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Innovators in the management of fluid overload

liver disease – cancer – heart failure

Investor presentation – July 2019

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Regulatory disclaimers:

- The **alfa**pump® has not yet received regulatory approval in the US and Canada. Any statement in this presentation about safety and efficacy of the **alfa**pump 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 **alfa**pump 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 **alfa**pump system in Europe, the US and Canada.

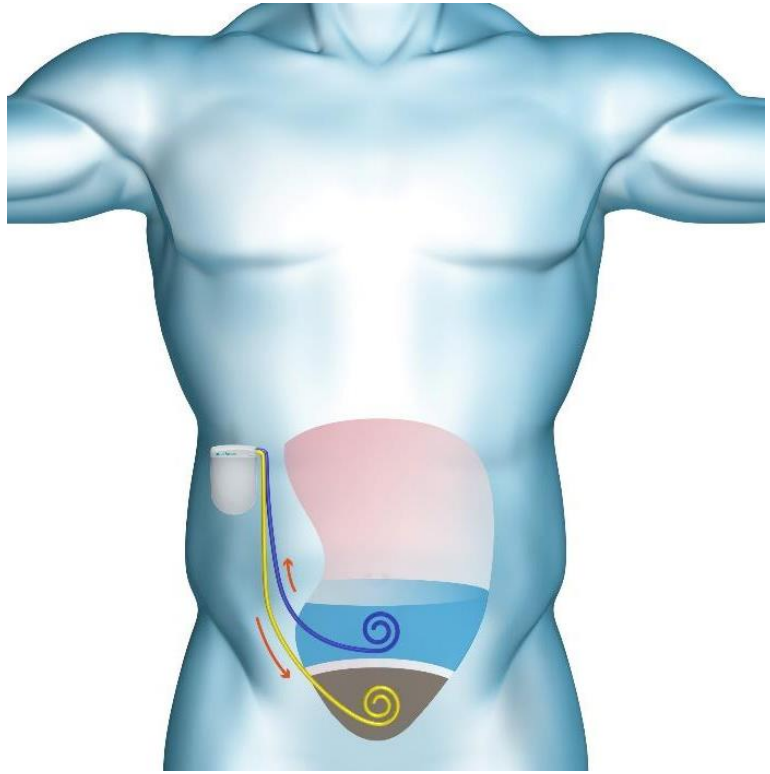
Company Overview

- Founded in 2006
- Headquarters in Gent, Belgium
- 37 employees
- IPO Euronext Brussels Feb ‘19: SEQUA
- **alfa**pump
  – Europe: focused commercialization
  – US: Breakthrough Device status, pivotal study about to start
- **alfa**pump DSR
  – in clinical development for volume overload due to heart failure

alfapump® platform

Unique capabilities to manage fluid imbalance

- Settings wirelessly adjusted
- Fully implantable
- Wireless battery charging
- Moves up to 4 litres / day
- No significant heating during charging and operation



- Remote data monitoring
- Long-term implantation & catheter patency
- Easy implantation
- Automatic operation
- Virtually non-clogging

Strong IP barriers through extensive patent portfolio & know-how

Commercial stage

Two products – one platform

alfapump®

proven step change in liver refractory ascites and malignant ascites;
over 700 devices implanted

alfapump platform

alfapump® DSR

breakthrough approach to fluid overload in heart failure

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

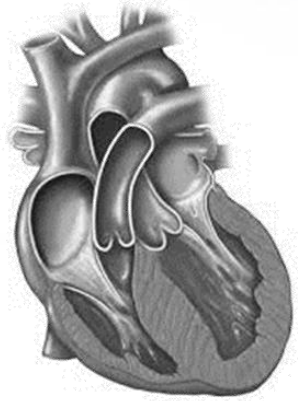
FDA IDE approval to start pivotal study (*)

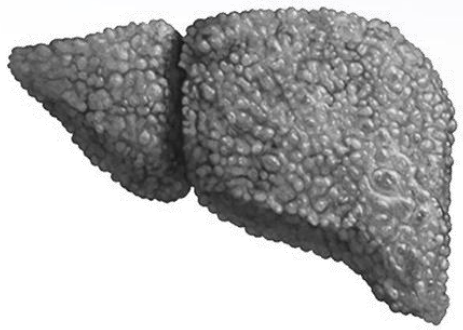
DSR clinical proof-of-concept achieved (*)

(*) announced since IPO

focus.

Liver disease and heart failure – large and growing markets





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Three platforms for growth

Balancing risk and reward

North American Liver & Cancer

~151K

refractory ascites patients due to alcoholic liver disease and NASH within next 10-20y[1]

~16K

Malignant ascites patients/y[2]

Heart Failure

US Market Information[3]:

~1 Million

hospitalisations/y due to volume overload by 2026[3]

$13 Billion

hospitalization costs; 90% of admissions due to volume overload

Europe Liver & Cancer

~89K

refractory ascites patients due to alcoholic liver disease and NASH within next 10-20y[1]

~18K

malignant ascites patients/y[2]

Source 1: Management estimate that is inclusive of estimated growth in prevalence of NASH for the US and EU5 based on GlobalData Epidemiology Forecast to 2026. Assumes 1/3 of existing market is due to hepatitis and will become negligible within the next 10 to 20 years.
Source 2: Management estimate based on WHO cancer incidence rates (2018) and Ayantunde & S. L. Parsons. Annals of Oncology 2007.
Source 3: GlobalData Heart Failure Epidemiology Forecast to 2026; Costanzo et al. (2007). Kiglore et al (2017)

alfapump®

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

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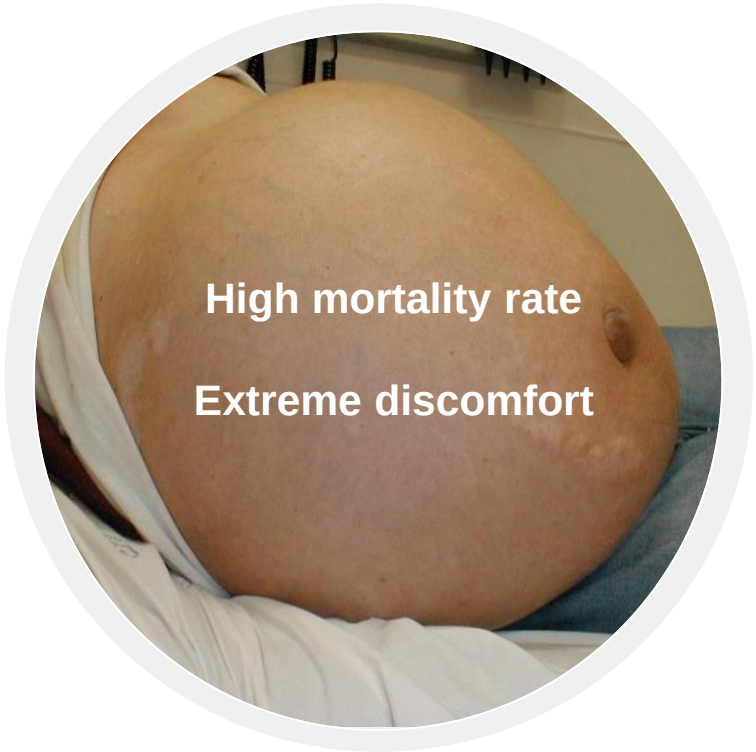
Liver cirrhosis and refractory ascites

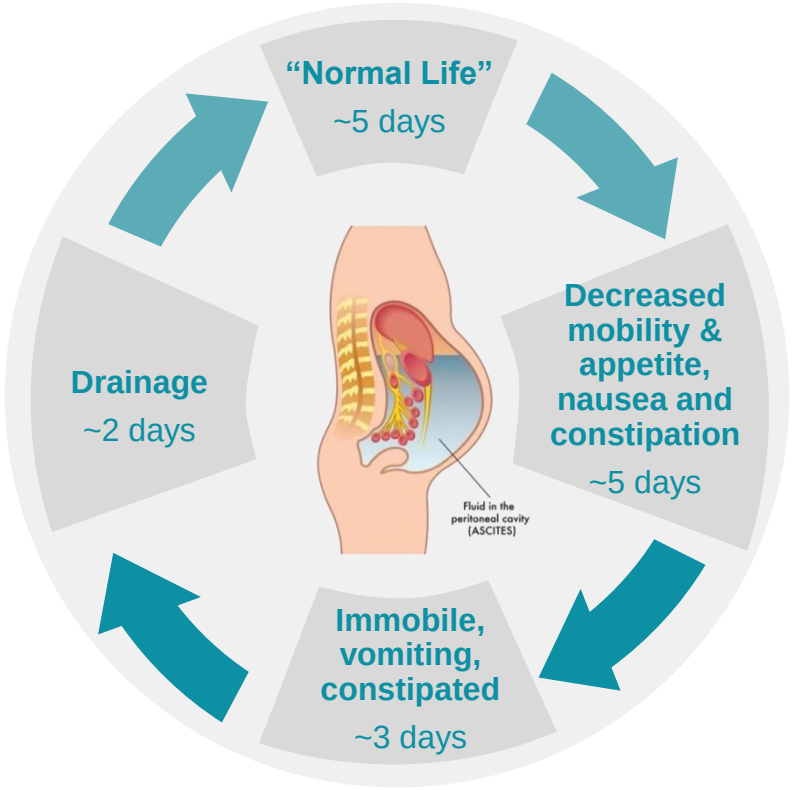
A key complication of liver cirrhosis, with a dramatic impact on quality of life

Viral infections (Hepatitis B & C)

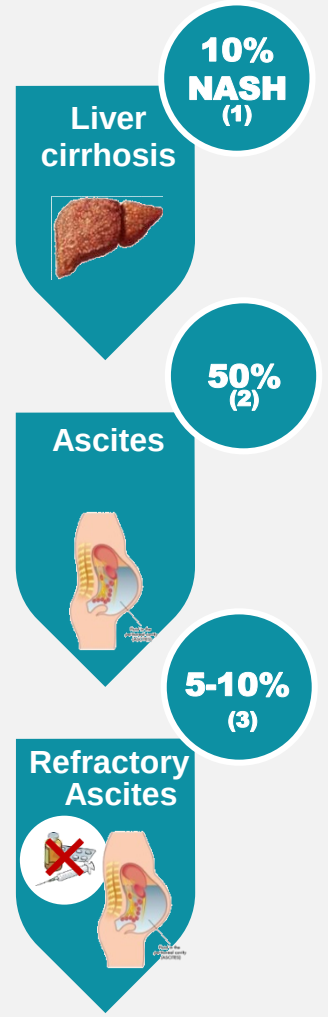
Alcoholic Liver Disease

Non-Alcoholic Steatohepatitis (NASH)





Typical patient life(4)



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.
Source 3: Ginès et al., NEJM 2004.
Source 4: Presentation of Dr. Rajiv Jalan at EASL in 2018, Large Volume Paracentesis (LVP) treatment cycle for refractory ascites

Cancer and malignant ascites

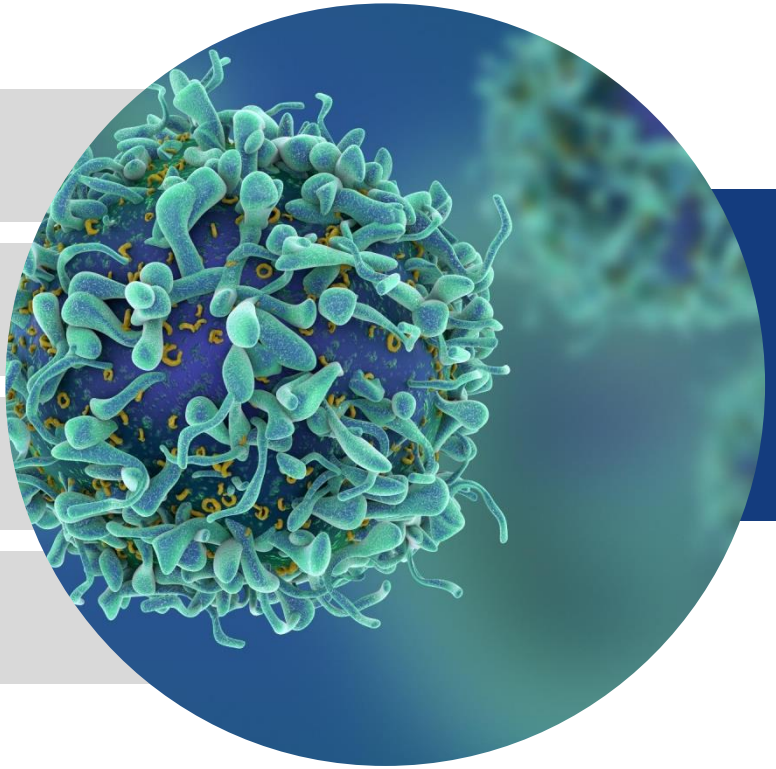
Severe complication of late-stage cancers

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**

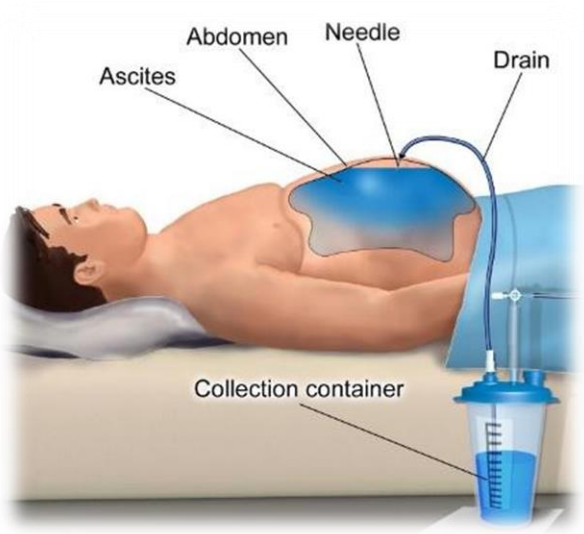


Clear unmet need for improving Quality of Life and the ability to increase cancer treatment intensity

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

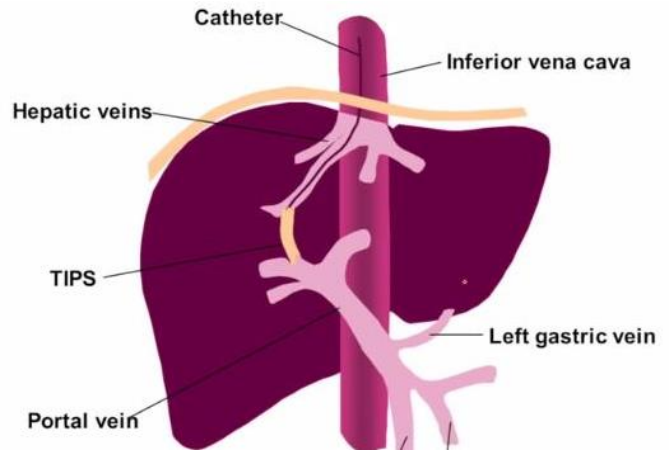
Severe limitations of existing therapies

Large Volume Paracentesis ("drainage")



Dramatically reduces quality of life

Transjugular Intrahepatic Portosystemic Shunt (TIPS)



Increases risk of hepatic encephalopathy above age of 65

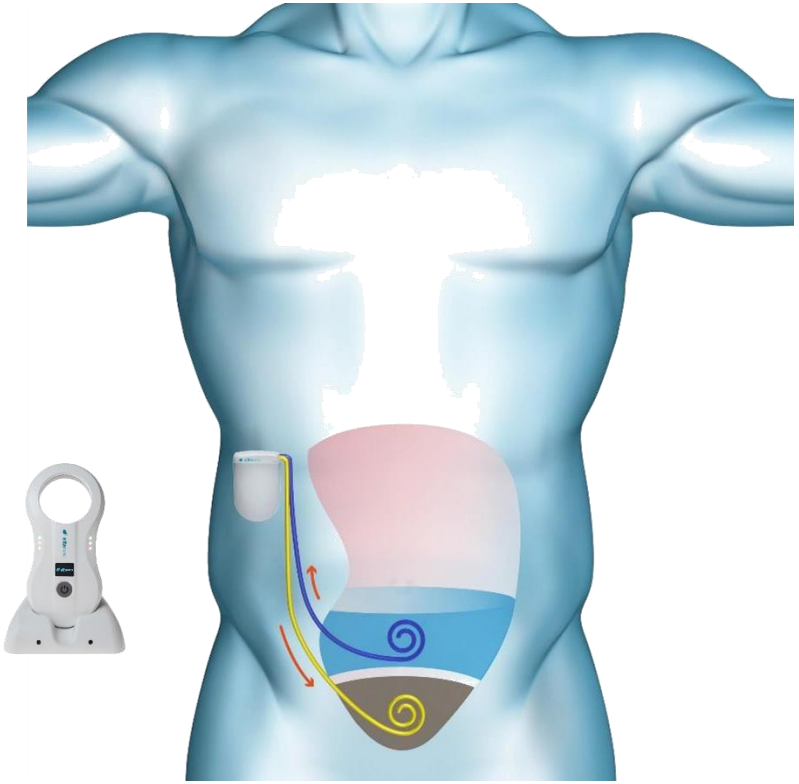
(typical age of NASH ascites patients)

Liver transplant

Limited availability and high costs

alfapump®

Fully implanted, automatic, wireless charged system for the long-term treatment of refractory liver ascites and malignant ascites



alfapump®

Smart Charger

Programmer

DirectLink Technology

Approved in Europe and Breakthrough Status in the US(1)

Over 700 implants and 400 years of patient experience

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

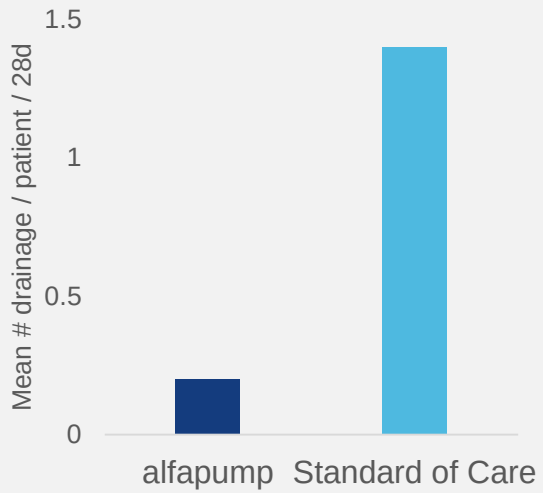
Current reimbursement:

- ✓ **Switzerland:** DRG
- ✓ **Germany:** DRG (NUB program(2))
- ✓ **UK:** NICE guidance “use with special arrangements” – local reimbursement
- ✓ **Belgium, Netherlands, Denmark, Israel:** special / hospital innovation budget

*Note 1: **alfa**pump is CE marked in Europe and is undergoing IDE clinical investigation in US and Canada*
Note 2 NUB: “Neue Untersuchungs- und Behandlungsmethode“ = temporary add-on payment to DRG for new diagnostic and treatment methods

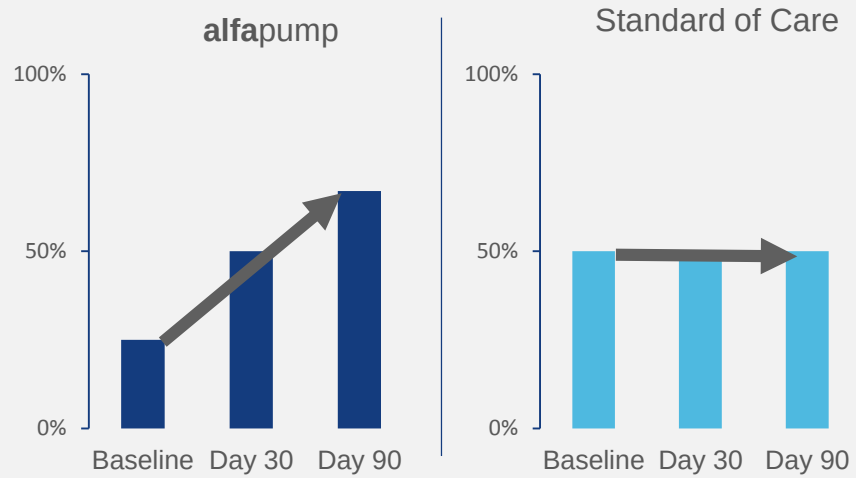
Key findings from alfapump® clinical studies

Drastically reduced need for drainage



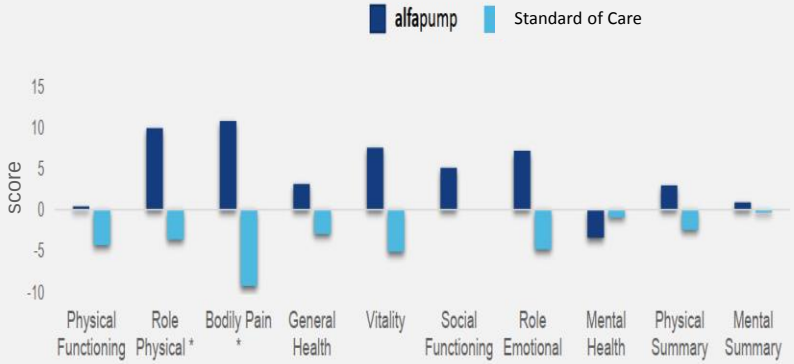
Results RCT study

Improved nutrition



Results RCT study

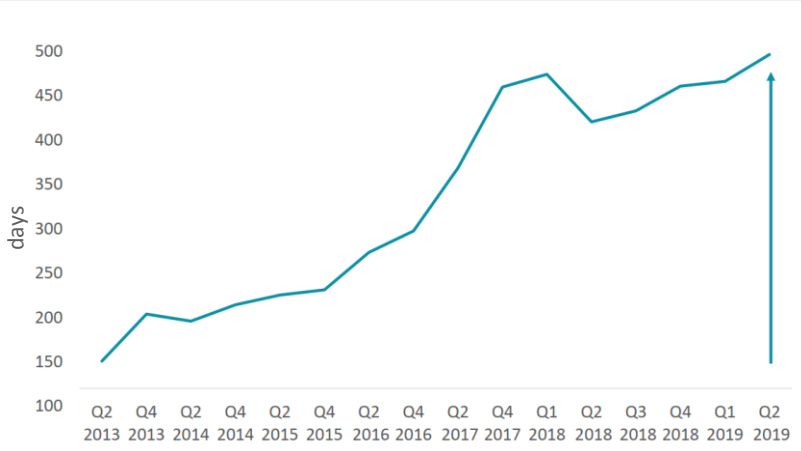
Improved quality of life



Results RCT study

** p<0.05*

Clear increase in clinical outcomes



Sequana Medical data

Commencing North American Pivotal Study

As well as additional studies in Europe

- **POSEIDON – pivotal study in US & Canada**
  - Unconditional IDE approval from FDA to start study
  - Up to **50 patients** implanted with the **alfa**pump in study cohort
  - 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
  - First patient in expected in H2 2019
  - Planned US launch **H1 2022**

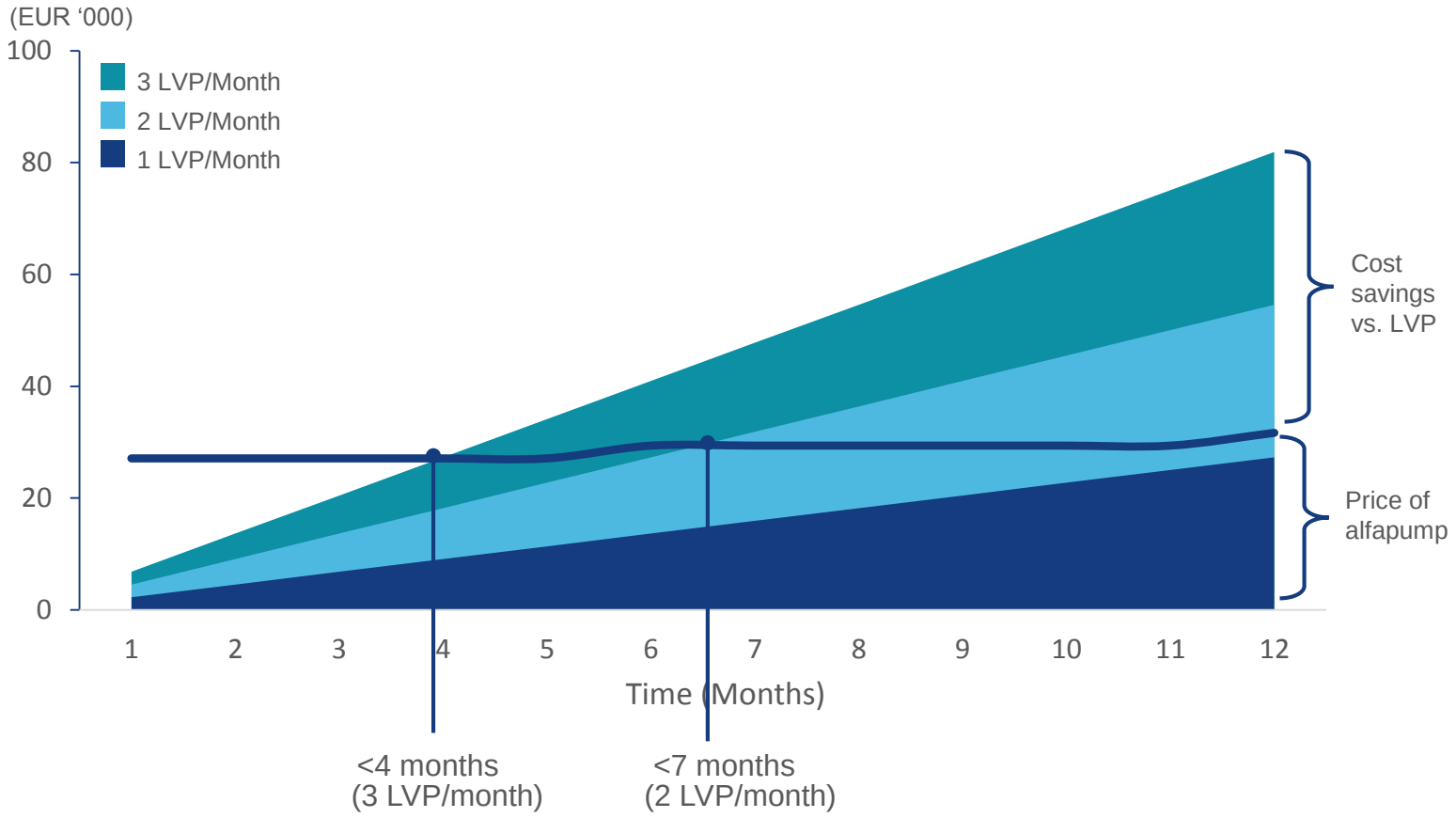
- **Building clinical evidence:**
  - Prospective malignant ascites study, TOPMOST registry, ARIA pump in France

alfapump® for liver refractory ascites

Strong health economics rationale

Elimination of regular drainage leads to substantial cost savings for hospitals and payers

As well as QoL benefits to patients and reduced burden on hospitals and doctors

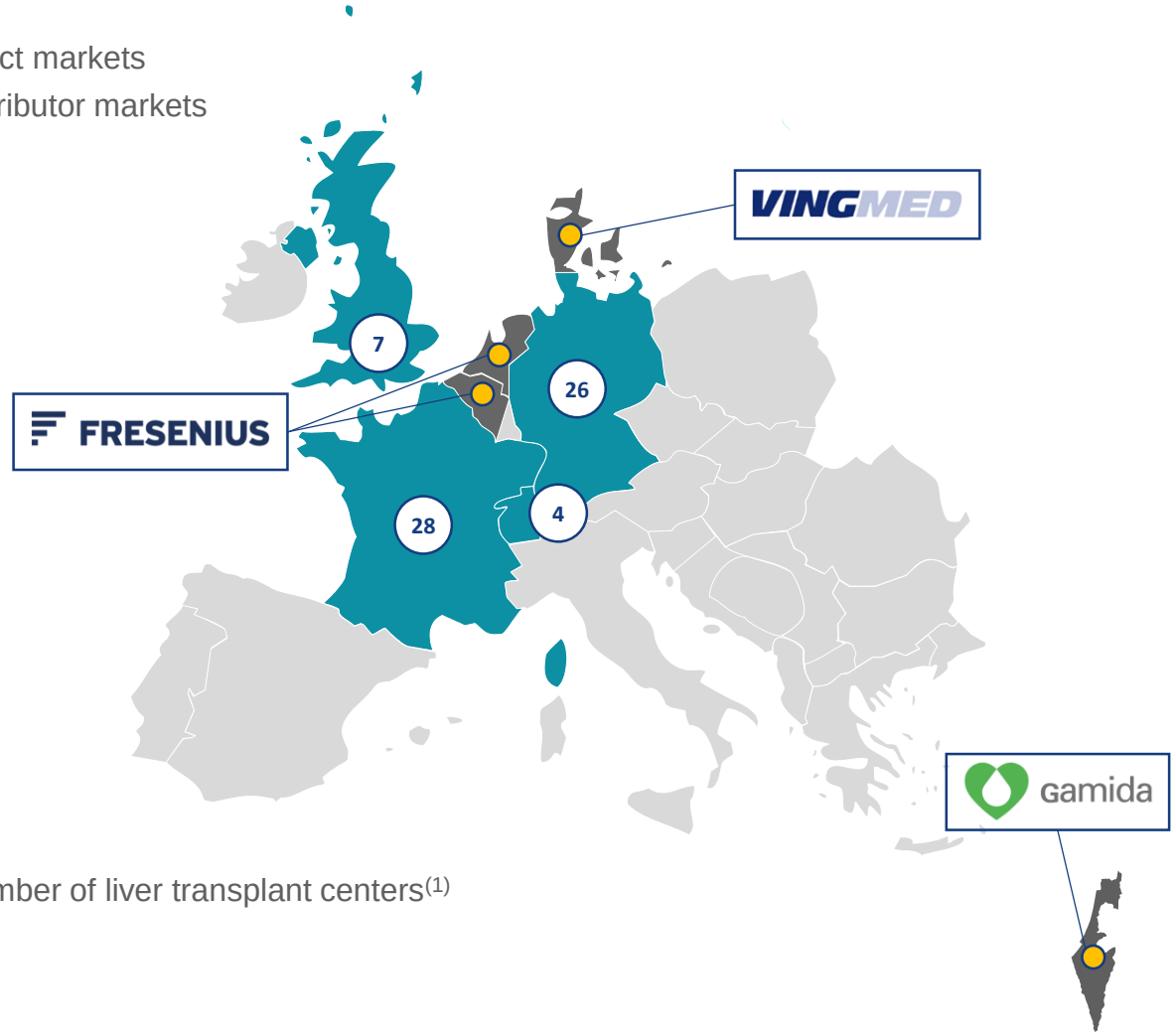


Analysis based on the German market and assumes no SAE

Focused European commercial activities

Targeted and specialist commercial team

Direct markets
Distributor markets



X Number of liver transplant centers(1)

14 person team

Focus on specialist centers

Raise awareness at community hospital level

Source 1: European Liver Transplant Registry (ELTR)

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 **alfa**pump 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 APT Alimentary Pharmacology & Therapeutics

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

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

AASLD AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

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 ALFApump System in Refractory Ascites

Targeting patients through print & social media

Alfapump - New ascites treatment for more quality of life

alfapump® DSR

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

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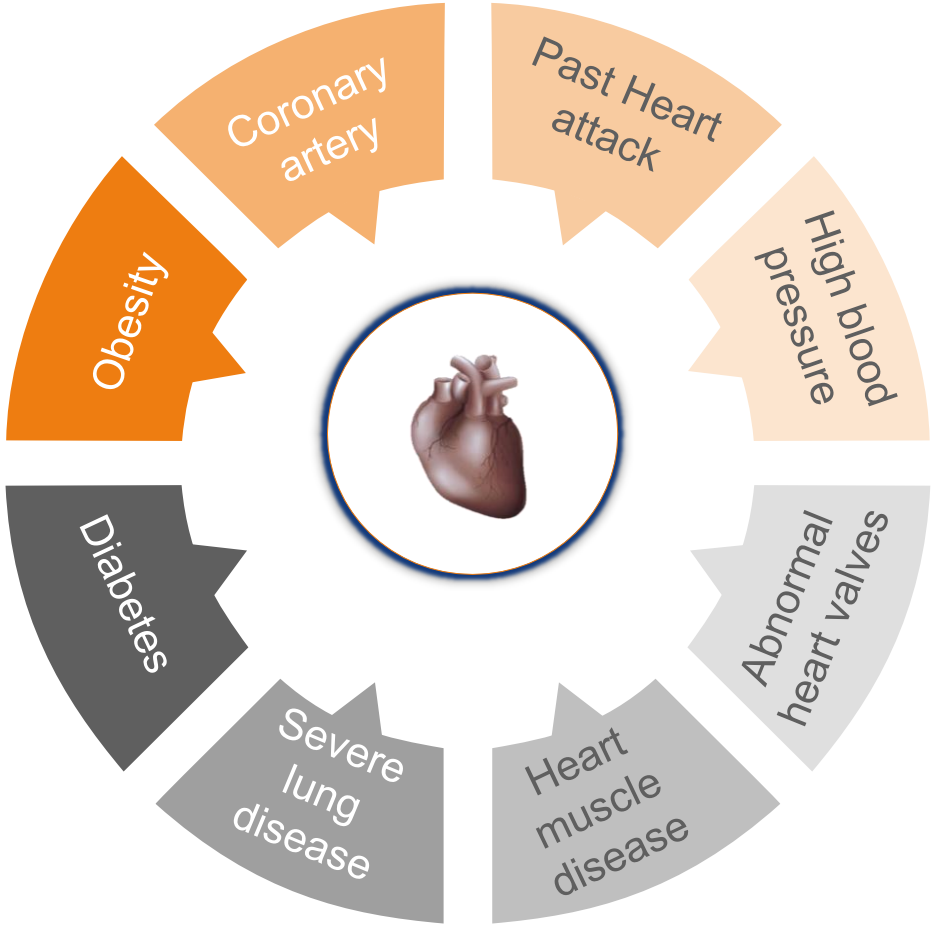
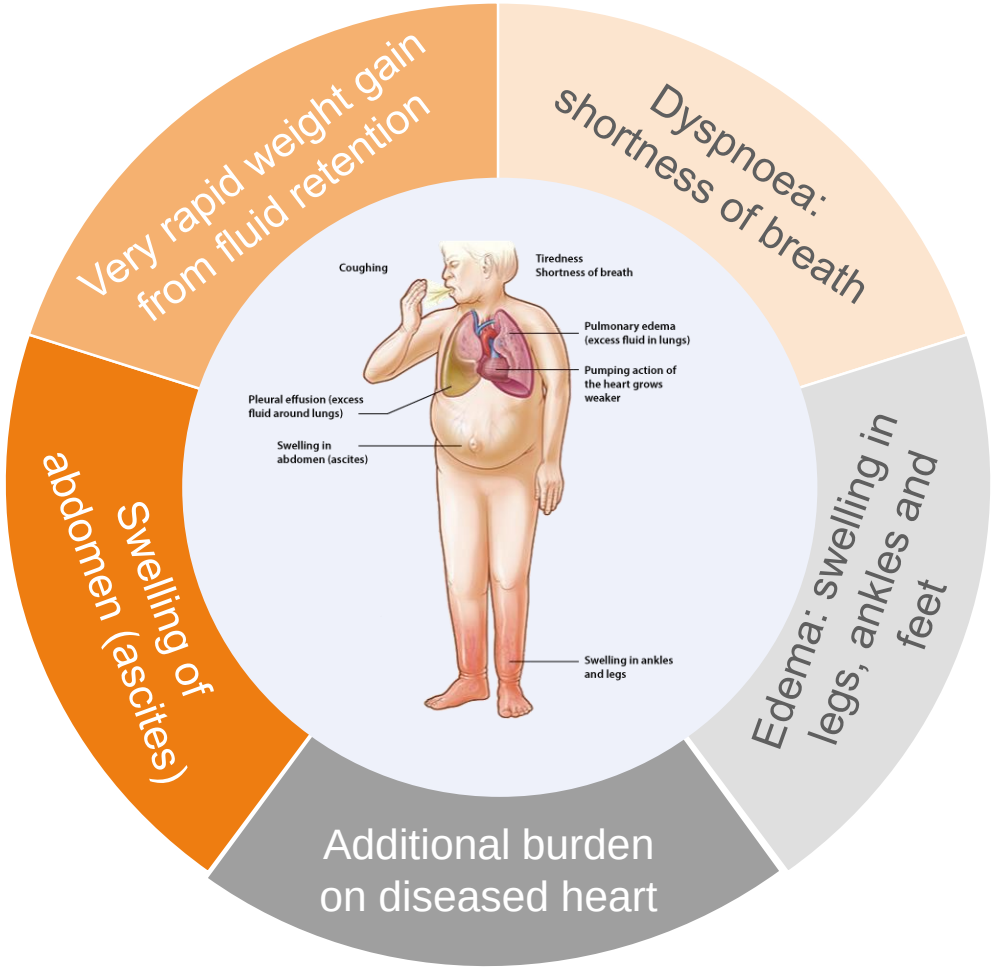
Heart failure is a large and growing market

Nearly 6.5 million US adults affected[1] ; volume overload is a key clinical consequence

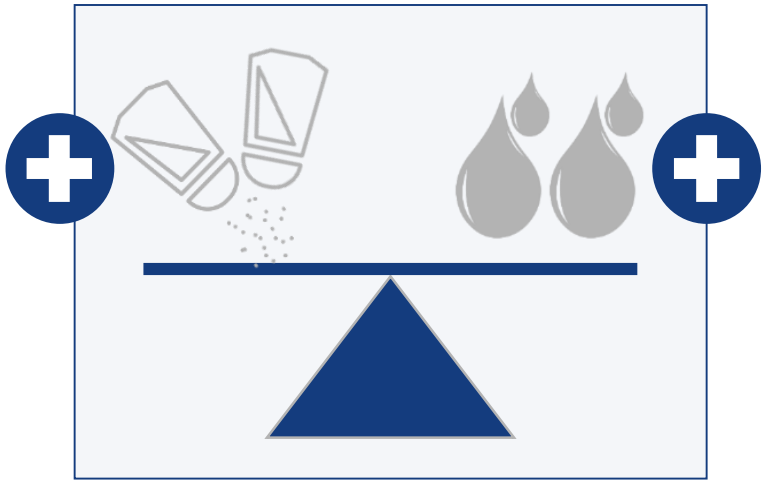


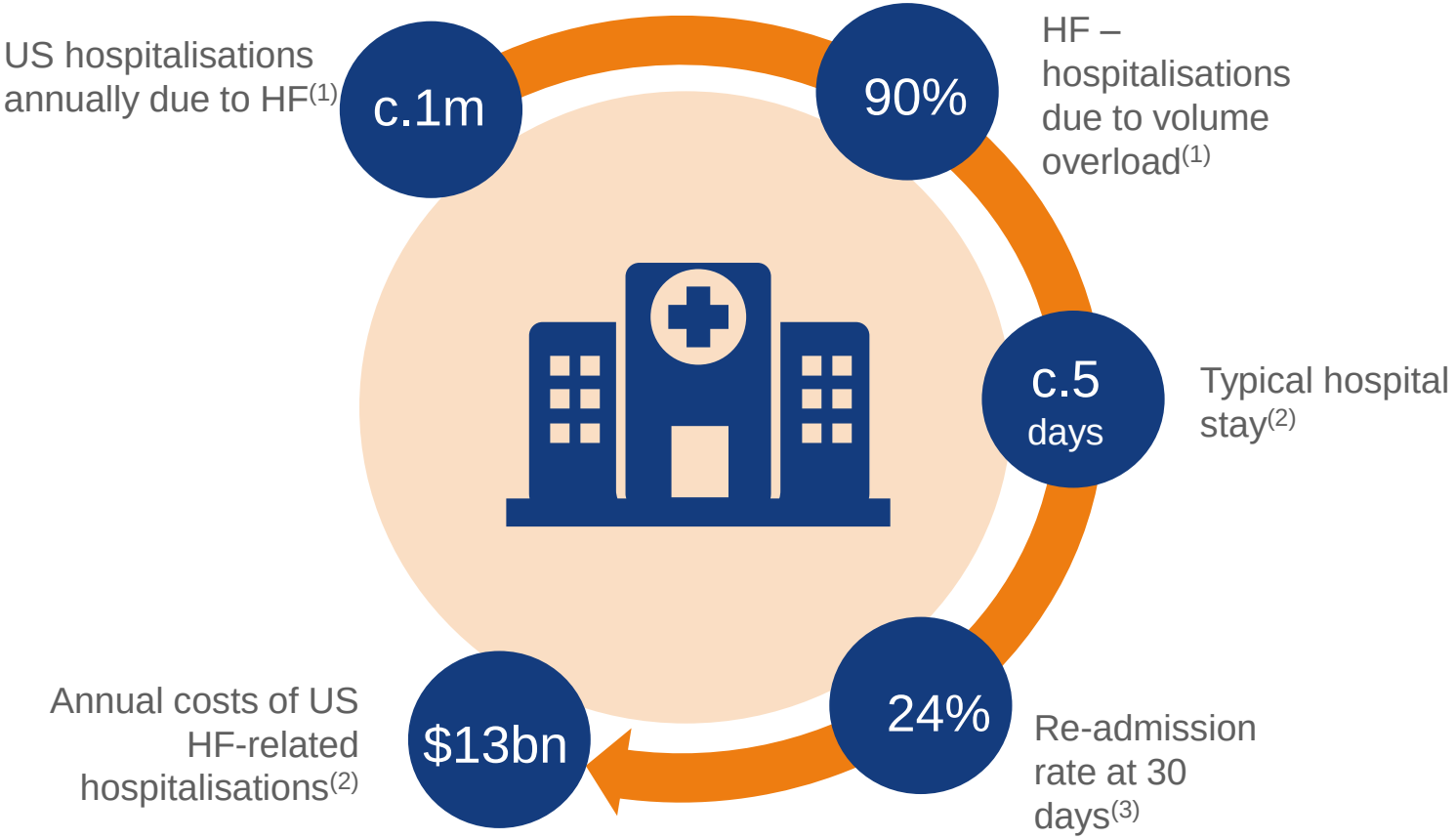


Source 1: Mozzafarian D, Benjamin EJ, Go AS, et al. Heart disease and stroke statistics—2017 update (adults: >=20 years of age)
Source causes & consequences: American Heart Association, Mayo clinical website

Volume overload in Heart Failure (HF)

$13 billion annual cost of HF-related hospitalisations; ~90% due to volume overload

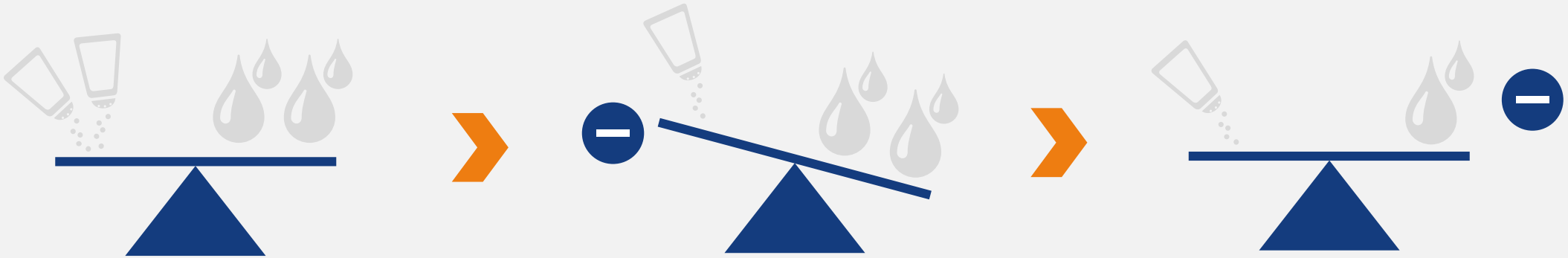




Source 1: Costanzo et al., J. Am. Coll., 2007; Source 2: Kilgore et al. (2017); Source 3: Ross et al. (2010)

Direct sodium removal (DSR)

Tackling sodium removal directly



Too much sodium drives fluid overload

Removing the sodium (DSR)

Elimination of excess fluid

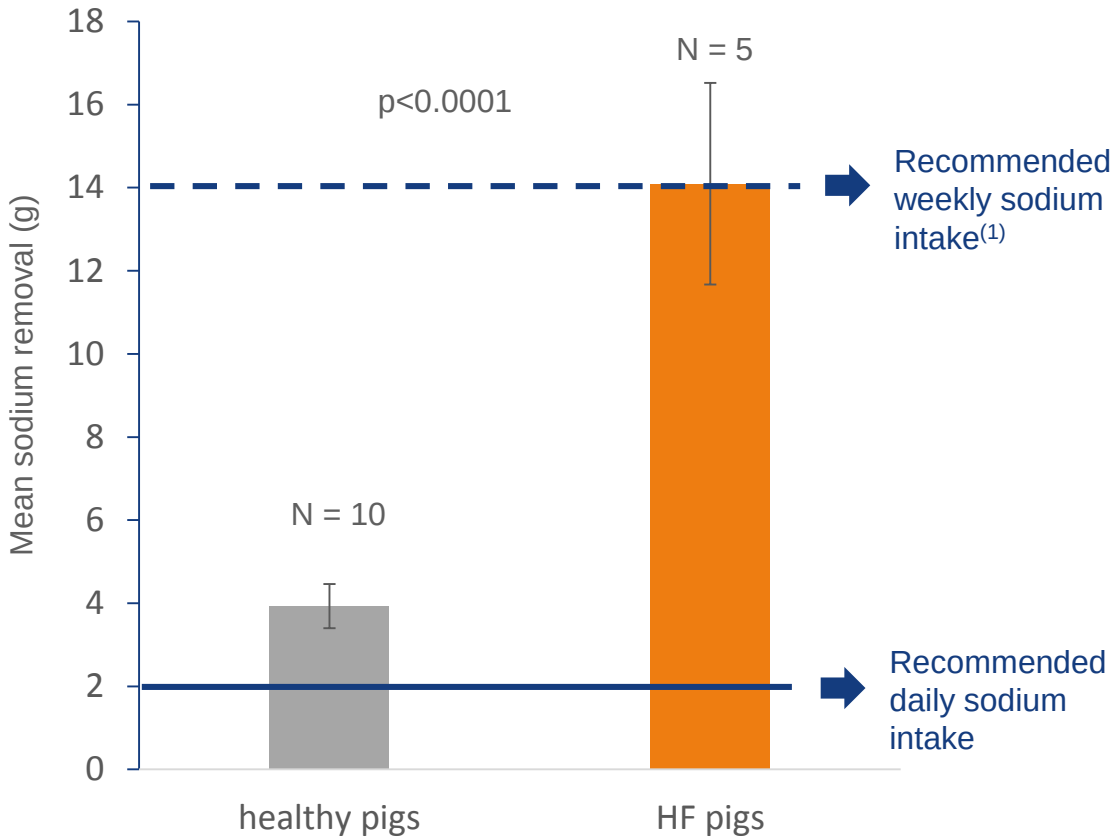
- Administer infusate to peritoneal cavity
- Infusate extracts sodium from the body
- Remove extracted sodium from peritoneal cavity
- Body restores balance by eliminating excess fluid

DSR pre-clinical Proof-of-Concept delivered

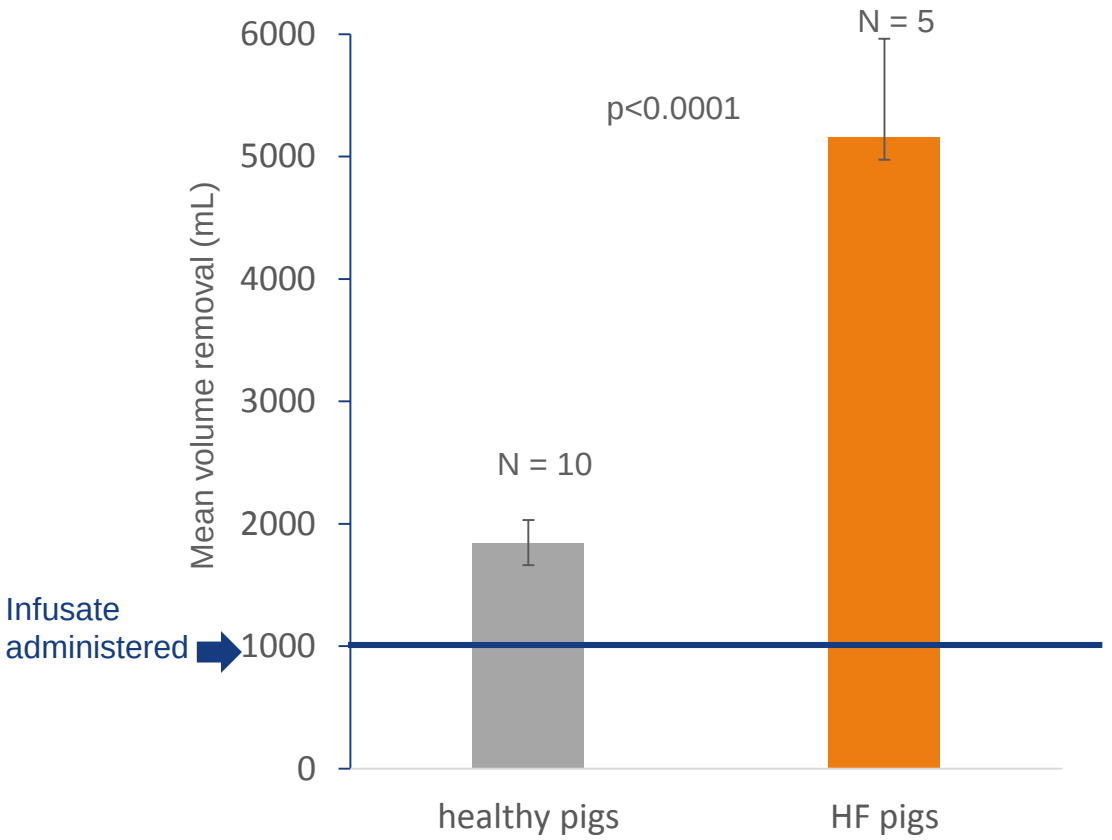
Yale

Study in healthy pigs and pigs with simulated heart failure (HF)

Clinically relevant removal of sodium



Effective fluid removal



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

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Yale

DSR clinical Proof-of-Concept 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 PD solution
- ✓ Minimal inter-patient variability

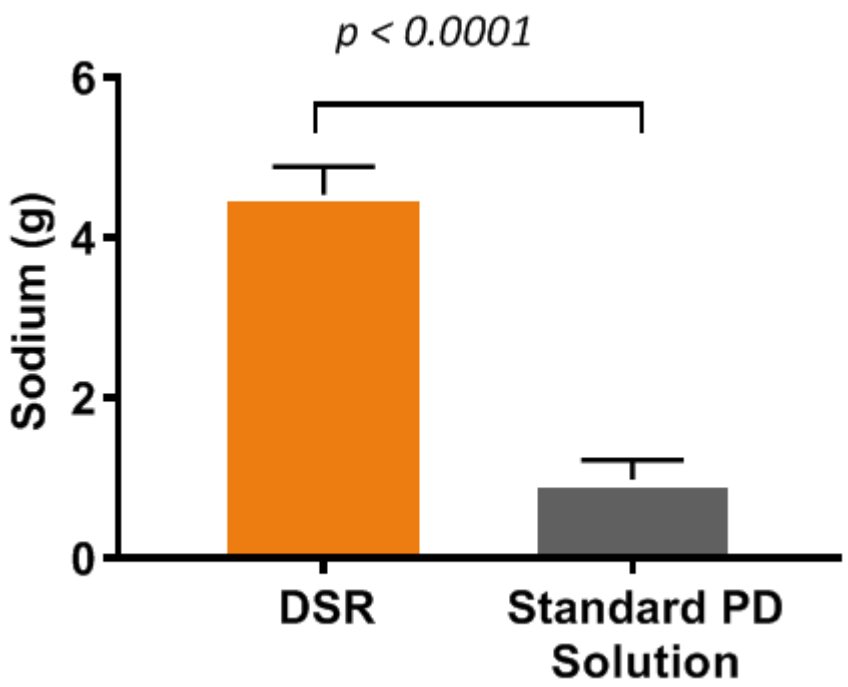
- Initiated and conducted by Dr. Testani at Yale University
- 10 peritoneal dialysis (PD) patients with PD catheter
- Cross-over design: DSR infusate (D10) vs. standard PD solution
- 1 litre infusate administration with 2 hour dwell

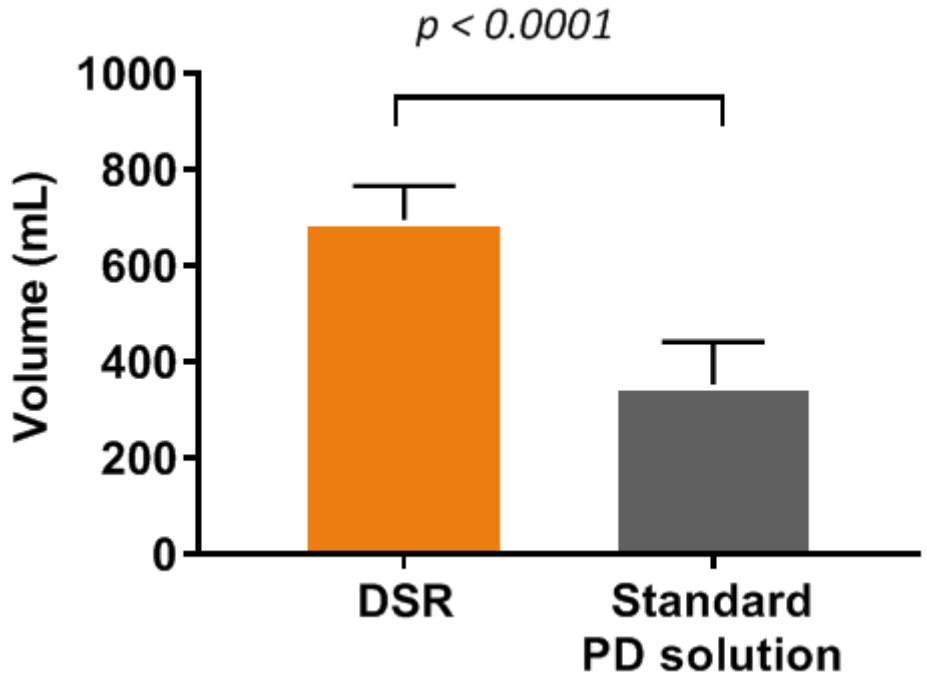
Results presented in late-breaking oral presentation at Heart Failure 2019

Nearly 5 gram sodium removal with single dose DSR

Without safety or tolerability issues

Yale





DSR can result in removal of large quantities of sodium and fluid in a safe and tolerable manner

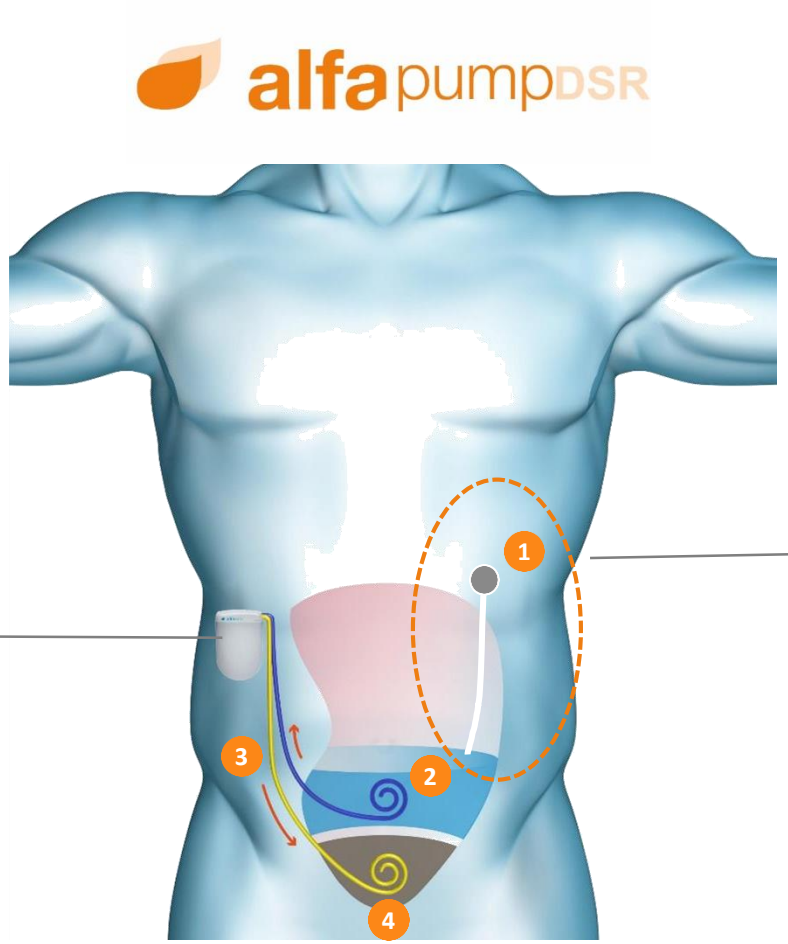
alfapump® DSR

Fully implanted and convenient system leveraging the alfapump experience

alfapump®

SmartCharger

Programmer



Implanted Port

Targeting alfapump DSR as chronic ambulatory therapy for HF patients that are not well controlled on diuretics

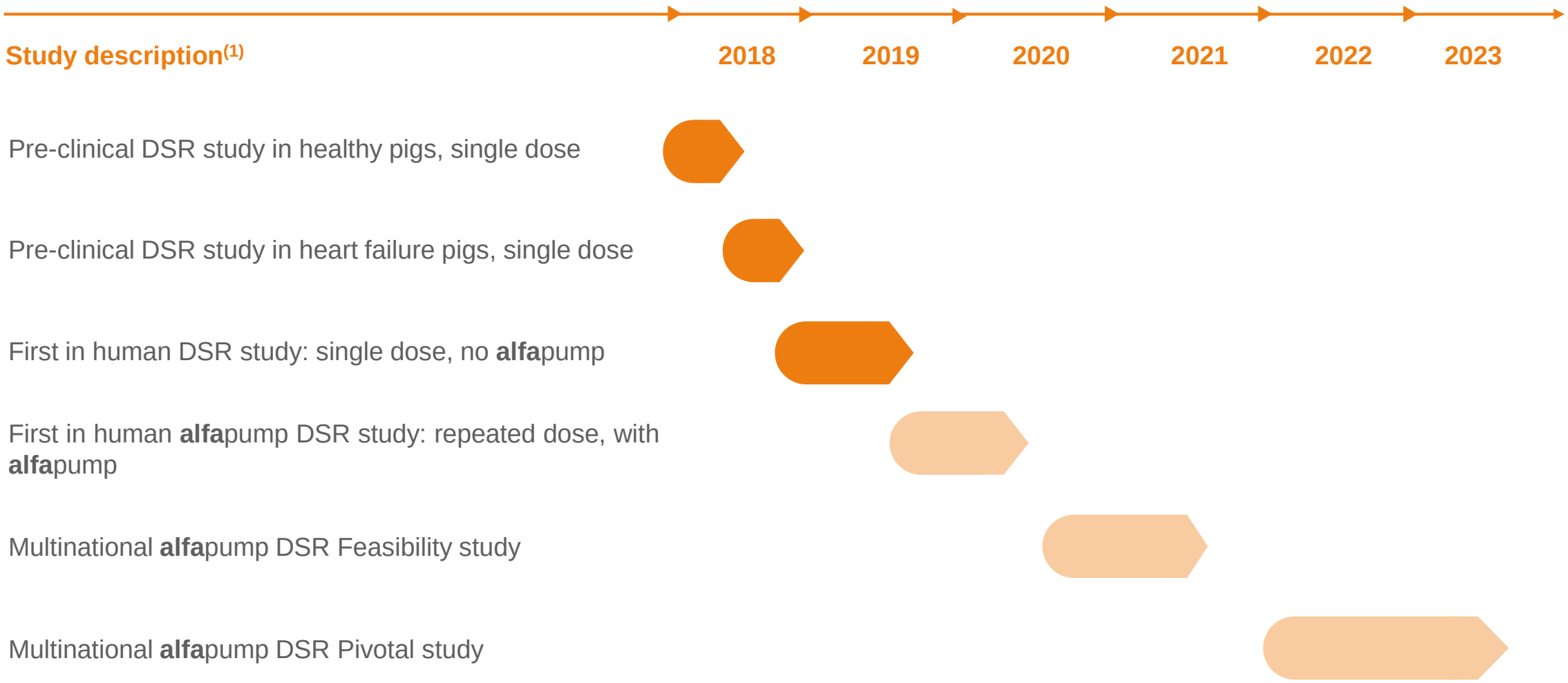
alfapump® DSR leverages on proven elements

Combining clinical proof-of-concept of DSR with validated alfapump platform

✓ **DSR**	- Safe & well-tolerated - Clinically relevant removal of sodium - Minimal patient inter-variability
✓ **alfa**pump	- Validated technical performance - Extensive clinical experience - Deep understanding of implementation
✓ **Implanted port**	- Many years of clinical experience

Preparations underway for repeated dose alfapump DSR study to commence in H2 2019

alfapump® DSR development overview



Note 1: study design and timelines subject to change

conclusion.

Proven **alfa**pump® platform; **strong IP** position; experienced **leadership team**

sequanamedical

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

Three platforms for growth

Near term activities

North American Liver & Cancer

- POSEIDON commencing in H2 2019 (FDA IDE approval received)

Heart Failure

- First in human repeated dose **alfa**pump DSR study commencing H2 2019

Europe Liver & Cancer

- Prospective study in malignant ascites & registry in liver
- Focused expansion in UK, DE, CH & FR

Strong news flow

Key anticipated milestones

H1 2019

- **alfa**pump® received FDA Breakthrough Device designation
- **alfa**pump included in German treatment guidelines (DGVS) for complications of liver cirrhosis
- Presented positive results of first-in-human single dose DSR study for volume overload in heart failure
- Received unconditional IDE approval from FDA to start North-American pivotal study (POSEIDON) in recurrent and refractory liver ascites patients

H2 2019

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

H1 2020

- Expected final German(1) reimbursement of **alfa**pump
- Completion of enrollment of POSEIDON in recurrent and refractory liver ascites patients
- Presentation of final results of first-in-human repeated dose **alfa**pump DSR study in heart failure patients with volume overload

IDE: Investigational Device Exemption; DSR: Direct Sodium Removal
Note 1: final German reimbursement = DRG incl ZE ("Zusatzentgelt"); ZE = DRG specific add-on payment granted permanently for specific case conditions and replaces temporary NUB add-on payment; ZE decisions are made once per year, at the beginning of each year

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