



## Innovators in the treatment of diuretic-resistant fluid overload

liver disease  malignant ascites  heart failure

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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.

## COVID-19 disclaimer:

- Sequana Medical is closely following the evolution of 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> 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.

# Behandelen van diuretica-resistente vochtoverbelasting

Grote en groeiende markten met duidelijke onvervulde medische behoeften

- Vochtoverbelasting is een wezenlijk klinisch probleem bij leverfalen, hartfalen, nierfalen en kanker
- Diuretica / “plaspillen” zijn de standaardbehandelingen
- In veel gevallen zijn diuretica niet meer werkzaam – en alternatieven hebben aanzienlijke nadelen
- Wij gebruiken onze **alfapump**<sup>®</sup> en **DSR**<sup>®</sup> technologieën om therapiën te ontwikkelen voor:
  - verbeterde klinische resultaten
  - betere levenskwaliteit voor patiënten
  - kostenbesparingen voor de gezondheidszorg

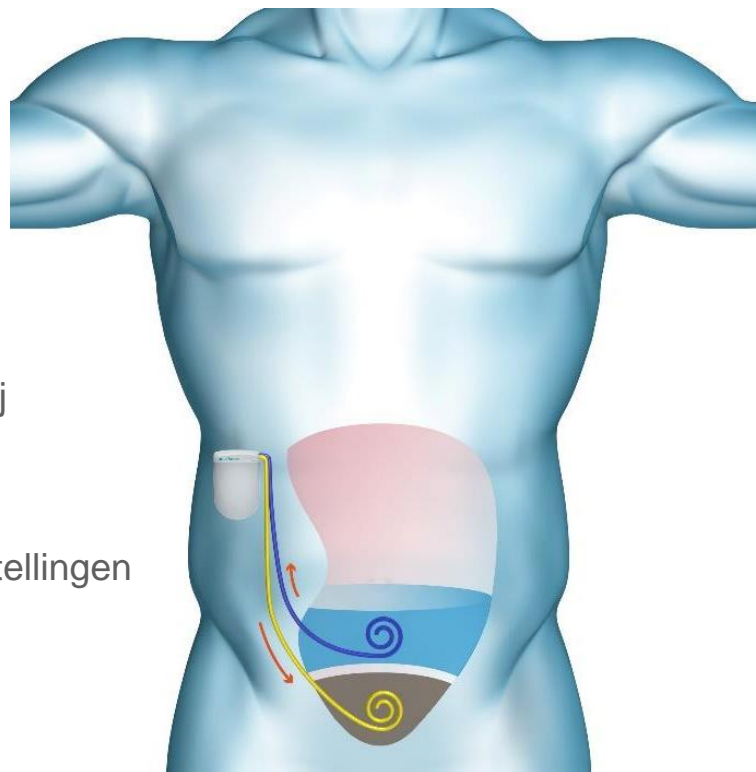


# alfapump® platform

Verwijderen van vocht uit de buikholte – samenwerking met de blaas



-  Volledig geïmplanteerd
-  Automatische werking
-  Draadloos opladen van de batterij
-  Draadloos aanpassen van de instellingen
-  Data monitoring van op afstand



-  Eenvoudige implantatie
-  Langetermijn implantatie & katheter doorgankelijkheid
-  Verwijdert tot 4 liter vocht / dag
-  Vrijwel geen verstoppingen
-  Geen significante opwarming tijdens opladen en werking

***Bewezen capaciteiten – meer dan 850 implantaties***  
***Sterke IP door uitgebreide octrooiportfolio & knowhow***

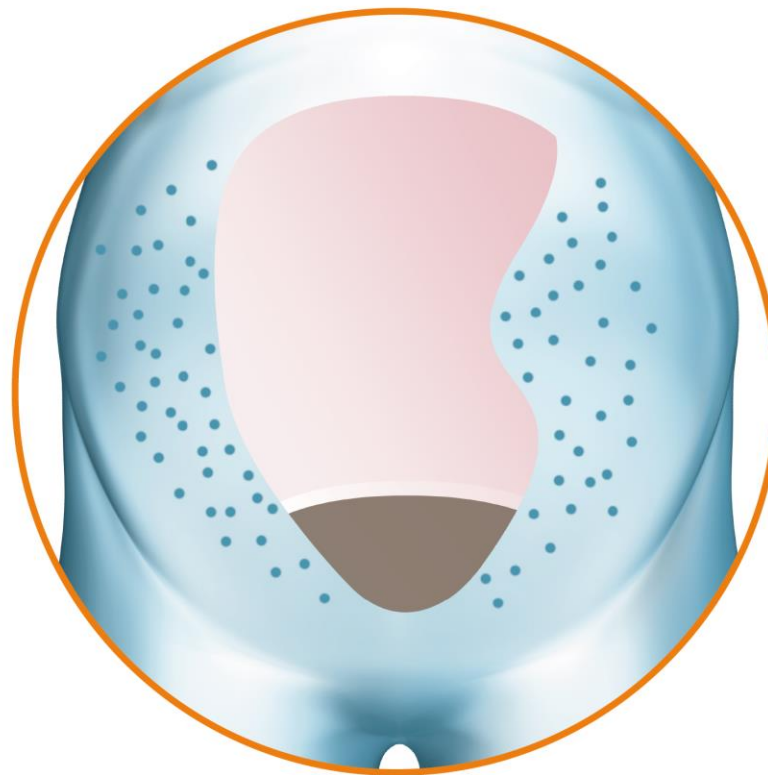


# Direct Sodium Removal (DSR<sup>®</sup>) platform

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



Teveel aan vocht in  
balans met teveel  
aan natrium

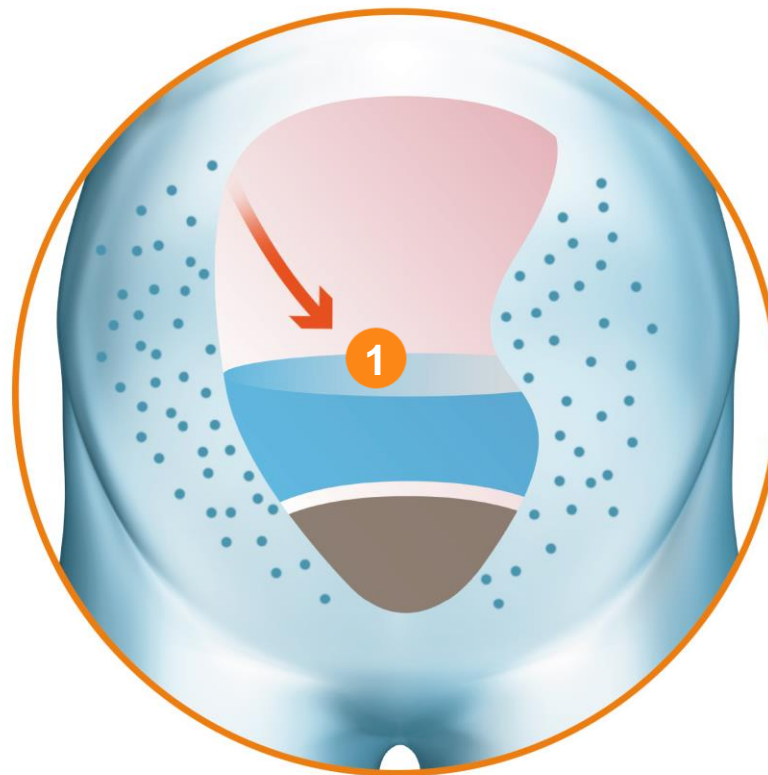




# Direct Sodium Removal (DSR<sup>®</sup>) platform

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

- 1 Natrium-arm DSR-infusate toegediend in de buikholte

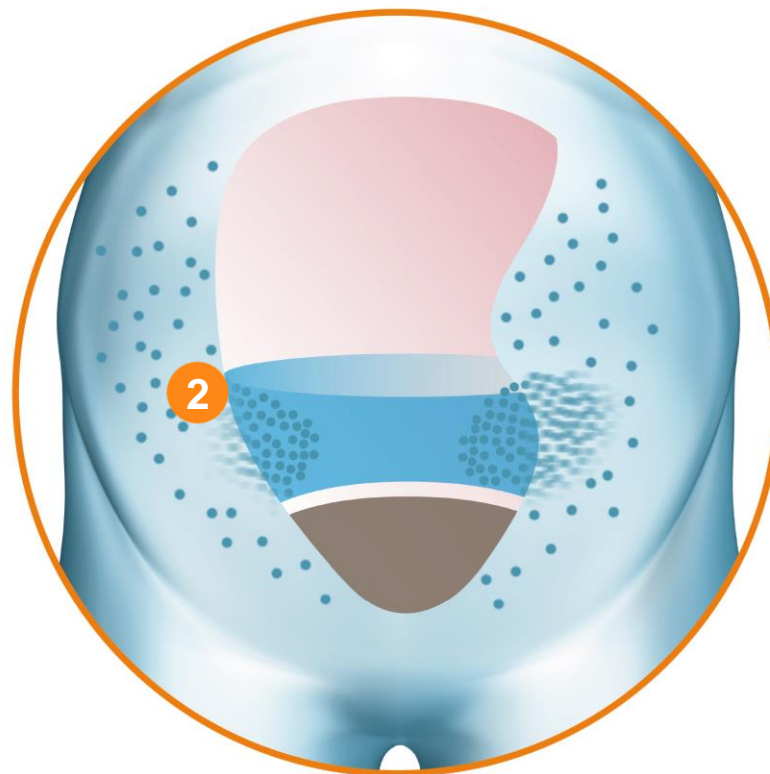




# Direct Sodium Removal (DSR<sup>®</sup>) platform

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

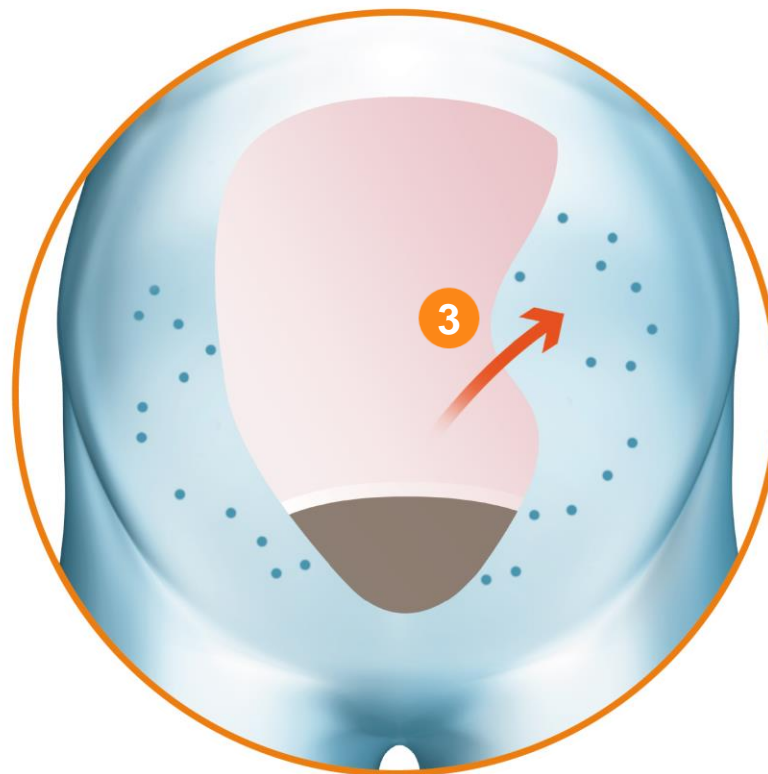
- 2 Natrium diffundeert vanuit het lichaam in het DSR-infusate



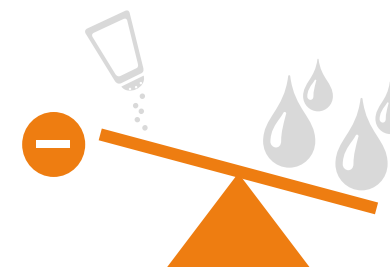


# Direct Sodium Removal (DSR<sup>®</sup>) platform

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



**3** DSR-infusate +  
geëxtraheerd natrium  
verwijderd uit het lichaam

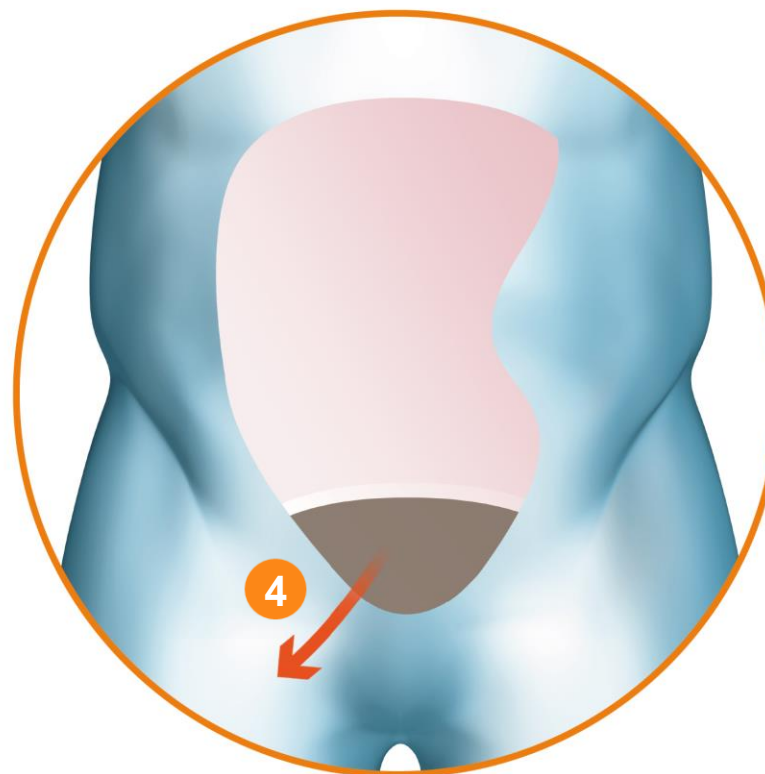




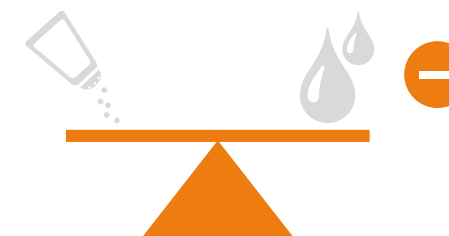


# Direct Sodium Removal (DSR<sup>®</sup>) platform

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



4 Lichaam verwijdt water om de natriumbalans te herstellen, en leidt tot verminderde vochtoverbelasting



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

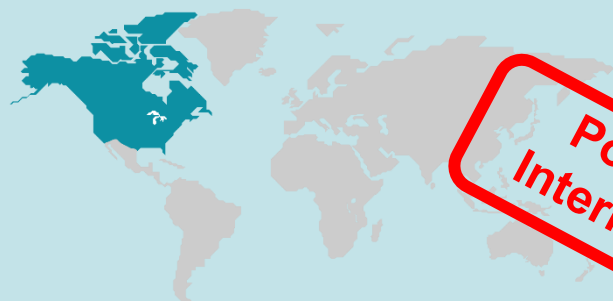
# Focus op 2 producten – € miljarden opportuniteiten



**alfapump<sup>®</sup>**

**Leverziekte (NASH) in N. Amerika**

> €3 miljard / jaar marktopportuniteit in VS<sup>(1)</sup>



**Positieve  
Interim Data**

**FDA** Breakthrough Device  
Designation

**POSEIDON** pivotale studie lopende

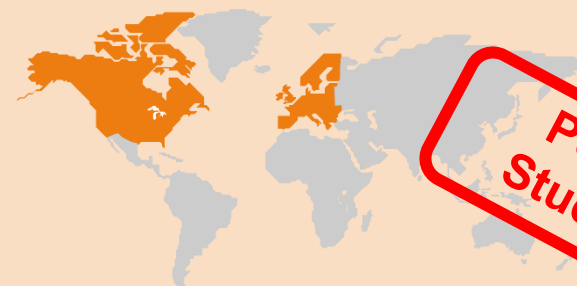
**Eigen commercialisatie**



**alfapump DSR<sup>®</sup>**

**Congestie als gevolg van Hartfalen**

> €5 miljard / jaar marktopportuniteit in EU & VS<sup>(2)</sup>



**Positieve  
Studie Data**

**SAHARA DESERT** studie lopende

**Partnering na werkzaamheidsstudie in de VS**

**Gebouwd op bewezen Europese klinische & commerciële ervaring**

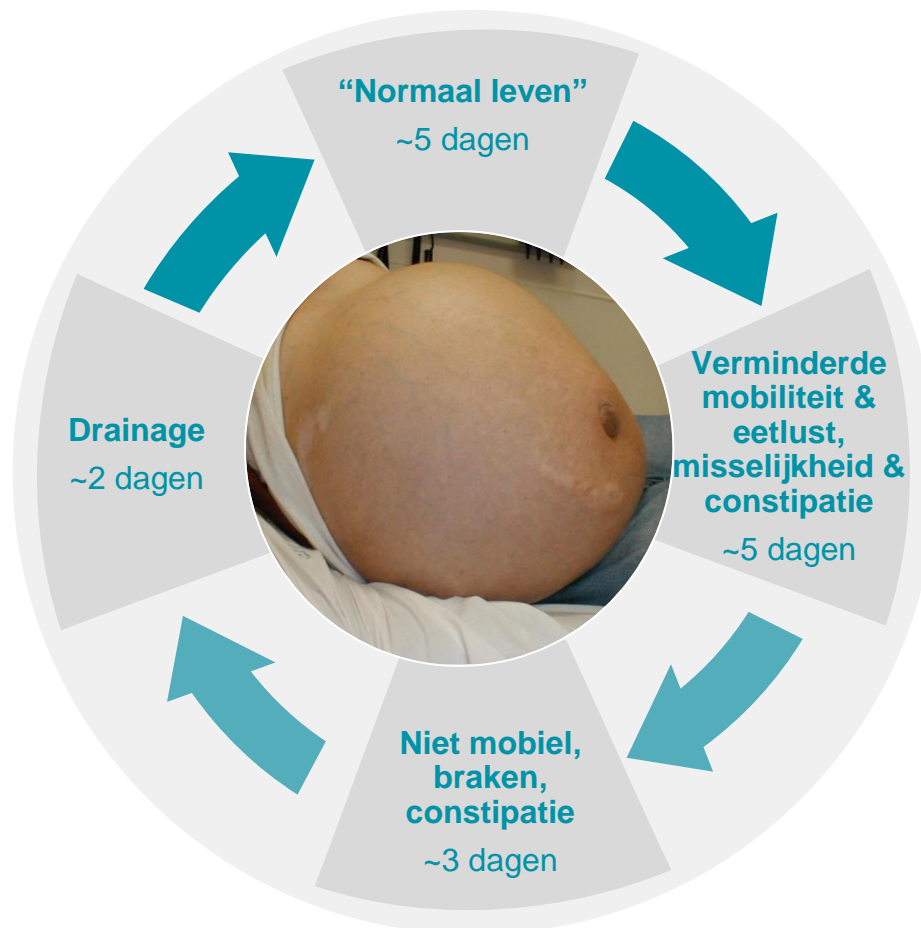
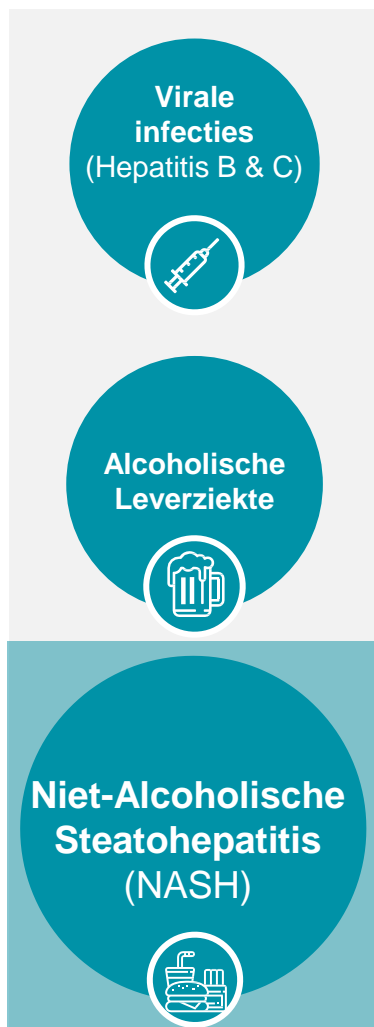
Bron 1: Management inschatting voor de VS binnen 10-20 jaar, inclusief de geschatte groei in prevalentie voor NASH in de VS, gebaseerd op GlobalData Epidemiology Forecast to 2026

Bron 2: Management inschatting voor de VS & EU tegen 2026 gebaseerd op GlobalData Heart Failure Epidemiology Forecast to 2026; Costanzo et al. (2007). Kiglore et al (2017)

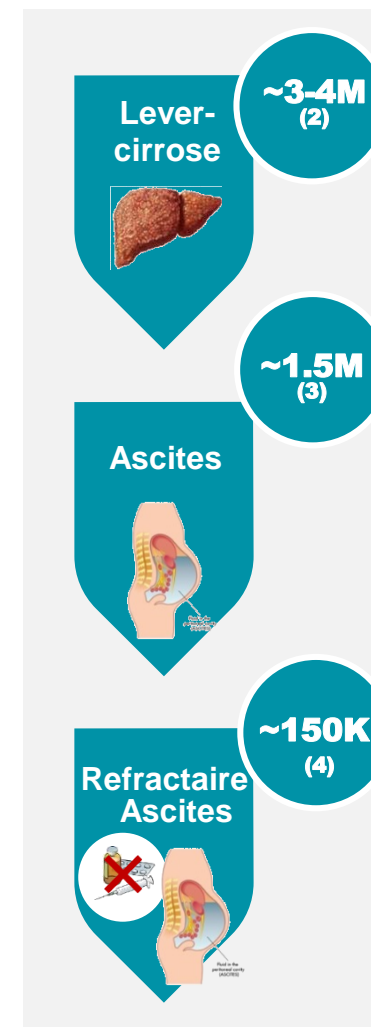


# Refractaire ascites – belangrijke complicatie van levercirrose

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



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



Noot: Prevalentie van NASH in de VS zal naar verwachting met 63% stijgen tussen 2015-2030; Estes et al., 2018

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

Bron 2: Management inschatting voor de VS gebaseerd op Estes et al; GlobalData Nash Epidemiology Forecast to 2026; Nouredin et al., 2013

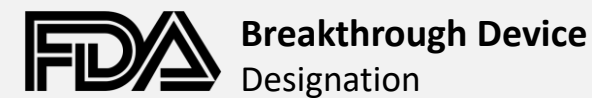
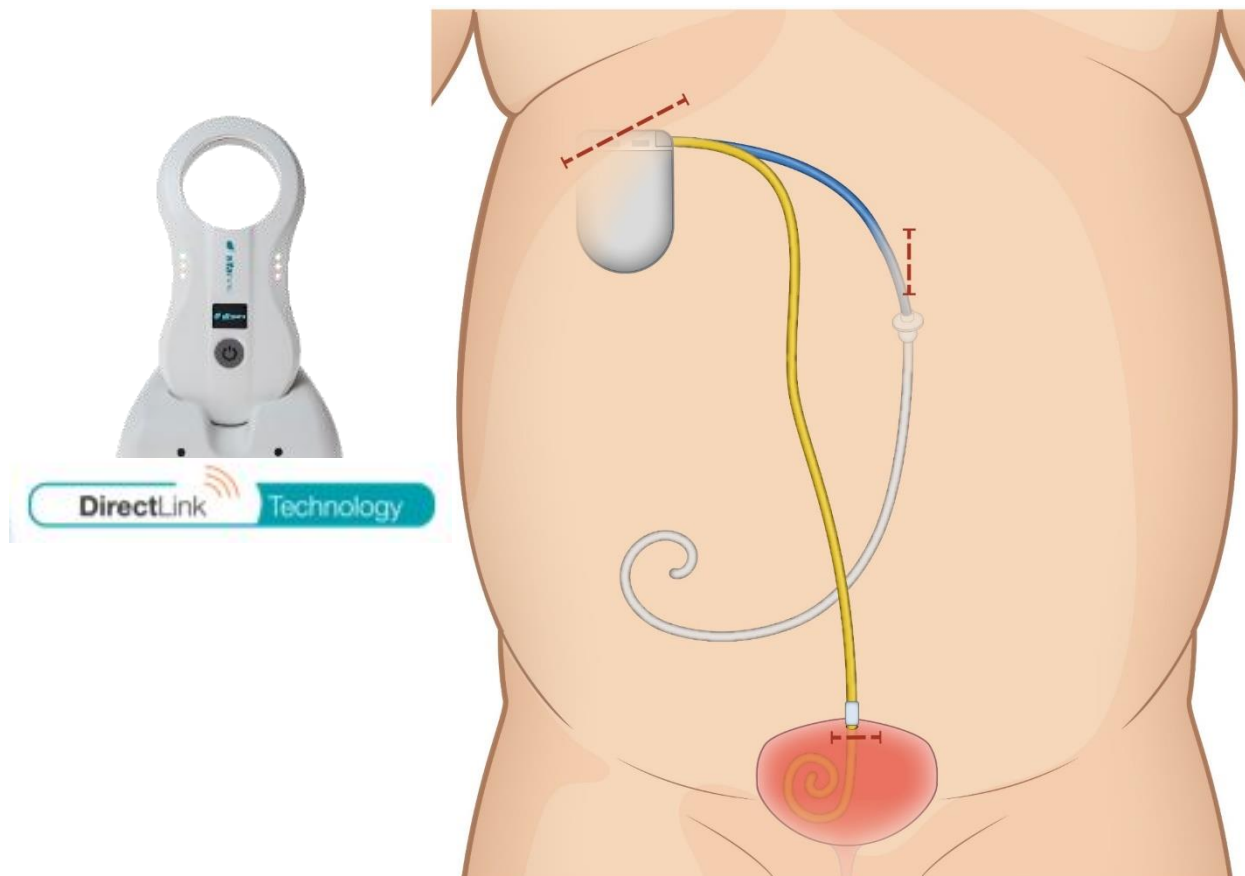
Bron 3: Runyon 2009: ongeveer 50% van patiënten met cirrose ontwikkelen ascites binnen de 10 jaar na diagnose

Bron 4: Ginès et al., NEJM 2004: refractaire ascites komt voor in 5-10% van de patiënten met cirrose



# alfapump® voor lange termijn therapie

Meer dan 850 implantaties en honderden jaren patiëntenervaring





# Sterke interim data van FDA pivotale studie (POSEIDON)

Tussentijdse data tonen aan dat we op schema zitten om de FDA-doelen voor goedkeuring te halen

- Vermindering van externe drainage met **meer dan 90%** (vs FDA-doelstelling van 50%)
- **Al onze patiënten** hadden  $\geq 50\%$  vermindering van externe drainages (vs FDA-doelstelling van 50%)
- Veiligheid **conform** verwachtingen
- **Snelle en aanhoudende verbetering** van de levenskwaliteit

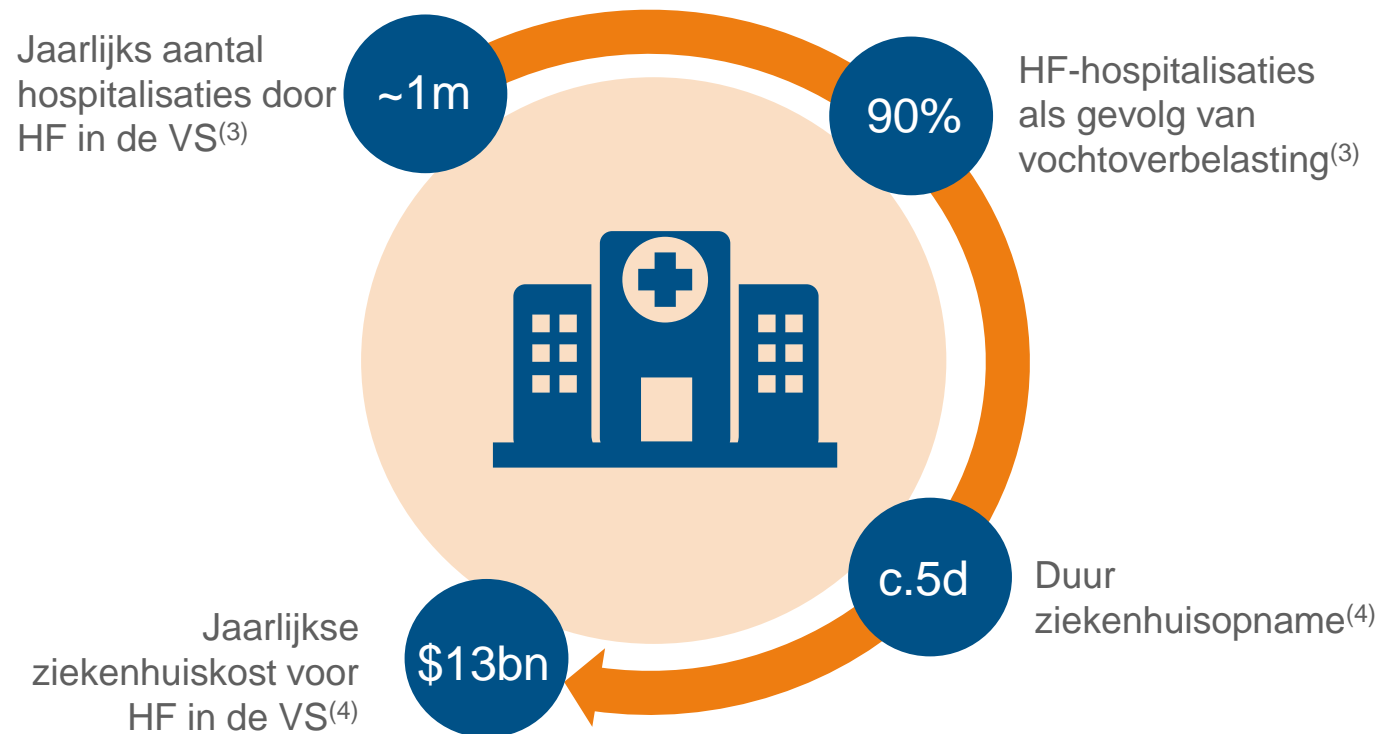
**Alle patiënten opgenomen in de studie verwacht vóór eind '21**

**Uitlezing primair eindpunt verwacht in Q4 '22**



# Diuretica-resistente congestie bij hartfalen

Duidelijke onvervulde behoefte en oorzaak van kosten voor patiënten met hartfalen

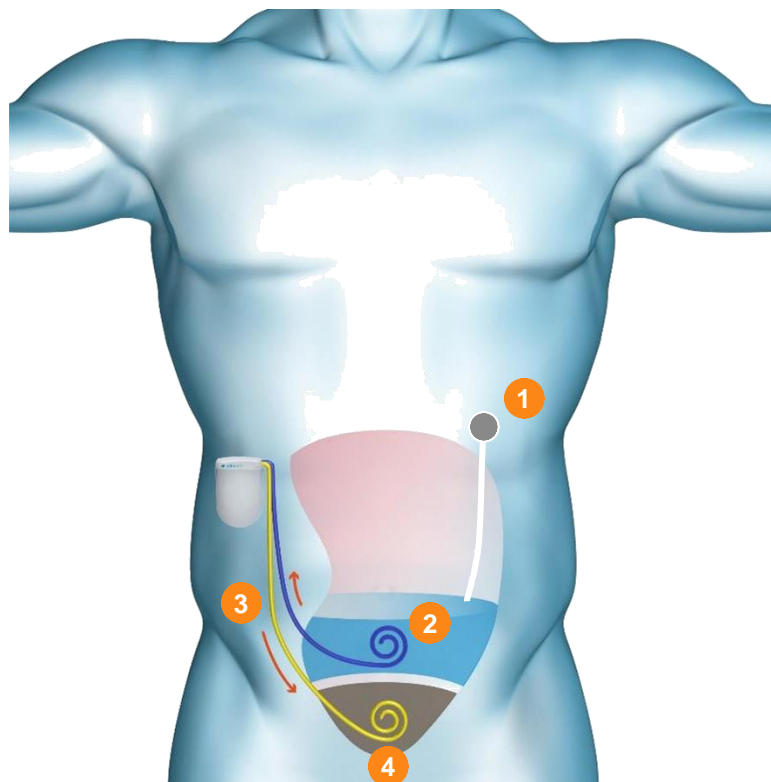


- 40% van patiënten met HF hebben een zwakke respons op intraveneuze lisdiuretica<sup>(1)</sup>
- 1 op 4 terug in het ziekenhuis binnen de 30 dagen<sup>(2)</sup>



# alfapump DSR<sup>®</sup> voor lange termijn therapie

Combineren van ons bewezen alfapump-platform met onze DSR-technologie



- 1 Toediening van ons DSR-infusate in de buikholte
- 2 DSR-infusate extraheert natrium uit de bloedbaan
- 3 **alfapump** pompt natrium en DSR-infusate in de blaas waar het natuurlijk wordt verwijderd
- 4 Lichaam herstelt natriumbalans door verwijderen van water zodat de vochtverbelasting vermindert



# Zeer bemoedigende resultaten van RED DESERT studie

Intensieve therapie om het natuurlijke vermogen van de nieren - het beheren van de vochtbalans - te herstellen

- Veilig en zeer effectief behoud van de vocht- en natriumbalans
- Drastische en langdurige verbetering van de respons op diuretica
- Aanzienlijke verbetering van de hart-nierfunctie

**Topline data SAHARA DESERT studie verwacht in H2 '22**



# Voortbouwend op onze twee platformen

Complementaire technologieën voor het behandelen van diuretica-resistente vochtoverbelasting

alfapump® 

alfapump DSR®

DSR® 

Leverziekte/ NASH  
&  
Maligne ascites

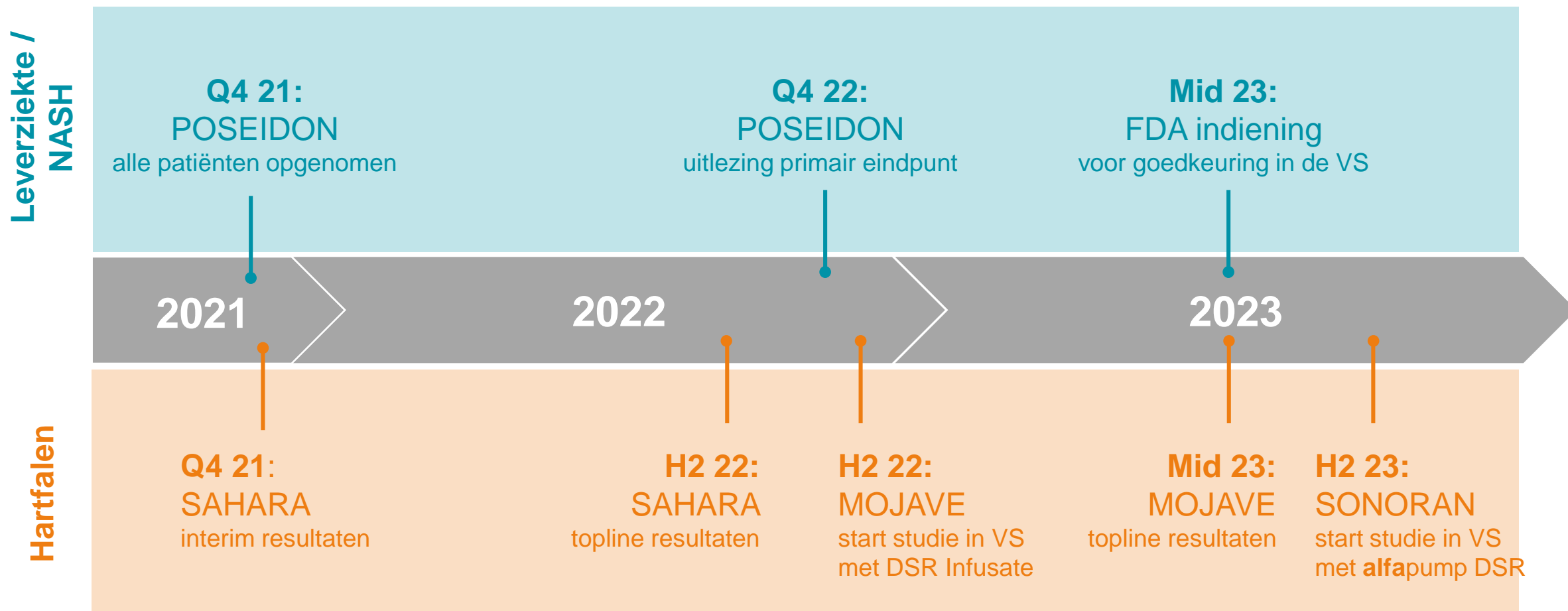
Congestief Hartfalen

Lange termijn  
therapie

Korte termijn  
therapie

*Evalueren van  
vochtoverbelasting bij  
Nierfalen*

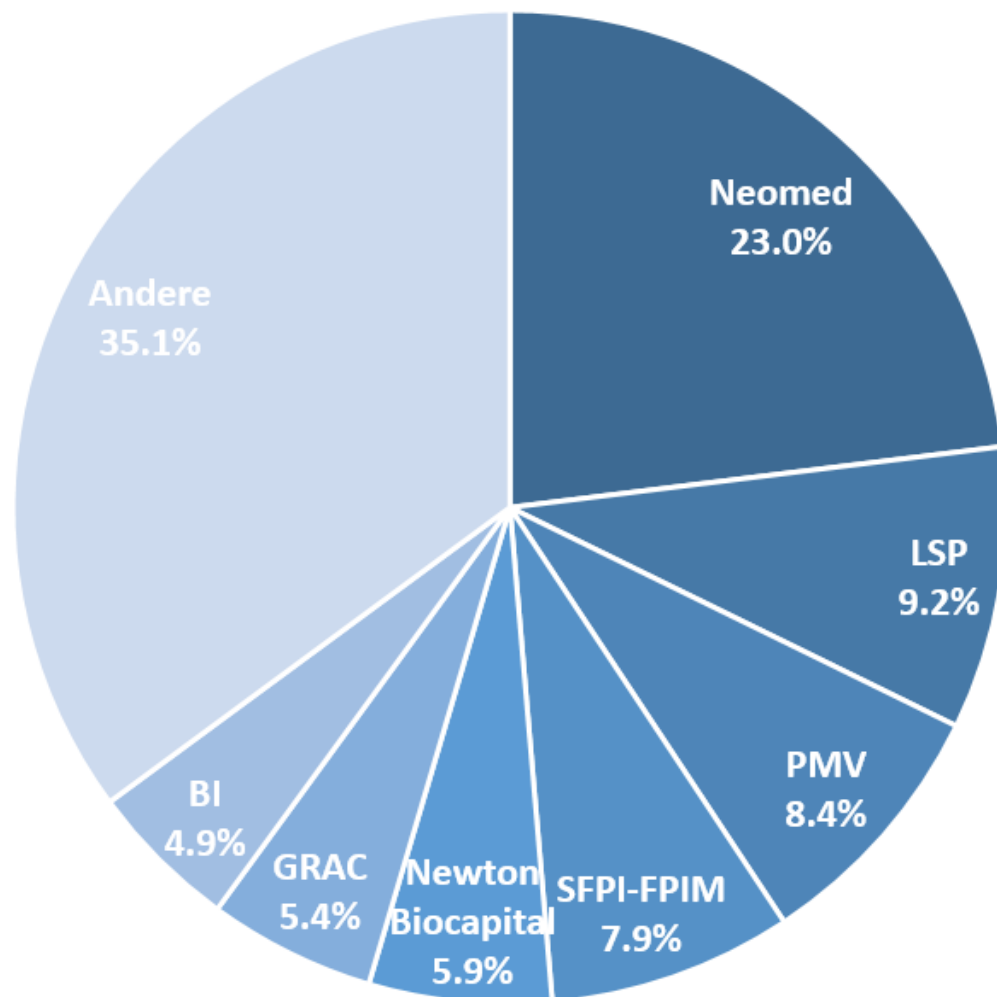
# Sterke vooruitzichten voor waardebeoordeling



Note: Gepresenteerde tijdlijnen zijn onderhevig aan verdere ontwikkelingen met betrekking tot de COVID-19-pandemie

# Aandeelhoudersstructuur en financieel overzicht

Ticker: SEQUA – Euronext Brussels



## Cash:

- Kaspositie €21,8 M (30 juni 2021)
- Cash runway tot in Q2 2022

## Aandeleninfo:

- 18,5 M uitstaande aandelen
- ~€130 M market cap (€7 / aandeel)

## Analisten:

- KBC Securities – Lenny Van Steenhuyse
- Kempen – Ingrid Gafanhão
- Kepler Cheuvreux – Matthias Maenhaut
- Mirabaud – Daniel Jelovcan
- H.C. Wainwright – Yi Chen, Raghuram Selvaraju



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