



sequanamedical



Innovators in management of
fluid imbalance disorders

liver disease - malignant ascites - heart failure

Investor presentation – June 2019

Disclaimer

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Regulatory Disclaimer

- 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.


Commercial stage

Positioned for growth




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 built on proven device platform



DGVS
Deutsche Gesellschaft für
Gastroenterologie,
Verdauungs- und
Stoffwechselkrankheiten

**FDA Breakthrough Device
Designation**

alfapump[®] platform

Unique capabilities to manage fluid imbalance



Pump volume easily adjusted



Fully implantable



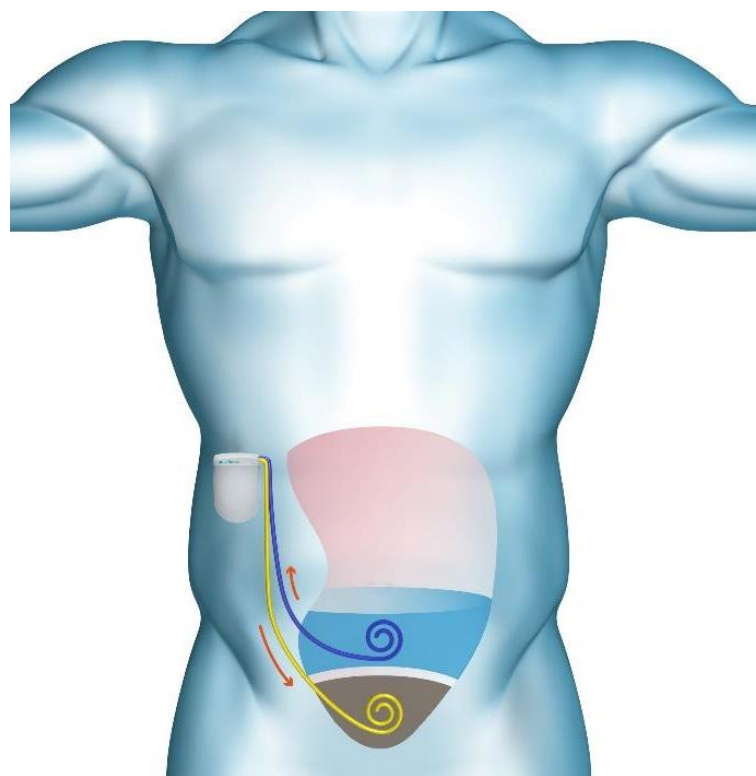
No significant heating during charging and operation



Moves up to 4 litres of fluid per day



Long-term implantation & catheter patency



Remote data monitoring



Battery charged through the skin



Easy implantation



Automatic operation



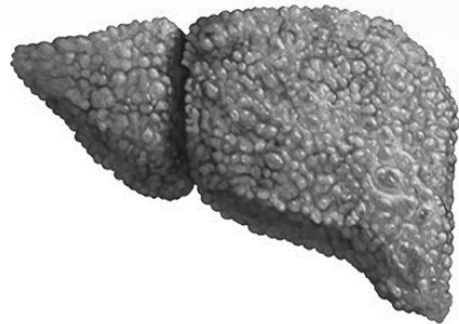
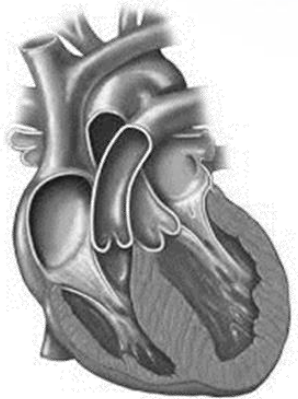
Virtually non-clogging

Strong IP barriers through extensive patent portfolio & know-how



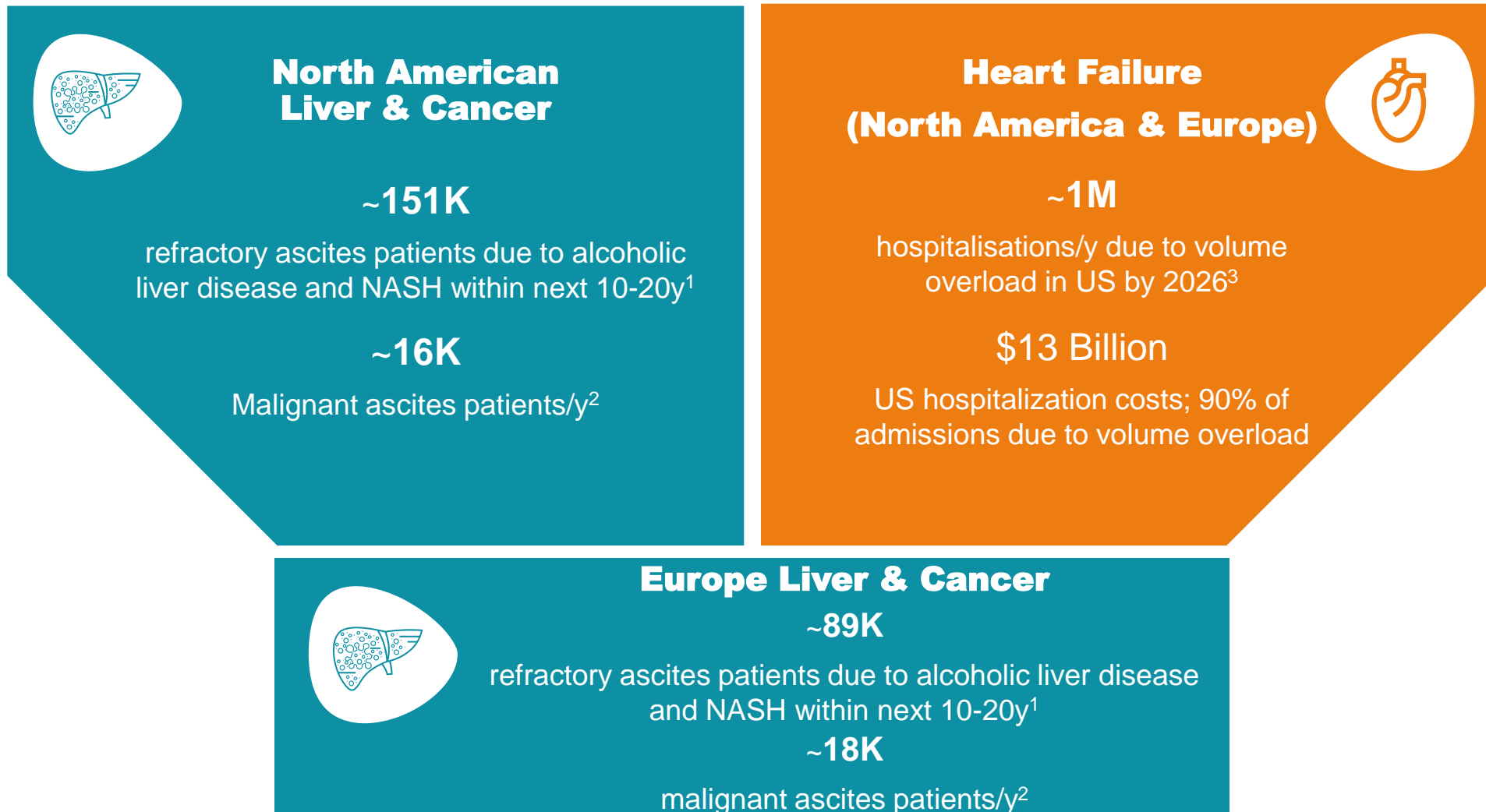
focus.

Liver disease
and heart failure – large
and growing markets



Three platforms for growth

Balancing risk and reward



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).



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)



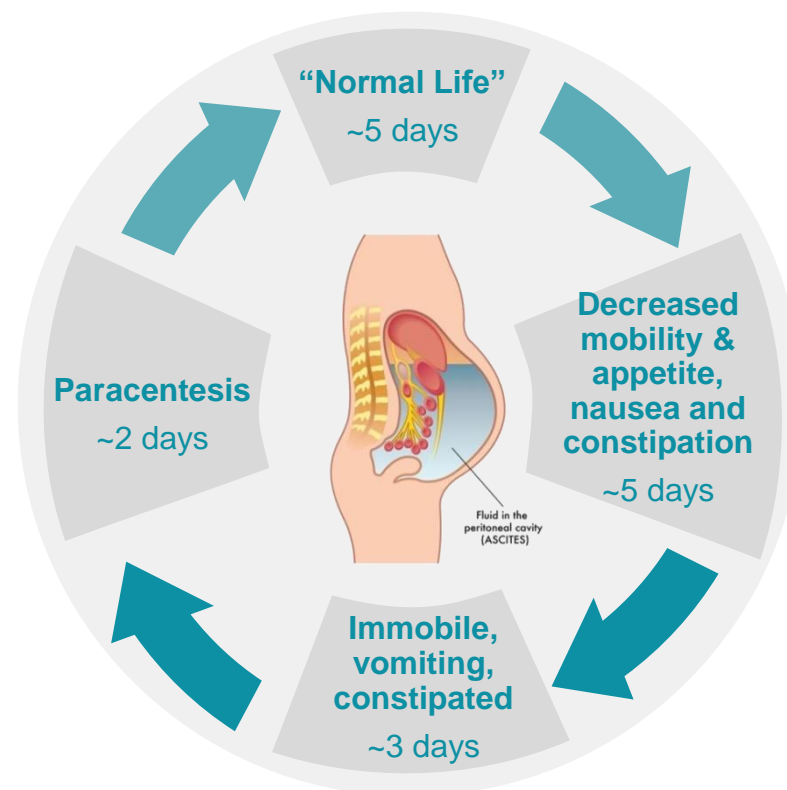
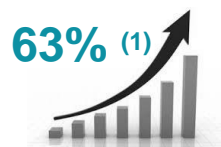
Alcoholic Liver
Disease (ALD)



Non-Alcoholic
Steatohepatitis
(NASH)



Leading
growth driver



Typical life for a patient with refractory ascites⁵

3-4m²

Liver
cirrhosis



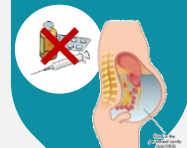
50%³

Ascites



7.5%⁴

Refractory
Ascites



Note 1: Prevalence of NASH in US is expected to increase by 63% between 2015-2030; Estes et al., 2018

Source 2: Management estimate in US based on Estes et al; GlobalData Nash Epidemiology Forecast to 2026; Noureddin et al., 2013

Source 3: Runyon 2009.

Source 4: Ginès et al., NEJM 2004.

Source 5: Presentation of Dr. Rajiv Jalan at EASL in 2018, Large Volume Paracentesis (LVP) treatment cycle for refractory ascites

Cancer and malignant ascites

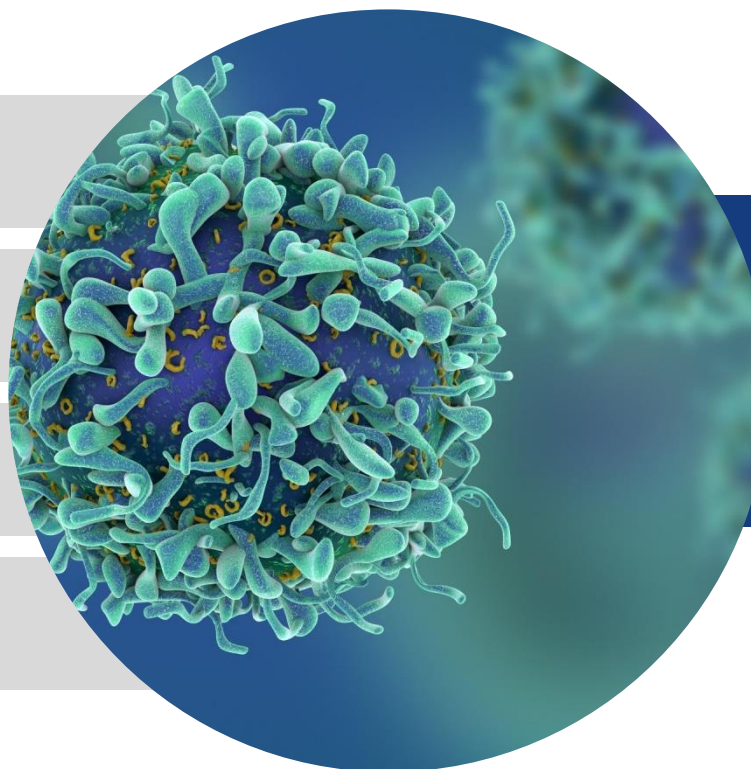
Severe complication of late-stage cancers

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

Breast and ovarian cancer have longest survival with ascites¹

Severe impact on **quality of life**

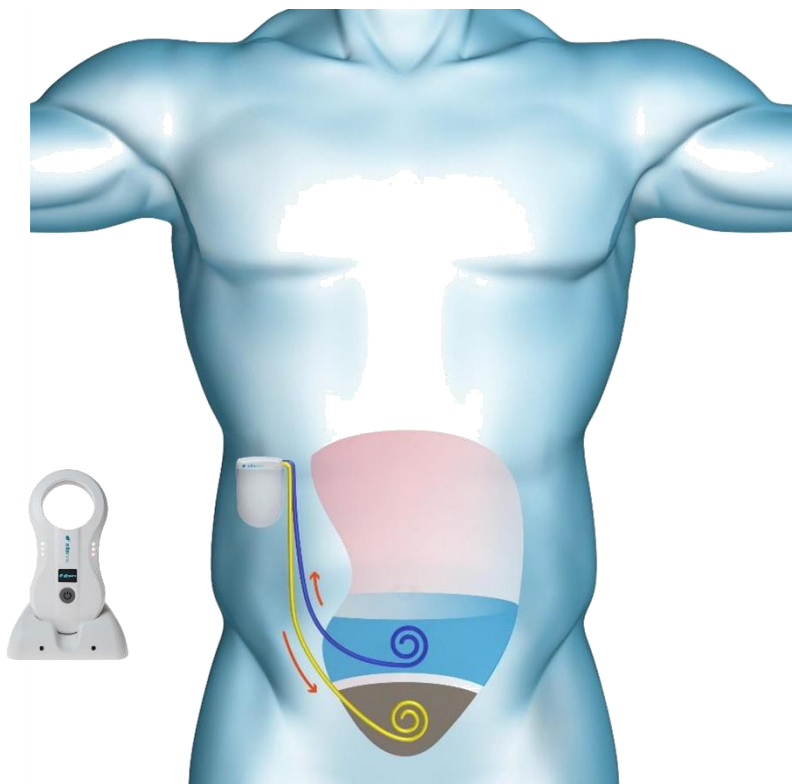
Reduces ability to undergo **anti-cancer treatment**



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

alfapump®

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



alfapump®



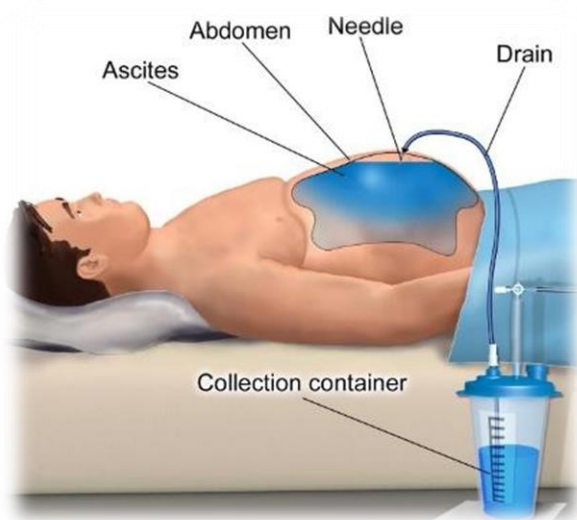
Smart Charger



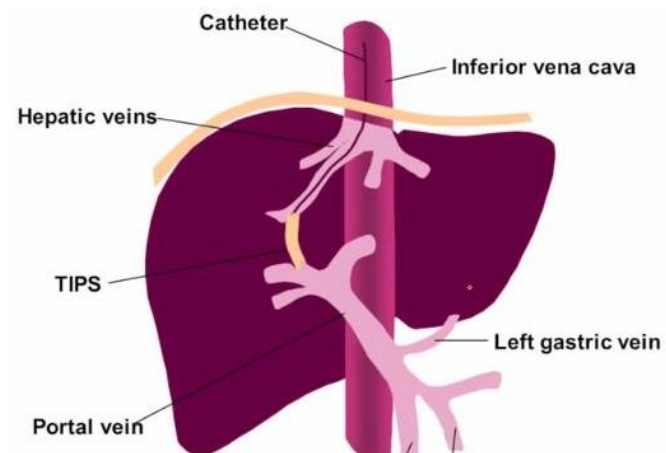
Programmer

Severe limitations of existing therapies

Large Volume Paracentesis (“drainage”)



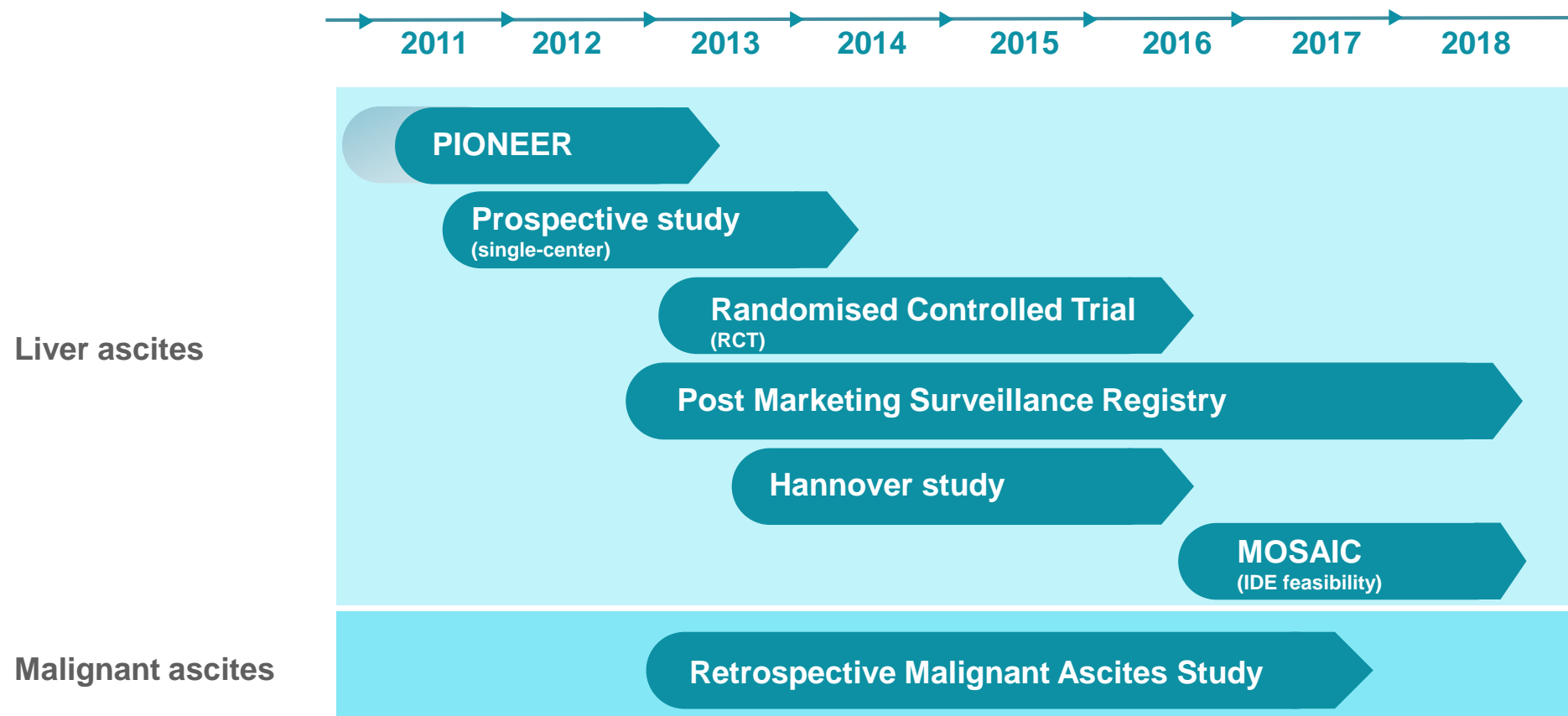
Transjugular Intrahepatic Portosystemic Shunt (TIPS)



Liver transplant



Validated clinical performance



Drastically reduced need for drainage



Improved nutrition



Improved patient quality of life

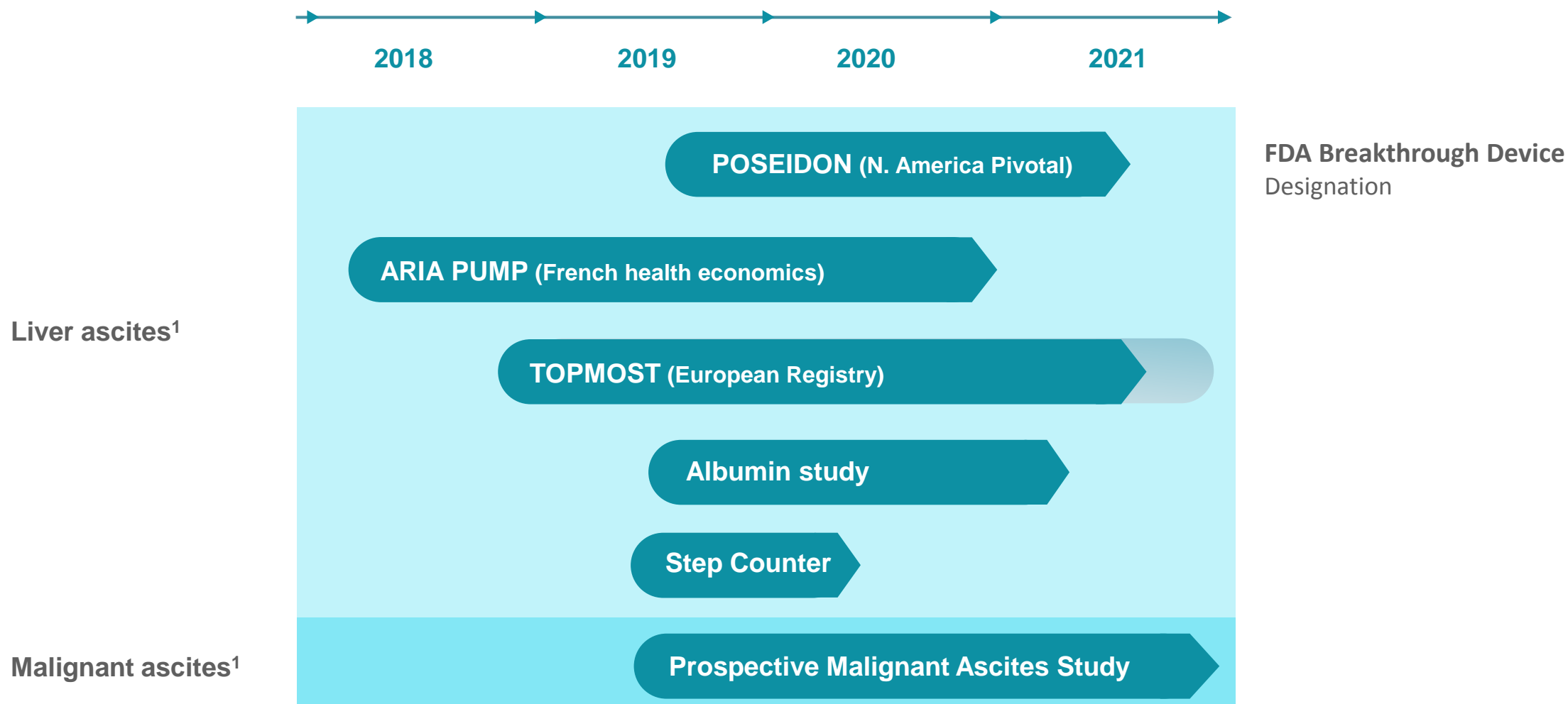


Complication rate dramatically reduced¹

Note 1: During these studies, there were a significant number of infections amongst *alfapump*[®] patients. In the RCT (the only study with a control arm), the rate of infections in the *alfapump*[®] treatment arm was comparable to the LVP standard of care arm.

Building further clinical evidence

For North American approval and broader international acceptance



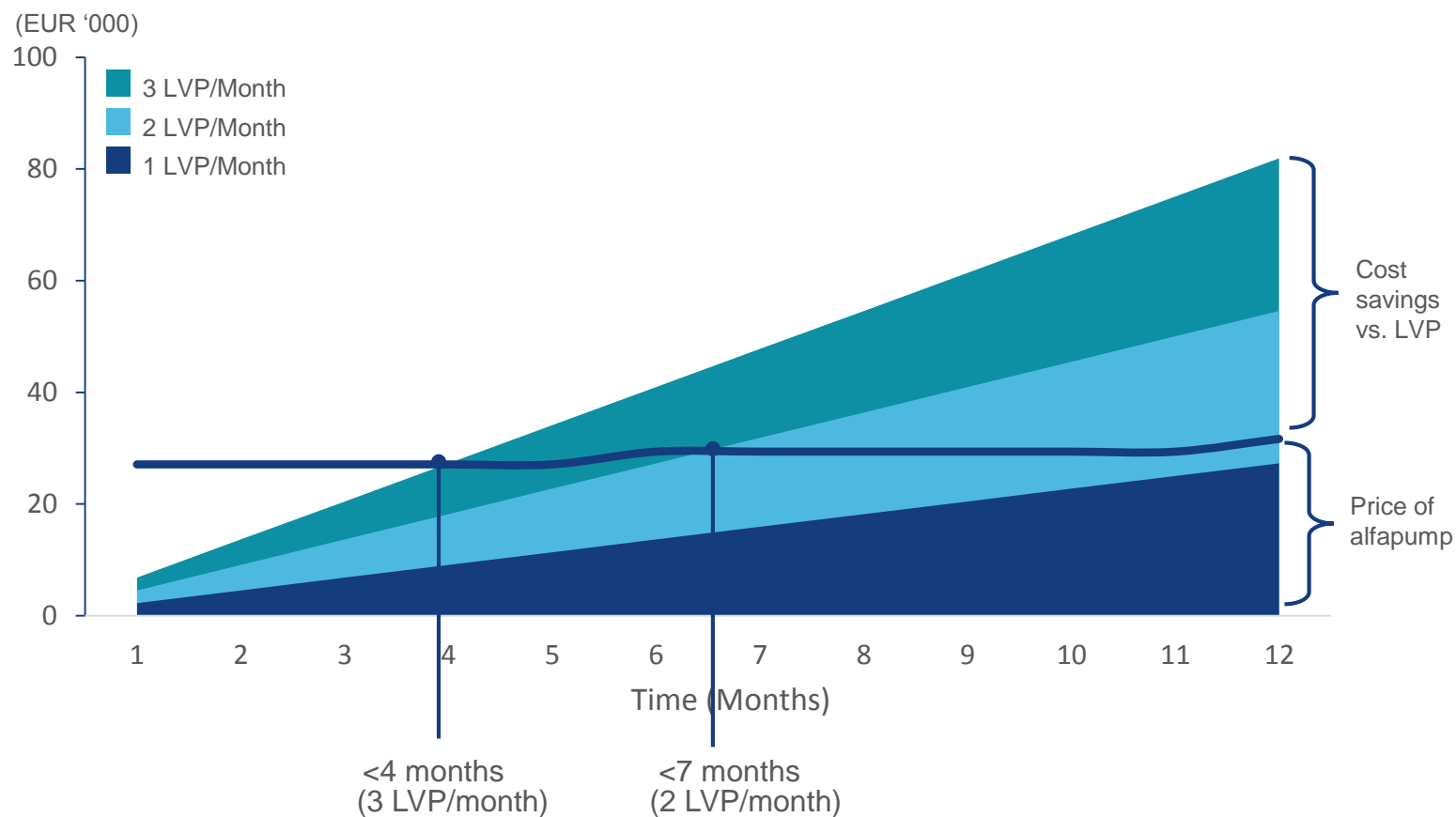
Note 1: study design subject to change

alfapump® for liver refractory ascites

Strong health economics rationale

- ✓ Typical patient needs 2-3 LVPs per month
- ✓ Analysis based on the German market and assumes no SAEs

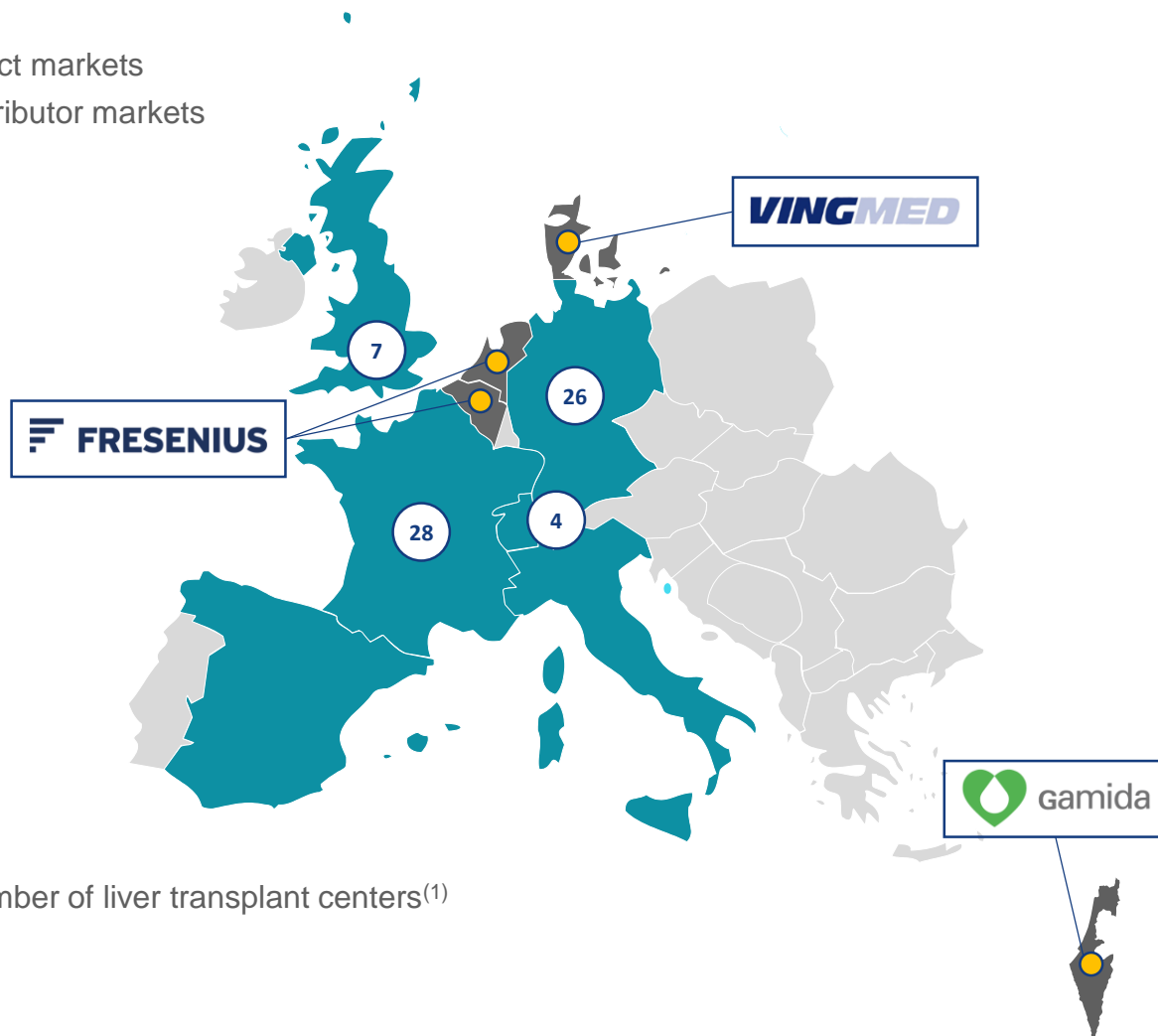
Elimination of need for drainage (LVP) leads to substantial cost reduction for hospitals and payers



Focused European commercial activities

Targeted and specialist commercial team

- Direct markets
- Distributor markets



X Number of liver transplant centers⁽¹⁾



12 person team

Focus on specialist centers

Raise awareness at community hospital level

- Current reimbursement:
- ✓ **Switzerland:** DRG
 - ✓ **Germany:** DRG (NUB program²)
 - ✓ **UK:** NICE guidance “use with special arrangements”
 - ✓ **Belgium, Netherlands, Denmark, Israel:** special / hospital innovation budget

Source 1: European Liver Transplant Registry (ELTR)
 Note 2: NUB: “Neue Untersuchungs- und Behandlungsmethode” = temporary 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 device platform

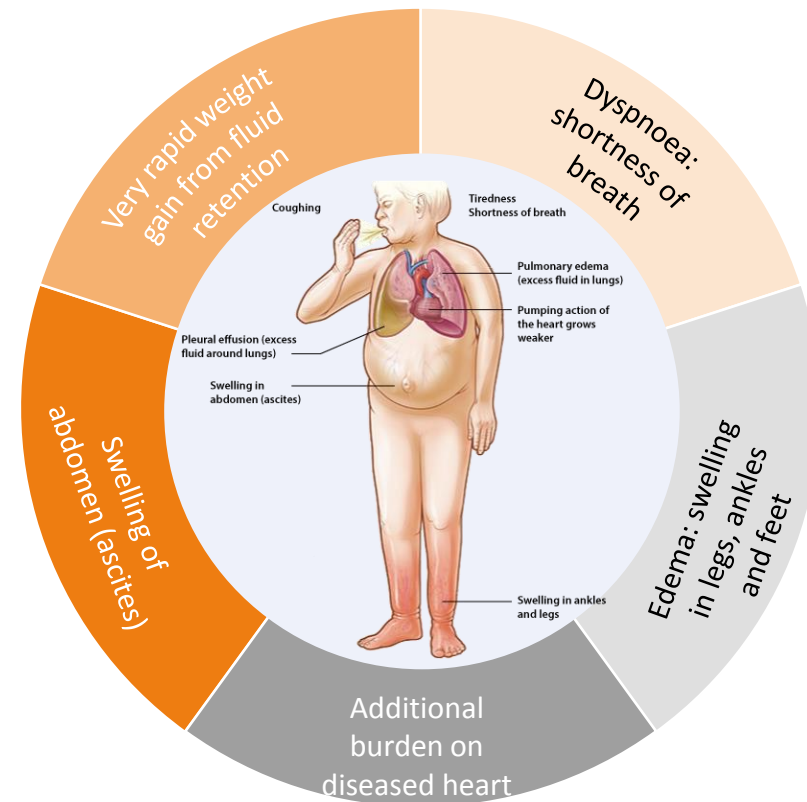
Heart failure is a large and growing market

Nearly 6.5 million US adults affected¹

Causes²

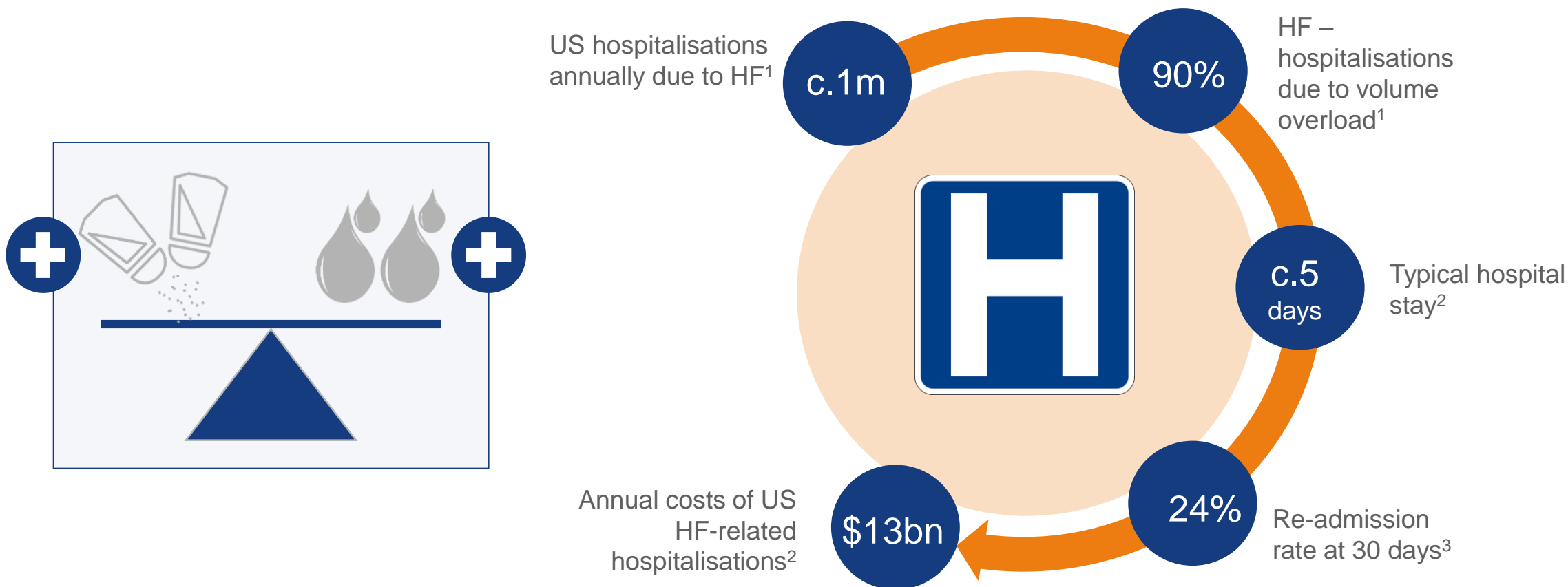


Volume overload is a key clinical consequence of HF³



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



**Administer
infusate to
peritoneal
cavity**

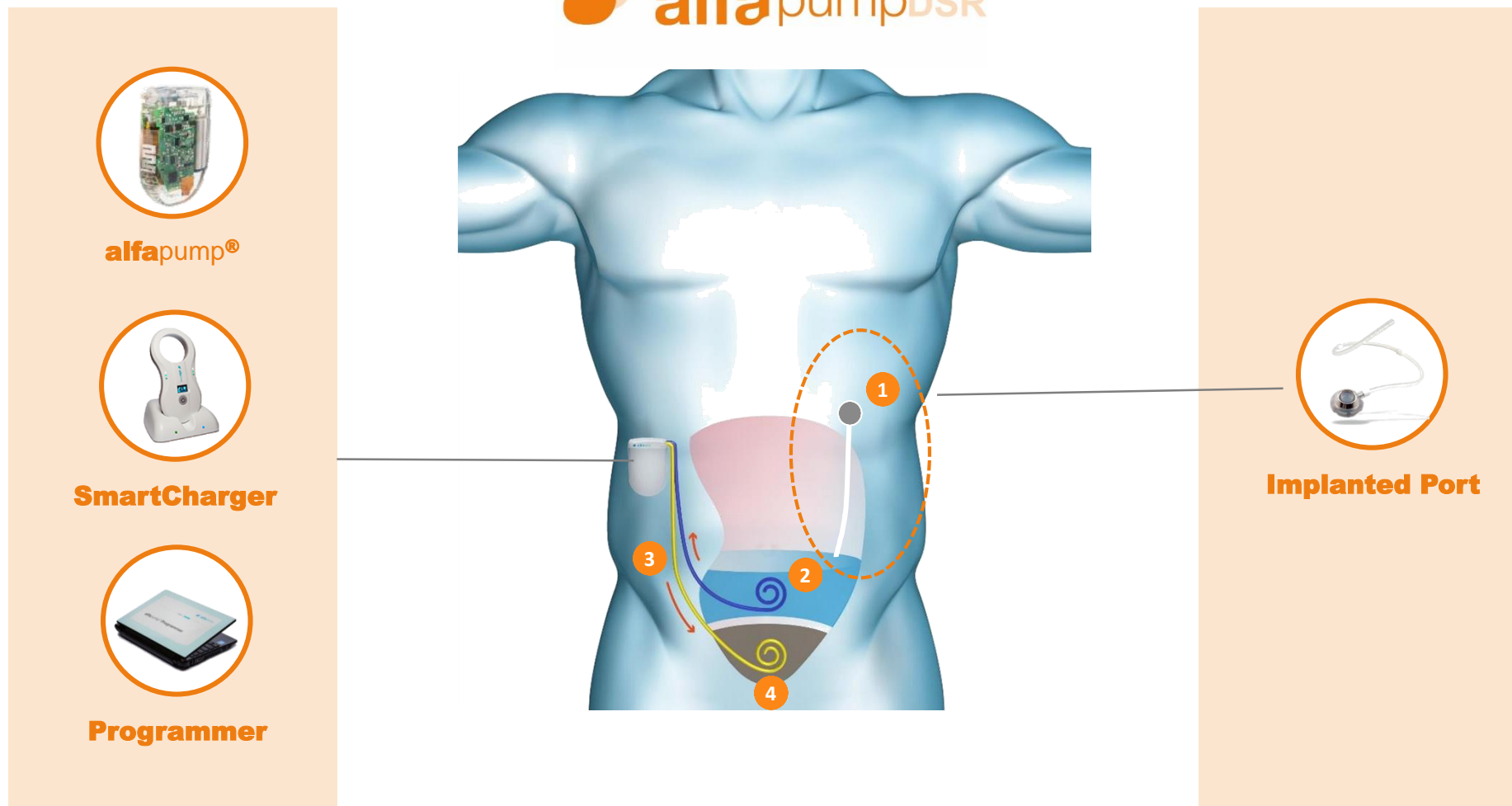
**Infusate
extracts
sodium from
the body**

**Remove
extracted
sodium from
peritoneal
cavity**

**Body restores
balance by
eliminating
excess fluid**

alfapump[®] DSR

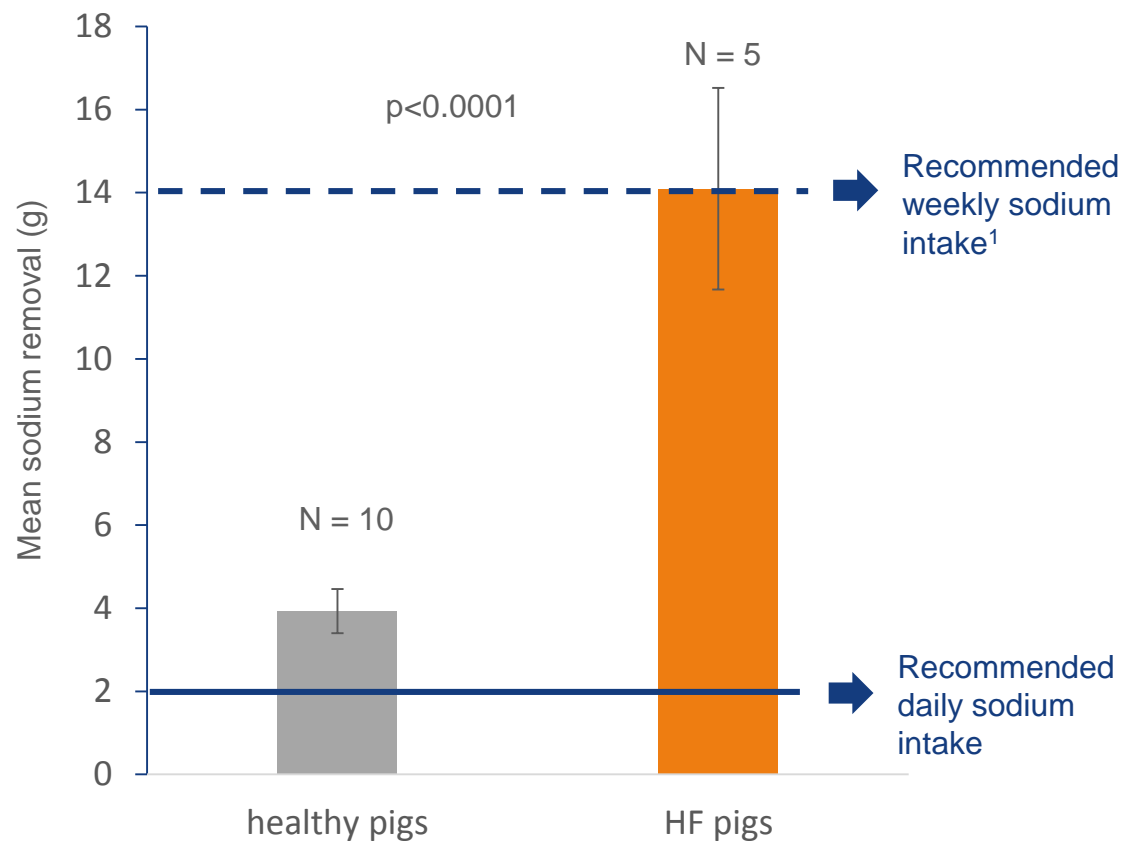
Fully implanted and convenient system leveraging on the alfapump experience



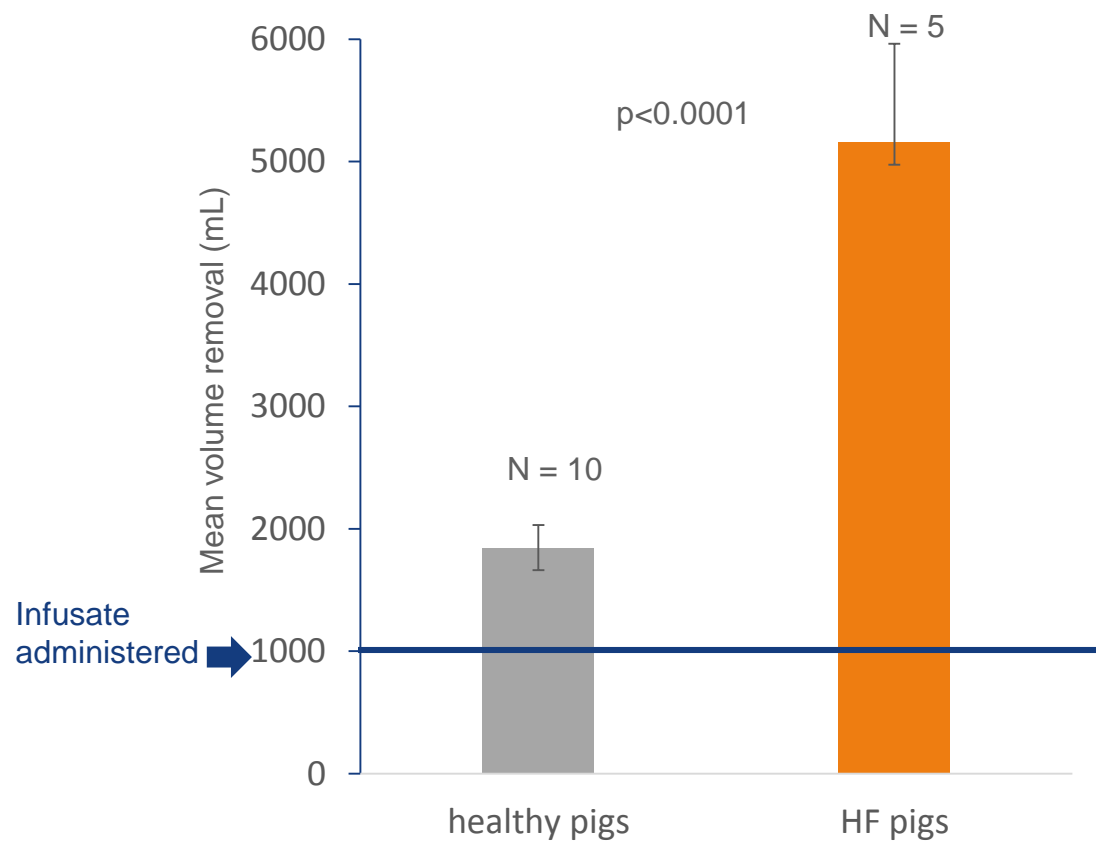
DSR pre-clinical Proof-of-Concept delivered

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)

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

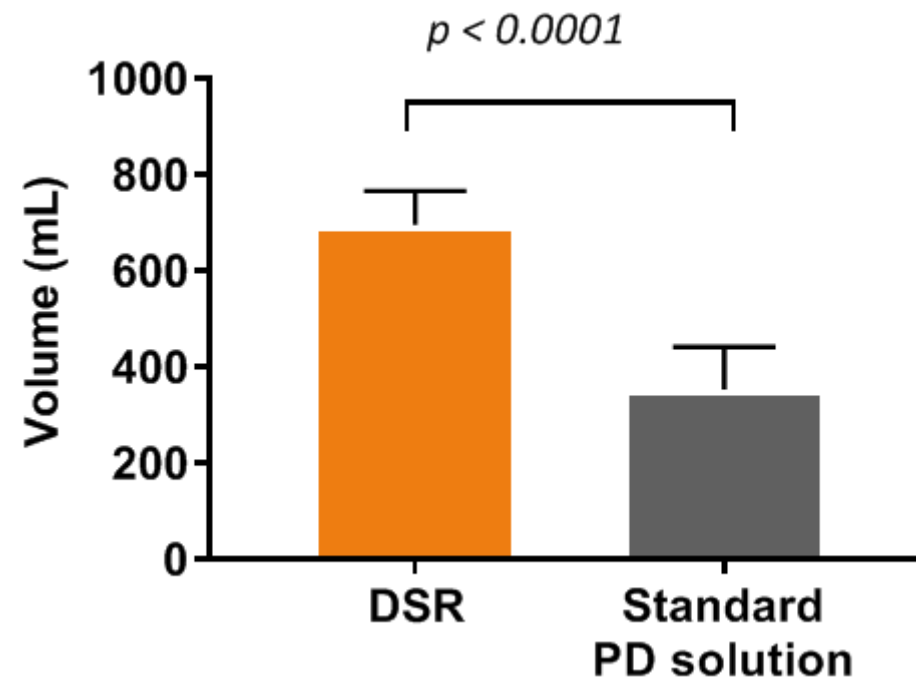
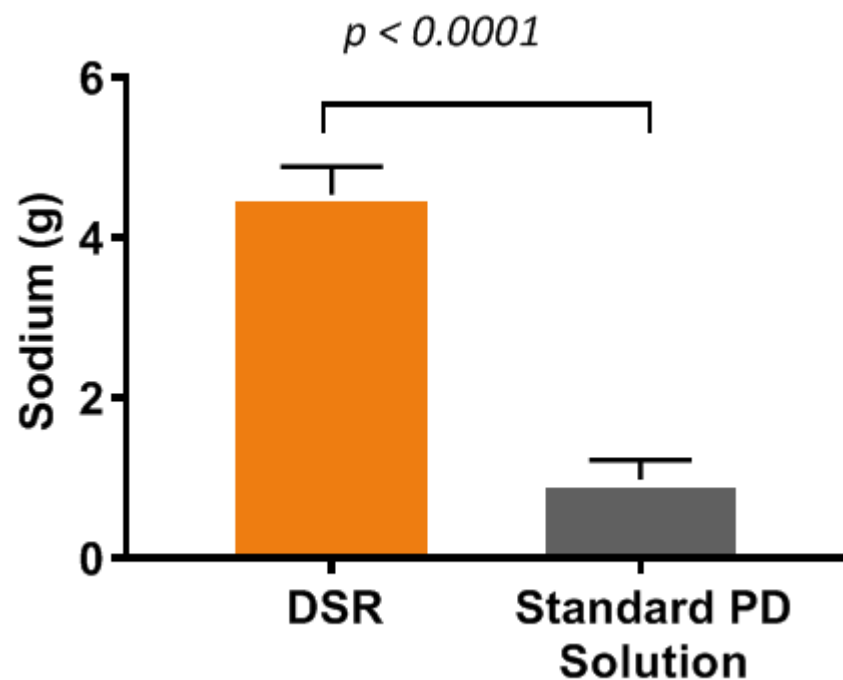
- Initiated and conducted by Dr. Testani at Yale University
- 10 peritoneal dialysis (PD) patients with PD catheter
- Cross-over design: DSR infusate (D10) vs. standard PD solution
- 1 litre infusate administration with 2 hour dwell

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

Nearly 5 gram sodium removal with single dose DSR

Substantial higher sodium and fluid removal with DSR vs standard PD solution

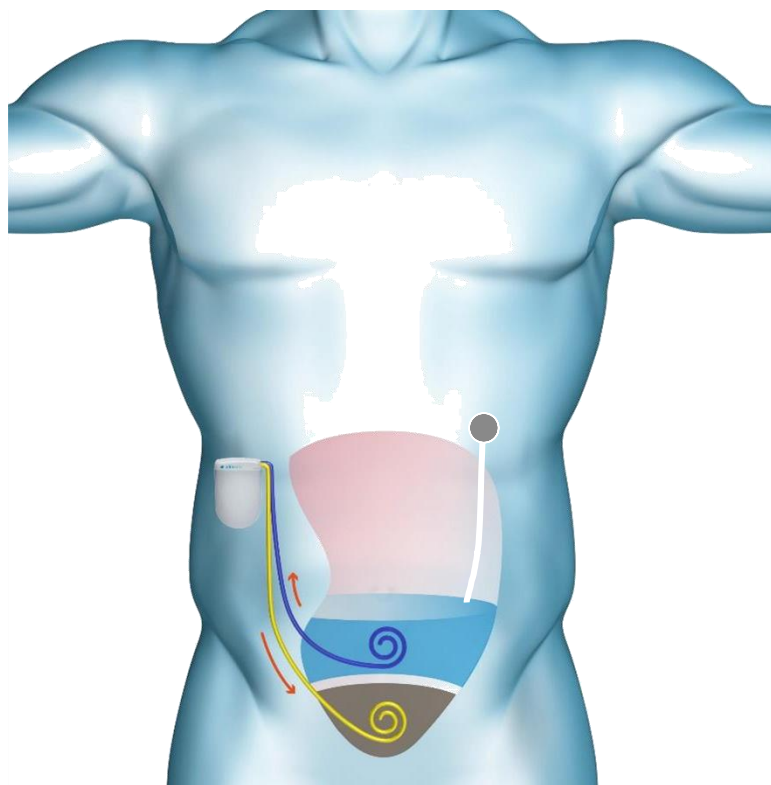
Yale



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

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

✓ alfapump

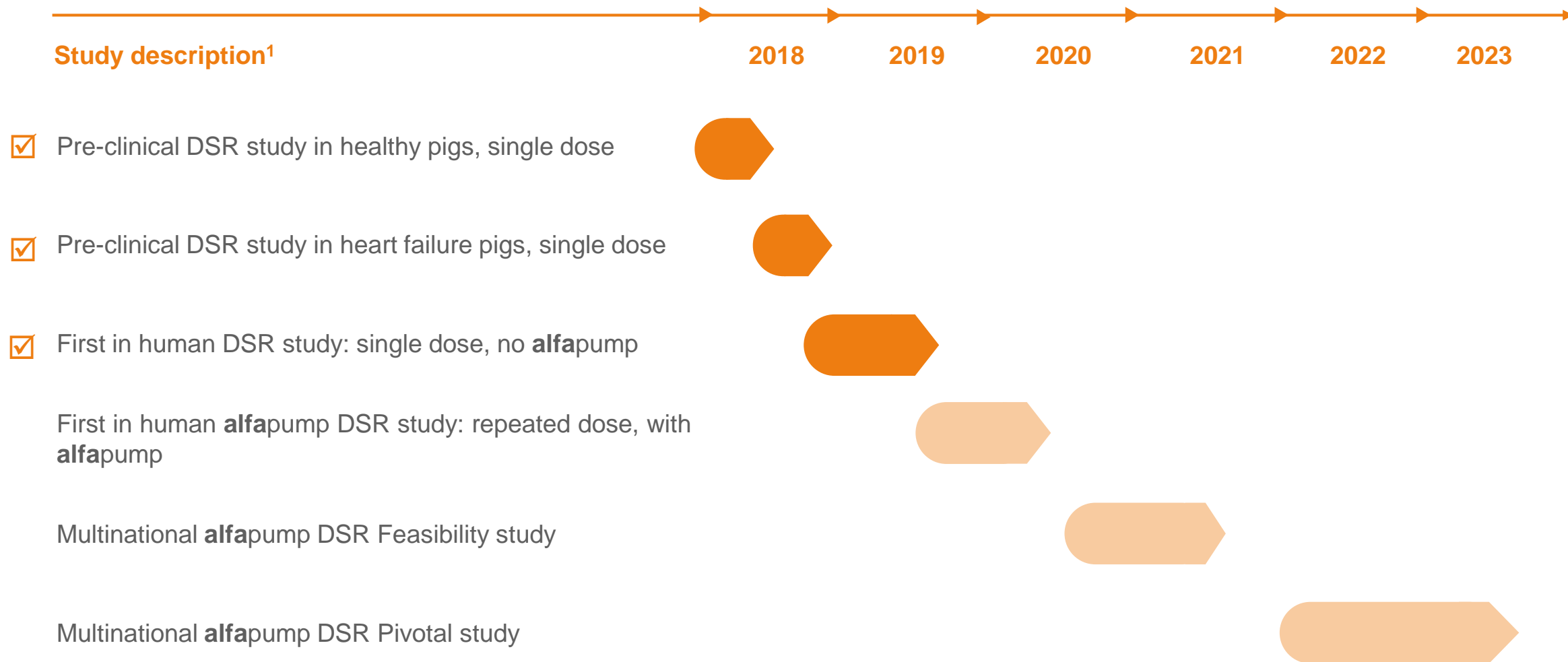
- Validated technical performance
 - eg pumping, charging, communication, patency, monitoring
- Extensive clinical experience
 - Over 700 implants and 400 patient years
- Deep understanding of implementation
 - eg implantation procedure

✓ 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 **alfapump**[®] platform;
strong IP position; experienced
leadership team



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



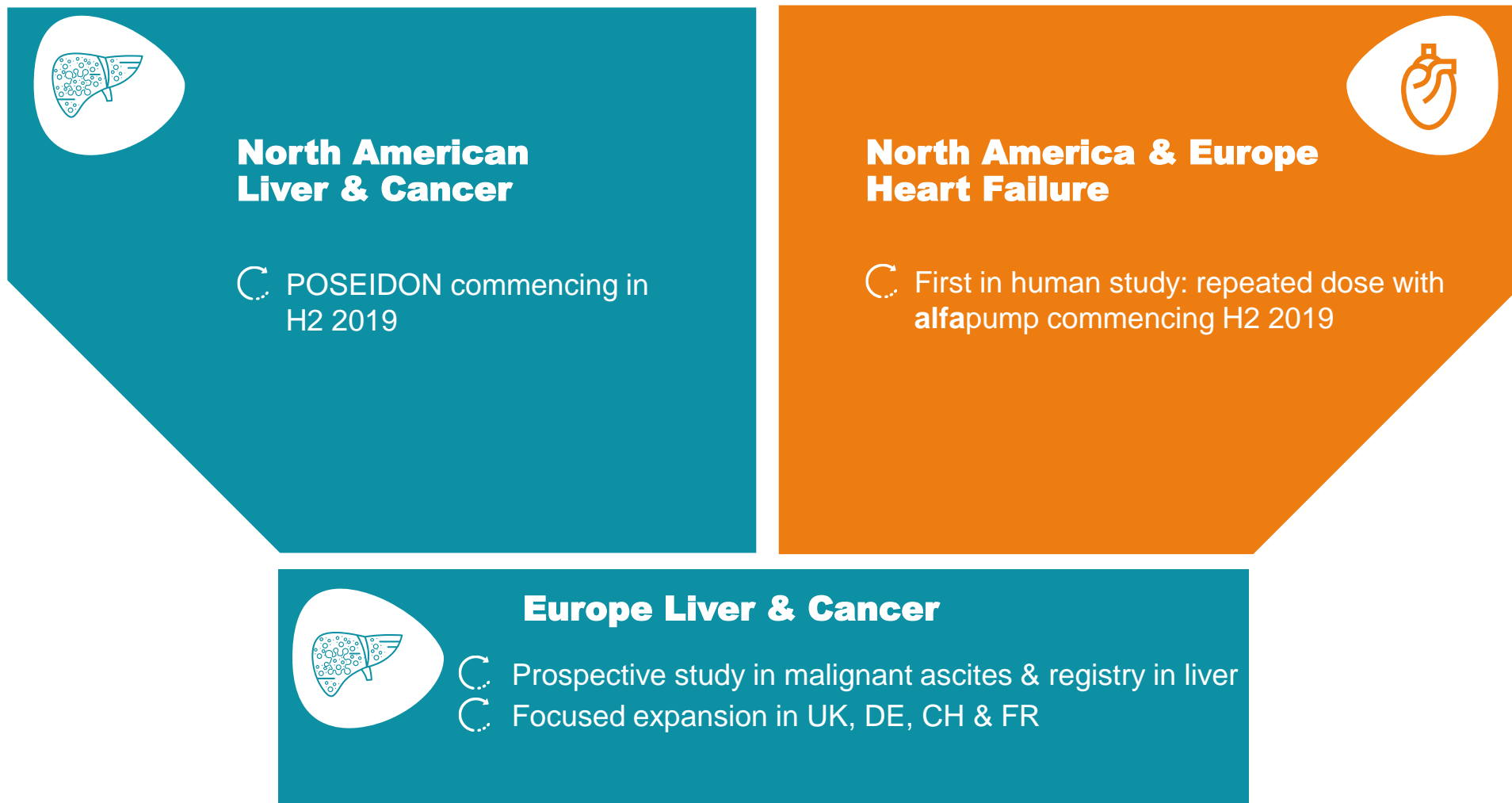
Erik Amble
Director



Jason Hannon
Director

Three platforms for growth

Balancing risk and reward



Strong news flow

Key anticipated milestones

H2 2018

- ✓ Completion of DSR study in pig heart failure model & presentation of results
- ✓ Presentation of clinical data on 17 malignant ascites patients in retrospective clinical study
- ✓ Outcome of NICE review of **alfapump**[®]
- ✓ Initiation of First in Human clinical study for heart failure, single dose
- ✓ Initiation of TOPMOST: European “Super Registry” (Reporting Data Regularly)

H1 2019

- ✓ Outcome of FDA Breakthrough Device designation
- ✓ Inclusion in German treatment guidelines (DGVS) for complications of liver cirrhosis
- ✓ Completion and presentation of results for First in Human DSR study for heart failure, single dose
 - Initiation of prospective malignant ascites study
 - Initiation of prospective albumin study

H2 2019

- Initiation of POSEIDON North-American pivotal study
- Expected Dutch reimbursement of **alfapump**[®]
- Presentation of initial results for First in Human heart failure study, repeated dose with **alfapump**[®] DSR

H1 2020

- Expected Belgian and final German¹ reimbursement of **alfapump**[®]
- Publication of clinical data from albumin study
- Full presentation of First in Human heart failure study, repeated dose with **alfapump**[®] DSR

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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