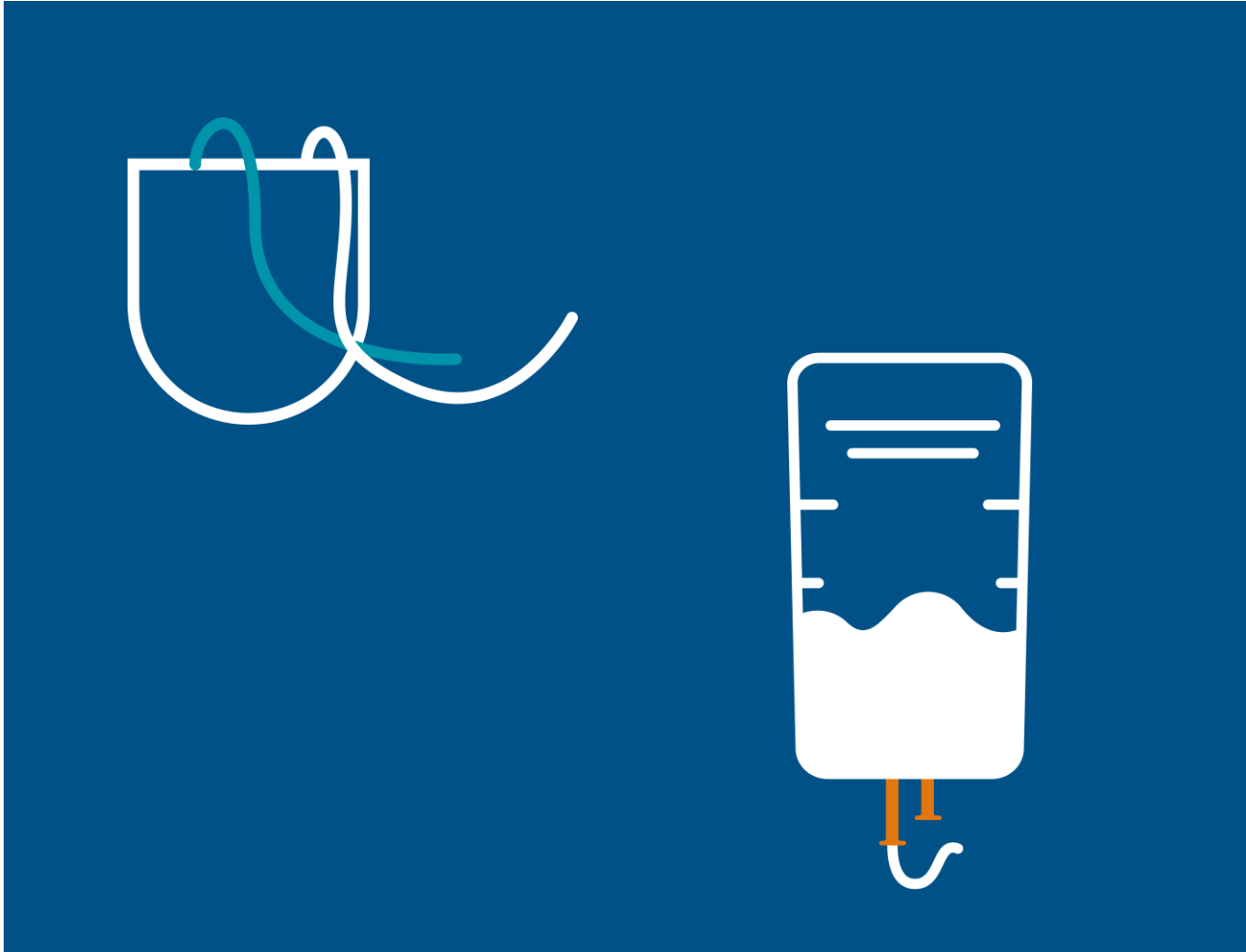


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# **Pioneers in the treatment of drug-resistant fluid overload**

liver disease, heart failure & cancer

Jefferies London Healthcare Conference

Ian Crosbie, CEO – 17 November 2022

Euronext: SEQUA.BR

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# Strongly 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**

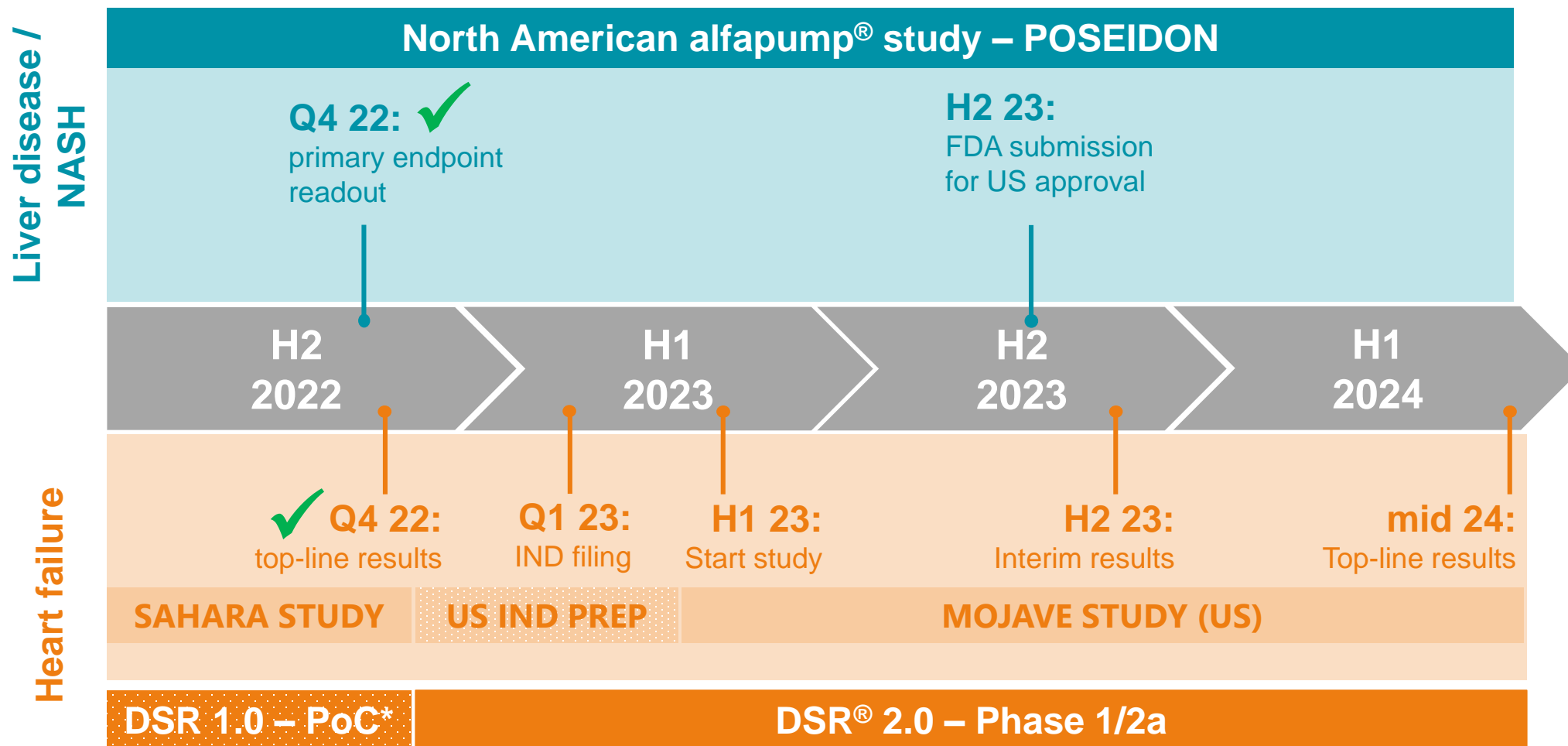


- **alfapump<sup>®</sup> in liver disease – market potential growing to over \$2 billion by 2032<sup>(1)</sup>**
  - NASH is changing liver cirrhosis market and driving growth
  - Approved in EU / FDA breakthrough designation in US
  - North American pivotal study – met all primary effectiveness endpoints with statistical significance and primary safety endpoint data in line with expectations
  - Direct commercialization in US through salesforce targeting liver transplant centres



- **DSR<sup>®</sup> in heart failure – multi-billion market opportunity**
  - Disease-modifying heart failure drug therapy
  - 1<sup>st</sup> generation DSR 1.0 – clinical proof-of-concept with durable clinical benefits
  - 2<sup>nd</sup> generation DSR 2.0 – strong IP, preparing US IND to start MOJAVE (Ph. 1/2a study in H1 '23)
  - Establish partnership based on MOJAVE readout

# 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



**alfapump<sup>®</sup>**

Proven step change in the treatment of liver  
refractory ascites



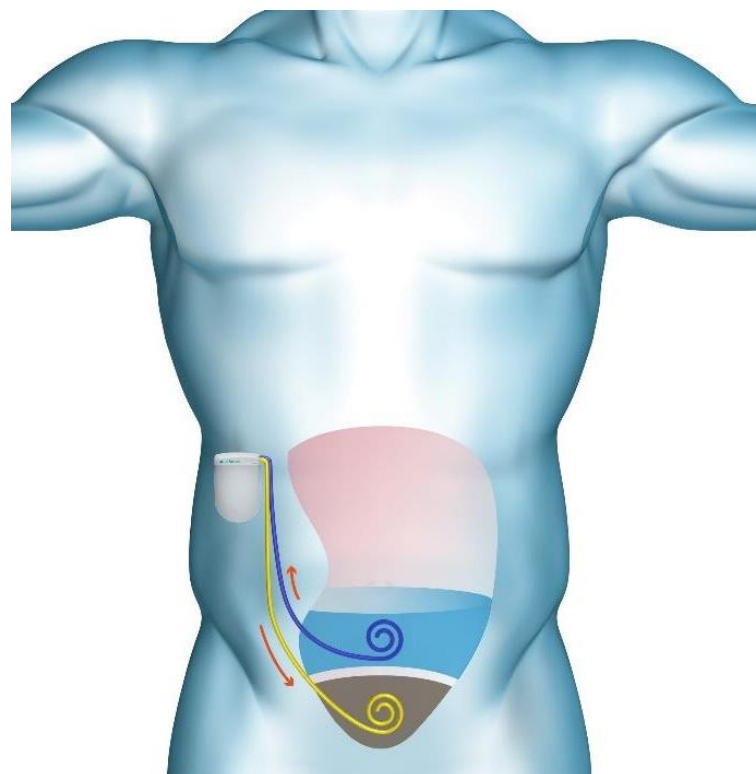
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# alfapump

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

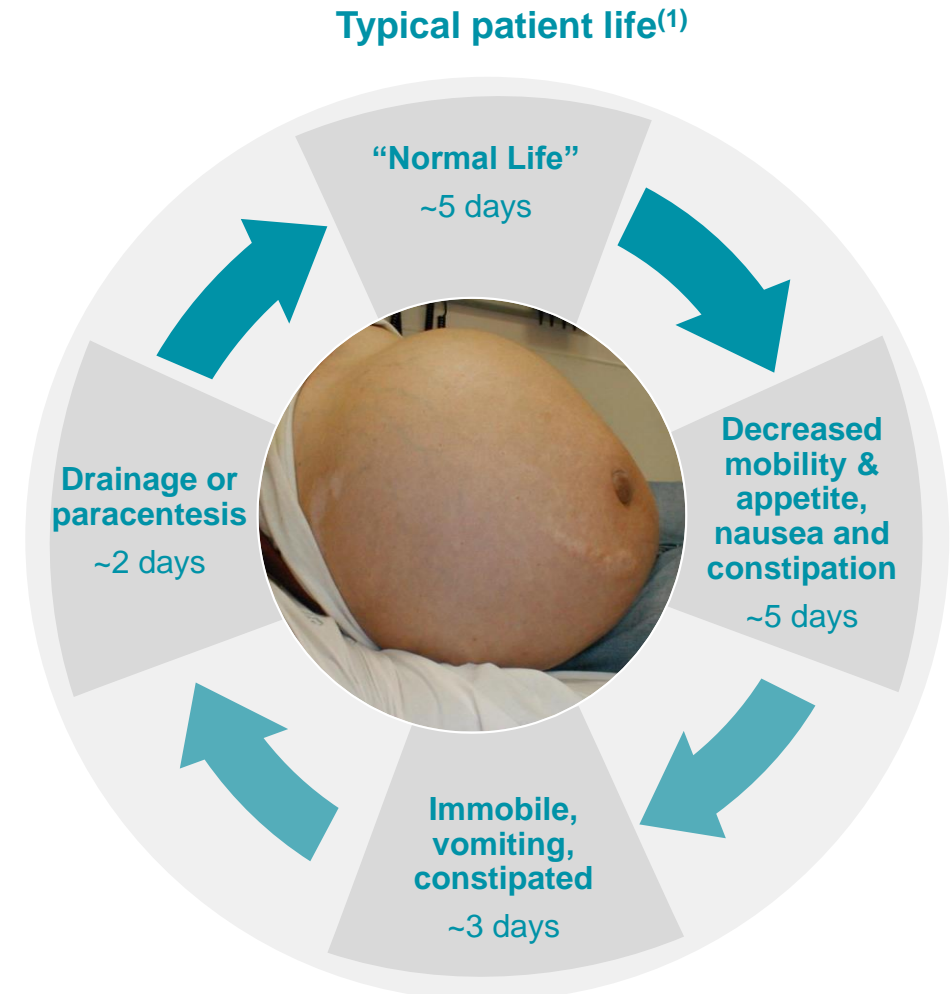
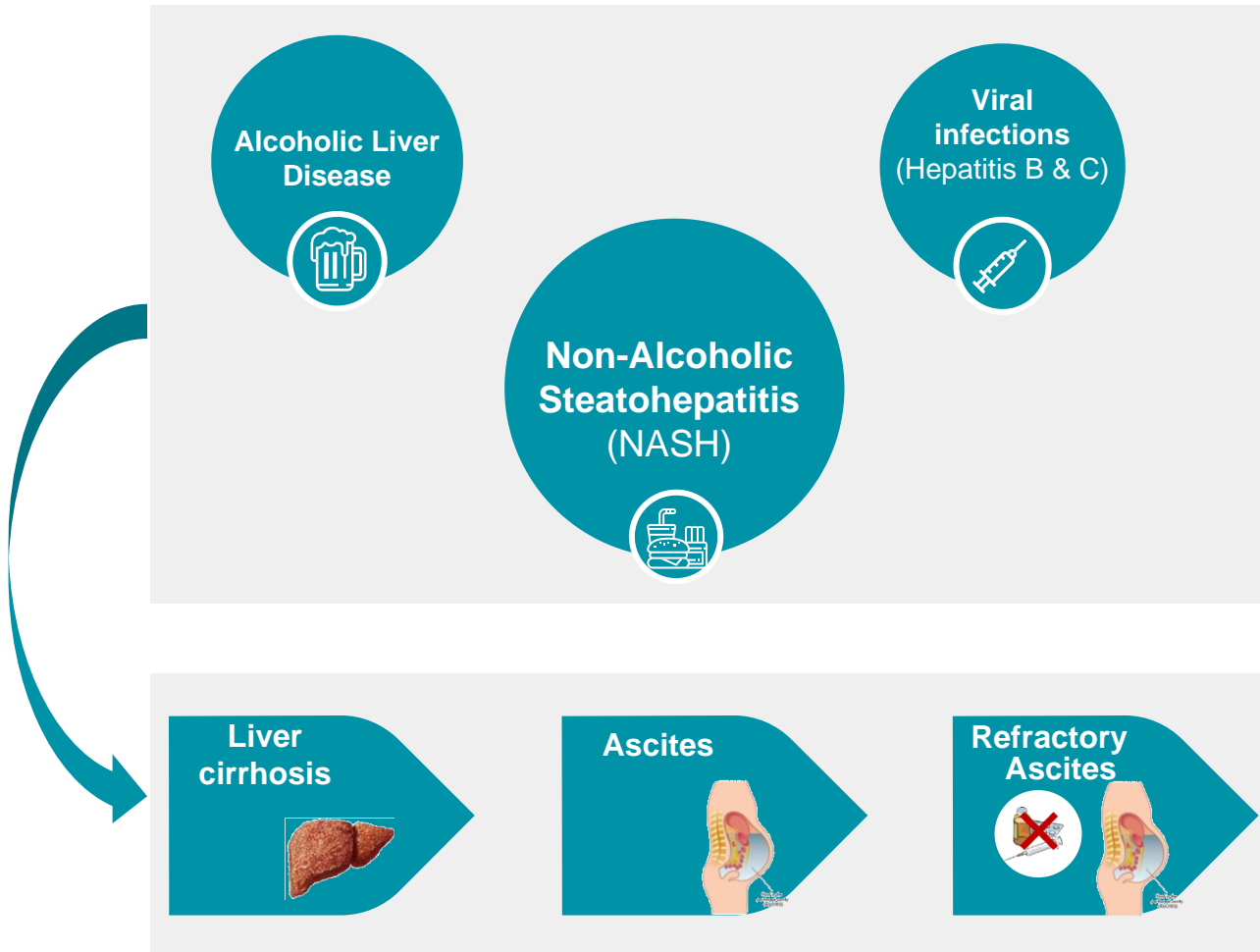


- ✓ Easy implantation
- ✓ Long-term implantation & catheter patency
- ✓ Moves up to 4 litres / day
- ✓ Virtually non-clogging
- ✓ No significant heating during charging and operation

***Proven capabilities – over 950 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



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

# 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 post- vs pre-implantation (p<0.001)
- **77% of patients** with at least 50% reduction in therapeutic paracentesis post- vs pre-implantation (p<0.001)

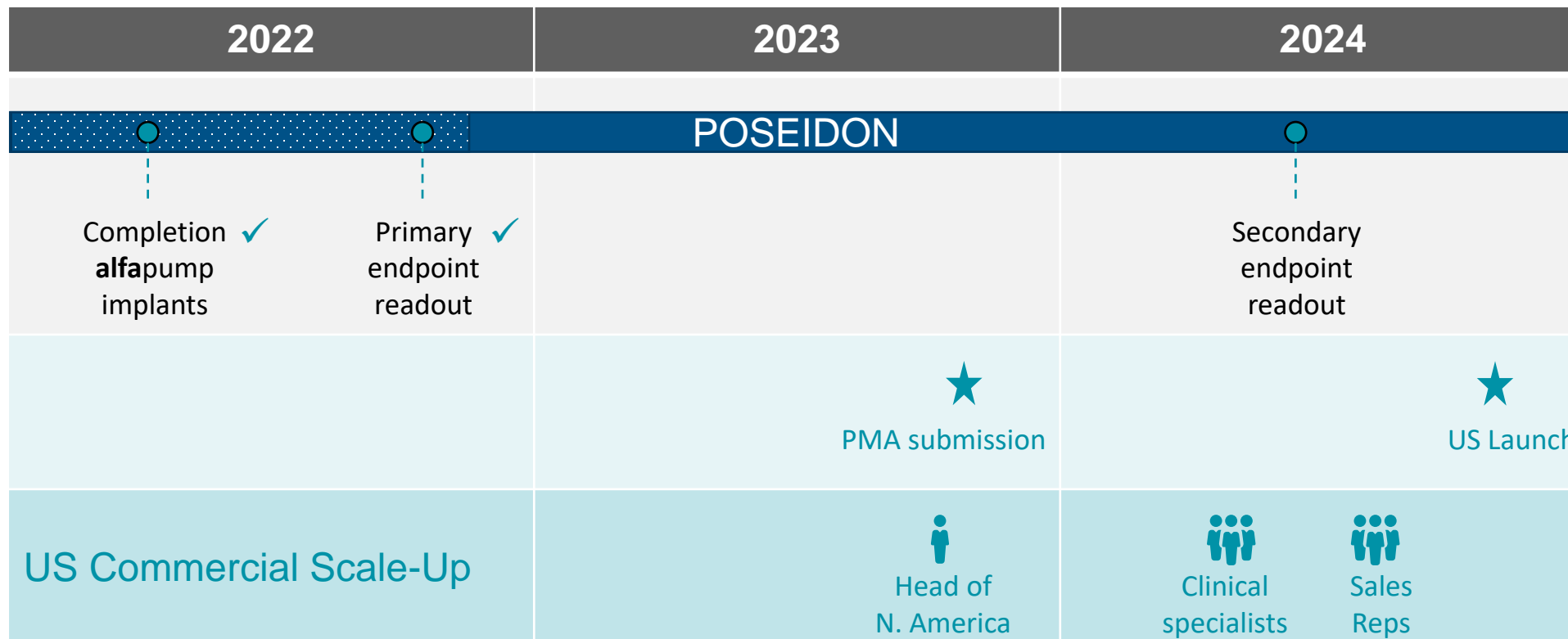
## Primary safety endpoint data in line with expectations

- 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*



# North American alfapump approval expected in 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*

# Large and growing North American patient population

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



- NASH is a key driver of growth, with alcohol continuing to play an important role
- Estimated incidence of 60%
- Market potential growing to **over \$2 billion by 2032\***
- US and Canada market assessment conducted by highly experienced international consulting group
  - Claims analysis for commercial and CMS patients requiring paracentesis procedure with liver disease diagnosis codes



\*Based on price of *alfapump*® of \$25K

# US – Go direct to 140 liver transplant centers

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



**DSR<sup>®</sup>**

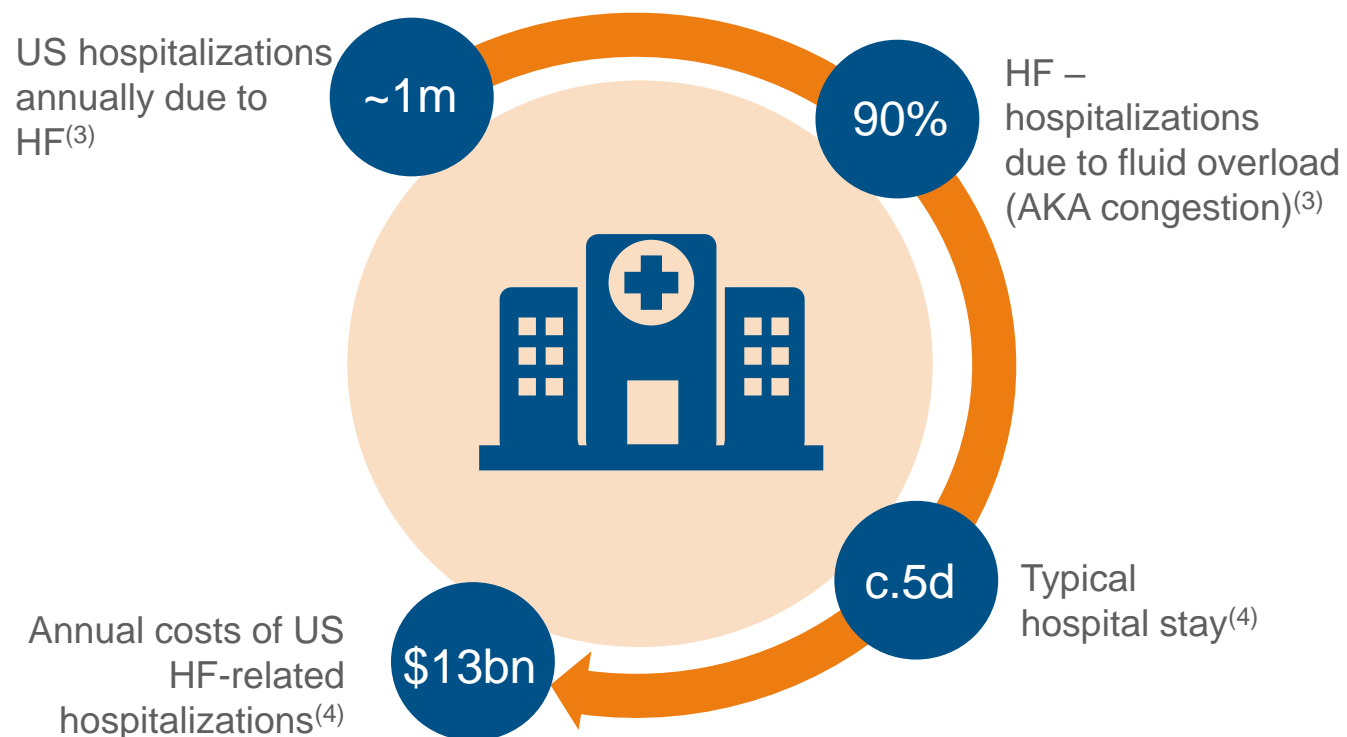
Disease-modifying heart failure drug therapy



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# Congestion is driver of morbidity and 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<sup>(1)</sup>*
- *24% re-admission rate at 30 days<sup>(2)</sup>*



# Direct Sodium Removal (DSR)

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

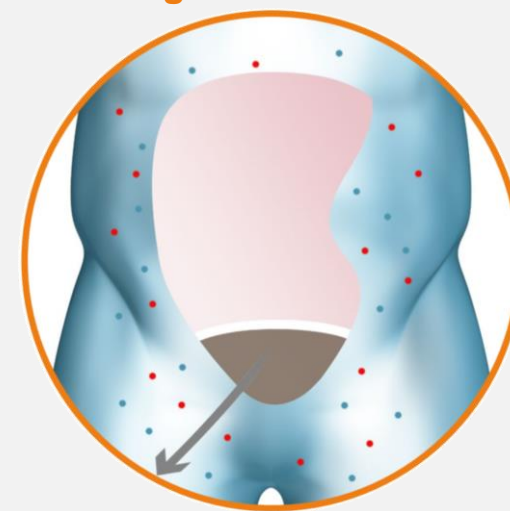
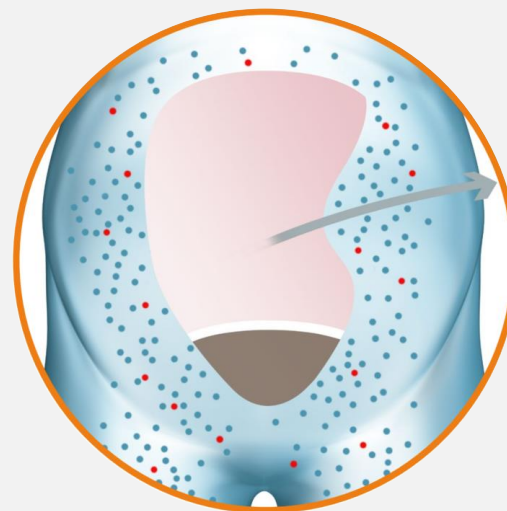
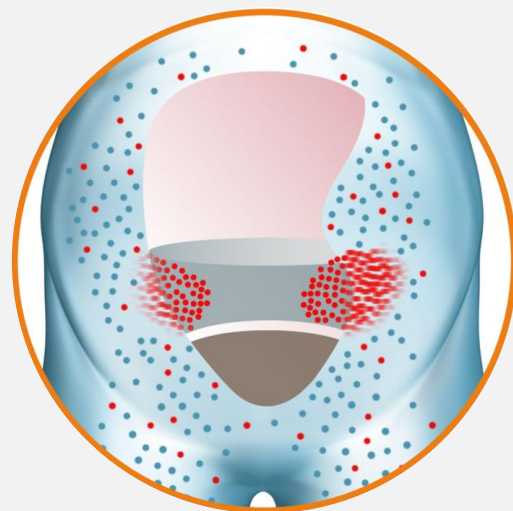
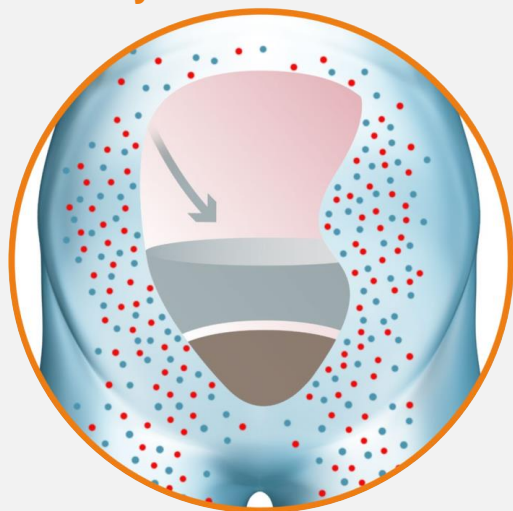


1 Sodium-free DSR product administered to peritoneal cavity

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*

# RED DESERT & SAHARA: Clinical Proof-of-Concept

8 euvolemic and 10 decompensated heart failure patients on high-dose loop diuretics treated with DSR

## 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 maintained for many months post-DSR therapy
- ✓ 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
- ✓ 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*

# Moving to proprietary DSR 2.0

Improved clinical and safety profile driving high margin recurring revenue stream

## DSR 1.0

### Sodium-free D10% (off-the-shelf)

- ✓ Clinical proof-of-concept
- ✓ Rapid clinical path
- ✗ Therapeutic profile / Ease of use
- ✗ Safety profile

**RED DESERT – SAHARA**



## DSR 2.0

### Sodium-free dextrose / icodextrin (proprietary)

- ✓ Improved therapeutic profile
- ✓ Favorable safety profile
- ✓ Strong granted IP position in US & Europe
  - “Low or no sodium drug for the treatment of heart failure”
  - Drives recurring revenue from high gross margin consumable
- First-in-human insights with single DSR treatment in up to 20 patients – safety and dosing
- Preparations US IND filing ongoing to start Phase 1/2a MOJAVE study in H1 2023

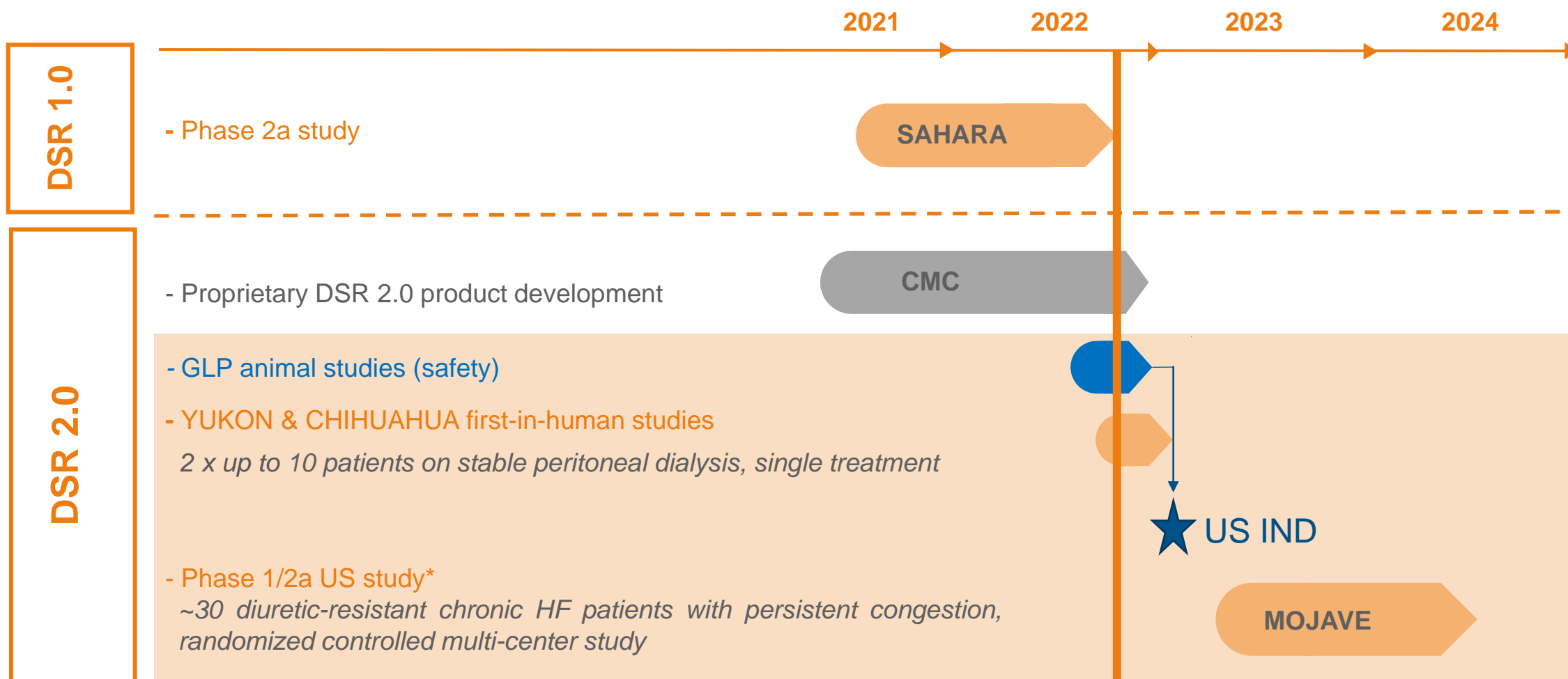
**YUKON – CHIHUAHUA – MOJAVE**





# MOJAVE as package for DSR partnering

Leveraging the strengths of established HF player to realise commercial potential of DSR



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

GLP: Good Laboratory Practice

# Multi-billion market opportunity

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 drug driven by:
  - ⇒ Reduction in re-hospitalization ~\$40K annual HF hospitalization cost per patient
  - ⇒ Increase in survival (gain in quality-adjusted life-year, “QALY”)

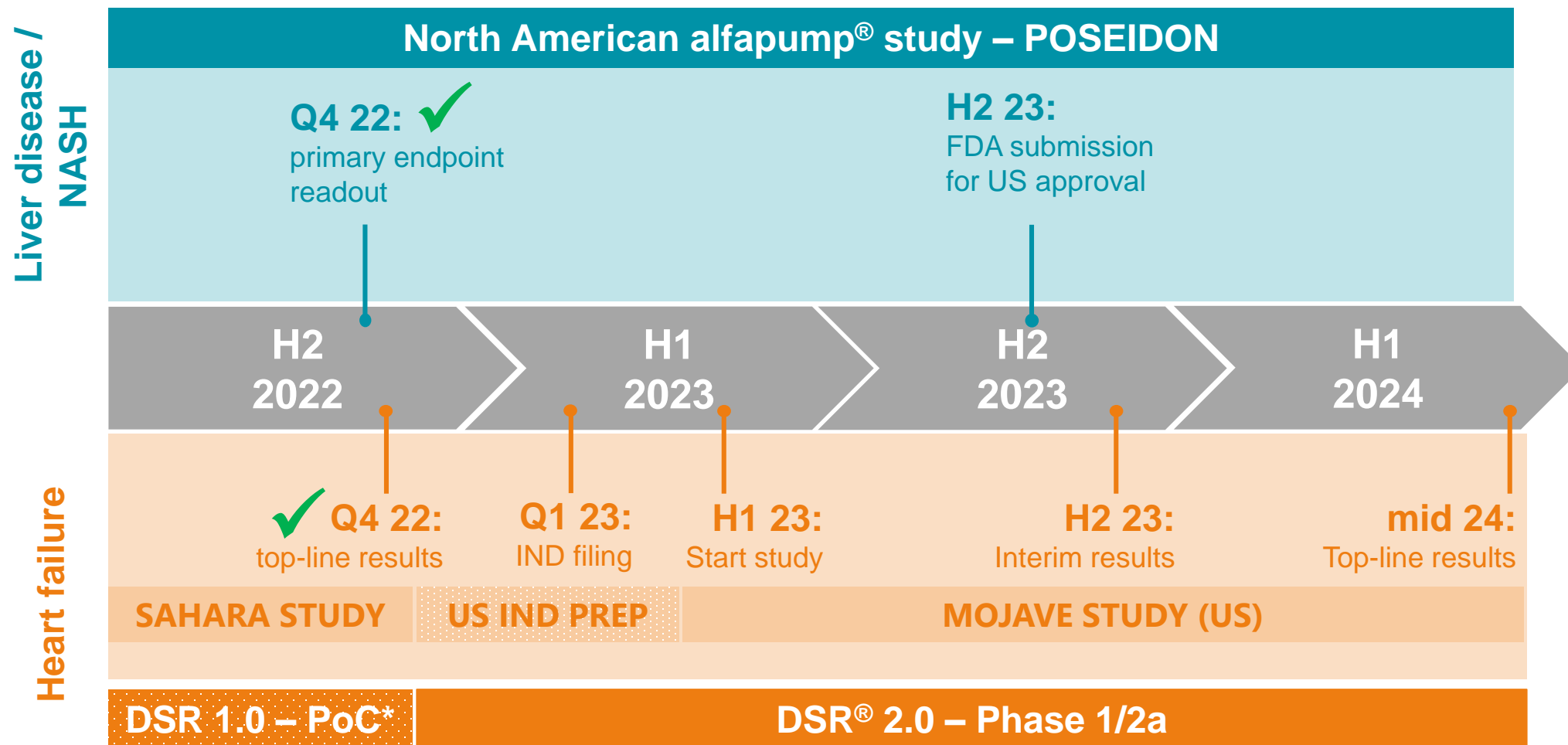


# Outlook

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

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**Thank You**

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