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H.C. Wainwright Global Investment Conference

Ian Crosbie, CEO – May 2022



Innovators in the treatment of diuretic-resistant fluid overload

liver disease  malignant ascites  heart failure

Disclaimers

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- The **alfapump**[®] system has not yet received regulatory approval in the United States and Canada. Any statement in this presentation about safety and efficacy of the **alfapump**[®] system does not apply to the United States and Canada. In the United States and Canada, the **alfapump**[®] system is currently under clinical investigation (POSEIDON Study) and is being studied in adult patients with refractory or recurrent ascites due to cirrhosis. For more information regarding the POSEIDON clinical study visit www.poseidonstudy.com.
- DSR[®] therapy is still under development and it should be noted that any statements regarding safety and efficacy arise from ongoing pre-clinical and clinical investigations which have yet to be completed. DSR[®] therapy is currently not approved for clinical research in the United States or Canada. There is no link between DSR[®] therapy and ongoing investigations with the **alfapump**[®] system in Europe, the United States or Canada.

COVID-19 disclaimer:

- 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 operations accordingly.
- Sequana Medical has put in place mitigation plans to minimise delays. The impact of increased demands on the healthcare systems, limitations on non-essential hospital visits and procedures, social-distancing and travel restrictions may result in further delays to execution of clinical studies and impact sales.
- Sequana Medical will continue to update the market as needed and whenever possible.

Note:

- alfapump**[®] is a registered trademark. DSR[®] and **alfapump DSR**[®] are registered trademarks in the Benelux, China, the EU, United Kingdom, and Hong Kong.

Uniquely positioned in two large markets



- **Proprietary technologies treating diuretic-resistant fluid overload**
 - Key clinical problem in liver disease, heart failure, renal failure and cancer
 - Diuretic-resistance is common – alternatives have significant disadvantages
- **Strong granted IP portfolio**

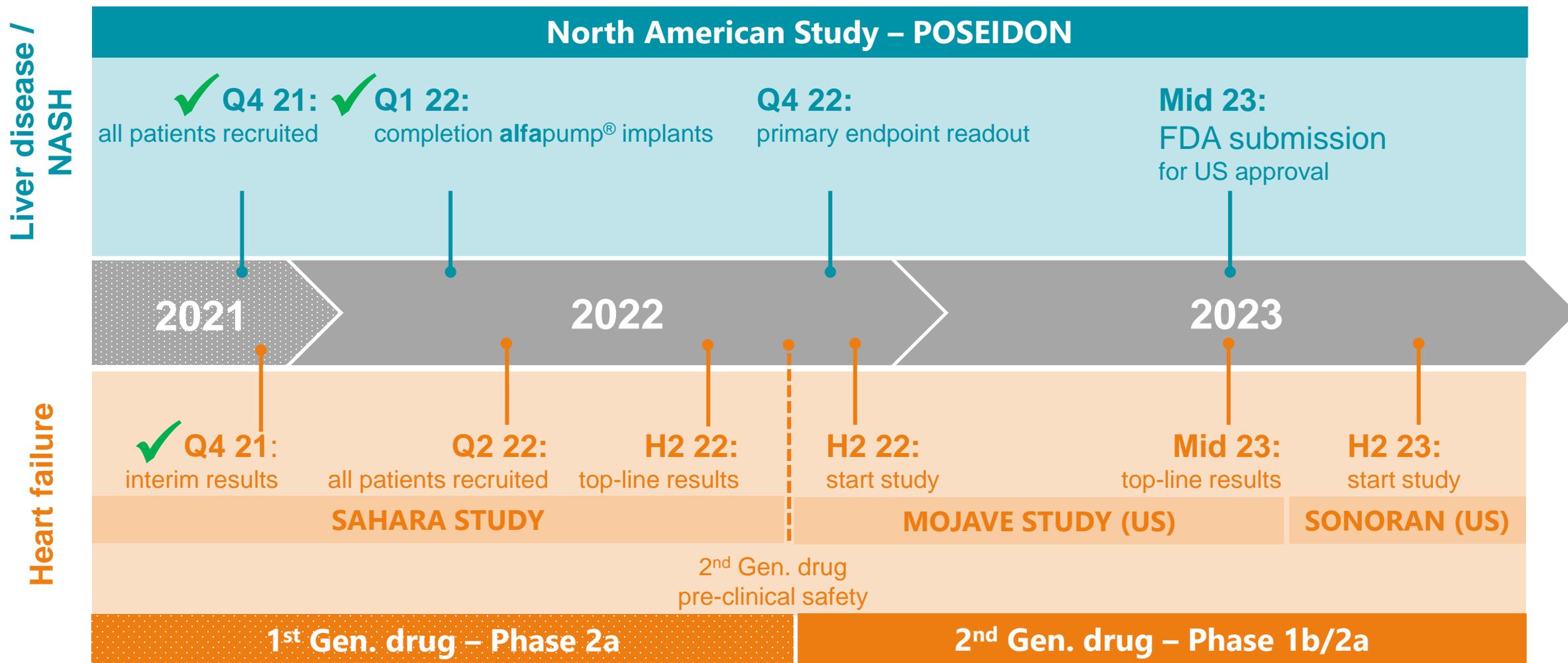


- **alfapump[®] in liver disease – over €3 Bn / year ⁽¹⁾**
 - NASH is changing liver cirrhosis market and driving growth
 - Approved in EU / FDA breakthrough designation in US
 - North American pivotal study de-risked / primary endpoint Q4 '22
 - Direct commercialisation in US



- **DSR[®] in heart failure – over €5 Bn / year ⁽²⁾**
 - Congestion is a key driver of heart failure and major clinical challenge
 - 1st Gen. drug – clinical proof-of-concept & encouraging Ph.2a data
 - Low-risk proprietary 2nd Gen. drug – on track for Q4 US clinical study
 - Partnering after US efficacy study

Strong outlook for value drivers



Note: Presented timelines are subject to further developments related to the COVID-19 pandemic



alfapump[®]

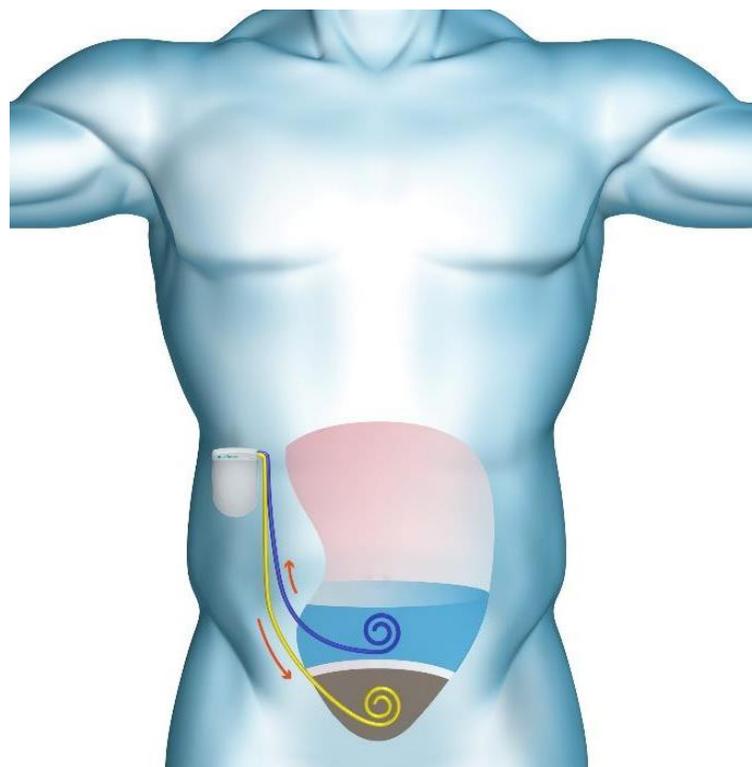
Proven step change in the
treatment of liver refractory
ascites

alfapump®

Eliminating fluid from the peritoneal cavity – working in partnership with the bladder



- ✓ Fully implanted
- ✓ Automatic operation
- ✓ Wireless battery charging
- ✓ Settings wirelessly adjusted
- ✓ Remote data monitoring

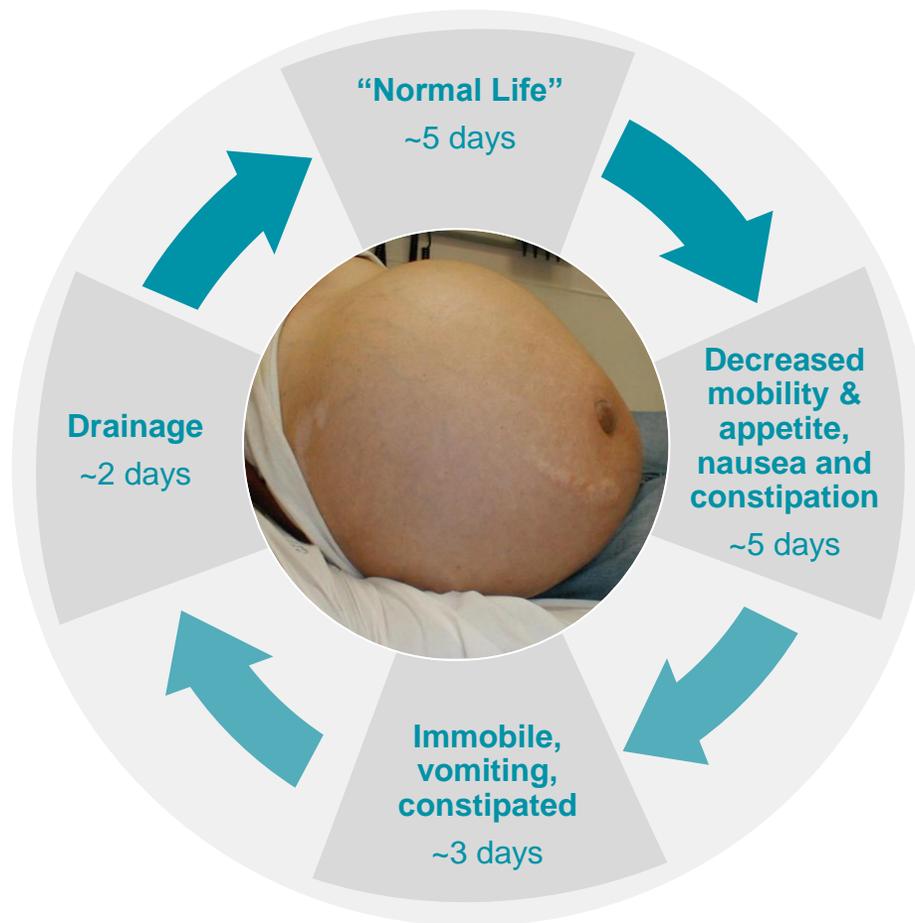


- ✓ Easy implantation
- ✓ Long-term implantation & catheter patency
- ✓ Moves up to 4 litres / day
- ✓ Virtually non-clogging
- ✓ No significant heating during charging and operation

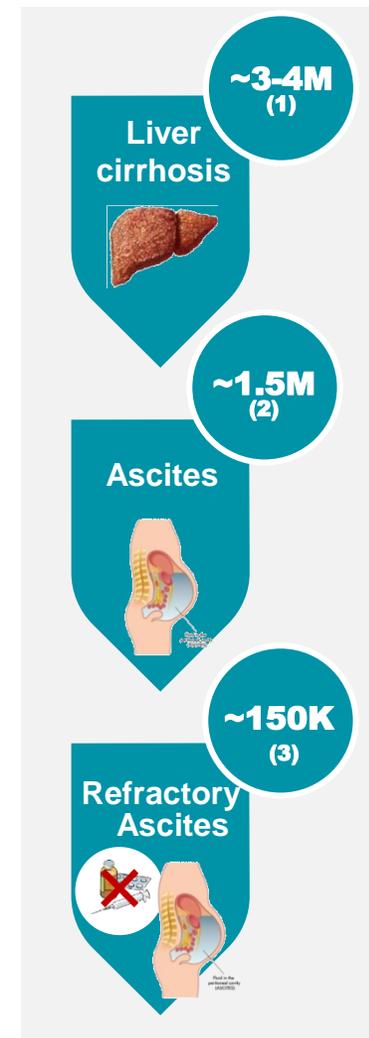
Proven capabilities – over 900 systems implanted
Strong IP barriers through extensive patent portfolio & know-how

Refractory ascites – key complication of liver cirrhosis

Fatty liver disease / NASH is driving dramatic growth and change in attitudes to liver cirrhosis patients



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; Nouredin 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

NASH transforming the face of liver cirrhosis

In US, liver cirrhosis is transitioning to a mainstream disease requiring modern treatment options



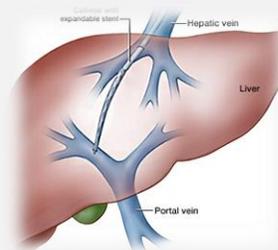
Limitations of existing therapies

Drainage (“Large Volume Paracentesis / LVP”)



Painful, Poor Quality of Life, Short Term Benefit

Transjugular Intrahepatic Portosystemic Shunt (TIPS)



Complications, Contraindications

Permanent Catheter System



External Catheter, Risk for Infections / Blockage

Liver transplantation



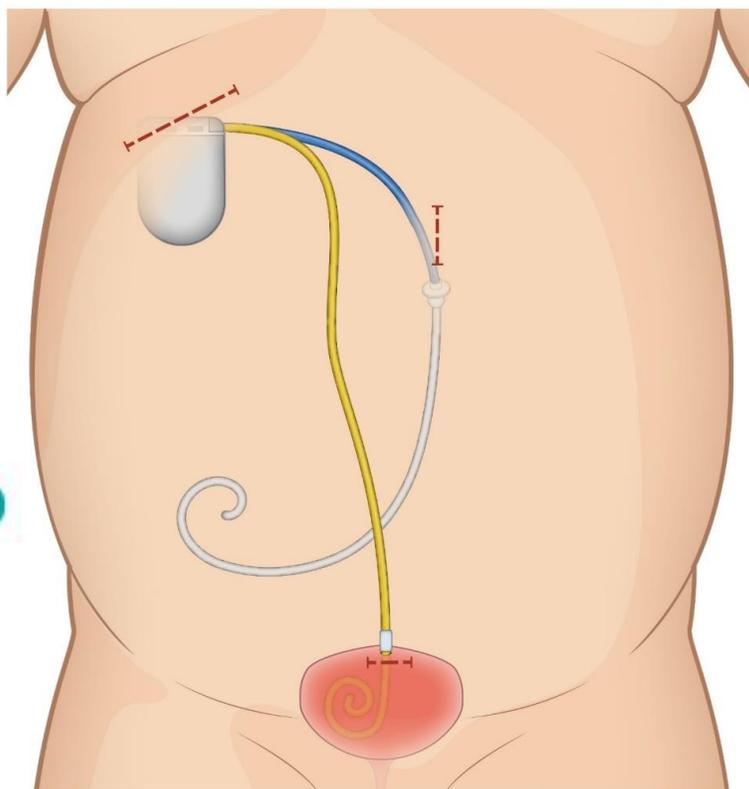
High Cost, Limited Availability

alfapump®



alfapump® strong clinical and economic rationale

Over 900 implants and hundreds of years of patient experience



- ✔ Reduced burden of disease
- ✔ Improved patient QoL
- ✔ Cost savings for hospitals and payers

Estimated treatment cost / patient*:

LVP: ~\$54K ↔ **alfapump®: ~\$35K**

~\$1.8K / LVP⁽¹⁾ ~\$25K / alfapump
 2 LVP / month ~\$10K / implantation
 15 months

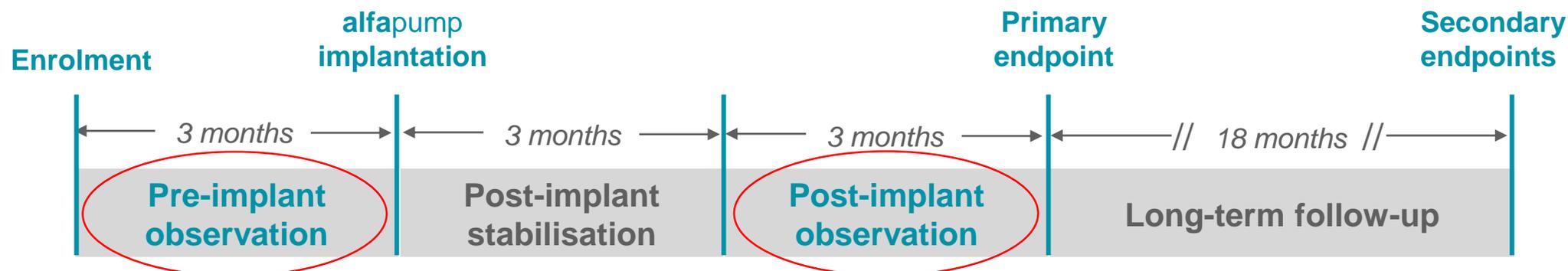
* Management estimate of US treatment costs, assuming no complications

QoL: Quality of Life; LVP: Large Volume Paracentesis



North American Pivotal Study (POSEIDON) underway

Pivotal Cohort of 40 implanted patients; Roll-In (“training”) cohort of 29 implanted patients



POSEIDON Study Endpoints

Primary efficacy: 1) 50% reduction in average monthly frequency of Therapeutic Paracentesis (“TP”) post-implant vs. pre-implant
2) 50% of patients achieve a 50% reduction in the requirement for TP post-implant vs. pre-implant

Primary safety: Rate of **alfapump** related re-interventions adjudicated by the Clinical Events Committee (CEC)

Secondary: QoL (SF36, Ascites-Q), nutritional status, health economics, safety (device and/or procedure-related AEs), survival

Interim POSEIDON: Positive for primary endpoints

Data from first 26 Roll-In patients clinically derisks the study

EFFICACY

- ✓ Over 90% reduction in mean Therapeutic Paracentesis (TP) frequency (primary endpoint >50% reduction)
- ✓ 100% patients with > 50% reduction in mean TP frequency per month (primary endpoint >50% of patients)

SAFETY

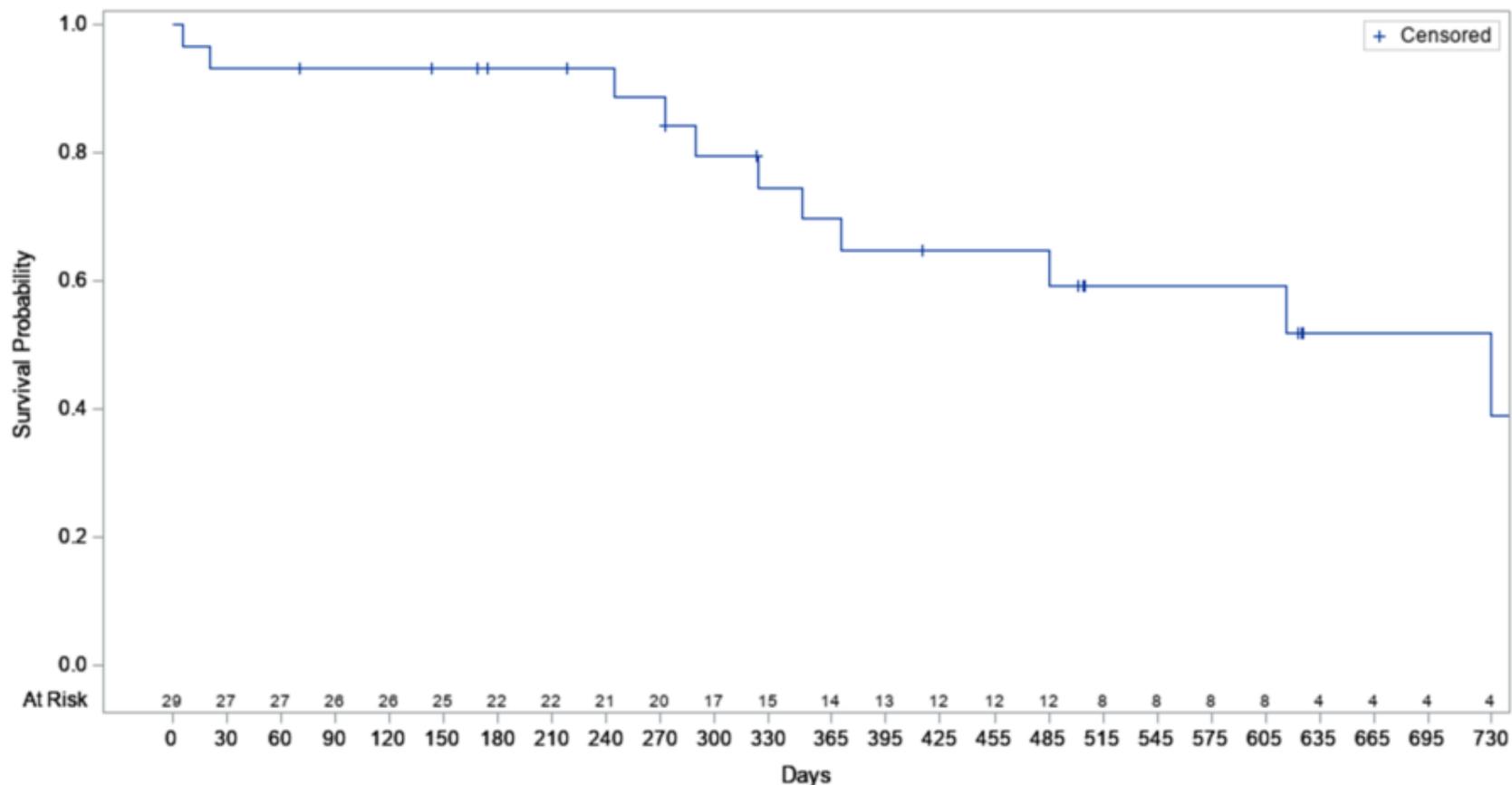
- ✓ In line with expectations – 3 composite primary safety events

QUALITY OF LIFE

- ✓ Clinically important improvement maintained for up to 12 months post-implantation

Interim POSEIDON: 70% survival at 12 months*

Compares favourably to published literature

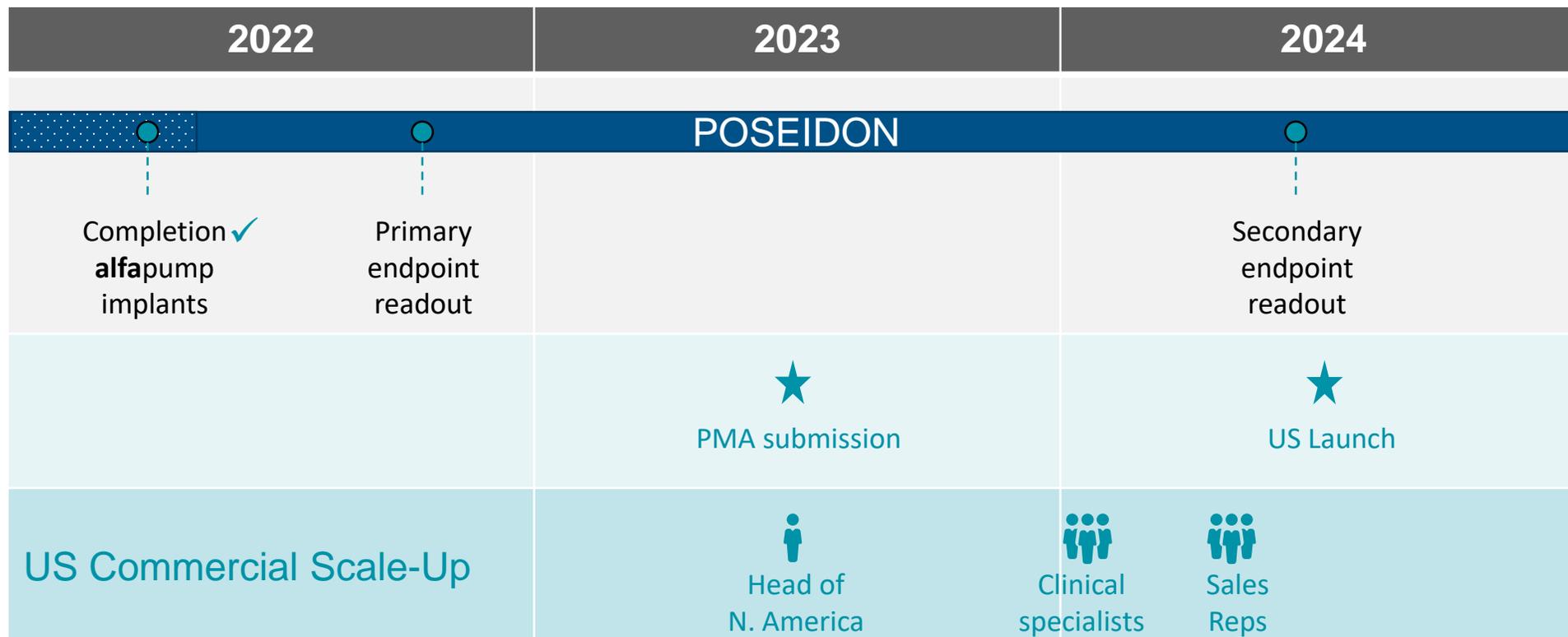


***Published literature cited in AASLD practice guidelines:
survival rate for refractory ascites patients of only 50% at 12 months¹***

*Preliminary survival rate analysis of Roll-In Cohort (25 March 2022)

Source 1: Biggins et al., *Hepatology*, Vol. 74, No. 2, 2021, AASLD Practice Guidance; Moreau R et al., *Liver International* 2004; 24: 457-464

North American alfapump® approval on track for 2024



*NTAP for breakthrough devices de-risks reimbursement in key Medicare population**

**On the basis of existing ICD-10 codes issued for the alfapump, the likely DRG coding will be 423, 424 and 425 "OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES"*

PMA: Pre-Market Approval; NTAP: New Technology Add-On Payment

US – Go direct to 140 liver transplant centres

Highly efficient approach to target doctors and patients – driven by treatment guidelines



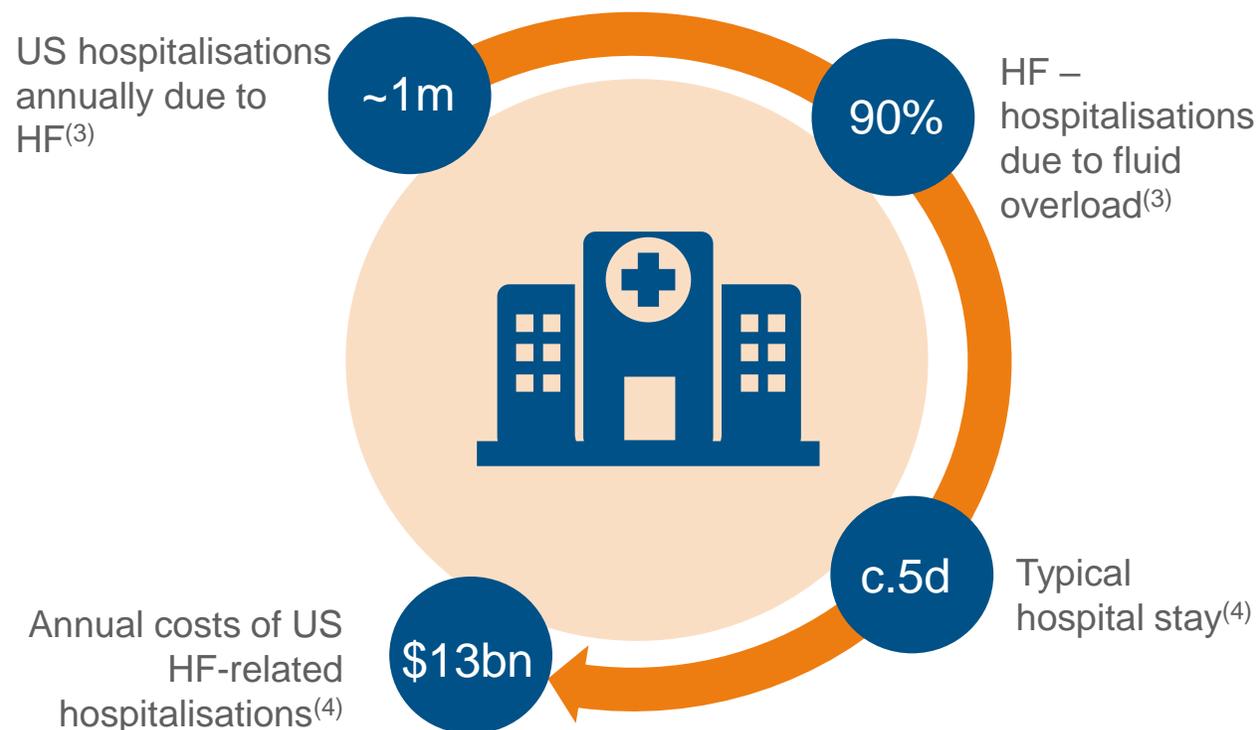


DSR[®]

Breakthrough approach to
heart failure

Diuretic-resistant congestion in heart failure

Removal of congestion without damaging renal function is a key therapeutic target and clinical challenge



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

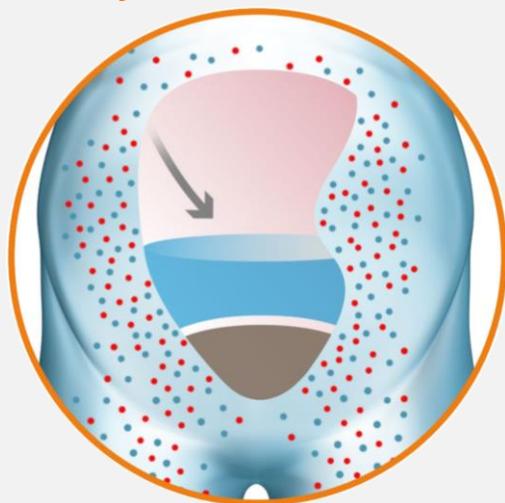


Direct Sodium Removal (DSR[®]) platform

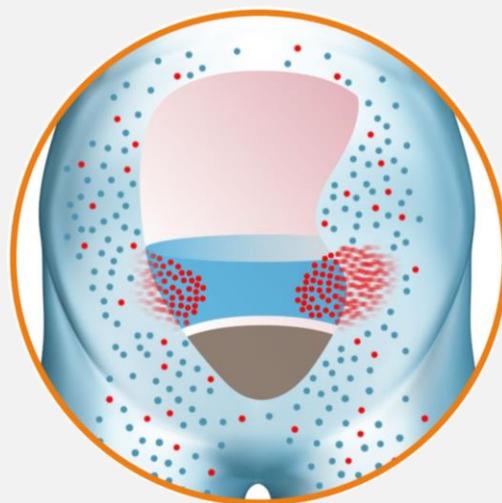
Eliminating fluid spread across the body – working in partnership with the kidneys



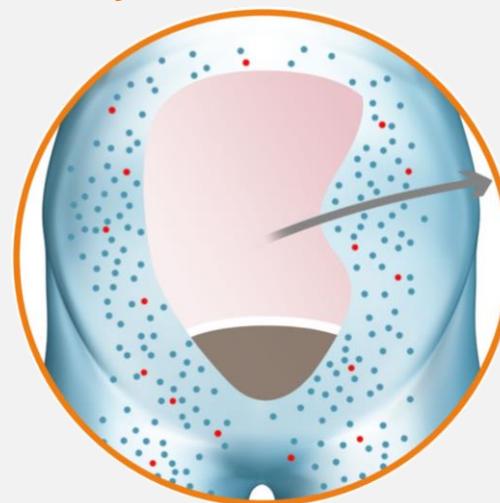
1 Sodium-free DSR infusate administered to peritoneal cavity



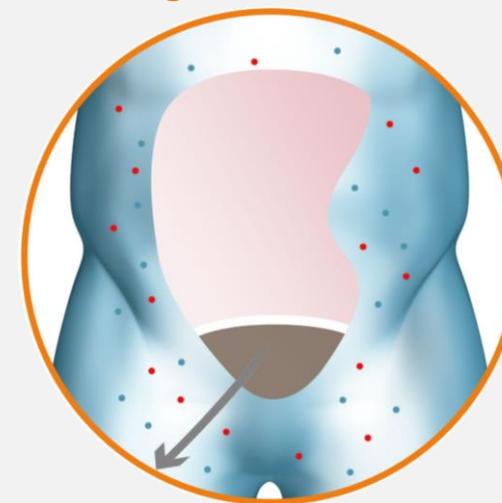
2 Sodium diffuses from body into DSR infusate



3 DSR infusate + extracted sodium removed from the body



4 Body eliminates free water to restore sodium balance, reducing the fluid overload

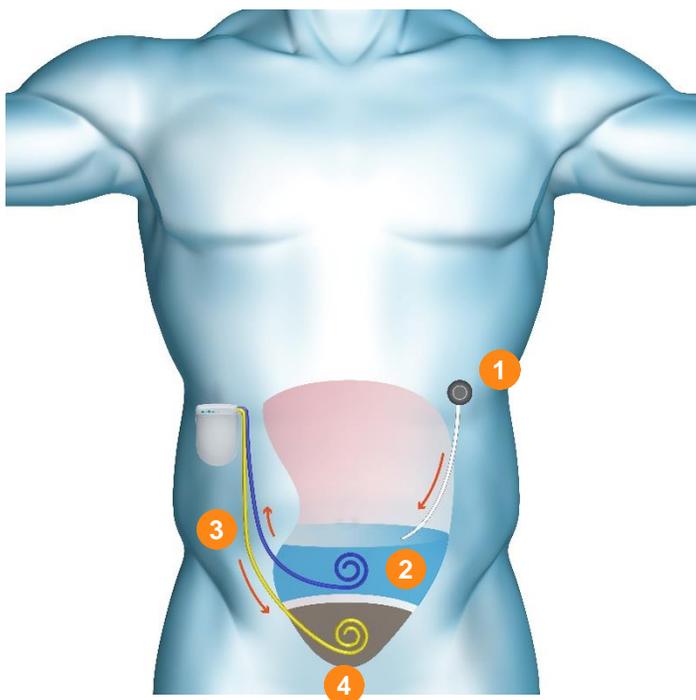


- water
- sodium

Fundamental patents to reduce fluid overload in heart failure patients granted in the US and Europe

alfapump DSR[®] leveraging proven alfapump[®] platform

Fully implanted system for long-term DSR[®] therapy – keeping patients out of the hospital



- 1 Sodium-free DSR infusate administered to peritoneal cavity via implanted subcutaneous port
- 2 Sodium diffuses into DSR infusate
- 3 **alfapump** pumps sodium-rich DSR infusate into the bladder
- 4 Body eliminates excess fluid through osmotic ultrafiltration and urination

DSR[®] – Encouraging Phase 2a heart failure data

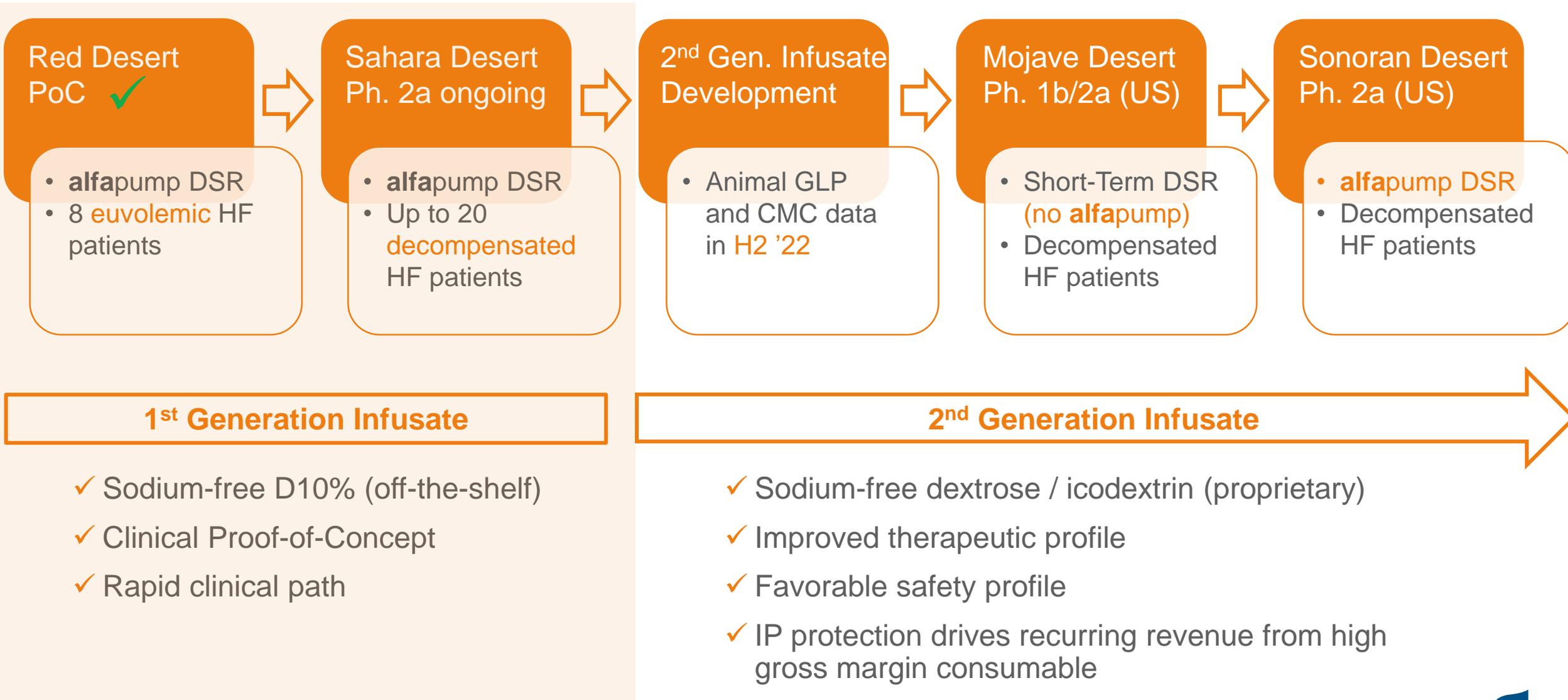
Clinical Proof-of-Concept demonstrating breakthrough potential in heart failure therapy

RED DESERT – Completed	SAHARA DESERT – Ongoing (Interim data)
8 Euvolemic heart failure patients	6 Decompensated heart failure patients
<p>✓ Safe & effective management of sodium & water</p>	<p>✓ Safe, effective & rapid decongestion, & restore euvolemia</p>
<p>✓ Clear improvement in cardio-renal status</p> <ul style="list-style-type: none"> • 30% decrease in NT-proBNP* • 22% increase in eGFR* 	<ul style="list-style-type: none"> • >30% decrease in NT-proBNP* • Stable eGFR*
<p>✓ Dramatic and durable improvement in diuretic response</p> <ul style="list-style-type: none"> • 40-96% reduction 9-19 months after study completion 	<ul style="list-style-type: none"> • >90% reduction 3 months* after intensive DSR therapy

* Mean value

NT-proBNP: N-terminal-pro hormone B-type Natriuretic Peptide (analysed in local lab); **eGFR:** estimated glomerular filtration rate

Moving to proprietary 2nd Generation Infusate



Red Desert
PoC ✓

- **alfapump** DSR
- 8 **euvolemic** HF patients

Sahara Desert
Ph. 2a ongoing

- **alfapump** DSR
- Up to 20 **decompensated** HF patients

2nd Gen. Infusate
Development

- Animal GLP and CMC data in H2 '22

Mojave Desert
Ph. 1b/2a (US)

- Short-Term DSR (no **alfapump**)
- Decompensated HF patients

Sonoran Desert
Ph. 2a (US)

- **alfapump** DSR
- Decompensated HF patients

1st Generation Infusate

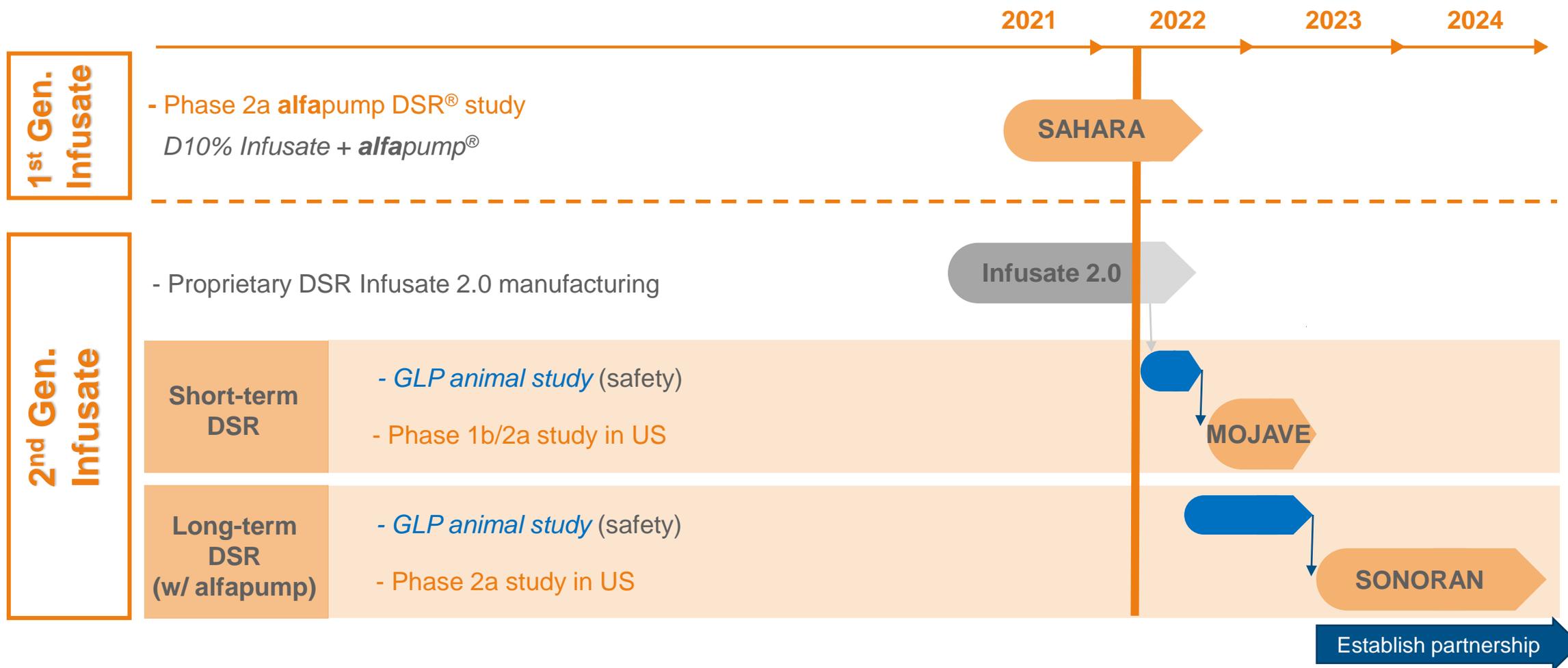
- ✓ Sodium-free D10% (off-the-shelf)
- ✓ Clinical Proof-of-Concept
- ✓ Rapid clinical path

2nd Generation Infusate

- ✓ Sodium-free dextrose / icodextrin (proprietary)
- ✓ Improved therapeutic profile
- ✓ Favorable safety profile
- ✓ IP protection drives recurring revenue from high gross margin consumable

DSR[®] – plan to partner after US efficacy study

Step-by-step approach to introduction of breakthrough heart failure therapy



Timelines subject to further developments related to the ongoing COVID-19 pandemic
Description and timing of these studies are subject to change and/or feedback from applicable regulatory authorities



Outlook

Strong **near term value drivers**
with clear **long term potential**



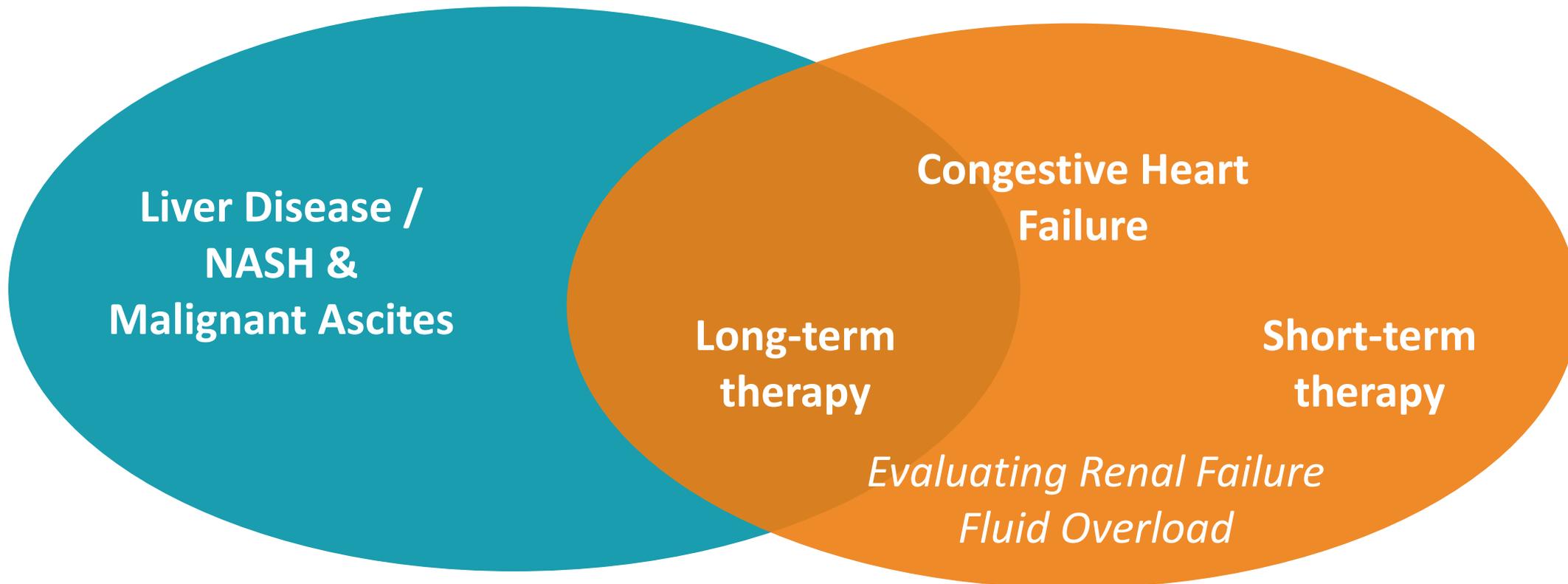
Building on our two proprietary platforms

Complementary approaches to diuretic-resistant fluid overload

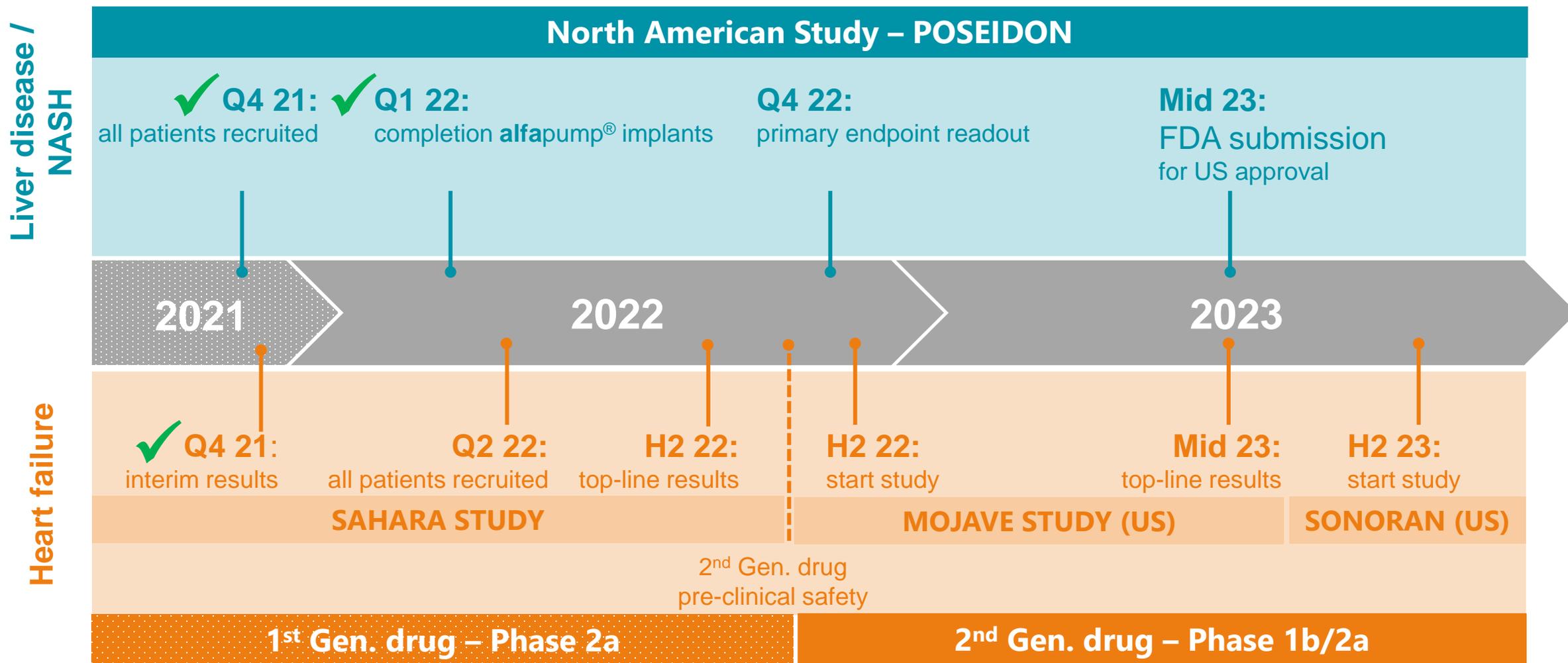
alfapump® 

alfapump DSR®

DSR® 



Strong outlook for value drivers



Note: Presented timelines are subject to further developments related to the COVID-19 pandemic

Strongly positioned for growth in both our markets



- **alfapump[®] in liver disease / NASH – over €3 Bn / year ⁽¹⁾**
 - NASH is changing liver cirrhosis market and driving growth
 - FDA breakthrough device status / Strong IP portfolio
 - North American pivotal study de-risked – Fully implanted / Positive interim data
 - North American approval on track for 2024 / Go direct to 140 liver transplant centres



- **DSR[®] in heart failure – over €5 Bn / year ⁽²⁾**
 - Clearing congestion while preserving renal function is a key objective of heart failure therapy
 - Clinical proof-of-concept with 1st Gen. drug – Encouraging phase 2a data
 - Development of proprietary 2nd Gen. drug – Strong IP / Driver of high margin recurring revenue
 - Establish partnership after US efficacy study mid-2023



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