sequanamedical

Innovators in the management of fluid overload

liver disease – malignant ascites – heart failure

Kepler Cheuvreux Belgian Life Science Day

22 June 2020

Ian Crosbie, CEO

Disclaimers

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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 and **alfa**pump DSR are 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, **alfa**pump DSR and ongoing investigations with the **alfa**pump system in Europe, the US and Canada.

COVID-19 notice

Sequana Medical is closely following the evolution of the COVID-19 global health crisis and is in **constant dialogue with its partners** to assess the impact and adapt its operations as necessary.

Although it is difficult to draw conclusions at this point on the systemic risk this disease could pose, the Company has put in place **mitigation plans to minimise delays**.

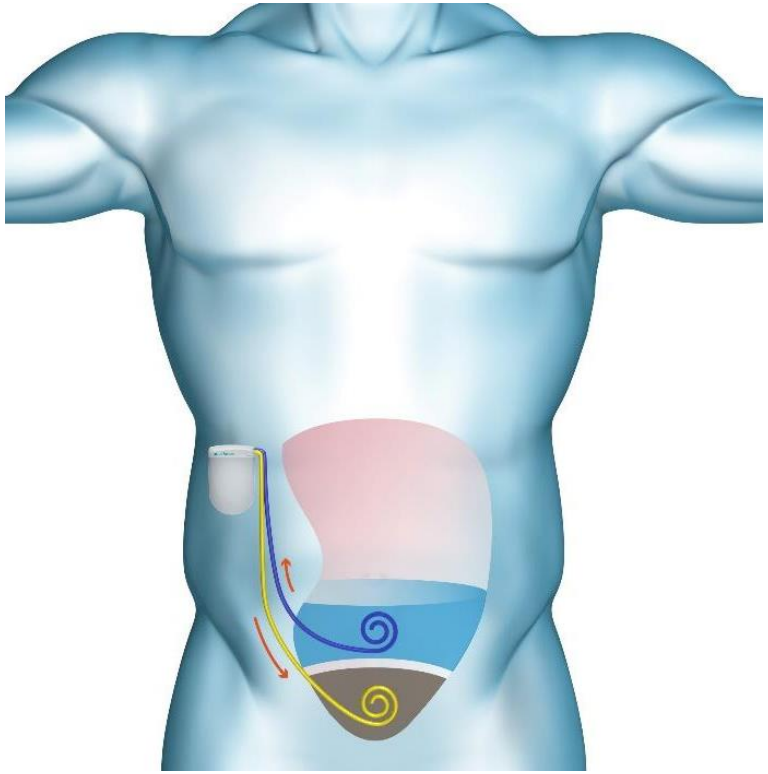
The impact of increased demands on the healthcare systems, restrictions on non-essential hospital visits and procedures, social-distancing and travel restrictions are expected to **result in delays to execution of clinical studies and impact sales**.

Sequana Medical will **update its guidance** on the expected impact and any material change in the Company's **operations and outlook when the situation is clarified**.

alfapump® 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

alfapump®

Liver Disease (NASH)

Proven step change in liver refractory ascites and malignant ascites

Over 750 devices implanted

~145 K

patients / year with refractory ascites due to NASH within next 10-20y(1)

> €3 Bn / year
market opportunity

alfapump® DSR

Heart Failure

Breakthrough approach to fluid overload in heart failure

Clinical proof-of-concept of Direct Sodium Removal (DSR)

~400 K

patients / year hospitalised for volume overload due to heart failure by 2026(2)

> €5 Bn / year
market opportunity

Built upon proven European clinical & commercial experience

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)

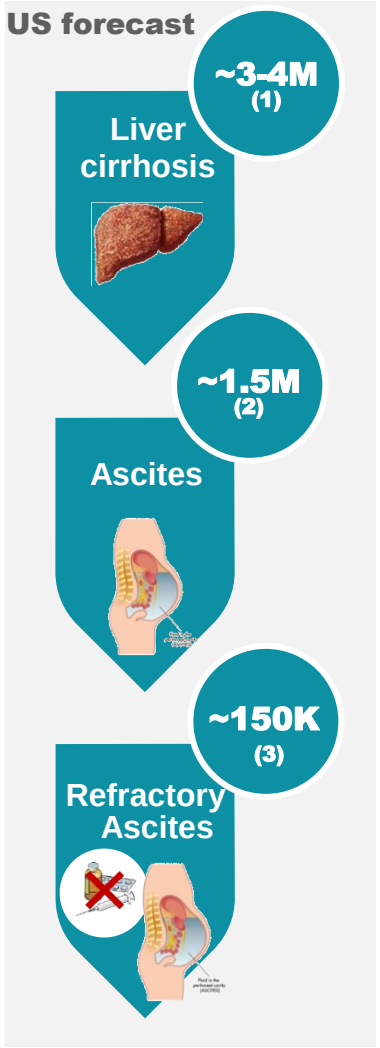
NASH drives US market attractiveness

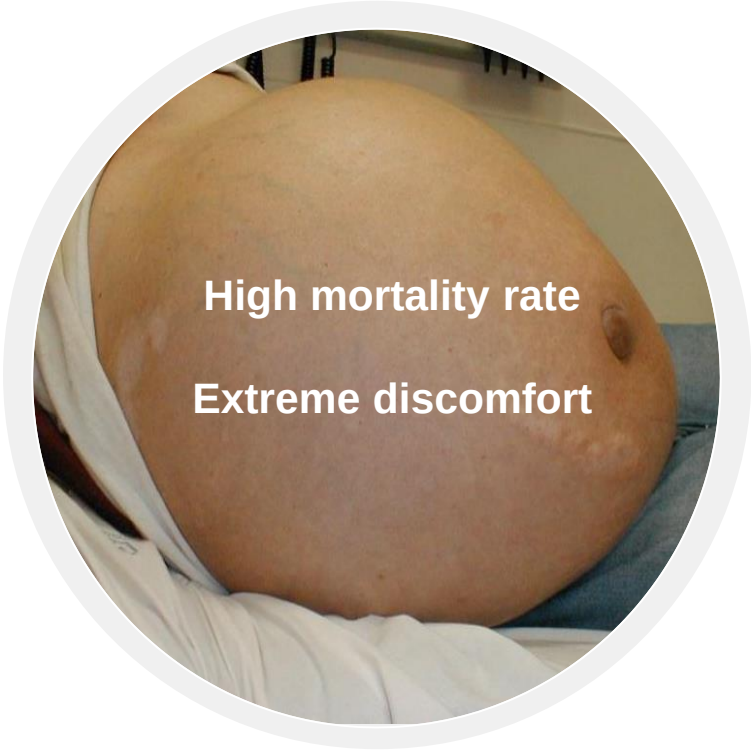
Stronger competitive position in a much larger and dynamic market

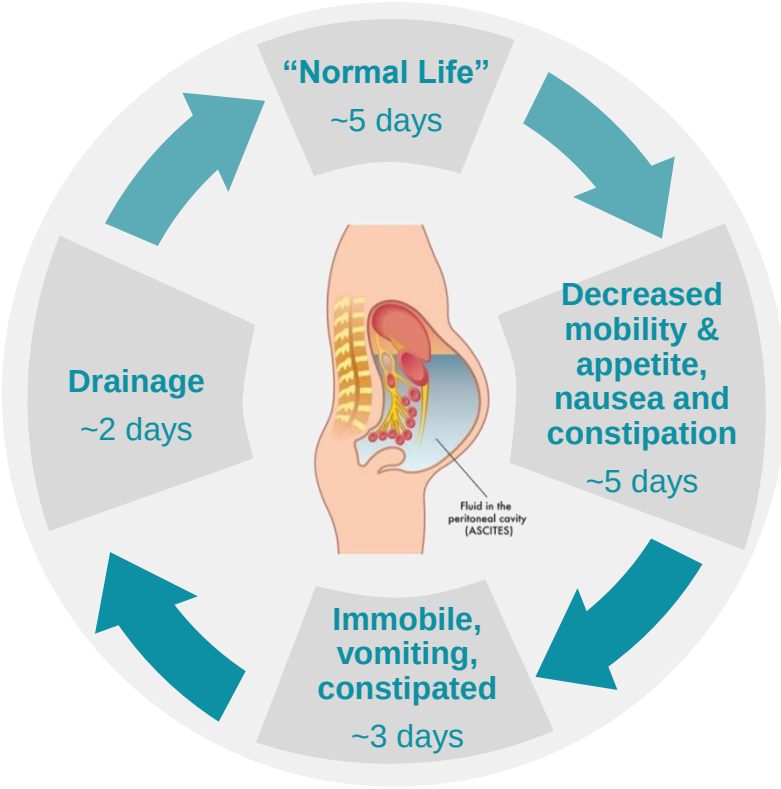
alfapump® market potential	~€0.4 Bn / year	>€3 Bn / year
Underlying disease	Alcoholic Liver Disease, Hepatitis	**NASH**
Patient characteristic	“Outside mainstream”	**“Mainstream”**
Average age	40-50 yr	**70 yr+**
alfapump competitive positioning	✓	✓✓

Notes: current estimated 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.
forecast 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.

Refractory ascites – a key complication of liver cirrhosis with a dramatic impact on quality of life







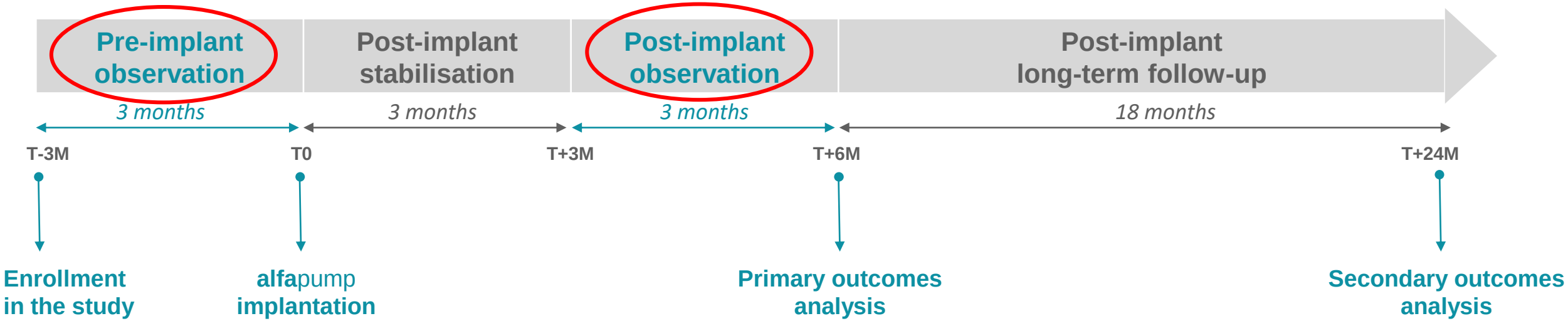
Typical patient life(4)

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

North American Pivotal Study (POSEIDON) underway

- Up to **50 patients** with recurrent or refractory ascites due to liver cirrhosis implanted with the **alfa**pump(1)
- Primary endpoint at **9 months after enrollment**:

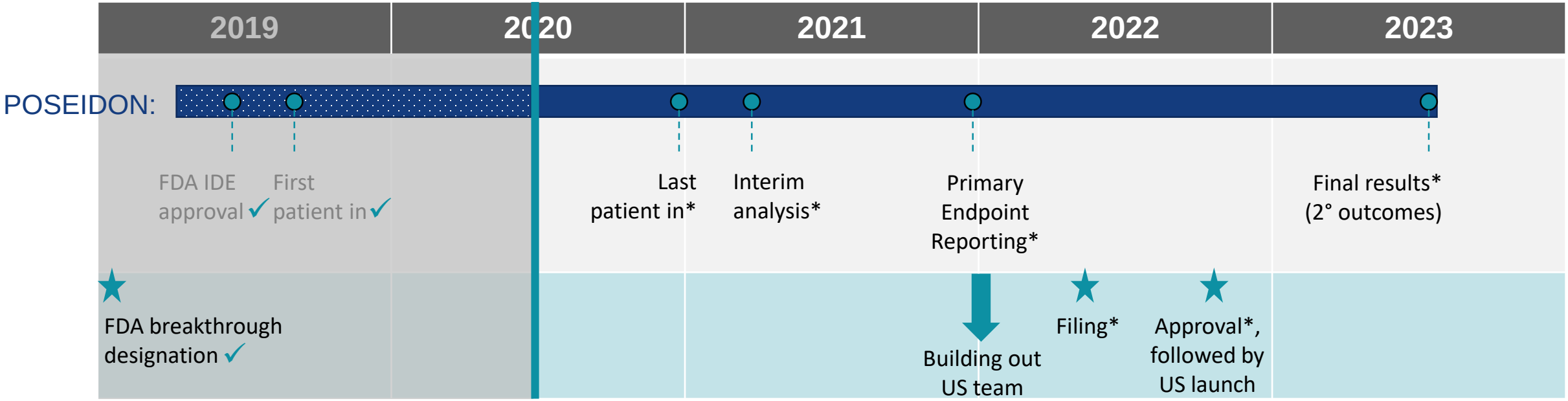
  ⇨ proportion of patients with a 50% reduction in average number of paracentesis per month post-implant vs pre-implant



Note 1: in Study Cohort

alfapump® US approval roadmap

Key anticipated milestones*

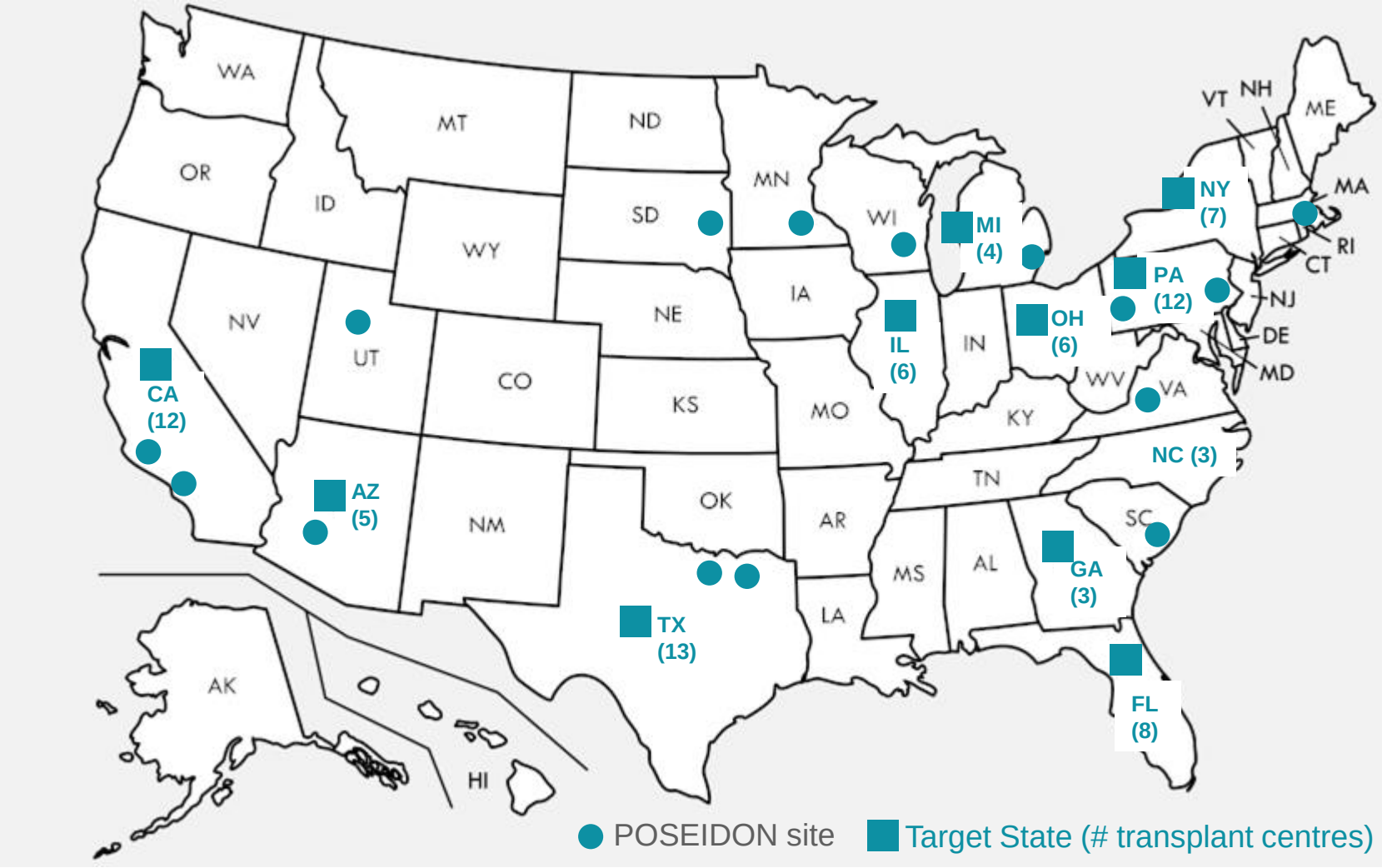


*Final CMS rule on reimbursement for breakthrough devices (NTAP) expected to further support reimbursement for the **alfa**pump*

* *Timings presented are based on an estimated delay of 6 months due to the COVID-19 pandemic. Updated guidance will be provided when the situation is clarified.*

FDA: Food and Drug Administration (US); IDE: Investigational Device Exemption; NTAP: New Technology Add-on Payment

Self-commercialisation in US through specialty salesforce

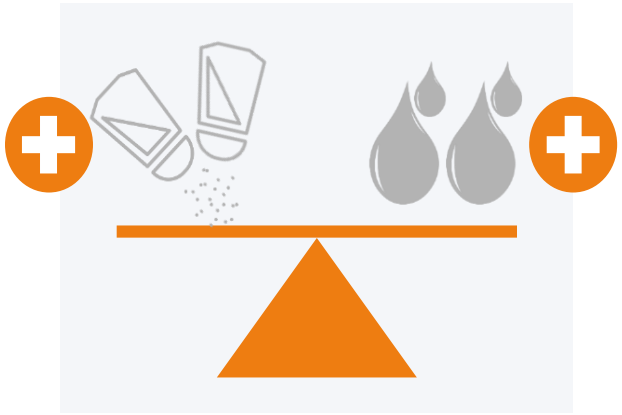


Initial focus on key transplant centres

~50 person team:

35 sales reps, 10 clinical, 5 corporate

Volume overload in heart failure – major clinical problem and key driver of costs



Excess sodium drives fluid overload

US hospitalisations annually due to HF[3]

~1m

90%

HF – hospitalisations due to volume overload[3]

c.5d

Typical hospital stay[4]

$13bn

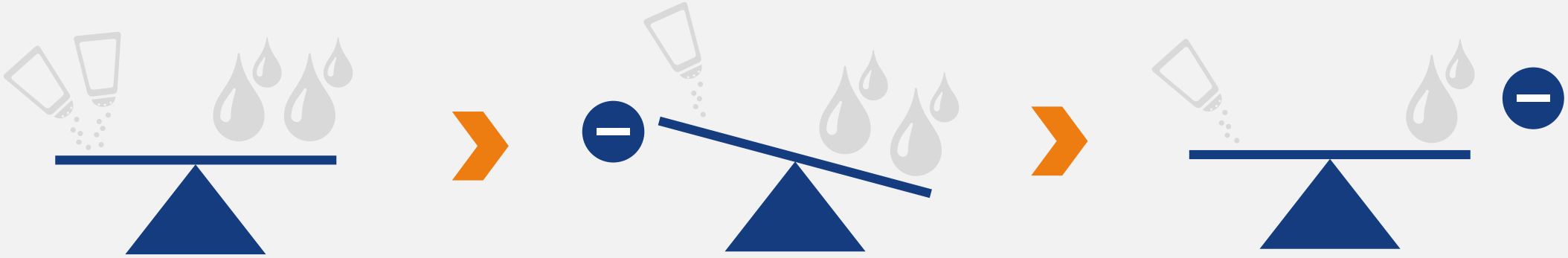
Annual costs of US HF-related hospitalisations[4]

- *40% of heart failure patients on IV loop diuretics have a poor response[1]*
- *24% re-admission rate at 30 days[2]*

Source 1: Testani, Circ Heart Failure, 2014 & 2016; Source 2: Ross et al. (2010); Source 3: Costanzo et al., J. Am. Coll., 2007; Source 4: Kilgore et al. (2017)

Direct sodium removal (DSR)

Remove the sodium and the body will eliminate the excess fluid



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
- alfapump® removes extracted sodium from peritoneal cavity via bladder
- Body restores balance by eliminating excess fluid

DSR pre-clinical and clinical Proof-of-Concept

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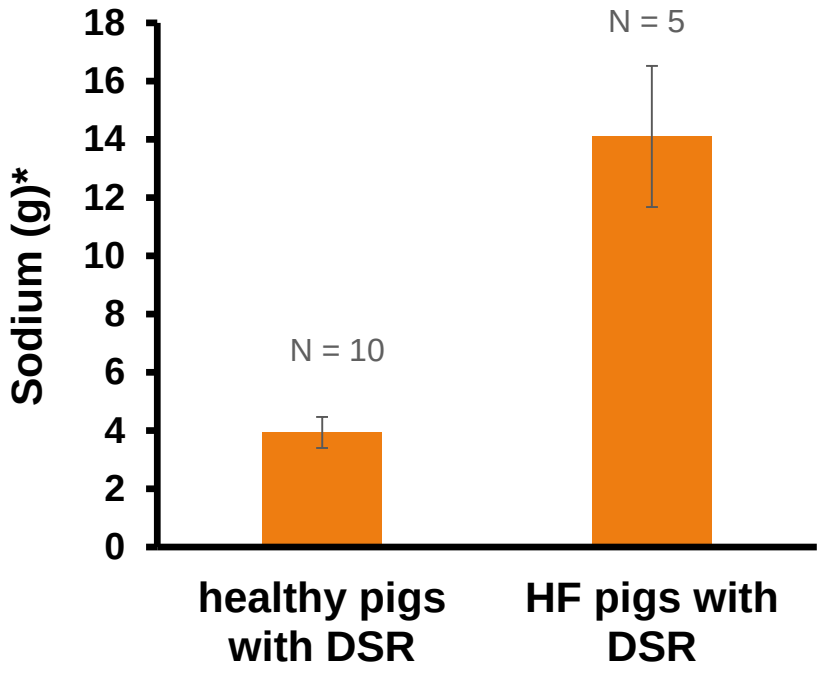
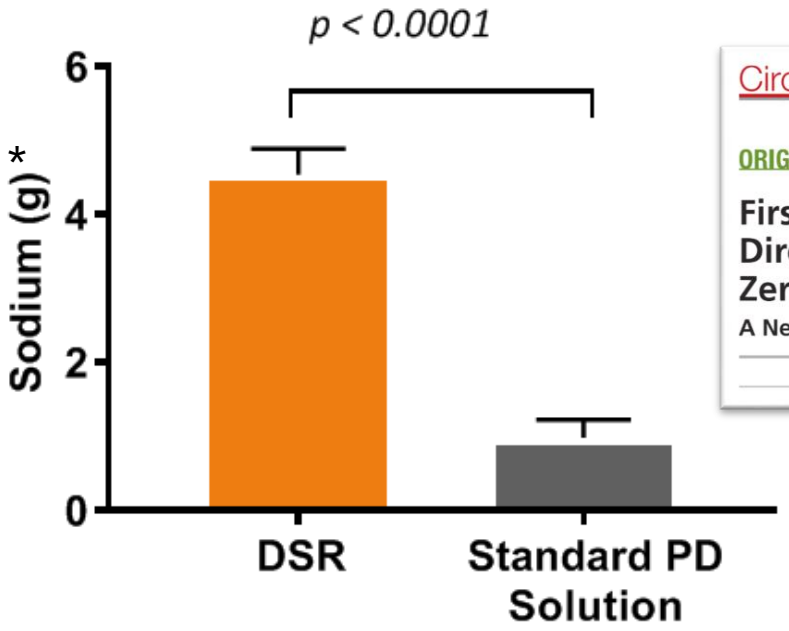
Yale

Pre-clinical studies[1]



First-in-human study[2] (N=10)




Circulation

ORIGINAL RESEARCH ARTICLE

First-in-Human Experience With Peritoneal Direct Sodium Removal Using a Zero-Sodium Solution

A New Candidate Therapy for Volume Overload

Editorial, see p 1054

Veena S. Rao, PhD

1: administration of 1 litre DSR infusate, with 2 hour dwell

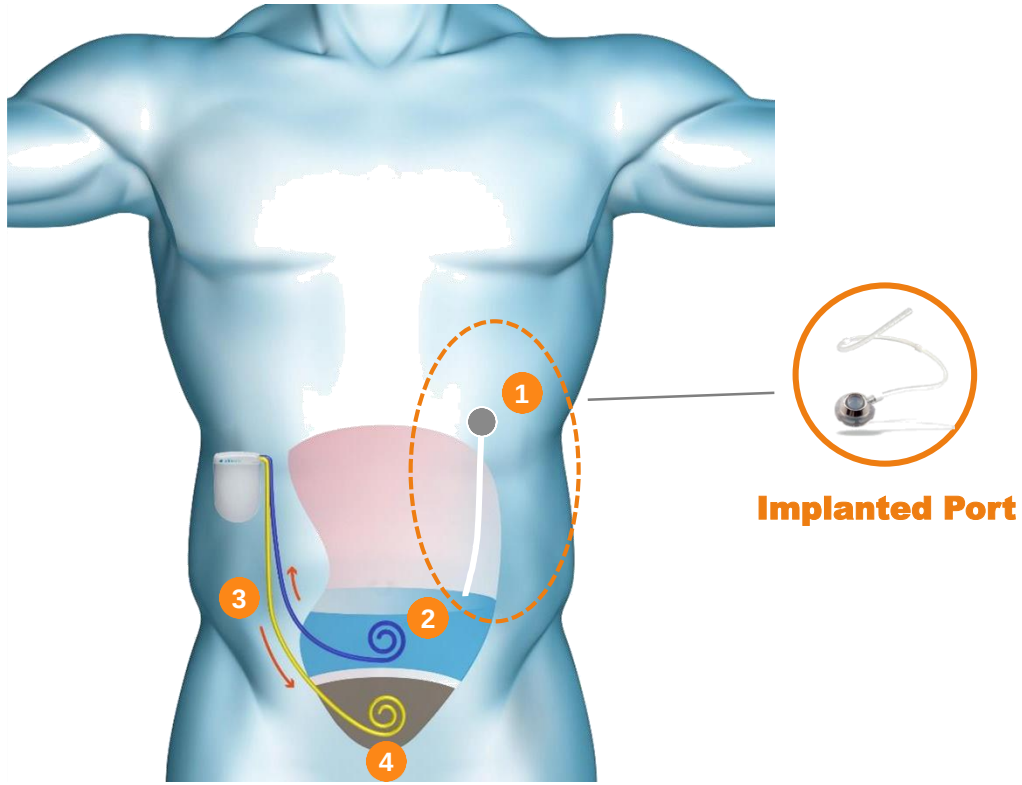
2: Cross-over study: administration of 1 litre DSR infusate (D10) vs. standard PD solution, with 2 hour dwell

** Weekly recommended intake for humans equals 14 grams (www.cdc.gov)*

DSR therapy is capable of removing large quantities of sodium in a safe, tolerable and consistent manner

alfapump® DSR

Fully implanted and convenient system for DSR therapy leveraging proven elements



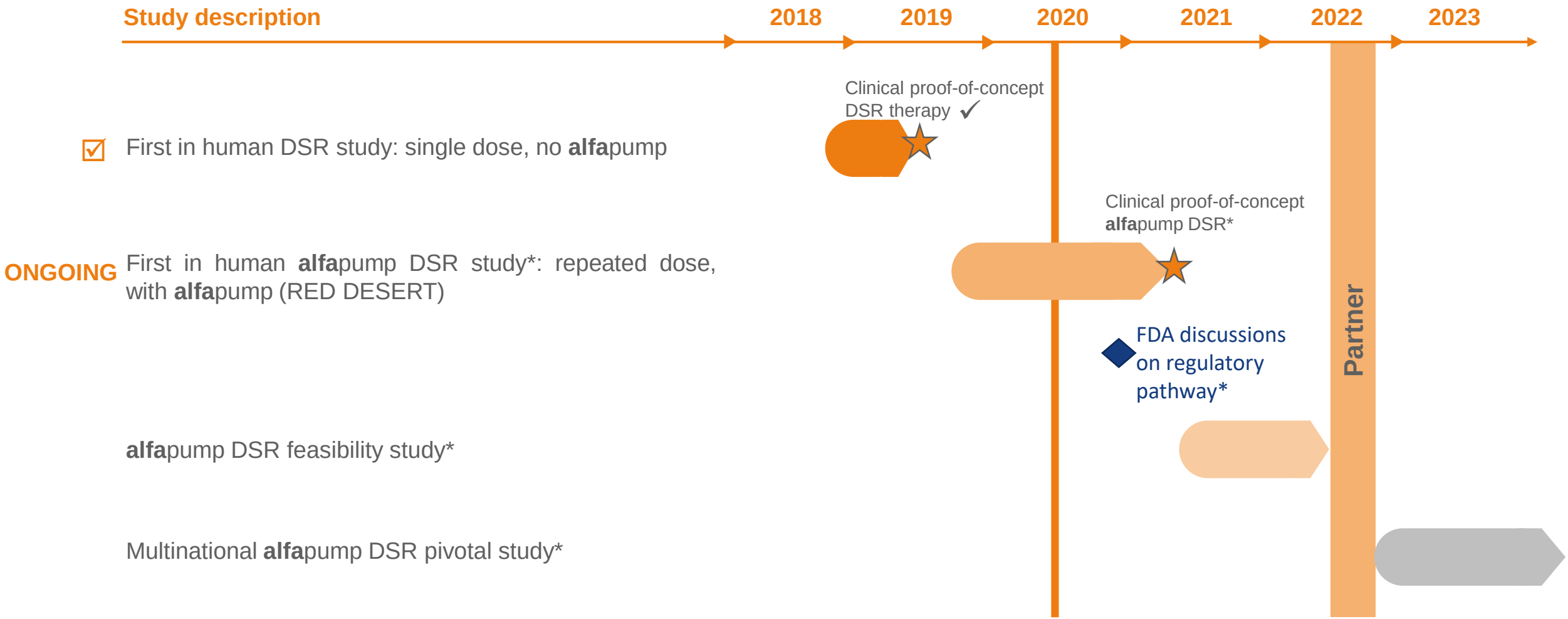
- ✓ DSR
- ✓ alfapump
- ✓ Implanted port

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

RED DESERT – First-In-Human Repeated Dose alfapump® DSR study ongoing

- Up to **10 patients** with heart failure on high dose diuretics across 2 centres (Belgium and Georgia)
- Patients put on a low sodium diet without diuretics and **implanted with alfa**pump **DSR system**
- Evaluation of safety and feasibility over a 6-week **alfa**pump DSR treatment
  - **Safety:** absence/rate of device, procedure and/or therapy related serious adverse events
  - **Feasibility:** ability of **alfa**pump DSR to maintain a neutral sodium balance and maintain euvolemia
- Explore potential impact of DSR therapy to **restore response to diuretics**

alfapump® DSR development overview



** Timings presented are based on an estimated delay of 6 months due to the COVID-19 pandemic. Updated guidance will be provided when the situation is clarified.*

Expected core value drivers*

alfapump®

Liver Disease (NASH)

- Completion patient enrolment in POSEIDON study (H2 2020)
- Interim results of POSEIDON study (H1 2021)

alfapump® DSR

Heart Failure

- Initial results of RED DESERT study (H2 2020)
- Presentation of results of RED DESERT study (H1 2021)

** Timings presented are based on an estimated delay of 6 months due to the COVID-19 pandemic. Updated guidance will be provided when the situation is clarified.*

Thank You

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