

sequanamedical

Finance Avenue – 20 november 2021

Kirsten Van Bockstaele, CFO & Lies Vanneste, IR



Innovators in the treatment of diuretic-resistant fluid overload

liver disease  malignant ascites  heart failure

Disclaimers

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- By attending the meeting where this presentation is presented or by accepting a copy of it, you agree to be bound by the foregoing limitations.

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.

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**[®] is a registered trademark. DSR[®] and **alfapump DSR**[®] 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 klinische 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**[®] en **DSR**[®] technologieën om therapiën te ontwikkelen voor:
 - verbeterde klinische resultaten
 - betere levenskwaliteit voor patiënten
 - kostenbesparingen voor de gezondheidszorg

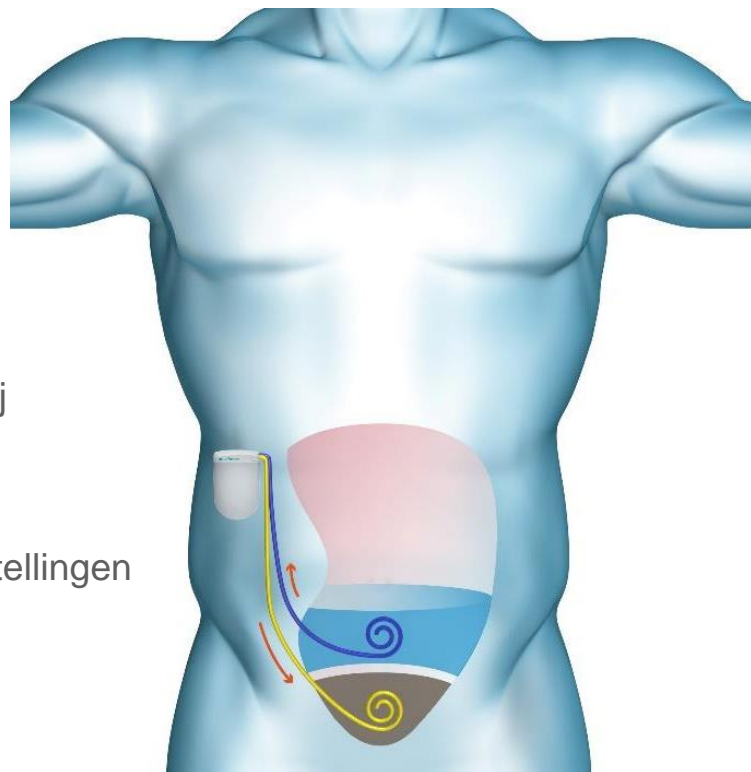


alfapump® platform

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

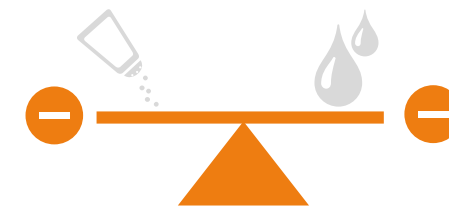
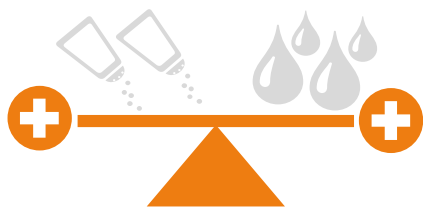


-  Eenvoudige implantatie
-  Lange-termijn implantatie & catheter doorgankelijkheid
-  Verwijdert tot 4 liter vocht / dag
-  Vrijwel geen verstoppingen
-  Geen significante opwarming tijdens opladen en werking

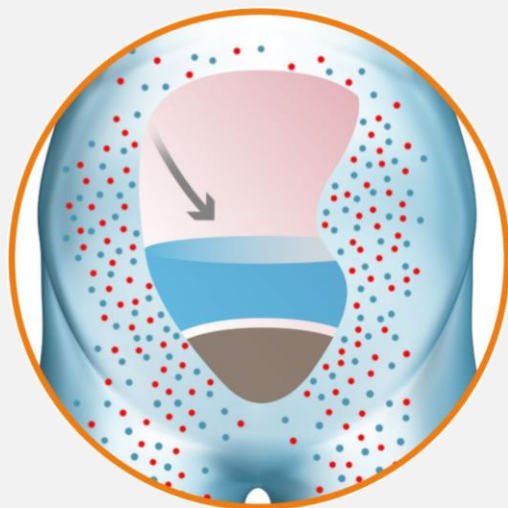
Bewezen capaciteiten – meer dan 850 implantaties
Sterke IP door uitgebreide octrooiportfolio & knowhow

Direct Sodium Removal (DSR®) platform

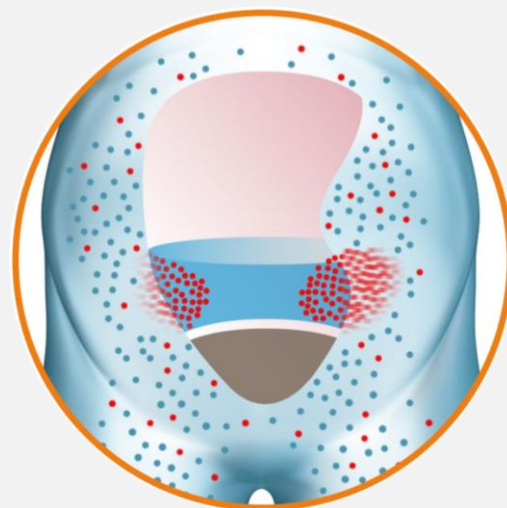
Verwijderen van vocht verspreid over het lichaam – samenwerking met de nieren



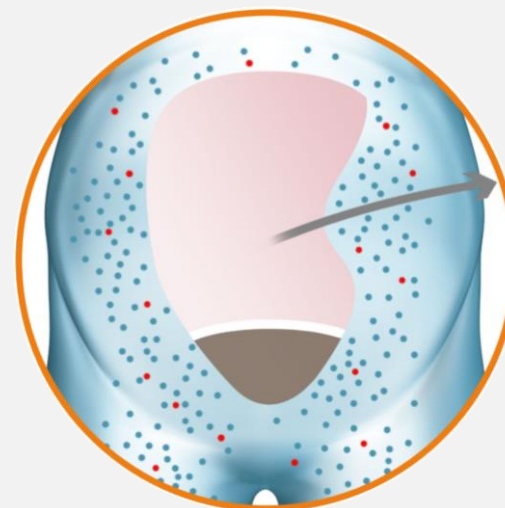
1 Natrium-arm DSR-infusate toegediend in de buikholte



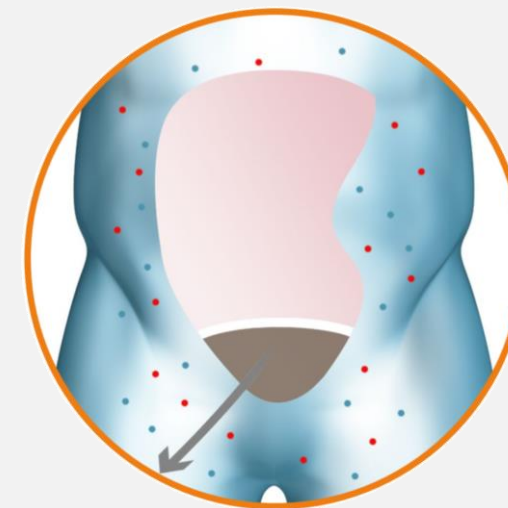
2 Natrium diffundeert vanuit het lichaam in het DSR-infusate



3 DSR-infusate + geëxtraheerd natrium verwijderd uit het lichaam



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



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

Focus op 2 producten – € miljarden opportuniteiten



alfapump[®]

Leverziekte (NASH) in N. Amerika

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



FDA Breakthrough Device
Designation

POSEIDON pivotale studie lopende

Sequana Medical salesforce



alfapump DSR[®]

Congestie als gevolg van Hartfalen

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



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)

Markt voor leverascites in de VS gedreven door NASH

Levercirrose verandert in een reguliere ziekte die moderne behandelingen vereist

| | | |
|--|--|---|
| |  |  |
| alfapump® marktpotentieel | ~€0,4 miljard / jaar | >€3 miljard / jaar |
| Onderliggende ziekte | Alcoholische leverziekte, Hepatitis | NASH |
| Type patiënten | “Niet regulier” | “Regulier” |
| Gemiddelde leeftijd | 40-50 j | +70 j |
| Concurrentiepositie van de alfapump | ✓ | ✓✓ |



alfapump®

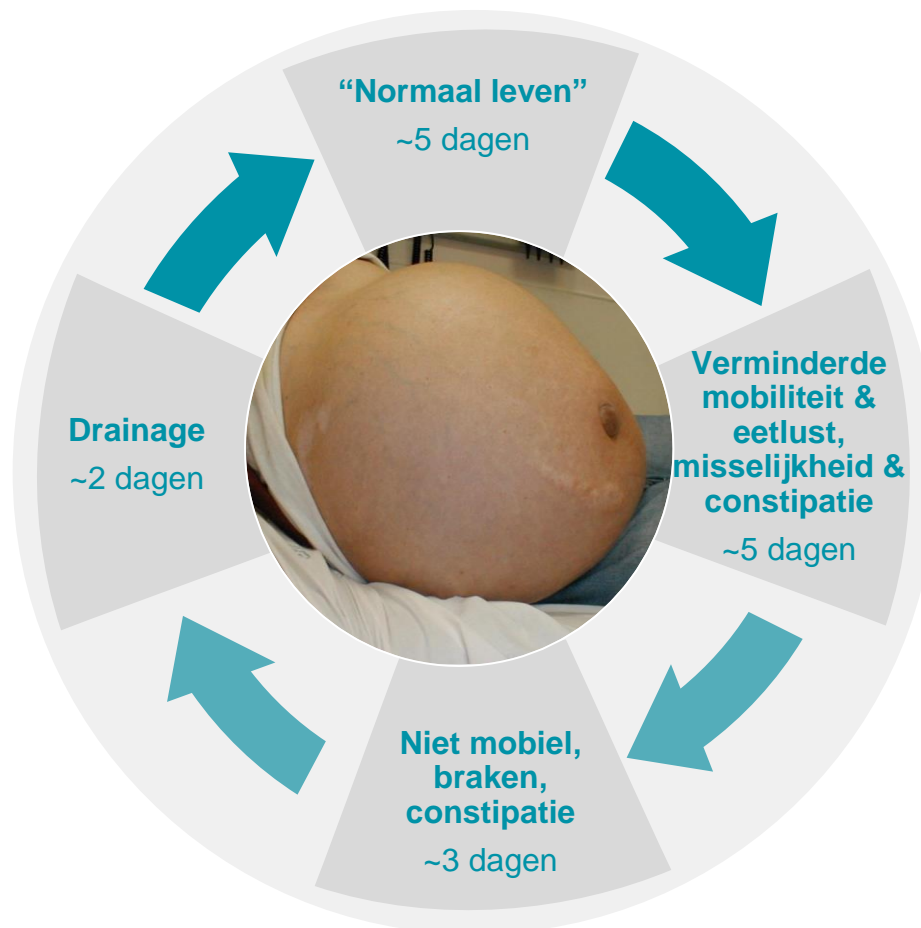
Bewezen stap voorwaarts voor
het behandelen van **refractaire**
leverascites en **maligne ascites**



Refractaire ascites – belangrijke complicatie van levercirrose

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

- Virale infecties (Hepatitis B & C)
- Alcoholische Leverziekte
- Niet-Alcoholische Steatohepatitis (NASH)



Typisch leven van een patiënt⁽¹⁾

- Levercirrose ~3-4M (2)
- Ascites ~1.5M (3)
- Refractaire Ascites ~150K (4)

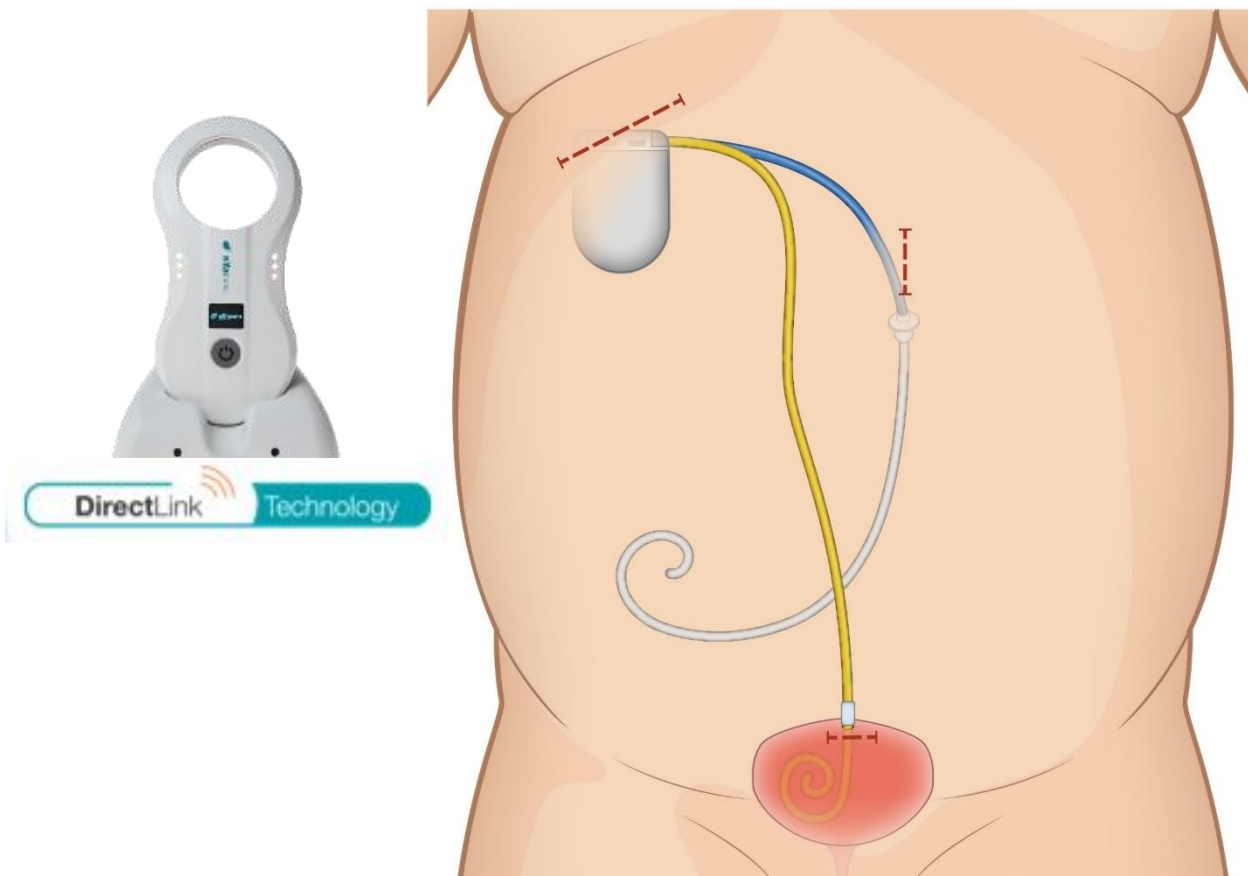
Noot: Prevalentie van NASH in de VS zal naar verwachting met 63% stijgen tussen 2015-2030; Estes et al., 2018

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



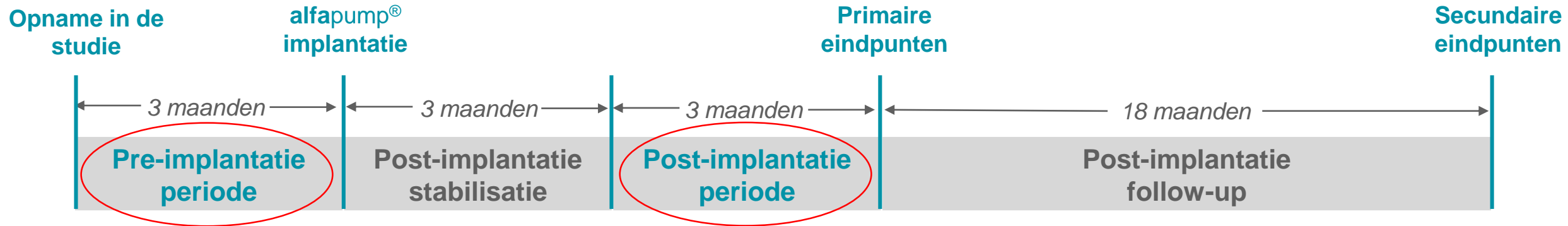
- ✔ Ziektelast verminderen
- ✔ Levenskwaliteit verbeteren
- ✔ Kosten verminderen





POSEIDON pivotale studie voor goedkeuring in N-Amerika

Patiënten met terugkerende of refractaire ascites door levercirrose



- **Pivotal Cohort:** ~50 patiënten met alfapump ⇒ analyse primair eindpunt
- **Roll-In Cohort:** ~35 patiënten met alfapump ⇒ “training cohort” / tussentijdse data



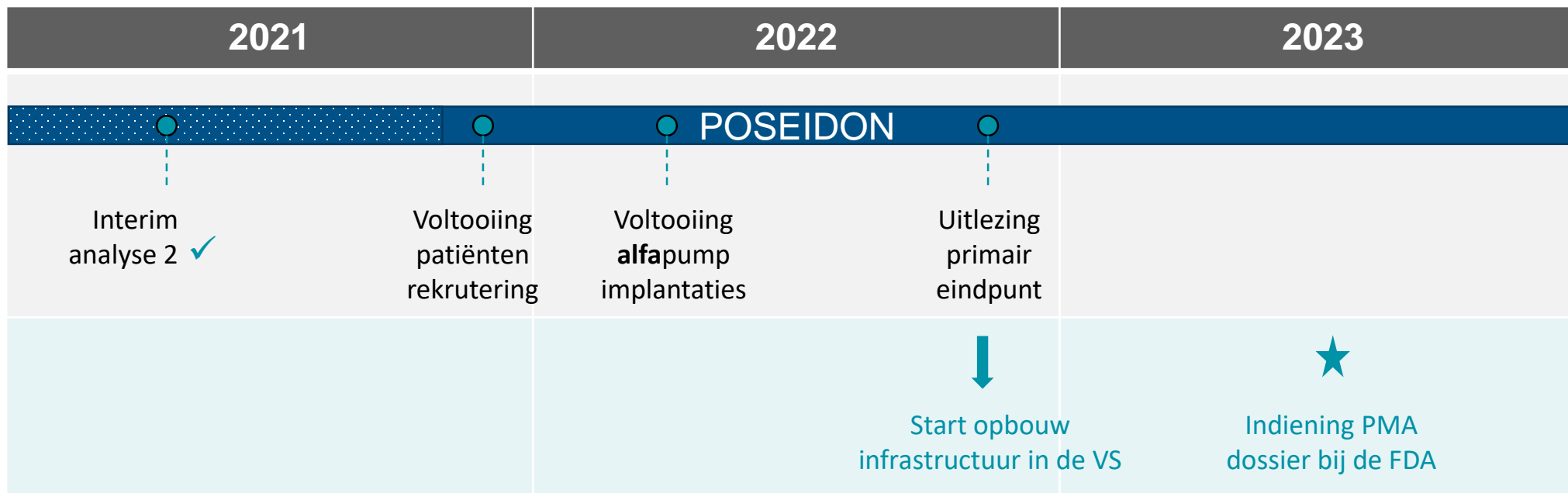
Sterke interim data van FDA pivotale studie (POSEIDON)

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 primair eindpunt van 50%)
- **Al onze patiënten** hadden $\geq 50\%$ vermindering van externe drainages (vs primair eindpunt van 50%)
- Veiligheid **conform** verwachtingen
- **Snelle en aanhoudende verbetering** van de levenskwaliteit



Op weg naar goedkeuring alfapump® in Noord-Amerika



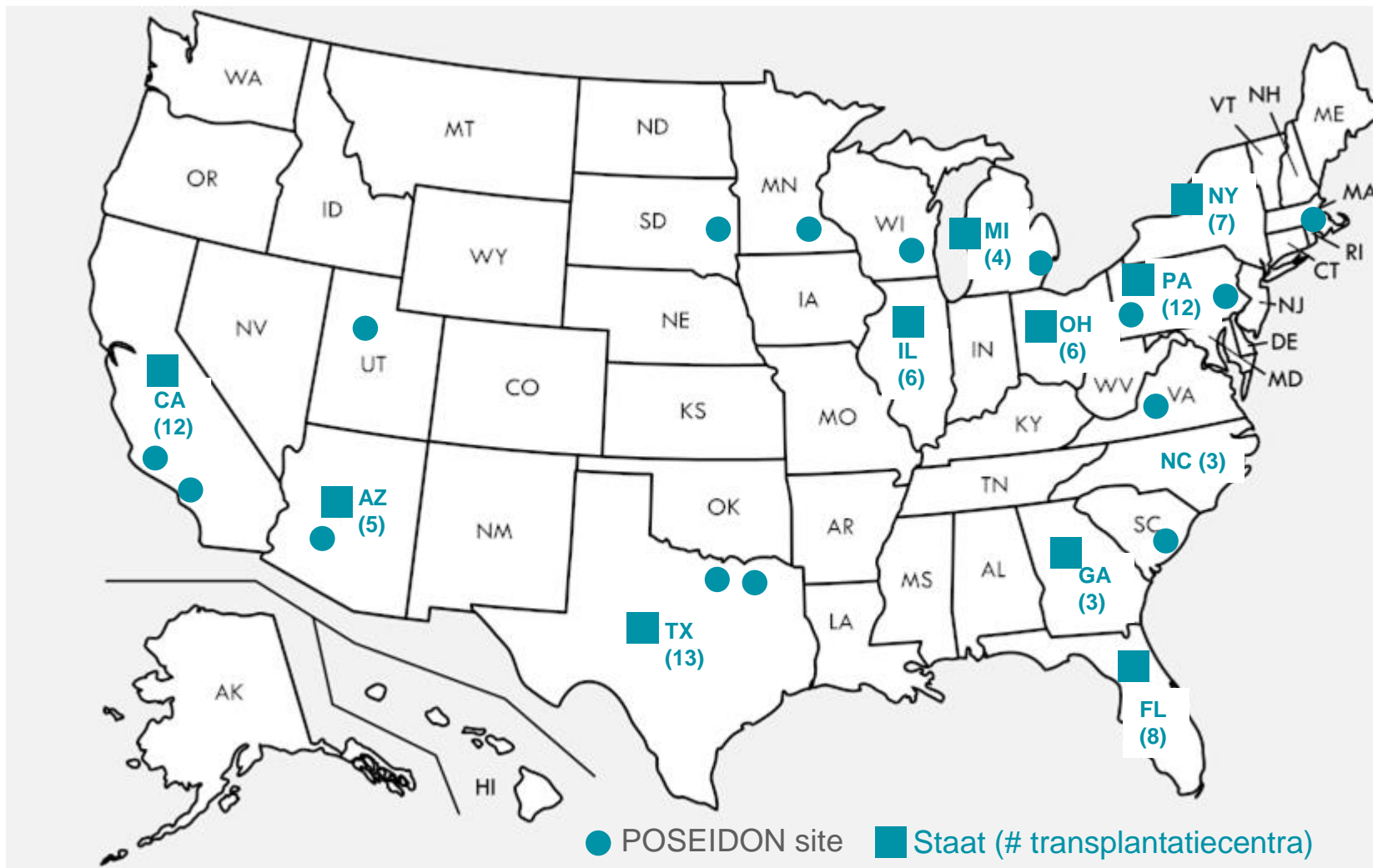
NTAP voor “breakthrough devices” verkleint terugbetalingsrisico in belangrijke Medicare populatie

PMA: Pre-Market Approval; NTAP: New Technology Add-On Payment

Noot: Gepresenteerde tijdslijnen zijn onderhevig aan verdere ontwikkelingen met betrekking tot de COVID-19-pandemie



Commercialisatie in de VS met gespecialiseerd team



Initiële focus op belangrijke transplantatiecentra

Team van ~50 personen:
 35 sales reps, 10 klinische,
 5 corporate



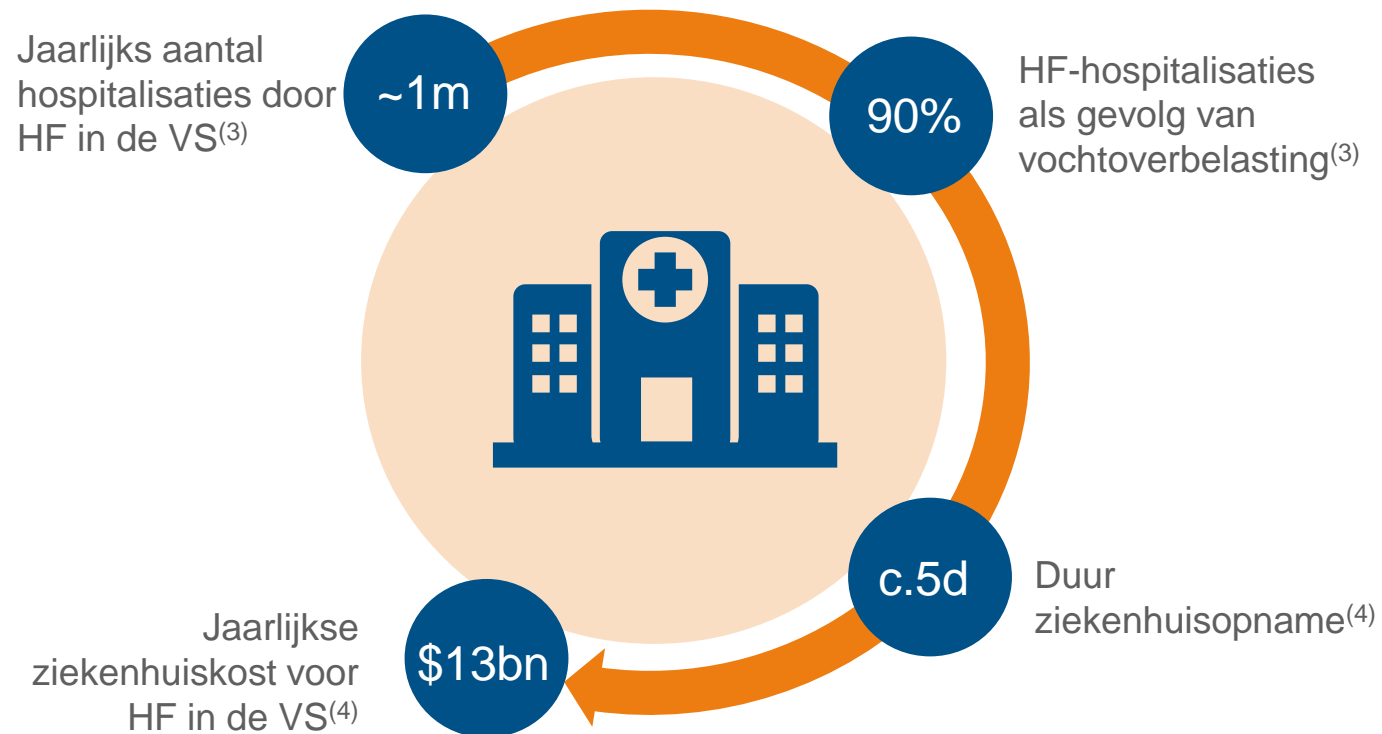
alfapump DSR[®]

Doorbraakbehandeling voor
**aanhoudende congestie in
hartfalen** gebruikmakend van
bewezen alfapump[®] platform



Diuretica-resistente congestie bij hartfalen

Duidelijke onvervulde behoefte en oorzaak van kosten voor patiënten met hartfalen

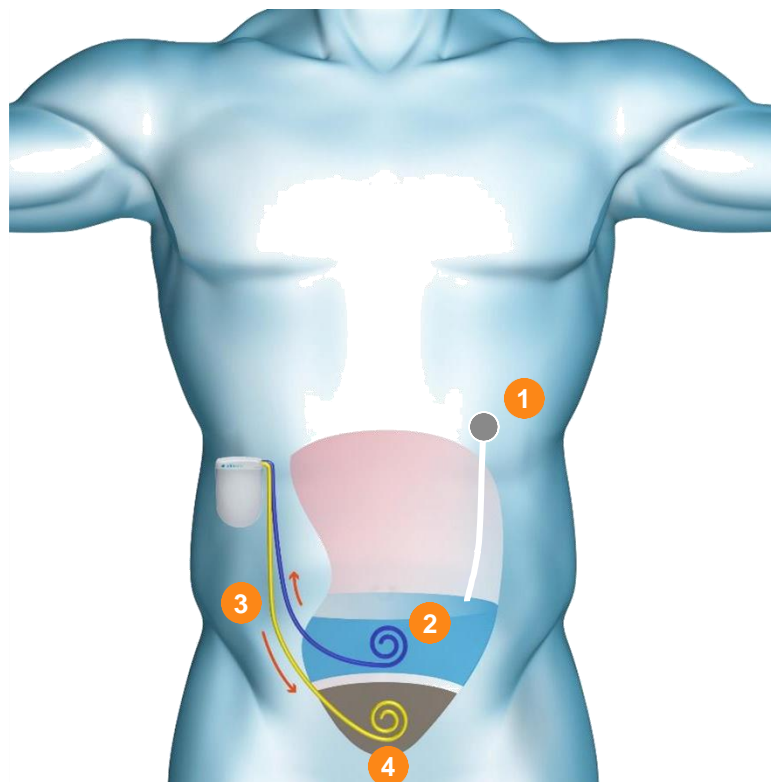


- 40% van patiënten met HF hebben een zwakke respons op intraveneuze lisdiuretica⁽¹⁾
- 1 op 4 terug in het ziekenhuis binnen de 30 dagen⁽²⁾



alfapump DSR[®] gebruikt bewezen alfapump[®] platform

Volledig geïmplanteerd systeem voor lange-termijn DSR[®] therapie



- 1 Toediening van natrium-arm DSR-infusate in de buikholte via geïmplanteerde poort onder de huid
- 2 Natrium diffundeert in het DSR-infusate
- 3 **alfapump** pompt natrium-rijk DSR-infusate in de blaas
- 4 Lichaam verwijdt overtollig vocht via osmotische ultrafiltratie en urinering



Zeer bemoedigende resultaten van RED DESERT studie

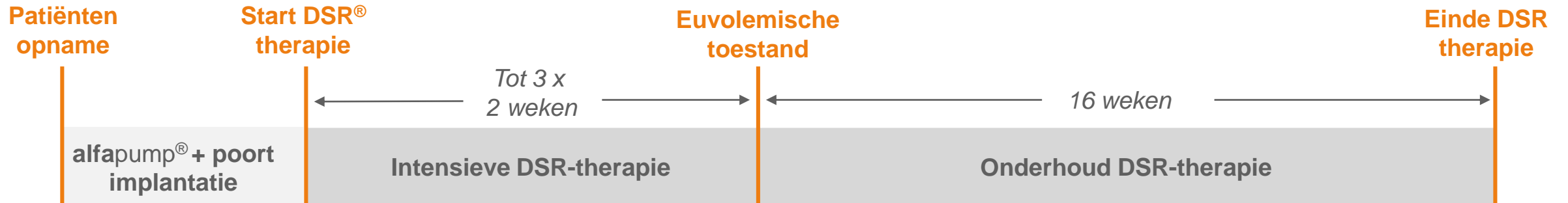
Intensieve therapie om het natuurlijke vermogen van de nieren - het beheren van de vochtbalans - te herstellen

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



SAHARA DESERT: Behandelen van aanhoudende congestie

20 patiënten met gedecompenseerd hartfalen met aanhoudende congestie op hoge dosis diuretica



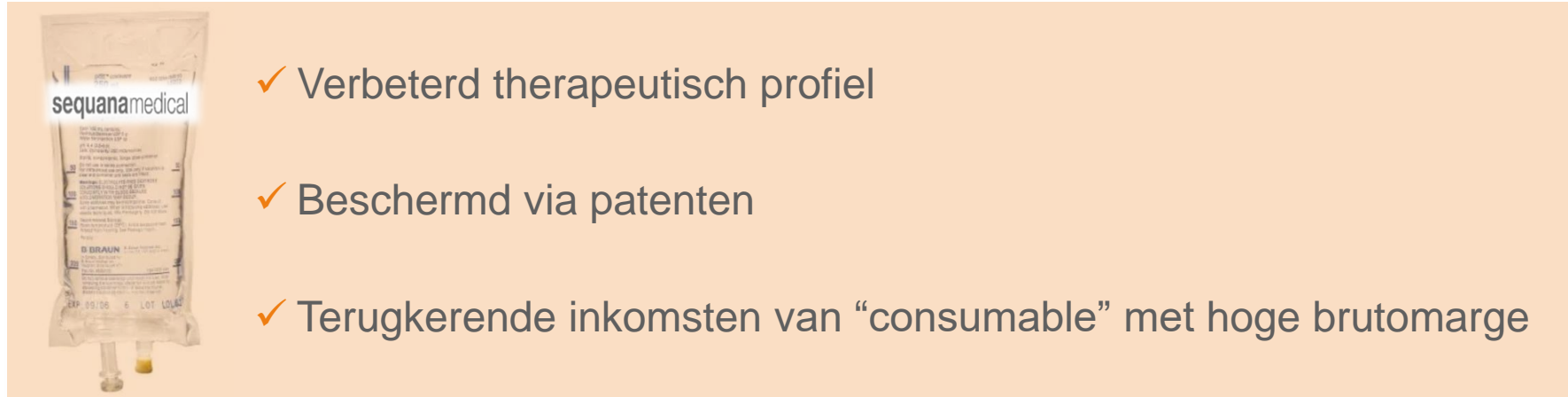
Studie Objectieven

- Mogelijkheid om aanhoudende congestie bij patiënten met hartfalen te verwijderen
- Mogelijkheid om de diuretische respons / hart- en nierfunctie te verbeteren en te behouden

Tussentijdse resultaten verwacht Q4 2021 / Topline resultaten verwacht H2 2022

Eigen DSR[®] Infusate 2.0 vergroot waardemodel

- Initieel werd D10% gebruikt als DSR-infusate voor snelste proof-of-concept
- We ontwikkelen ons **eigen “next-generation” DSR-infusate:**



Noot: Deze afbeelding is alleen bedoeld ter illustratie



Korte-termijn DSR[®] – Risico markttoelating verlagen

Regulatoire vereenvoudiging en voorbereiding van de markt voor toelating van de alfapump DSR[®]

Korte-termijn DSR – “drug only”

- “éénmalig” ~2 weken intensieve DSR behandeling
- Met peritoneale catheter (geen **alfapump**)

Lange-termijn alfapump DSR[®] – “drug / device”

- Terugkerende intensieve DSR behandeling met tussenpauzes
- Met **alfapump**



Mikt op eerdere toegang tot de VS



Snellere acceptatie door klinische gemeenschap



Ondersteuning van markt-toelating **alfapump** DSR



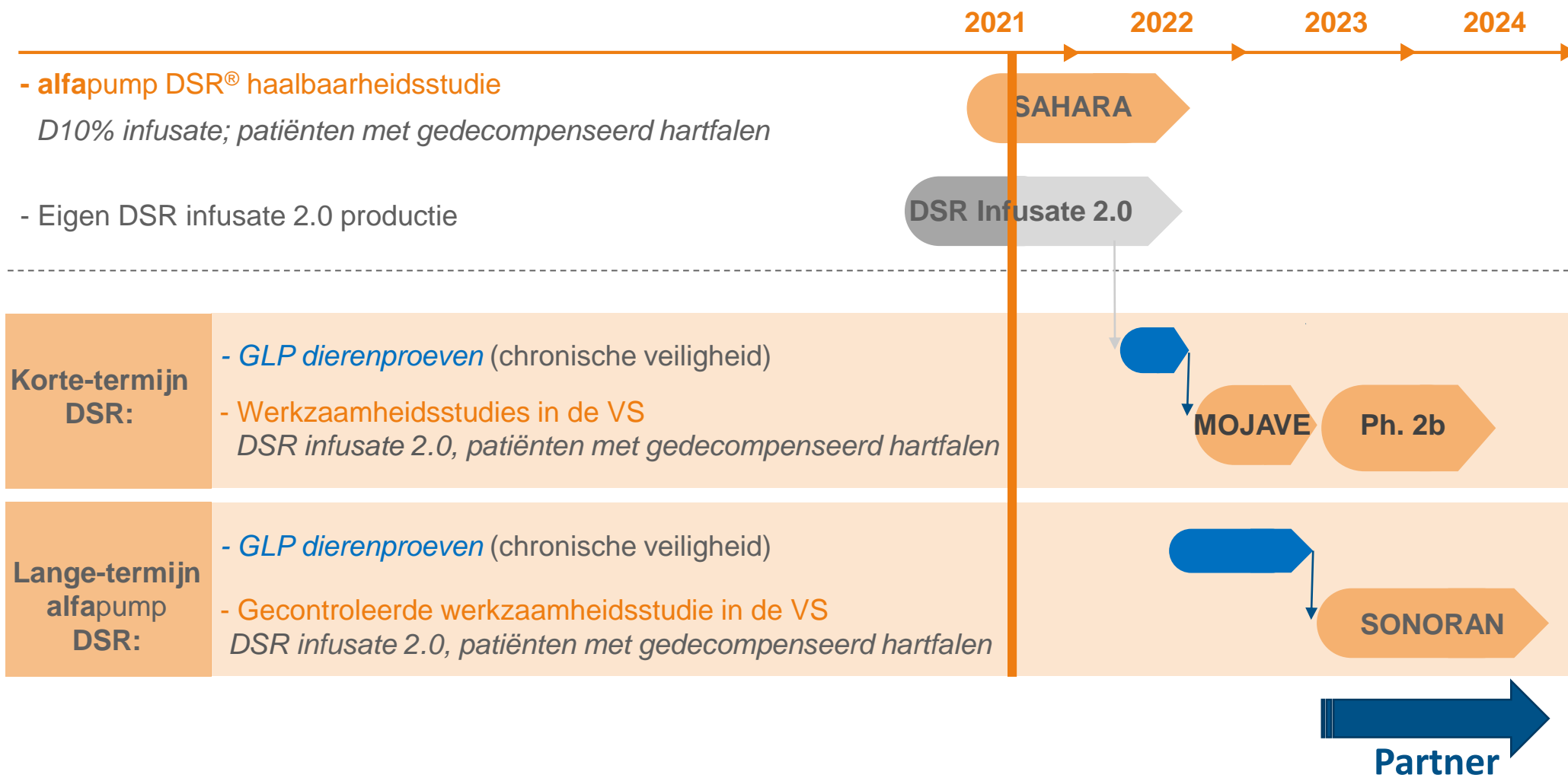
Vergroot potentiële marktopportunititeit

Aanpakken van residuele congestie en herstellen van diuretische respons en hart- en nierfunctie bij patiënten met diuretica-resistent hartfalen



DSR[®] – Robuust ontwikkelingsprogramma*

Stapsgewijze aanpak voor introductie van “breakthrough” therapie



* Tijdslijnen onder voorbehoud van verdere ontwikkelingen in verband met de aanhoudende COVID-19 pandemie
Beschrijving en timing van deze onderzoeken zijn onderhevig aan wijzigingen en/of feedback van toepasselijke regelgevende instanties

A grid of white medical devices, possibly patient warming units, arranged on shelves. Each device has a circular opening at the top and a glowing light at the bottom. The lights are in various colors, including blue, green, and purple. The background is a light blue gradient.

Outlook

Sterke **waardebepalers op korte termijn** met duidelijk **lange-termijn potentieel**

Voortbouwend op onze twee platformen

Complementaire technologieën voor het behandelen van diuretica-resistente vochtoverbelasting

alfapump® 

alfapump DSR®

DSR® 

Leverziekte/ NASH
&
Maligne ascites

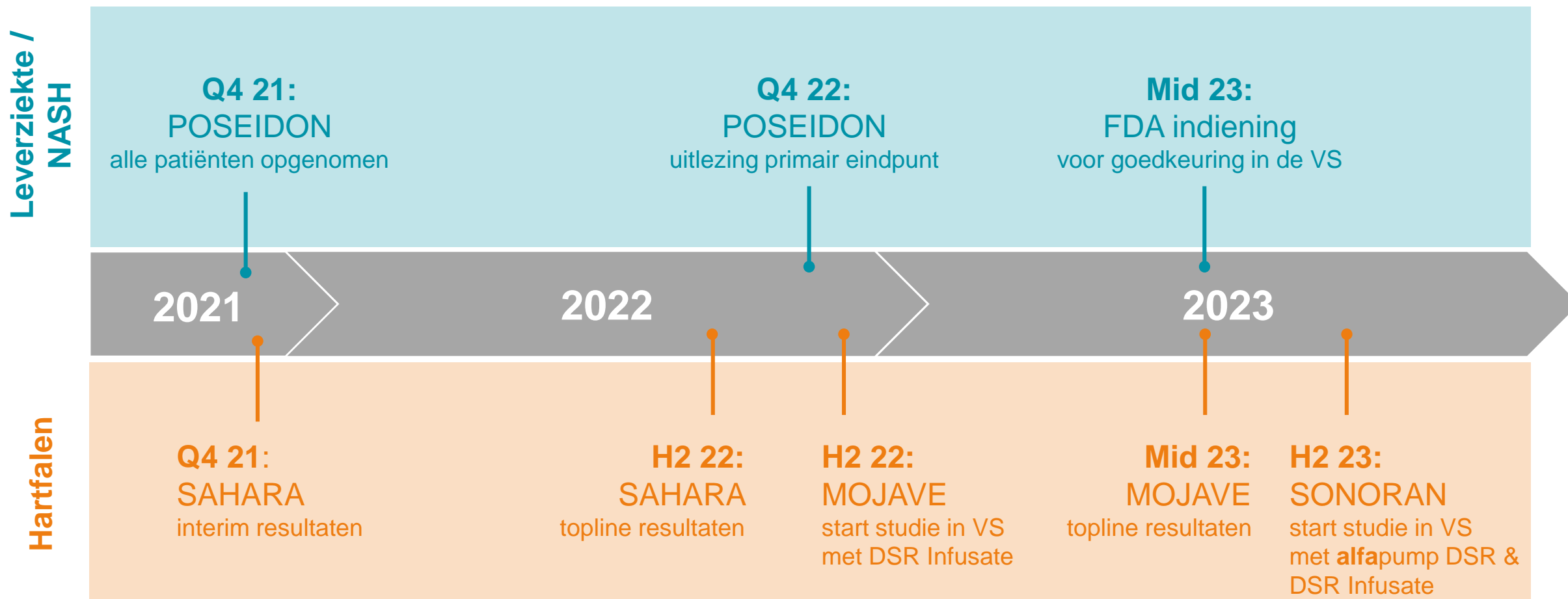
Congestief Hartfalen

Lange-termijn
therapie

Korte-termijn
therapie

*Evalueren van
vochtoverbelasting bij
Nierfalen*

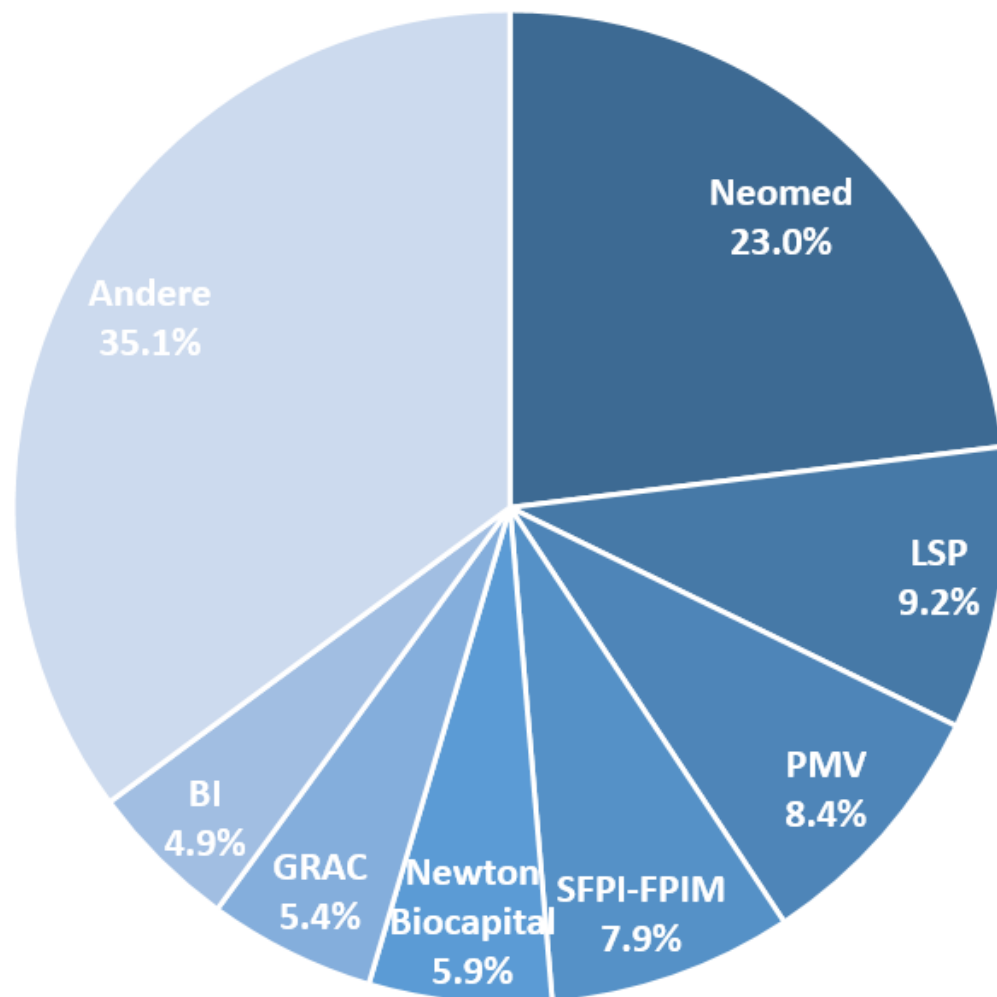
Sterke vooruitzichten voor waardebeoordeling



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
- ~€140 M market cap (~€7,5 / 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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