

# sequana medical



Innovators in the management  
of **fluid overload**

liver disease – malignant ascites – heart failure

Investor presentation – December 2019

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## Regulatory disclaimers:

- The **alfapump**<sup>®</sup> 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

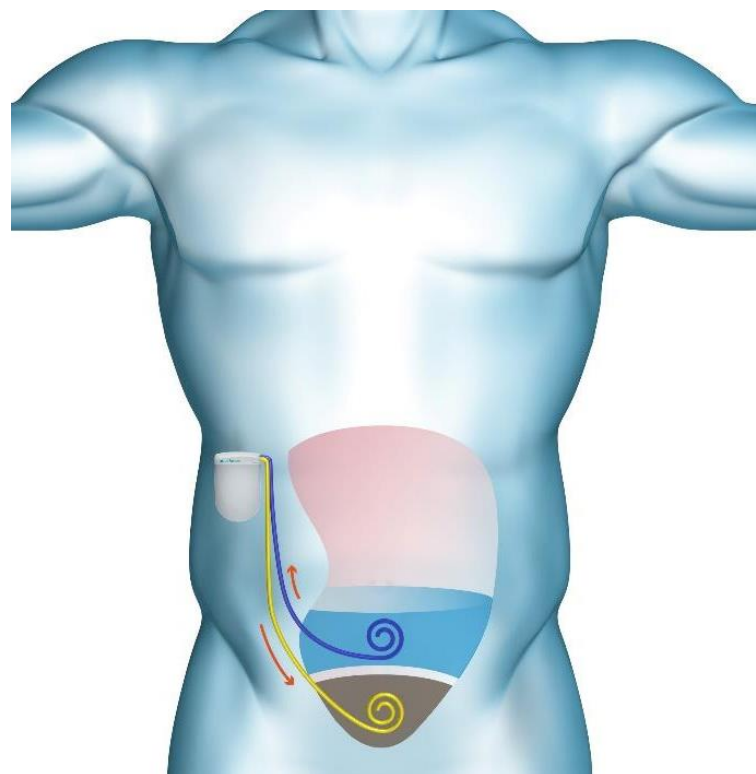
- Founded in 2006
- Gent, Belgium (HQ): corporate, clinical, commercial
- Zurich, Switzerland: manufacturing, engineering, QA/RA
- ~45 employees
- Euronext Brussels: SEQUA  
– market cap: ~€85 M



# alfapump<sup>®</sup> 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<sup>pump</sup> platform



**alfapump<sup>®</sup>**

proven step change in liver refractory ascites and malignant ascites;

over 700 devices implanted



**alfapump<sup>®</sup> 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<sup>(1)</sup>

**> €3 Bn / year**  
market opportunity



## Heart Failure in EU+US

~400 K patients hospitalised / year

for volume overload due to heart failure by 2026<sup>(2)</sup>

**> €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

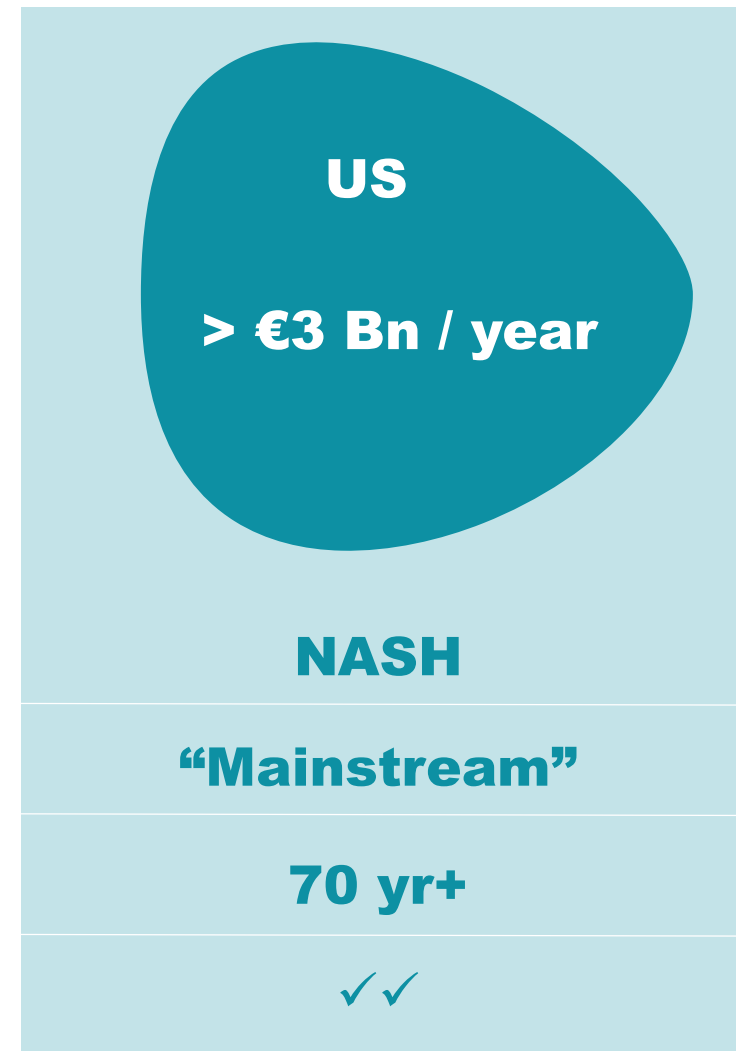
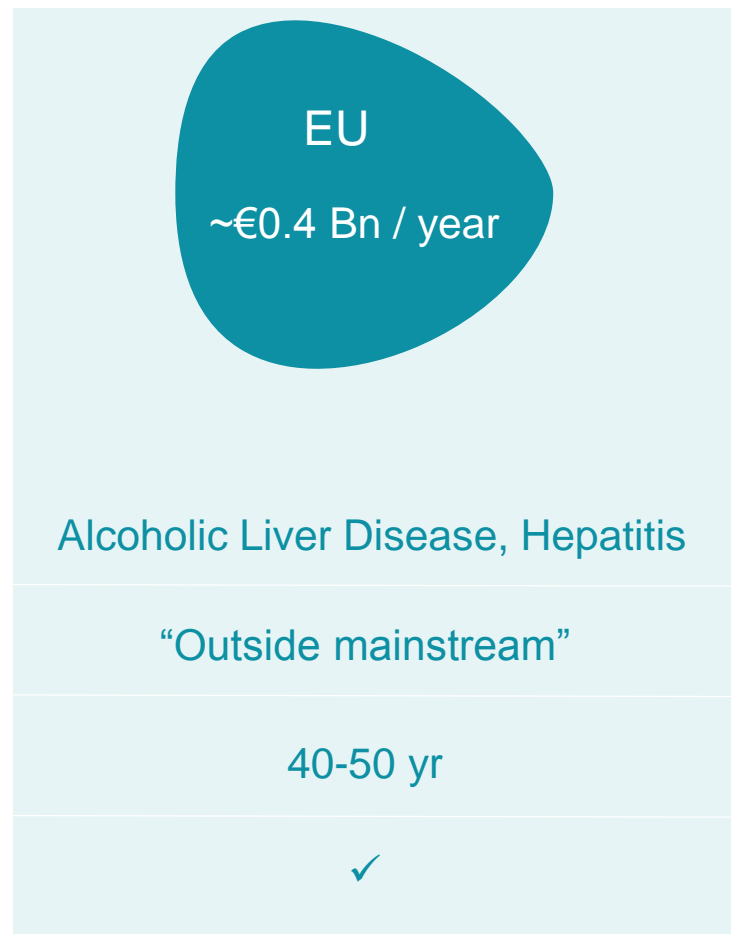
| **alfapump**<sup>®</sup> market potential |

| 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

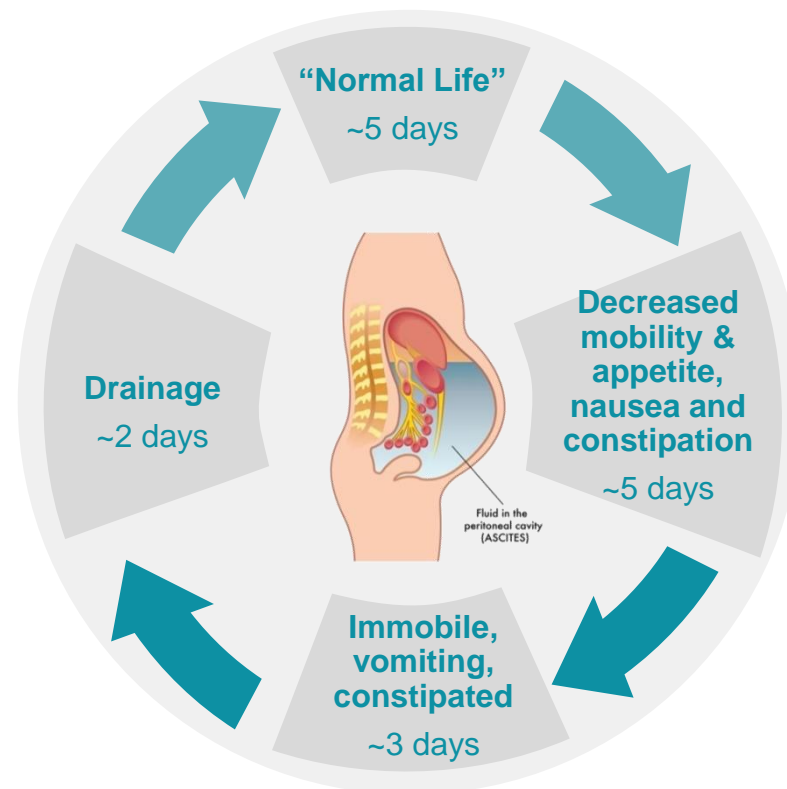
Viral infections  
(Hepatitis B & C)



Alcoholic Liver Disease



Non-Alcoholic Steatohepatitis (NASH)



Typical patient life<sup>(4)</sup>

## US forecast

~3-4M  
(1)

Liver cirrhosis



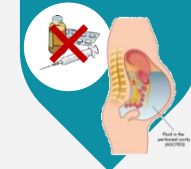
~1.5M  
(2)

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

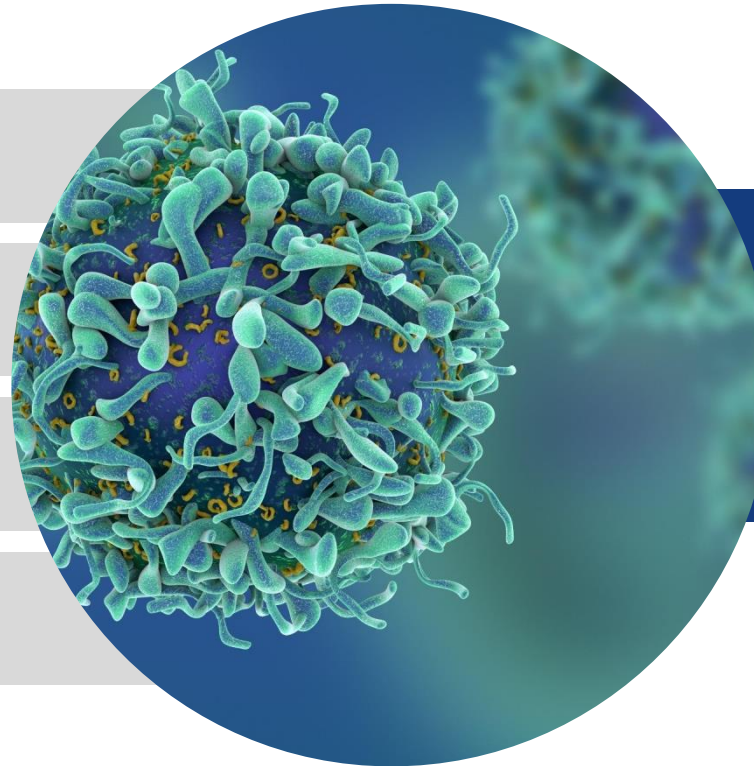
Severe complication of late-stage cancers

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

**Breast and ovarian cancer** have longest survival with ascites<sup>(1)</sup>

Severe impact on **quality of life**

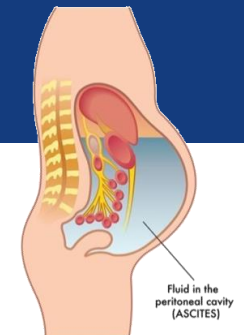
Reduces ability to undergo **anti-cancer treatment**



Malignant ascites due to breast and ovarian cancer<sup>(2)</sup>:

EU5: ~18K

US: ~16K



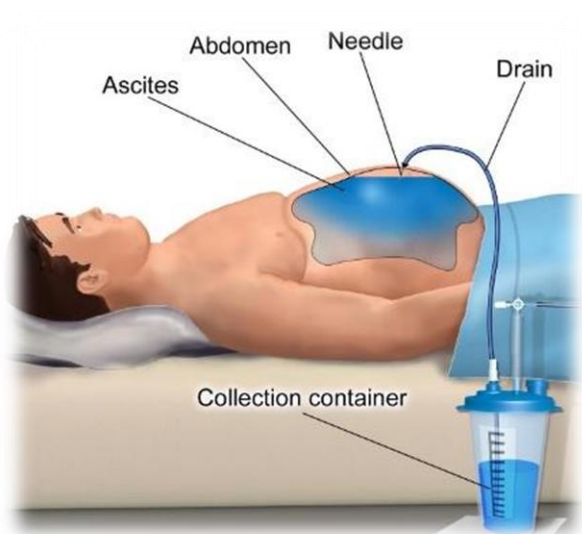
*Clear unmet need for improving Quality of Life and the ability to increase cancer treatment intensity*

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.

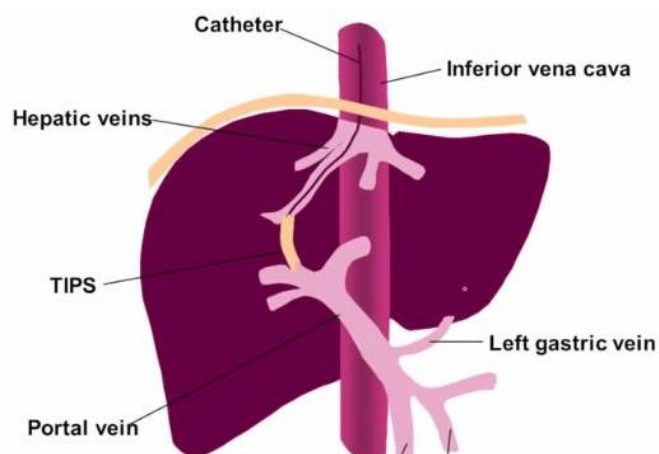
# Severe limitations of existing therapies

## 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)*

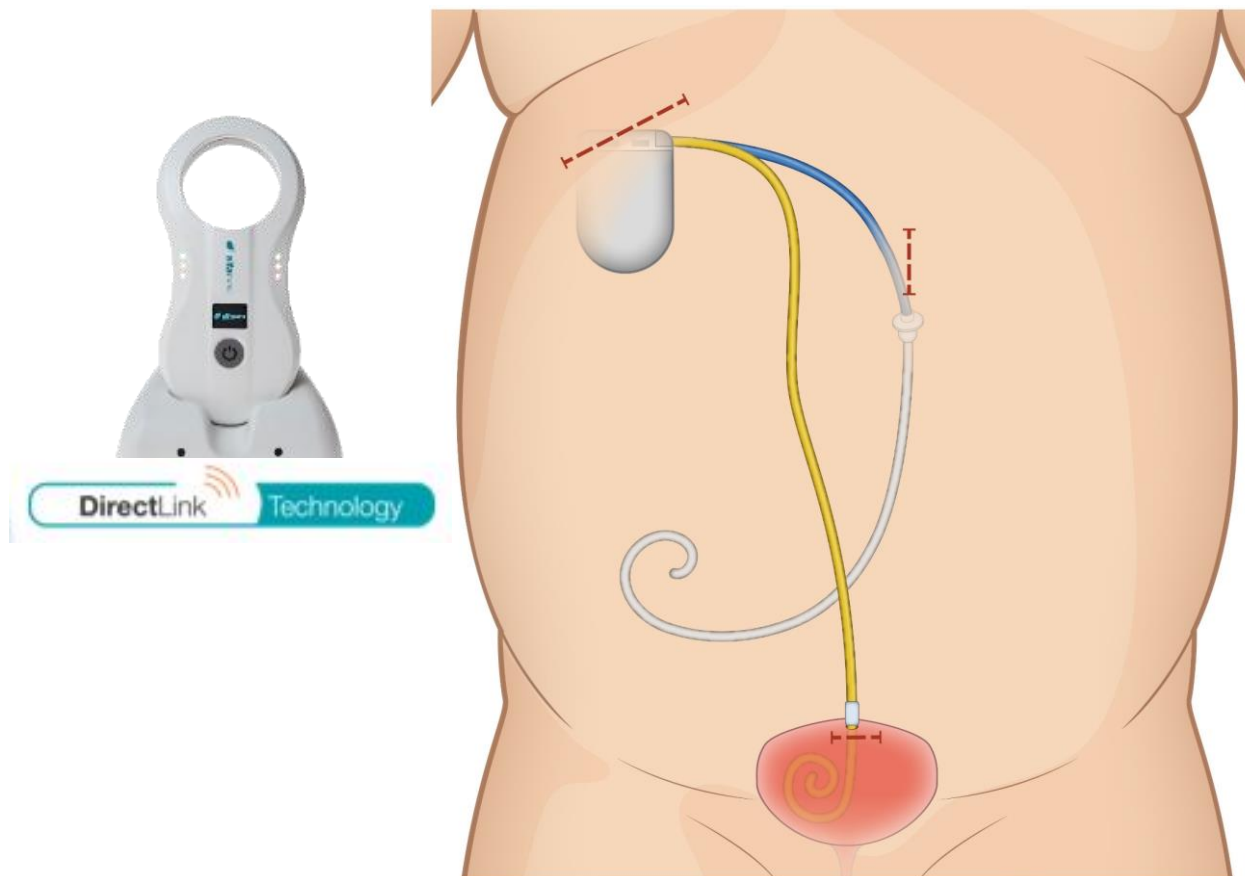
## Liver transplant



*Limited availability and high costs*

# alfapump® for long-term treatment

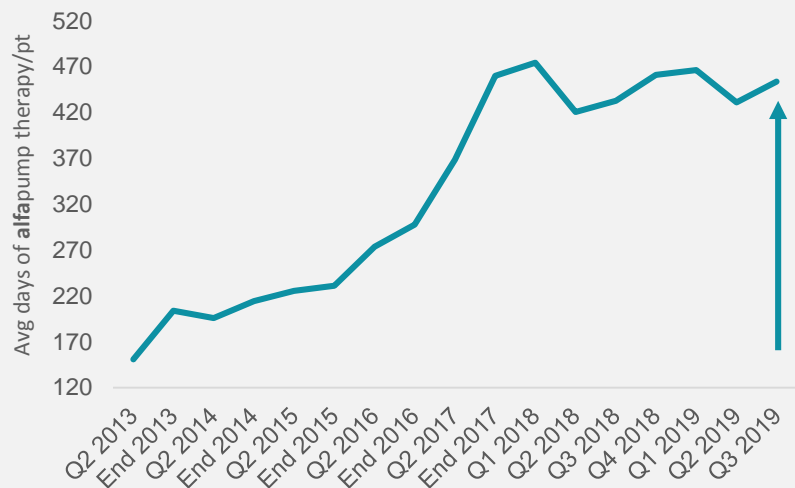
Over 700 implants and hundreds of years of patient experience



# Strong clinical validation



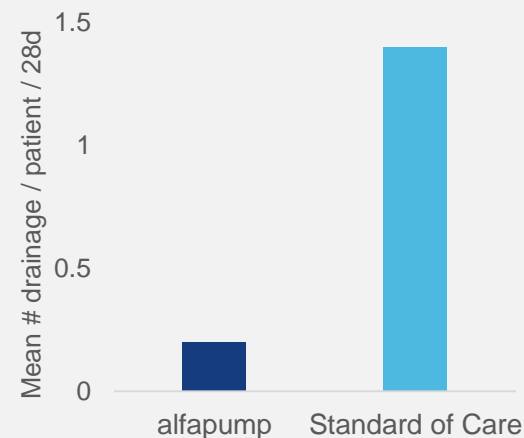
**Clear increase in clinical outcomes**



Sequana Medical data



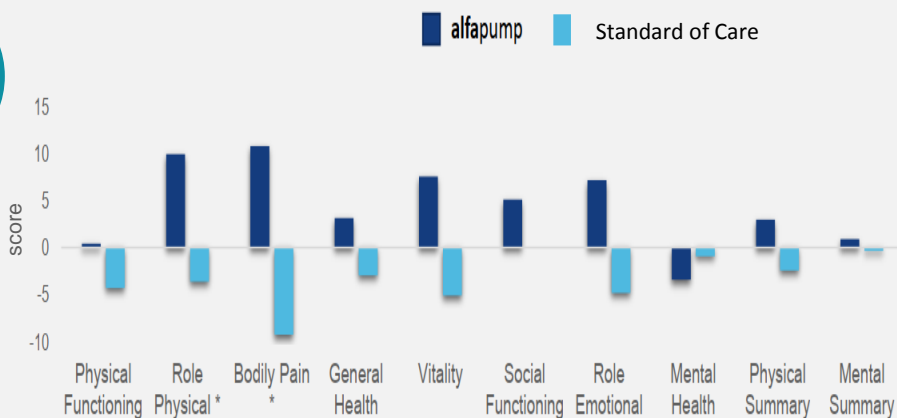
**Drastically reduced need for drainage**



Results RCT study



**Improved quality of life**



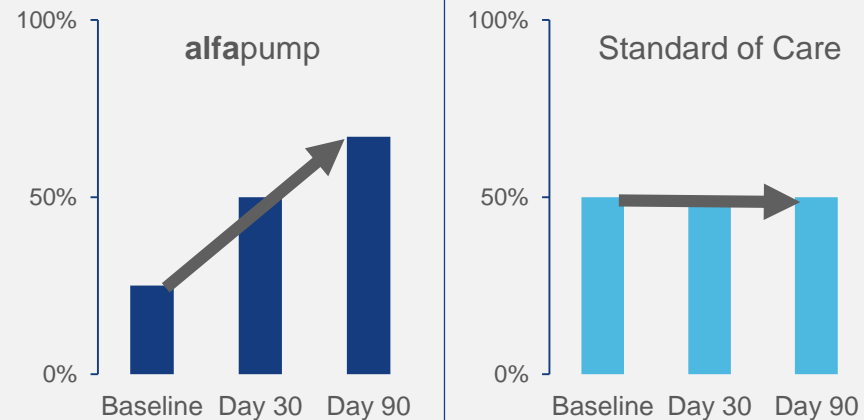
Results RCT study

\* p<0.05



**Improved nutrition**




**% patients adequately nourished**

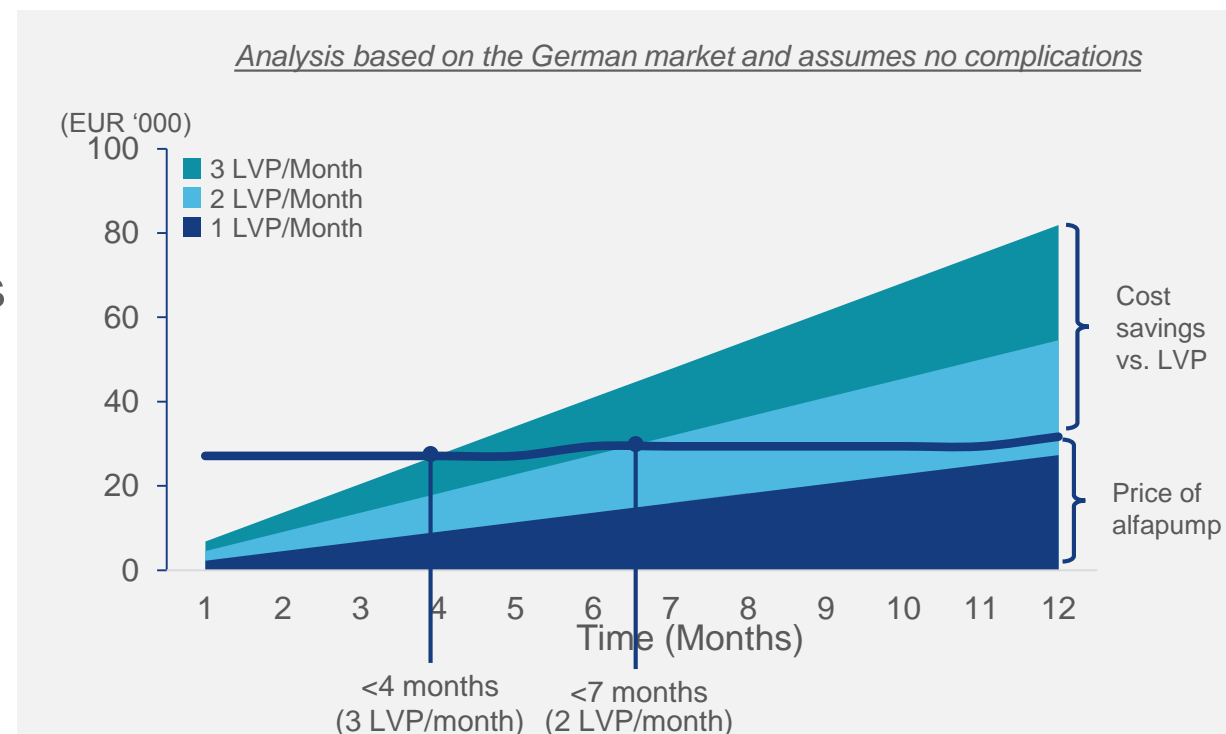


Results RCT study

# Strong health economics rationale

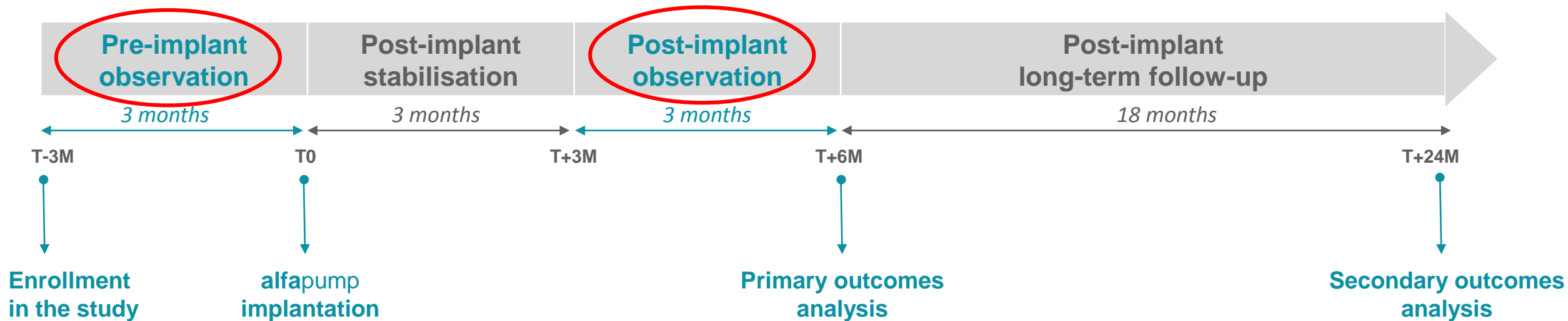
Significant reduction in regular drainage leads to:

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



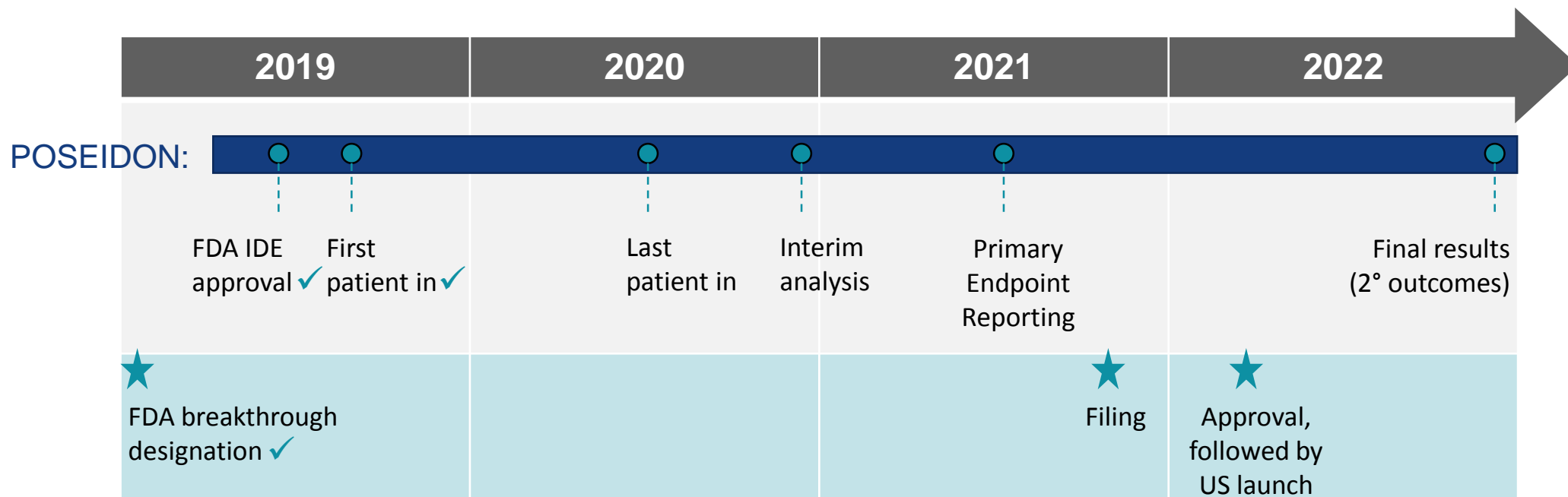
# North American Pivotal Study (POSEIDON) started

- Up to **50 patients** implanted with the **alfapump**<sup>(1)</sup>
- 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

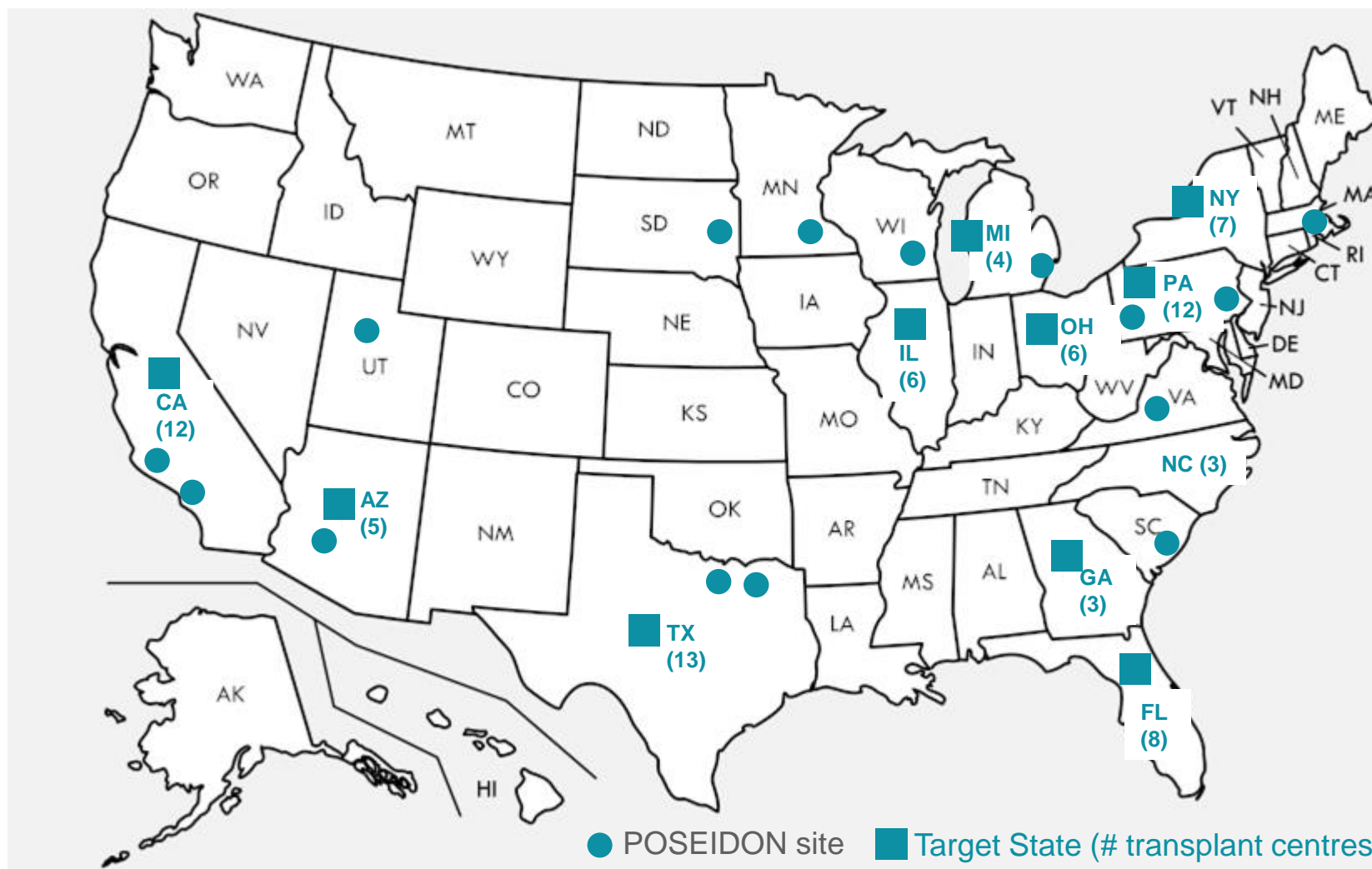


*Proposed CMS rule on reimbursement for breakthrough devices (NTAP)*

*Positive development for the **alfapump***



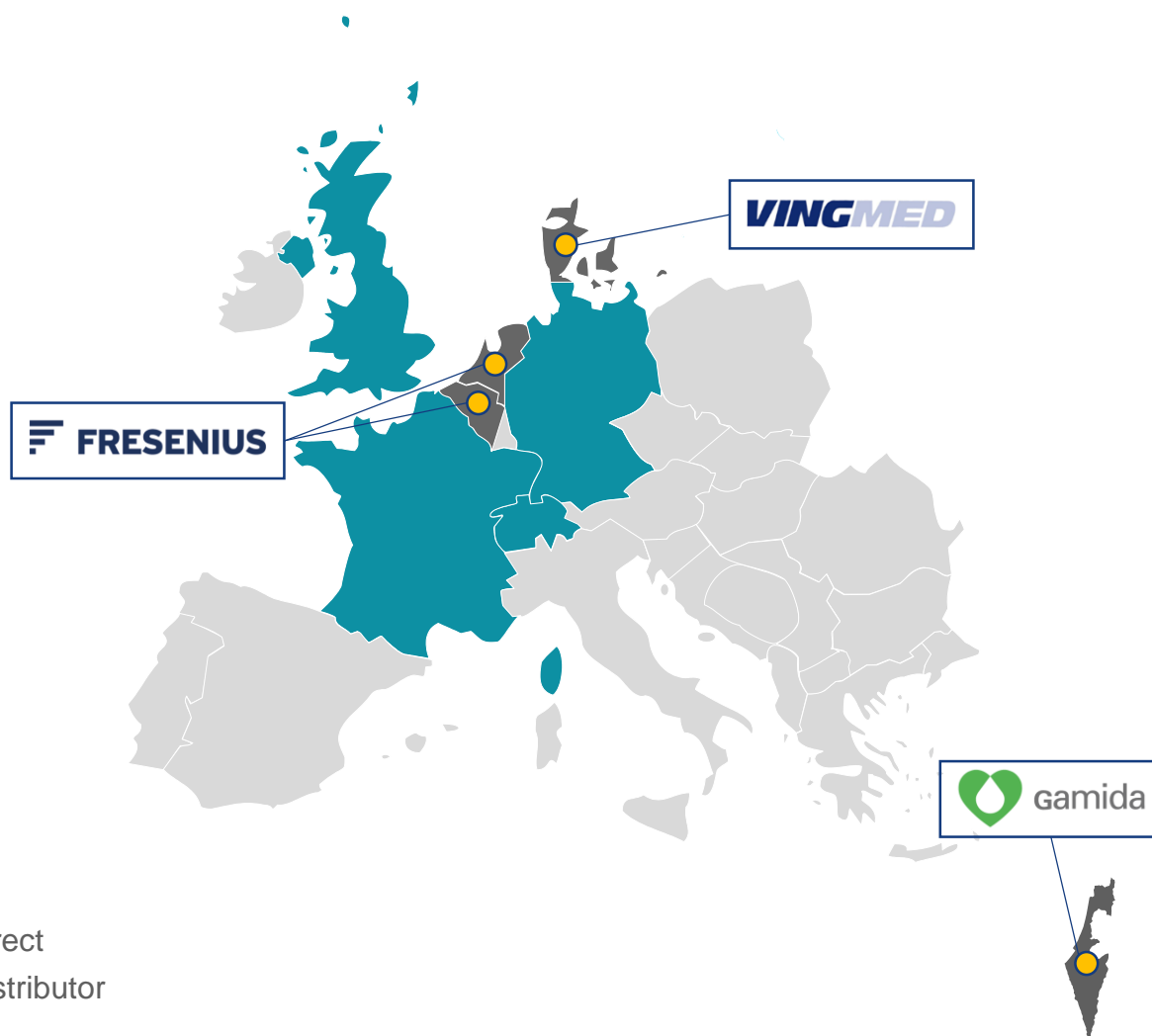
# Go Direct in US through target specialist salesforce



Initial focus on key transplant centres: 35 sales reps, 10 clinical support, 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<sup>(1)</sup>)
- ✓ **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

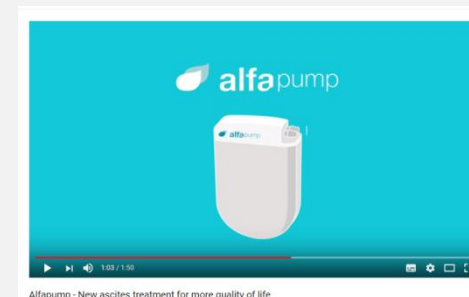
### Treatment of refractory ascites with an automated low-flow ascites pump in patients with cirrhosis

G. Stirnimann<sup>1</sup> | T. Berg<sup>2</sup> | L. Spahr<sup>3</sup> | S. Zeuzem<sup>4</sup> | S. McPherson<sup>5</sup> | F. Lammert<sup>6</sup> | F. Storni<sup>1</sup> | V. Banz<sup>1</sup> | J. Babatz<sup>7</sup> | V. Vargas<sup>8</sup> | A. Geier<sup>9</sup> | A. Stallmach<sup>10</sup> | C. Engelmann<sup>2</sup> | C. Trepte<sup>11</sup> | J. Capel<sup>11</sup> | A. De Gottardi<sup>1</sup>



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



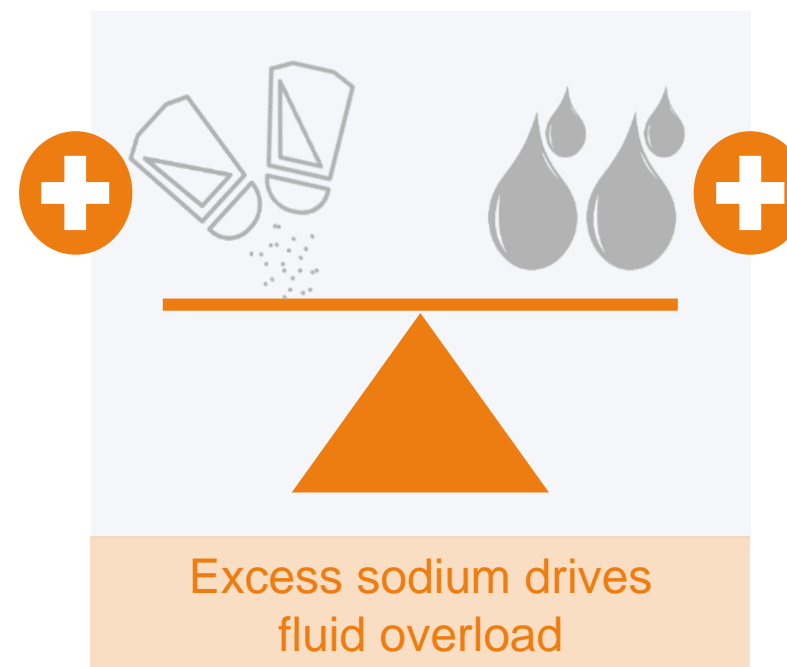
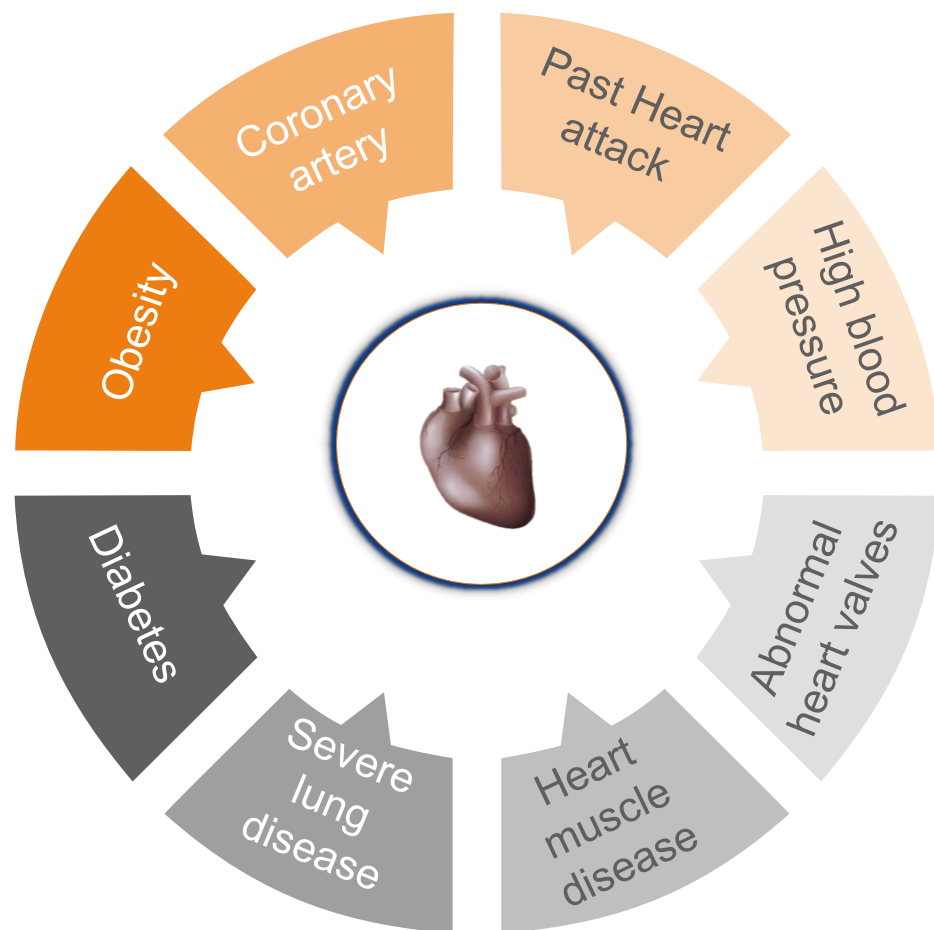


# alfapump® DSR

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

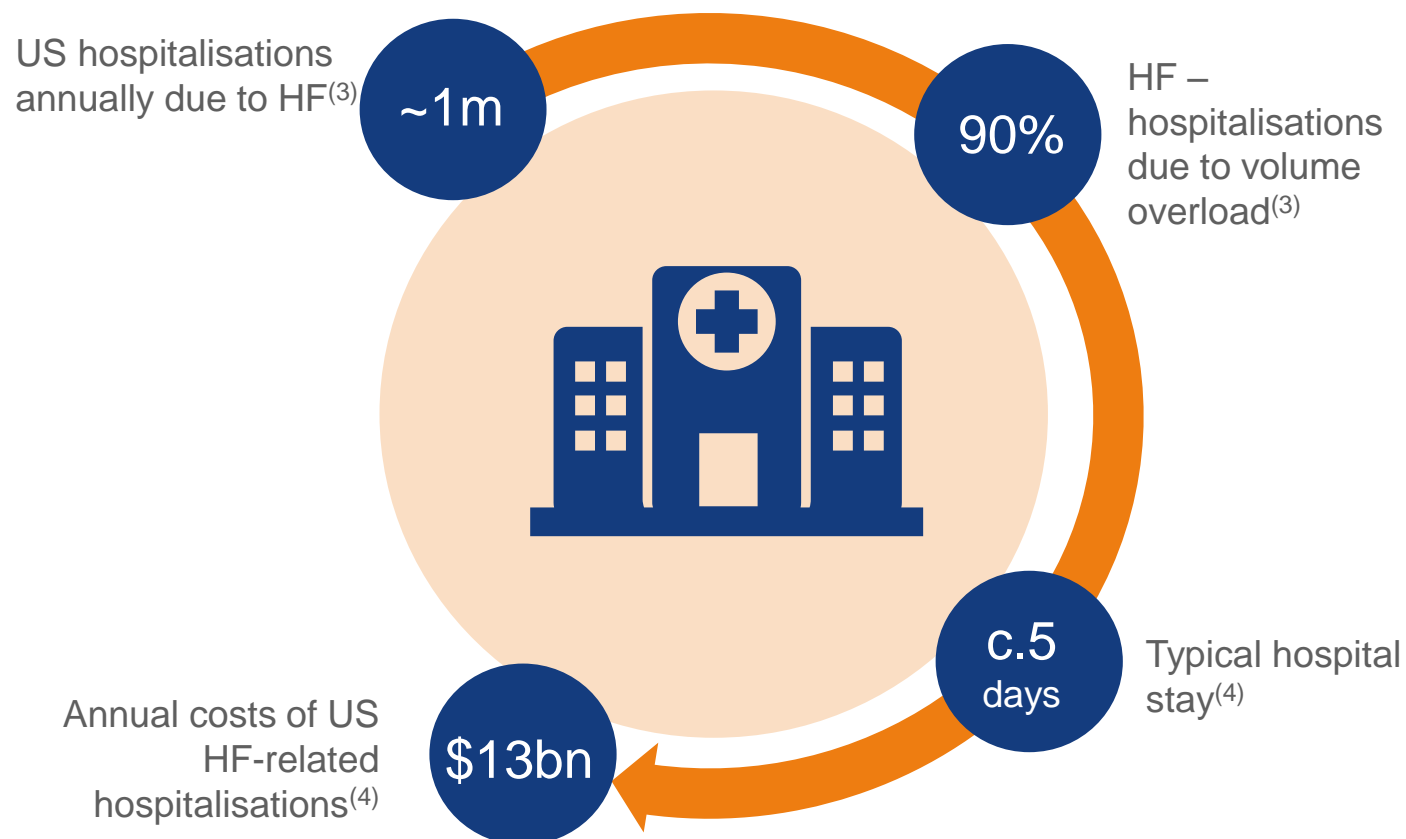
# Volume overload in heart failure is a major problem...

Over 26 million people affected by heart failure worldwide<sup>(1)</sup>



Source 1: Global Public Health Burden of Heart Failure, Lars H. Lund  
 Source causes & consequences: American Heart Association, Mayo clinical website

# ...and a key driver of costs

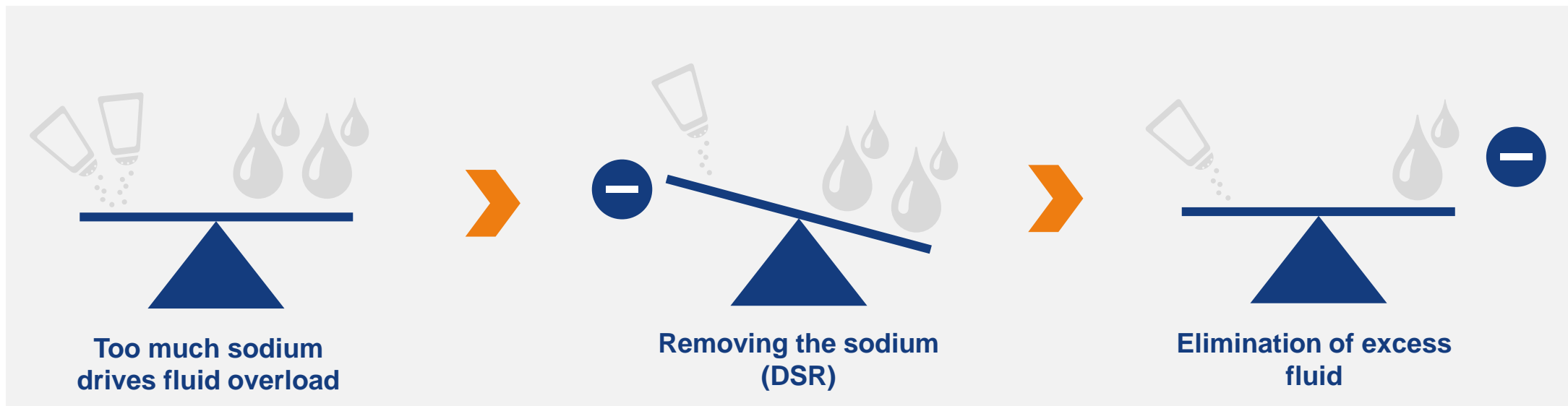


*40% of heart failure patients are poorly controlled with diuretics<sup>(1)</sup>*

*24% re-admission rate at 30 days<sup>(2)</sup>*

# 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

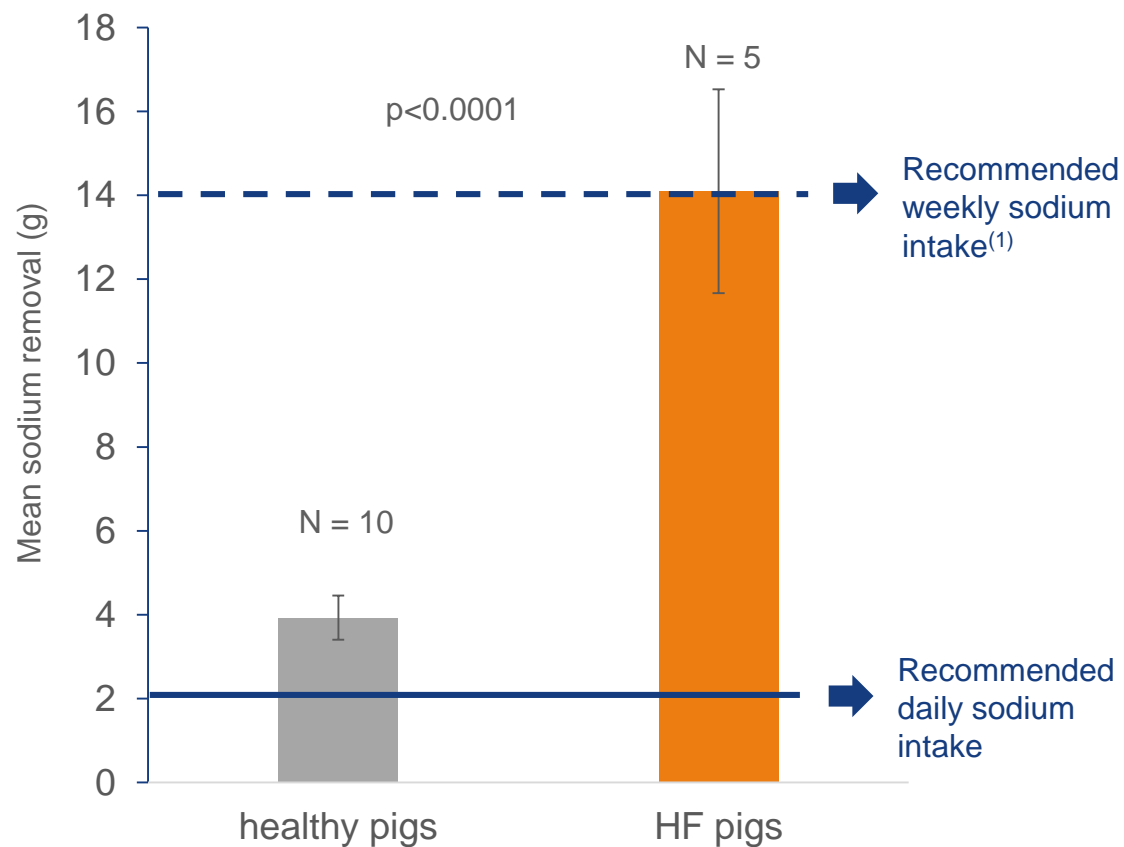
alfapump®  
removes  
extracted sodium  
from peritoneal  
cavity via  
bladder

Body restores  
balance by  
eliminating  
excess fluid

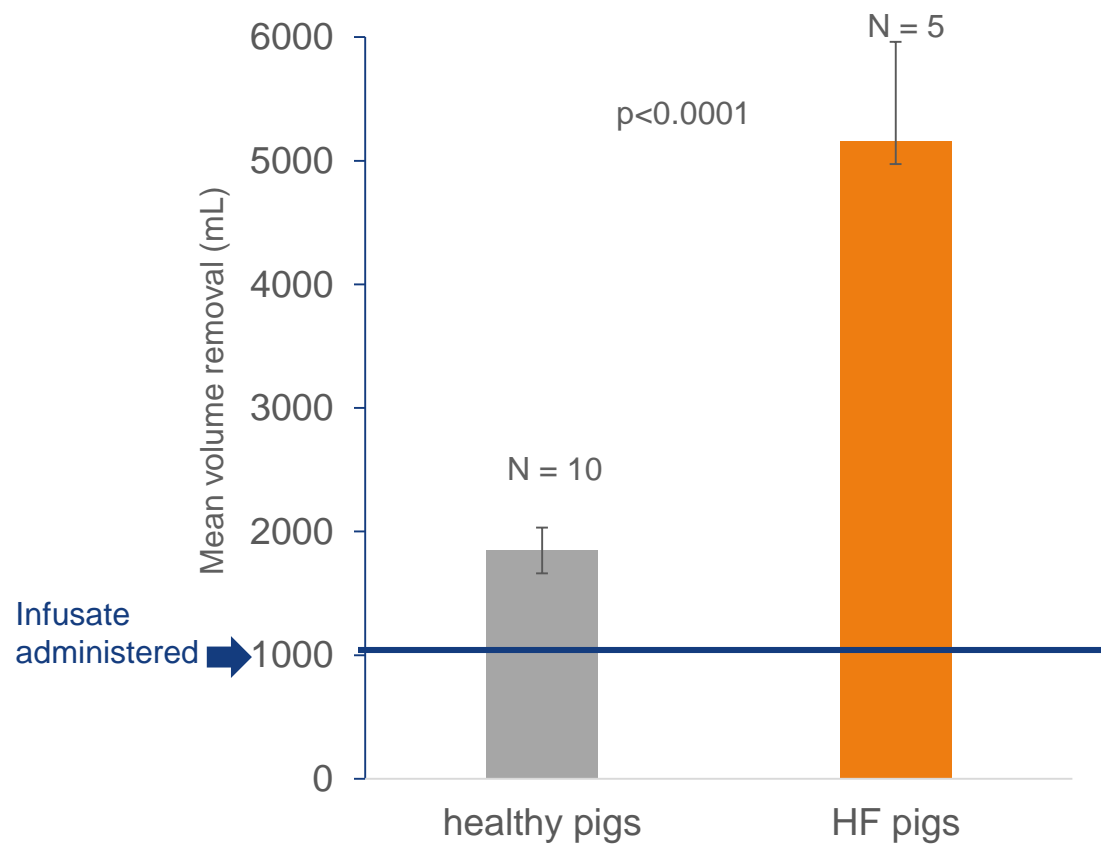
# DSR pre-clinical Proof-of-Concept

Clinically relevant sodium and fluid removal

## Clinically relevant removal of sodium



## Effective fluid removal

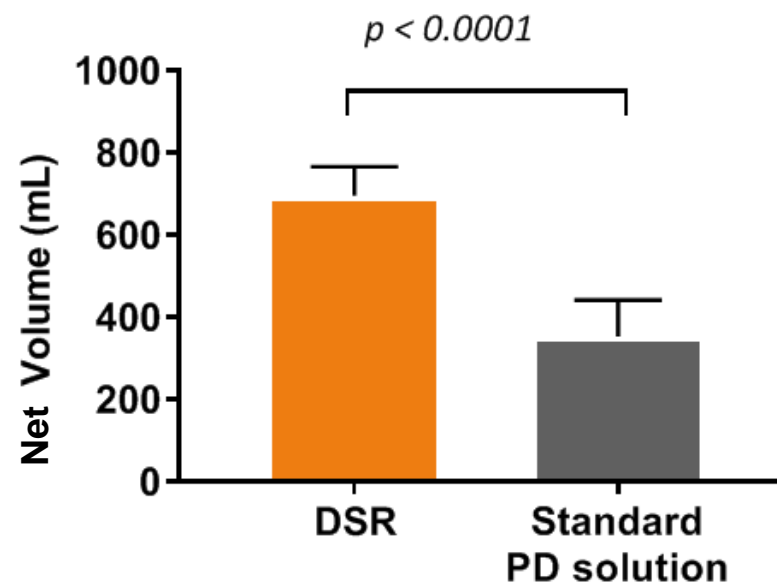
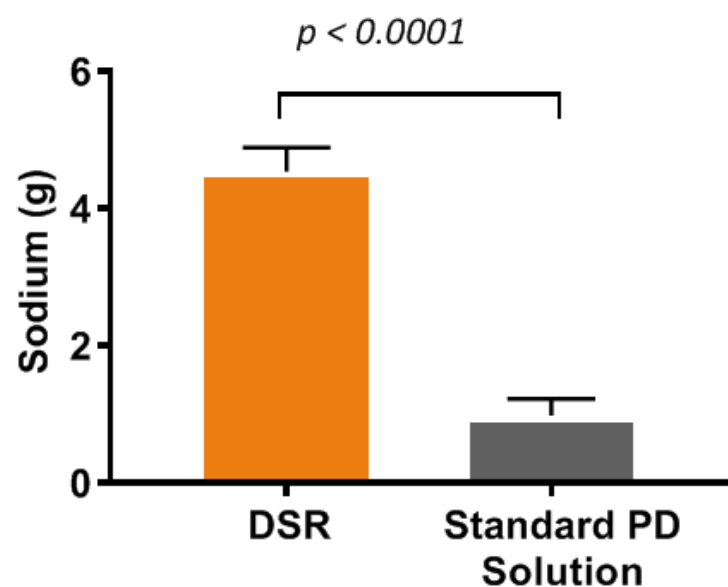


Source 1: Weekly recommended intake for humans equals 14 grams ([www.cdc.gov](http://www.cdc.gov))



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

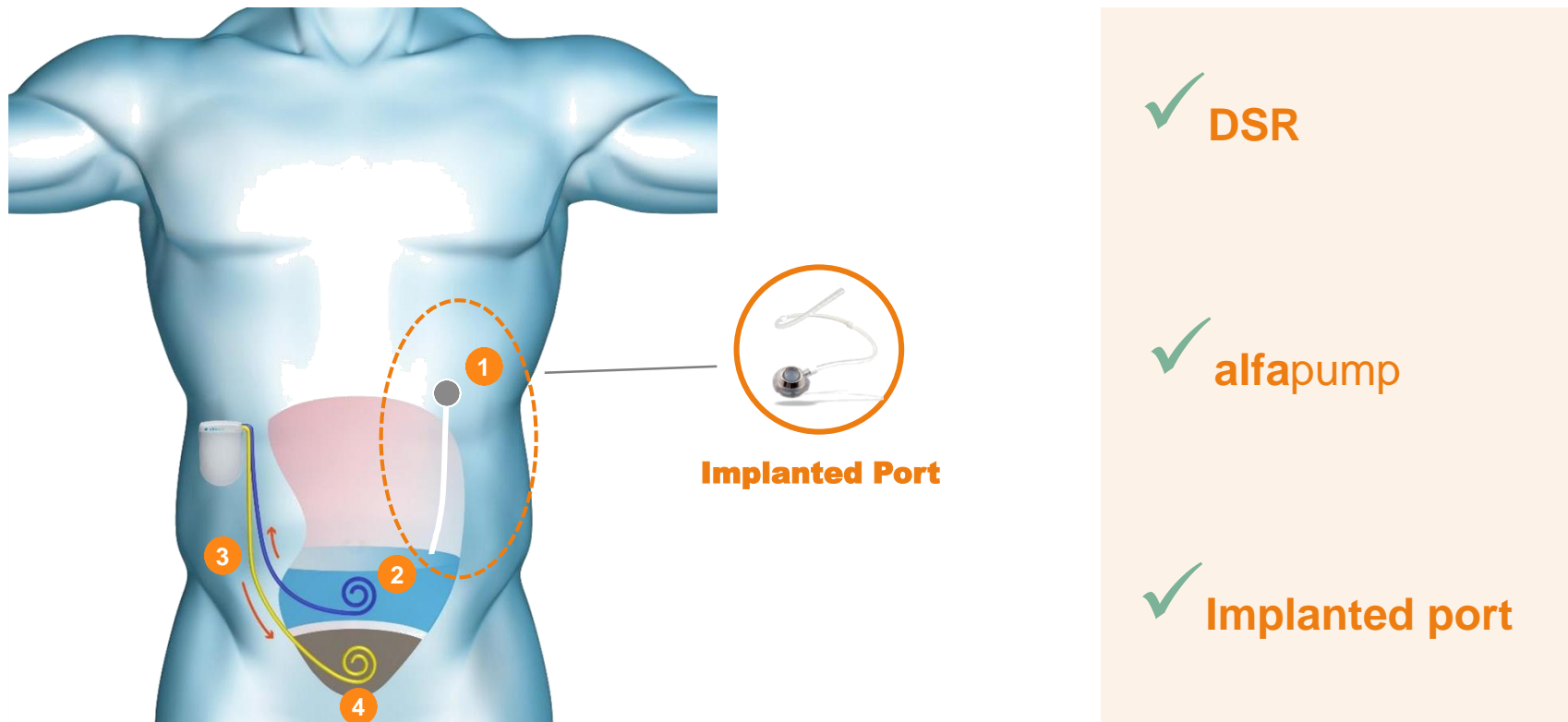
- ✓ DSR therapy was safe & well-tolerated with no adverse events or significant discomfort
- ✓ Substantially higher sodium removal with DSR vs standard Peritoneal Dialysis (PD) solution
- ✓ Minimal inter-patient variability



*Results presented at  
Heart Failure 2019  
and TCT 2019*

# alfapump<sup>®</sup> DSR

Fully implanted and convenient system for DSR therapy leveraging proven elements



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

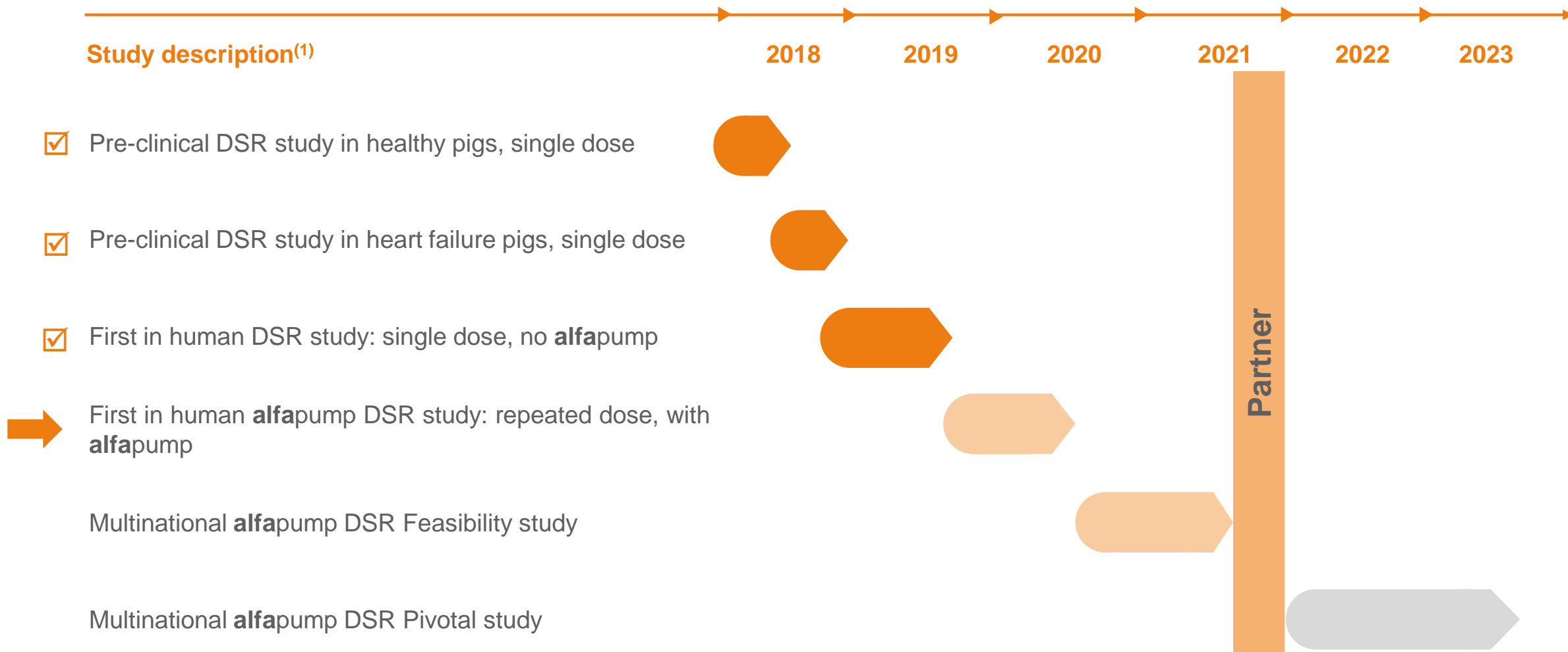
Professor and Chairman of the Department of Medicine at the University of Mississippi Medical Center



**Dr. Jeffrey Testani**

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

# alfapump<sup>®</sup> DSR development overview



Note 1: study design and timelines subject to change



# Conclusion

Experienced **leadership team**

**Value creation** on the short term

# Strong organisation

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

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## 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

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## 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

## H2 2019

- ✓ Initiation of North American pivotal study (POSEIDON) in recurrent and refractory liver ascites patients
  - Initiation of Prospective Malignant Ascites Study (ProMAS)
  - Initiation of Step Counter study in refractory liver ascites patients
  - Initiation of first repeated dose **alfapump** DSR study in heart failure patients with volume overload
  - Initial results of first repeated dose **alfapump** DSR study in heart failure patients with volume overload

## H1 2020

- Expected final German<sup>(1)</sup> reimbursement of **alfapump**
- Completion of enrolment of POSEIDON study in recurrent and refractory liver ascites patients
- Presentation of final results of first repeated dose **alfapump** DSR study in heart failure patients with volume overload

## H2 2020

- 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
- Interim results of POSEIDON study in recurrent and refractory liver ascites patients

# Back-up

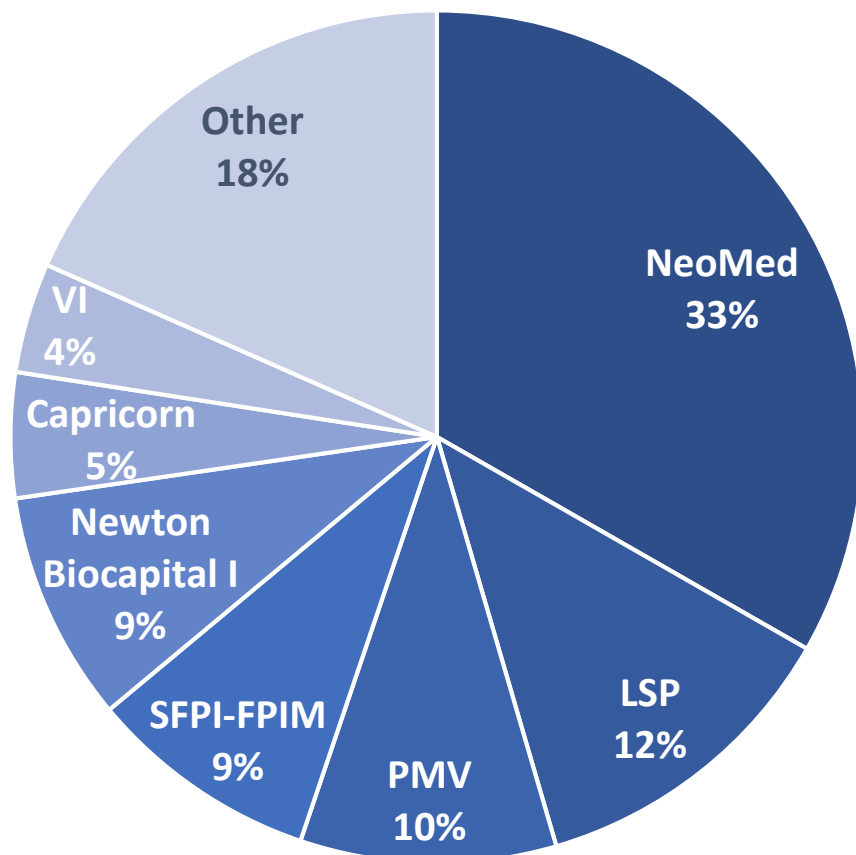




# Shareholders base and financial overview

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



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