



sequanamedical



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

Kempen Life Sciences Conference

Amsterdam – 16 April 2019

Ian Crosbie, CEO

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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 the management of liver disease and cancer; over 700 devices implanted



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



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)



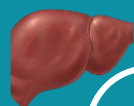
Non-Alcoholic
Steatohepatitis
(NASH)



High mortality rate

Extreme discomfort

Healthy
liver



330m

NAFLD



1/3¹

NASH



1/4 -
1/3¹

Cirrhosis



10%²

Ascites



50%³

Refractory
Ascites



7.5%⁴

Source 1. Management estimate based on Estes et al. 2018 1/4

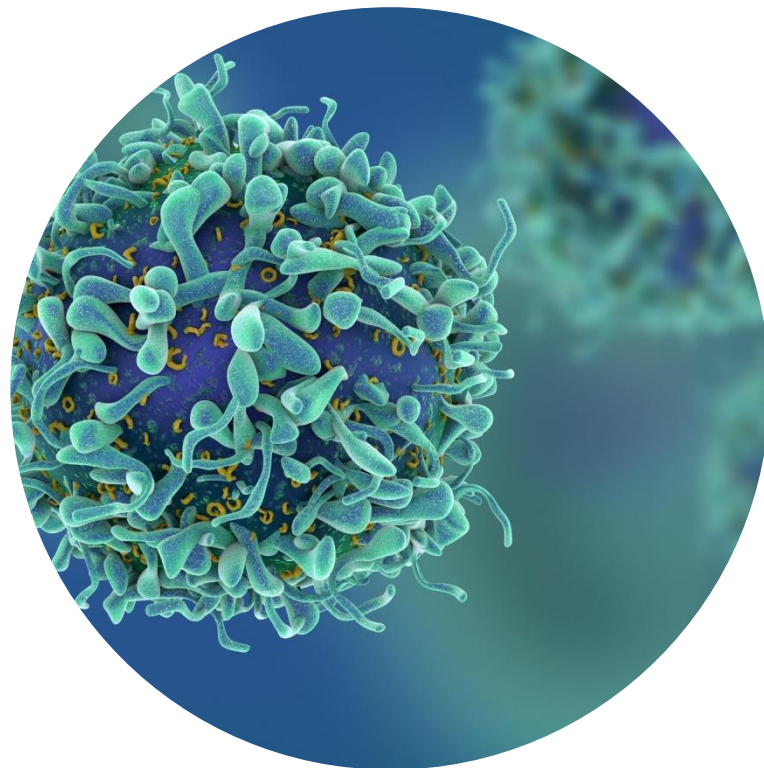
Source 2. Management estimate based on GlobalData Nash Epidemiology Forecast to 2026; Nouredin et al., 2013

Source 3: Runyon 2009.

Source 4: Dancygier, 2010; Stimimann et al., Aliment Pharmacol Ther. 2017; Ginès et al., NEJM 2004.

Cancer and malignant ascites

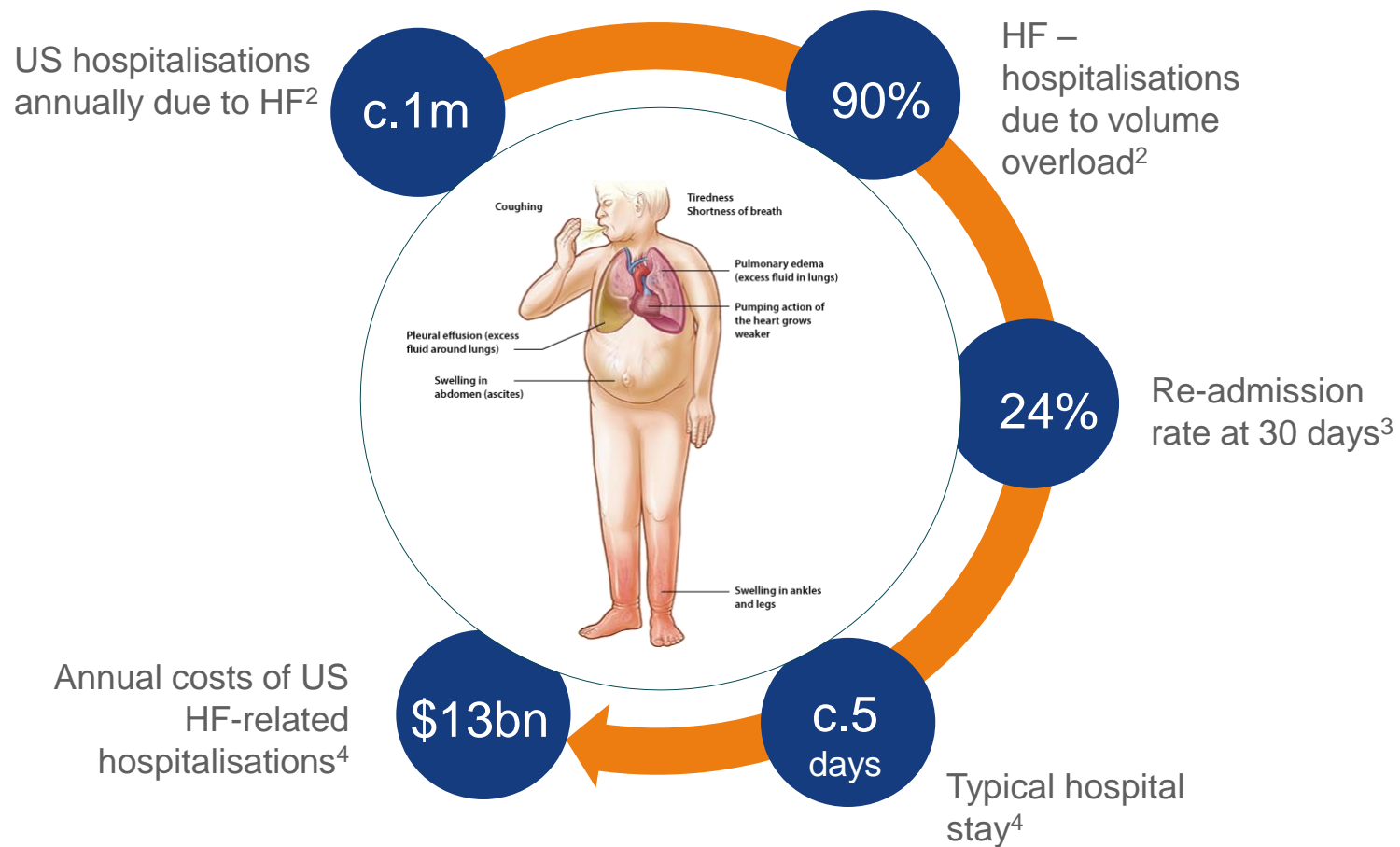
A severe complication of late-stage cancers – focus on breast and ovarian cancers



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

Heart failure and volume overload

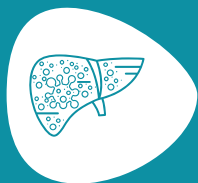
A key clinical consequence of heart failure (HF)



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)

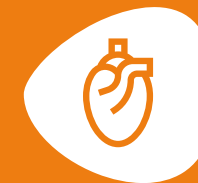
Three platforms for growth

Balancing risk and reward



North American Liver & Cancer

- ~**151K** refractory ascites patients 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

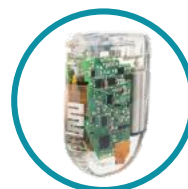
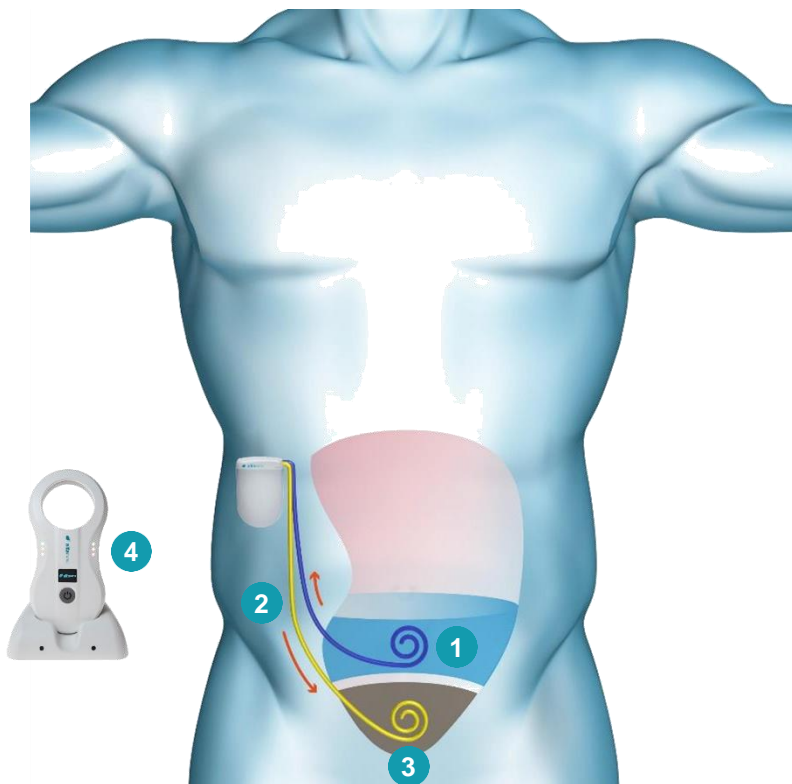


Europe Liver & Cancer

- ~**89K** refractory ascites patients within next 10-20y¹
- ~**18K** malignant ascites patients/y²

alfapump®

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



alfapump®



Smart Charger



Programmer

Validated clinical performance

Over 700 implants, included in EASL clinical practice guidelines for decompensated liver cirrhosis and granted Breakthrough Device designation by the FDA



**Drastically
reduced need
for drainage**



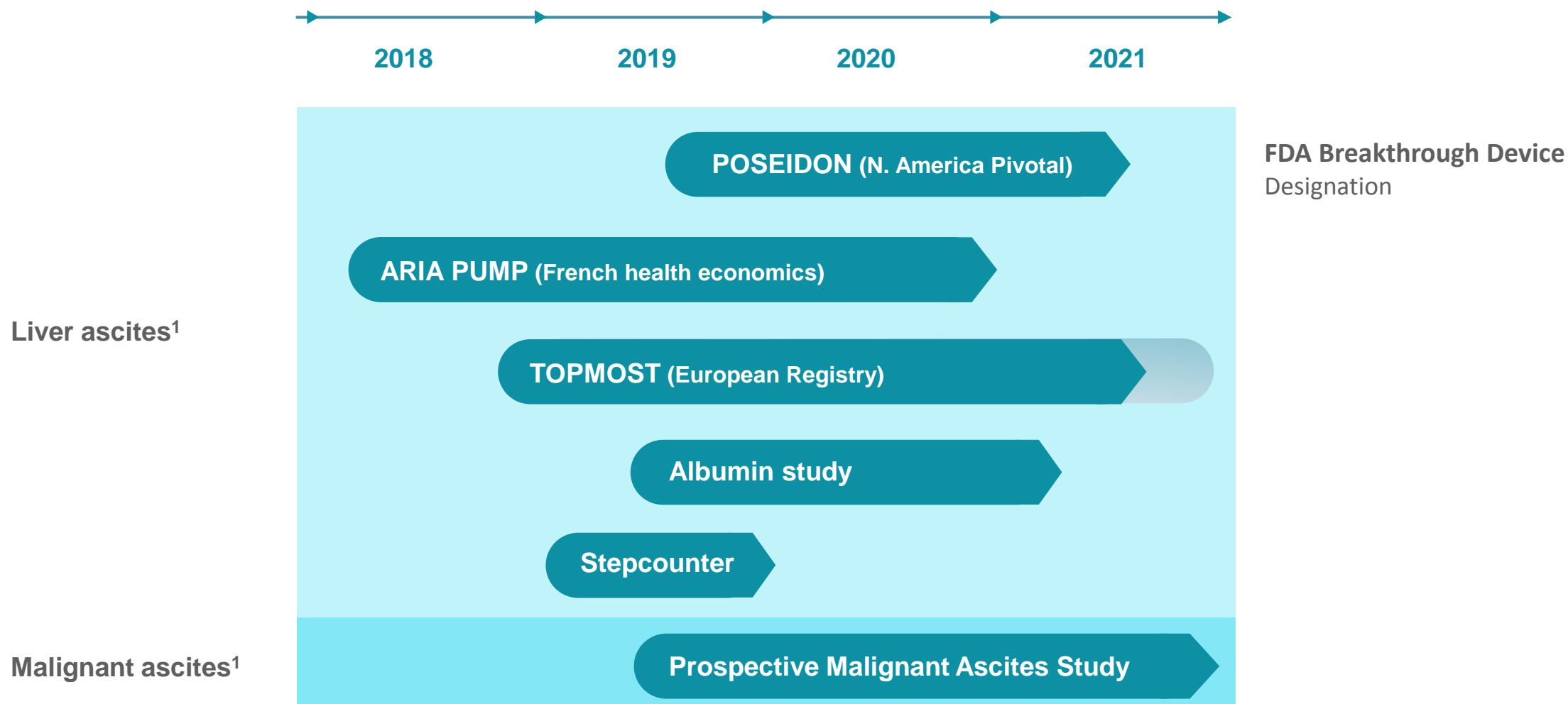
**Improved
nutrition**



**Improved
patient quality
of life**

Building further clinical evidence

For North American approval and broader international acceptance

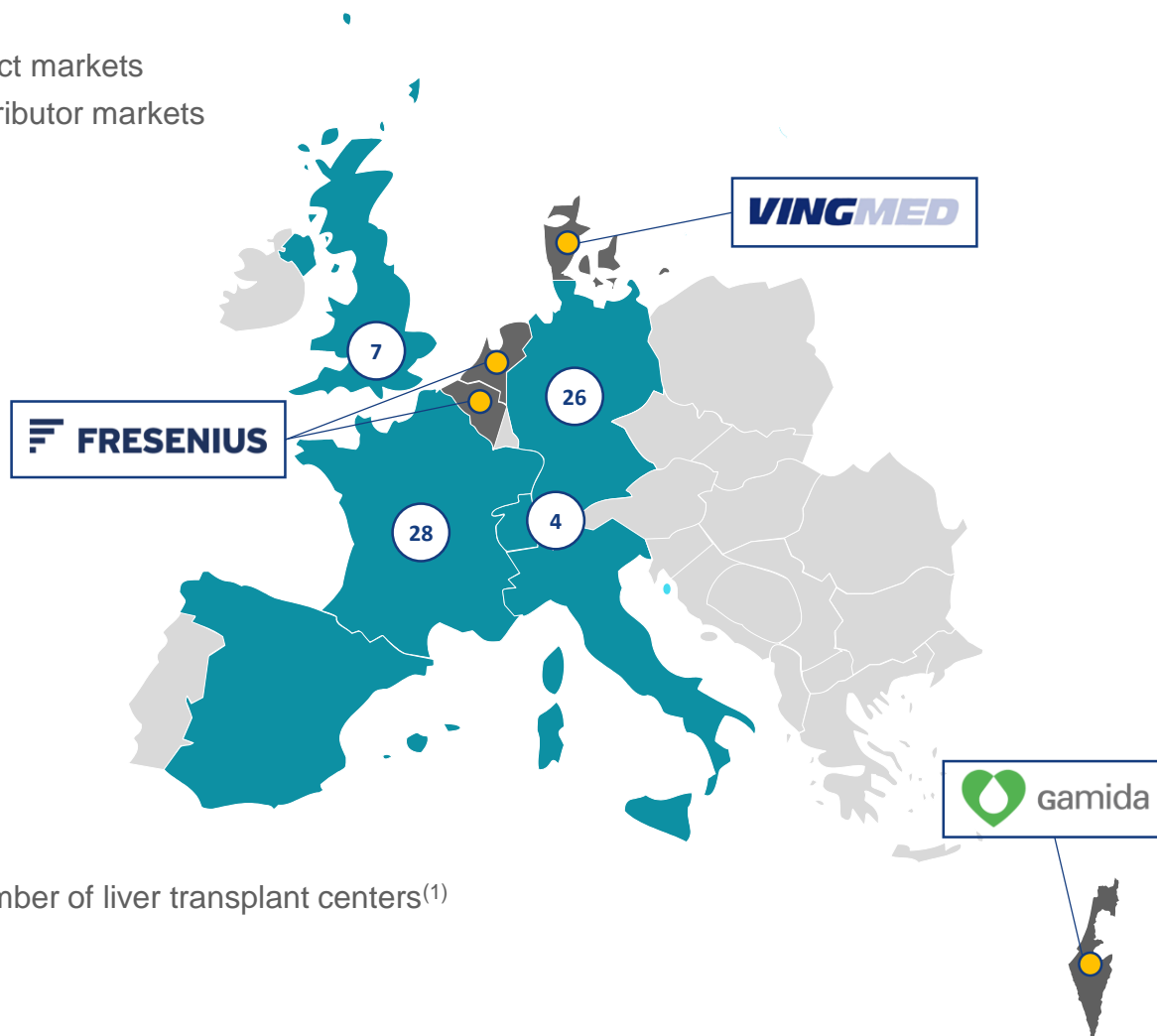


Note 1: study design subject to change

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

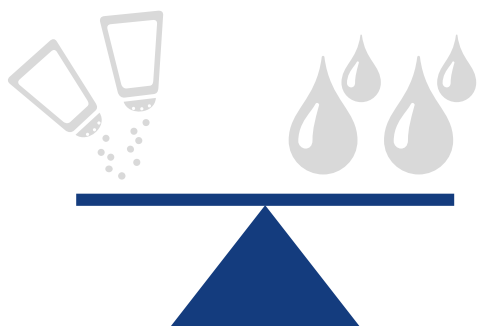
Raise awareness at community hospital level

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

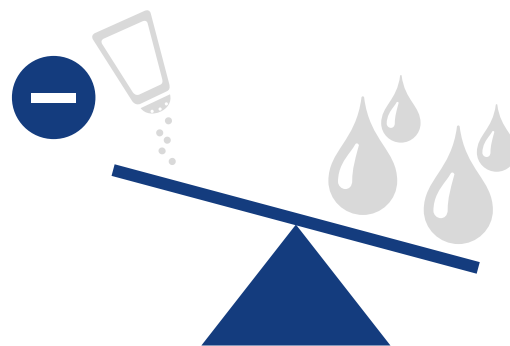
Source 1: European Liver Transplant Registry (ELTR)
 Note 2: NUB: “Neue Untersuchungs- und Behandlungsmethode” = temporary add-on payment to DRG for new diagnostic and treatment methods

Direct sodium removal (DSR)

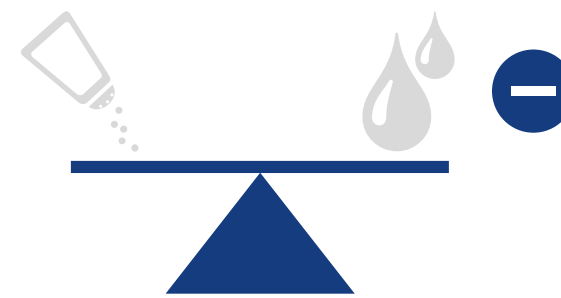
Breakthrough therapy in heart failure, tackling Sodium Removal Directly



Volume overload
in heart failure



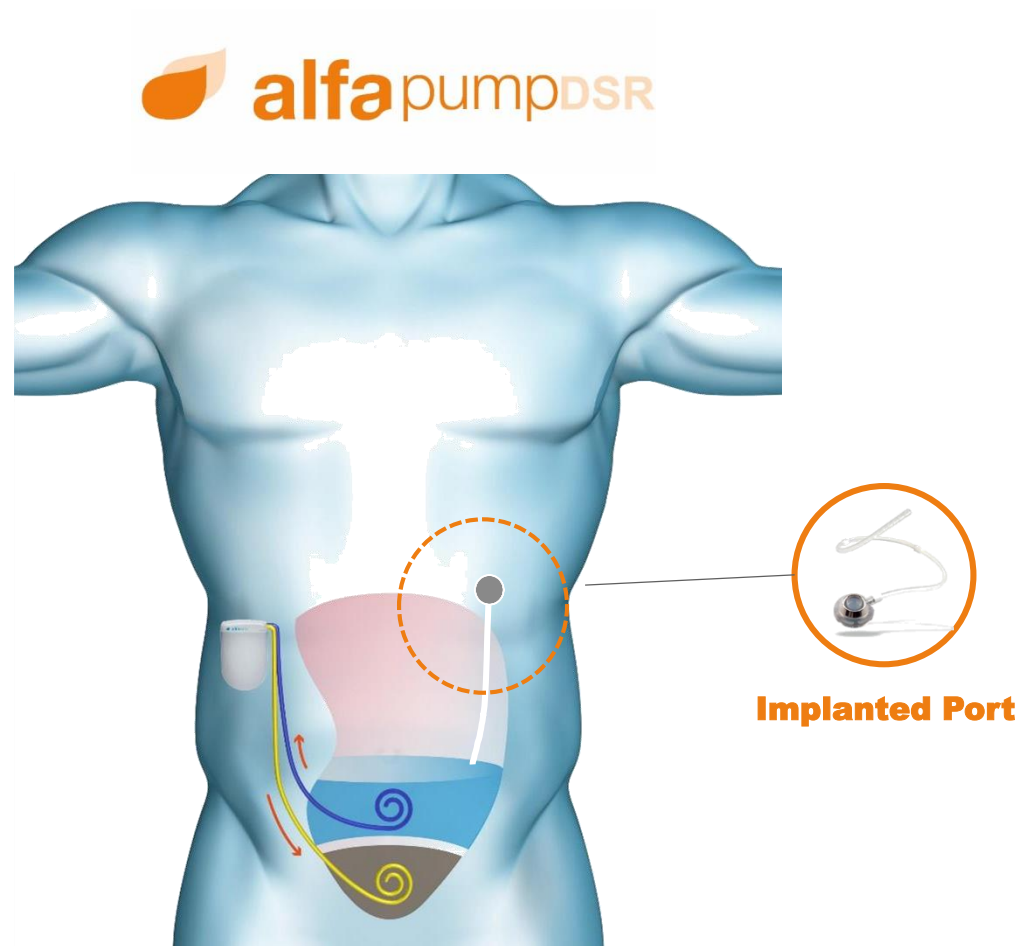
Removing the
sodium (DSR)



Elimination of
excess fluid

alfapump DSR

Fully implanted and convenient system leveraging on the alfapump experience



Administer infusate to the peritoneal cavity



Infusate extracts sodium from the body



Remove extracted sodium from peritoneal cavity

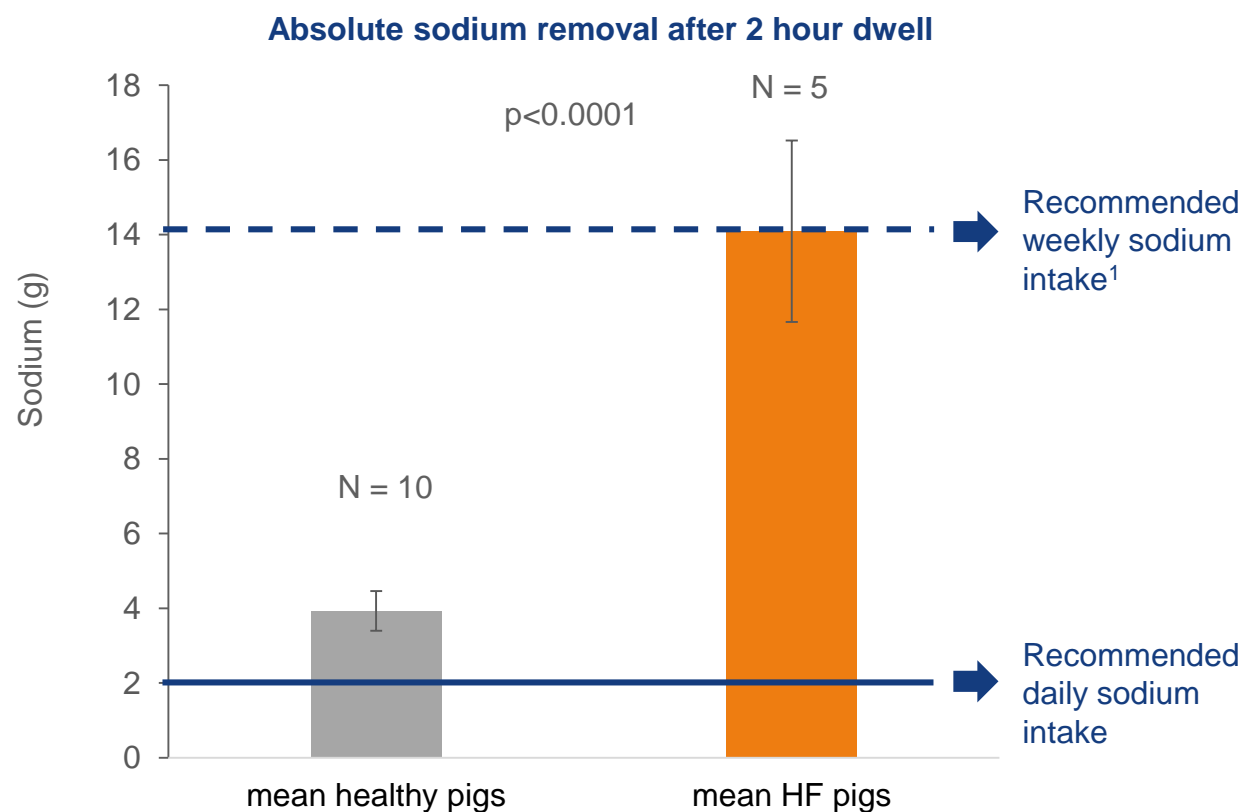


Body restores balance by eliminating excess fluid

DSR – clinically relevant removal of sodium

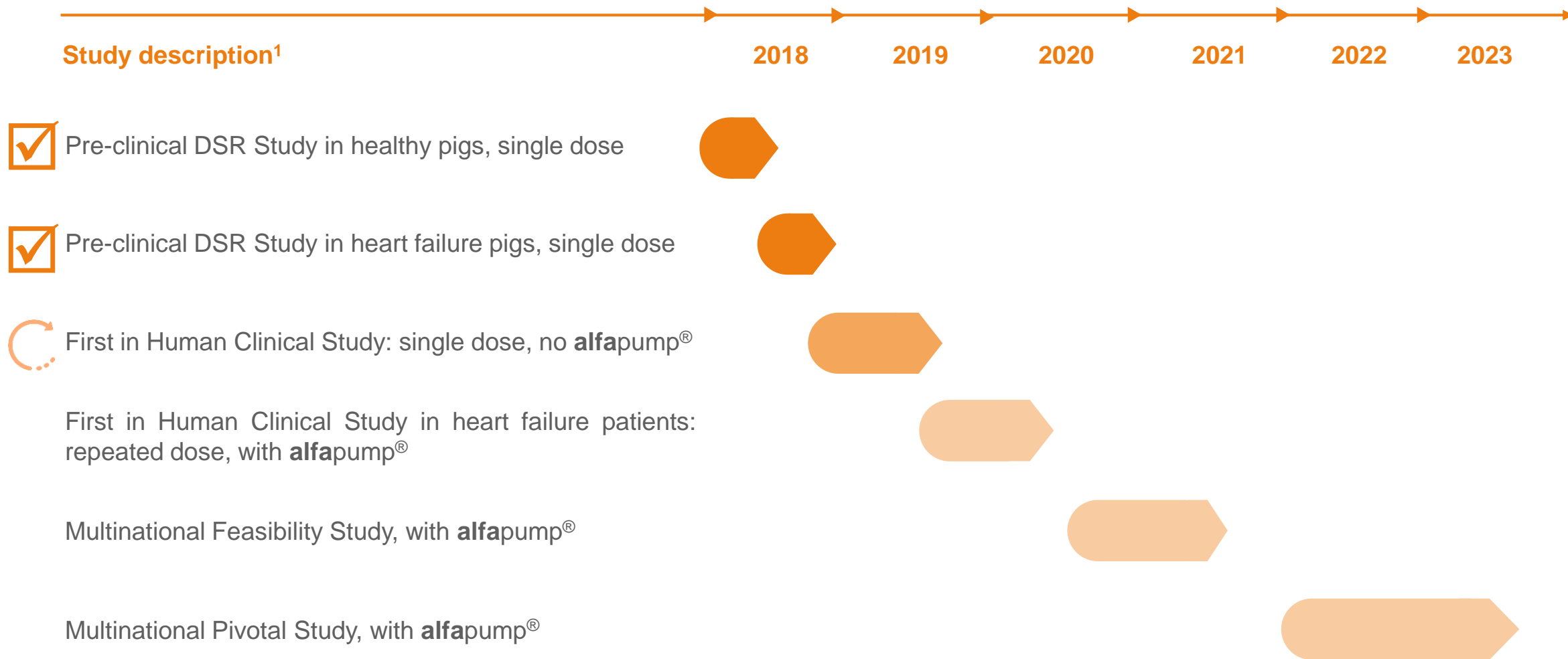
DSR proof of concept study in healthy pigs and pigs with simulated heart failure (HF)

Yale



alfapump[®] DSR

Development overview



Note 1: study design subject to change

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
- **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**[®]
- **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