

Pioneers in the treatment of fluid overload

Liver disease, Heart failure & Cancer

Investor presentation – March 2023

Euronext: SEQUA.BR

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Regulatory disclaimer:

- 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.

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:

- alfapump**® is a registered trademark. DSR® and **alfapump** 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**

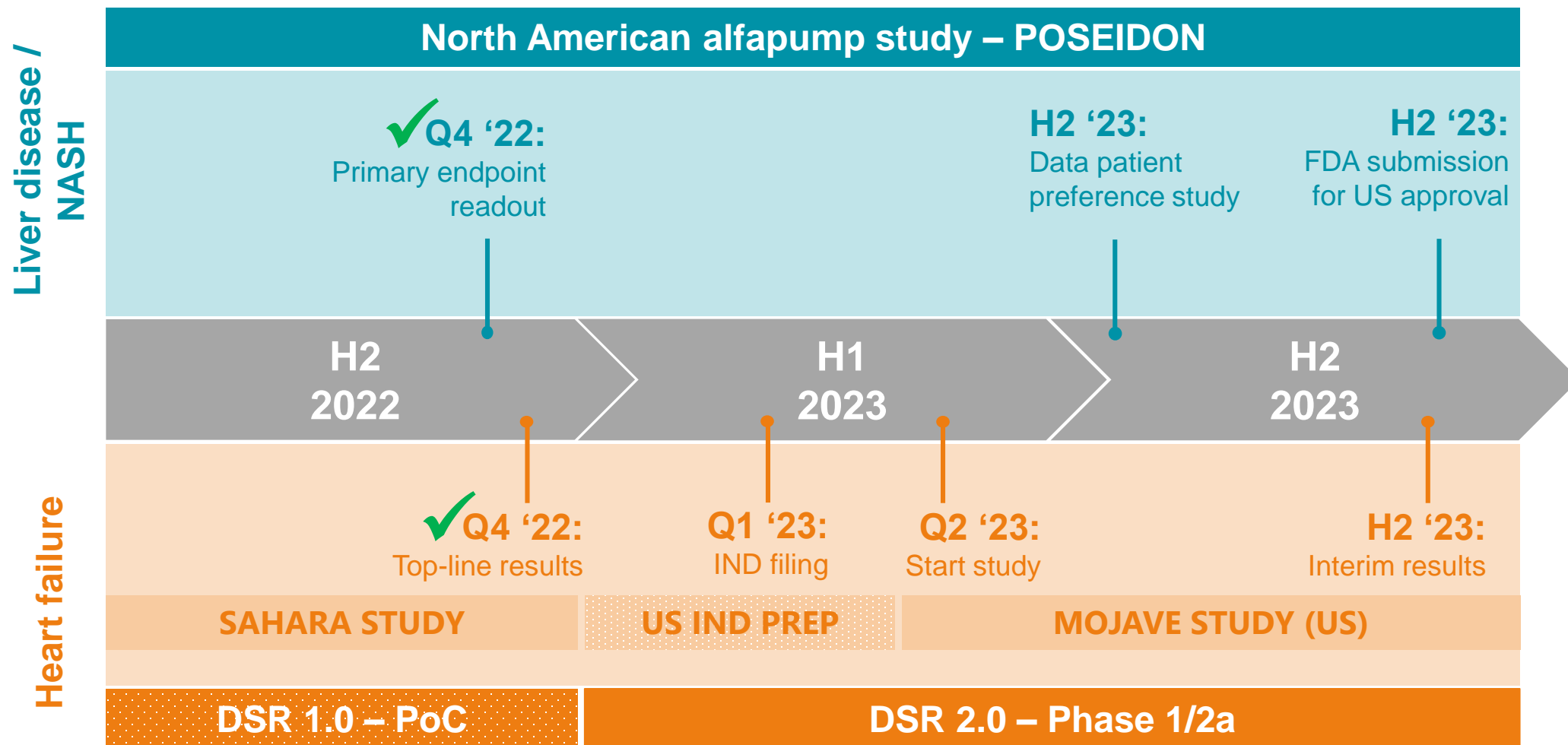


- **alfapump® in liver disease – market potential growing to over \$2.5 billion by 2035⁽¹⁾**
 - Approved in EU / FDA breakthrough designation in US
 - North American pivotal POSEIDON study – all primary endpoints successfully met
 - PMA filing to US FDA planned for H2 '23
 - Direct commercialization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

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[®]

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



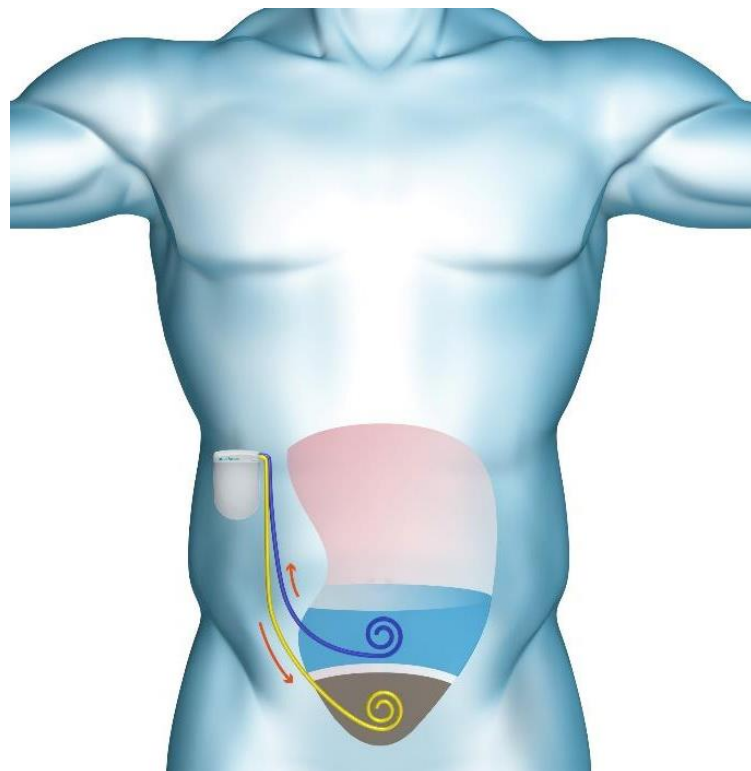
Wireless battery charging



Settings wirelessly adjusted



Remote data monitoring



Easy implantation



Long-term implantation & catheter patency



Moves up to 4 litres / day



Virtually non-clogging

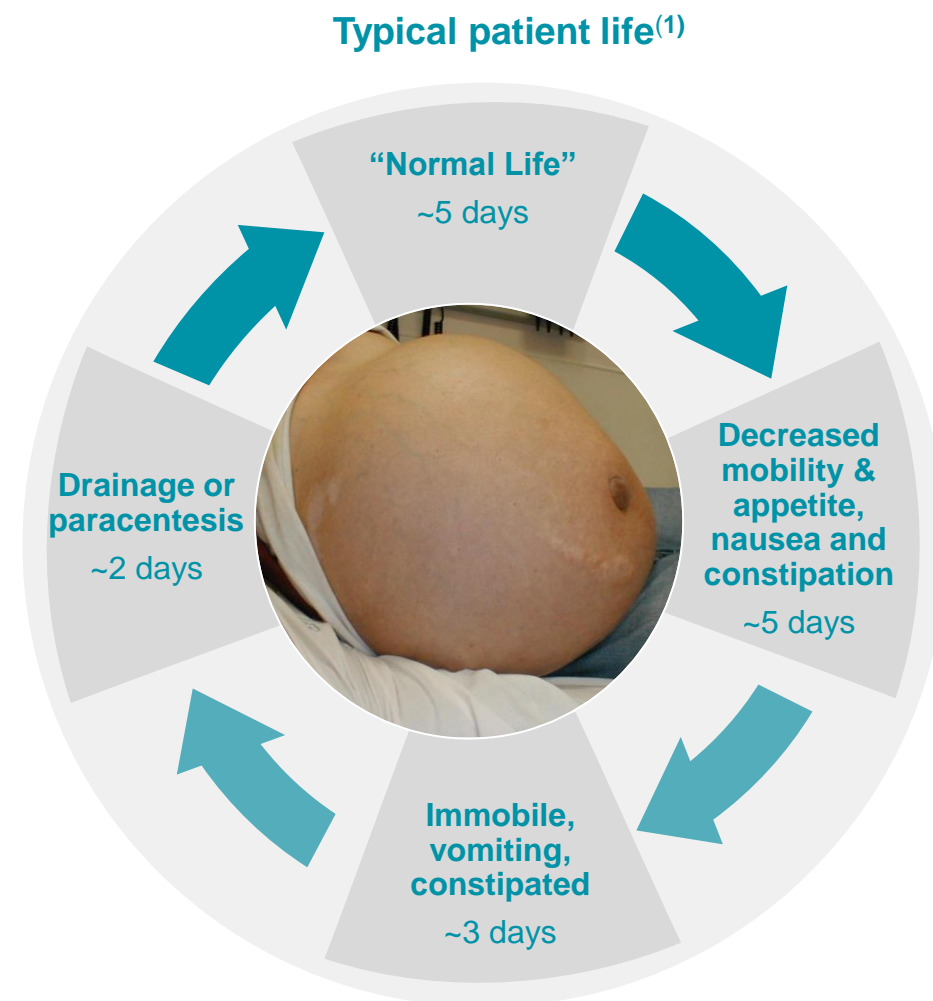
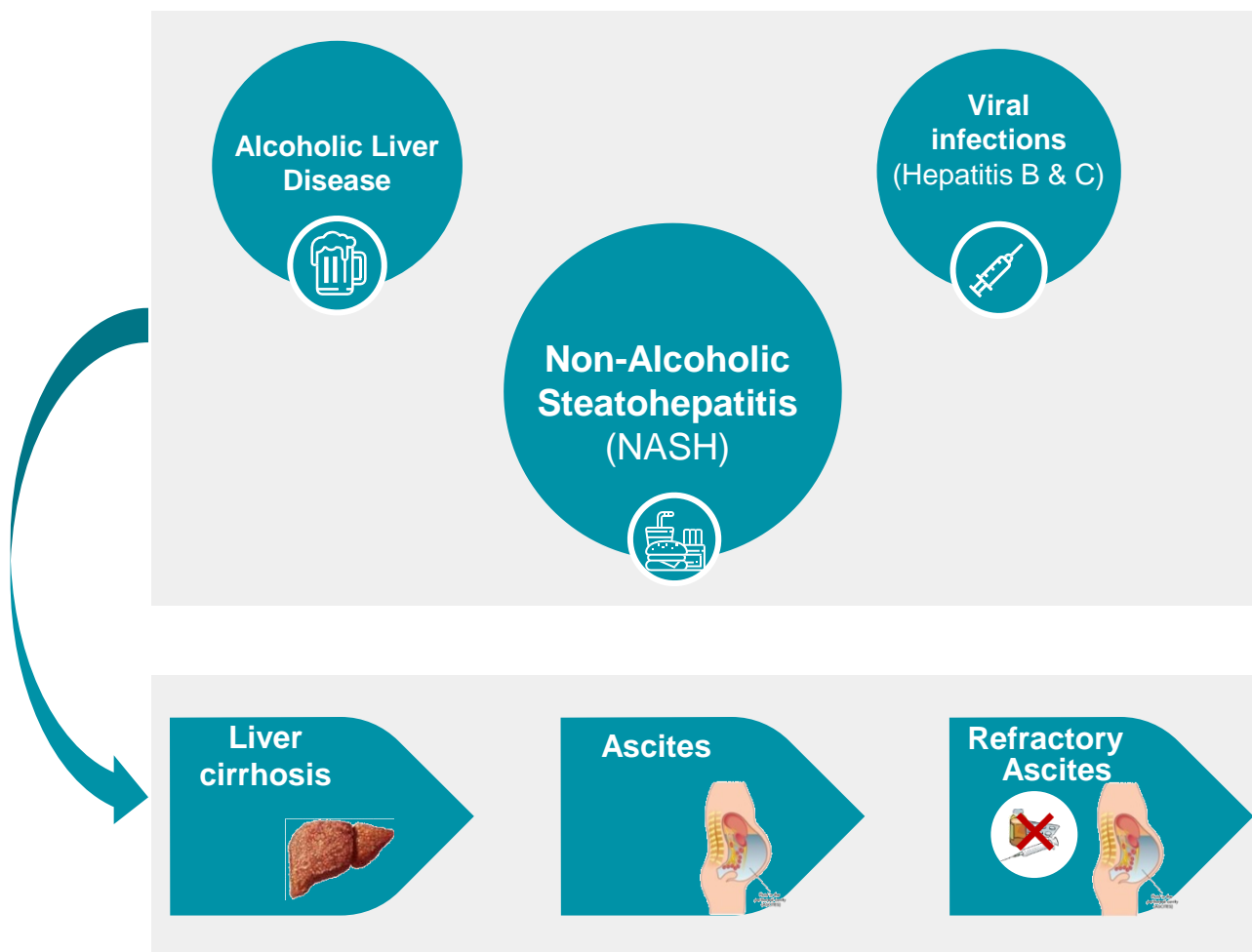


No significant heating during charging and operation

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

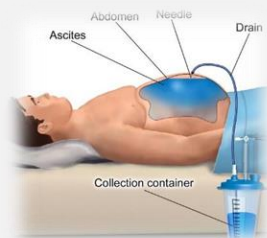
Refractory ascites – key complication of liver cirrhosis

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



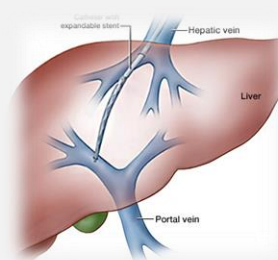
Limitations of existing therapies

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



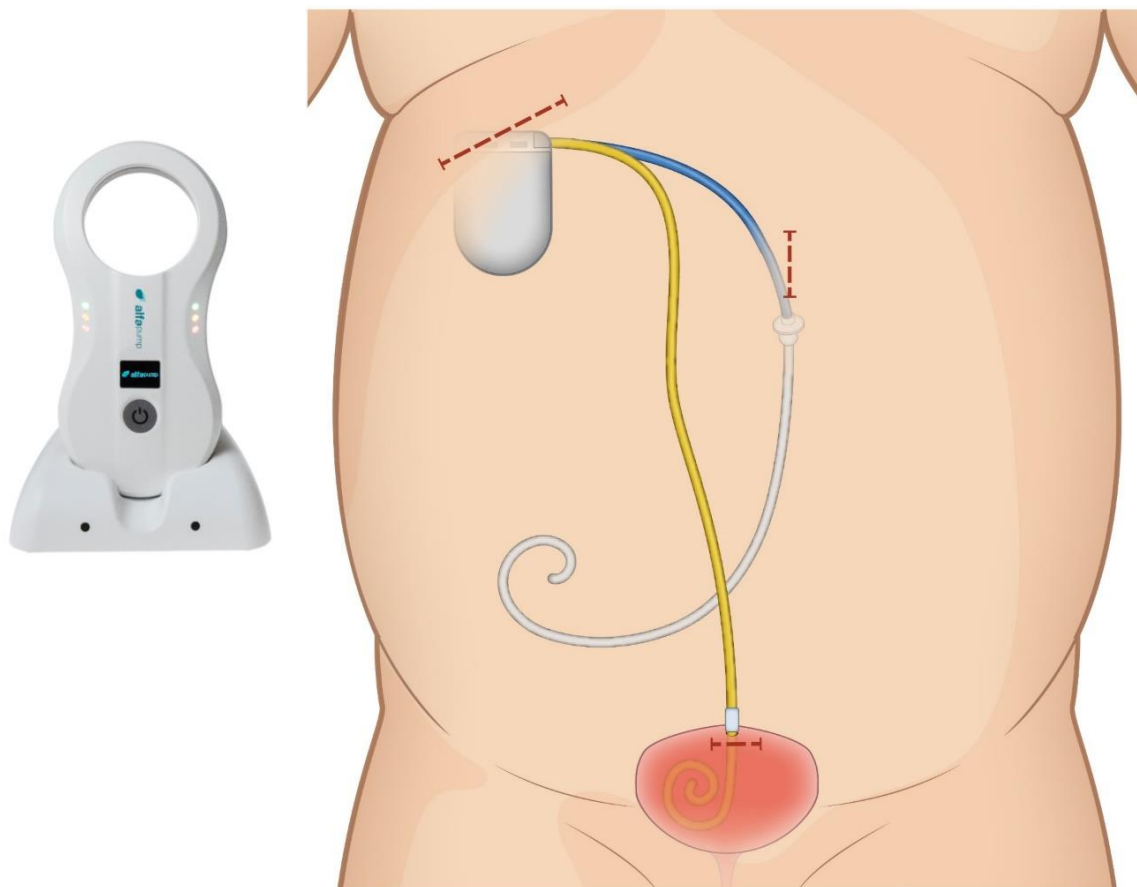
High Cost, Limited Availability

alfapump



alfapump strong clinical and economic rationale

Over 950 implants and hundreds of years of patient experience



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

Estimated treatment cost / patient*:

LVP: ~\$66K



alfapump: ~\$37K



**Breakthrough Device
Designation**

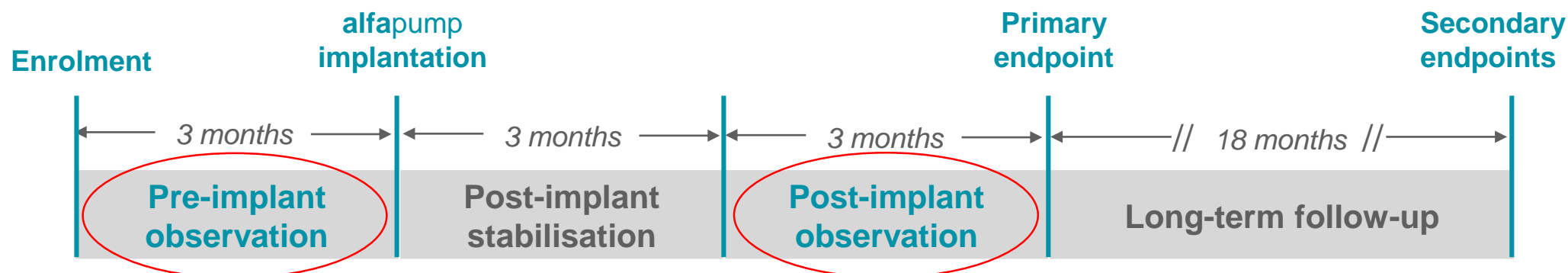


NICE
National Institute for
Health and Care Excellence



POSEIDON – North American pivotal study

Pivotal Cohort of 40 patients implanted with the alfapump



POSEIDON primary effectiveness endpoint hypotheses:

- 1) median per-patient ratio of post-implant three-month observation period to the pre-implant three-month observation period with respect to number of therapeutic paracentesis (TP) is less than 0.5 (or a median reduction of at least 50%)
- 2) at least 50% of patients achieve a 50% reduction in the requirement for TP in the same period

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 **alfapump**, 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 **alfapump** procedure*
- ✓ NTAP for breakthrough devices provides additional 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

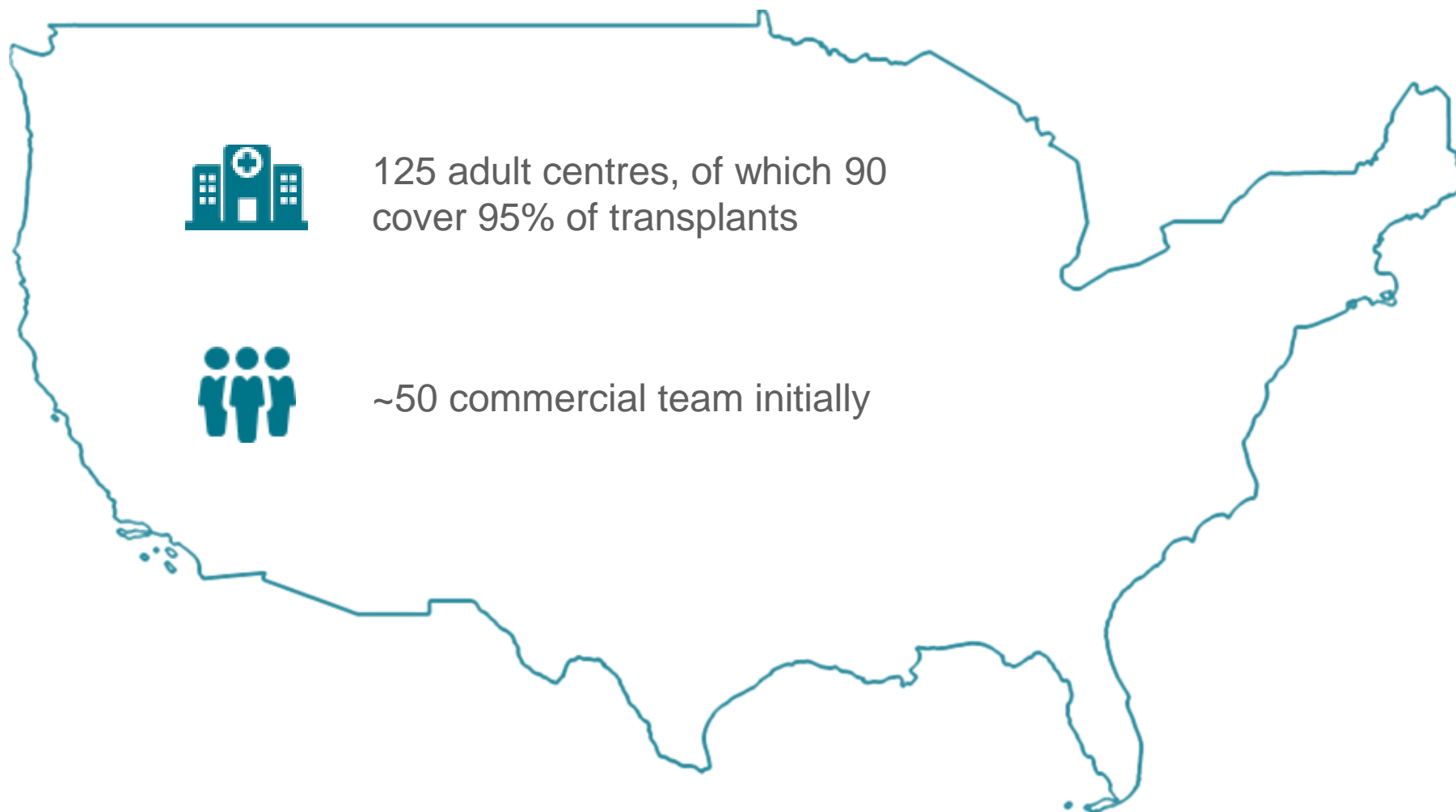
Over
170,000

2035

Market potential growing to over \$2.5 billion by 2035

US – Go direct to 90 liver transplant centers

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



DSR®

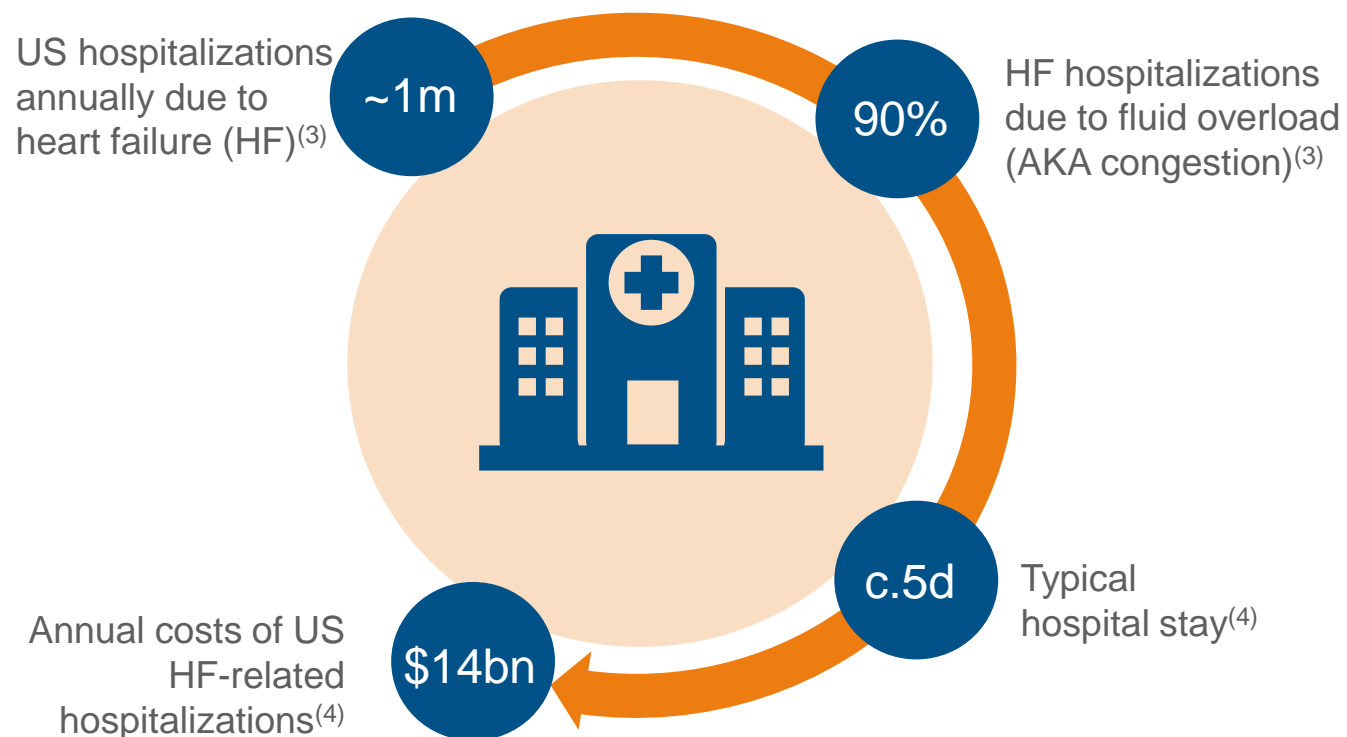
Disease-modifying heart failure drug therapy



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Congestion is key driver of morbidity & hospitalization

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

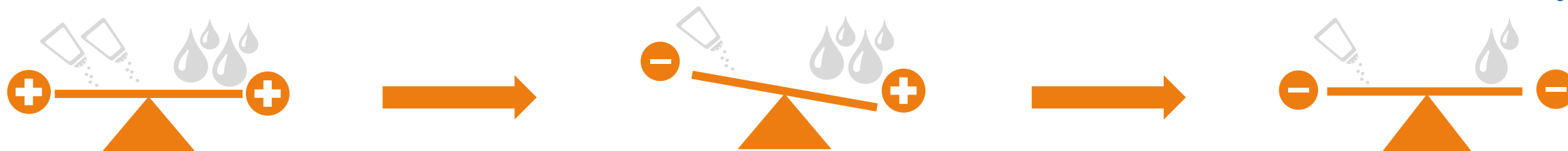


- *40% of heart failure patients on IV loop diuretics have a poor response⁽¹⁾*
- *24% re-admission rate at 30 days⁽²⁾*

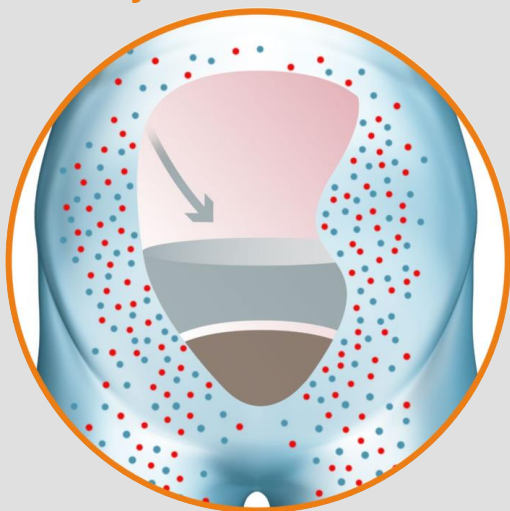


Direct Sodium Removal (DSR)

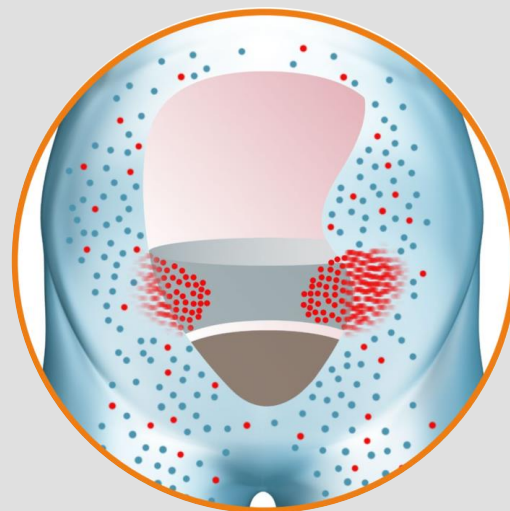
Eliminating fluid spread across the body – working in partnership with the kidneys



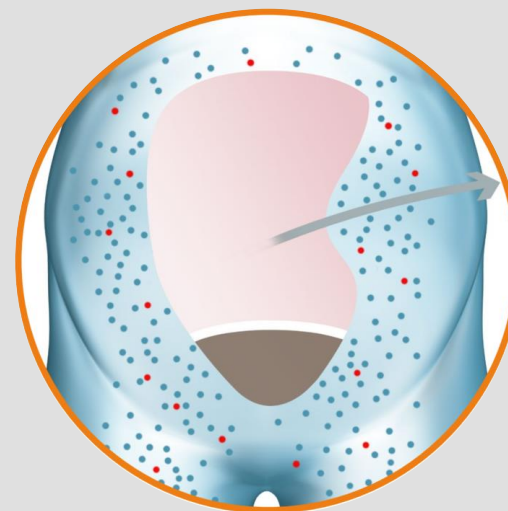
- 1 Sodium-free DSR product administered to peritoneal cavity



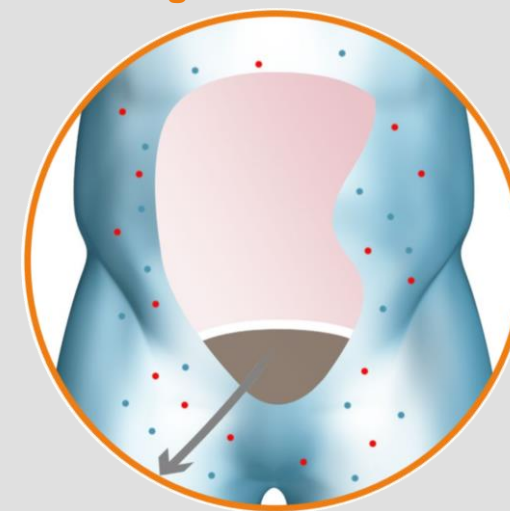
- 2 Sodium diffuses from body into DSR product



- 3 DSR product + extracted sodium removed from body



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



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

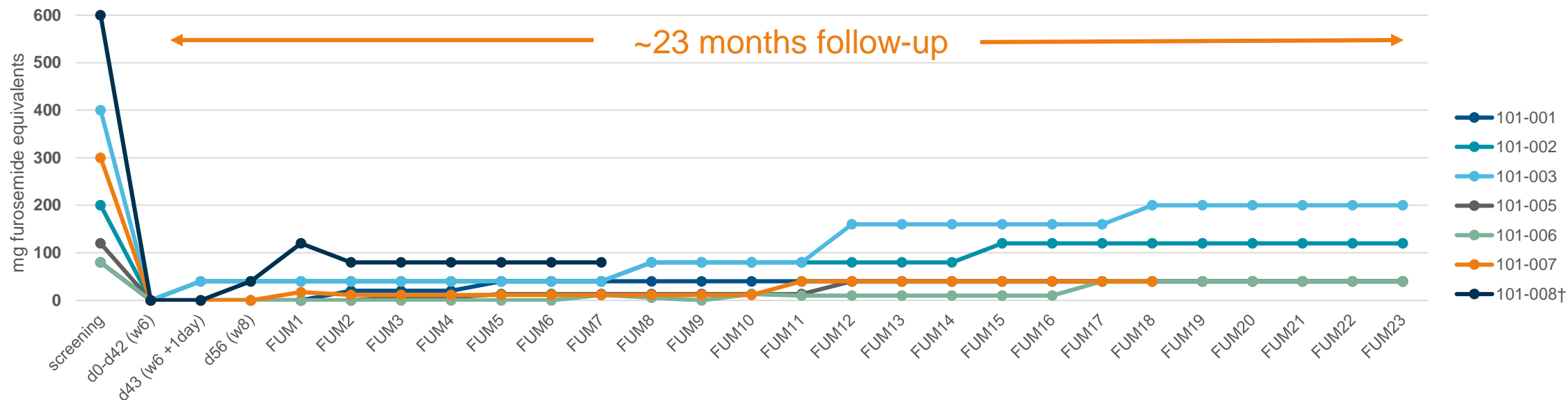
- ✓ No congestion-related heart failure re-hospitalizations
- ✓ Long-term and major reduction in loop diuretic dosing post-DSR therapy
- ✓ One class improvement of NYHA status
- ✓ Over 75% reduction in predicted one-year mortality based on Seattle Heart Failure Model

“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

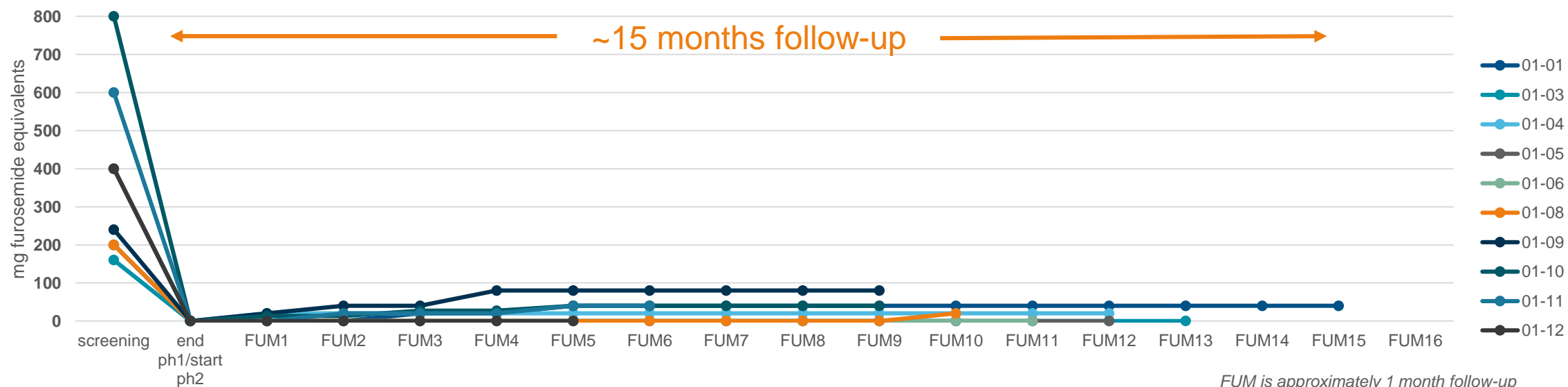
Long-term & major reduction in loop diuretic dosing

Clear demonstration of improvement in cardio-renal health – driving improved clinical outcomes

RED DESERT



SAHARA



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)

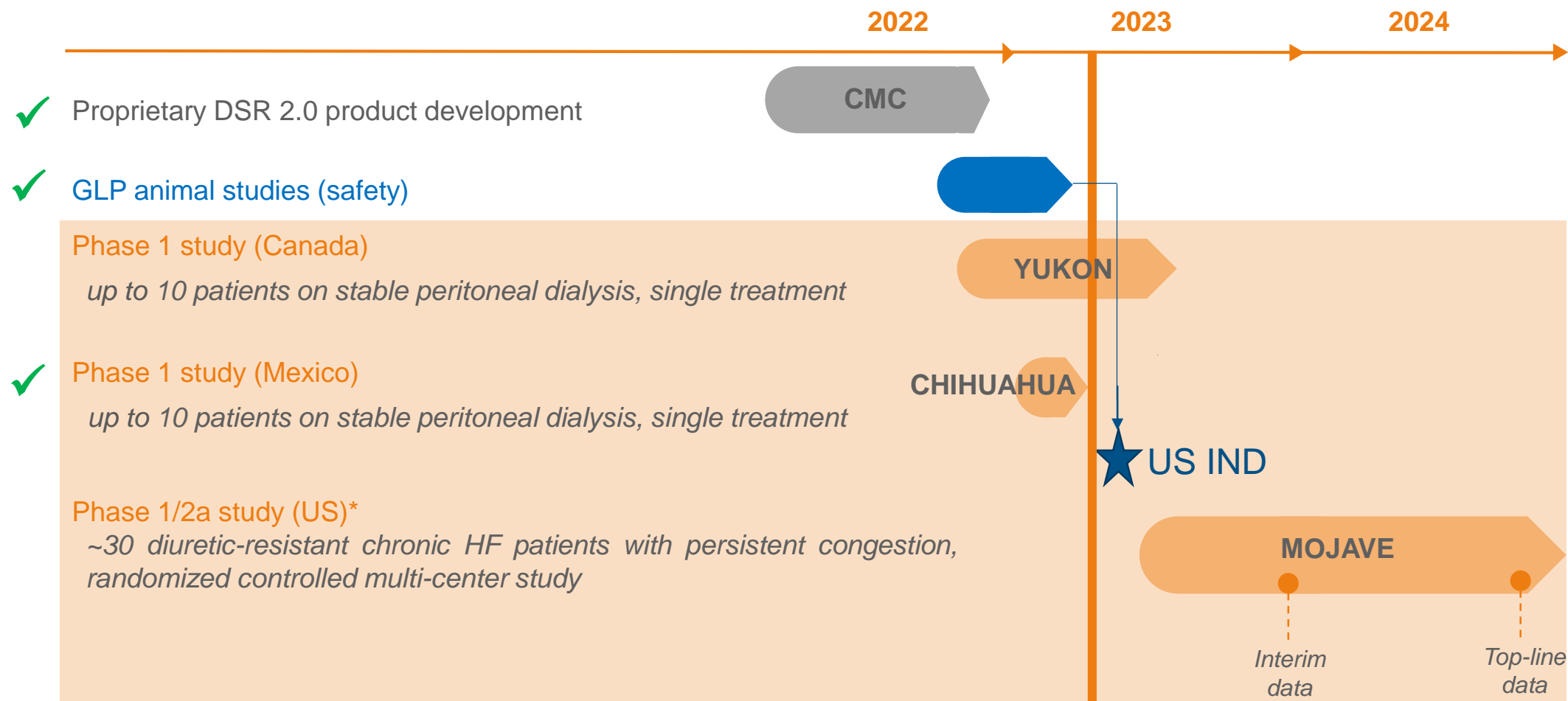
- ✓ Improved therapeutic profile
- ✓ Favorable safety profile
- ✓ Strong granted IP position in US & Europe
 - “Low or no sodium drug for the treatment of heart failure”
 - Drives recurring revenue from high gross margin consumable

✓ 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”)

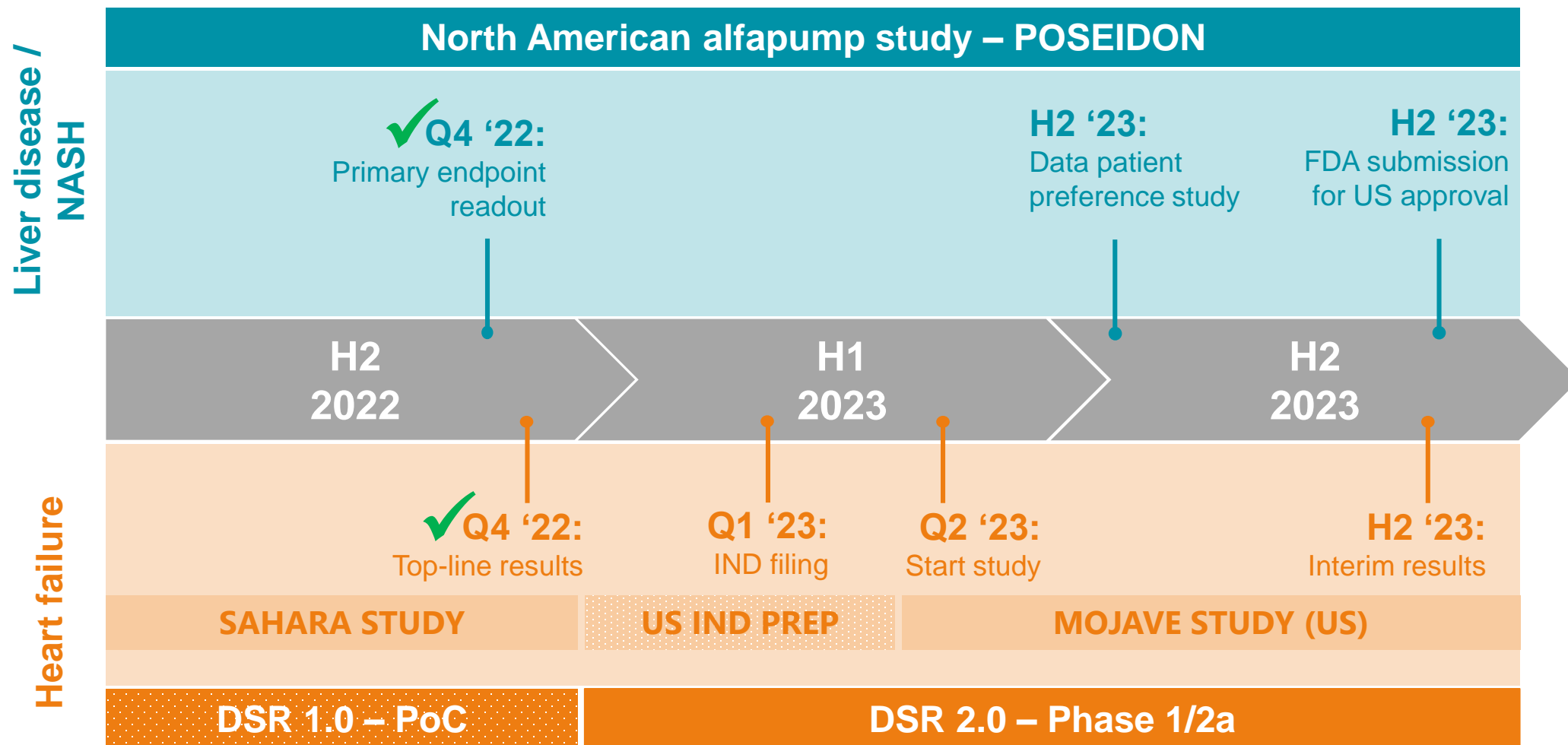


Outlook

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

Contact info

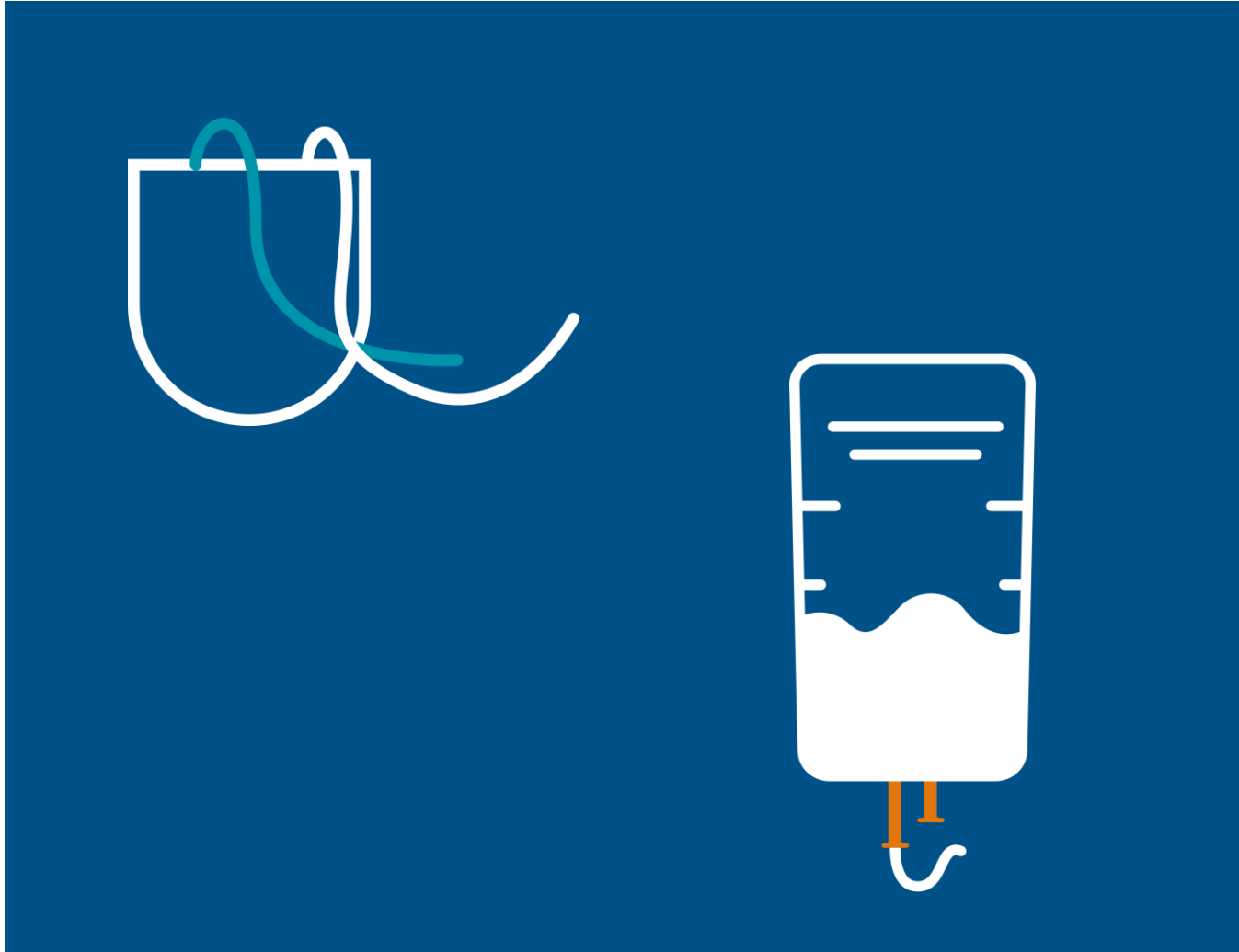
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Back-up

Sequana Medical NV

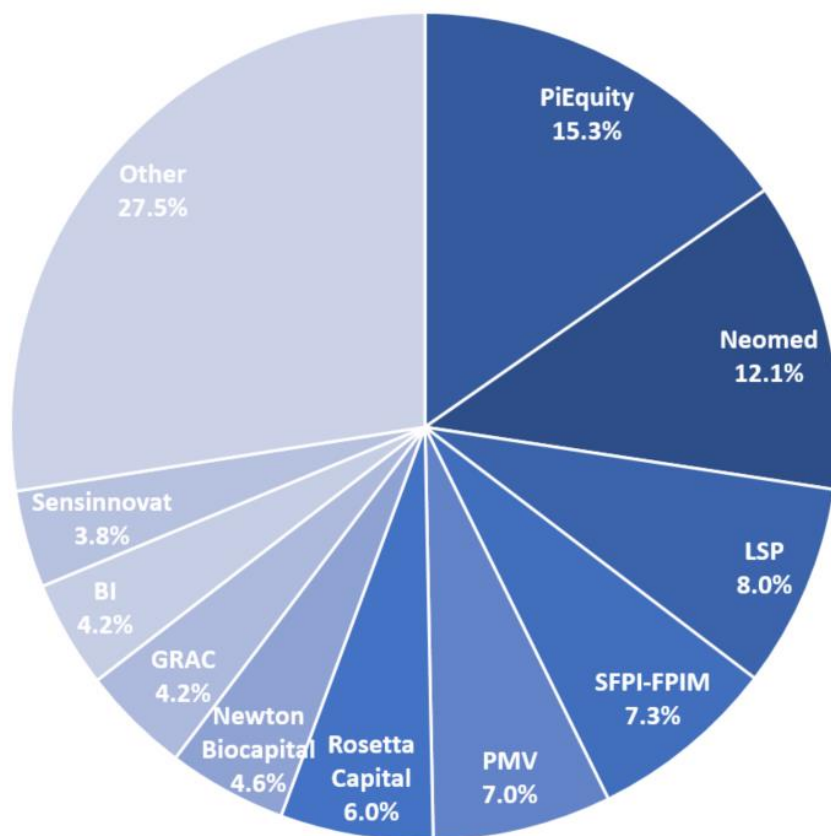
- Founded in 2006
- Gent, Belgium (HQ): corporate, clinical, commercial
- Zurich, Switzerland: manufacturing, engineering, QA/RA
- >70 employees
- Euronext Brussels: SEQUA



Shareholders base and financial overview

Ticker: SEQUA – Euronext Brussels

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



- Analysts:
 - Degroof Petercam – Laura Roba
 - Edison – Pooya Hemami
 - H.C. Wainwright – Yi Chen
 - KBC Securities – Jeroen Van den Bossche
 - Van Lanschot Kempen – Suzanne van Voorthuizen
 - Kepler Cheuvreux – Arsene Guekam
- Cash (31 December 2022): €18.9M
- Cash runway into mid-2023

Strong organisation

Highly experienced leadership team supported by committed and well-reputed shareholders

Executive team:



Ian Crosbie
Chief Executive Officer



Kirsten Van Bockstaele
Chief Financial Officer



Oliver Gödje
Chief Medical Officer



Dragomir Lakic
VP Manufacturing



Gijs Klarenbeek
Senior Medical Advisor



Martijn Blom
Chief Commercial Officer



Timur Resch
Global VP QM/QA/RA



Andreas Wirth
VP Engineering

Board of Directors:



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Board Chairman



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Chief Executive Officer



Wim Ottevaere
Director



Jackie Fielding
Director



Rudy Dekeyser
Director



Doug Kohrs
Director



Alex Clyde
Director

Leading experts as Heart Failure Scientific Advisors



Dr. Maria Rosa Costanzo

Medical Director of the Edward Center for Advanced Heart Failure
Medical Director Heart Failure Research for the Advocate Heart Institute



Dr. Wilson Tang

Professor of Medicine at Cleveland Clinic Lerner College of Medicine at Case Western Reserve University



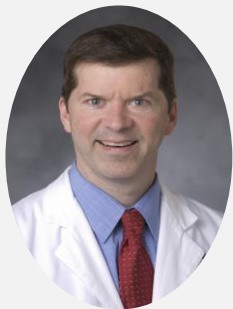
Dr. Javed Butler

Professor and Chairman of the Department of Medicine at the University of Mississippi Medical Center



Dr. Jeffrey Testani

Associate Professor of Medicine and Director of Heart Failure Research at Yale University School of Medicine



Dr. Michael Felker

Professor of Medicine in the Division of Cardiology at Duke University School of Medicine
Director of Cardiovascular Research at the Duke Clinical Research Institute and Vice-Chief for Clinical Research in the Division of Cardiology



Dr. Udelson

Chief of the Division of Cardiology at Tufts Medical Center
Professor of Medicine and Radiology at Tufts University School of Medicine