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Pioneers in the treatment of fluid overload

Transforming lives in liver disease, heart failure & cancer

March 2024

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 liver cirrhosis.
- 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. 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® and DSR® are registered trademarks.

Sequana Medical NV (EBR: SEQUA)

Company Overview

- Innovative treatments for fluid overload – targeting refractory liver ascites and heart failure / cardiorenal syndrome
- ~50 employees with deep expertise in medical devices and product development
- HQ in Ghent, Belgium
- Manufacturing and operations in Zurich, Switzerland
- Listed on Euronext Brussels (EBR: SEQUA)
- Targeting NASDAQ listing

Major Shareholders

EQT Life Sciences

PARTNERS IN EQUITY

ROSETTA CAPITAL

Programs

Medical Device	Indication	Development	Pivotal Trial	Commercial
alfapump Europe	Refractory liver & malignant ascites	Medical Device Regulation (MDR) approval in 2023		
alfapump US	Recurrent or refractory liver ascites	FDA breakthrough device designation		

Therapeutic	Indication	Phase I	Phase II	Phase III
DSR Europe	Heart failure / Cardiorenal Syndrome	RED DESERT & SAHARA: PoC		
DSR US	Heart failure / Cardiorenal Syndrome	MOJAVE: Phase I/IIa		

Derisked commercial medtech targeting US approval H2 this year

- Targeting large and strongly growing markets with clear unmet needs
- alfapump Breakthrough device designation, expecting US PMA approval in H2 ’24
- alfapump De-risked commercial-stage asset with over 1,000 implants to date
- DSR Strong proof-of-concept clinical data with US confirmatory study ongoing
- Attractive valuation versus historical levels despite strong clinical progress; with strong pipeline of upcoming news flow generating key value inflection points
- Consistent track record of achieving milestones
- Targeting NASDAQ listing
- Experienced leadership team and supportive shareholders

Targeting large and strongly growing markets with unmet clinical needs

alfapump

Medical device for recurrent and refractory ascites due to liver cirrhosis

- Growth in non-alcoholic steatohepatitis (“NASH”) drives attractive commercial opportunity
- $2.4bn[1] market growing at 9% $CAGR_{25-32}$
- Standard of care has severe limitations, little innovation
- FDA breakthrough device status; approved in EU
- Successful North American pivotal study – primary endpoints met, strong clinical & commercial profile
- PMA accepted by FDA; approval anticipated in H2 ‘24
- Derisked reimbursement position, supporting price of $30k at 80% gross margin

DSR

Novel drug treatment for cardiorenal syndrome in heart failure

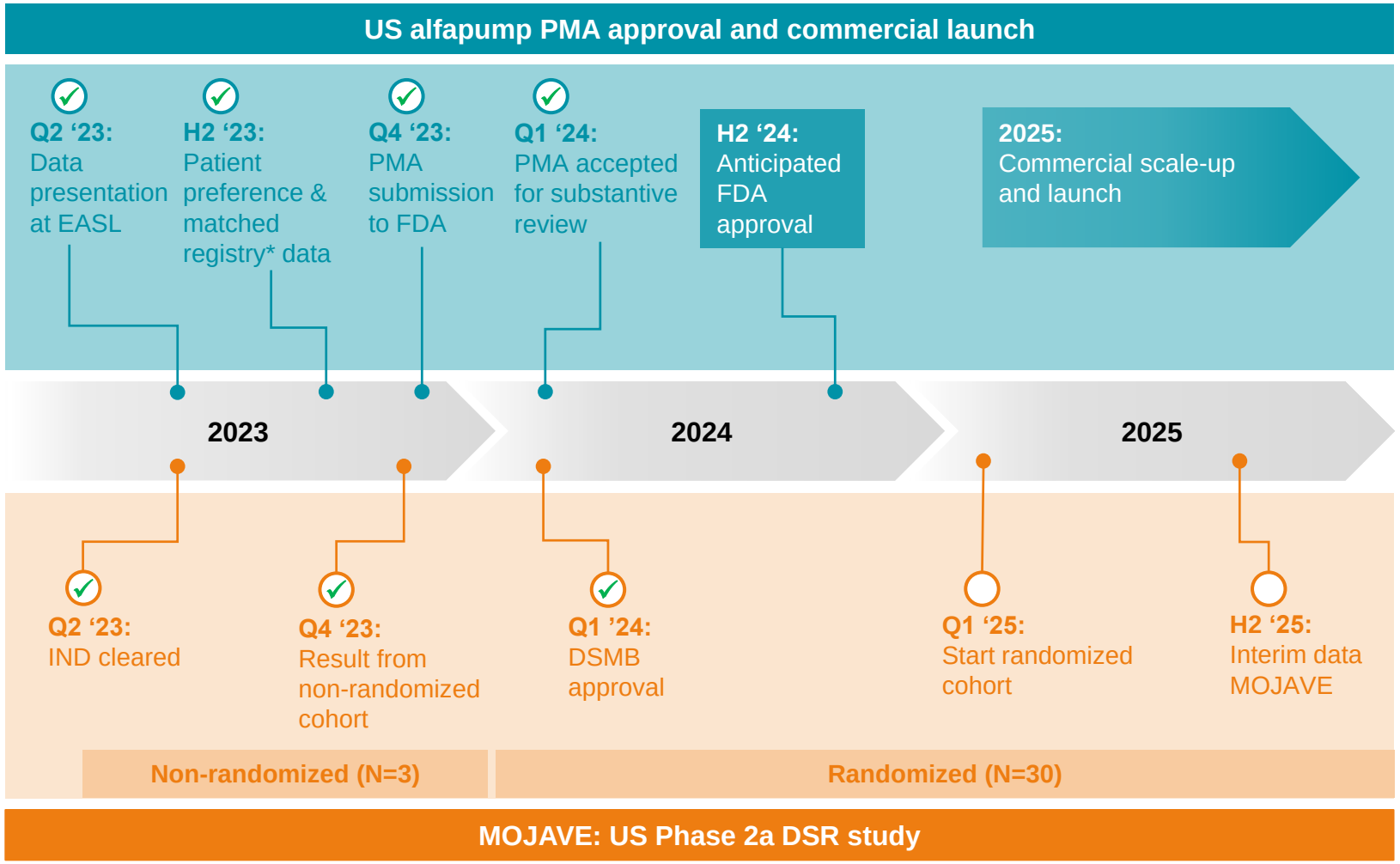
- Unmet needs in cardiorenal syndrome drives the commercial opportunity
- Clinical proof-of-concept as disease-modifying drug therapy
- Dramatic and durable impact on disease-status
- Low development risk, favourable safety profile & strong IP
- US Phase IIa randomized controlled study underway – positive data from initial patient cohort
- Over $9bn addressable market in the US[2]
- Partnering based on US Phase IIa readout planned for 2026

[1] Based on US and Canada market assessment conducted by highly experienced international consulting group, estimating 147,400 patients with recurrent or refractory ascites in North America by 2032 and based on an indicative price of $30k per alfapump; [2]Management estimate of ~200k chronically congested HF patients hospitalized per year in the US with a US annual HF hospitalization cost per patient of $45k

Strong near-term value inflection points

alfapump
Liver disease / NASH

DSR
Heart failure



alfapump – derisked path to US commercializion in a specialty market

alfapump US approval and commercialization is derisked

- Approved in Europe
- 1,000 patients have been implanted with **alfa**pump
- Concentrated market – 90 liver implant centers address large majority of patients
- Attractive pricing ($30k per implant) and gross margin (80%)
- Derisked reimbursement position benefiting from FDA breakthrough designation

alfapump commercial and financial plan

- Forecast annualized revenues of over €35MM within 3 years of commercial launch
  - Estimated cash of €82MM (following PMA approval) to reach this milestone
- Cashflow breakeven forecast at approx. €50MM (1,750 **alfa**pumps) annually – representing less than 7% of market prevalence in our Priority One Market alone
  - Estimated cash of approx. €90MM (following PMA approval) to reach this milestone

Future strategy

- Targeting NASDAQ listing
- Partnering of DSR following completion of MOJAVE study in 2026

alfapump

Proven step change in the treatment of refractory liver ascites

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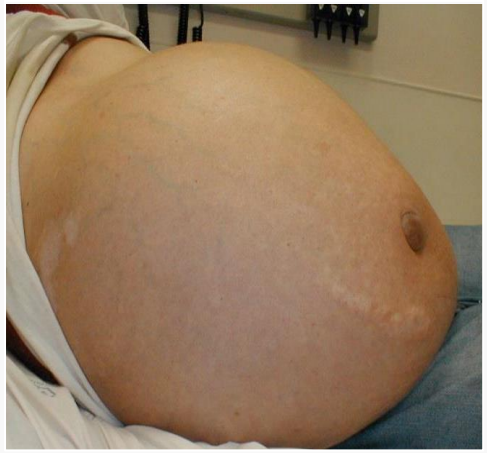
Refractory ascites is a complication of liver cirrhosis and leads to poor quality of life and increased mortality rates



- **Non-alcoholic steatohepatitis ("NASH")**
- Alcoholic liver disease

↓

Liver cirrhosis

↓

Liver ascites

↓

Recurrent or refractory[1] ascites

- NASH is driving growth and change in attitudes to liver cirrhosis patients
- Ascites is the build up of fluid in the abdomen, most often due to liver cirrhosis
- Approximately 10% of liver ascites patients do not respond to drugs and develop recurrent or refractory ascites
  - Refractory ascites patients have one-year mortality rate of 49%[2]
- Patients have a poor quality of life and suffer from severe clinical problems including immobility, constipation and vomiting
- Standard of care has severe limitations with limited alternatives:

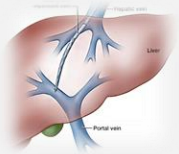
SoC: Paracenteses (drainage)

Painful, poor quality of life, short-term benefits (5d.)

Permanent catheter system

External catheter, risk for infections or blockage

Transjugular intrahepatic portosystemic shunt (TIPS)

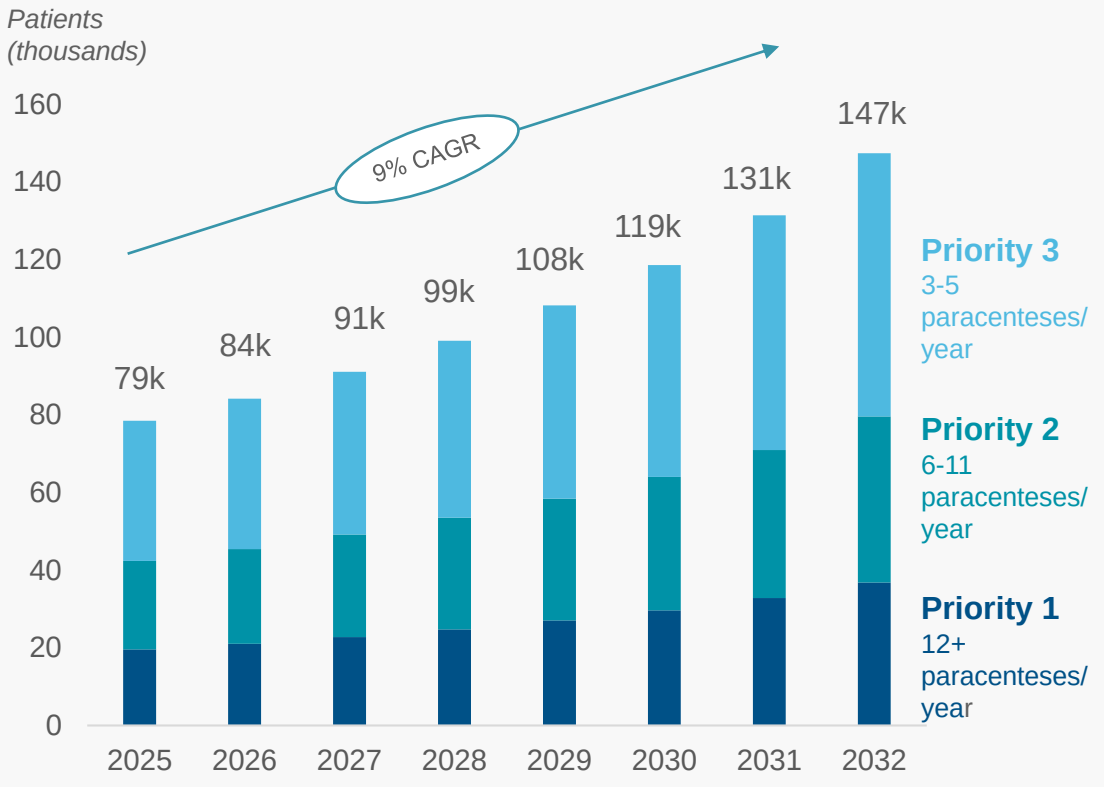


Severe complications and contra-indications

[1] *Refractory: Treatment resistant;* [2] *Siqueira F et al Gastroenterol Hepatol 2009*

$2.4bn recurrent and refractory ascites market for **alfa**pump - growing at 9% per year

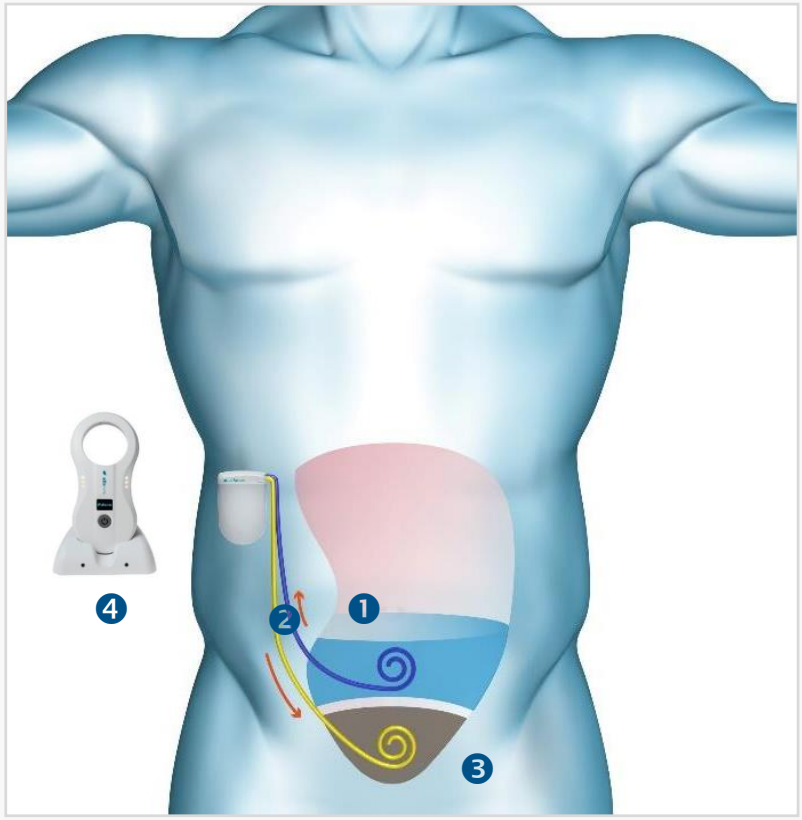
Recurrent and refractory ascites prevalence
US and Canada markets, by priority group



- ~78,500[1] patients are currently affected by refractory ascites in the US and Canada
- Projected to grow rapidly at 9% CAGR reaching 147,400 patients by 2032, primarily driven by the increasing prevelance of NASH
- Total addressable market in the US and Canada is estimated to be $2.4bn at launch
- **~$600m priority 1 target market segment at launch**
  - 25% of the total[2]
  - Highest clinical burden, costs and impact on QoL
  - Limited competition

[1] Based on US and Canada market assessment conducted by highly experienced international consulting group, estimating 147,400 patients with recurrent or refractory ascites in North America by 2032 and based on an indicative price of $30k per alfapump; [2] Based on US and Canada market assessment by 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; Medicare Inpatient & Outpatient Hospital Standard Analytical Files 2019.CMS, Baltimore, MD. www.cms.hhs.gov

Proven step change for refractory liver ascites - over 1,000 systems implanted



DGVS | FDA Breakthrough Device Designation | CE | EASL™ The Home of Hepatology | NICE National Institute for Health and Care Excellence

alfapump mechanism of action

- Automatic and continuous removal of ascitic fluid from the abdomen (1) into the bladder (2) and expelled through normal urination (3)
- Hand-held SmartCharger (4) recharges device & automatically communicates data to Sequana technicians for reporting to clinicians

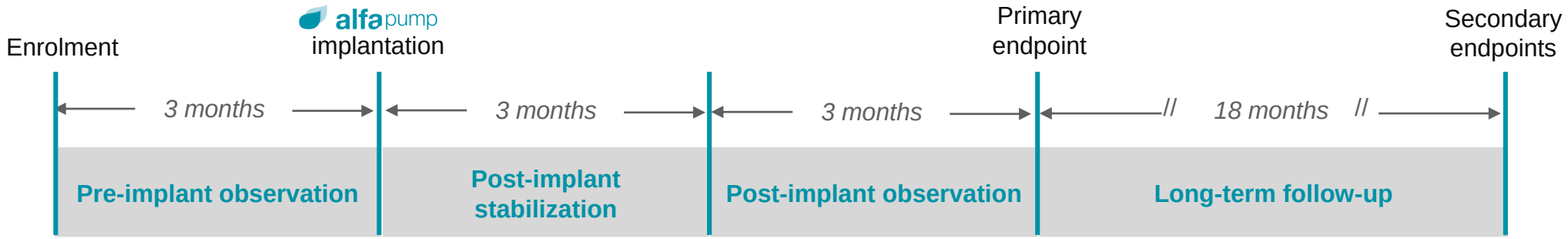
alfapump differentiated features

- Autonomous, once-implantable device that can drain up to 4L fluid / day
- Wirelessly charged through the skin
- Settings are wirelessly adjusted
- DirectLink data reporting via mobile network

POSEIDON: successful North American pivotal PMA study

Trial design overview

Pivotal cohort of n=40 patients with recurrent or refractory ascites due to liver cirrhosis



POSEIDON data overview

- Primary effectiveness endpoints exceed pre-defined thresholds for study success
  - **100%** median per-patient reduction in therapeutic paracentesis (N=40; p<0.001)[1] *vs at least 50%*
  - **77% of patients** with at least 50% reduction in therapeutic paracentesis (N=40; p<0.001)[1] *vs at least 50%*
- Primary safety endpoint data in line with expectations
  - No unanticipated adverse device effects
  - 6 primary safety events (3 explants due to skin erosion & 3 explants due to moderate bladder discomfort)
- Clinically meaningful and statistically significant improvement in quality of life[2]

[1] Post- vs. pre-implant observation period; [2] quality of life assessed through the physical component score of SF36 and the Ascites Q score, at 6- and 12-months post-implant compared to baseline

Sustained effective control of ascites and robust safety profile at 12 months post-implant

- Complete elimination of needle paracentesis usage
  - Maintaining 100% median per-patient reduction in therapeutic paracentesis (N=19, p<0.001)[1]
- Robust safety profile demonstrated despite disease progression
  - 2 pumps explanted (1 patient with urinary tract infection and 1 patient with wound dehiscence)[2]
  - Number of major adverse events and serious infections in line with expectations
  - Stable kidney function maintained
- Maintained clinically meaningful improvement in quality of life[3]
- Survival probability of 70% at 12- and 18-months post-implant
  - Comparing favourably to literature citing only ~17% predicted survival at 12 months and ~5% at 18 months[4]

alfapump

- PMA filed in December ‘23 / PMA accepted for substantive review in January ’24
- FDA approval anticipated in H2 ‘24

[1] 7-12 month post-implant period vs 3 month pre-implant observation period; [2] during 7-12 month post-implant; [3] at 12 months post-implant compared to baseline; [4] Salerno et al., Gastroenterology 2007; 133:825-834; predicted survival probability for refractory ascites patients with a MELD score of 15 and receiving paracentesis

Strong clinical & commercial messaging to patients and clinicians

- US patients have a strong preference for the **alfa**pump® vs large volume paracentesis[1]
  - Reduction in paracentesis frequency and additional ascites good health days are important attributes
  - **alfa**pump® risk-benefit profile from POSEIDON pivotal cohort is superior to what patients require from a novel implantable pump

- **alfa**pump® safety profile is comparable to standard of care[2]
  - **alfa**pump® patients benefit from significantly reduced number of paracentesis procedures and improved quality of life without increased risk of death or hospitalization compared to standard of care

[1] Patient preference study using discrete-choice experiment methodology to elicit patient preference for attributes of an implantable pump as a novel interventional treatment for ascites, N=125 US patients with comparable patient profile to pivotal cohort in POSEIDON study [2] Comparing outcomes in terms of death, hospitalization rate and liver transplant of POSEIDON pivotal cohort (6 months post-implant) to matched patient group from NACSELD registry with POSEIDON

Attractive pricing with derisked reimbursement

- Existing DRG code and breakthrough device designation derisks reimbursement
- Coding – strong existing DRG codes enhanced by NTAP
  - Targeting $30k based upon existing US hospital DRG[1, 2] payment enhanced by NTAP[4] due to FDA Breakthrough Device Designation - Gross margin of 80%
  - CPT[3] Category III codes granted by AMA
- Coverage – FDA breakthrough designation provides clear benefits
  - Proposed TCET[5] pathway expected to provide automatic coverage of breakthrough devices for 4 years with a pathway for permanent coverage

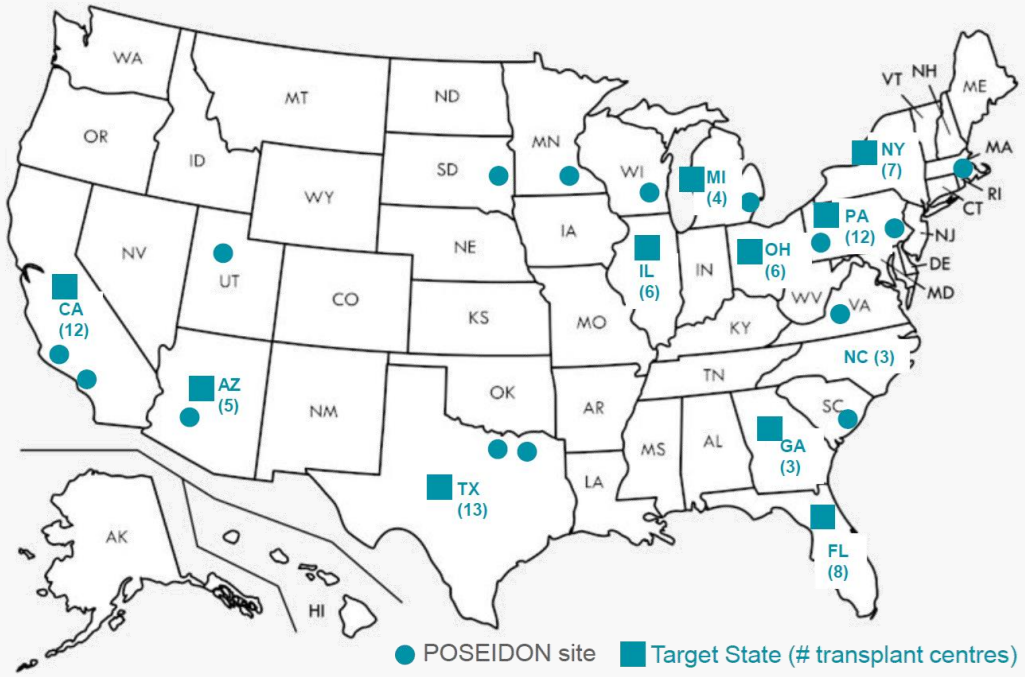
Key payers

- Dominant payer will be Medicare
- Additional potential from Veteran Affairs

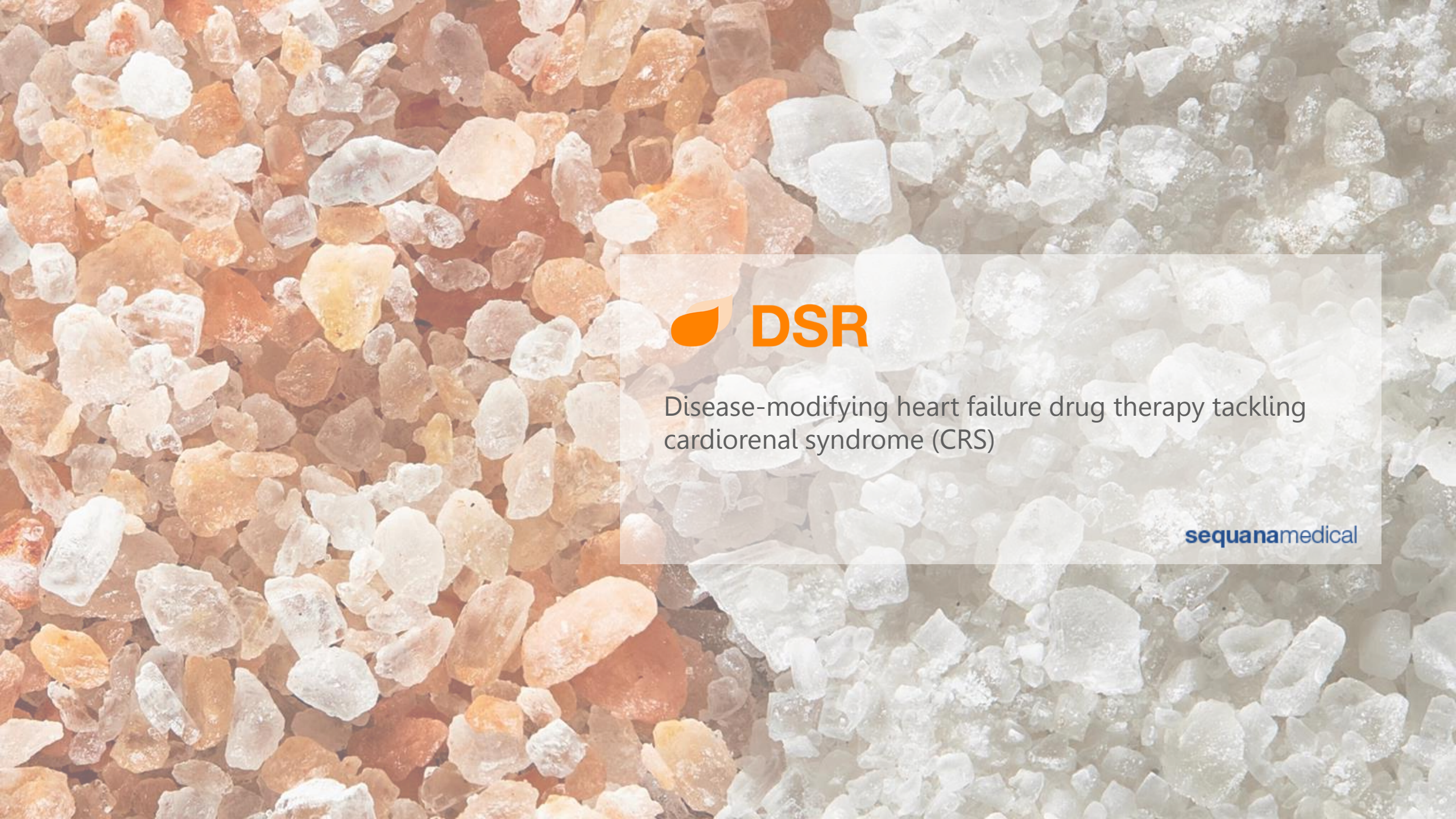
[1] On the basis of existing ICD-10 codes issued for the alfapump, the likely DRG coding will be 423 "OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES", payments adjusted with Medicare inflation rates to 2025;
[2] DRG: Diagnosis Related Group; [3] CPT: Current Procedural Terminology; [4] NTAP: New Technology Add-On Payment ; [5] TCET: Transitional Coverage of Emerging Technologies

Strong go-to-market strategy targeting 90 US transplant centers

Overview of high-volume target transplant centres in the US



- Patients diagnosed with ascites are referred to liver transplant centers for transplant assessment
- 90 US liver transplant centres cover 95% of all liver transplants in the US
- Early adoption through experienced POSEIDON sites
- Positive feedback from direct interaction with key hepatologists and interventional radiologists


DSR
Disease-modifying heart failure drug therapy tackling cardiorenal syndrome (CRS)
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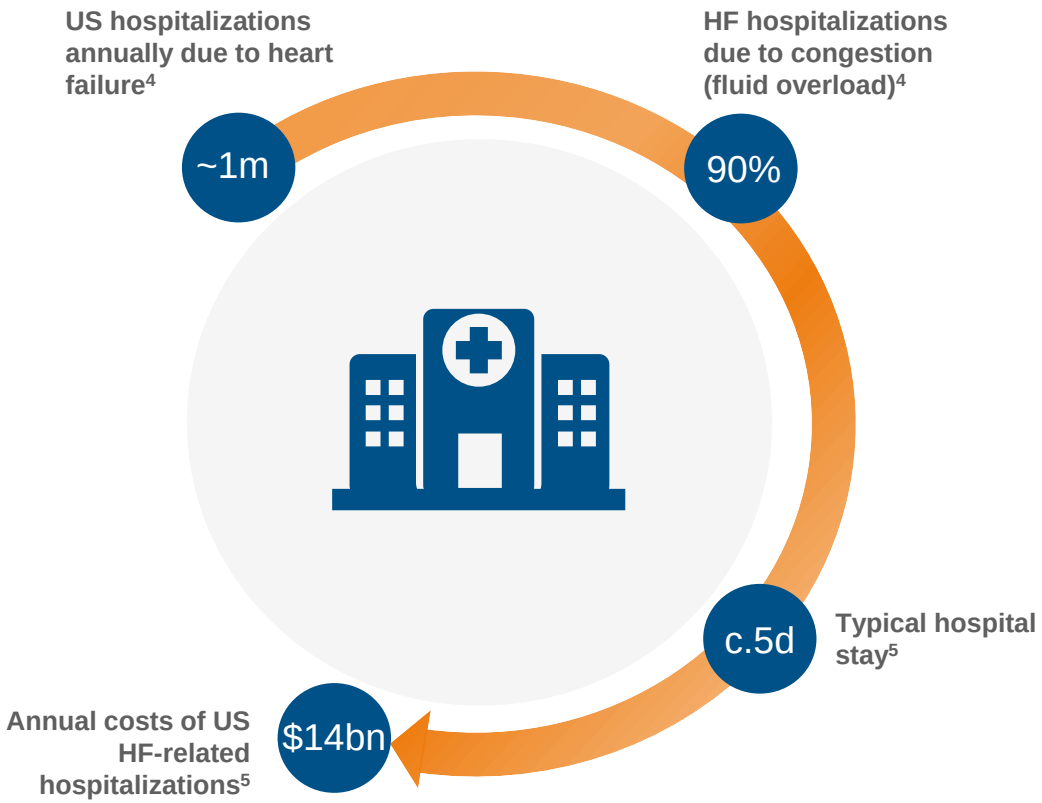
Cardio-renal syndrome (“CRS”): clear need for durable treatments for congestion (AKA fluid overload) without use of loop diuretics

- Combined, and self-reinforcing dysfunction of heart and kidneys

- Clinical profile manifests as a challenging to break self-reinforcing negative feedback cycle
  - Poor cardiac output leads to sodium retention by kidney, which results in fluid overload, which places increased burden on the damaged heart, further impacting cardiac output

- Loop diuretics are mainstay of decongestion therapy but exacerbate many of the core underlying mechanisms of CRS, worsening diuretic resistance and CRS itself

Congestive heart failure is a significant healthcare cost burden, and limited effective treatments exist

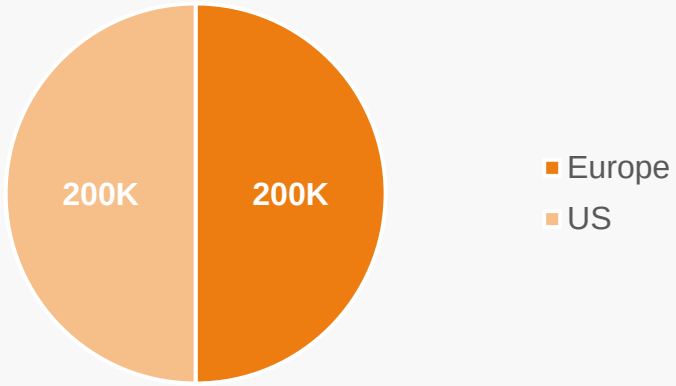


- Congestion (fluid overload) is a key driver of morbidity and hospitalisation
- Diuretic resistance is common and effective treatments are limited[1]
- 40% of heart failure patients on IV loop diuretics do not respond effectively to treatment[2]
- 1 in 4 patients are readmitted to hospital with 30-days of discharge[3]

[1] Testani et al J AM Coll 2014; [2] Testani et al 2016 , [3]Ross et al, 2010 ; [4]Costanzo et al, 2007 ; [5] Urbich et al, 2000

Multi-billion commercial opportunity driven by reducing hospitalizations

Chronic congestive heart failure hospitalizations per year
US and Europe



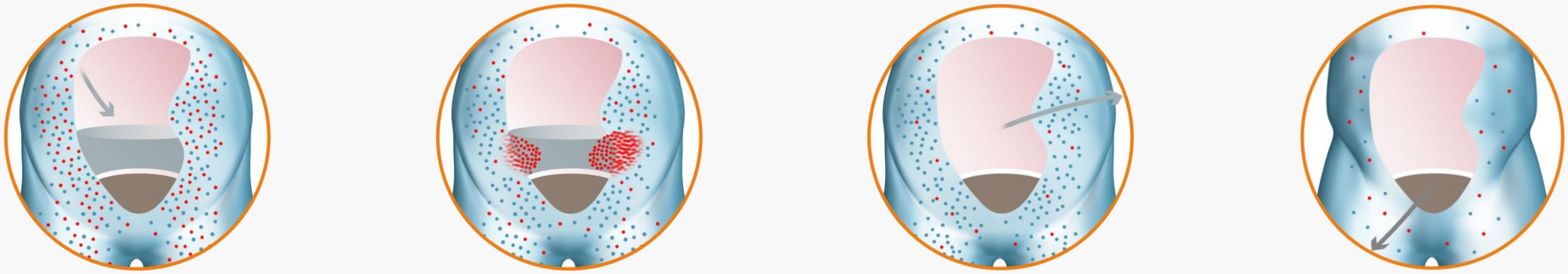
Total addressable market
US

$45k
US annual heart failure hospitalization cost per patient

>$9bn
DSR® addressable market in the US

- ~400k chronic congestive heart failure patients hospitalized per year in the US and Europe (“frequent flyers”)
- Potential for premium DSR pricing through reduced hospitalizations and improved survival rates

DSR (Direct Sodium Removal) targets key driver of congestion



Fundamental patents to reduce fluid overload in heart failure patients granted in US, Europe & China

[1] *Rao et al Circulation 2020*

Breaking the vicious cycle of cardiorenal syndrome

Clinical proof-of-concept from RED DESERT and SAHARA studies

- Complete replacement of loop diuretics with safe, rapid and effective decongestion and maintenance of euvolemia
- Normalization of renal diuretic-response
- Long-lasting reduction in loop diuretic needs
- Improvement in renal function

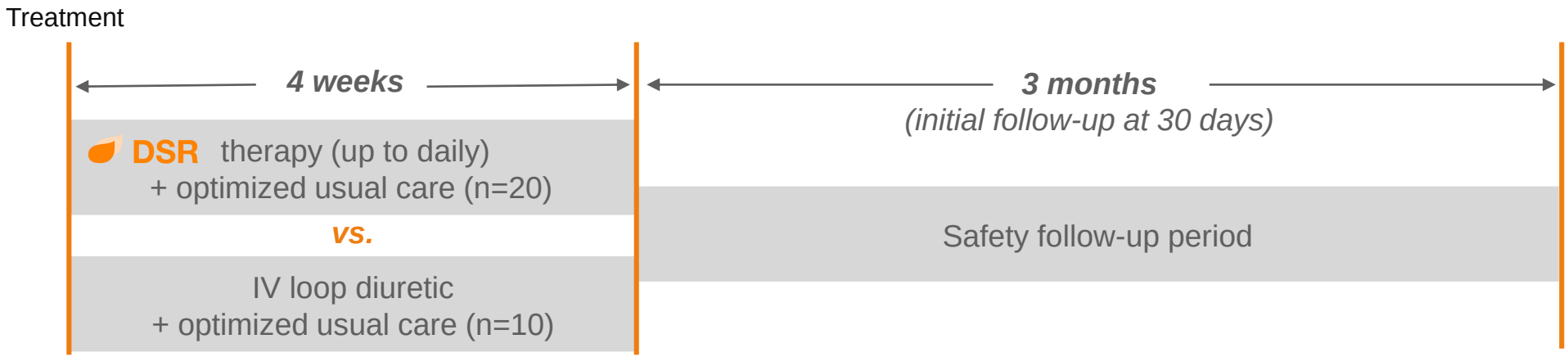
Leading to improved clinical outcomes

- No congestion-related heart failure re-hospitalizations
- One class improvement of NYHA[1] status
- Over 75% reduction in predicted one-year mortality[2]

[1] NYHA: New York Heart Association ; [2] Based on Seattle Heart Failure Model

MOJAVE: Phase IIa randomized controlled US study

Trial design overview



Trial endpoints

Seeking to replicate strong outcomes seen from RED DESERT and SAHARA in randomised, controlled study of US patients

- **Safety:** rate of adverse and serious adverse events
- **Efficacy:** improvement in diuretic response (6-hour urine sodium output)
- **Exploratory:** change in weight (volume status), creatinine (renal function), natriuretic peptides (heart function), NYHA[1] functional class, number of heart failure related re-hospitalizations

[1] *NYHA: New York Heart Association*

Strong data from non-randomized cohort

Non-randomized cohort (n=3) endpoint data

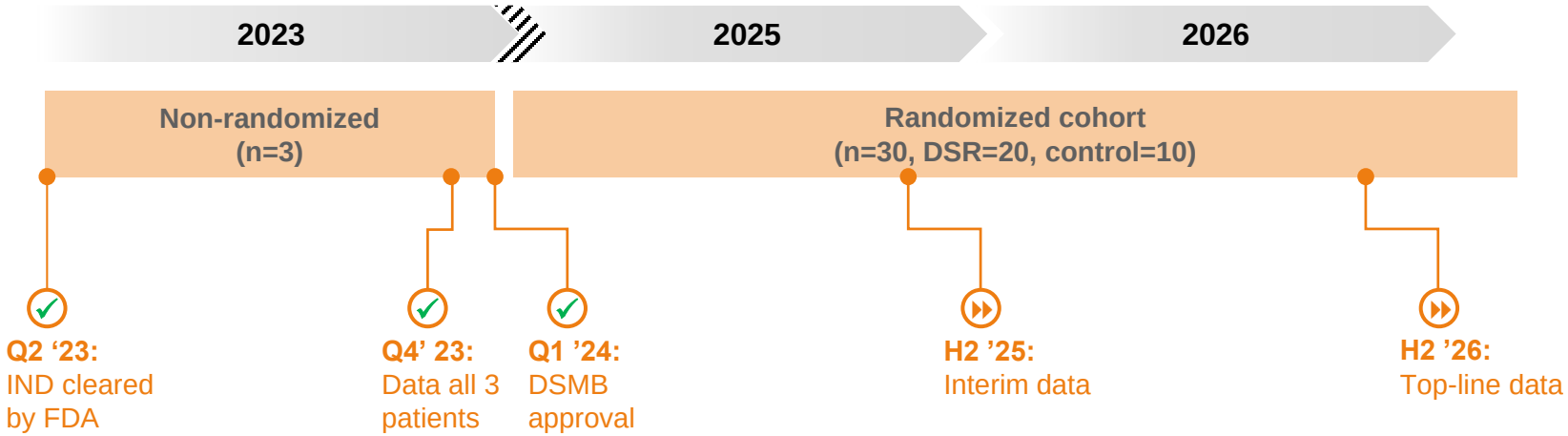
Confirmed outcomes from RED DESERT and SAHARA studies

- Safe and effective maintenance of euvolemia without the need for loop diuretics
- Considerable benefit in cardio-renal health
- Large improvement in diuretic response[1] and virtual elimination of loop diuretics up to ~4 months after DSR therapy[2]

DSMB approval to start randomized cohort

MOJAVE timeline overview

Top-line data in H2 ’26 intended to deliver the clinical data package for partnering



[1] *Mean increase of 324% in six-hour urinary sodium excretion after 4-week DSR therapy vs baseline ;* [2]*Respectively 97%, 100% and 95% reduction in furosemide equivalent dose at 15, 15 and 9 weeks after 4-week DSR therapy vs baseline*

Future outlook

Strong near-term value drivers and inflection points

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Strong near-term value inflection points

alfapump

- US FDA approval expected H2 ’24
- US commercial-scale up and launch in 2025

DSR

- Interim results expected H2 ’25 and top-line data in H2 ’26
- Partnering following completion of MOJAVE study

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

Gijs Klarenbeek
Senior Medical Advisor

Dragomir Lakic
VP Manufacturing

Martijn Blom
Chief Commercial Officer

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