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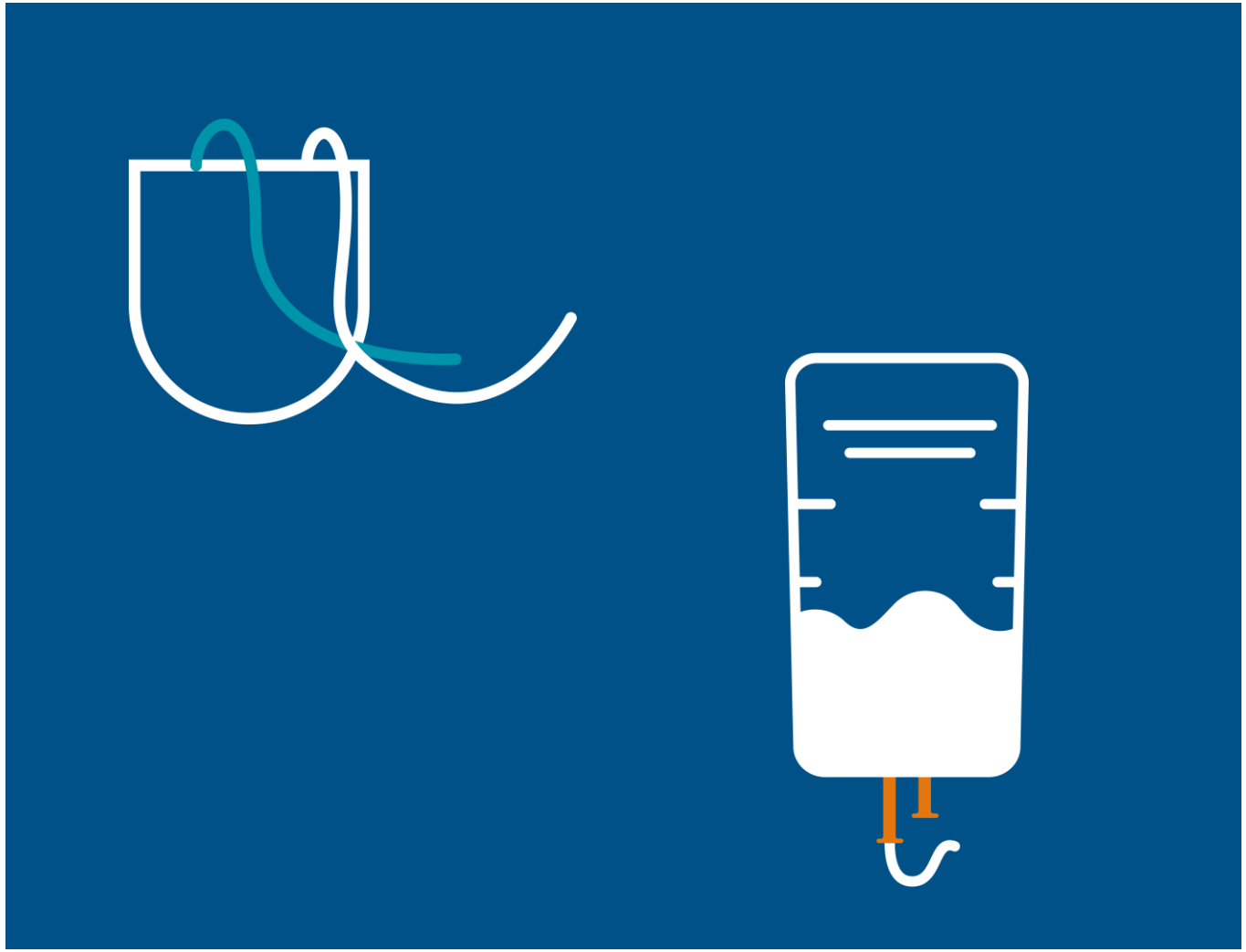

# Pioneers in the treatment of fluid overload

## Liver disease, Heart failure & Cancer

BioCapital Europe 2023

Ian Crosbie, CEO Sequana Medical

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- The **alfa**pump® system has not yet received regulatory approval in the United States and Canada. Any statement in this presentation about safety and efficacy of the **alfa**pump® system does not apply to the United States and Canada. In the United States and Canada, the **alfa**pump® 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 **alfa**pump® system in Europe, the United States or Canada.

**General disclaimer:**

- Sequana Medical is closely following the evolution of macroeconomic conditions, the geopolitical situation in Ukraine and 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:**

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

# Leading player in the treatment of fluid overload

- **Proprietary technologies meeting large and unmet clinical needs**
  - Key clinical problem in liver disease, heart failure, renal failure and cancer
  - We are not replacing diuretics – we are targeting those patients for whom they are not effective
  - Diuretic-resistance is common and alternative treatments have significant disadvantages
- **Strong granted IP portfolio**

- **alfapump® in liver disease – market potential growing to over $2.5 billion by 2035**(1)
  - Approved in EU / FDA breakthrough designation in US
  - North American pivotal POSEIDON study – all primary endpoints successfully met
  - PMA filing to US FDA planned for H2 ‘23
  - Direct commercialization in US through salesforce targeting liver transplant centres

- **DSR® in heart failure – multi-billion market opportunity in EU and US**
  - Disease-modifying heart failure drug therapy
  - 1st generation DSR 1.0 – clinical proof-of-concept
  - 2nd generation DSR 2.0 – strong IP, preparing US IND to start Ph. 1/2a MOJAVE study in Q2 ’23
  - Establish partnership based on MOJAVE readout

*Source 1: Based on US and Canada market assessment conducted by highly experienced international consulting group, estimating over 170,000 patients with recurrent or refractory ascites in North America by 2035, with estimated incidence of 60% and based on $25K for price of **alfa**pump*

***PMA:** Pre-Market Approval; **IP**: Intellectual Property; **IND**: Investigational New Drug*

# alfapump®

Proven step change in the treatment of liver refractory ascites

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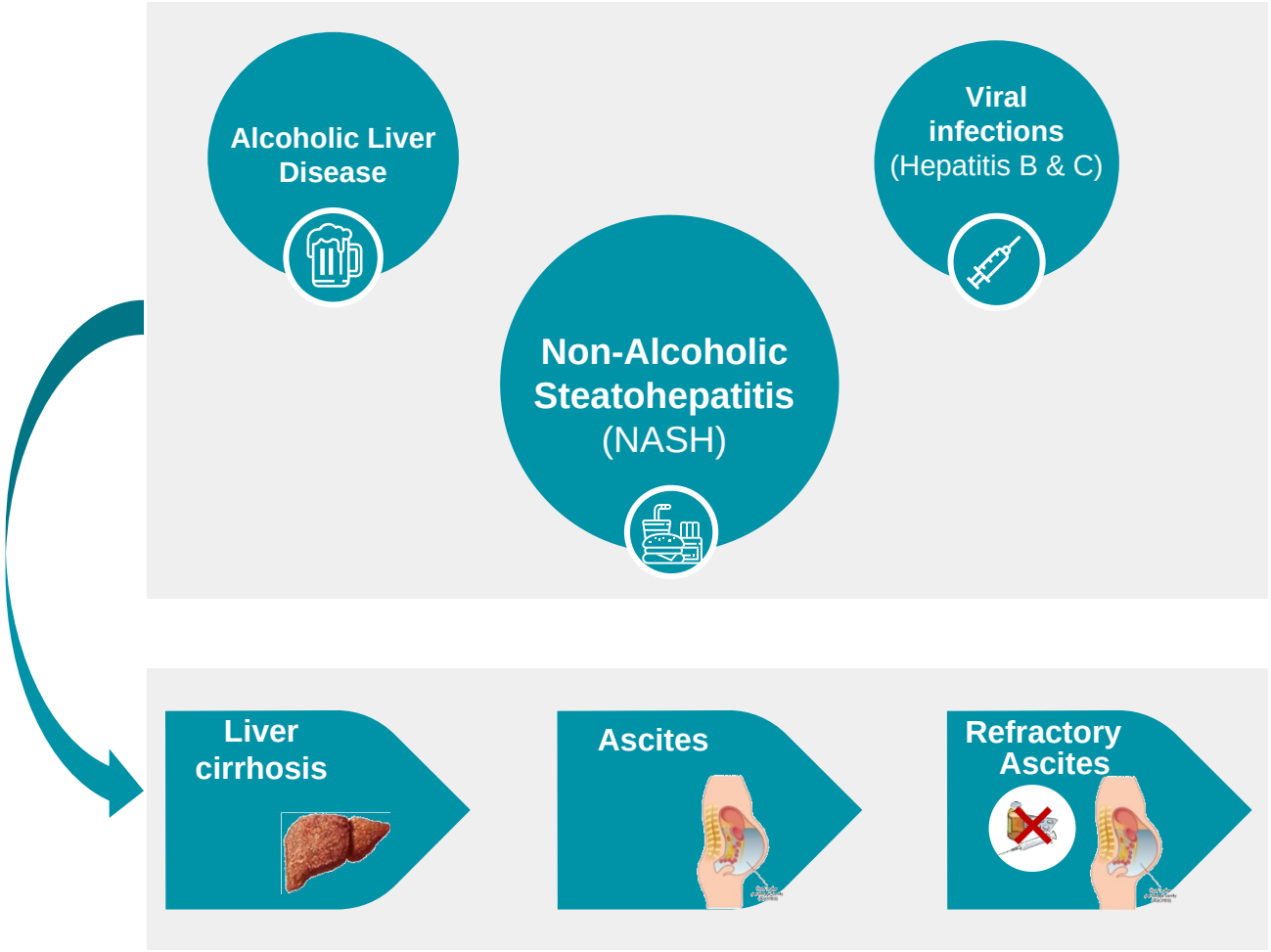
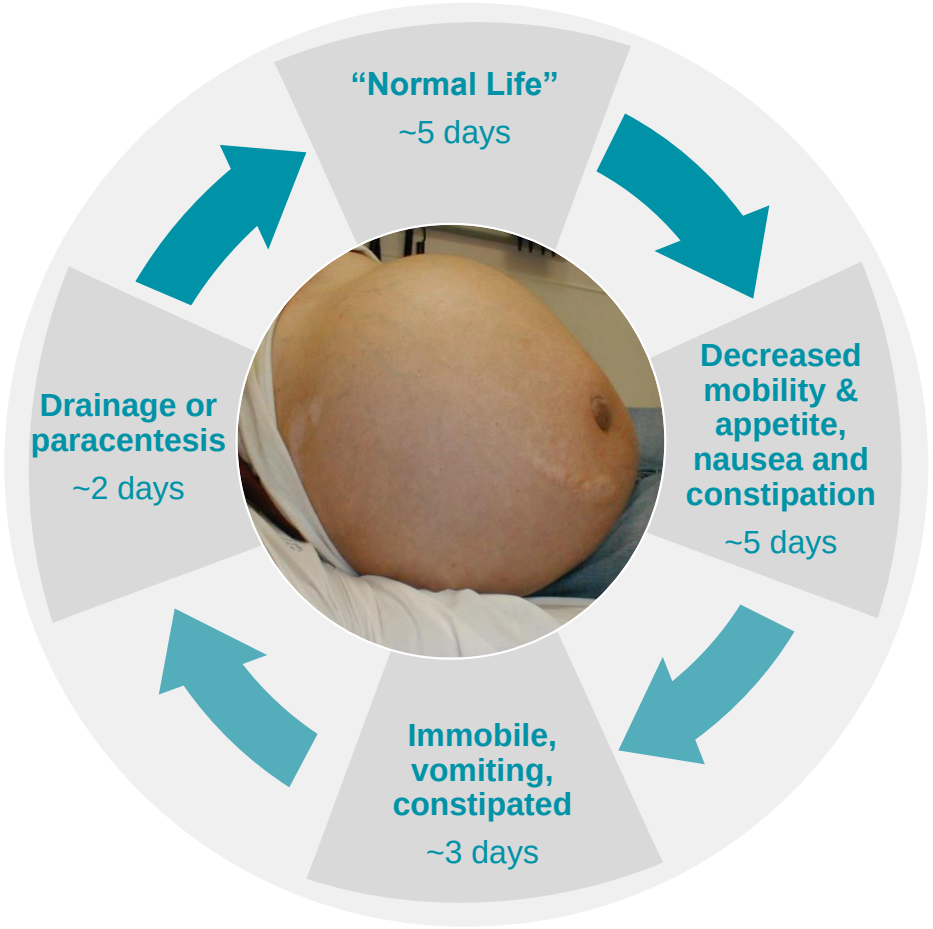
# Refractory ascites – key complication of liver cirrhosis

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



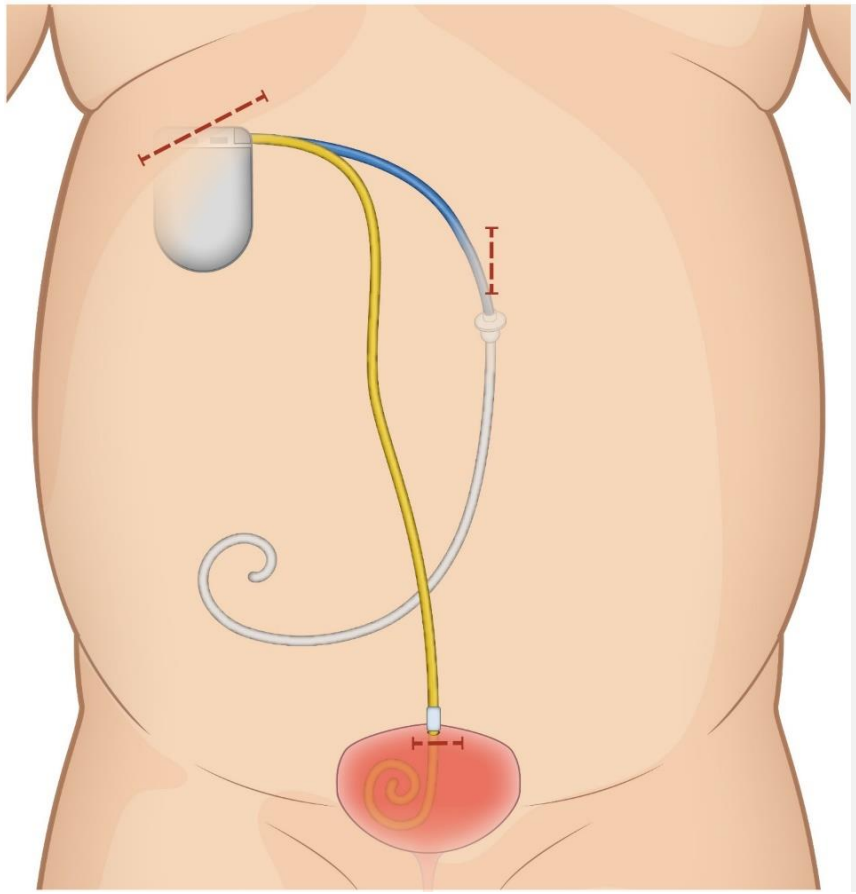

## Typical patient life[1]




*Source 1: Presentation of Dr. Rajiv Jalan at EASL in 2018, Large Volume Paracentesis (LVP) treatment cycle for refractory ascites*

# alfapump

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



- Fully implanted
- Automatic operation
- Wireless battery charging
- Remote data monitoring

FDA **Breakthrough Device** Designation

CE

EASL The Home of Hepatology

NICE National Institute for Health and Care Excellence

DGVS Deutsche Gesellschaft für Gastroenterologie, Verdauungs- und Stoffwechselkrankheiten

***Proven capabilities – over 950 systems implanted***
***Strong IP barriers through extensive patent portfolio & know-how***

# POSEIDON – successful North American pivotal study

**40 patients with recurrent or refractory ascites due to liver cirrhosis implanted with the alfapump**

## Primary effectiveness endpoints exceed predefined thresholds for study success

- **100%** median per-patient reduction in therapeutic paracentesis (p<0.001) (1)
  - *vs hypothesis of at least a 50% reduction*
- **77% of patients** with at least 50% reduction in therapeutic paracentesis (p<0.001) (1)
  - *vs hypothesis of at least 50% of patients*

## Primary safety endpoint data in line with expectations

- No unanticipated adverse device effects
- 6 primary safety events

***"These positive top-line results are very encouraging, indicating that the alfapump could provide great benefits to patients with cirrhosis and ascites, and dramatically reduce their visits to the hospital for paracentesis." – Dr. Wong, Principal Investigator POSEIDON***

(1) *Post vs Pre-Implantation*

# Well positioned for successful US commercialization

## Publications & presentations

Submit POSEIDON data for presentation at medical liver meeting & publication in peer-reviewed journal in 2023

## US patient preference study

Survey study to quantify patients' preferences for **alfa**pump, including risk-benefit assessment

Top-line data expected in H2 2023

## US filing & approval

PMA filing planned for H2 2023

FDA approval anticipated in H2 2024

## Reimbursement for alfapump de-risked

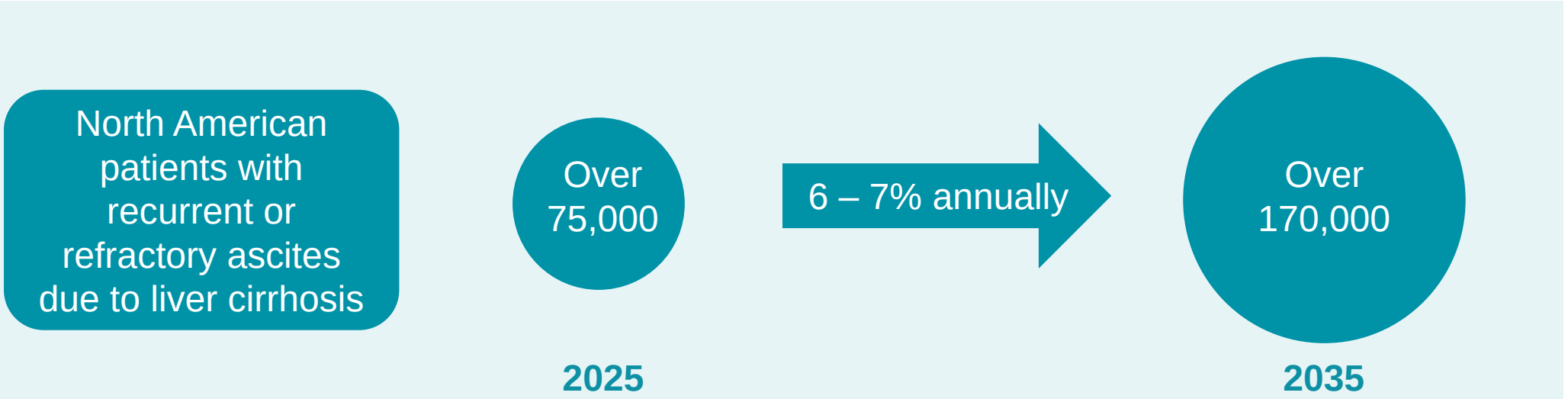
- ✓ Existing hospital DRG payment for **alfa**pump procedure*
- ✓ NTAP for breakthrough devices provides additional reimbursement in key Medicare population

**On the basis of existing ICD-10 codes issued for the **alfa**pump, 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*

# Large and growing North American patient population

**NASH is forecast to drive significant growth for many years – and changing attitudes to cirrhosis**

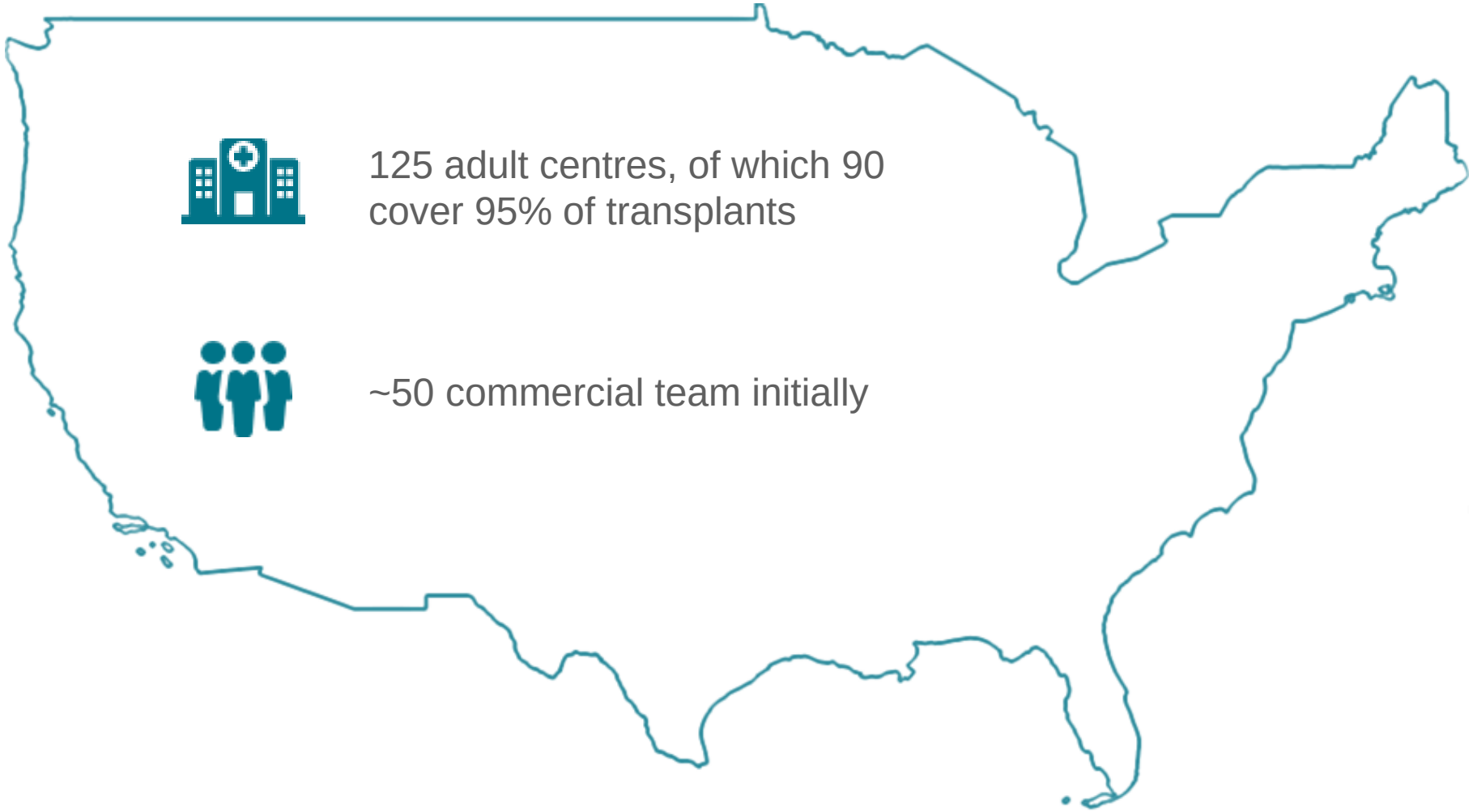



***Market potential growing to over $2.5 billion by 2035***

*Source: Based on US and Canada market assessment conducted by highly experienced international consulting group, using claims analysis for commercial and CMS (Center for Medicare and Medicaid Services) patients requiring paracentesis procedure with liver disease diagnosis codes; based on incidence rate of 60% and **alfa**pump price of $25K*

# US – Go direct to 90 liver transplant centers

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



125 adult centres, of which 90 cover 95% of transplants

~50 commercial team initially

*Source: Organ Procurement & Transplantation Network, US Dept of HHS (optn.transplant.hrsa.gov)*

# DSR®

Disease-modifying heart failure drug therapy

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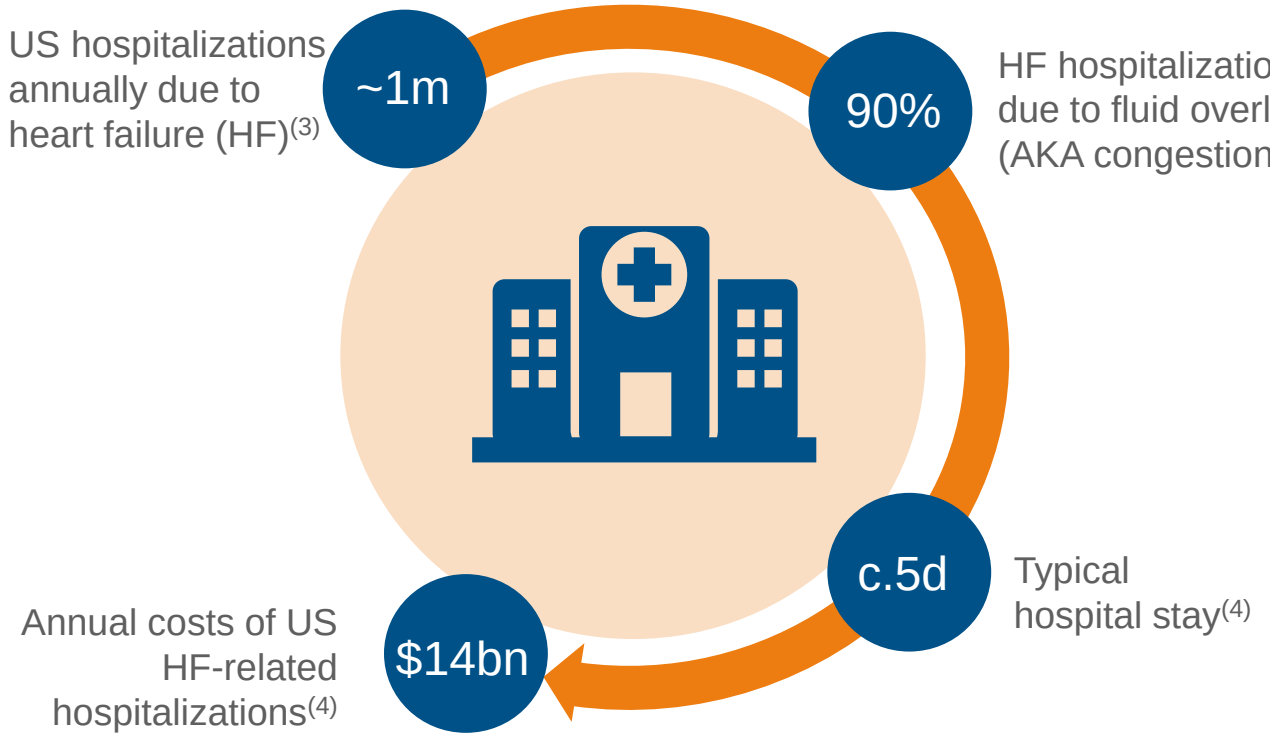
# Congestion is key driver of morbidity & hospitalization

**Diuretic-resistance is common and there are few effective clinical alternatives**



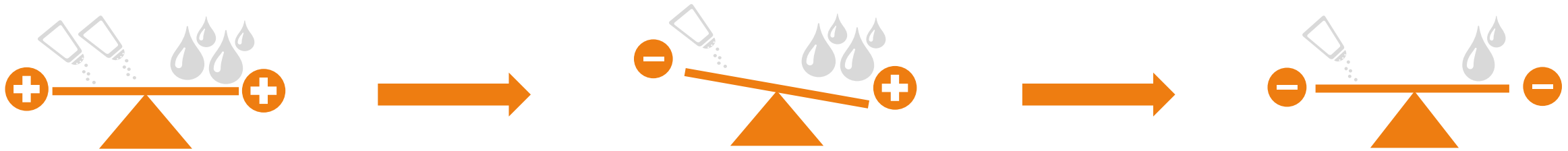

- *40% of heart failure patients on IV loop diuretics have a poor response(1)*
- *24% re-admission rate at 30 days(2)*



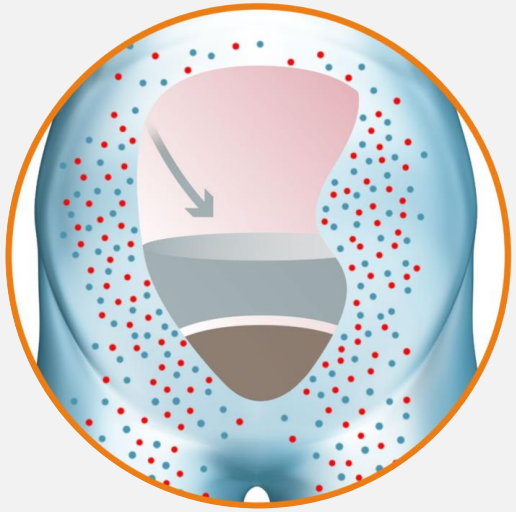
*Source 1: Testani, Circ Heart Failure, 2014 & 2016; Source 2: Ross et al. (2010); Source 3: Costanzo et al., J. Am. Coll., 2007; Source 4: Urbich et al. (2020)*

# Direct Sodium Removal (DSR)

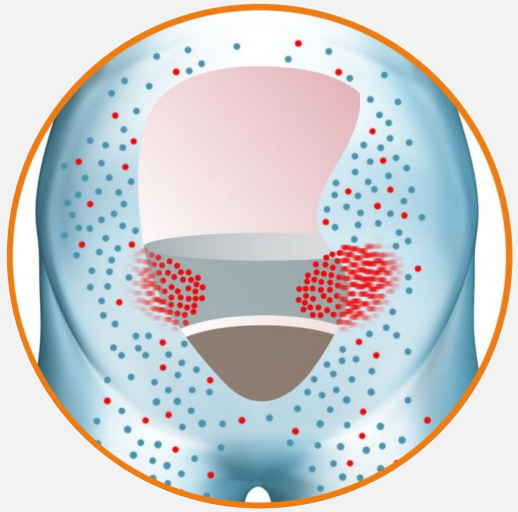
**Eliminating fluid spread across the body – working in partnership with the kidneys**



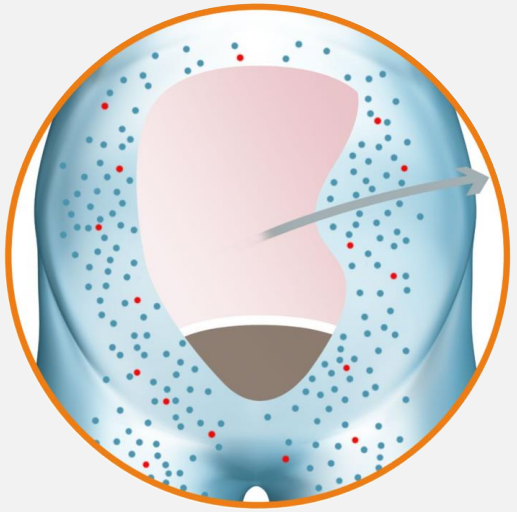
**1** Sodium-free DSR product administered to peritoneal cavity



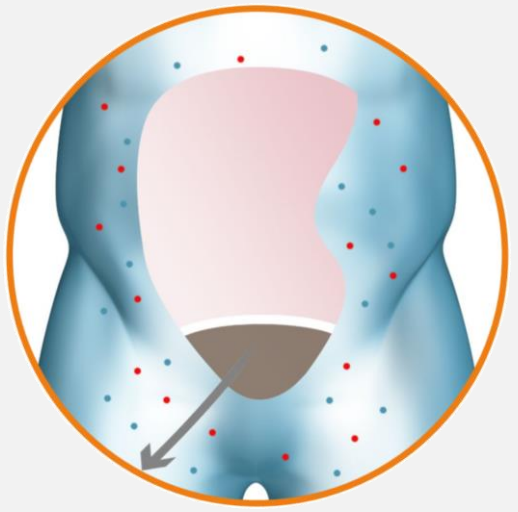
**2** Sodium diffuses from body into DSR product



**3** DSR product + extracted sodium removed from 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***

# DSR – disease-modifying heart failure drug therapy

**RED DESERT and SAHARA deliver clinical proof-of-concept of DSR with long-lasting clinical benefits**

## Clinically meaningful decongestion and durable improvements in cardio-renal health

- ✓ Safe, effective and rapid elimination of fluid overload / restoring euvolemia
- ✓ Considerable benefit in cardio-renal status
- ✓ Dramatic and sustained improvement in diuretic response

## Leading to improved clinical outcomes

- ✓ No congestion-related heart failure re-hospitalizations
- ✓ Long-term and major reduction in loop diuretic dosing post-DSR therapy
- ✓ One class improvement of NYHA status
- ✓ Over 75% reduction in predicted one-year mortality based on Seattle Heart Failure Model

***"These results are highly encouraging and indicate the potential for DSR therapy to deliver clinically meaningful decongestion and durable improvements in cardio-renal function and thus diuretic response" – Dr. Testani, Yale***



***NYHA**: New York Heart Association classification, data collected outside study protocols of RED DESERT and SAHARA*

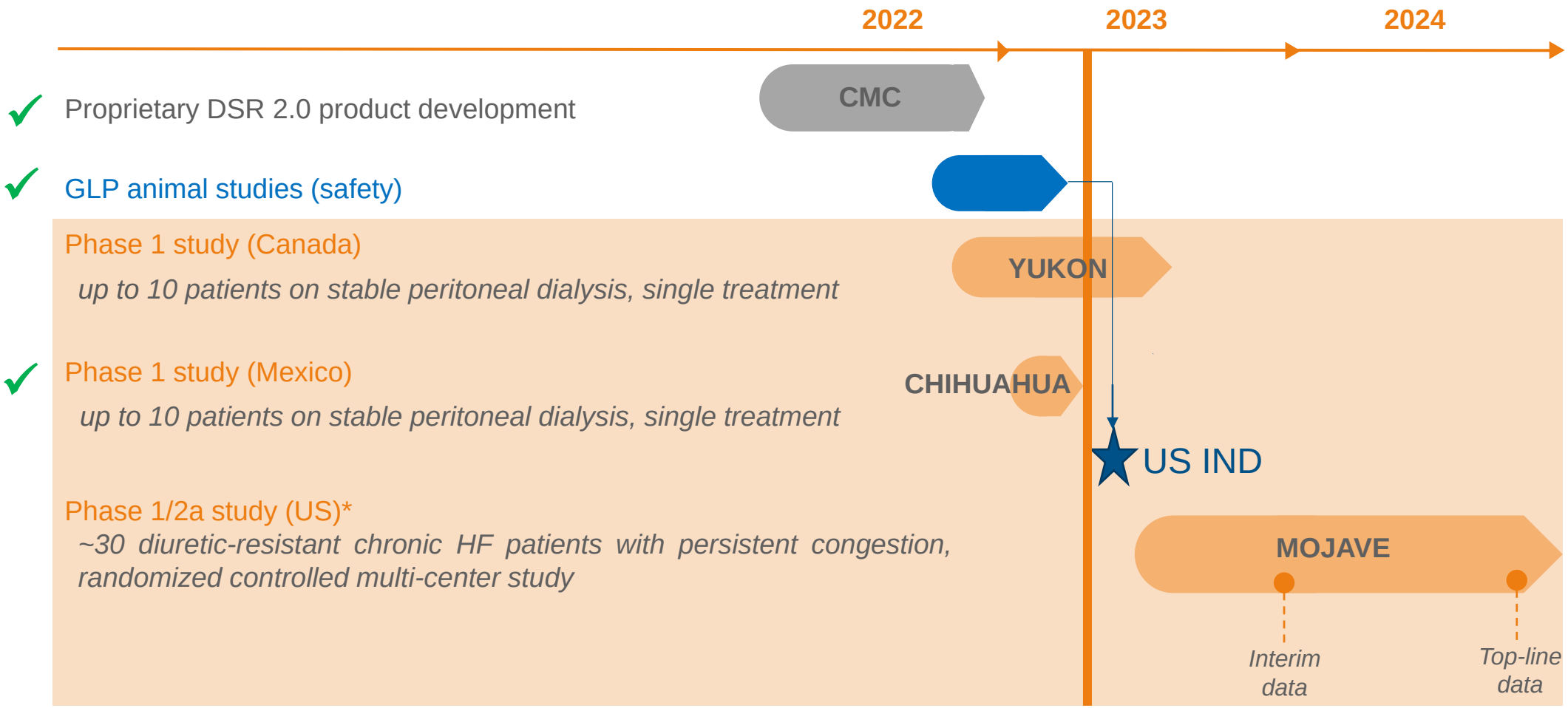
# DSR 2.0 has improved therapeutic and safety profile

**Strong granted IP drives high margin recurring revenue stream**

| DSR 1.0<br>Sodium-free D10% (off-the-shelf) | DSR 2.0<br>Sodium-free dextrose / icodextrin (proprietary) |
|---|---|
| ✓ Clinical proof-of-concept<br>✓ Rapid clinical path<br>~ Therapeutic profile / Ease of use<br>~ Safety profile | ✓ Improved therapeutic profile<br>✓ Favorable safety profile<br>✓ Strong granted IP position in US & Europe<br>• "Low or no sodium drug for the treatment of heart failure"<br>• Drives recurring revenue from high gross margin consumable |
| ✓RED DESERT ✓SAHARA | ✓CHIHUAHUA – YUKON – MOJAVE |

# On track to commence MOJAVE in Q2

**Intended to deliver the clinical data package required for partnering transaction**




** Description and timing of this study is subject to change and/or feedback from applicable regulatory authorities*

# Multi-billion market opportunity for DSR product

**Delivering value through reduced hospitalization and improved survival**

- ~400K chronically congested HF patients hospitalized per year in the US and EU (“frequent flyers”)
  - High cost patients with major burden on healthcare systems, payors and patients

- Value based pricing of DSR product driven by:
  - ⇨ Reduction in re-hospitalization ~$45K annual HF hospitalization cost per patient
  - ⇨ Increase in survival (gain in quality-adjusted life-year, “QALY”)

# Outlook

Strong near term value drivers with clear long term potential

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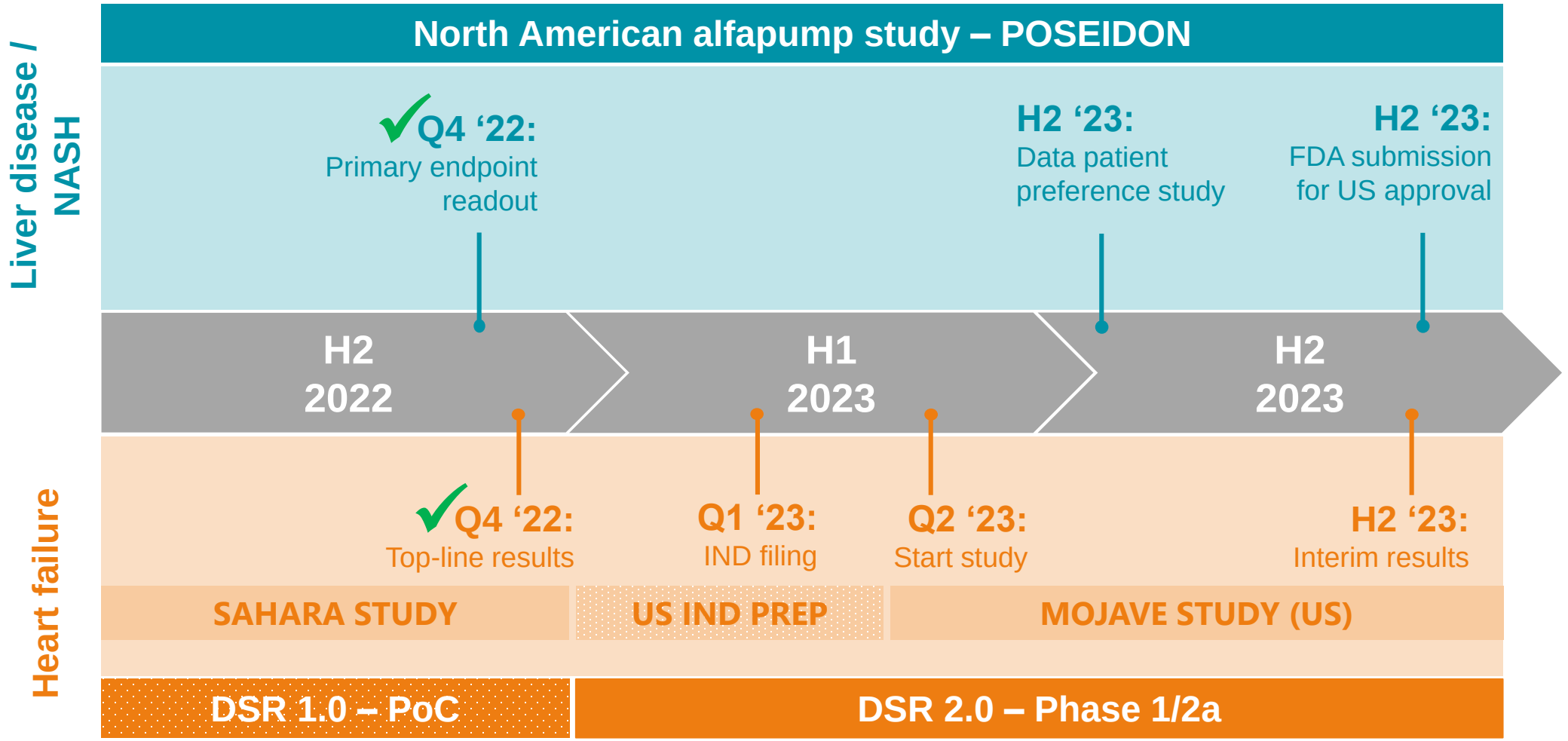
# Strong outlook for value drivers




*Note: Description and timing of these studies are subject to change and/or feedback from applicable regulatory authorities*

***PoC**: Clinical Proof-of-Concept*

# Leader in large and growing markets with unmet needs

## alfapump® in liver disease – market potential growing to over $2.5 billion by 2035(1)

- NASH is changing liver cirrhosis market and driving strong growth
- Approved in EU / FDA breakthrough device status / Strong IP portfolio
- North American pivotal study – reported strong primary endpoint data
- North American approval expected in 2024 / Go direct to 90 adult liver transplant centers

## DSR® in heart failure – multi-billion market opportunity in EU and US

- Disease-modifying heart failure drug therapy – short course of therapy
- Clinical proof-of-concept with DSR 1.0 – important and durable clinical benefits
- Transitioning to proprietary DSR 2.0 – low development risk, improved profile & strong IP
- Establish partnership based on US Phase 1/2a randomized controlled MOJAVE study

*Source 1: Based on US and Canada market assessment conducted by highly experienced international consulting group, estimating over 170,000 patients with recurrent or refractory ascites in North America by 2035, with estimated incidence of 60% and based on $25K for price of **alfa**pump*

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