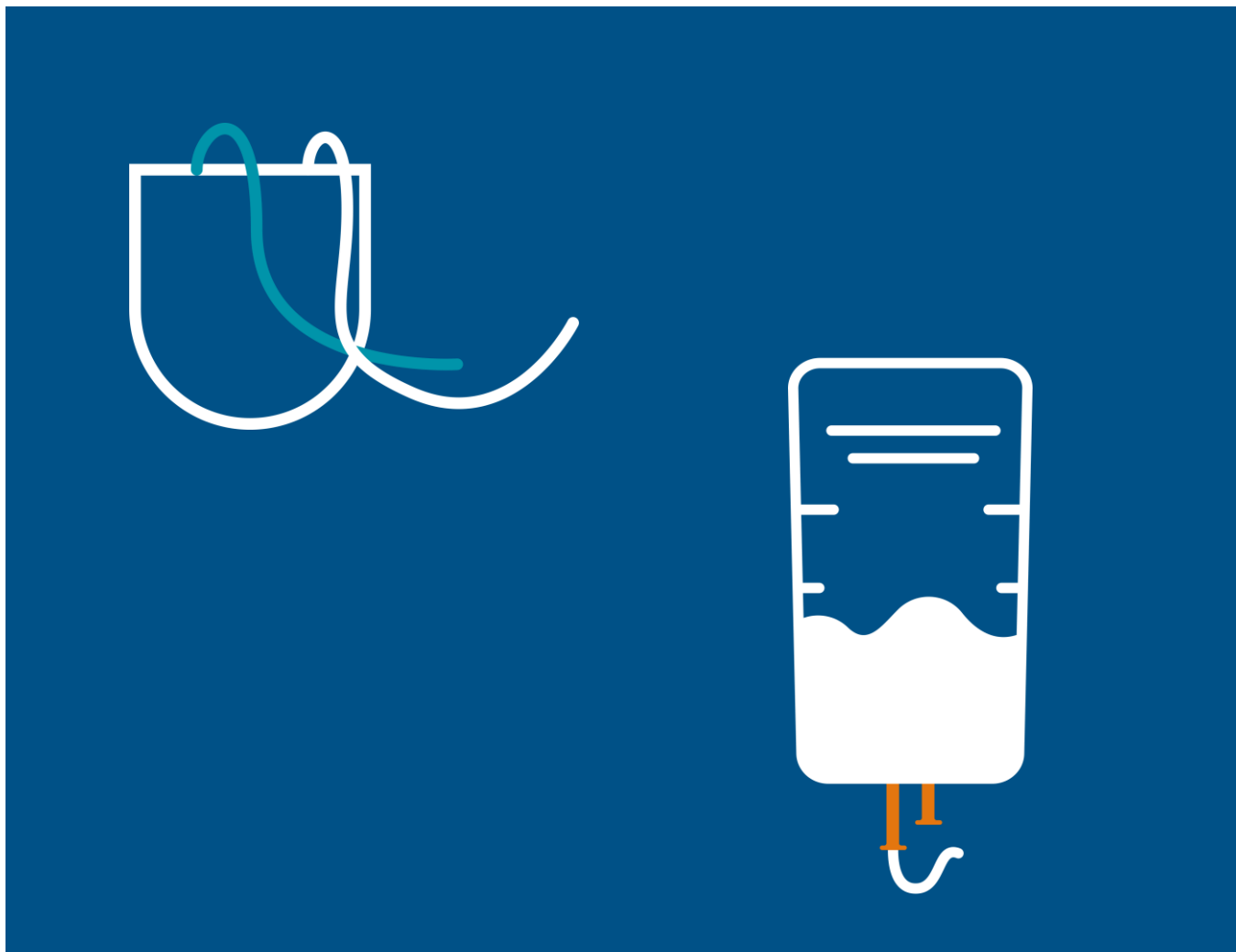


**sequana**medical



# **Pioniers in de behandeling van vochtoverbelasting**

Leveraandoeningen, Hartfalen & Kanker

Finance Avenue – 18 november 2023

Kirsten Van Bockstaele, CFO

Lies Vanneste, Director IR

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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 liver cirrhosis.
- 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. 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:

- **alfapump**<sup>®</sup> and DSR<sup>®</sup> are registered trademarks.

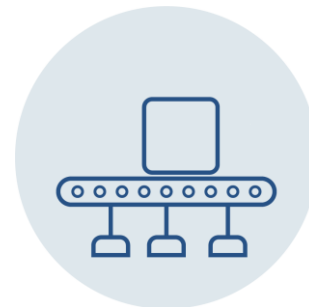
# Sequana Medical NV



2006



Gent



Zürich



>60 werknemers



SEQUA



alfapump<sup>®</sup>



DSR<sup>®</sup>



80 patenten

# Sterke organisatie

Zeer ervaren managementteam ondersteund door gerenommeerde aandeelhouders

## Executive team:



**Ian Crosbie**  
Chief Executive Officer



**Kirsten Van Bockstaele**  
Chief Financial Officer



**Oliver Gødje**  
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

## Raad van Bestuur:



**Pierre Chauvineau**  
Board Chairman



**Rudy Dekeyser**  
Director



**Wim Ottevaere**  
Director



**Jackie Fielding**  
Director



**Doug Kohrs**  
Director



**Alex Clyde**  
Director



**Kenneth Macleod**  
Director



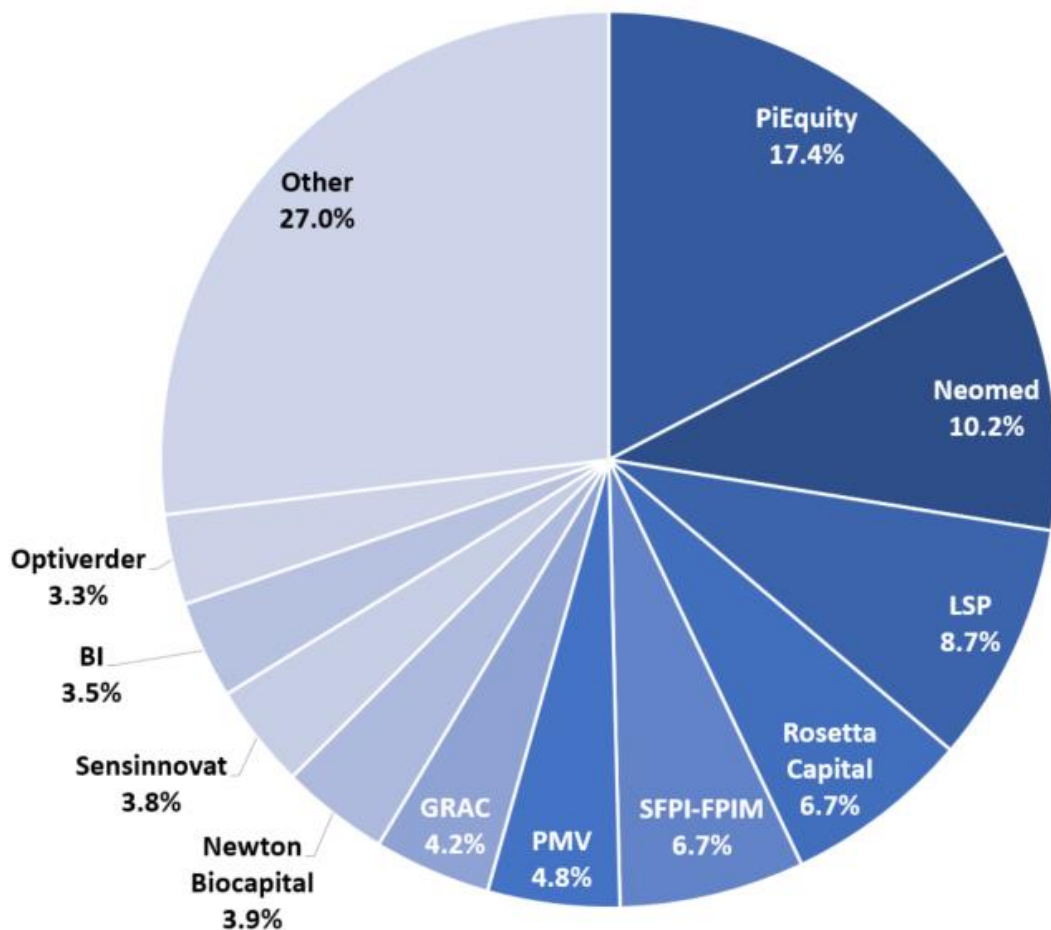
**Ids van der Weij**  
Director



**Ian Crosbie**  
Chief Executive Officer

# Aandeelhoudersstructuur en financieel overzicht

Ticker: SEQUA – Euronext Brussels



## Cash:

- Kaspositie: €17,1 M (30 juni 2023)
- Cash runway tot in Q1 2024

## Aandeleninfo:

- 28,2 M uitstaande aandelen
- ~€75M market cap

## Analisten:

- Degroof Petercam – Laura Roba
- Edison Research – Pooya Hemami
- H.C. Wainwright – Yi Chen
- KBC Securities – Jacob Mekhael
- Kempen – Luísa Morgado





**alfapump<sup>®</sup>**

Bewezen behandeling voor refractaire  
ascites door levercirrose

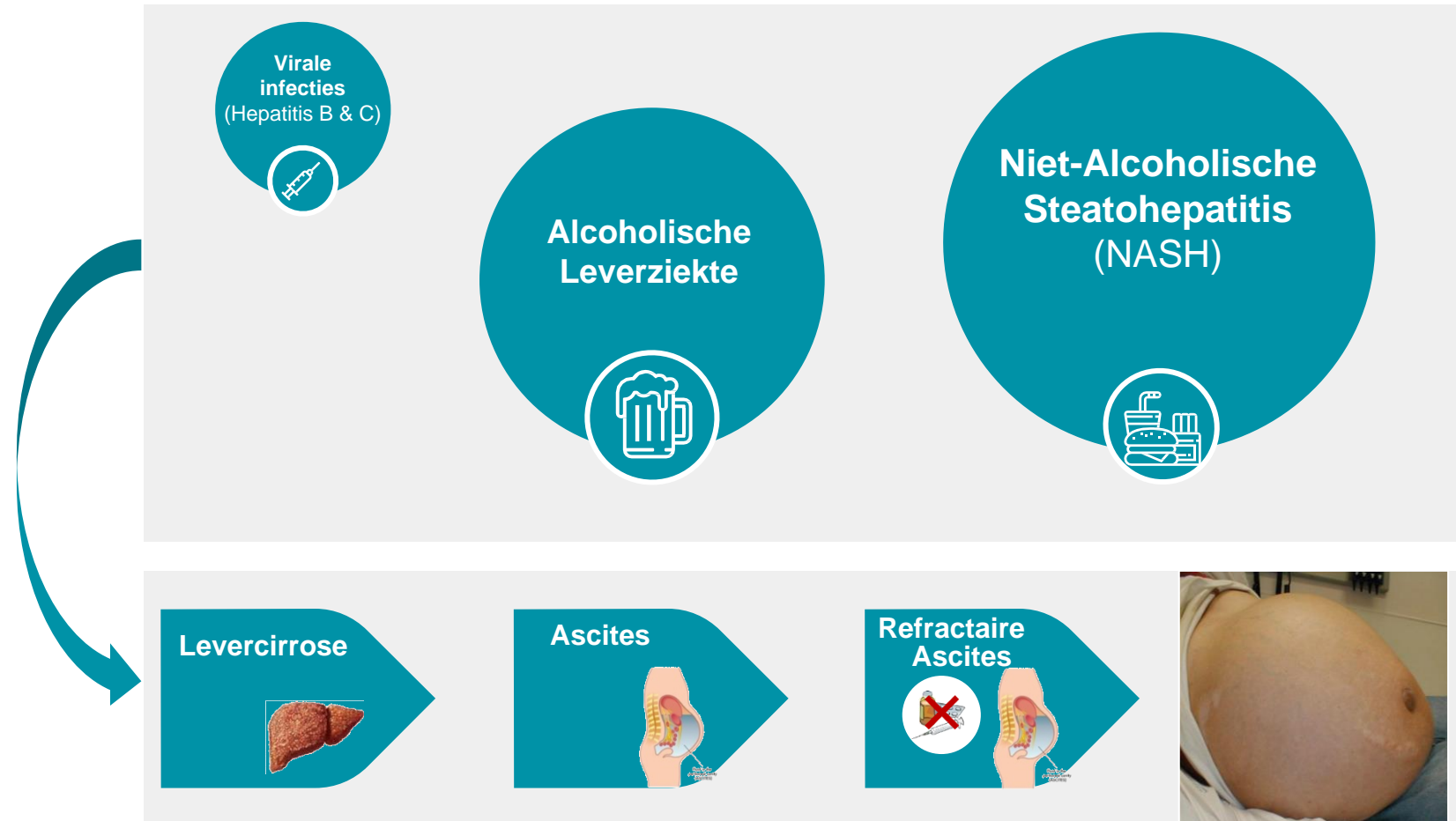


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# Ascites – belangrijke complicatie van levercirrose

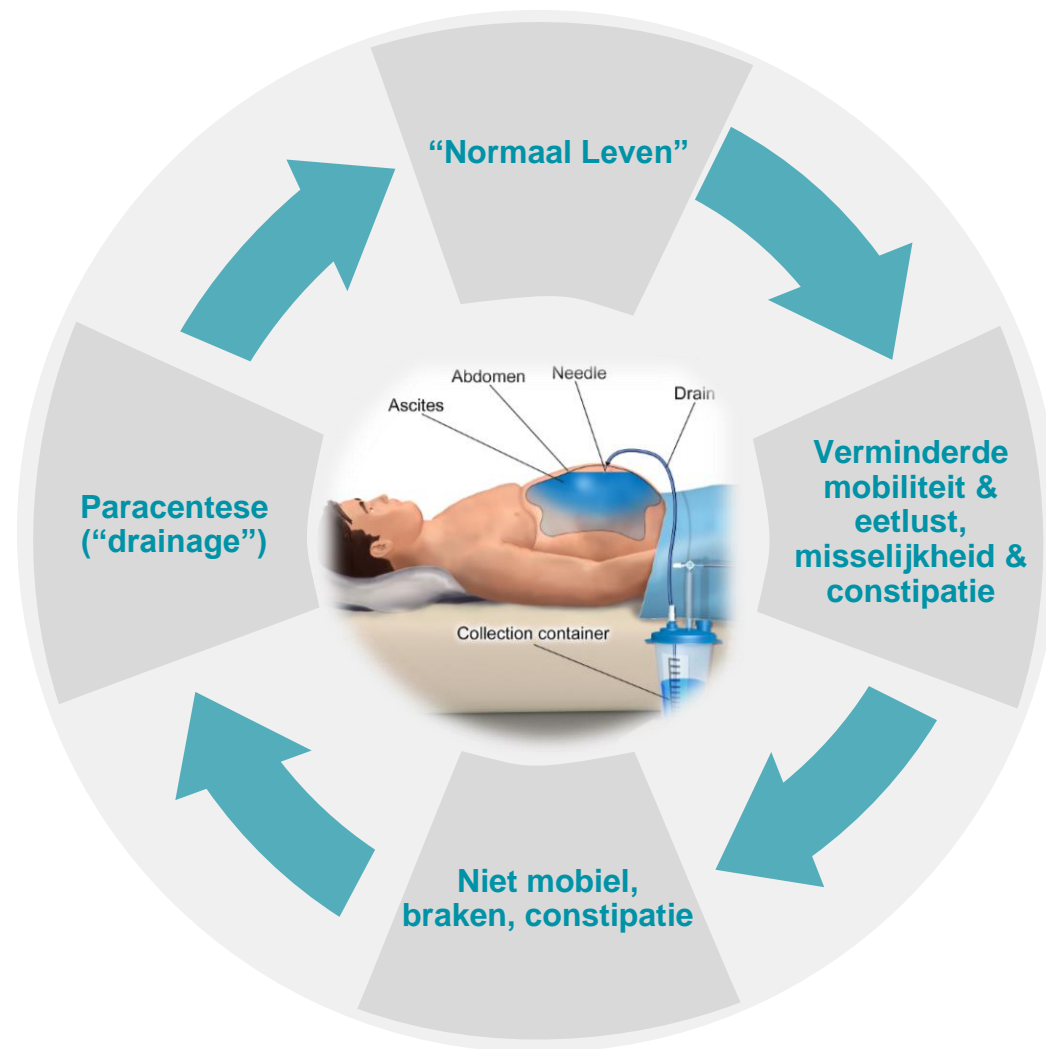
Vette leverziekte / NASH zorgt voor dramatische groei en verandering in houding tov patiënten met levercirrose





# Weinig innovatie of nieuwe behandelingen

Paracentese (“drainage”) is pijnlijk en belastend met grote impact op de levenskwaliteit







# alfapump – continue verwijdering van ascites via blaas

Volledig geïmplanteerd automatisch systeem voor implantatie op lange termijn



Draadloos opladen van batterij



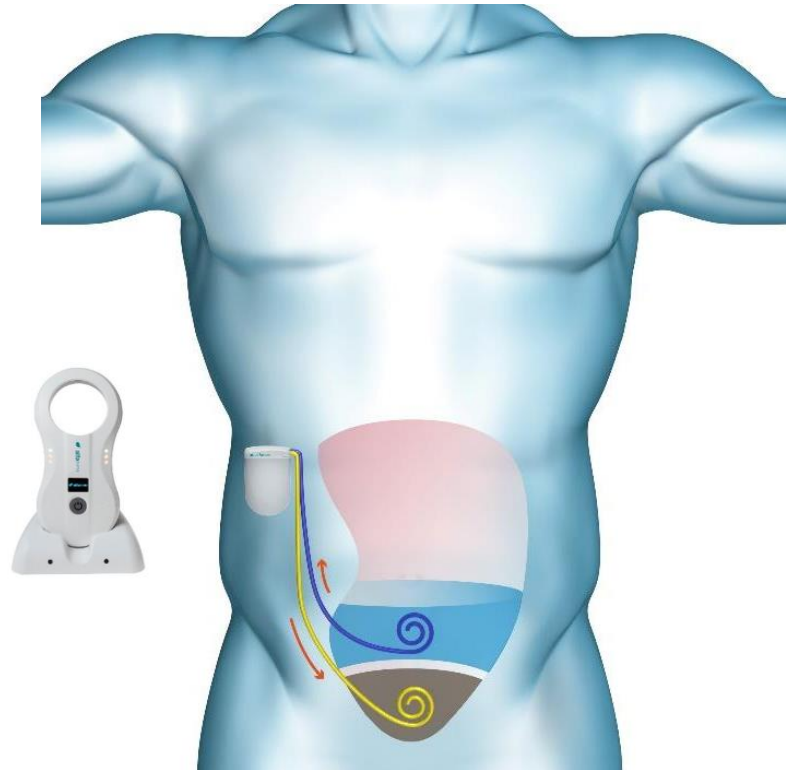
Draadloos aanpassen van instellingen



Data monitoring op afstand



Verwijdert tot 4 liter vocht/dag



Breakthrough Device Designation

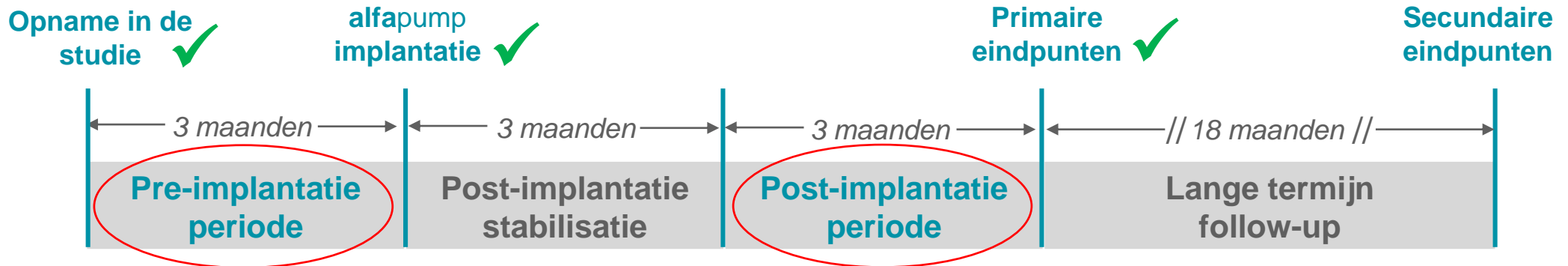


**Meer dan 1.000 systemen geïmplanteerd**  
**Sterke IP door uitgebreide octrooiportfolio & know-how**



# POSEIDON – Successvolle N-Amerikaanse studie

Pivotal Cohort van 40 patiënten met terugkerende of refractaire leverascites geïmplant met de alfapump



- ✓ Alle primaire eindpunten bereikt met statistische significantie ( $p < 0,001$ )
- ✓ Vrijwel volledige eliminatie van paracentese (“drainage”) na implantatie
- ✓ Robuust veiligheidsprofiel ondanks progressie van de ziekte
- ✓ Aanzienlijke verbetering in levenskwaliteit tot 12 maanden na implantatie\*
- ✓ Overlevingskans van 70% op 12 en 18 maanden na implantatie >> gunstig tov literatuur<sup>(1)</sup>

\* Kwaliteit van leven beoordeeld aan de hand van de fysieke componentscore van SF36 en de Ascites Q-score, na implantatie vergeleken met baseline

Bron 1: Salerno et al., Gastroenterology 2007; 133:825-834; voorspelde overlevingskans voor patiënten met refractaire ascites met een MELD-score van 15 en die paracentese krijgen



# Goedkeuring alfapump in VS verwacht in H2 2024

Bestaande ziekenhuiscodes en breakthrough device status zijn positief voor de terugbetaling van de alfapump

## Goedkeuring door FDA verwacht in H2 2024

- Positieve pre-PMA meeting met FDA gehouden
- Op schema voor indiening PMA dossier tegen eind dit jaar

## Medicare als belangrijkste betaler

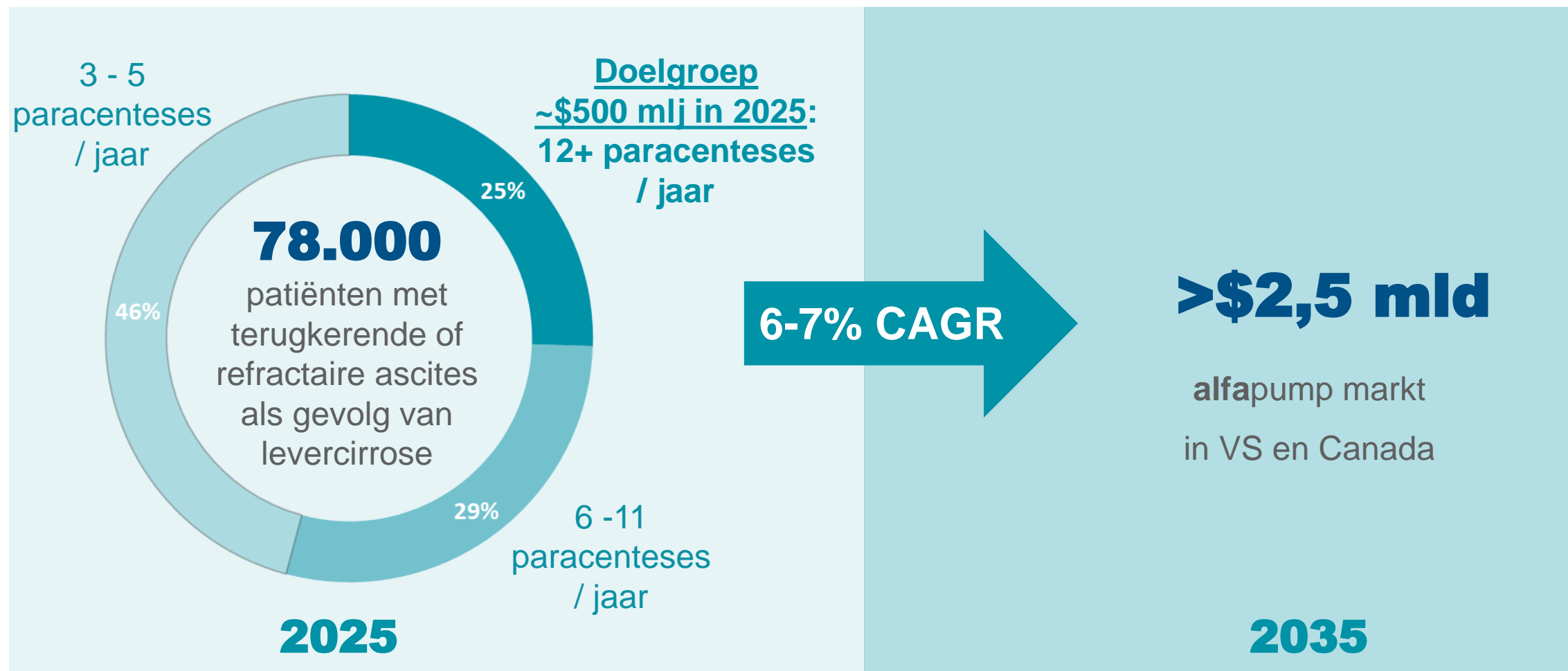
- Bestaande ziekenhuiscode (DRG) voor **alfapump** procedure betaalt gemiddeld \$60-70K\*
- Dit ondersteunt een prijs voor **alfapump** van **minstens \$25K** (brutomarge >75%)

\*Op basis van de bestaande ICD-10-codes zal de waarschijnlijke DRG-codering voor de **alfapump** 423 "OTHER HEPATOBILIARY OF PANCRAS O.R. PROCEDURES" zijn, aangepast met Medicare-inflatiecijfers tot 2025



# Grote en sterk groeiende Noord-Amerikaanse markt

NASH zal naar verwachting nog vele jaren voor aanzienlijke groei zorgen en verandert houding tov cirrose



*Bronnen:* Gebaseerd op marktbeoordeling in de VS en Canada door internationale adviesgroep, met behulp van claimanalyse voor commerciële en CMS (Center for Medicare and Medicaid Services) patiënten die een paracentese procedure nodig hebben met diagnosecodes voor leveraandoeningen; Medicare Inpatient & Outpatient Hospital Standard Analytical Files 2019.CMS, Baltimore, MD. [www.cms.hhs.gov](http://www.cms.hhs.gov); rekening houdend met een incidentie van 60% en een **alfapump**-prijs van \$25K.

**CAGR:** Compound Annual Growth Rate of samengestelde jaarlijkse groeisnelheid



# VS – Directe verkoop naar 90 levertransplantatiecentra

Zeer efficiënte benadering van artsen en patiënten – gestuurd door behandelingsrichtlijnen

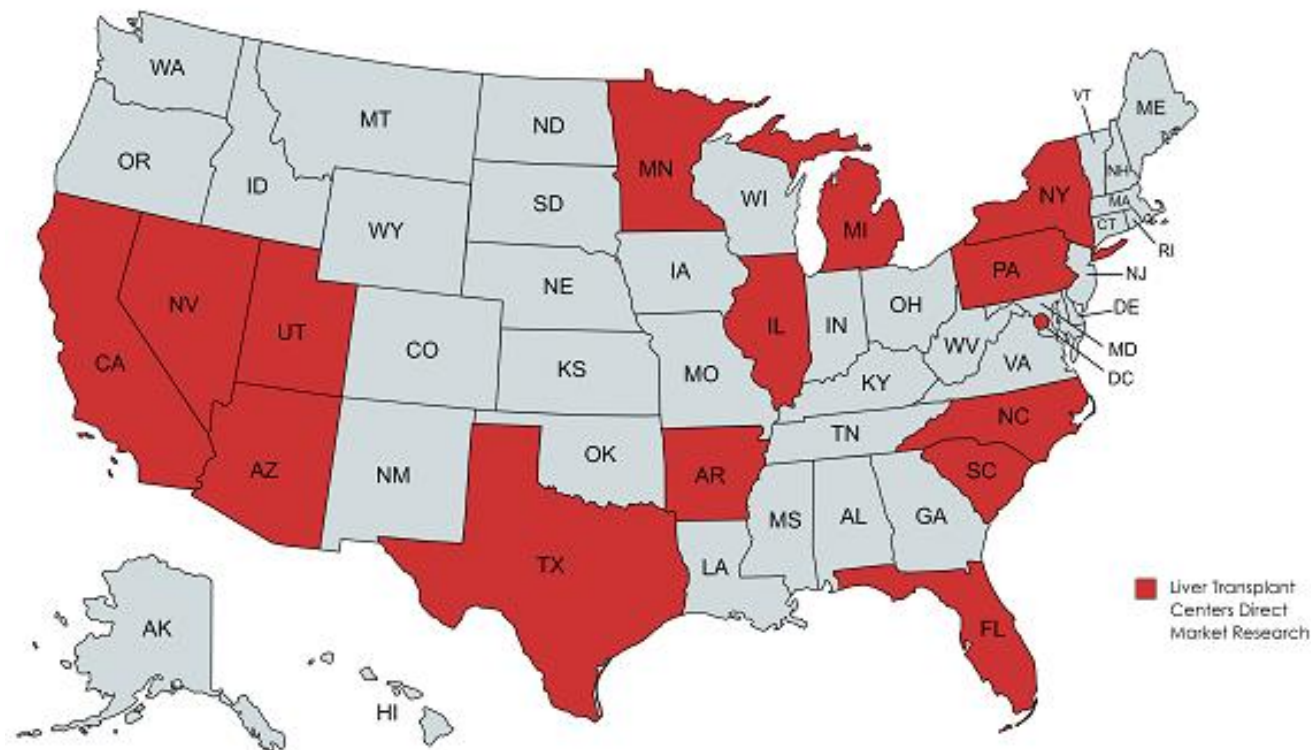


Reeds 35 top centra bezocht en **alfapump** programma besproken met diensthoofd levertransplantatie



Directe interactie met:

- 50 Hepatologen
- 20 Interventionele Radiologen
- 2 Levertransplantatiechirurgen





**DSR<sup>®</sup>**

Ziektemodificerende therapie voor hartfalen



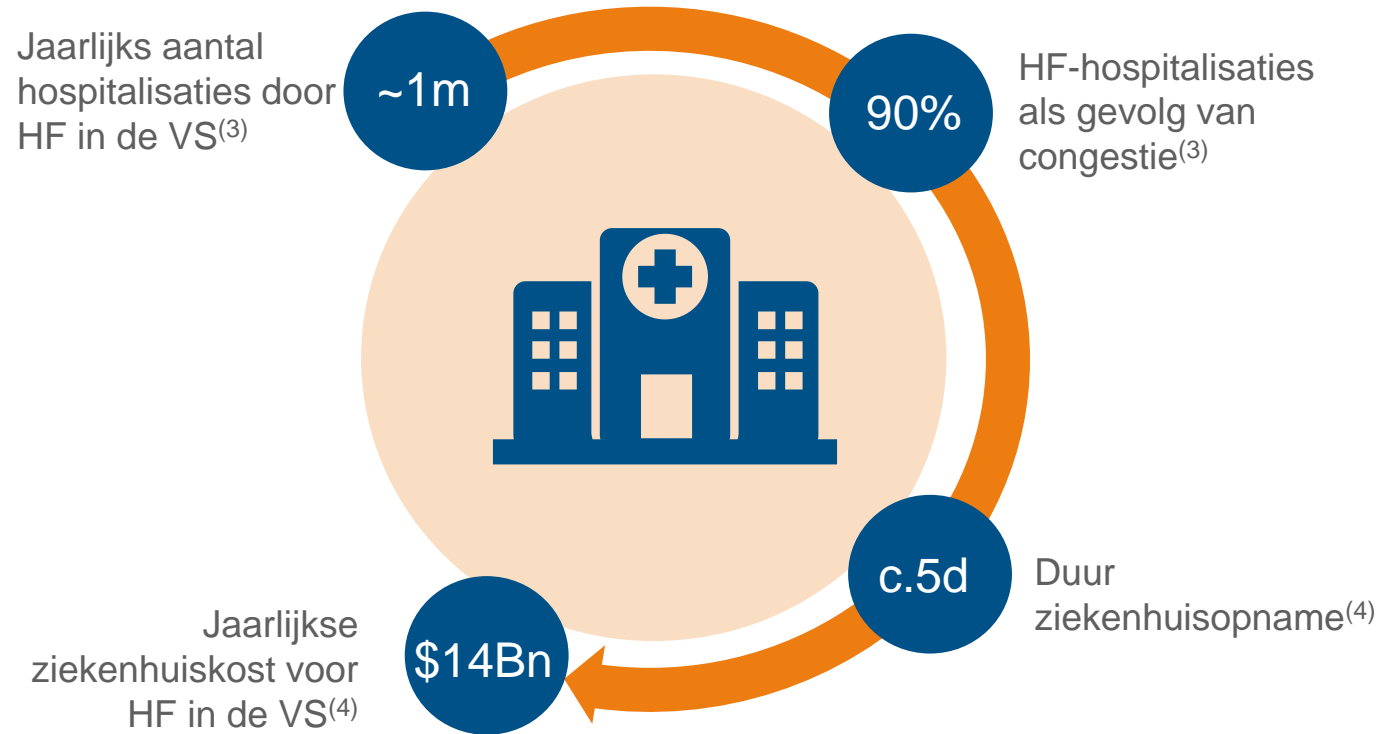
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# Congestie is oorzaak van morbiditeit en hospitalisatie

Diuretica-resistentie bij hartfalen komt vaak voor en er zijn weinig effectieve klinische alternatieven

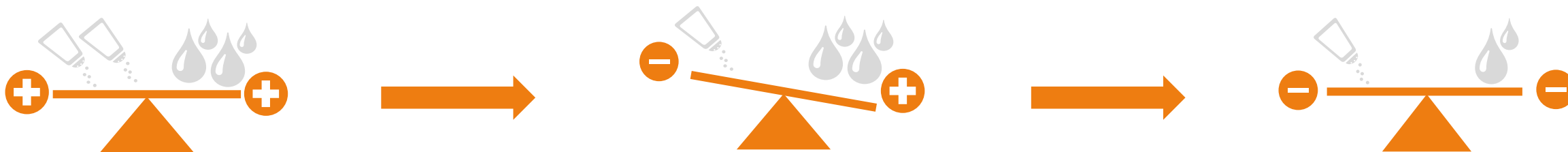


- 40% van patiënten met HF hebben een zwakke respons op intraveneuze lisdiuretica<sup>(1)</sup>
- 1 op 4 terug opgenomen in het ziekenhuis binnen de 30 dagen<sup>(2)</sup>



# Direct Sodium Removal (DSR)

Verwijderen van vocht verspreid over het lichaam – samenwerking met de nieren

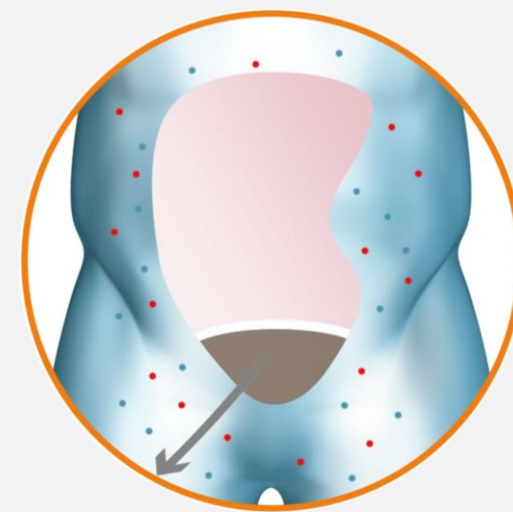
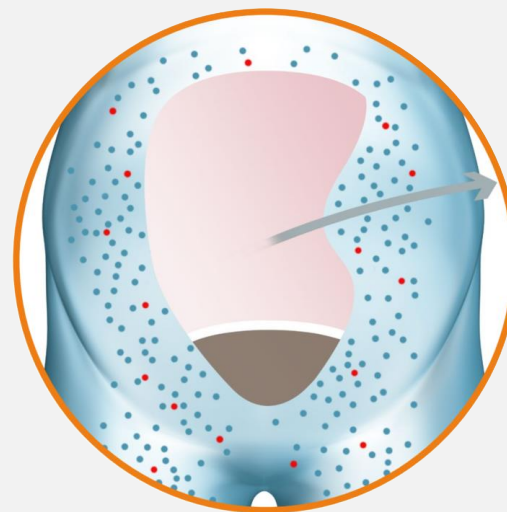
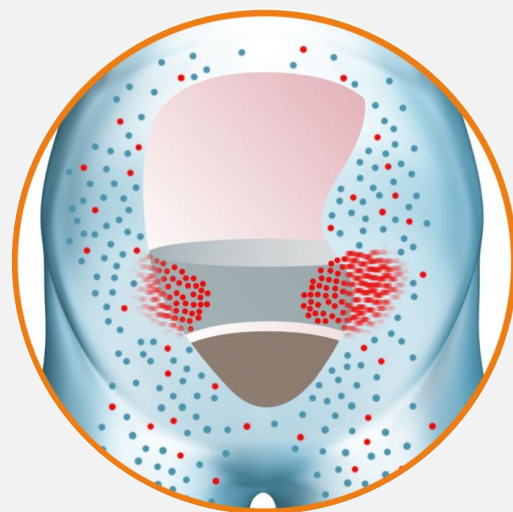
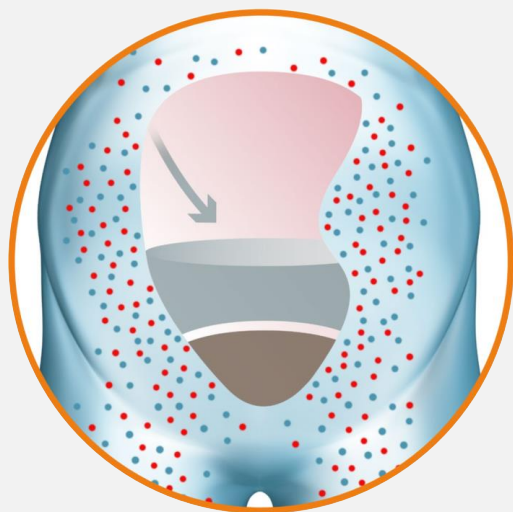


1 Natriumvrij DSR product toegediend in de buikholte

2 Natrium diffundeert vanuit het lichaam in DSR product

3 DSR product + geëxtraheerd natrium verwijderd uit het lichaam

4 Lichaam verwijdert water om de natriumbalans te herstellen, wat leidt tot verminderde vochtoverbelasting



- water
- natrium

*Fundamentele patenten toegekend in de VS, Europa en China om vochtoverbelasting bij patiënten met hartfalen te verminderen*

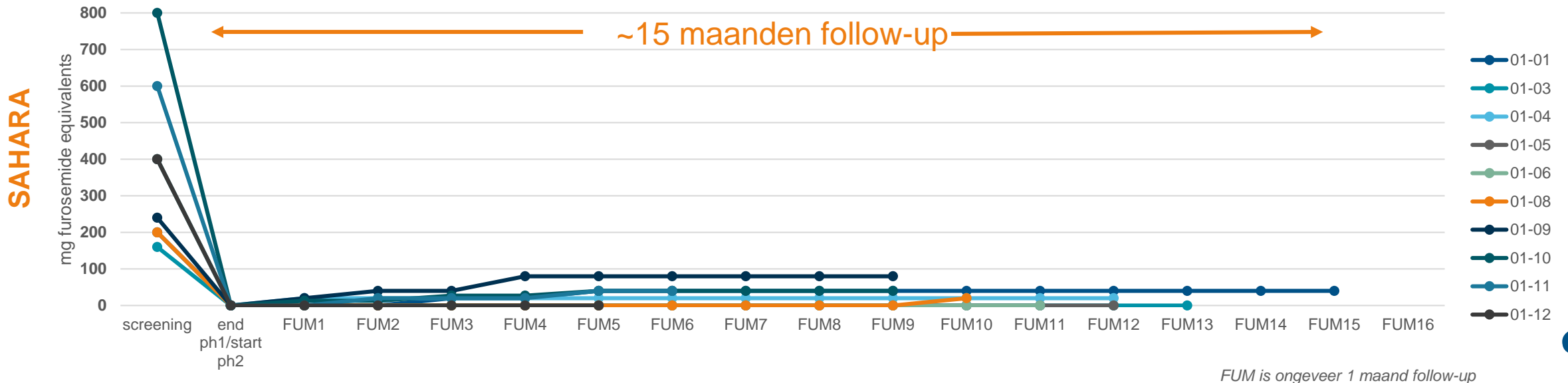


# RED DESERT & SAHARA

Fase 2a proof-of-concept studies van DSR 1.0 in diuretica-resistente hartfalen patiënten

## Effectieve verwijdering van vocht en duurzame verbeteringen in hart- en nierfunctie

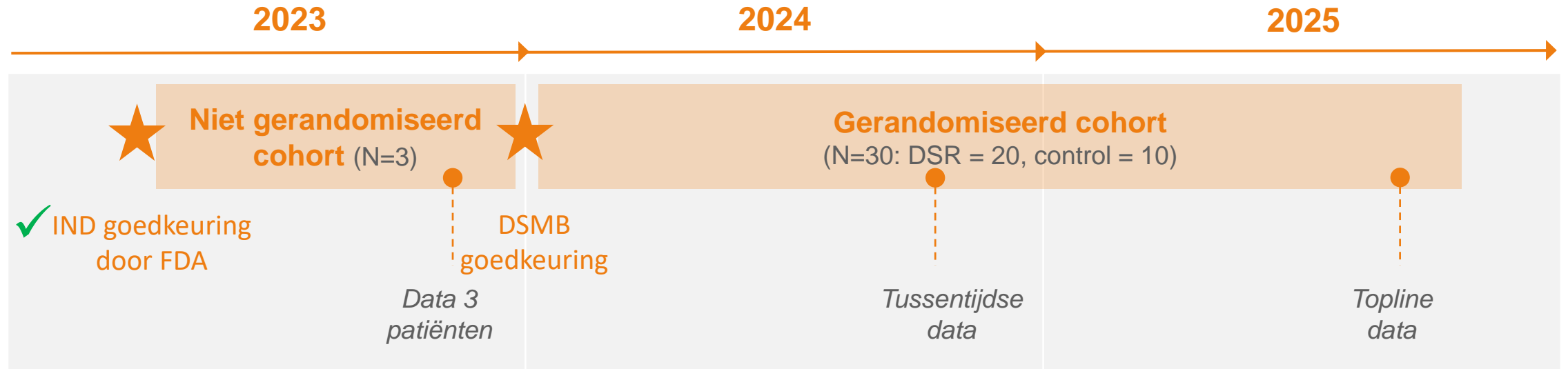
- ✓ Volledige vervanging van lisdiuretica
- ✓ Veilige, effectieve en snelle verwijdering van te veel aan vocht / herstel van euvolemie
- ✓ Langdurige vermindering van de behoefte aan lisdiuretica
- ✓ Aanzienlijk voordeel voor hart- en nierfunctie
- ✓ Geen heropnames in het ziekenhuis voor congestie-gerelateerd hartfalen





# MOJAVE – Fase 1/2a studie in VS met DSR 2.0

Eerste 2 patiënten met success behandeld, zonder de noodzaak van lisdiuretica

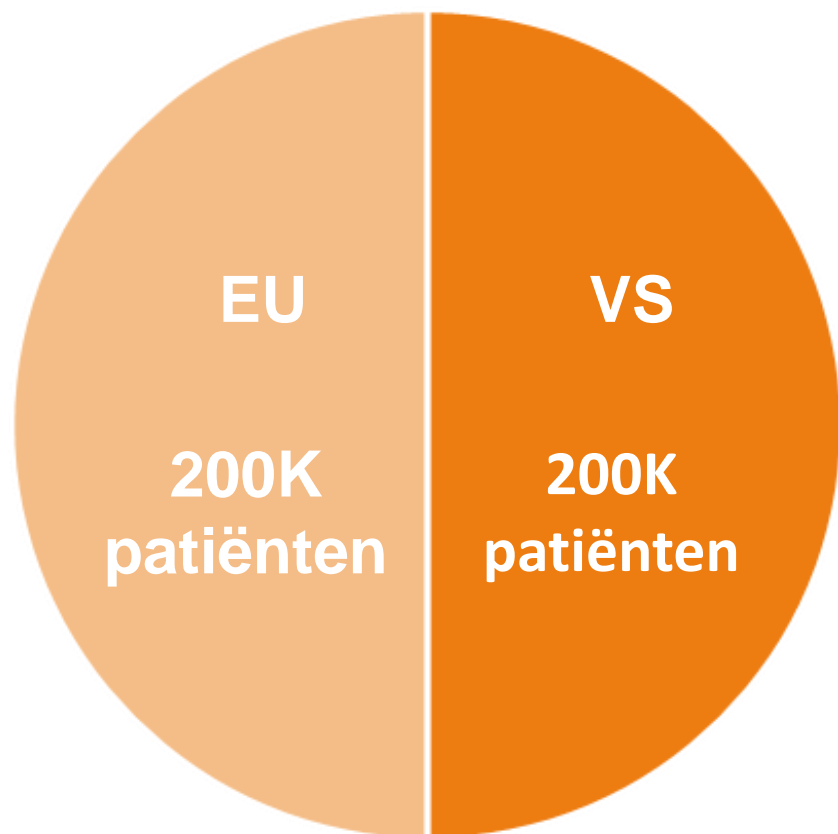


**Topline data H2 2025 bedoeld om klinisch datapakket aan te leveren voor partnerschap**



# Zeer grote commerciële opportuniteit

~400.000 chronische HF-patiënten met congestie worden jaarlijks in het ziekenhuis opgenomen in de VS en EU



**>\$9 mld**

Potentiële markt voor  
DSR in de VS





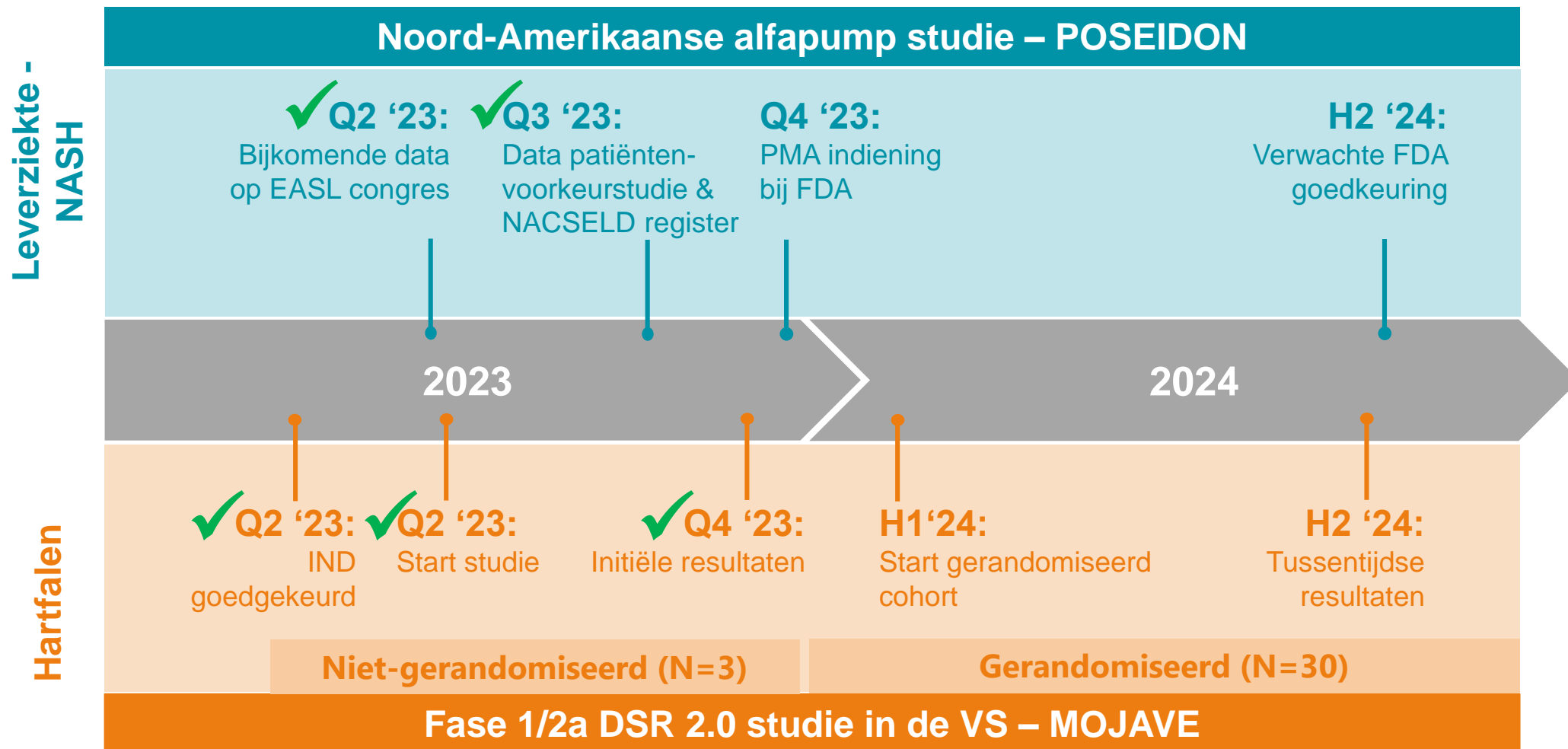
# Vooruitzichten

Waardebepaling op korte termijn met lange-  
termijn potentieel

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# Sterke vooruitzichten voor waardebeoordeling



# Vochtoverbelasting – grote markten met sterke groei

Sterke klinische en commerciële productprofielen in levercirrose en hartfalen



## alfapump in levercirrose

- Markt groeit tot ruim 2,5 miljard dollar in 2035<sup>(1)</sup>
- FDA breakthrough status / Goedgekeurd in EU
- Succesvolle N-Amerikaanse studie – primaire eindpunten bereikt, sterk klinisch profiel
- Indiening PMA dossier gepland voor Q4 '23 met FDA goedkeuring verwacht in H2 '24
- Directe verkoop in de VS
- Sterk terugbetalingsprofiel – bestaande codes voor ziekenhuis en voordeel uit andere initiatieven



## DSR in hartfalen

- Multi-miljard marktopportuniteit
- Nieuwe behandeling voor cardiorenaal syndroom
- Klinische proof-of-concept als ziektemodificerende behandeling voor HF
- DSR 2.0; laag ontwikkelingsrisico, verbeterd profiel & sterke patentbescherming
- Fase 1/2a gerandomiseerde studie in de VS (MOJAVE) gestart; positieve data van eerste patiënten
- Partnering op basis van MOJAVE data gepland voor '25

**Groei van levercirrose als gevolg van NASH en aanpak van het cardiorenaal syndroom bij hartfalen zorgen voor enorme commerciële kansen voor Sequana Medical**

Bron 1: Gebaseerd op marktbeoordeling in de VS en Canada door zeer ervaren internationale adviesgroep, gebruik makende van claimanalyse voor commerciële en Medicare patiënten die een paracenteseprocedure met diagnosecodes voor leveraandoeningen nodig hebben; rekening houdend met incidentie van 60% en prijs alfapump van \$25K

PMA: Pre-Market Approval – dossier om commerciële goedkeuring aan te vragen in de VS

## Contact info

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