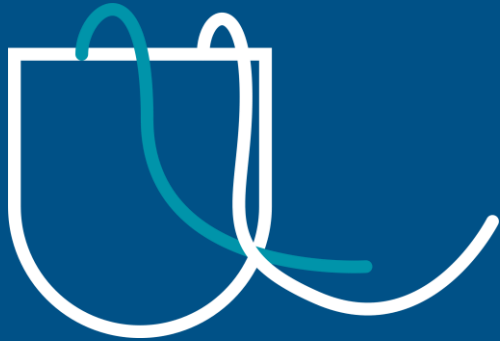


**sequana**medical



# **FY 2022 Financial Results & Business Update**

Webcast presentation – 9 February 2023

# Today's presenters



**Ian Crosbie**  
Chief Executive Officer



**Kirsten Van Bockstaele**  
Chief Financial Officer

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- Regulatory disclaimer:**
- The **alfapump**<sup>®</sup> 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**<sup>®</sup> system does not apply to the United States and Canada. In the United States and Canada, the **alfapump**<sup>®</sup> 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](http://www.poseidonstudy.com).
  - DSR<sup>®</sup> 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<sup>®</sup> therapy is currently not approved for clinical research in the United States or Canada. There is no link between DSR<sup>®</sup> therapy and ongoing investigations with the **alfapump**<sup>®</sup> 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:**
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# Strong progress in both programs

alfapump on track for PMA filing and DSR on track for start of MOJAVE, a US randomized controlled study

## alfapump<sup>®</sup> – US approval in liver disease expected in 2024



- ✓ Primary effectiveness endpoints of pivotal POSEIDON study substantially exceeding predefined thresholds for study success and safety in line with expectations
- ✓ Data from POSEIDON Roll-In Cohort presented at the AASLD - The Liver Meeting<sup>®</sup>
- ✓ Preparations for PMA ongoing; plan to submit to US FDA in H2 2023

## DSR<sup>®</sup> – clinical evidence of disease-modifying heart failure drug therapy



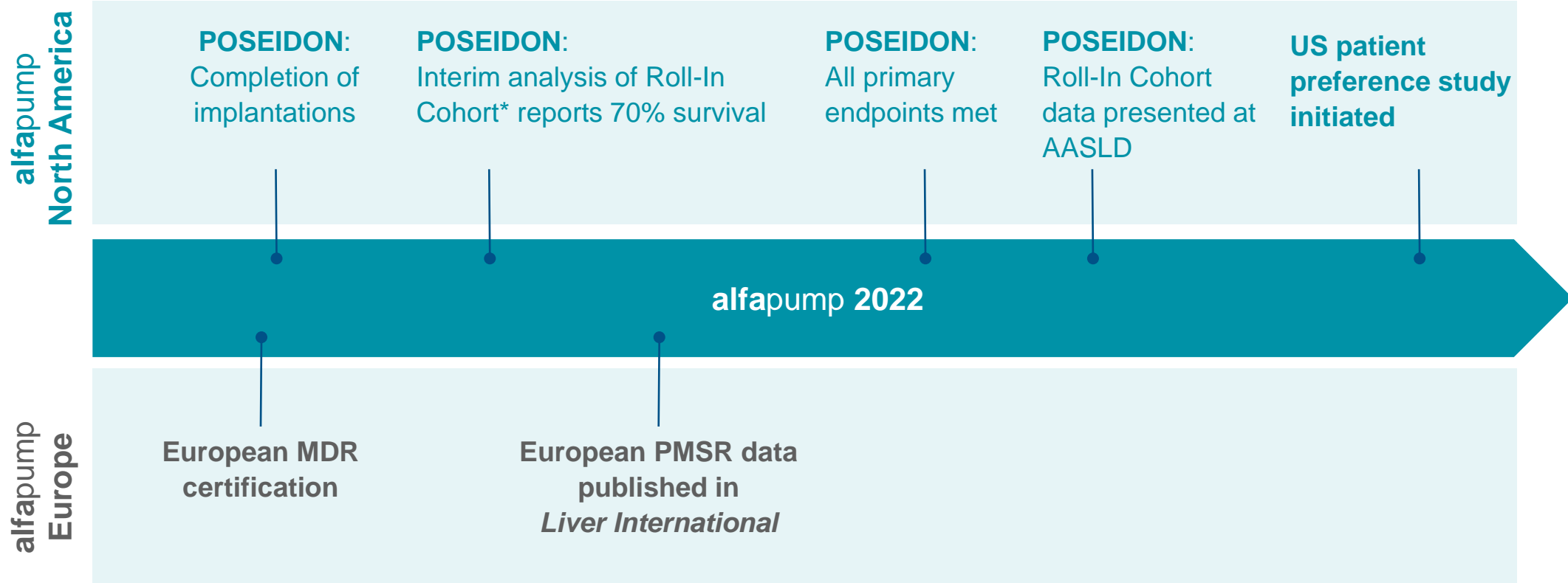
- ✓ Data from SAHARA Phase 2a study with DSR 1.0 show important and long-lasting clinical benefits
- ✓ No congestion related re-hospitalizations observed during study follow-up and 75% reduction in predicted one-year mortality based on Seattle Heart Failure model
- ✓ DSR 2.0 shows consistent safety as compared to the standard peritoneal dialysis solution in GLP animal studies
- ✓ Preparations for US IND filing of DSR 2.0 ongoing; plan to start US Phase 1/2a MOJAVE study in Q2 2023
- ✓ Additional DSR patent granted in the US covering the expansion of the composition of matter and method

## Total liquidity position of €18.9 million at end December 2022 and cash runway into mid-2023

- ✓ Equity placement of €28.4 million in March 2022
- ✓ €10 million drawdown of Kreos loan facility in September 2022



# FY '22 in Review: alfapump® in liver disease / NASH



\*Date of analysis 25 March 2022, as part of a general safety assessment

AASLD: American Association for the Study of Liver Diseases – The Liver Meeting®; MDR: Medical Device Regulation; PMSR: Post Marketing Surveillance Registry

# 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

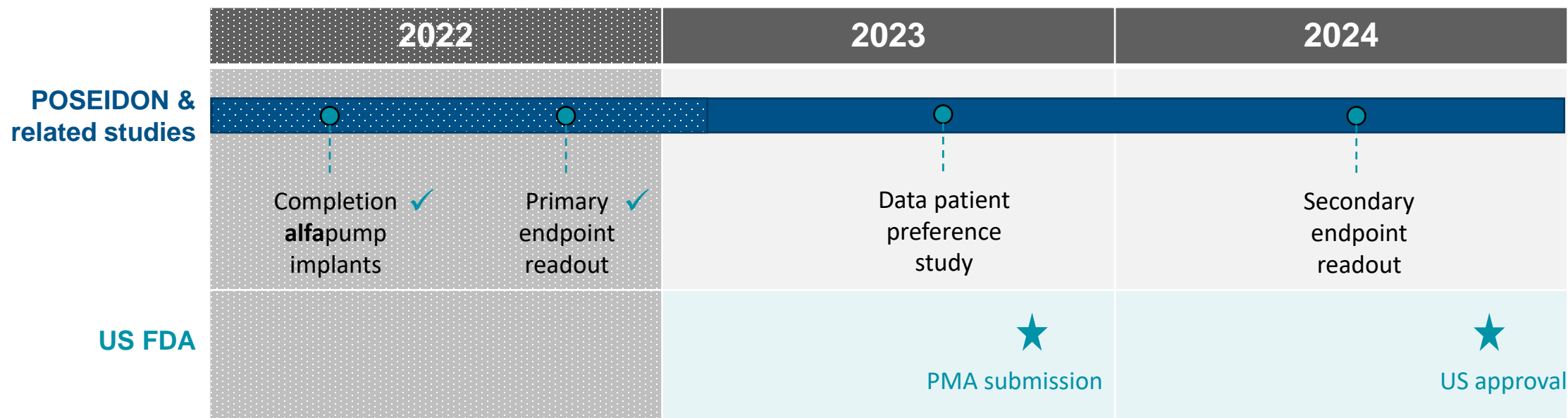
- **100%** median per-patient reduction in therapeutic paracentesis post- vs pre-implantation ( $p < 0.001$ ), vs hypothesis of at least a 50% reduction
- **77% of patients** with at least 50% reduction in therapeutic paracentesis post- vs pre-implantation ( $p < 0.001$ ), vs hypothesis of at least 50%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

# 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

North American patients with recurrent or refractory ascites due to liver cirrhosis

Over 75,000

2025

6 – 7% annually

Over 170,000

2035

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

*\*Based on incidence rate of 60% and **alfapump** price of \$25K*

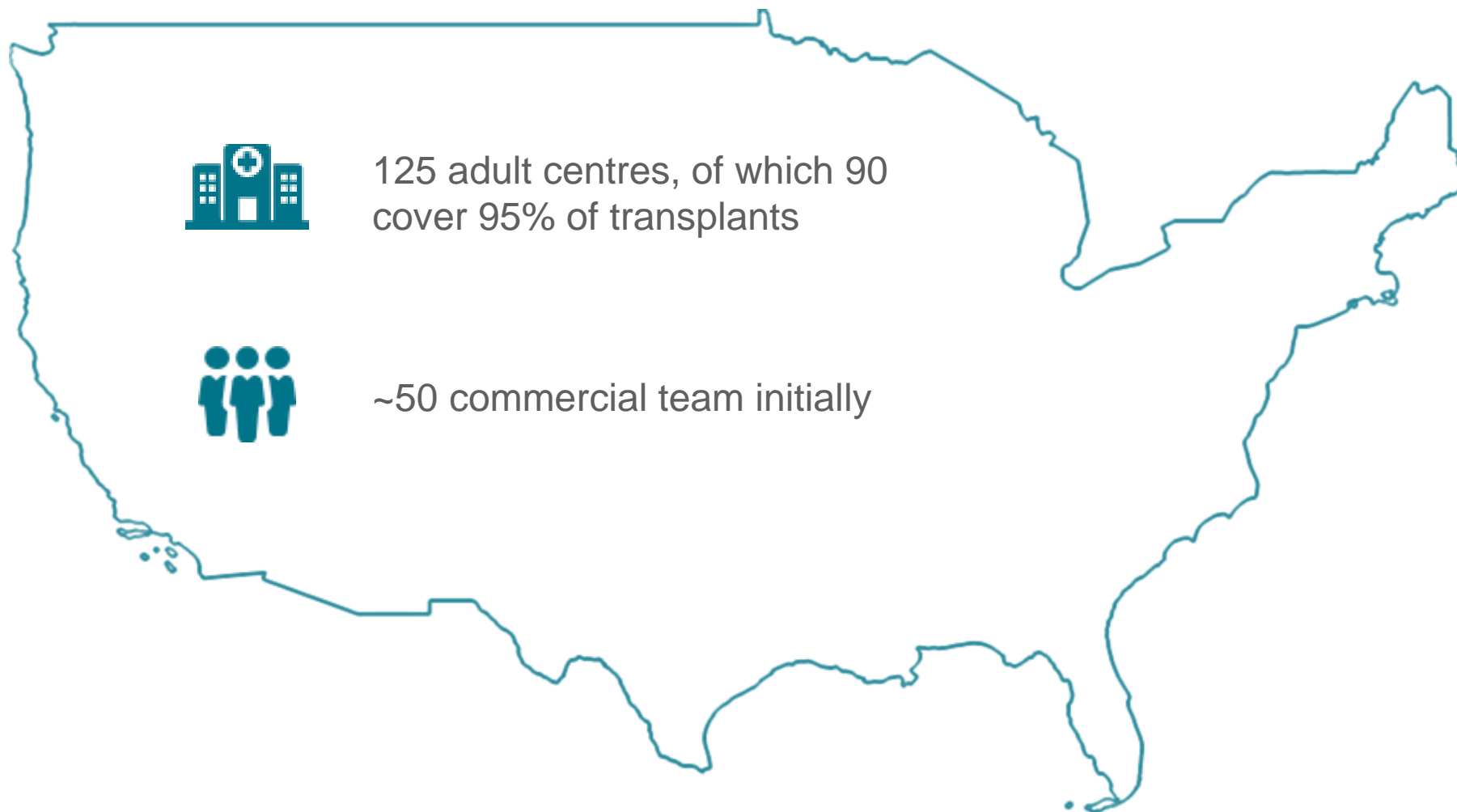
*Source: Based on US and Canada market assessment conducted by highly experienced international consulting group, using claims analysis for commercial and CMS patients requiring paracentesis procedure with liver disease diagnosis codes*

**CMS:** Center for Medicare and Medicaid Services



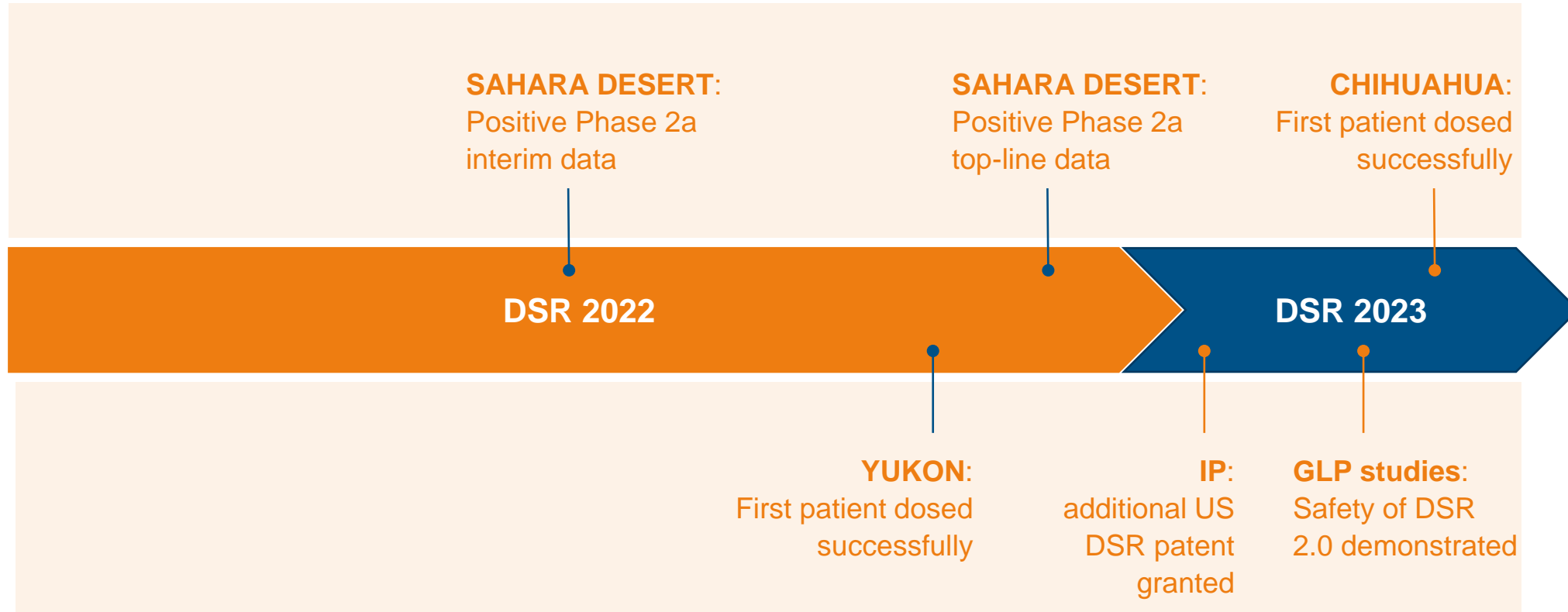
# US – Go direct to 90 liver transplant centers

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





# FY '22 and YTD '23 in Review: DSR<sup>®</sup> in heart failure



# 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 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*

# DSR 2.0 has improved therapeutic and safety profile

Strong granted IP drives 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)

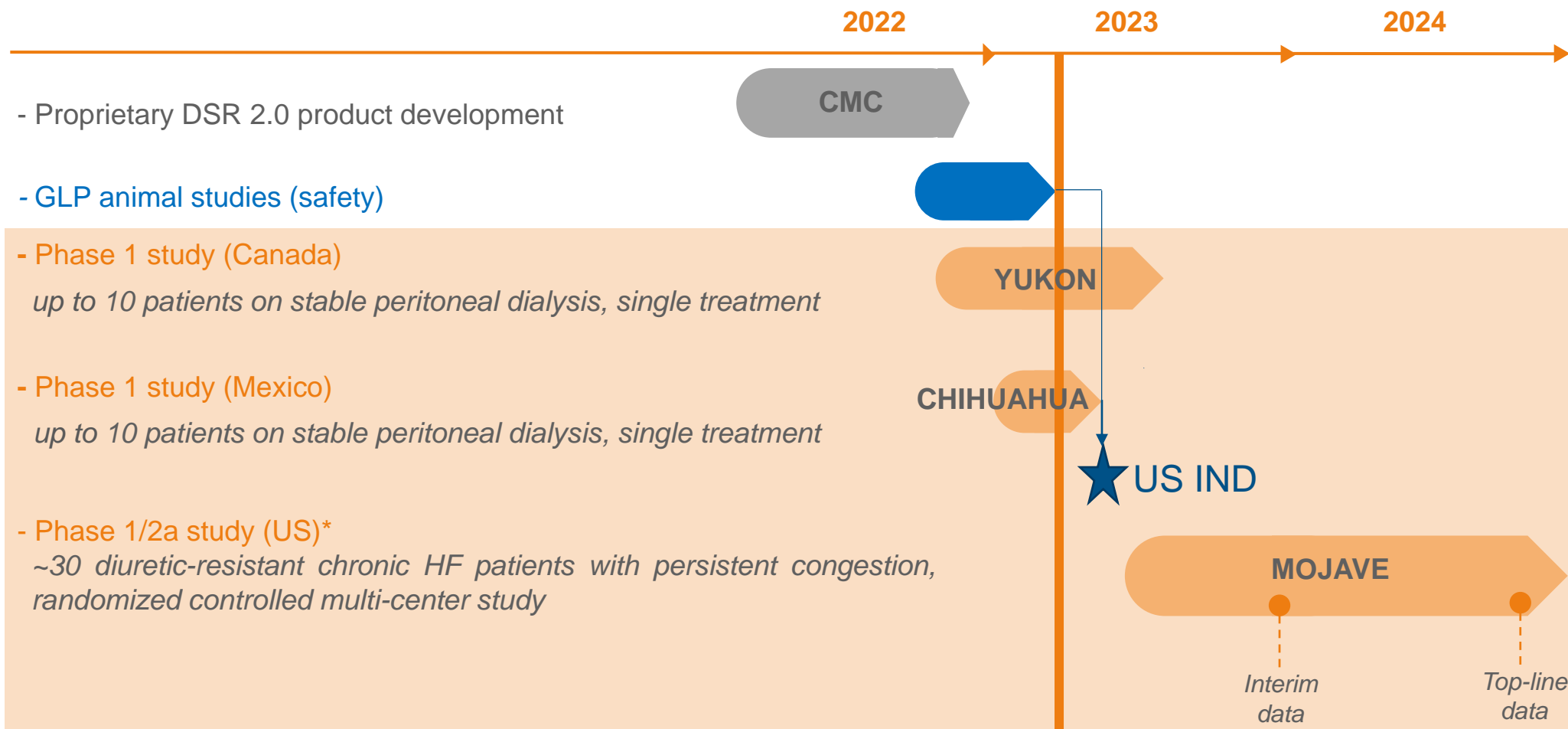
- ✓ Improved therapeutic profile
- ✓ Favorable safety profile
- ✓ Strong granted IP position in US & Europe
  - “Low or no sodium drug for the treatment of heart failure”
  - Drives recurring revenue from high gross margin consumable
- ✓ No difference in systemic and local toxic effects observed in animals treated repeatedly with DSR 2.0, compared to standard PD solution
  - 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 Q2 '23

**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

# 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”)

# Key financial results FY 2022

Cash runway into mid-2023

**Revenue: €923K**

- Resumed commercial activity in Europe as the impact of COVID declines

**Operating expenses: - €29.3M**

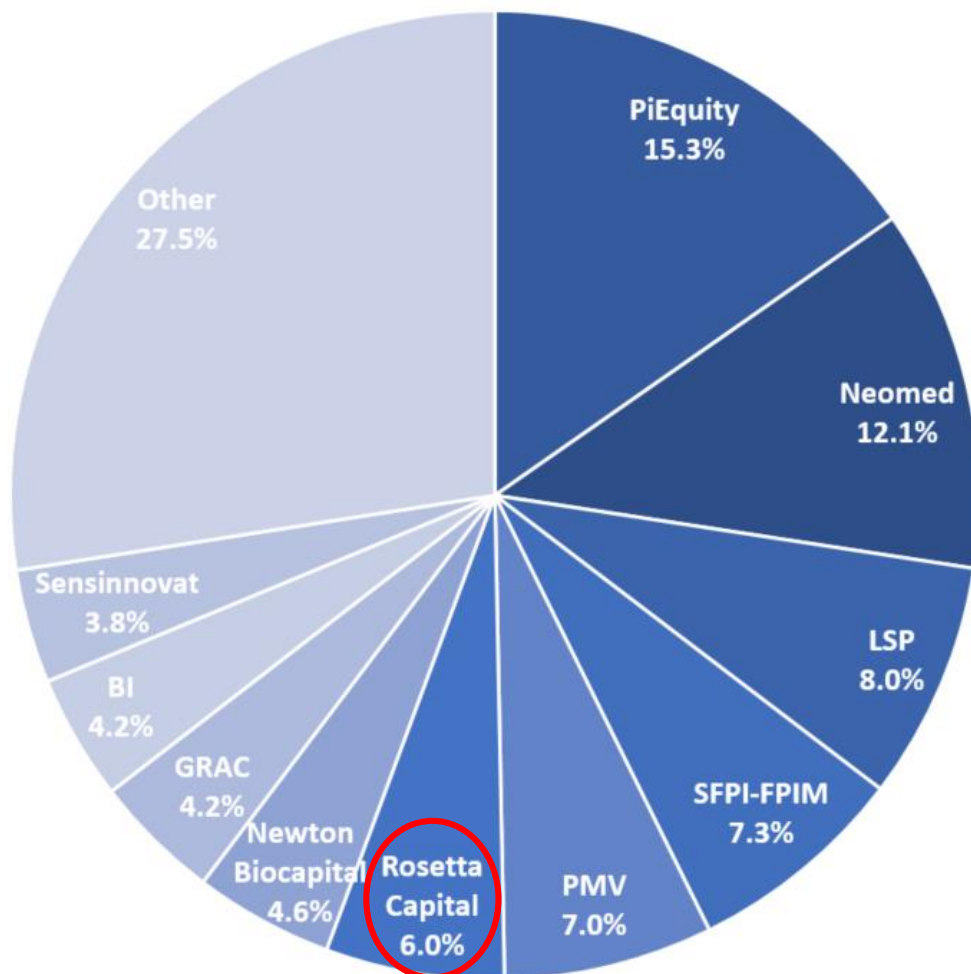
- Preparation of submissions for marketing approval in US and Canada
- Pre-clinical and clinical development of proprietary DSR therapy

**Net result: - €30.8M**

**Cash position of €18.9M at December 31, 2022**

# Shareholder base

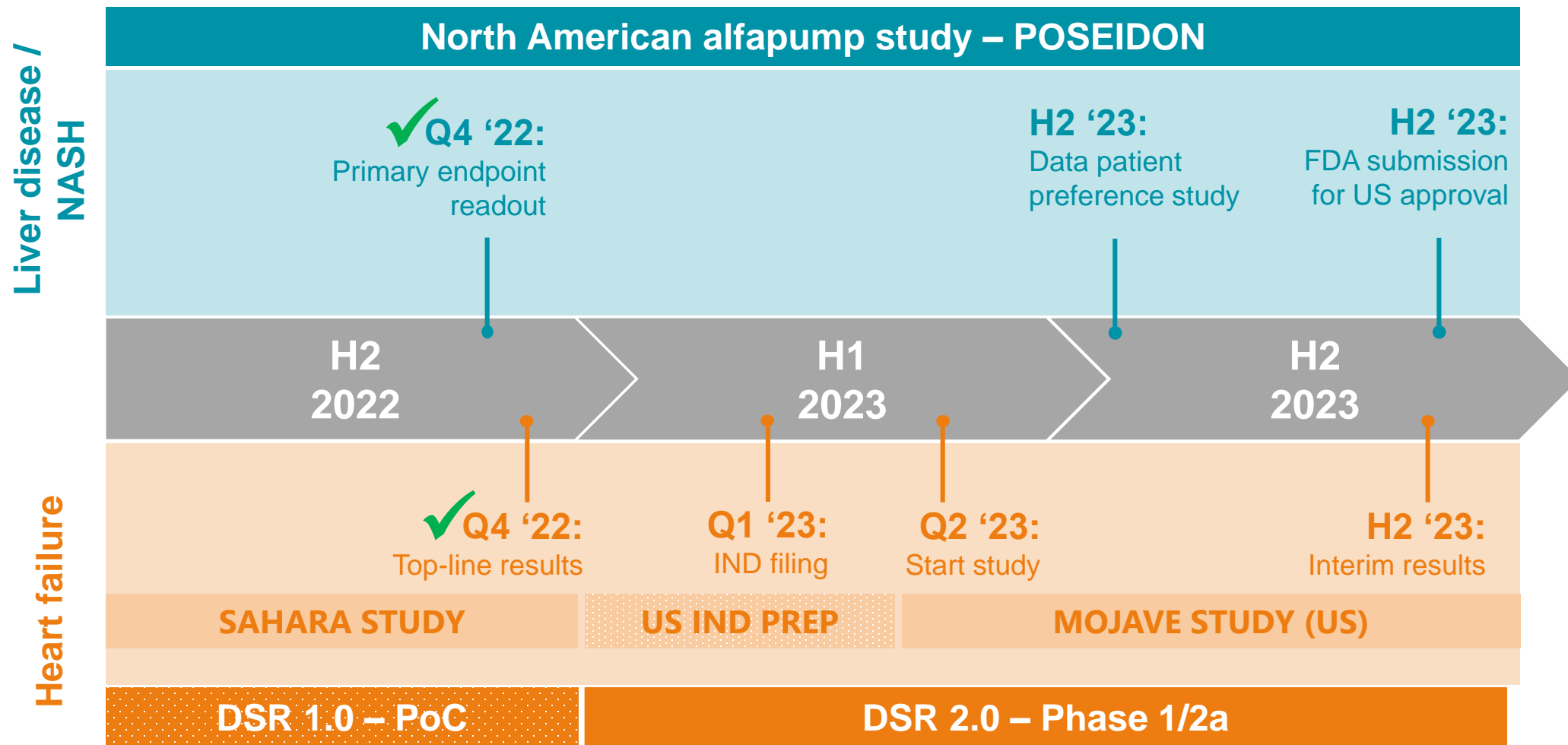
Share transfer from Neomed V to Rosetta Capital, a long-term life sciences shareholder



- Outstanding shares: 23.7M
- Outstanding shares corresponding to outstanding share options: 2.7M



# 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

# Q&A

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