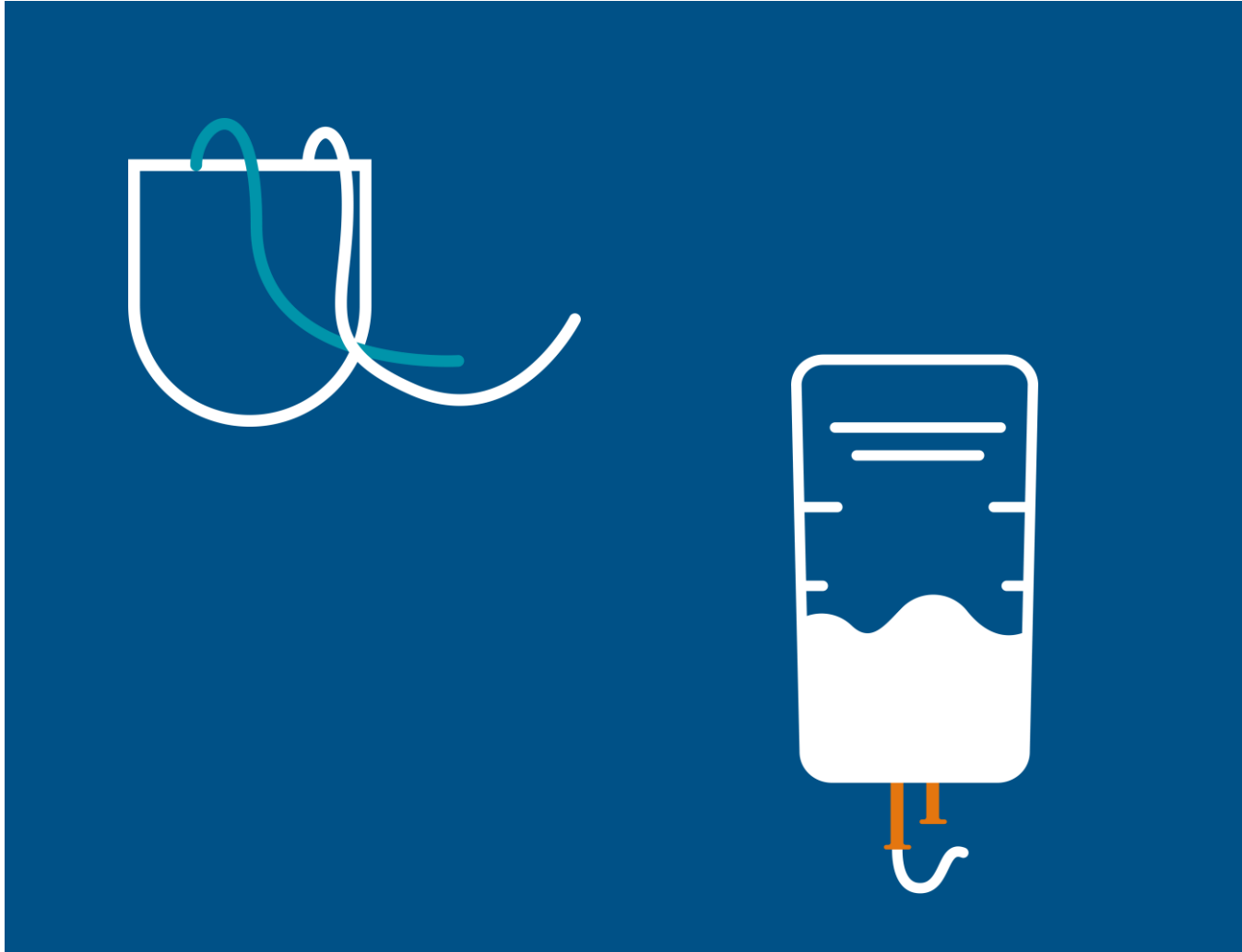


**sequana**medical



# **Pioniers in de behandeling van vochtoverbelasting**

leveraandoeningen, hartfalen & kanker

VFB Happening – 25 maart 2023

Kirsten Van Bockstaele, CFO & Lies Vanneste, IR

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- 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.

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- 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> is a registered trademark. DSR<sup>®</sup> and **alfapump DSR**<sup>®</sup> are registered trademarks in the Benelux, China, the EU, United Kingdom, and Hong Kong.

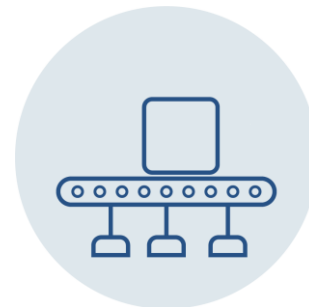
# Sequana Medical NV



2006



Gent



Zürich



>70 werknemers



SEQUA



alfapump<sup>®</sup>



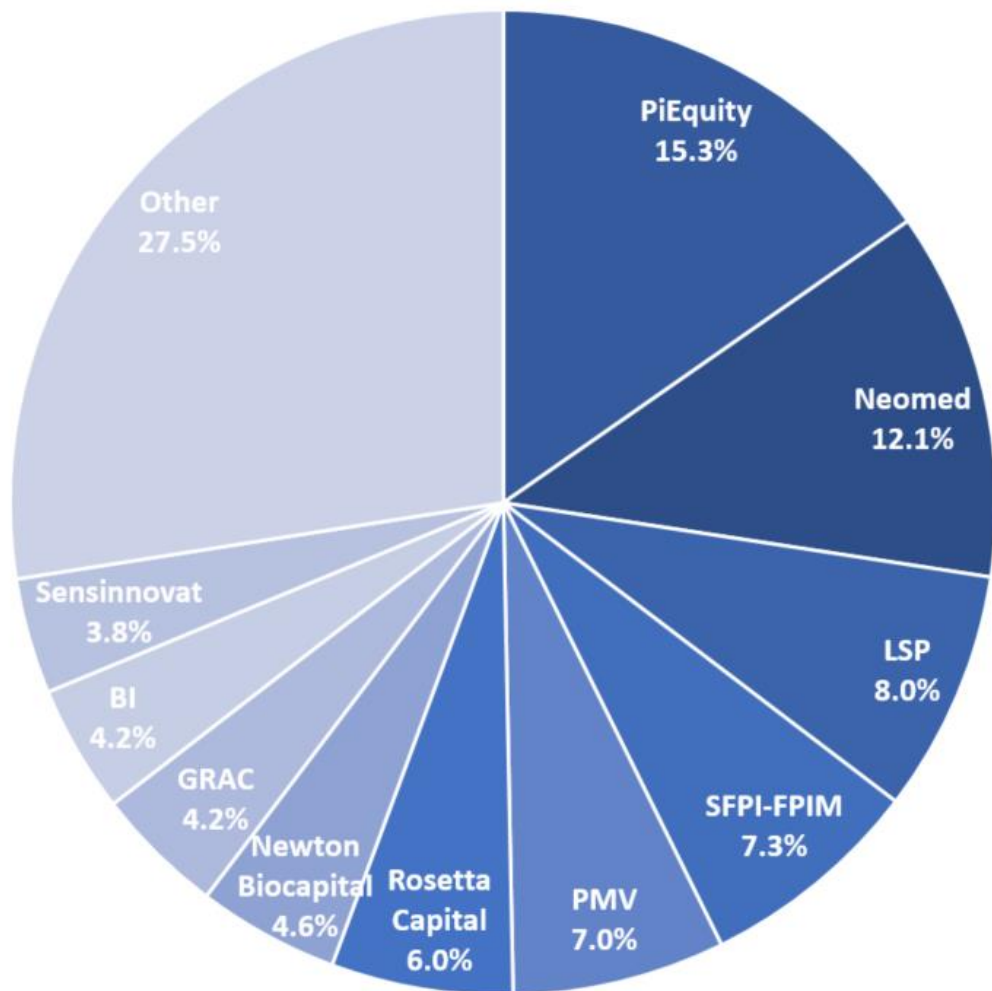
DSR<sup>®</sup>



93 patenten

# Aandeelhoudersstructuur en financieel overzicht

Ticker: SEQUA – Euronext Brussels



## Cash:

- Kaspositie: €18,9 M (31 december 2022)
- Cash runway tot midden 2023

## Aandeleninfo:

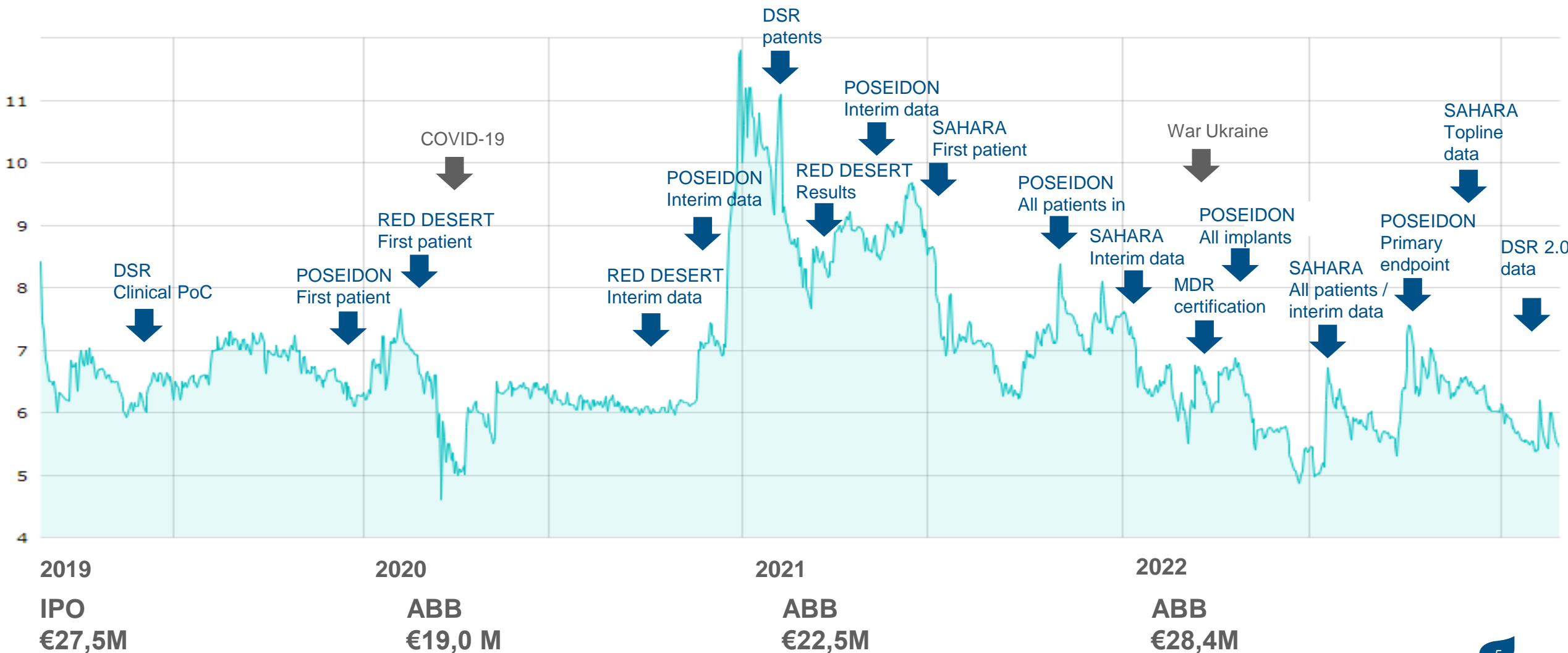
- 23,7 M uitstaande aandelen
- ~€130M market cap

## Analisten:

- Degroof Petercam – Laura Roba
- Edison Research – Pooya Hemami
- H.C. Wainwright – Yi Chen
- KBC Securities – Jeroen Van den Bossche
- Kempen – Suzanne van Voorthuizen
- Kepler Cheuvreux – Arsene Guekam

# Het aandeel sinds de beurgang in 2019

Cashflow & Newsflow zijn belangrijke troeven voor het aandeel



# Leider in grote en groeiende markten met hoge medische nood



- **alfapump® in leverziekte – groeiend marktpotentieel tot meer dan \$2,5 mld tegen 2035<sup>(1)</sup>**
  - NASH verandert de markt voor levercirrose en stimuleert de groei
  - Goedgekeurd in EU / FDA breakthrough device status / sterke IP
  - N-Amerikaanse pivotale studie – positieve primaire eindpuntdata gerapporteerd
  - N-Amerikaanse goedkeuring verwacht in 2024 / directe verkoop via 90 levertransplantatiecentra



- **DSR® in hartfalen – aanzienlijke marktopportuniteit in EU en de VS**
  - Ziekte-modificerende therapie voor hartfalen
  - Eerste generatie DSR 1.0 – klinische proof-of-concept
  - Tweede generatie DSR 2.0 – verbeterd therapeutisch en veiligheidsprofiel & sterke IP
  - Partnering op basis van Fase 1/2a studie in de VS met DSR 2.0 verwacht in 2024



**alfapump<sup>®</sup>**

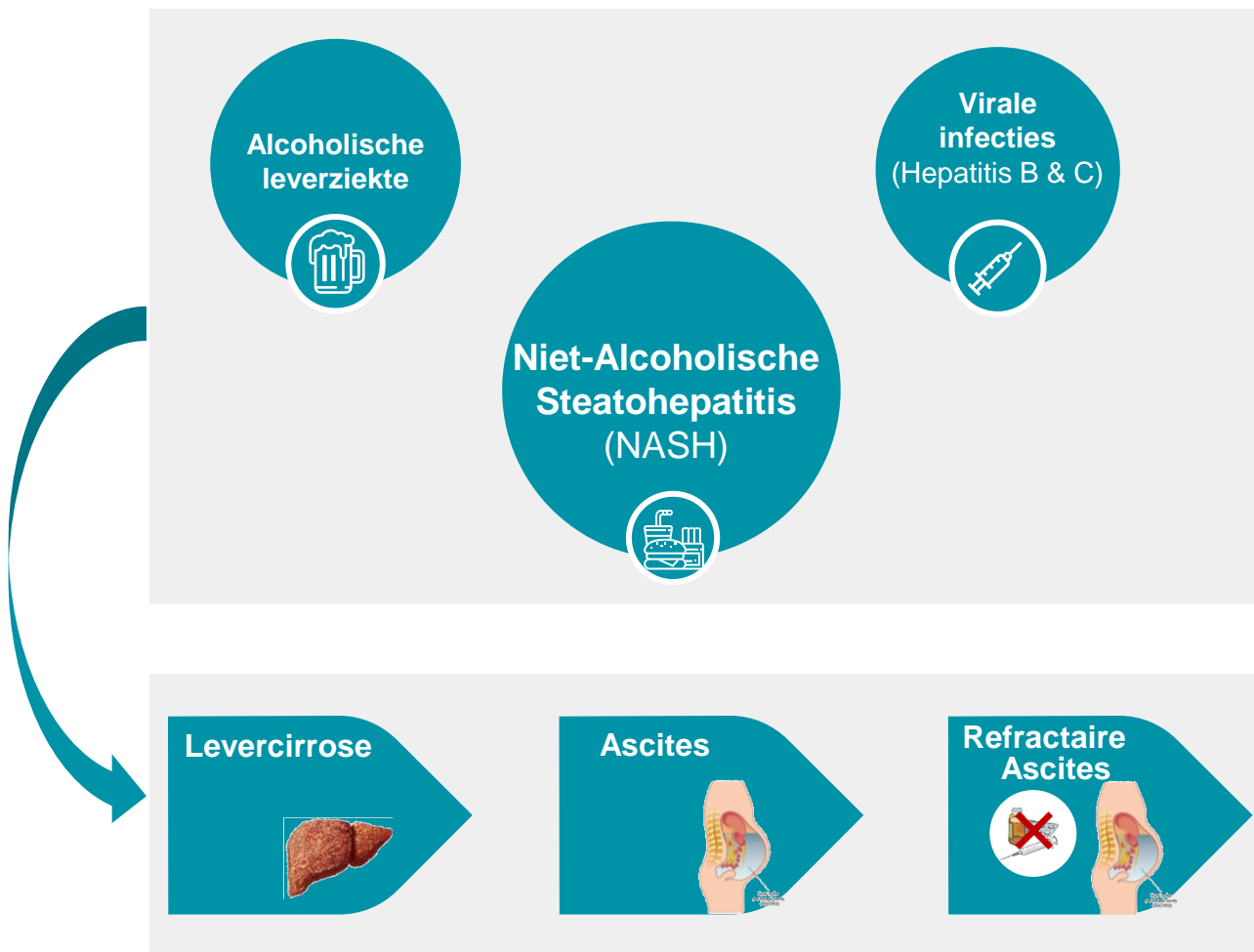
Bewezen behandeling voor refractaire  
ascites door levercirrose



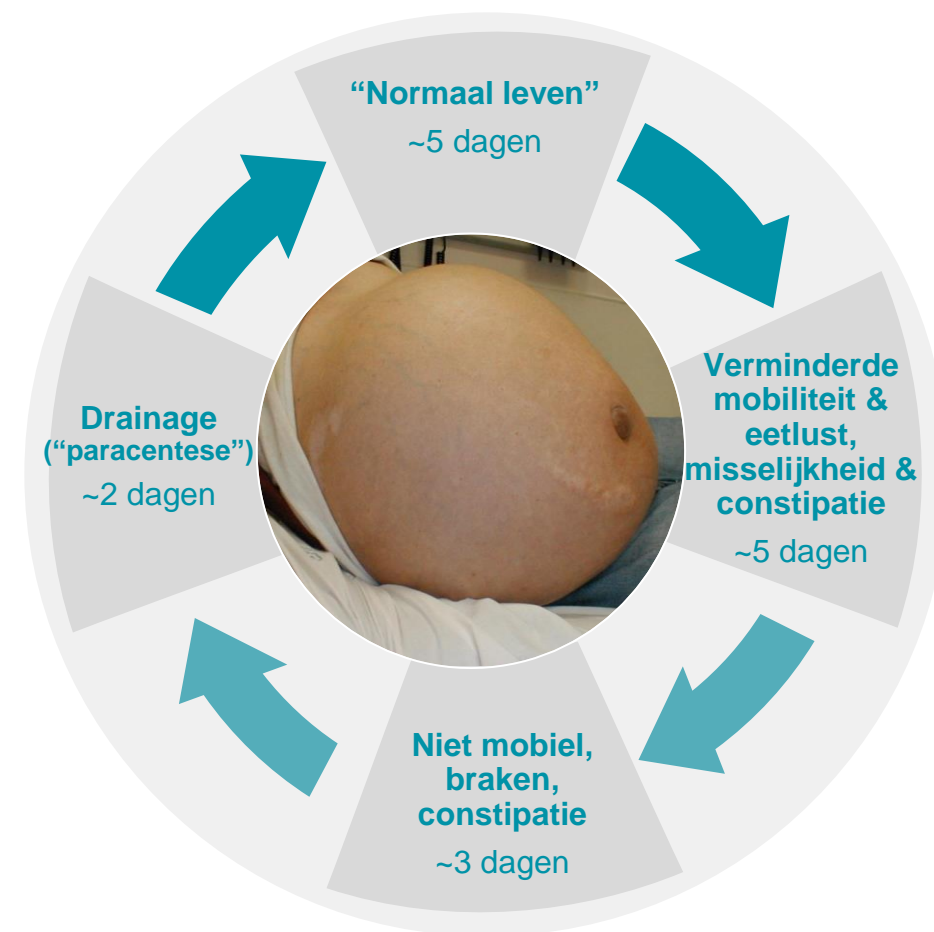
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# Refractaire ascites – belangrijke complicatie van levercirrose

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



Typisch leven van een patiënt<sup>(1)</sup>

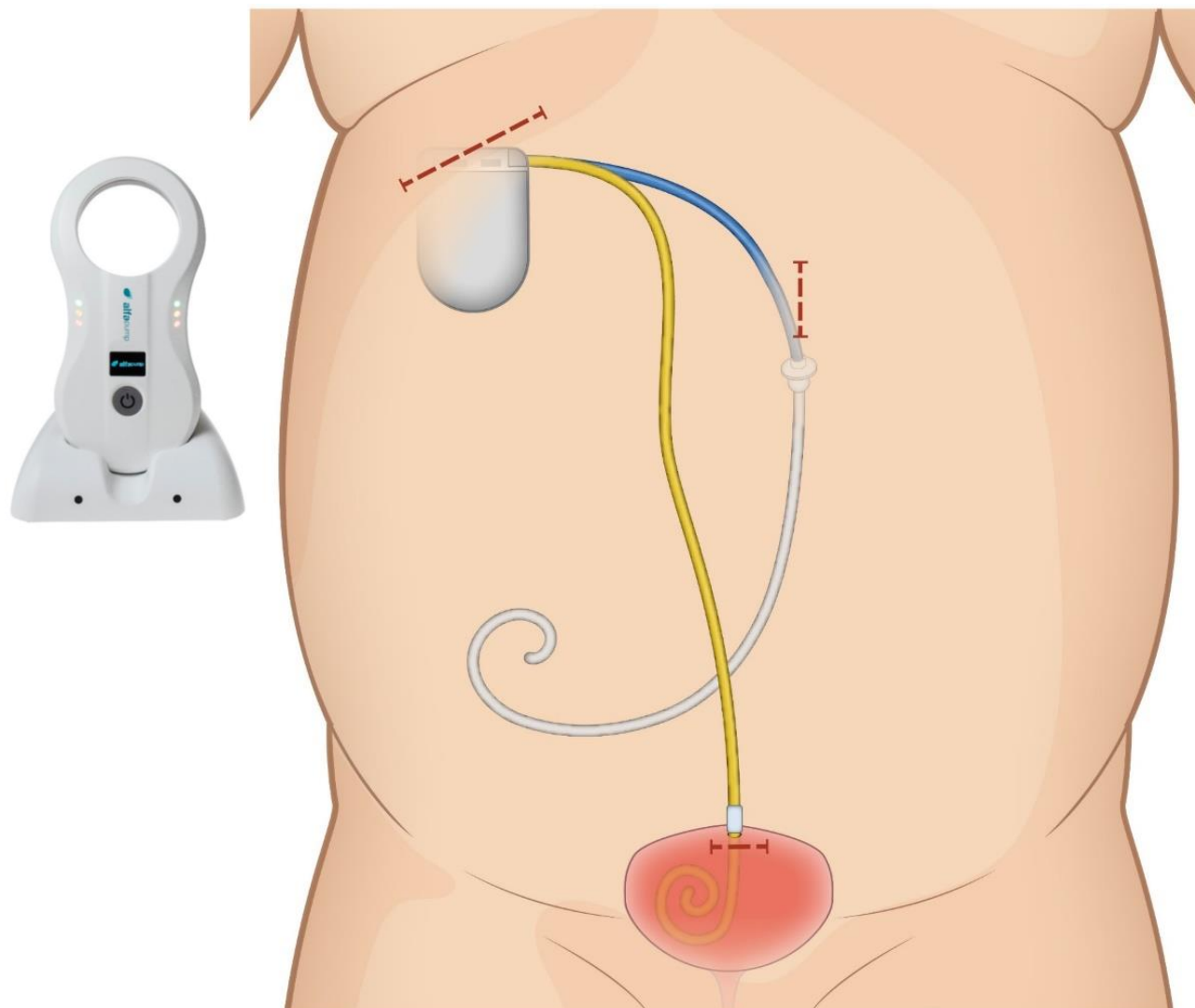


Bron 1: Presentatie van Dr. Rajiv Jalan op EASL in 2018, Behandelingscyclus voor grootvolume paracentese van refractaire ascites



# alfapump

Verwijderen van vocht uit de buikholte – samenwerking met de blaas



**FDA** Breakthrough Device Designation



Meer dan 950 implantaties  
Uitgebreide octrooiportefeuille & know-how

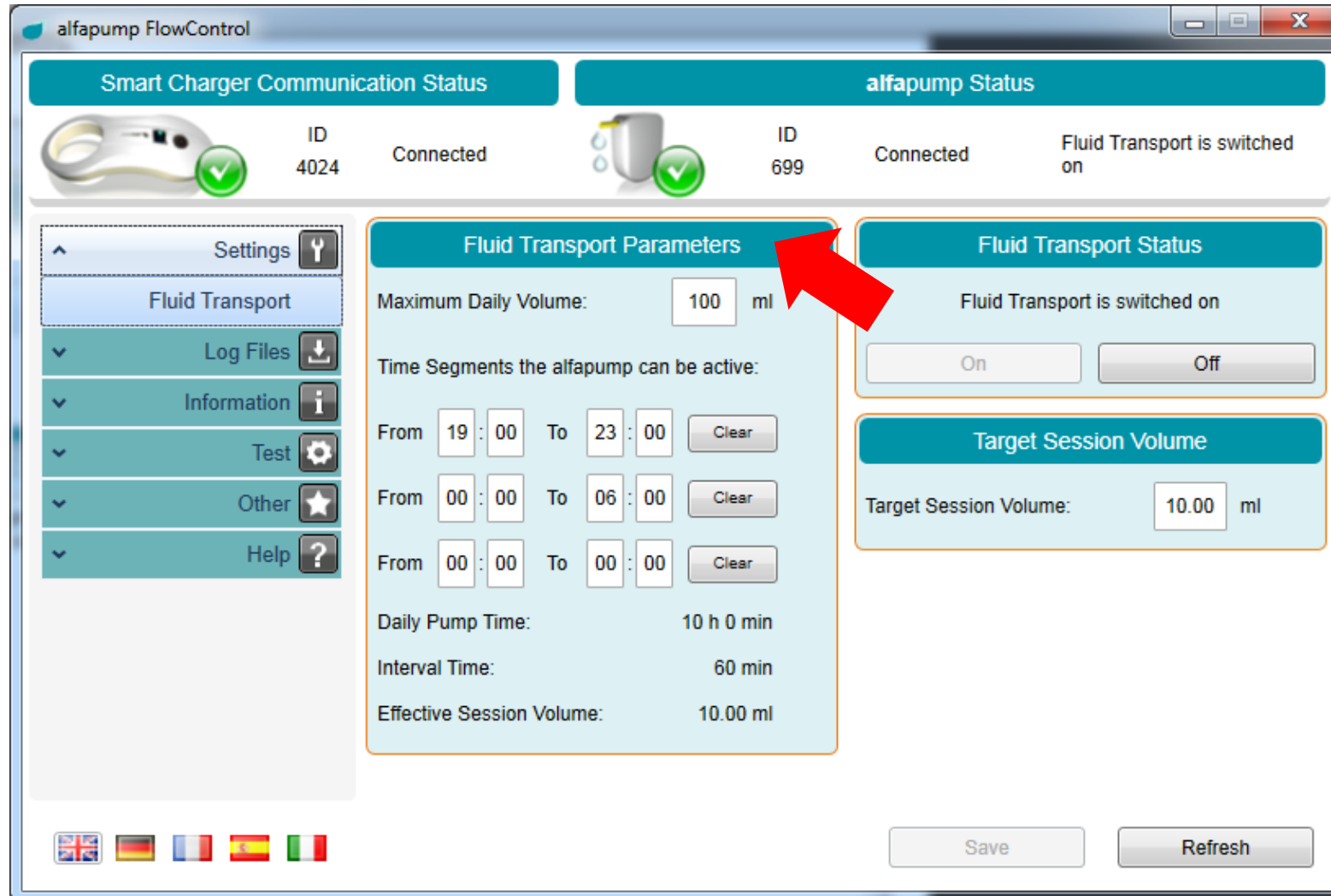
# SmartCharger

Draadloos opladen van de pomp doorheen de huid



# Draadloos aanpassen van de instellingen

Voor optimale vochtverwijdering op maat van de patiënt



The screenshot displays the 'alfapump FlowControl' software interface. At the top, there are two status bars: 'Smart Charger Communication Status' and 'alfapump Status'. The 'Smart Charger' section shows ID 4024, Connected, with a green checkmark. The 'alfapump' section shows ID 699, Connected, and 'Fluid Transport is switched on', also with a green checkmark. A left sidebar contains navigation options: Settings (wrench icon), Fluid Transport (selected), Log Files (download icon), Information (info icon), Test (gear icon), Other (star icon), and Help (question mark icon). The main area is divided into three panels. The 'Fluid Transport Parameters' panel, highlighted with a red arrow, includes: Maximum Daily Volume: 100 ml; Time Segments the alfapump can be active: From 19:00 To 23:00 (Clear), From 00:00 To 06:00 (Clear), From 00:00 To 00:00 (Clear); Daily Pump Time: 10 h 0 min; Interval Time: 60 min; Effective Session Volume: 10.00 ml. The 'Fluid Transport Status' panel shows 'Fluid Transport is switched on' with 'On' and 'Off' buttons. The 'Target Session Volume' panel shows 'Target Session Volume: 10.00 ml'. At the bottom, there are 'Save' and 'Refresh' buttons. Language flags for UK, Germany, France, Spain, and Italy are visible at the bottom left.



# Data monitoring van op afstand

Behandelende artsen ontvangen wekelijkse rapporten



Dear Dr.

Thank you for choosing **alfapump** with DirectLink Technology.

Pump serial no.: **6110**  
 Days since implant: **441**  
 Total volume of fluid removed: **534.0 liters**  
 Average daily volume of the last 7 complete days: **1047.8 ml**

The alfapump is functioning well and has been adequately charged.

Please find below the daily statistics from the last 8 days for this **alfapump**.

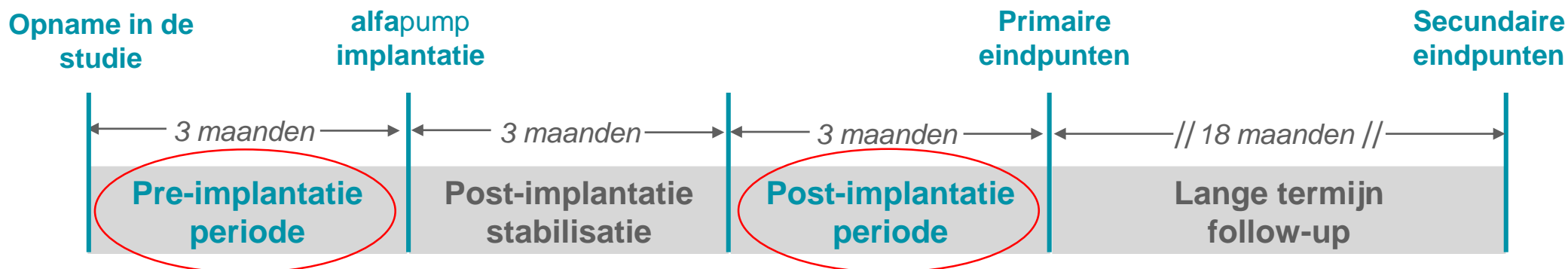
Date	Target Daily Volume [ml]	Total Volume transported [ml]	% Target Daily Volume Transported	Effective Pump Charging Time [min:sec]
01.10.2018	1300	1152	89	59:21
02.10.2018	1300	895	69	56:00
03.10.2018	1300	1135	87	81:09
04.10.2018	1300	1100	85	56:08
05.10.2018	1300	904	70	48:13
06.10.2018	1300	1089	84	55:12
07.10.2018	1300	1060	82	45:07
08.10.2018 (incomplete) data from 00:00 to 18:18	1300	892	69	06:37

For questions please do not hesitate to contact us by replying to this email.

Best regards

# POSEIDON – Noord-Amerikaanse pivotale studie

40 patiënten met terugkerende of refractaire leverascites werden geïmplanteerd met de alfapomp



# POSEIDON – positieve topline data

Alle primaire eindpunten van de studie werden bereikt

## Primaire effectiviteitseindpunten overschrijden vooraf gedefinieerde drempels voor studiesucces

- **Mediaan van 100%** per patiënt vermindering in paracentese ( $p < 0,001$ ) <sup>(1)</sup>
  - *vs hypothese van ten minste 50% vermindering*
- **77% van de patiënten** met minstens 50% vermindering in paracentese ( $p < 0,001$ ) <sup>(1)</sup>
  - *vs hypothese van minstens 50% van de patiënten*

## Primaire veiligheidseindpunten in lijn met de verwachtingen

- Geen onverwachte nadelige toesteleffecten
- 6 primaire veiligheidsincidenten

***“Deze positieve topline resultaten zijn zeer bemoedigend en wijzen erop dat de alfapomp grote voordelen kan bieden aan patiënten met cirrose en ascites, en hun bezoeken aan het ziekenhuis voor paracentese drastisch kan verminderen.” – Dr. Wong, Hoofdonderzoeker POSEIDON studie***

<sup>(1)</sup> Post vs Pre-Implantatie

# Goed gepositioneerd voor succesvolle commercialisatie in de VS



## Publicaties & presentaties

Voorstellen POSEIDON data op medisch congres en publicatie in erkend tijdschrift in **2023**



## Patiënten voorkeurstudie in VS

Enquêtestudie om de voorkeuren van patiënten voor de **alfapump** te kwantificeren, inclusief risicobatenanalyse

Topline data verwacht in **H2 2023**



## Indiening & goedkeuring in VS

Indiening dossier gepland voor **H2 2023**

FDA goedkeuring verwacht in **H2 2024**

- ✓ **alfapump kan gebruik maken van bestaande codes voor terugbetaling van ziekenhuiskosten**
- ✓ **NTAP regeling voor breakthrough devices levert bijkomende terugbetaling**

# Grote en groeiende N-Amerikaanse patiëntenpopulatie

NASH zal naar verwachting nog vele jaren een aanzienlijke groei veroorzaken – en een veranderende houding tegenover cirrose

N-Amerikaanse  
patiënten met  
terugkerende of  
refractaire ascites  
tgv levercirrose

Meer dan  
75.000

2025

6 – 7% per jaar

Meer dan  
170.000

2035

***Marktpotentieel groeit tot meer dan \$2.5 miljard 2035***



# VS – Directe verkoop naar 90 levertransplantatiecentra

Zeer efficiënte benadering van artsen en patiënten – gestuurd door behandelingsrichtlijnen



125 centra voor volwassenen, waarvan 90 centra 95% van de transplantaties uitvoeren



Initieel commercieel team van ~50 mensen

**DSR<sup>®</sup>**

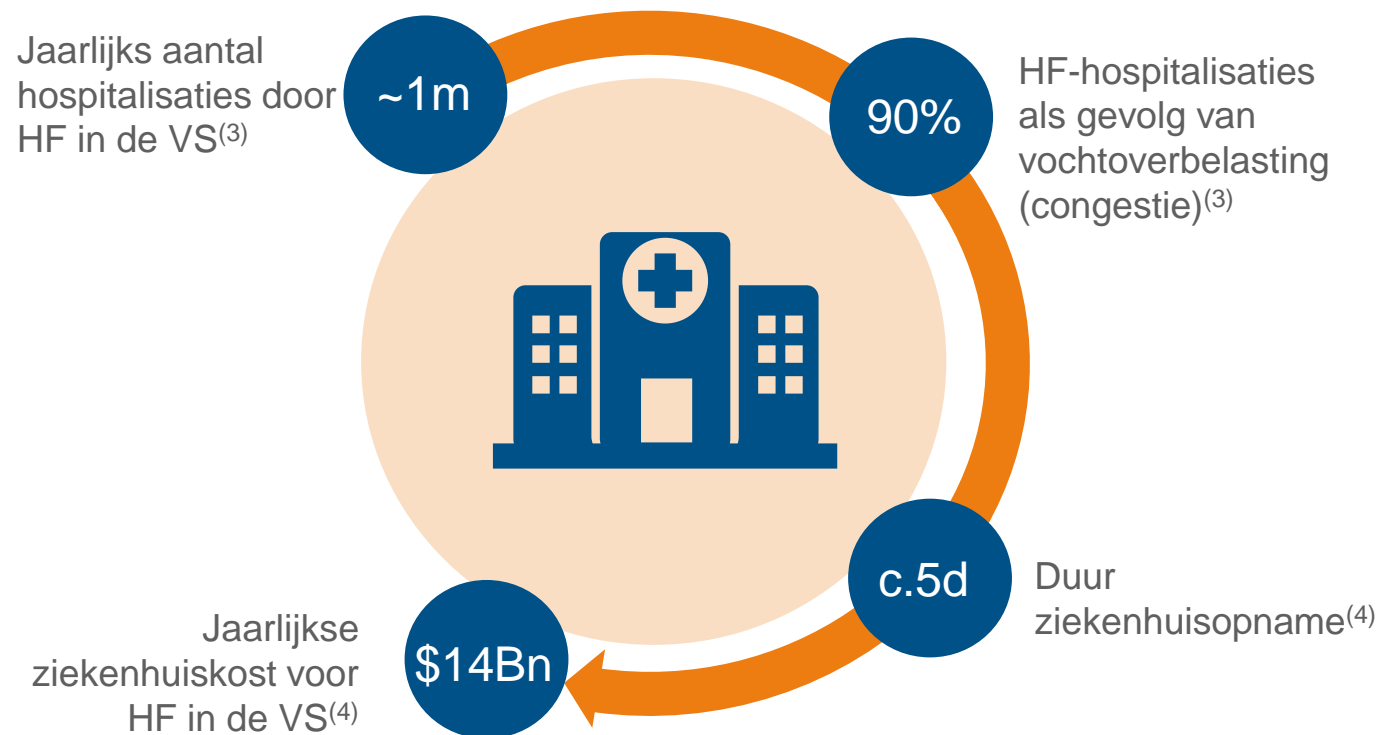
Ziekte-modificerende therapie voor hartfalen



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# Congestie is oorzaak van morbiditeit en hospitalisatie

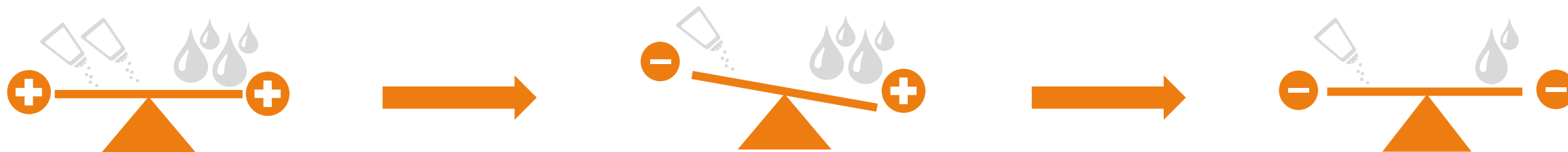
Diuretica-resistentie komt vaak voor en er zijn weinig effectieve klinische alternatieven



- 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

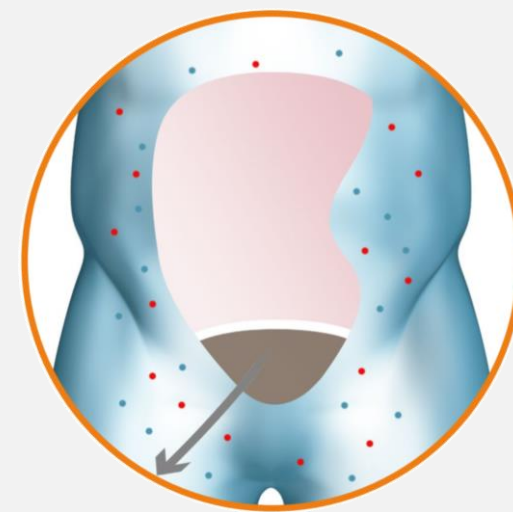
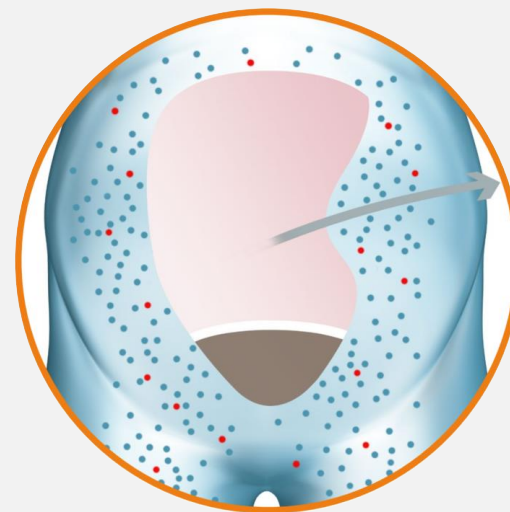
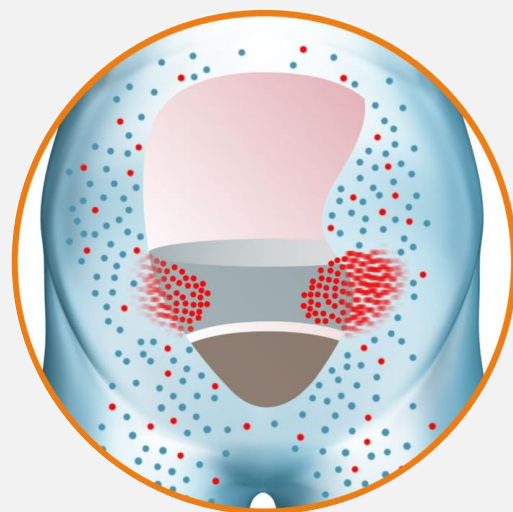
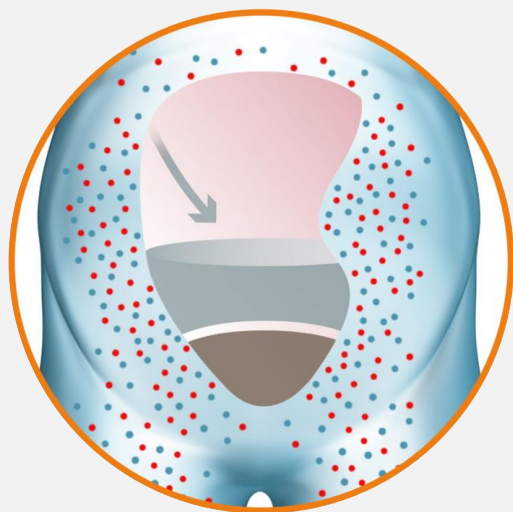


1 Natriumvrij DSR product toegediend in de buikholte

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 vochtverbelasting



- water
- natrium

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

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

18 patiënten met hartfalen op hoge doses diuretica voor vochtoverbelasting behandeld met DSR 1.0

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

- ✓ Veilige, effectieve en snelle verwijdering van te veel aan vocht en herstel van euvolemie
- ✓ Aanzienlijk voordeel voor hart- en nierfunctie behouden tot vele maanden na DSR behandeling
- ✓ Drastische en aanhoudende verbetering in de respons op diuretica

## Leiden tot betere klinische resultaten

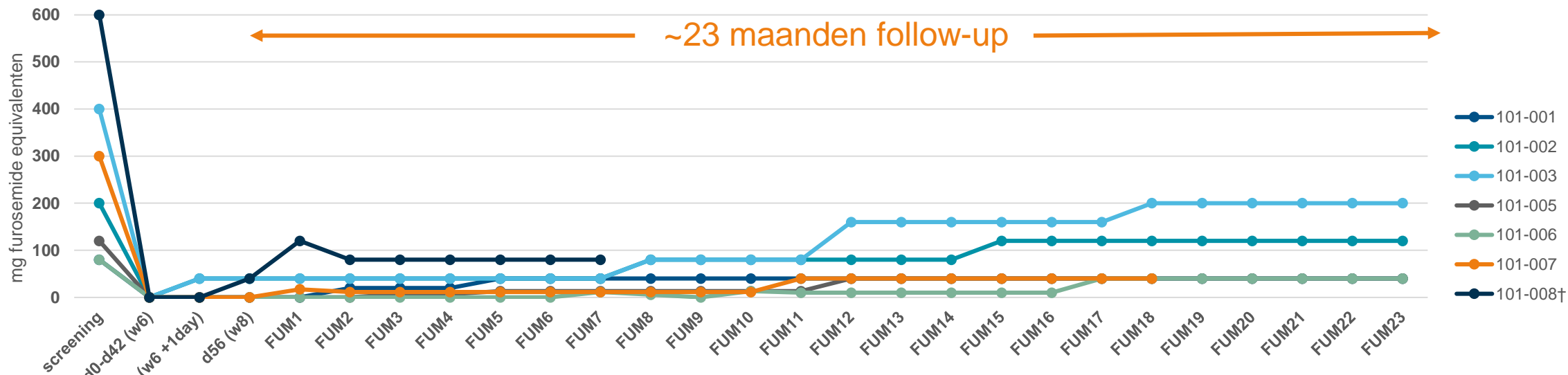
- ✓ Geen heropnames in het ziekenhuis voor congestie-gerelateerd hartfalen
- ✓ Langdurige en aanzienlijke vermindering in de dosis diuretica
- ✓ Verbetering van de NYHA\* status met één klasse
- ✓ 75% vermindering van de voorspelde één-jaars sterfte op basis van het Seattle Heart Failure model

*“Deze resultaten zijn zeer bemoedigend en wijzen op het potentieel van DSR-therapie om klinisch zinvolle decongestie en duurzame verbeteringen van de hart-en nierfunctie en dus van de diuretische response te bewerkstelligen” – Dr. Testani*

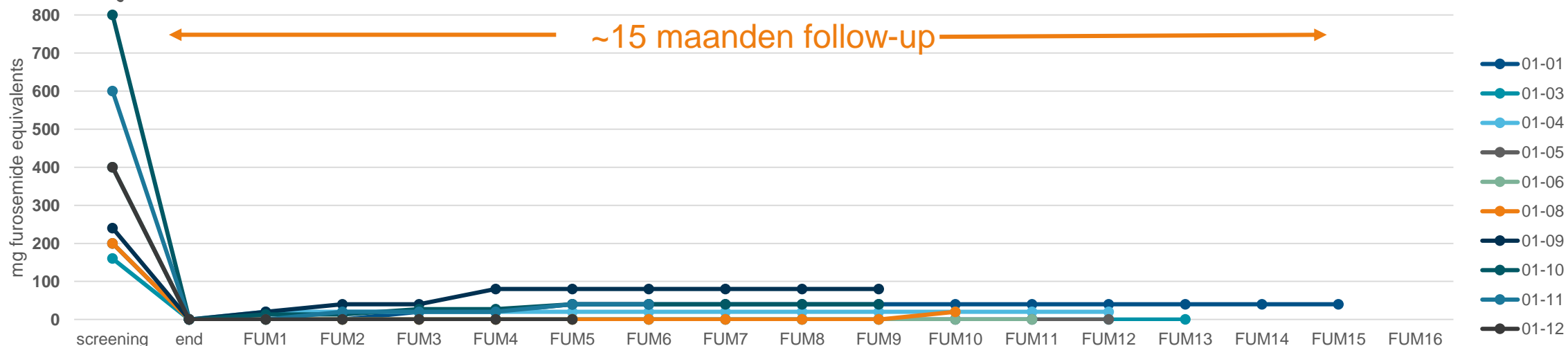
# Langdurige en aanzienlijke vermindering in dosis lisdiuretica

Duidelijk aantoonbare verbetering van de gezondheid van hart en nieren – leidt tot betere klinische resultaten

RED DESERT



SAHARA



FUM is ongeveer 1 maand follow-up

# DSR 2.0: Verbeterd therapeutisch en veiligheidsprofiel

Sterke patenten zorgen voor een terugkerende inkomstenstroom met een hoge marge

## DSR 1.0

Natriumvrij D10% (vrij verkrijgbaar)

- ✓ Klinische proof-of-concept
- ✓ Snel klinisch traject
- ~ Therapeutisch profiel / Gebruiksvriendelijk
- ~ Veiligheidsprofiel

✓ RED DESERT ✓ SAHARA



## DSR 2.0

Natriumvrij dextrose / icodextrine (eigen merk)

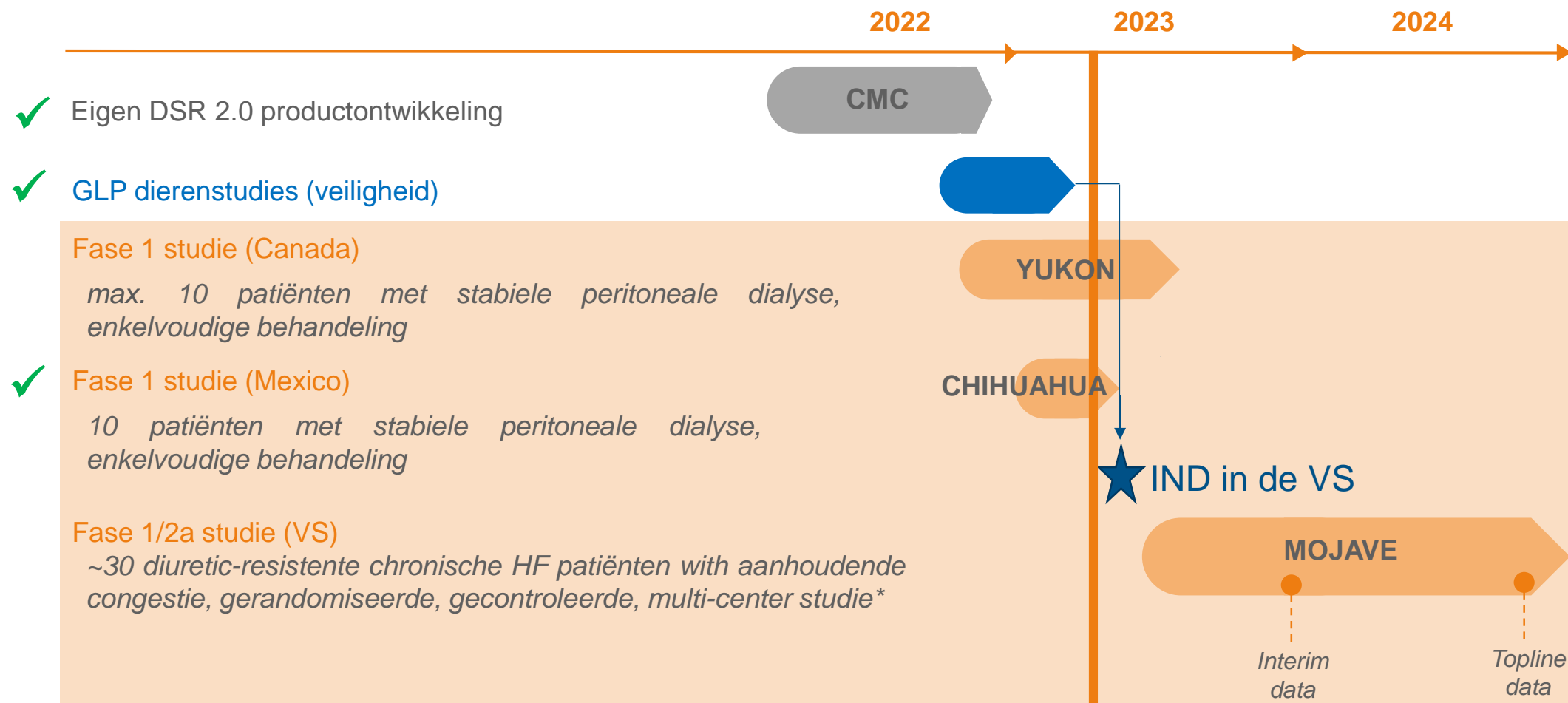
- ✓ Verbeterd therapeutisch profiel
- ✓ Gunstig veiligheidsprofiel
- ✓ Sterke patenten in de VS & Europa
  - “Medicijn met geen of weinig natrium voor behandeling van hartfalen”
  - Zorgt voor terugkerende inkomsten met een hoge brutomarge

✓ CHIHUAHUA – YUKON – MOJAVE



# Op schema om MOJAVE te starten in Q2

Bedoeld om het klinische datapakket te leveren voor partnering



\* Beschrijving en timing van deze studie zijn onder voorbehoud van wijzigingen en/of feedback van toepasselijke regelgevende instanties

GLP: Good Laboratory Practice; IND: Investigational New Drug



# Aanzienlijke marktopportuniteit voor DSR product

Meerwaarde creëren door minder ziekenhuisopnames en betere overlevingskansen

- ~400K patiënten met chronisch congestief HF per jaar in het ziekenhuis opgenomen in de VS en EU
  - Zorgen voor hoge kosten en een grote last voor gezondheidszorgsystemen, “payers” en patiënten
- Prijszetting DSR-therapie gebaseerd op meerwaarde door:
  - ⇒ Vermindering van heropnames ~ \$40K jaarlijkse HF hospitalisatiekosten per patiënt
  - ⇒ Toename in overleving (verhoging *in quality-adjusted life-year*, “QALY”)

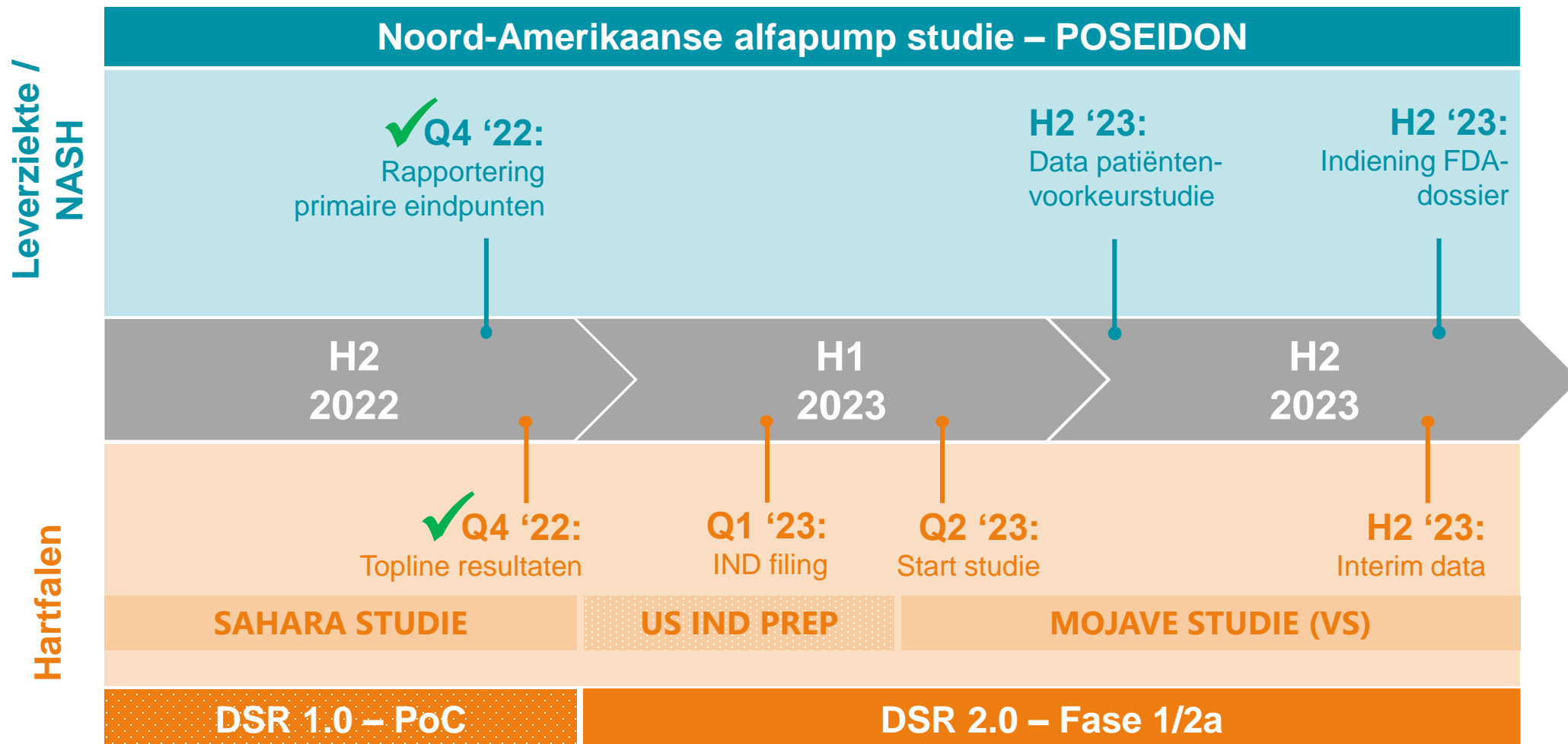
An aerial photograph of turbulent water, showing swirling eddies and white foam against a deep green background. The water appears to be in a narrow channel or around a rock formation, creating a complex, chaotic pattern of currents and whirlpools.

# Vooruitzichten

Waardebepaling op korte termijn met lange-  
termijn potentieel

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# Belangrijke vooruitzichten in 2023



Noot: Beschrijving en timing van deze studies zijn onder voorbehoud van wijzigingen en/of feedback van toepasselijke regelgevende instanties

PoC: Klinische Proof-of-Concept

## **Contact info**

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