



sequanamedical



Innovators in the management of liver disease, heart failure, malignant ascites and other fluid imbalance disorders.

Investor presentation – May 2019

Disclaimer

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Commercial stage

medtech positioned for long-term growth

Focus

on liver disease and heart failure – large and growing markets

alfapump®

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



1913 DGVS

Deutsche Gesellschaft für Gastroenterologie, Verdauungs- und Stoffwechselkrankheiten

FDA Breakthrough Device Designation

Strong

organization led by an experienced leadership team; strong IP position

alfapump® DSR

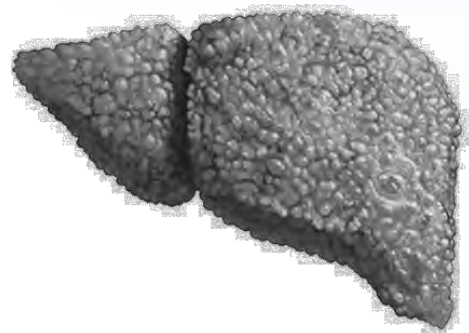
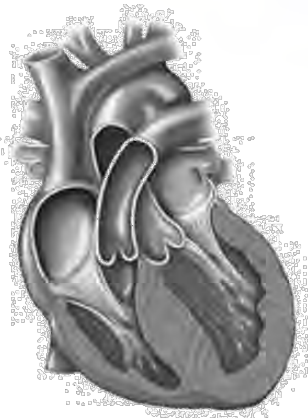
breakthrough approach to fluid overload in heart failure built on proven device platform





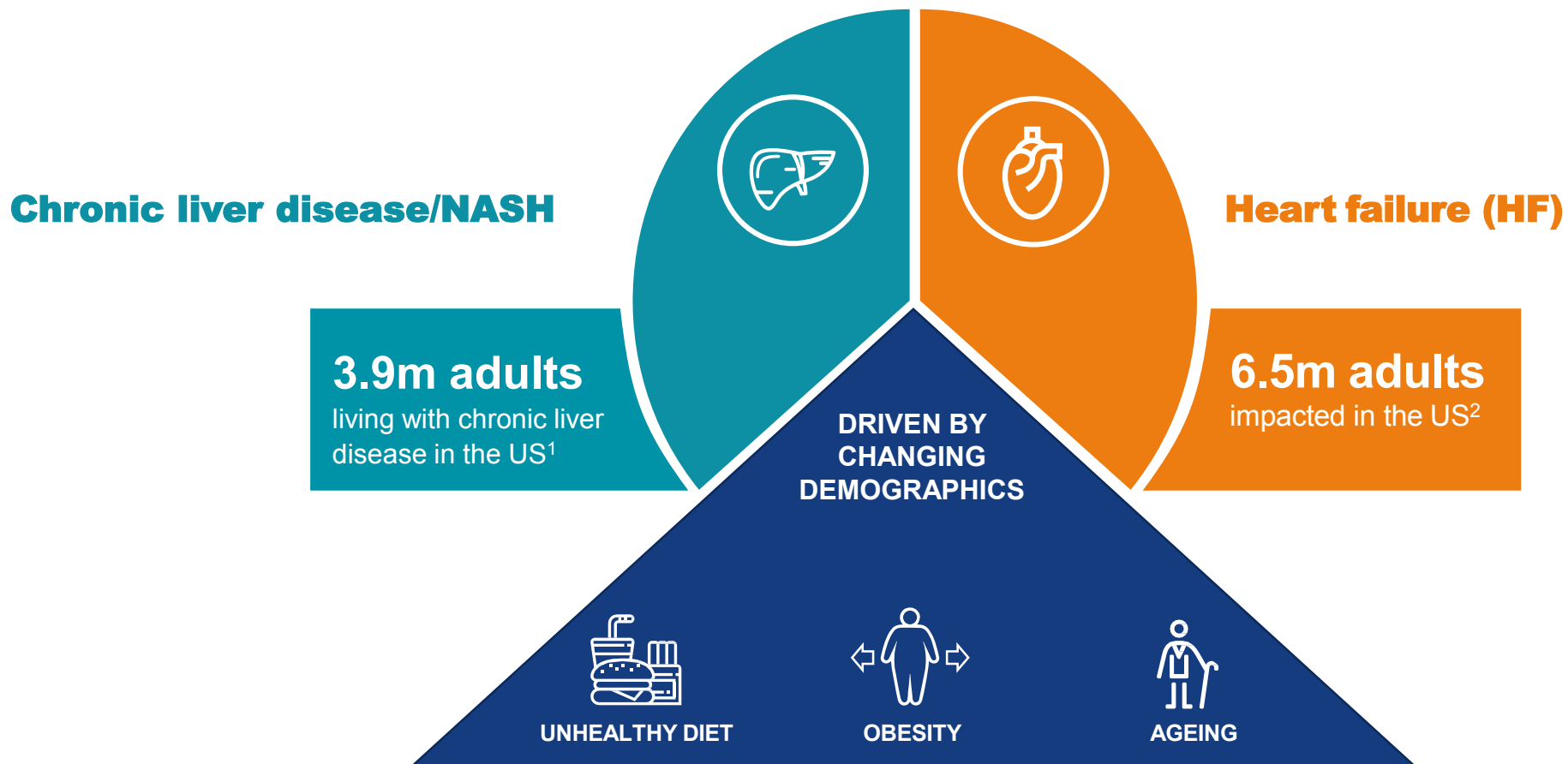
focus.

Focus on **liver disease**
and **heart failure** – large
and growing markets



Liver disease and heart failure

Large and growing markets driven by unhealthy lifestyles and ageing populations



Source 1: Centres for Disease Control and Prevention (CDC)
 Source 2: Mozzafarian D, Benjamin EJ, Go AS, et al. Heart disease and stroke statistics—2017 update (adults: >=20 years of age)

Liver cirrhosis and refractory ascites

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

Viral infections
(Hepatitis B & C)



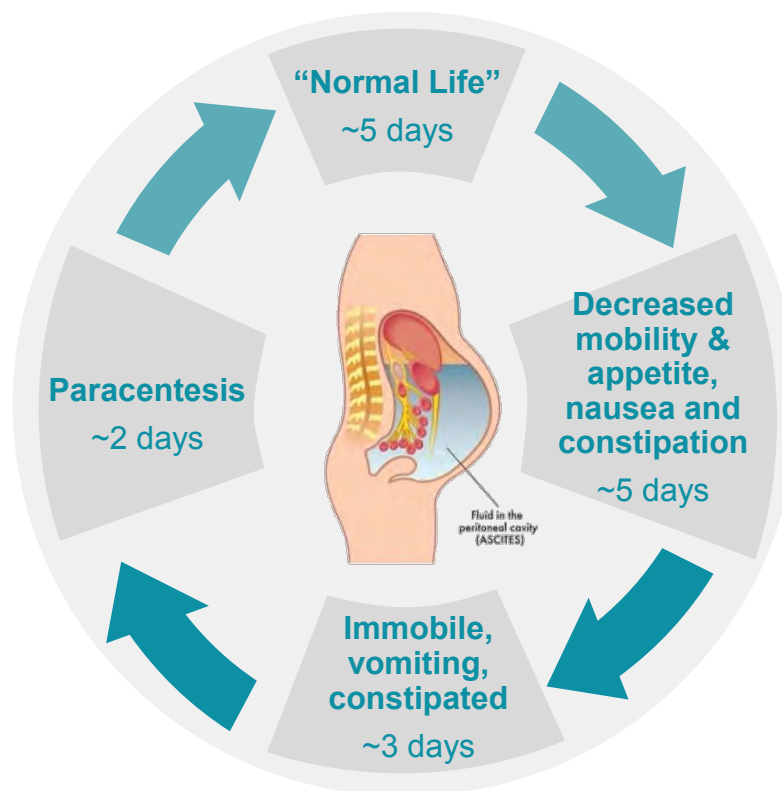
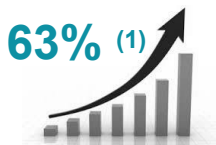
Alcoholic Liver
Disease (ALD)



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

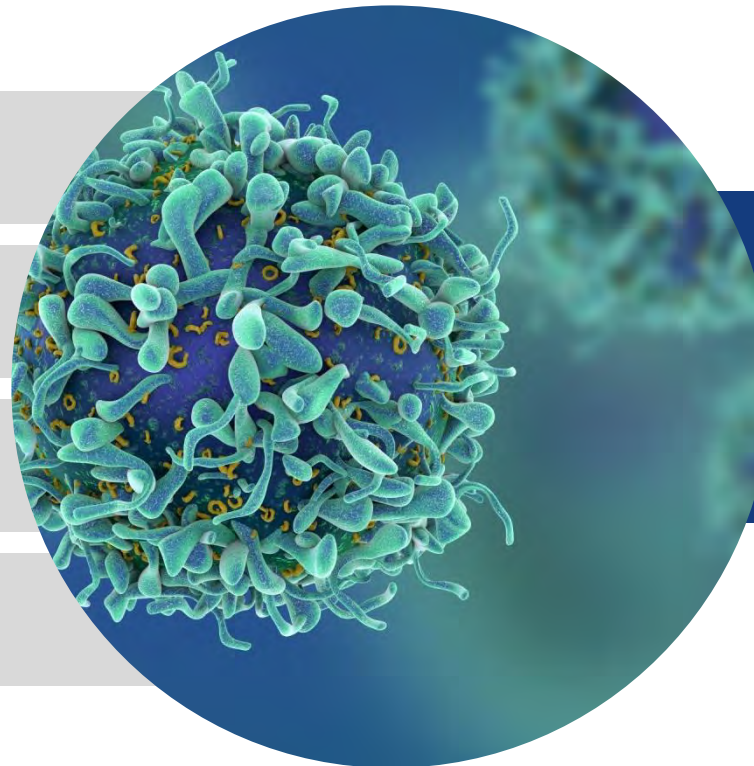
A severe complication of late-stage cancers

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**

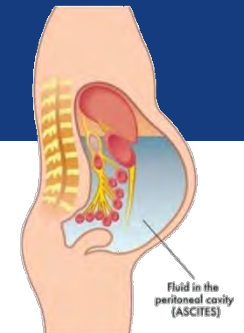
Reduces ability to undergo **anti-cancer treatment**



Malignant ascites due to breast and ovarian cancer²:

EU5: ~18K

US: ~16K



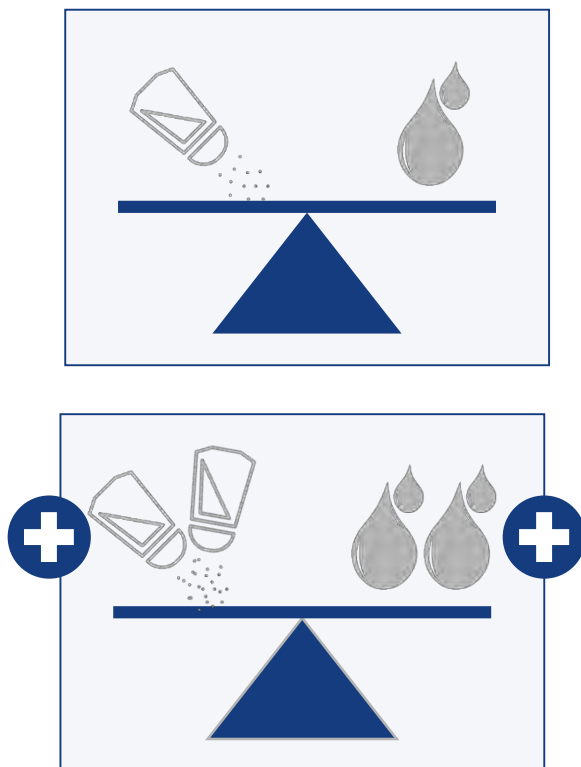
Clear unmet need for improving Quality of Life and the ability to increase cancer treatment intensity

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.

Heart failure and volume overload

A key clinical consequence of heart failure (HF)

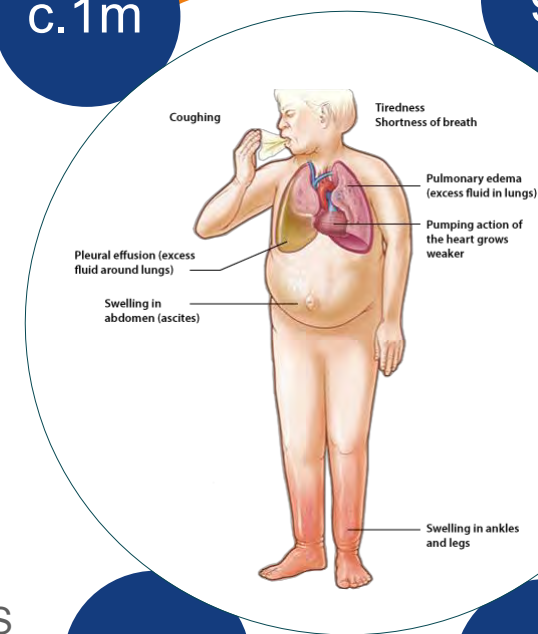


US hospitalisations annually due to HF²

c.1m

90%

HF – hospitalisations due to volume overload²



24%

Re-admission rate at 30 days³

Annual costs of US HF-related hospitalisations⁴

\$13bn

c.5 days

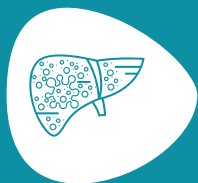
Typical hospital stay⁴

Source 1: Global Public Health Burden of Heart Failure, Lars H. Lund
 Source 2: Costanzo et al., J. Am. Coll., 2007
 Source 3: Ross et al. (2010)
 Source 4: Kilgore et al. (2017)

Clear unmet need to reduce hospitalisations, improve Quality of Life and reduce mortality

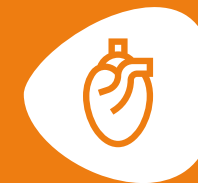
Three platforms for growth

Balancing risk and reward



North American Liver & Cancer

- ~**151K** refractory ascites patients due to alcoholic liver disease and NASH within next 10-20y¹
- ~**16K** Malignant ascites patients/y²



North America & Europe Heart Failure

- ~**1m** hospitalisations/y due to volume overload in US by 2026³
- ~**1.2m** hospitalisations/y due to volume overload in EU5 by 2026³



Europe Liver & Cancer

- ~**89K** refractory ascites patients due to alcoholic liver disease and NASH within next 10-20y¹
- ~**18K** malignant ascites patients/y²

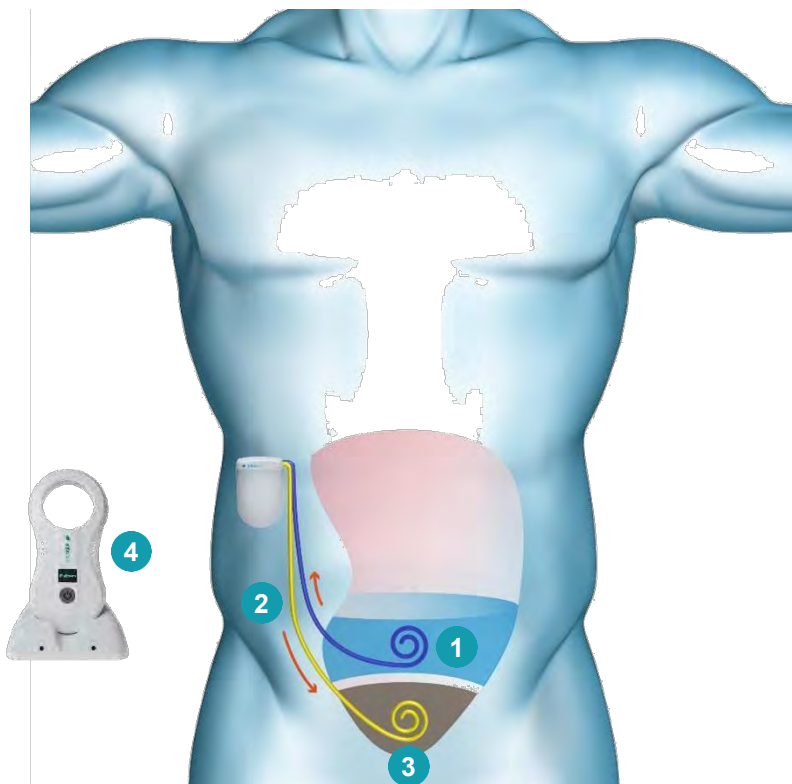


change.

alfapump[®] – proven step change
in the management of liver
refractory ascites and malignant
ascites

alfapump®

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



alfapump®



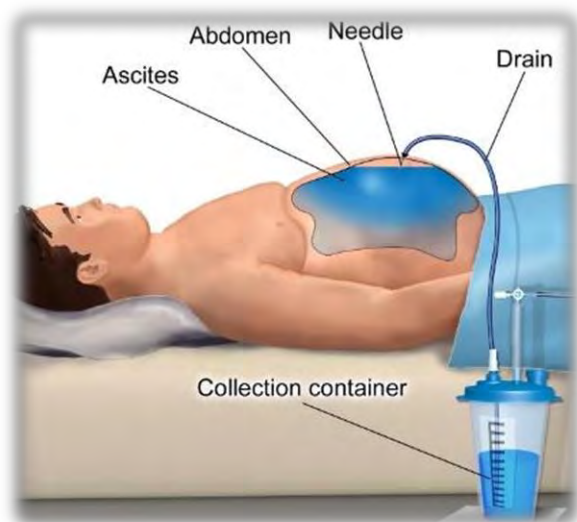
Smart Charger



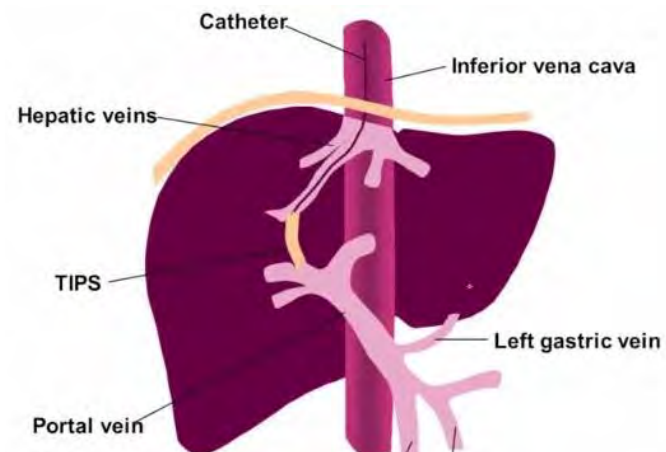
Programmer

Severe limitations of existing therapies

Large Volume Paracentesis (“drainage”)



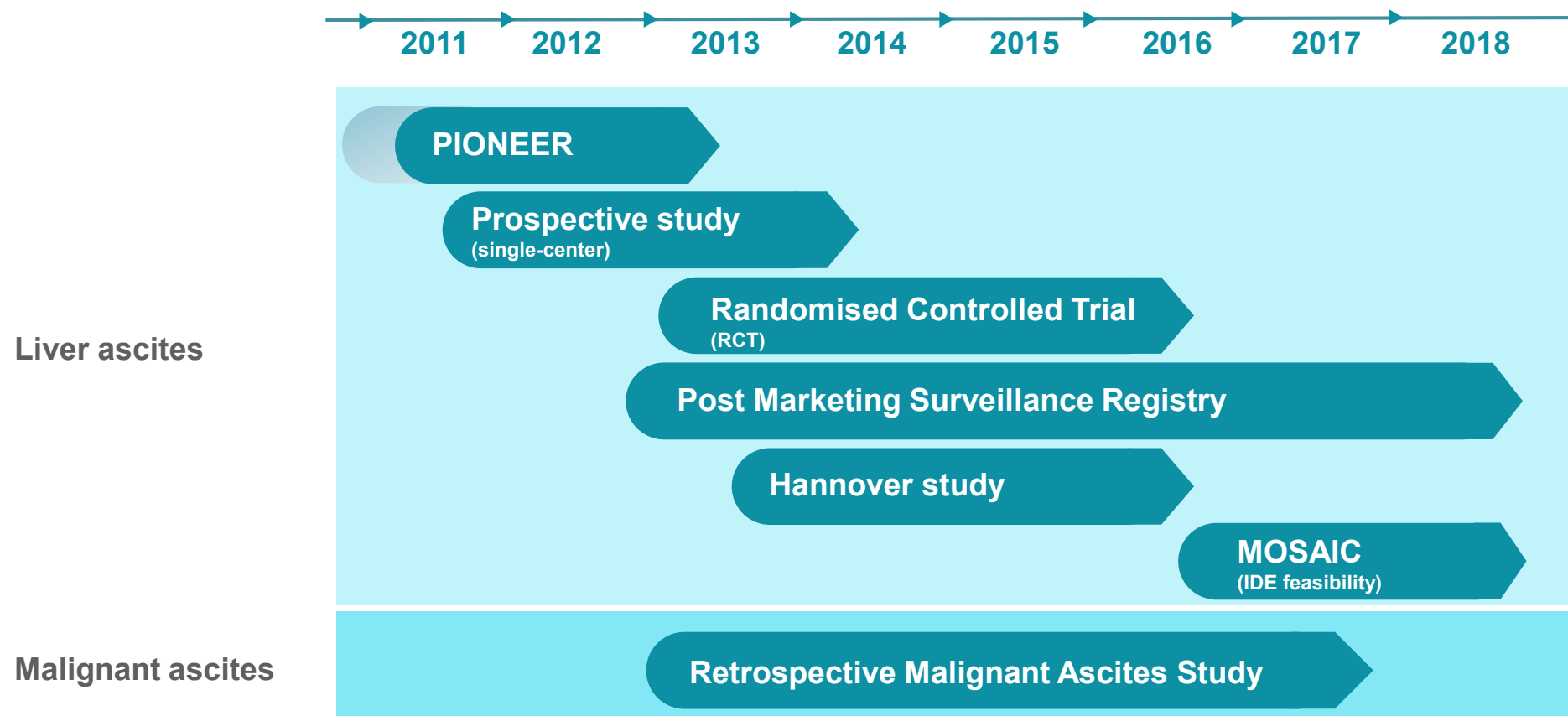
Transjugular Intrahepatic Portosystemic Shunt (TIPS)



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.

Independent third party endorsement

As well as over 700 implants and 400 years of patient experience

- Inclusion in EASL guidelines



- FDA Breakthrough Device designation

- NICE recommendation – from “Research Use Only” to “Special Arrangements”

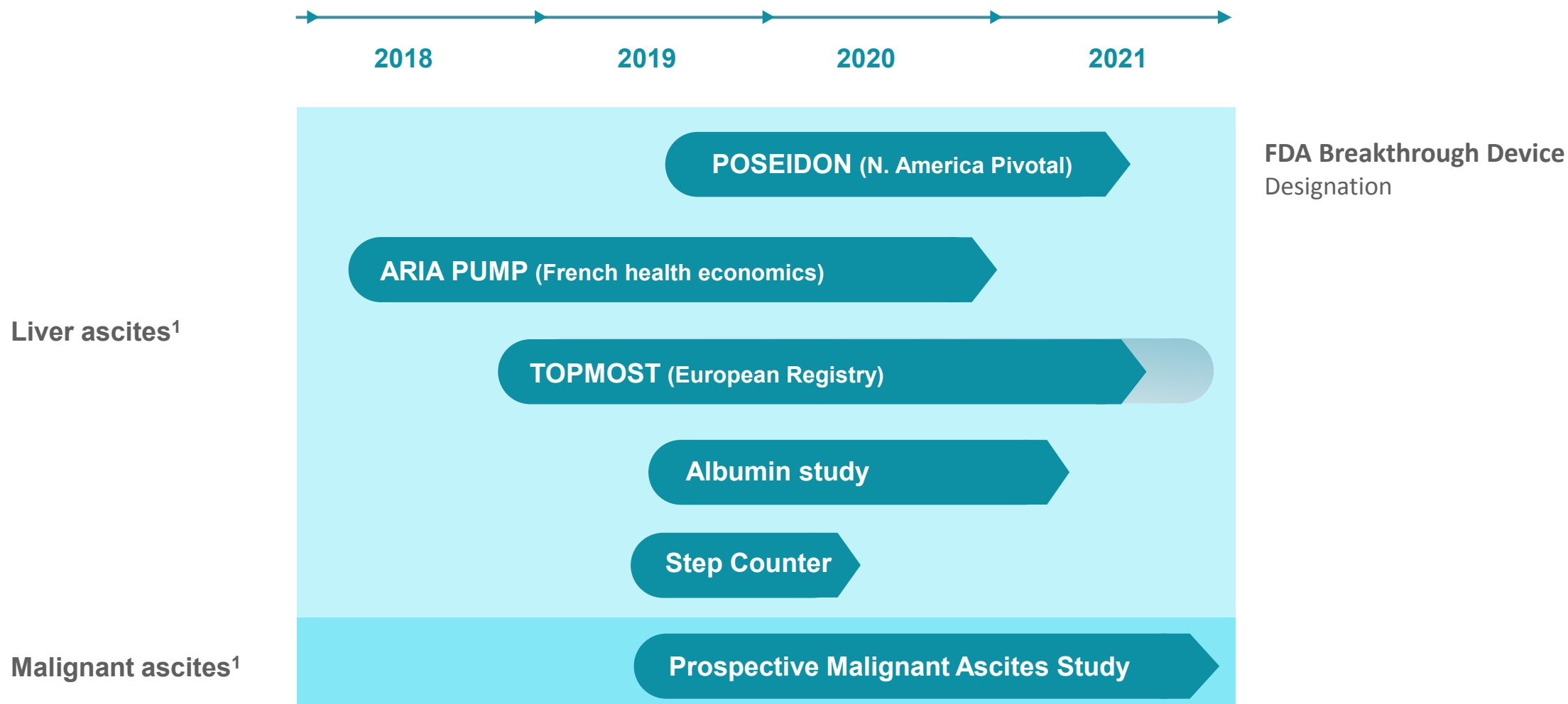


- Inclusion in DGVS Guidelines



Building further clinical evidence

For North American approval and broader international acceptance



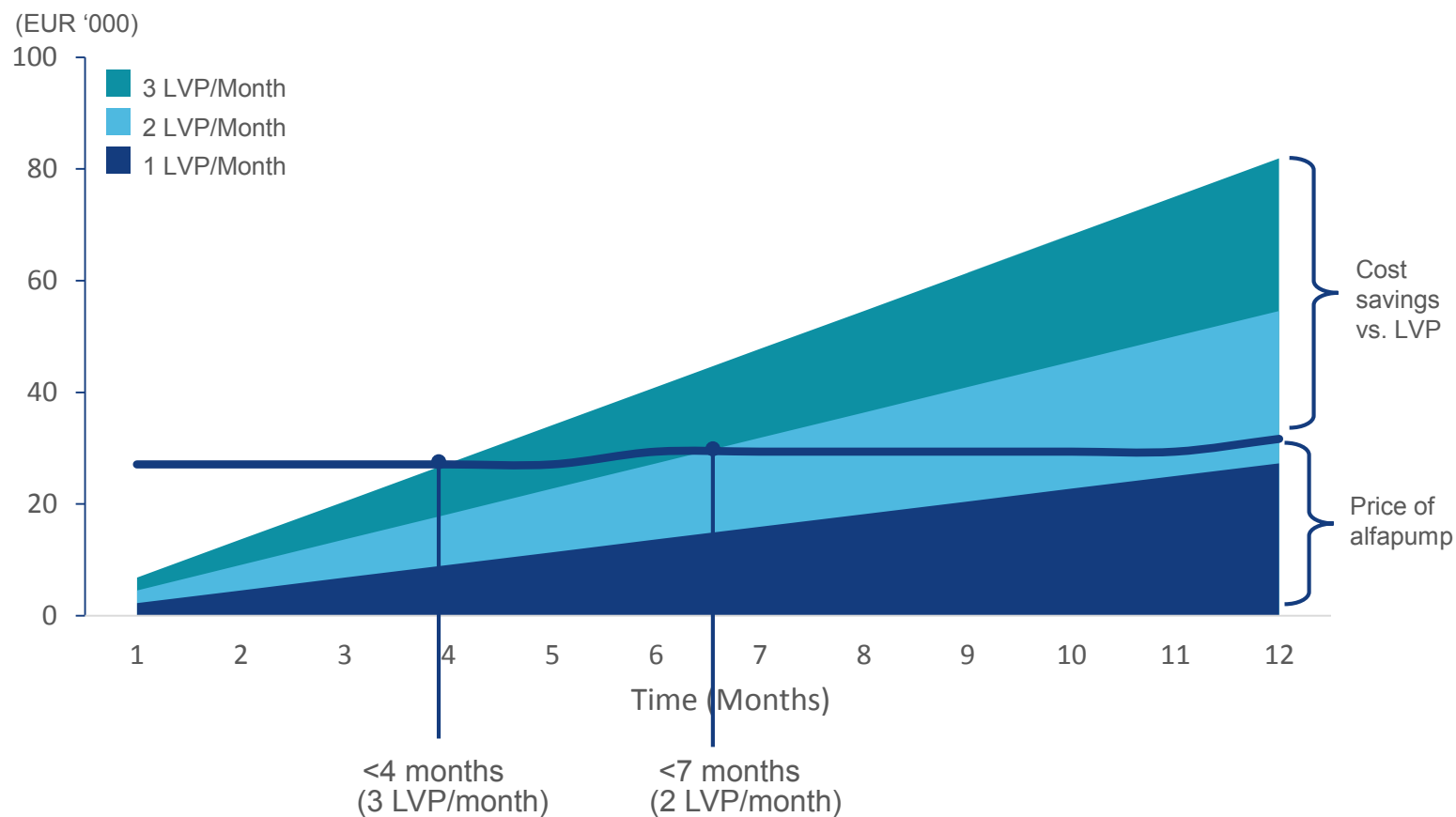
Note 1: study design subject to change

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

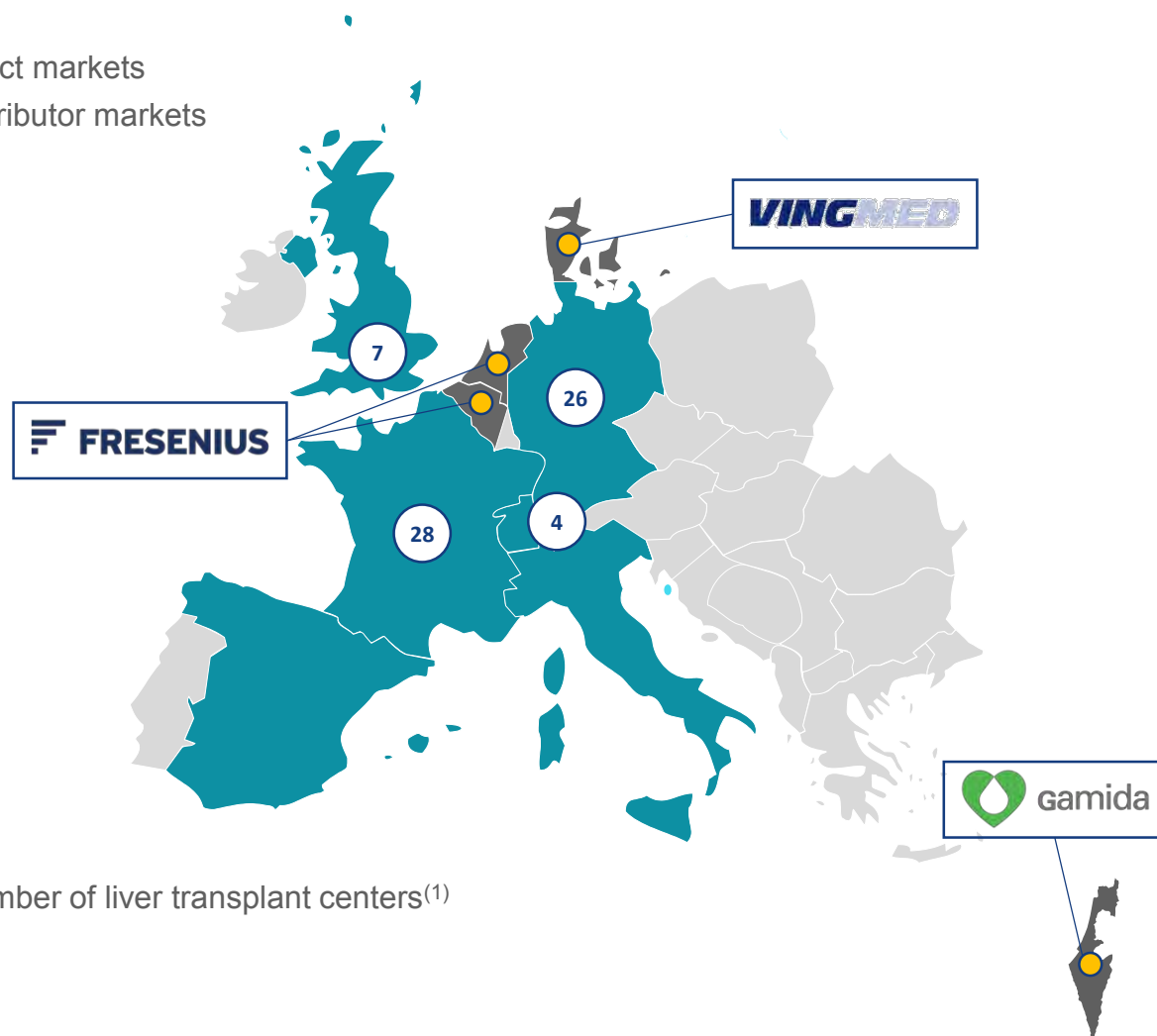
Elimination of need for drainage (LVP) leads to substantial cost reduction for hospitals and payers



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

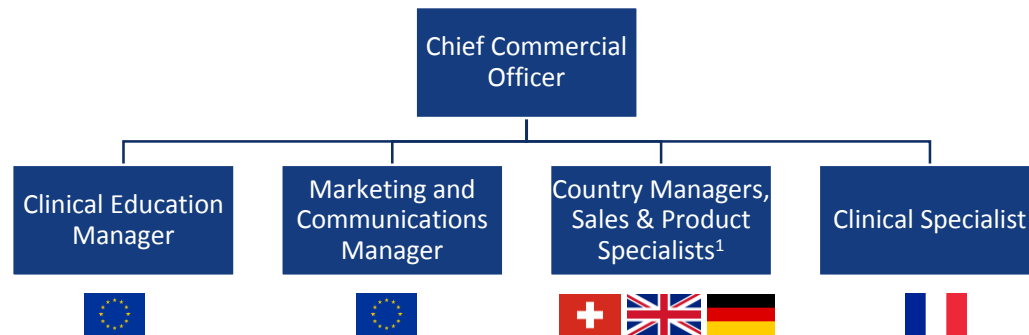
Raise awareness at community hospital level

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

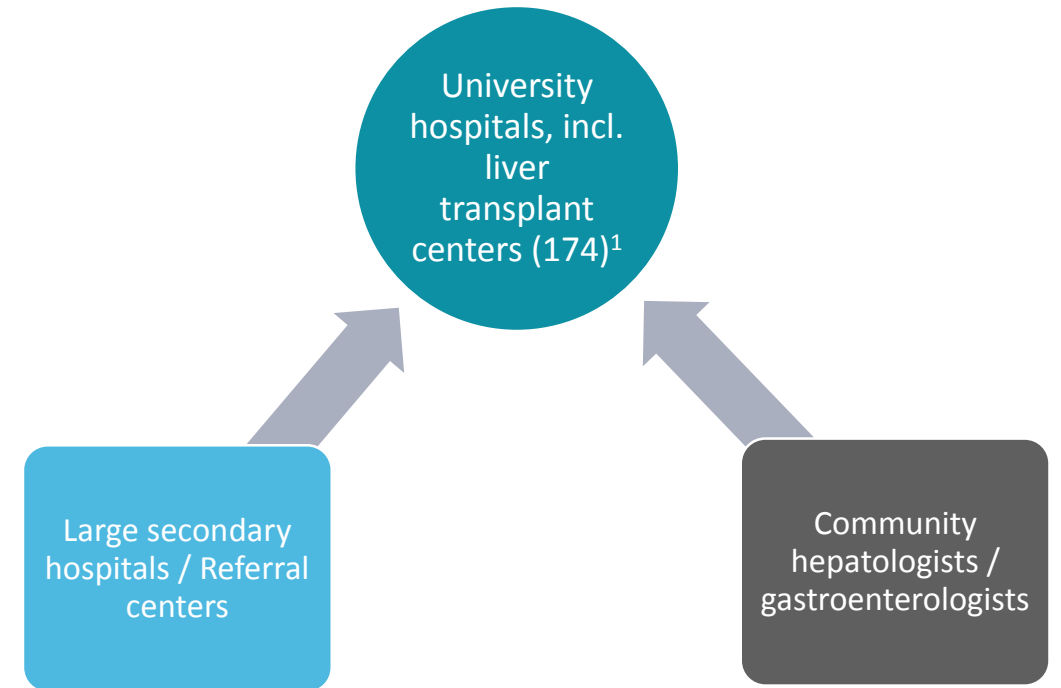
Source 1: European Liver Transplant Registry (ELTR)
 Note 2: NUB: “Neue Untersuchungs- und Behandlungsmethode” = temporary add-on payment to DRG for new diagnostic and treatment methods

Commercial roll-out in Europe

Direct access to core markets through local teams with strong local market knowledge



Focus on limited number of specialist centers and raise awareness of referral network



Source 1: European Liver Transplant Registry (ELTR)

Creating awareness

Among patients and the medical community

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.14931

WILEY | **APPT** Alimentary Pharmacology & Therapeutics

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

G. Stimimann¹ | 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



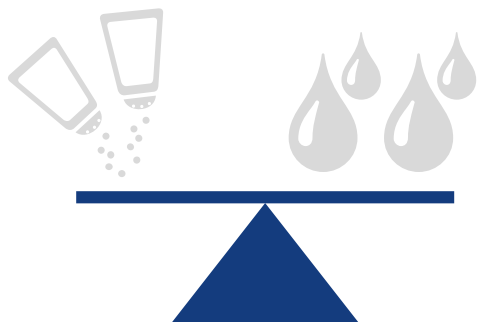


breakthrough.

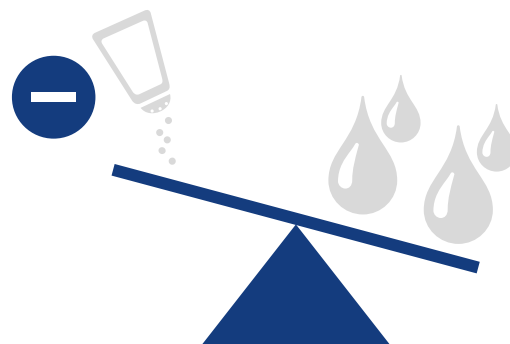
alfapump[®] DSR – breakthrough approach to **volume overload in heart failure** built on proven device platform

Direct sodium removal (DSR)

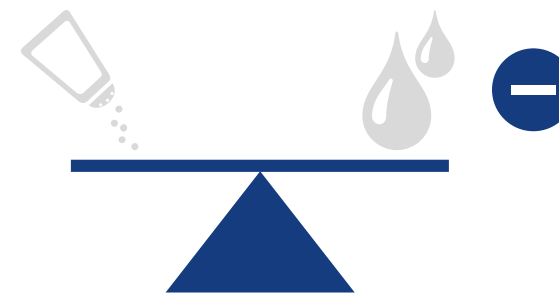
Tackling Sodium Removal Directly



Volume overload
in heart failure



Removing the
sodium (DSR)



Elimination of
excess fluid

DSR

How to remove the sodium

**Administer
infusate to
peritoneal
cavity**

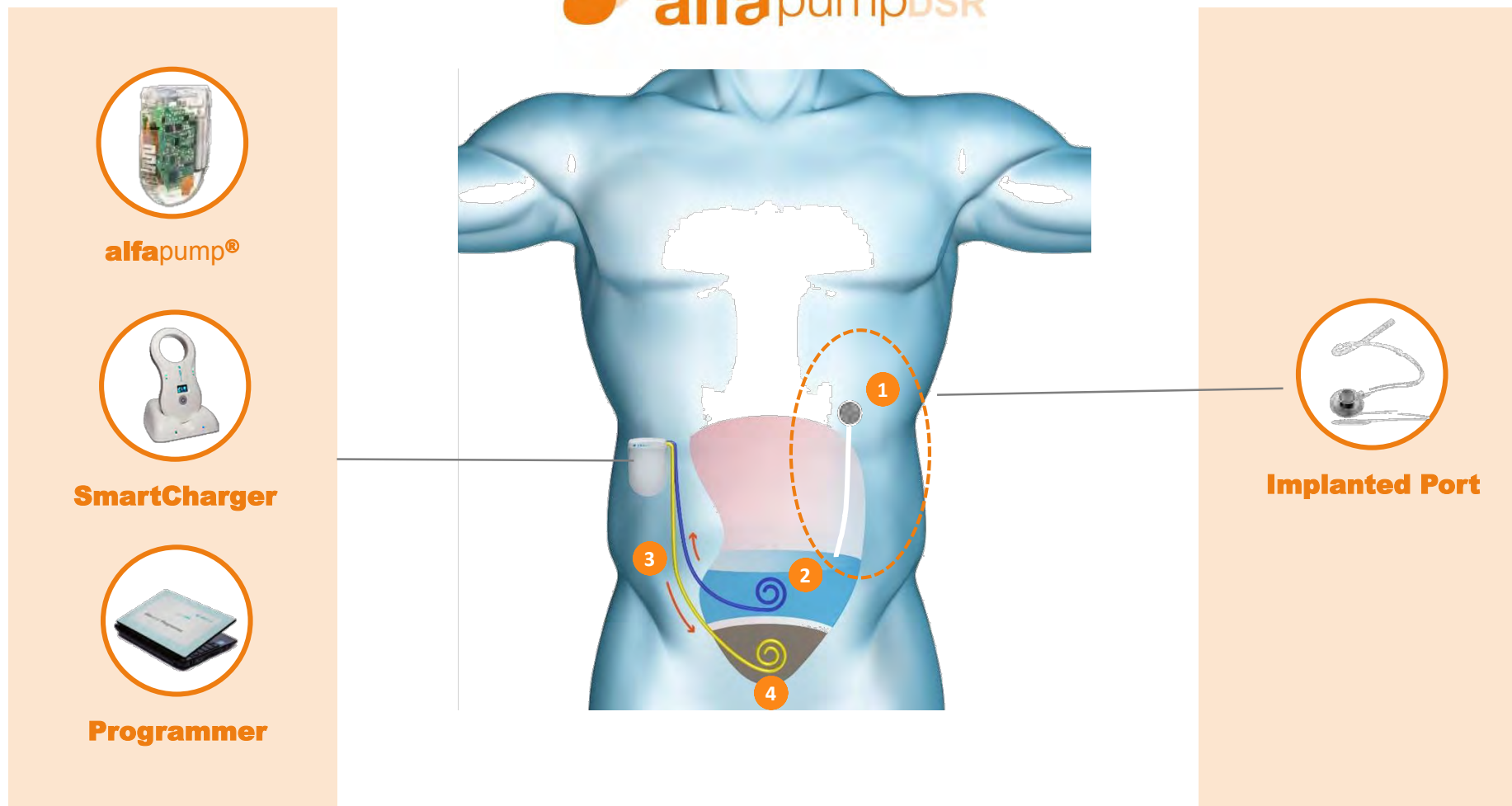
**Infusate
extracts
sodium from
the body**

**Remove
extracted
sodium from
peritoneal
cavity**

**Body restores
balance by
eliminating
excess fluid**

alfapump[®] DSR

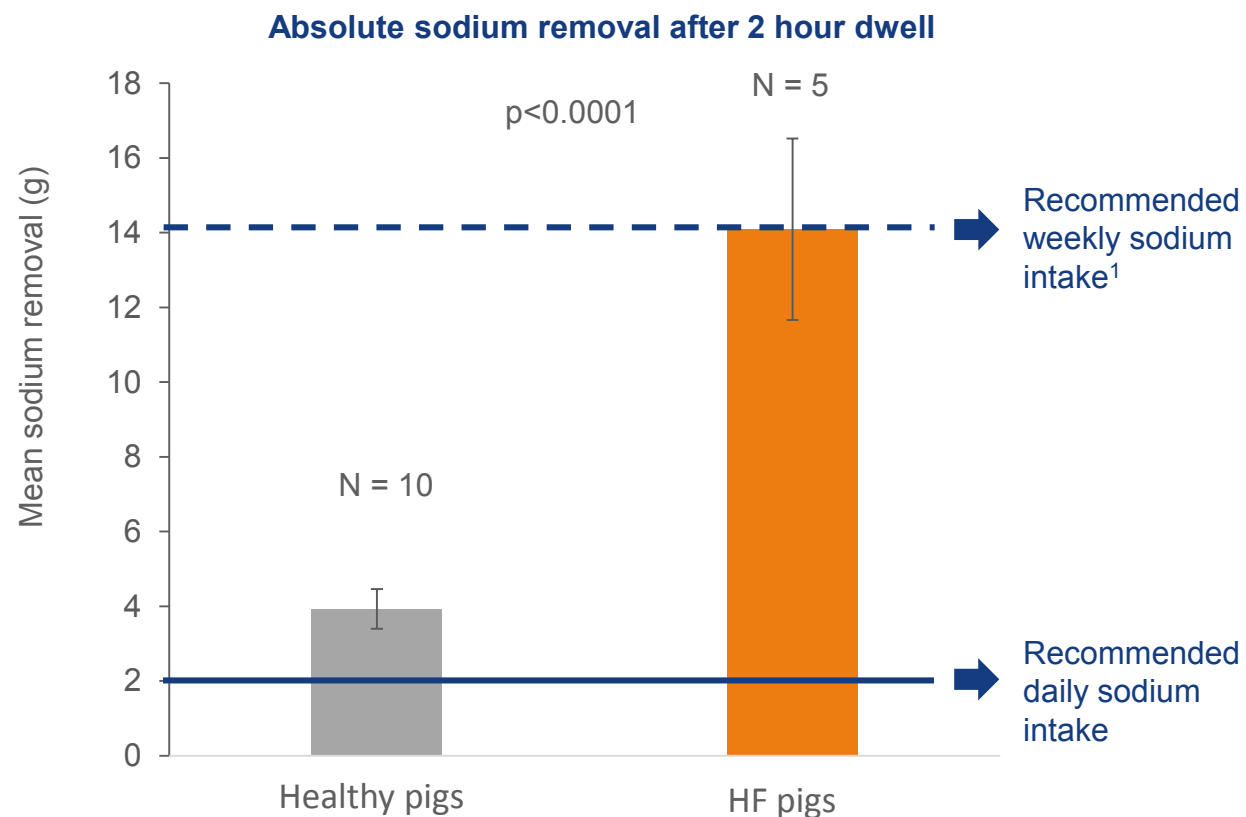
Fully implanted and convenient system leveraging on the alfapump[®] experience



DSR: pre-clinical Proof-of-Concept delivered

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

Yale



*Clinically
relevant
removal of
sodium*

DSR: First-in-Human Proof-of-Concept study selected for late-breaking presentation at Heart Failure 2019

Yale

- Conducted by Dr. Testani at Yale University
- Up to 20 human subjects, peritoneal dialysis (“PD”) patients with peritoneal catheter
- Cross-over design: D10 DSR infusate vs. standard PD solution
- 1 litre infusate administration with 2 hour dwell

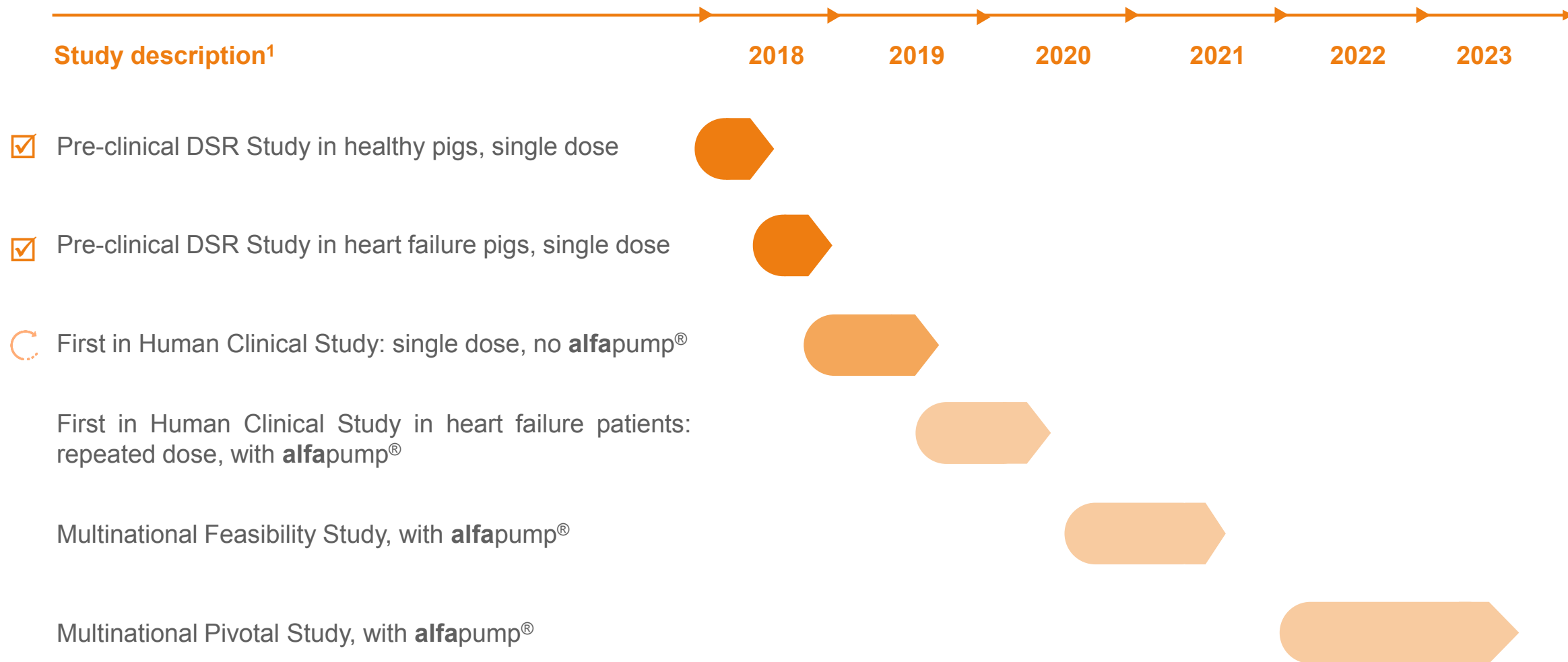
Key Objectives

- Safety & tolerability
- “Sodium removal” – efficacy & inter-patient variability (“Does it work and is it repeatable?”)

Results will be presented by Dr. Testani during late-breaking abstract session at Heart Failure 2019 on 27 May 2019

alfapump[®] DSR

Development overview

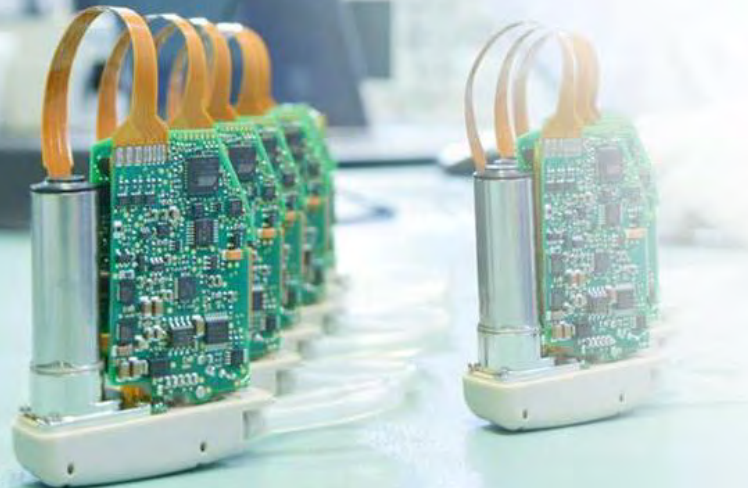


Note 1: study design subject to change



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 Hannon¹
Director

Note 1: subject to approval of his appointment at the AGM on 23 May 2019

alfapump[®] platform

Unique capabilities to manage fluid imbalance



Pump volume easily adjusted



Fully implantable



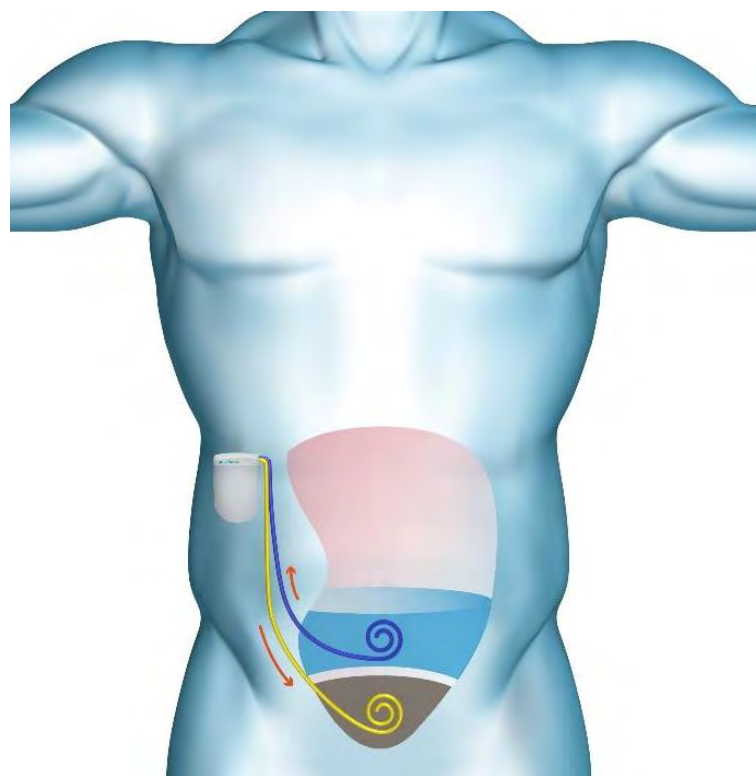
No significant heating during charging and operation



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

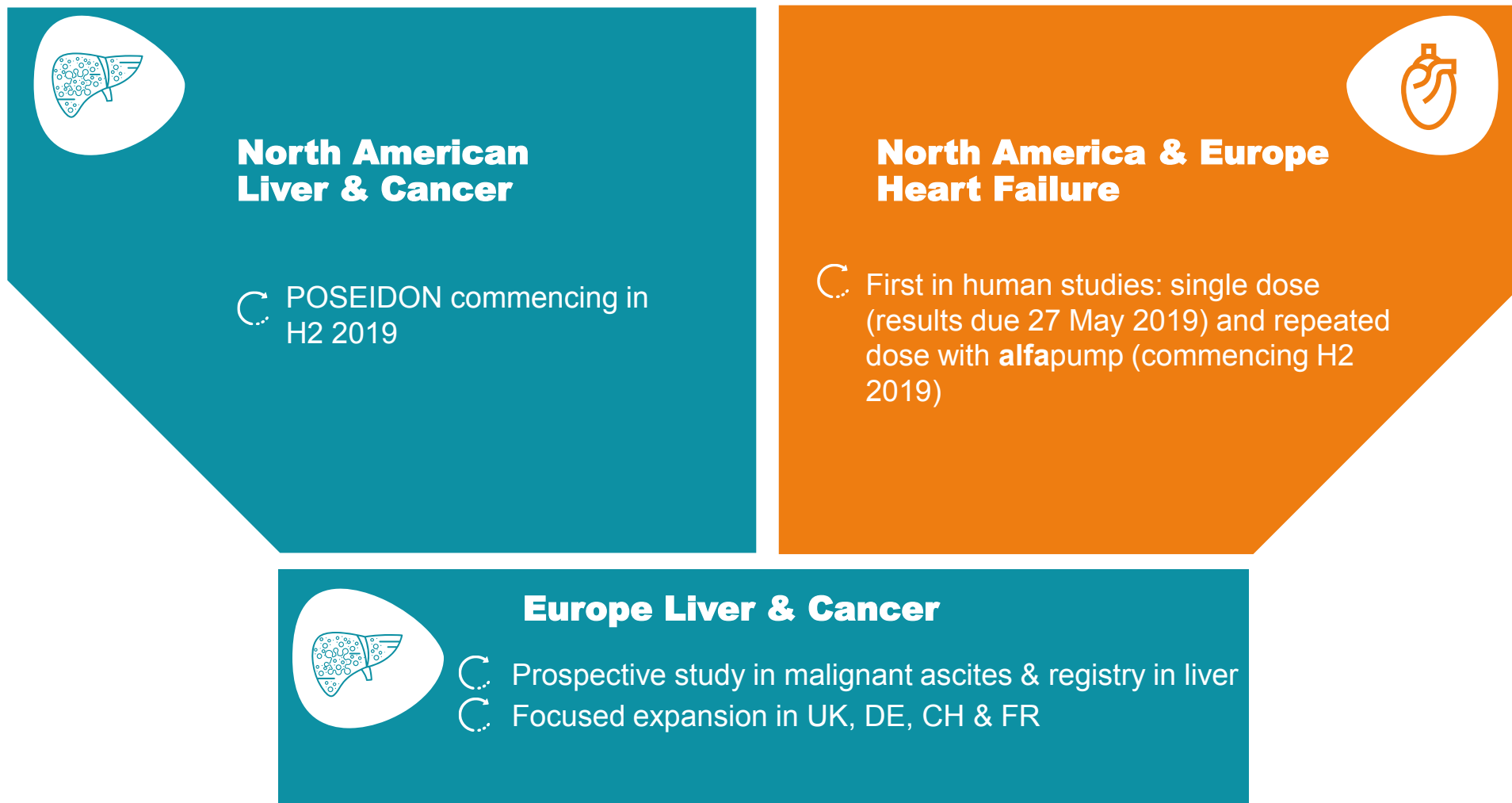


Virtually non-clogging

Strong IP barriers through extensive patent portfolio & know-how

Three platforms for growth

Balancing risk and reward



Upcoming news flow

Key catalysts and development 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 initial results for First in Man heart failure study, 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**[®]
- Completion and presentation of initial results for First in Man 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 Man 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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