

sequana medical



Vernieuwers in de behandeling
van **vochtophoping**

leveraandoeningen – maligne ascites – hartfalen

Finance Avenue – 16 november 2019

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Regulatory disclaimers:

- The **alfapump**® has not yet received regulatory approval in the US and Canada. Any statement in this presentation about safety and efficacy of the **alfapump** does not apply to the US and Canada because the device is currently undergoing clinical investigation in these territories.
- Sequana Medical's proprietary DSR therapy is under development and Sequana Medical is developing **alfapump** DSR (Direct Sodium Removal) to deliver a convenient and fully implanted system for DSR therapy. DSR therapy is still in development and it should be noted that any statements in this presentation regarding safety and efficacy arise from pre-clinical and clinical studies and ongoing 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 US and Canada.

Bedrijfsoverzicht

- Opgericht in 2006
- Hoofdkantoor in Gent, België
- Productie in Zürich, Zwitserland
- ~45 werknemers
- Euronext Brussels: SEQUA
- Uniek **alfapump**[®] platform
 - ⇒ sterke IP
 - ⇒ >700 toestellen geïmplanteerd
 - ⇒ toepassingen in leverziekte, kanker en hartfalen



Ervaren management team

Executive team:



Ian Crosbie
Chief Executive Officer



Kirsten Van Bockstaele
Chief Financial Officer



Martijn Blom
Chief Commercial Officer



Gijs Klarenbeek
Chief Medical Officer



Dirk Fengels
Vice President Engineering
& Manufacturing



Timur Resch
Global VP
QM/QA/RA

Raad van Bestuur:



Pierre Chauvineau
Board Chairman



Ian Crosbie
Chief Executive Officer



Rudy Dekeyser
Director



Wim Ottevaere
Director



Erik Amble
Director

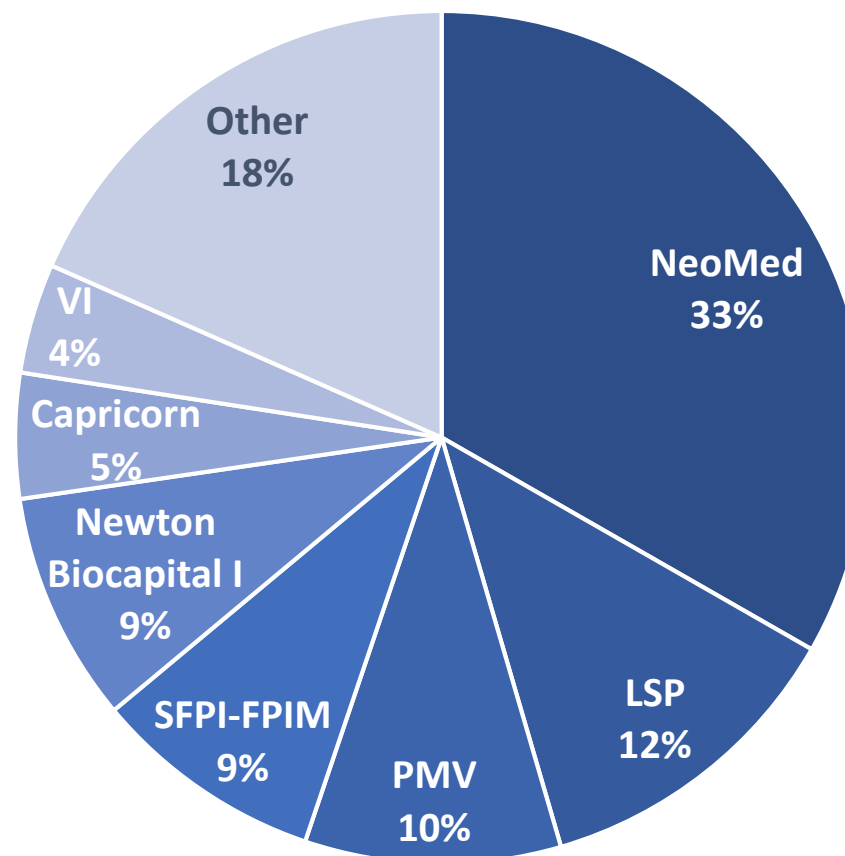


Jason Hannon
Director

Aandeelhoudersstructuur

Ticker: SEQUA – Euronext Brussels

- Market cap (oktober 2019): ~€90M
- Kaspositie (30 juni 2019): €12,9M



alfapump® platform

Automatisch vocht verwijderen gebruik makend van de blaas



Volledig geïmplanteerd



Automatische werking



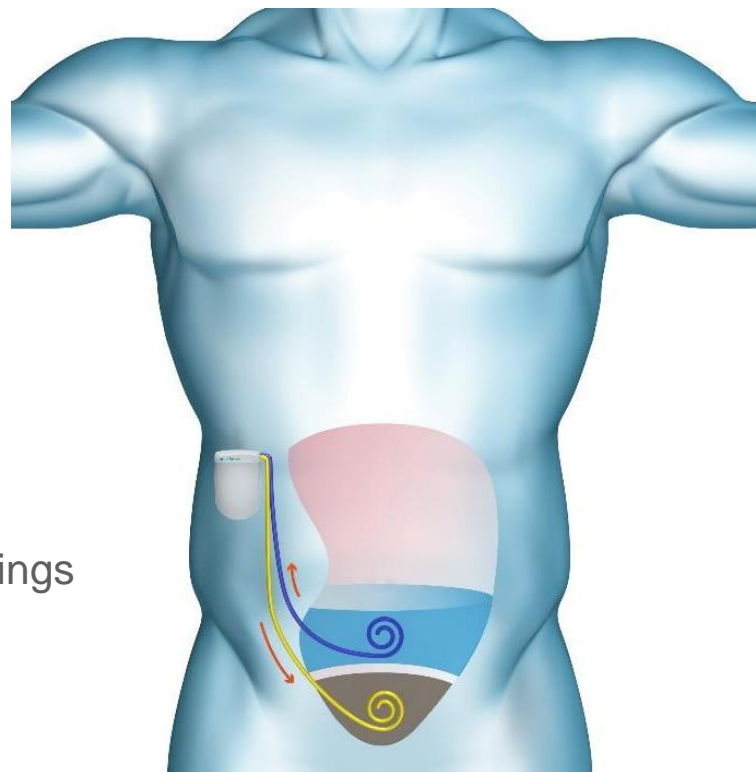
Draadloos opladen van de batterij



Draadloos aanpassen van de settings



Data monitoring van op afstand



Eenvoudige implantatie



Lange-termijn implantatie en catheter doorlaatbaarheid



Verwijdert tot 4 liter / dag



Vrijwel geen verstoppingen



Geen significante opwarming tijdens opladen en werking

Sterke IP door uitgebreide octrooiportfolio en knowhow

Eén platform – twee producten

alfapump platform



alfapump[®]

Bewezen stap voorwaarts in refractaire lever ascites en maligne ascites;

meer dan 700 pompen geïmplanteerd



alfapump[®] **DSR**

In ontwikkeling voor vochtophoping bij hartfalen;

klinische proof-of-concept van “direct sodium removal (DSR)” of “directe natrium verwijdering”



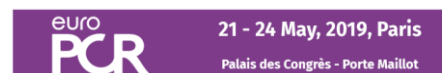
Breakthrough Device
Designation



NICE
National Institute for
Health and Care Excellence



1913 DGVS
Deutsche Gesellschaft für
Gastroenterologie,
Verdauungs- und
Stoffwechselkrankheiten



Focus op NASH en hartfalen

Grote marktopportunities met hoge onbeantwoorde medische behoefte



Lever (NASH) in VS

~145 K patiënten / jaar

met refractaire ascites door NASH binnen de 10-20j⁽¹⁾

> €3 Bn / jaar

markt opportuniteit



Hartfalen in EU+VS

~400 K patiënten gehospitaliseerd / jaar
voor vochtophoping door hartfalen tegen 2026⁽²⁾

> €5 Bn / jaar

markt opportuniteit

Gebouwd op bewezen Europese klinische & commerciële ervaring

NASH: niet-alcoholische steatohepatitis

Bron 1: Management inschatting inclusief geschatte groei in prevalentie voor NASH in VS gebaseerd op GlobalData Epidemiology Forecast to 2026
Bron 2: Management inschatting gebaseerd op GlobalData Heart Failure Epidemiology Forecast to 2026; Costanzo et al. (2007). Kiglore et al (2017)



Refractaire ascites is een ernstige complicatie van levercirrose

Forecast VS

Gezonde lever

330m



NAFLD*

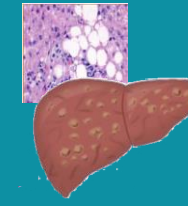
~1/3¹



* NAFLD: niet-alcoholische leververvetting

NASH*

~1/4-
1/3¹



* NASH: niet-alcoholische steatohepatitis

Levercirrose

10%²



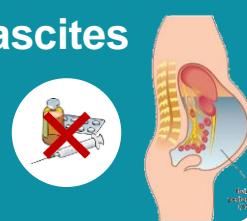
Ascites

50%³



Refractaire ascites

7.5%⁴



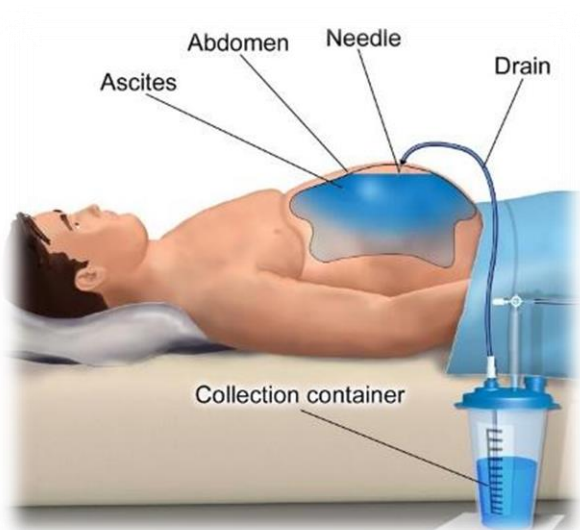
~150k



Bron 1: Management inschatting gebaseerd op Estes et al. 2018
 Bron 2: Management inschatting gebaseerd op GlobalData Nash Epidemiology Forecast to 2026; Nouredin et al., 2013
 Bron 3: Runyon 2009
 Bron 4: Ginès et al., NEJM 2004

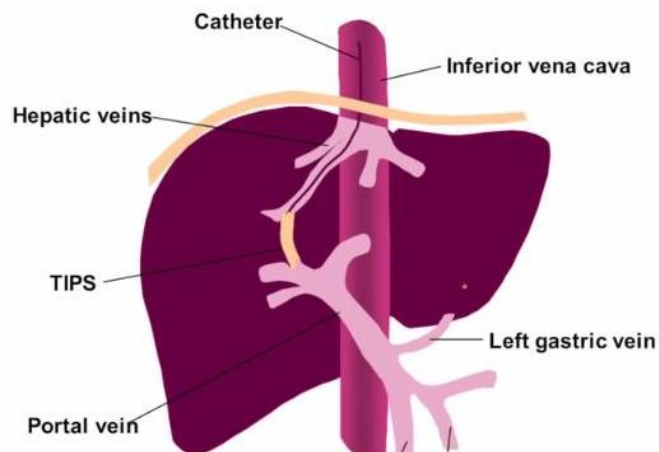
Huidige behandelingen hebben sterke beperkingen

Grootvolume Paracentese (LVP of “drainage”)



*Drastische
vermindering van de
levenskwaliteit*

Transjugular Intrahepatic Portosystemic Shunt (TIPS)



*Verhoogd risico op
hersenschade bij >65j
(typische leeftijd van NASH patiënten doelgroep)*

Levertransplantatie

**Synergie met
alfapump®
(wachtlijst voor
transplantatie)**

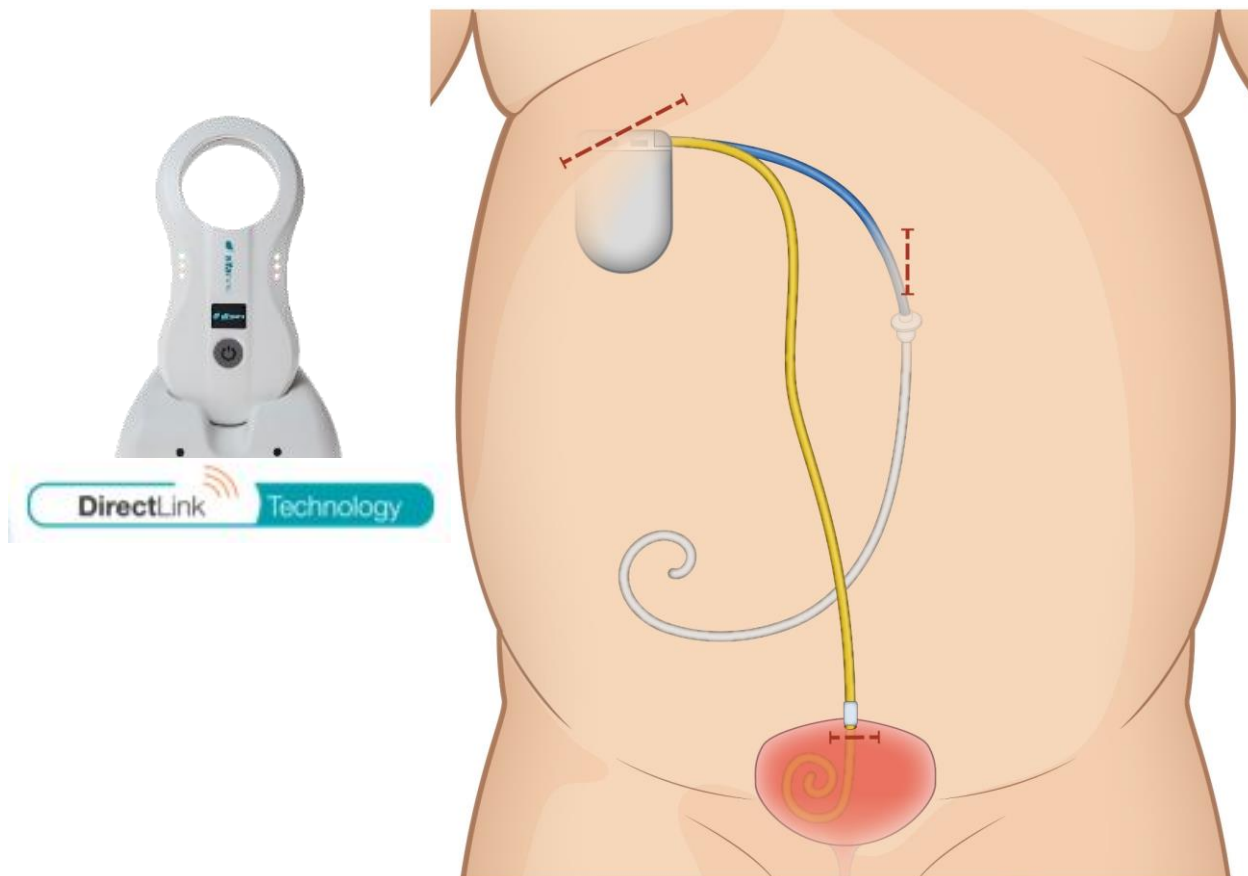


*Beperkt beschikbaar en
hoge kosten*



alfapump® is een lange-termijn behandeling

Volledig implanteerbaar, automatisch, draadloos opgeladen systeem



- ✓ Vermindering van de “ziektelast”
- ✓ Verbetering van de levenskwaliteit
- ✓ Vermindering van de kost voor ziekenhuizen en overheden

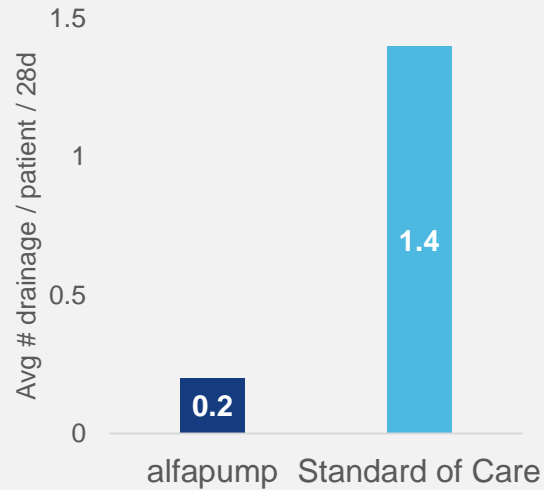




Sterke klinische validatie



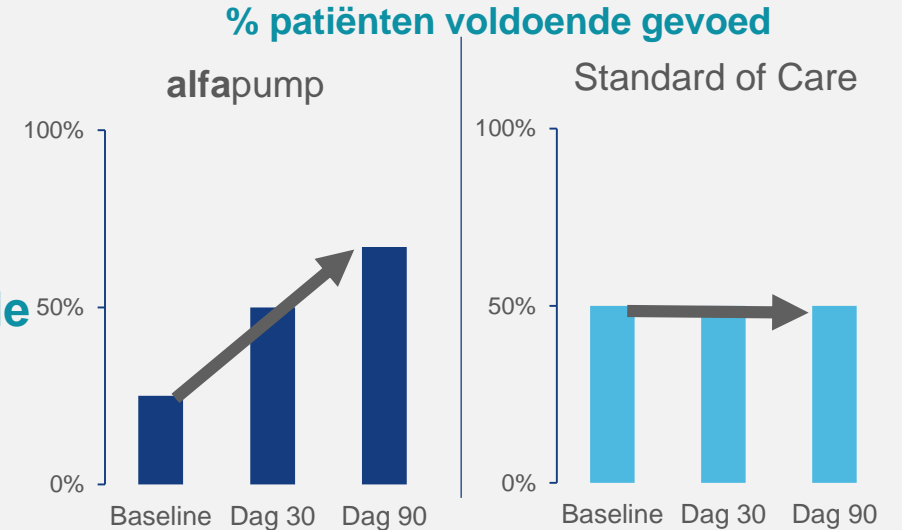
**Drastische
vermindering
van drainages**



Resultaten van RCT studie



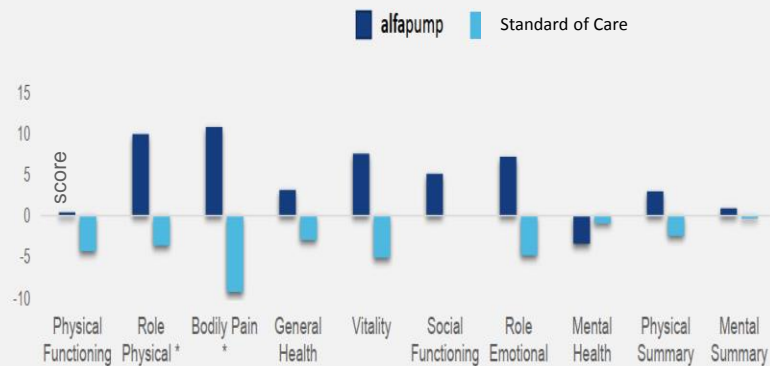
**Betere
nutritionele
toestand**



Resultaten van RCT studie



**Betere
levens-
kwaliteit**

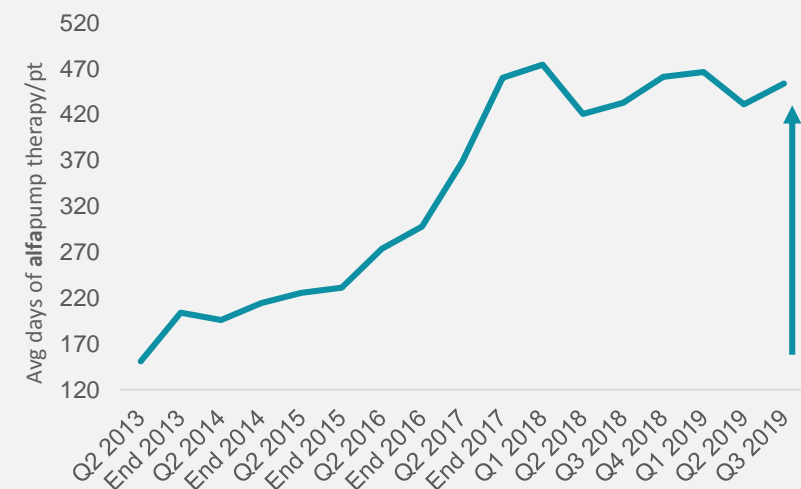


Resultaten van RCT studie

* p<0.05



**Betere
klinische
resultaten**



Sequana Medical data

NASH maakt de Amerikaanse markt aantrekkelijk

Sterkere concurrentiepositie in een veel grotere en meer dynamische markt

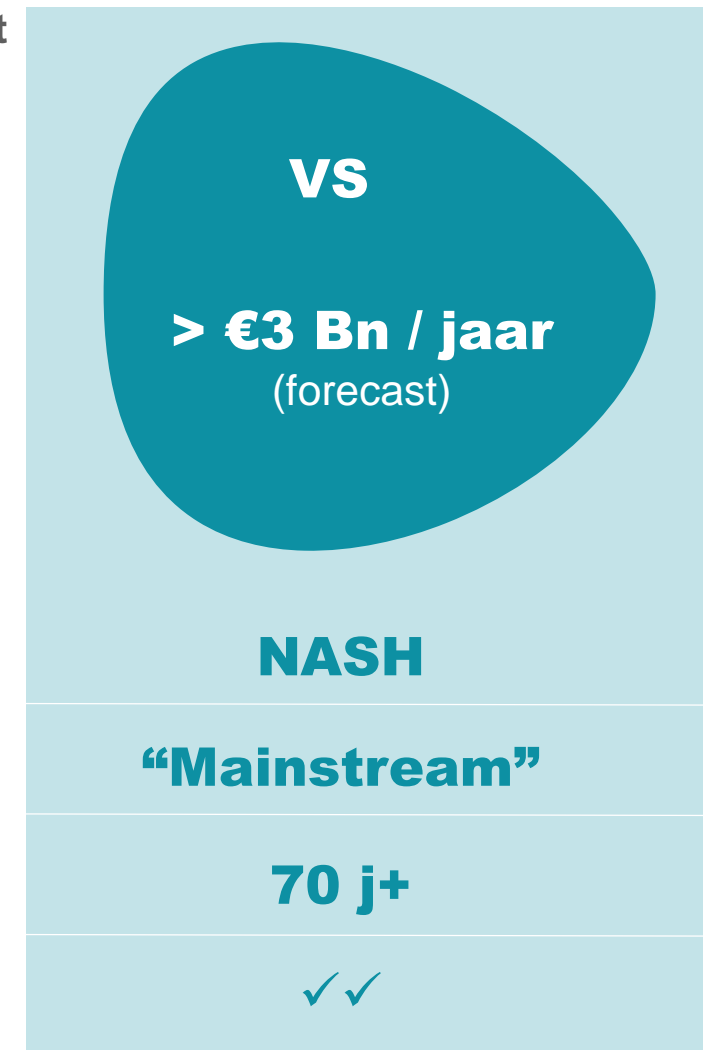
| **alfapump**[®] markt potentieel |

| Onderliggende ziekte |

| Patiënten doelgroep |

| Gemiddelde leeftijd |

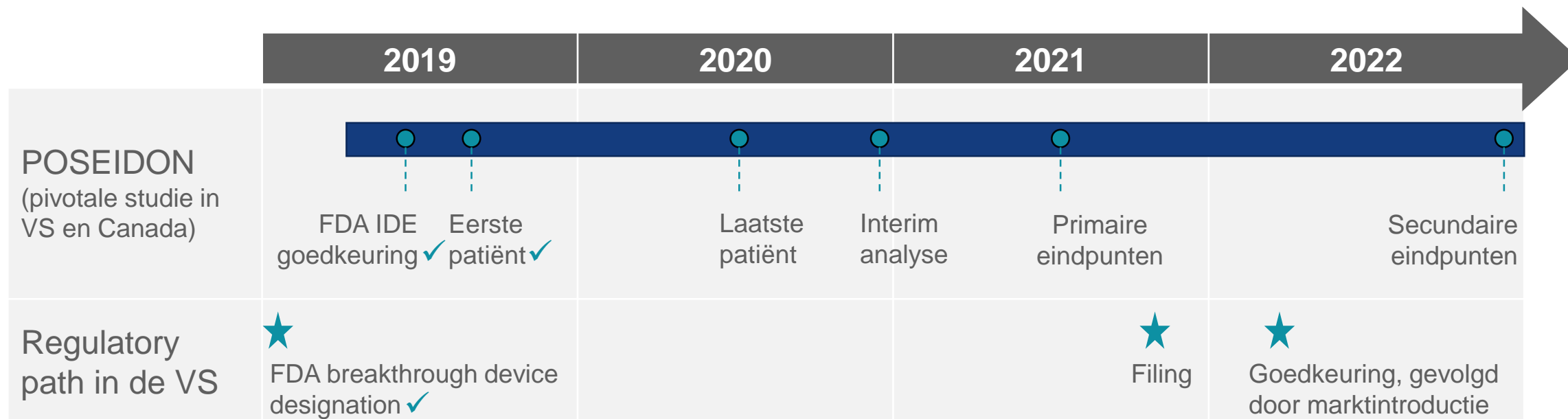
| **alfapump** positie |





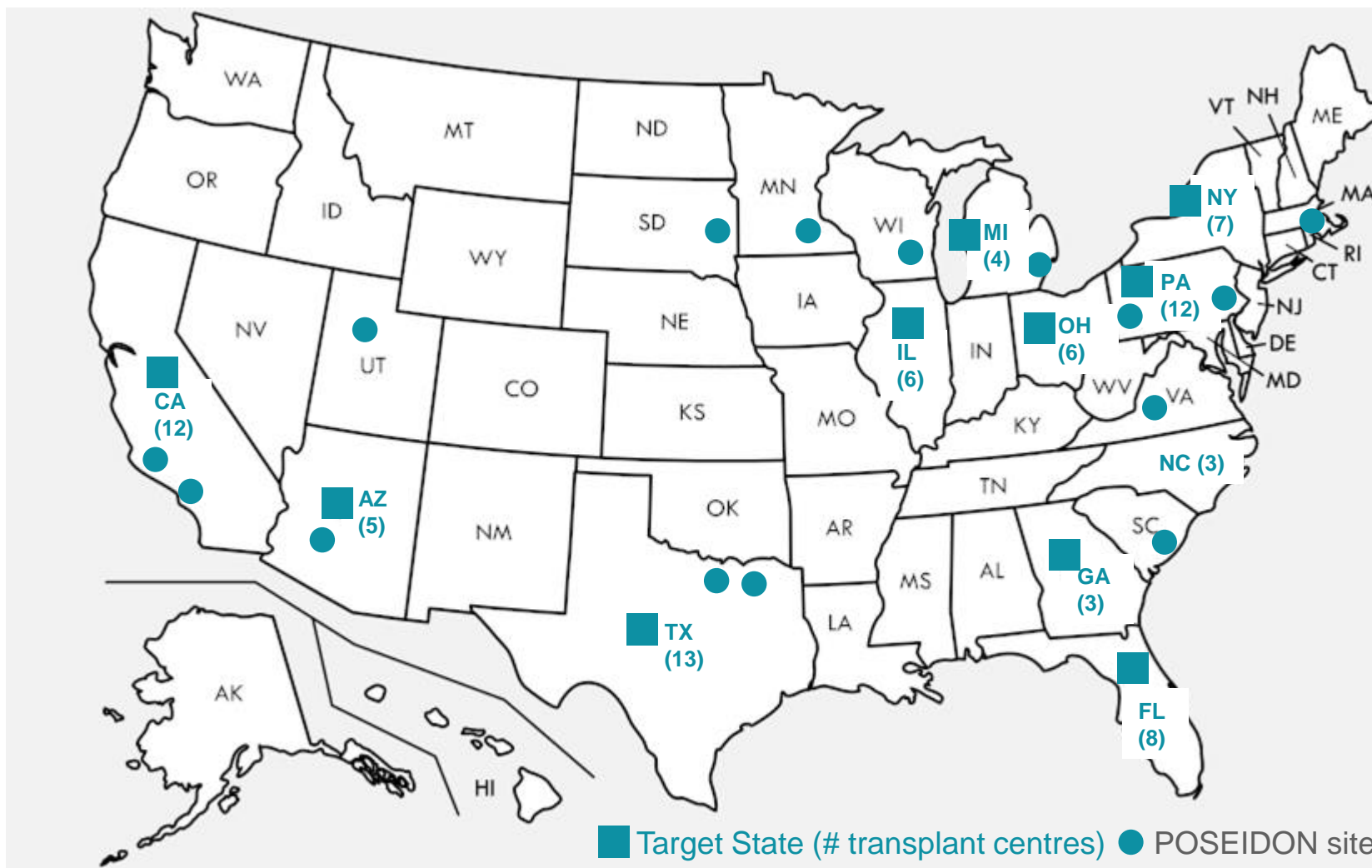
alfapump[®] roadmap voor goedkeuring in de VS

Belangrijke verwachte mijlpalen



Voorgestelde CMS-regel inzake terugbetaling voor breakthrough devices
Positieve ontwikkeling voor de alfapump

Directe verkoop in VS met specifiek verkoopsteam



Initiële focus op belangrijkste transplantatie centra:
35 sales reps, 10 clinical support, 5 corporate



Vochtophoping in hartfalen is een groot probleem en een belangrijke oorzaak van de kost

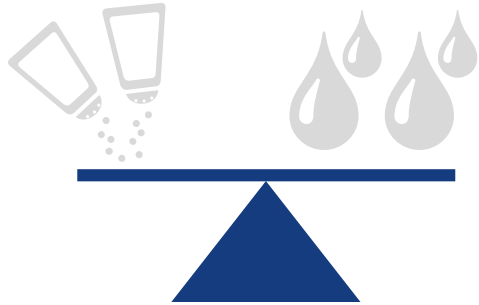


40% van hartfalen patiënten zijn moeilijk te behandelen met diuretica

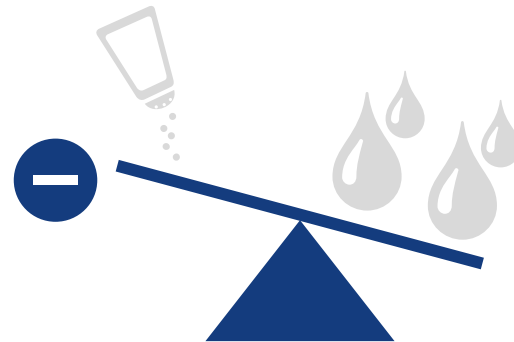
\$13 miljard jaarlijkse kost in de VS door hartfalen-gerelateerde hospitalisatie waarvan ~90% te wijten is aan vochtophoping



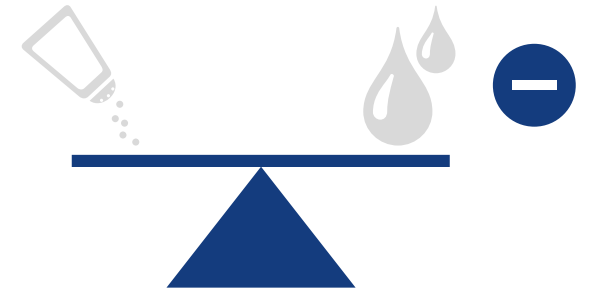
Direct sodium removal of directe natrium verwijdering (DSR)



Te veel natrium (zout) leidt tot vochtophoping



Verwijderen van het natrium (zout) via DSR

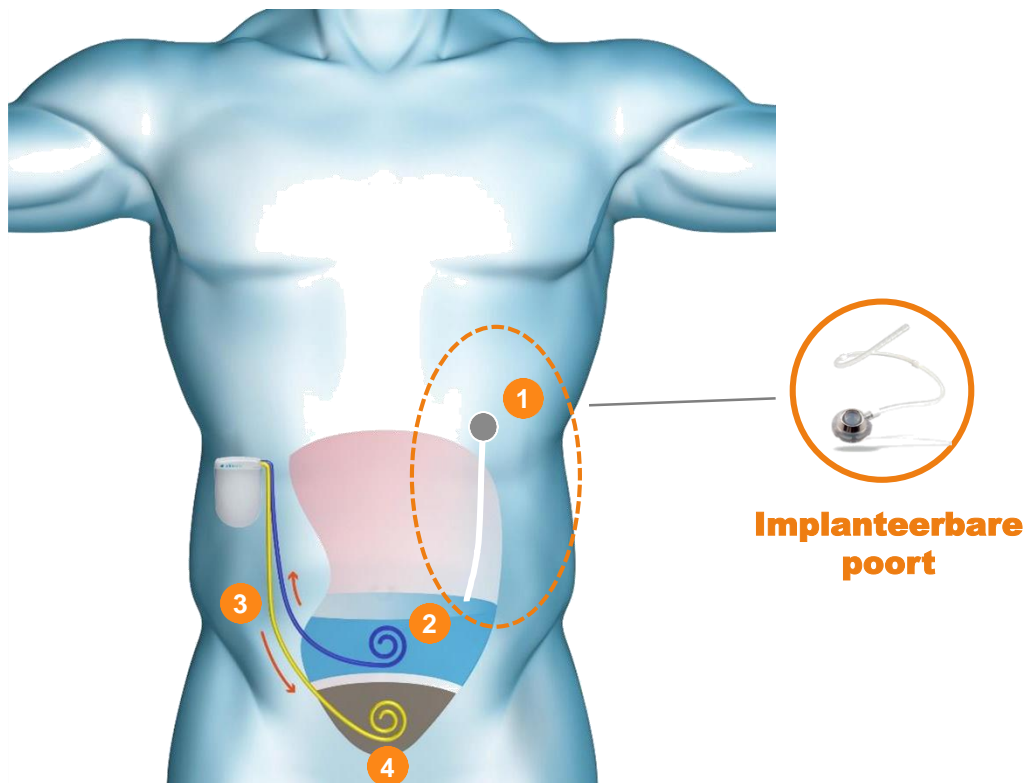


Eliminatie van overtollig vocht door lichaam



alfapump[®] DSR

Een volledig implanteerbaar en handig systeem voor DSR therapie dat gebruik maakt van bewezen elementen



✓ DSR

✓ alfapump

✓ Implanteerbare poort

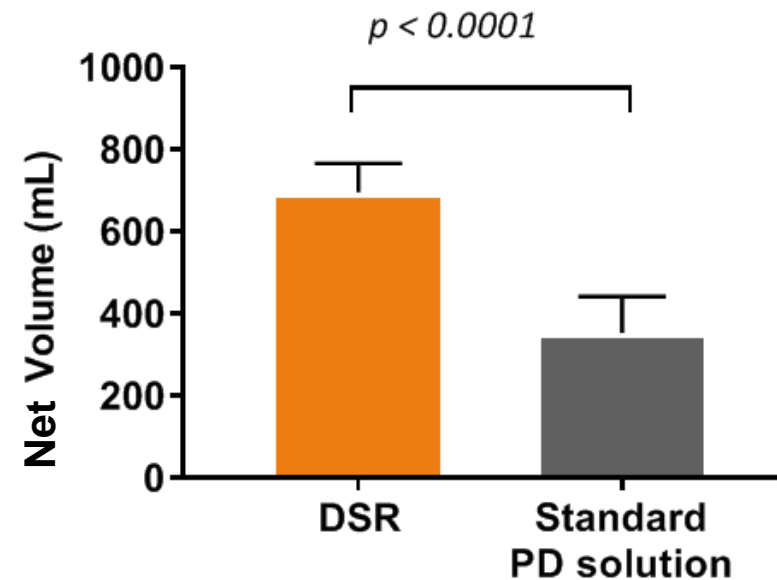
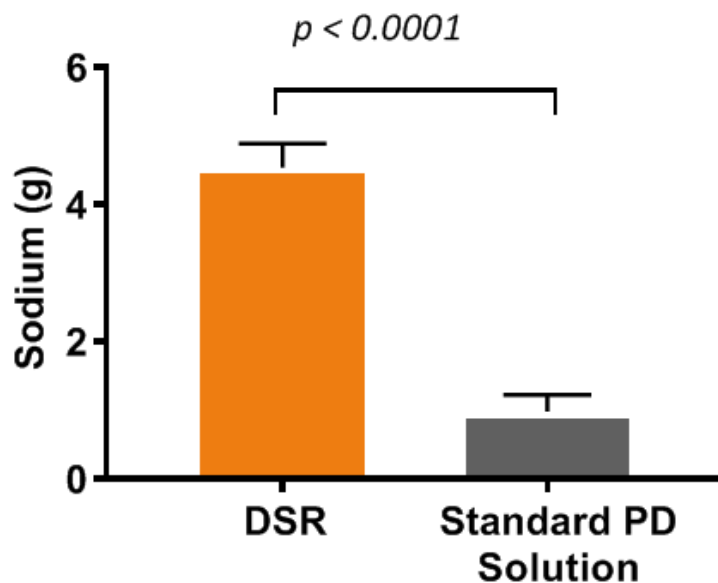
Potentieel chronische behandeling voor patiënten met hartfalen die moeilijk te behandelen zijn met diuretica



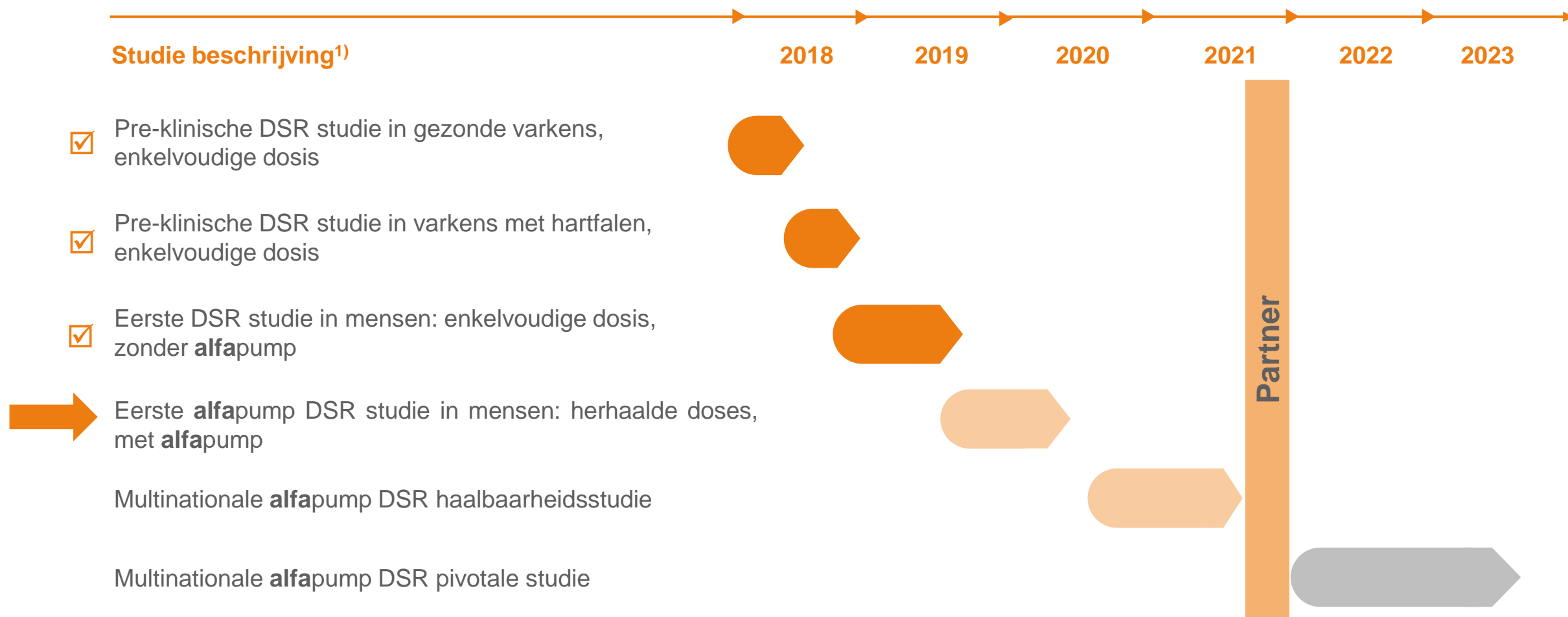
Klinische proof-of-concept van DSR therapie

Primaire en secundaire eindpunten behaald

- ✓ DSR therapie was veilig en verdraagbaar zonder bijwerkingen of ongemakken
- ✓ Aanzienlijk hogere zoutverwijdering met DSR vs standaard dialyse oplossing
- ✓ Consistente resultaten tussen de patiënten onderling



alfapump® DSR ontwikkeling – overzicht



Wetenschappelijke adviseurs voor hartfalen:



Dr. Butler



Dr. Costanzo



Dr. Tang



Dr. Testani

Vooruitzichten / potentiële mijlpalen

H2 2019

- alfapump** Start van POSEIDON studie in patiënten met terugkerende en refractaire lever ascites
- alfapump** Start van Prospectieve Maligne Ascites Studie (ProMAS)
- alfapump** Start van Step Counter studie in patiënten met refractaire lever ascites
- alfapumpDSR** **Start van eerste alfapump DSR studie in patiënten met vochtophoping door hartfalen**
- alfapumpDSR** Initiële resultaten van eerste **alfapump** DSR studie in patiënten met vochtophoping door hartfalen

H1 2020

- alfapump** Te verwachten finale Duitse terugbetaling van de **alfapump**
- alfapumpDSR** **Finale resultaten van eerste alfapump DSR studie in patiënten met vochtophoping door hartfalen**
- alfapump** **Einde recrutering patiënten met terugkerende en refractaire lever ascites in POSEIDON studie**

Veelzijdig alfapump® platform met waardecreatie op korte termijn



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