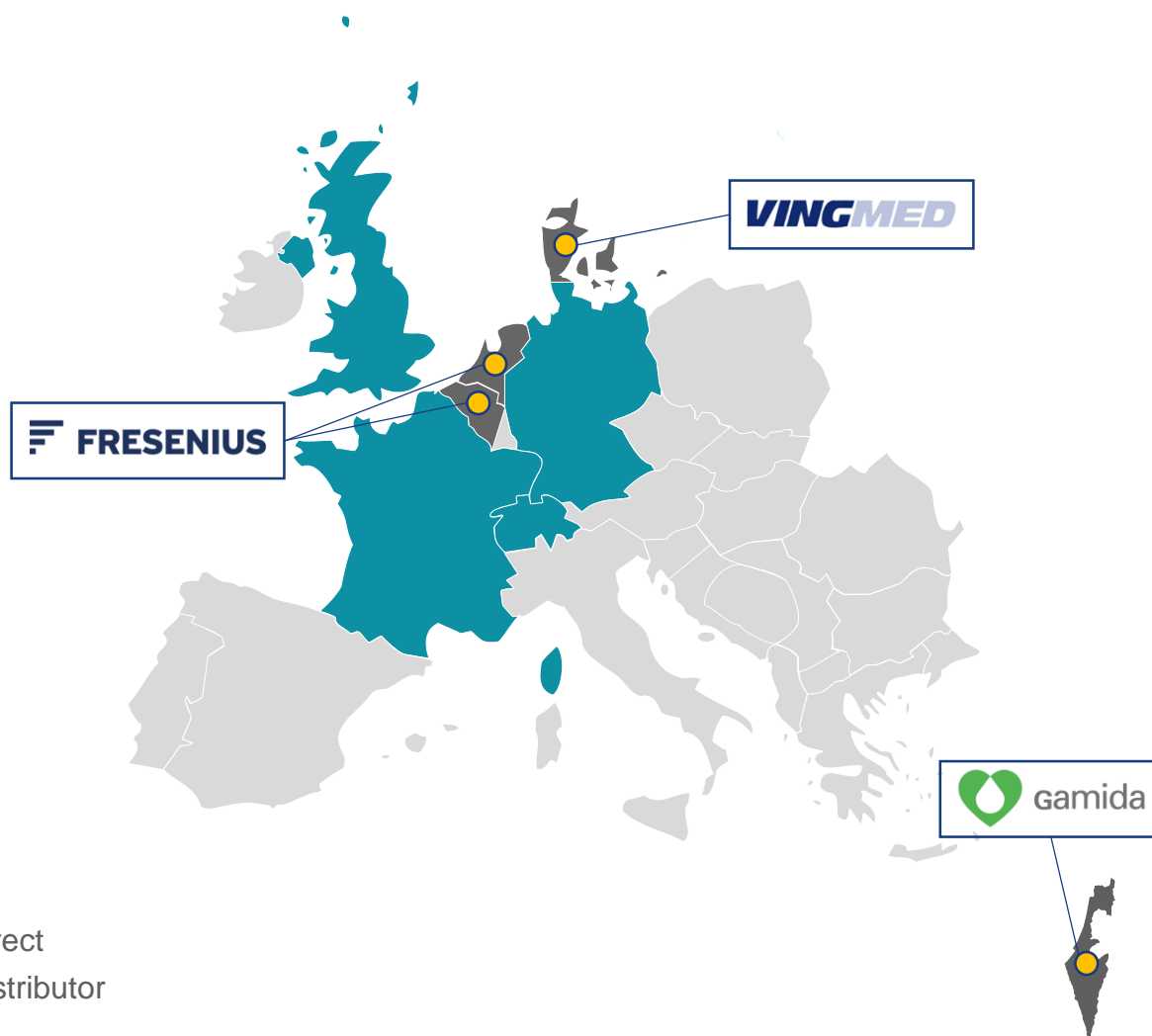


Initial focus on key transplant centres

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

Focused European commercial activities

Building real world clinical experience and awareness



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”

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

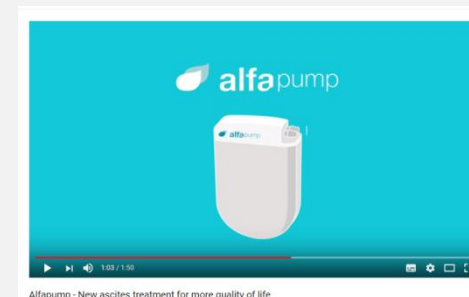
Treatment of refractory ascites with an automated low-flow ascites pump in patients with cirrhosis

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

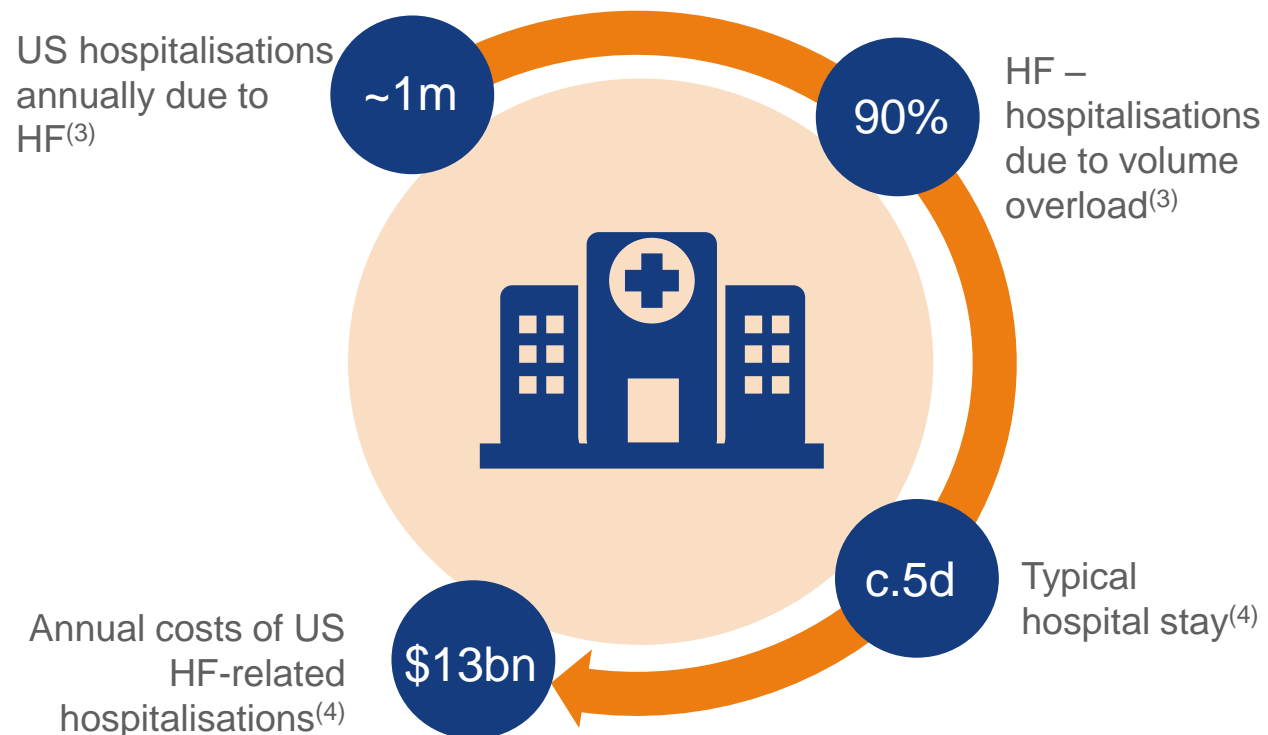
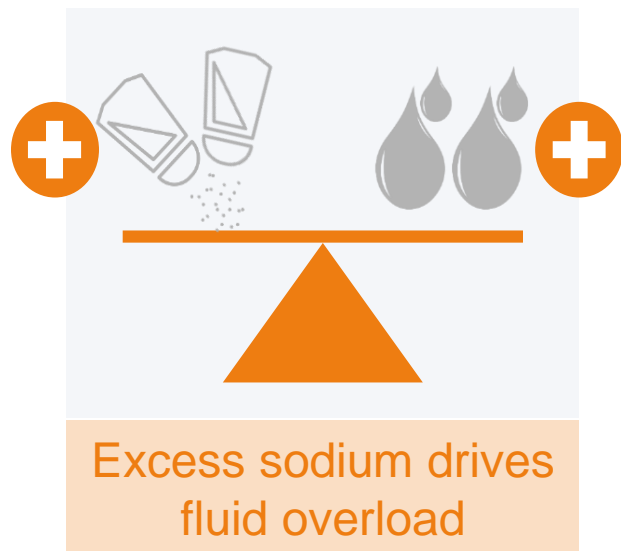




alfapump[®] DSR

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

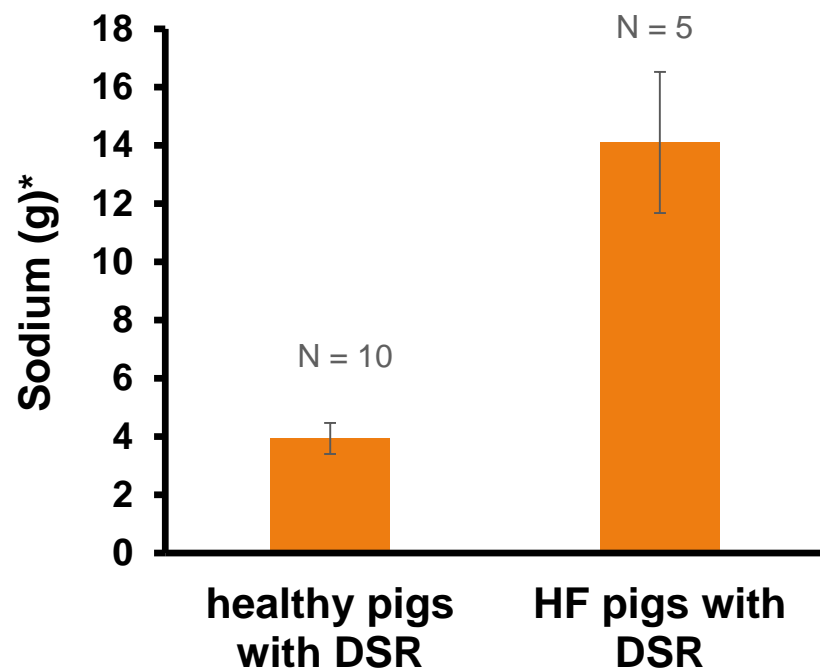
Infusate extracts sodium from the body

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

Body restores balance by eliminating excess fluid

DSR pre-clinical and clinical Proof-of-Concept

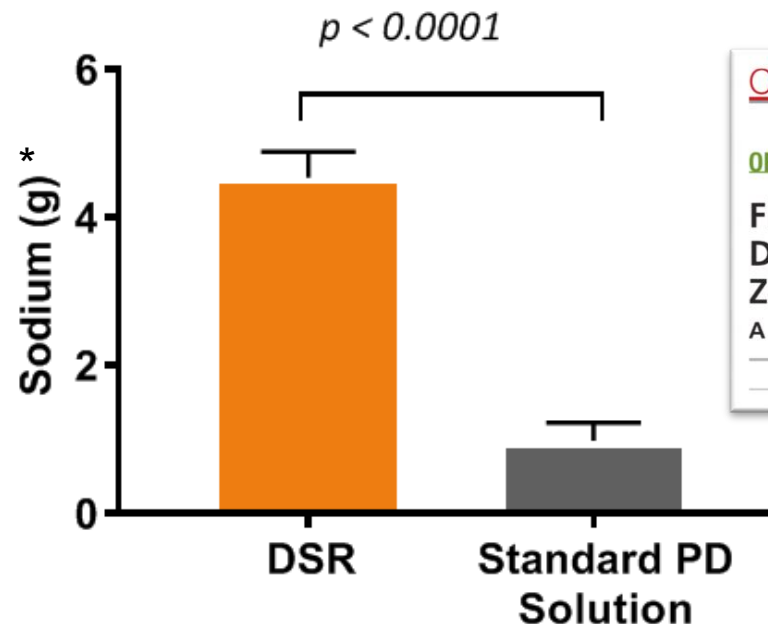
Pre-clinical studies¹



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)



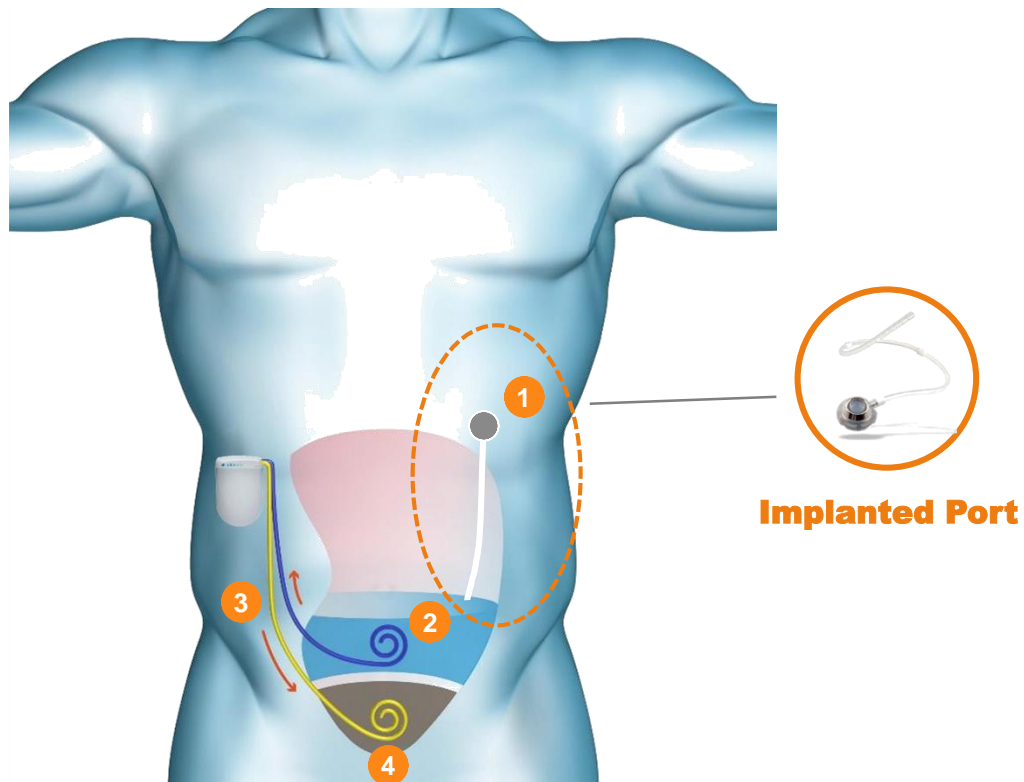
2: Cross-over study: administration of 1 litre DSR infusate (D10) vs. standard PD solution, with 2 hour dwell



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

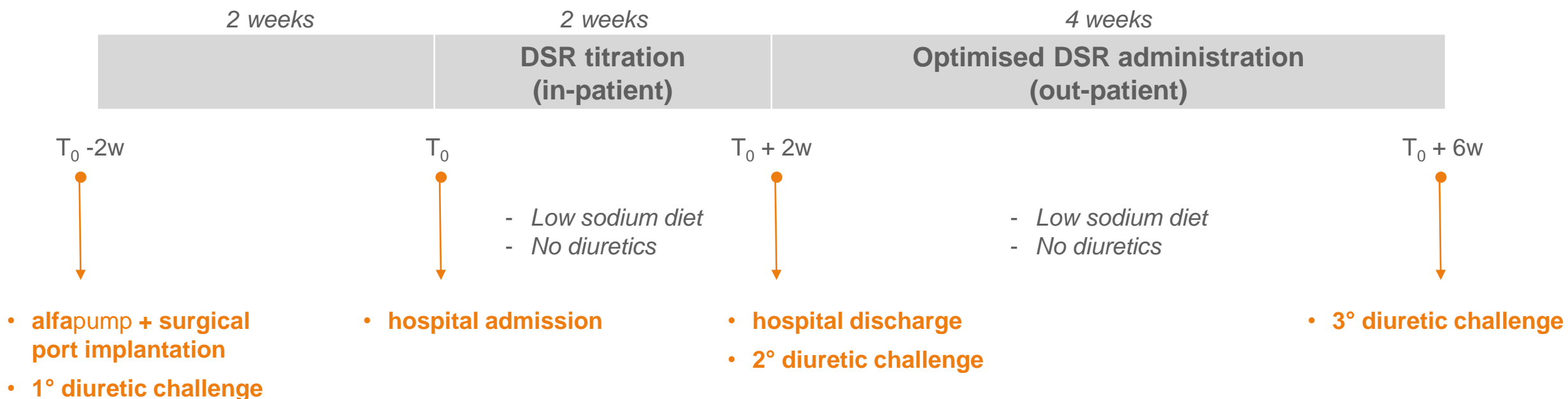


- ✓ DSR
- ✓ alfapump
- ✓ Implanted port

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**



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

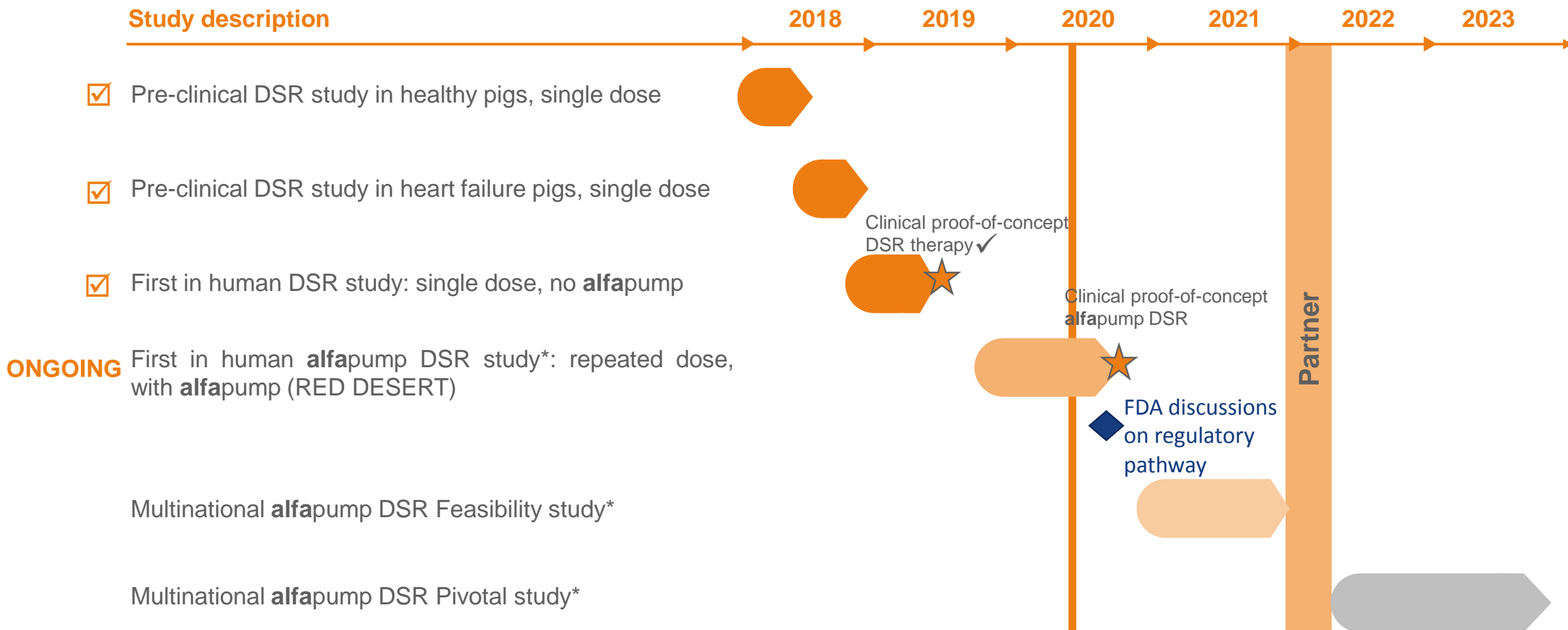
Professor and Chairman of the Department of Medicine at the University of Mississippi Medical Center



Dr. Jeffrey Testani

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

alfapump[®] DSR development overview



*Note: study design and timings presented in this slide reflect pre-COVID-19 expectations and will be delayed due to the COVID-19 pandemic



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 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

H2 2020

-
- Presentation of 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

**Note: These timings will be delayed due to the COVID-19 pandemic. Updated guidance will be provided when the situation is clarified.*

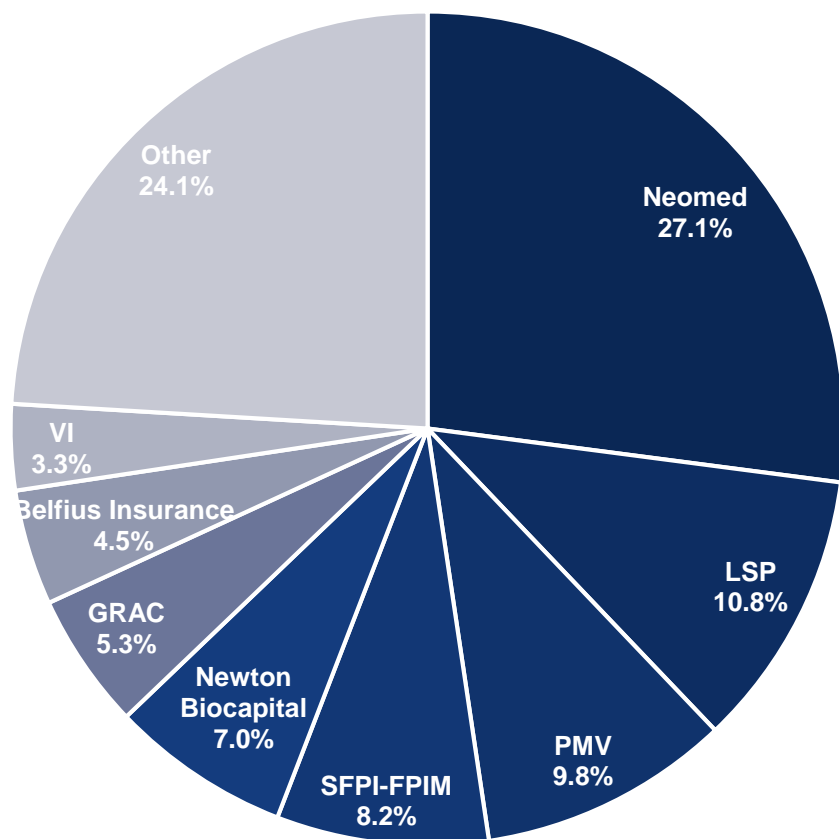
Back-up



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



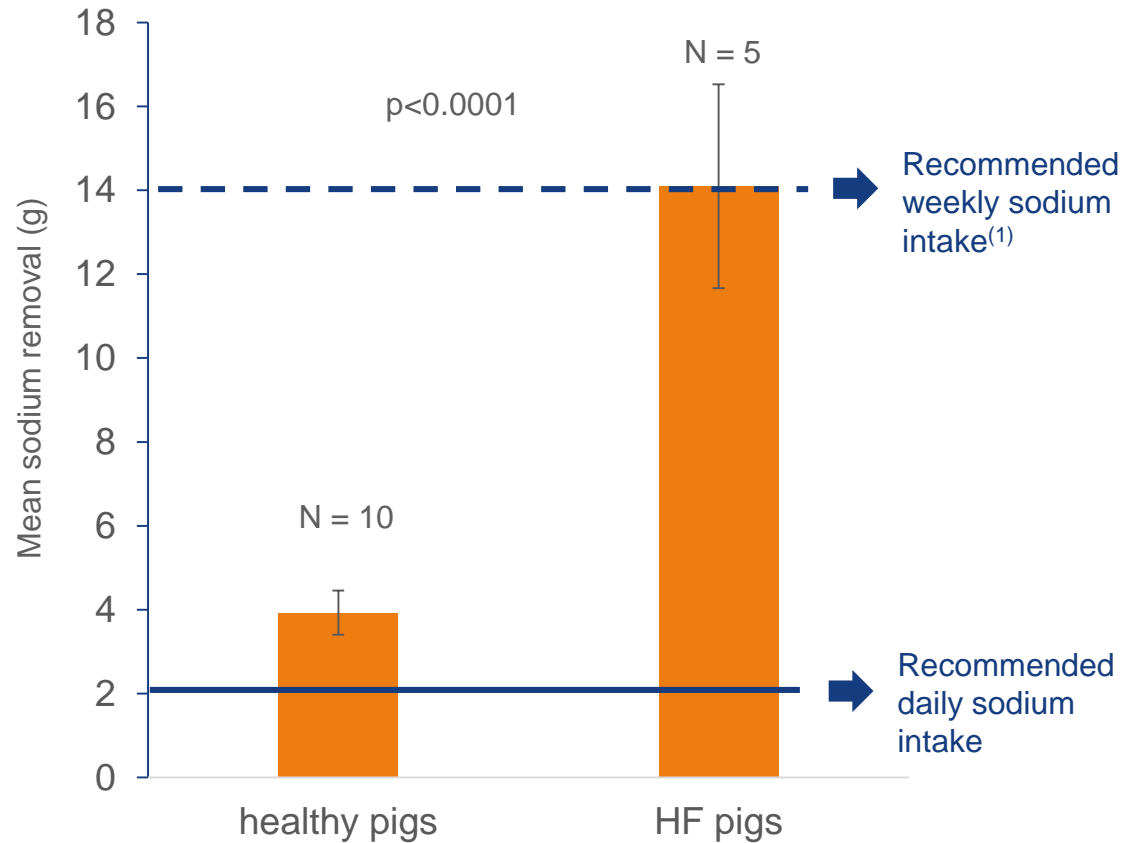
- Analysts:
 - KBC Securities – Sandra Cauwenberghs & Lenny Van Steenhuyse
 - Kempen – Ingrid Gafanhão
 - Kepler Cheuvreux – Matthias Maenhaut & Kris Kippers
 - Mirabaud – Daniel Jelovcan
- Cash (31 December 2019): €5.6M
- Equity financing (22 January 2020): €19.0 M
- Financial calendar
 - Half year results 2020: 3 September 2020



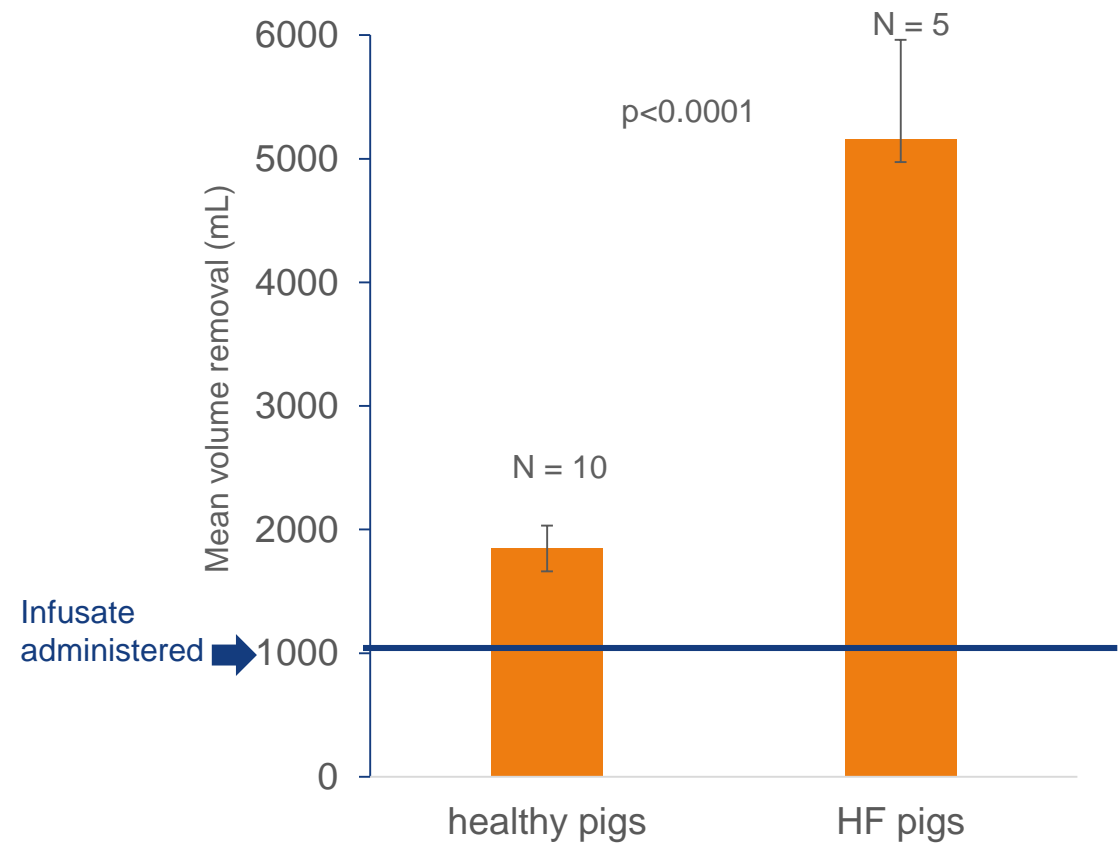
DSR pre-clinical Proof-of-Concept

Clinically relevant sodium and fluid removal

Clinically relevant removal of sodium



Effective fluid removal

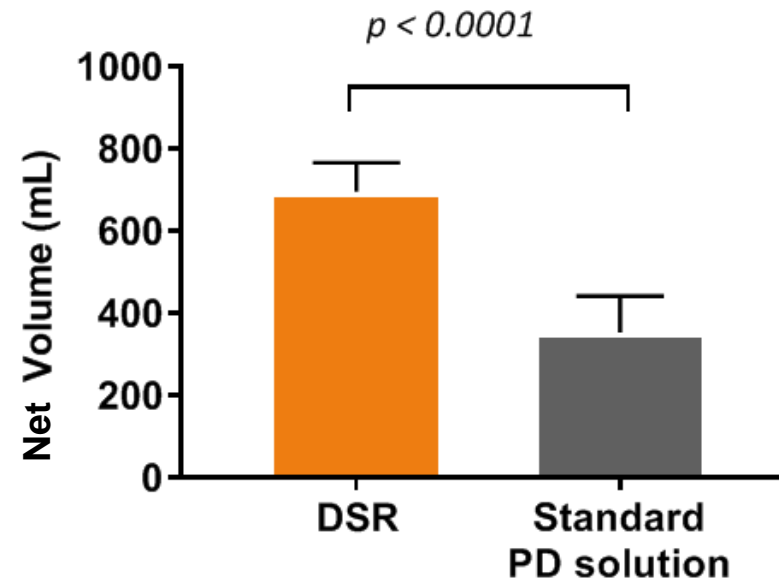
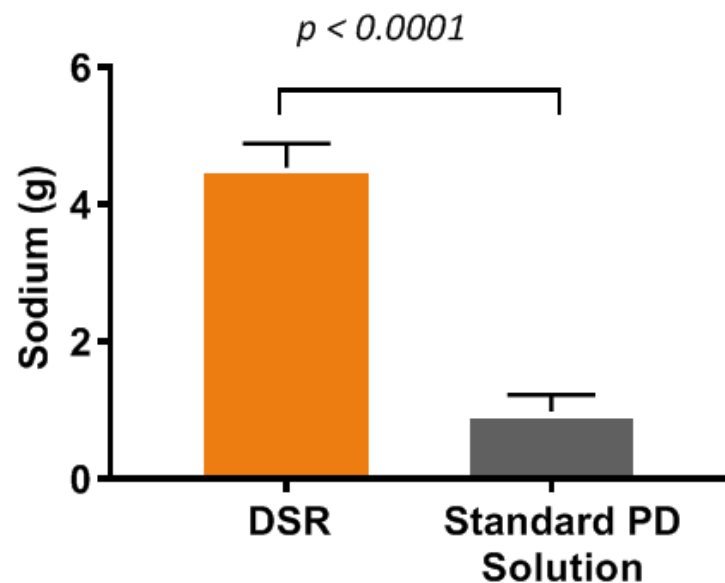


Source 1: Weekly recommended intake for humans equals 14 grams (www.cdc.gov)



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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IR@sequanamedical.com



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www.sequanamedical.com