

sequana medical



Vernieuwers in de behandeling
van **vochtophoping**

leveraandoening – maligne ascites – hartfalen

KBC Dag van de Belegger – 9 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

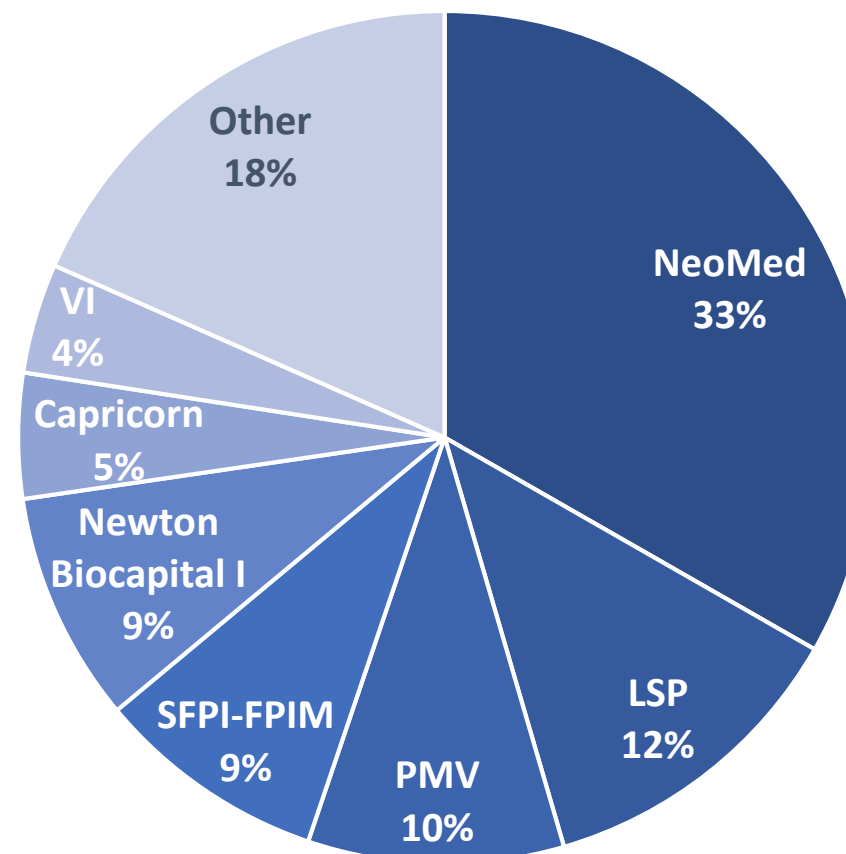


Jason Hannon
Director

Aandeelhoudersstructuur

Ticker: SEQUA – Euronext Brussels

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



Sterke vooruitgang geboekt sinds IPO



alfapump[®] Noord-Amerika

- ✓ Start van POSEIDON, onze pivotale **alfapump** studie in patiënten met terugkerende en refractaire ascites door levercirrose



alfapump[®] DSR

- ✓ Klinische proof-of-concept van DSR-therapie voor behandeling van vochtophoping in hartfalen



alfapump[®] Europa

- ✓ **alfapump** opgenomen in Duitse behandelingsrichtlijnen (DGVS) voor complicaties van levercirrose

alfapump[®] platform



alfapump® platform

Automatisch vocht verwijderen gebruik makend van de blaas



Volledig geïmplanteerd



Automatische werking



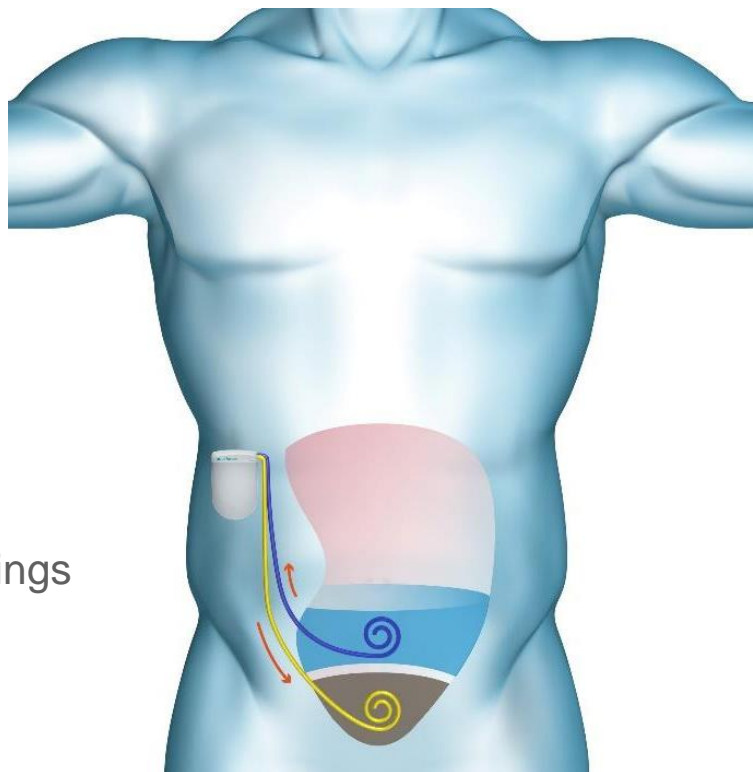
Draadloos opladen van de batterij



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



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)

NASH maakt de Amerikaanse markt aantrekkelijk

Sterkere concurrentiepositie in een veel grotere en meer dynamische markt

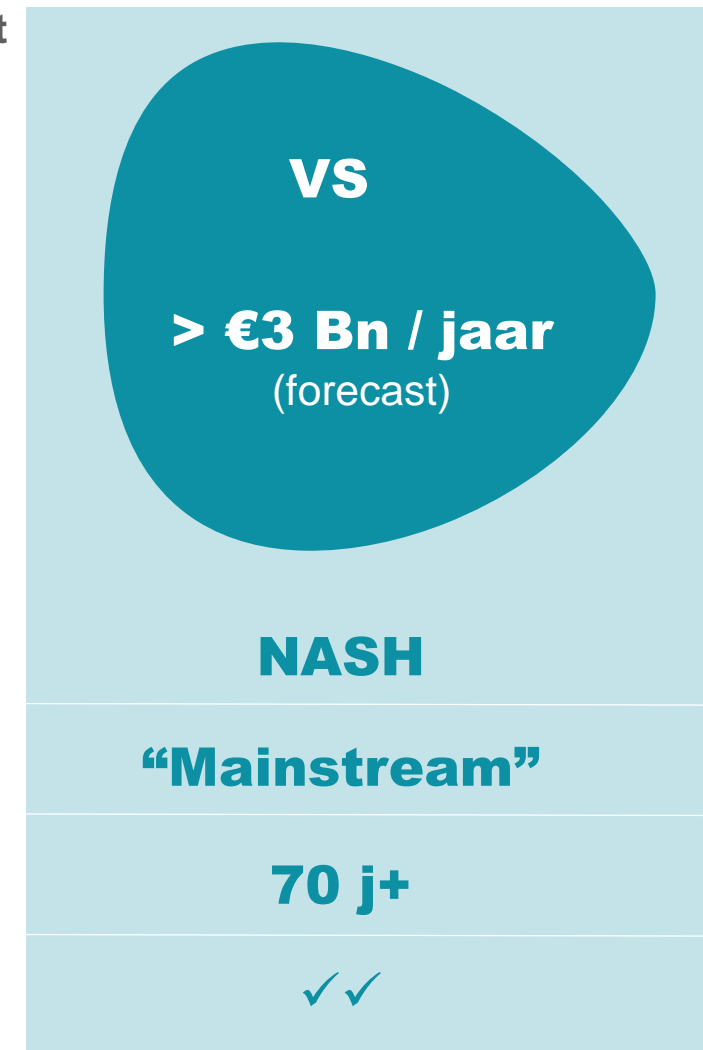
| **alfapump**[®] markt potentieel |

| Onderliggende ziekte |

| Patiënten doelgroep |

| Gemiddelde leeftijd |

| **alfapump** positie |





alfapump®

Bewezen stap voorwaarts voor
refractaire lever ascites en
maligne ascites

Levercirrose

Grote en groeiende markt door ongezonde levensstijl en vergrijzing

Virale infecties
(Hepatitis B & C)



Alcohol



Niet-Alcoholische
Steatohepatitis
(NASH)



Stijgende prevalentie,
voornamelijk in de VS



LEVERSTEATOSE: Tijdbom in de hepatologie



Wie leverproblemen zegt, denkt vaak aan te veel alcohol.

Maar bij een grote groep mensen is er een andere oorzaak. Naar schatting heeft 30 procent van de Belgen last van leververvetting veroorzaakt door overgewicht.

Leverspecialisten trekken aan de alarmbel.



Refractaire ascites is een ernstige complicatie van levercirrose

Forecast VS

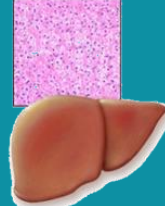
Gezonde lever

330m



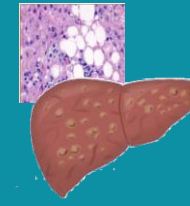
NAFLD*

~1/3¹



NASH*

~1/4-1/3¹

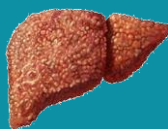


* NAFLD: niet-alcoholische leververvetting

* NASH: niet-alcoholische steatohepatitis

Levercirrose

10%²



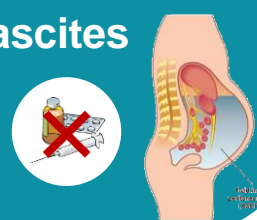
Ascites

50%³



Refractaire ascites

7.5%⁴



~150k



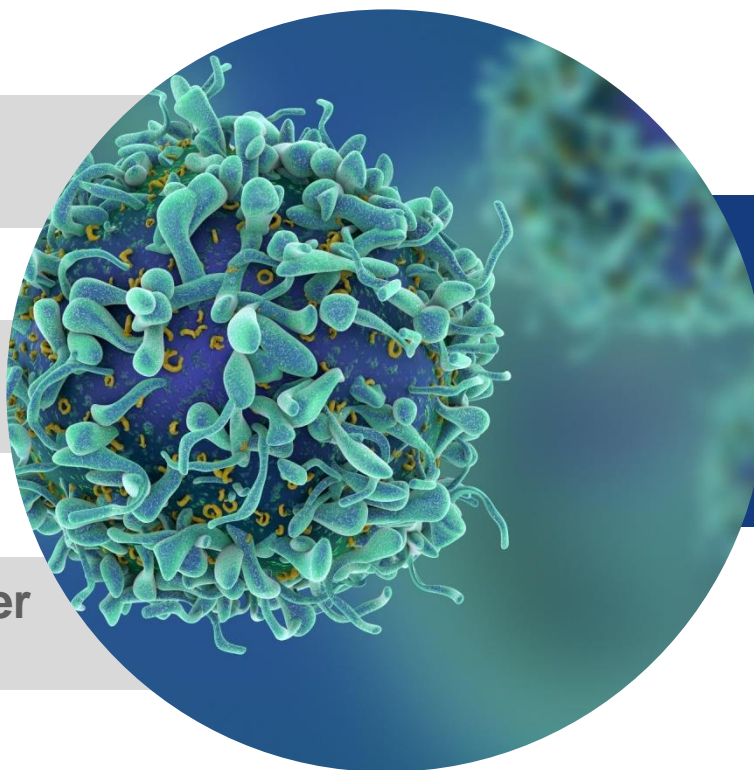
Bron 1: Management inschatting gebaseerd op Estes et al. 2018
 Bron 2: Management inschatting gebaseerd op GlobalData Nash Epidemiology Forecast to 2026; Nouredin et al., 2013
 Bron 3: Runyon 2009
 Bron 4: Ginès et al., NEJM 2004

Maligne ascites is een ernstige complicatie in laat-stadium kanker

Vochtophoping in de buik door drainage van het lymfesysteem

Zware impact op de levenskwaliteit

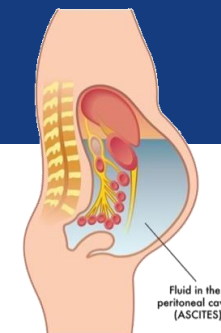
Vermindert het vermogen om anti-kanker therapieën te weerstaan



Maligne ascites in borst en eierstokkanker¹:

EU5: ~18K

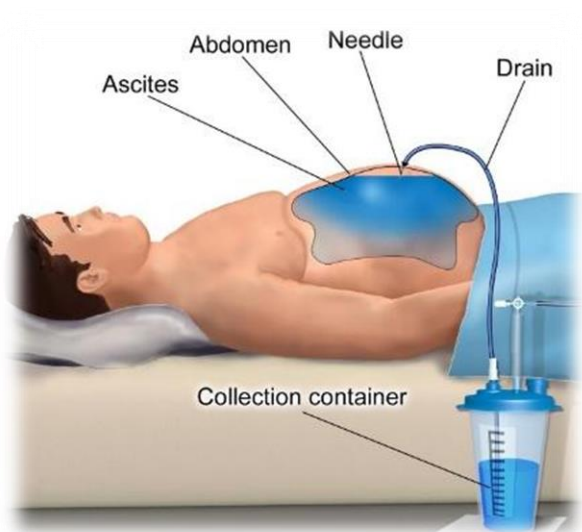
US: ~16K



Behoeftte om de levenskwaliteit te verbeteren en de intensiteit van anti-kanker therapieën te verhogen

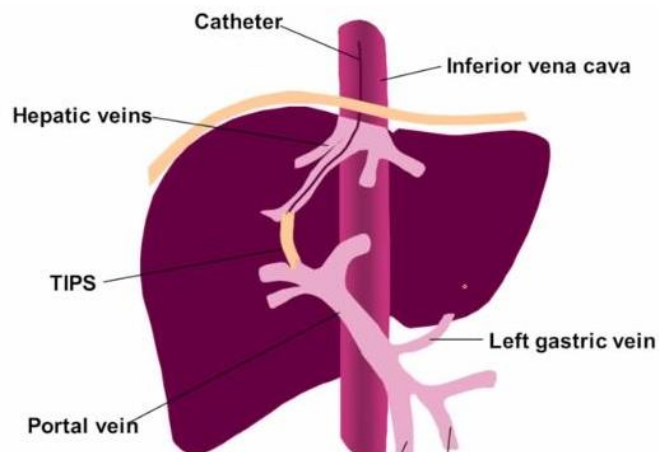
Huidige behandelingen hebben sterke beperkingen

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

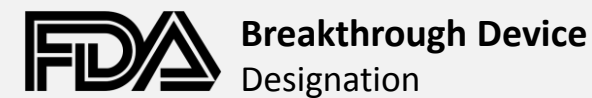
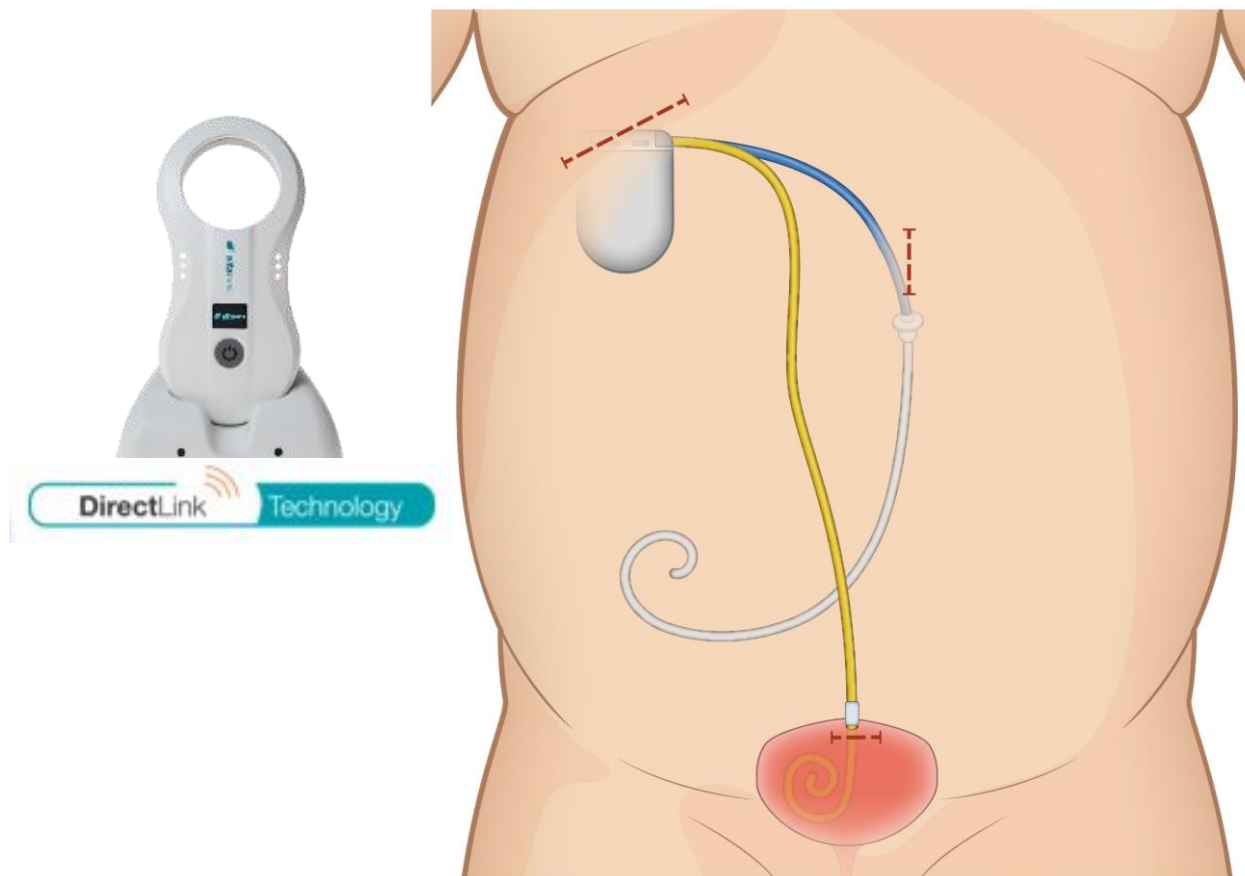
**Synergie met alfapump®
(wachtlijst voor transplantatie)**



Beperkt beschikbaar en hoge kosten

alfapump[®] is een lange-termijn behandeling

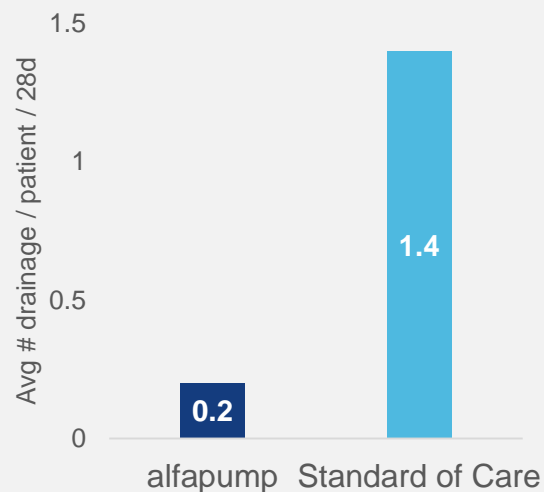
Volledig implanteerbaar, automatisch, draadloos opgeladen systeem



Sterke klinische validatie



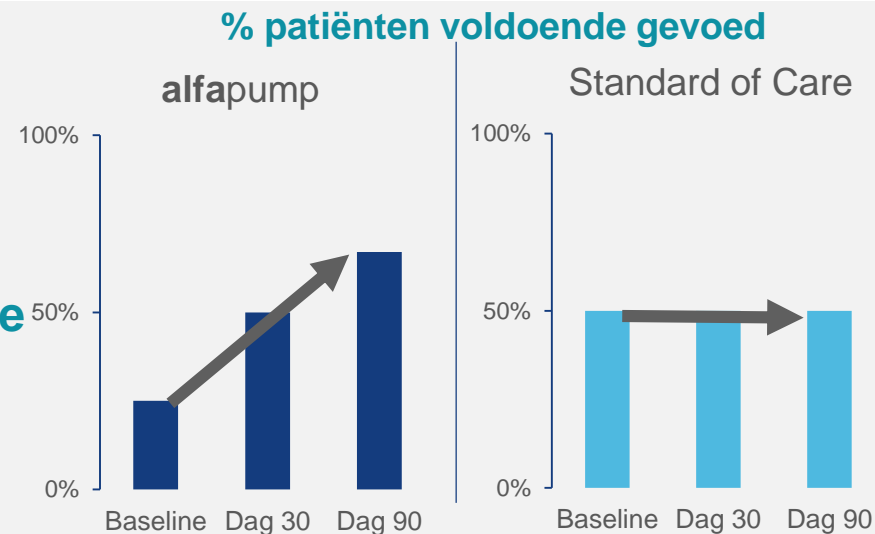
**Drastische
vermindering
van drainages**



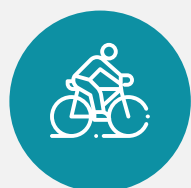
Resultaten van RCT studie



**Betere
nutritionele
toestand**



Resultaten van RCT studie



**Betere
levens-
kwaliteit**

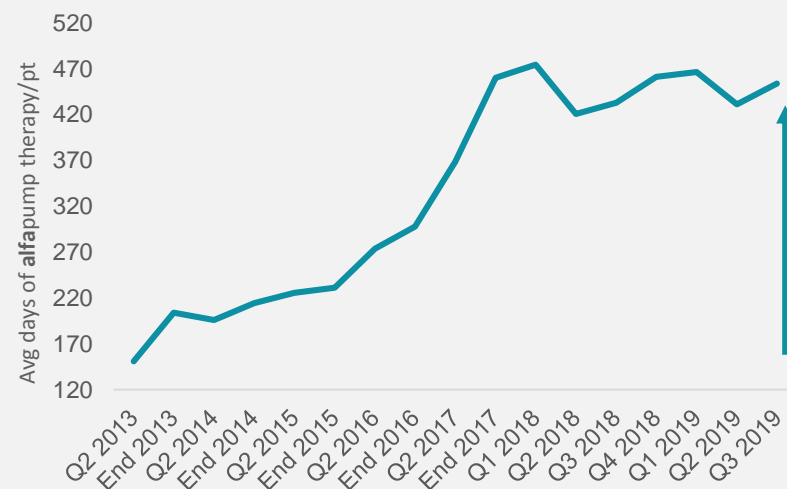


Resultaten van RCT studie

* p<0.05



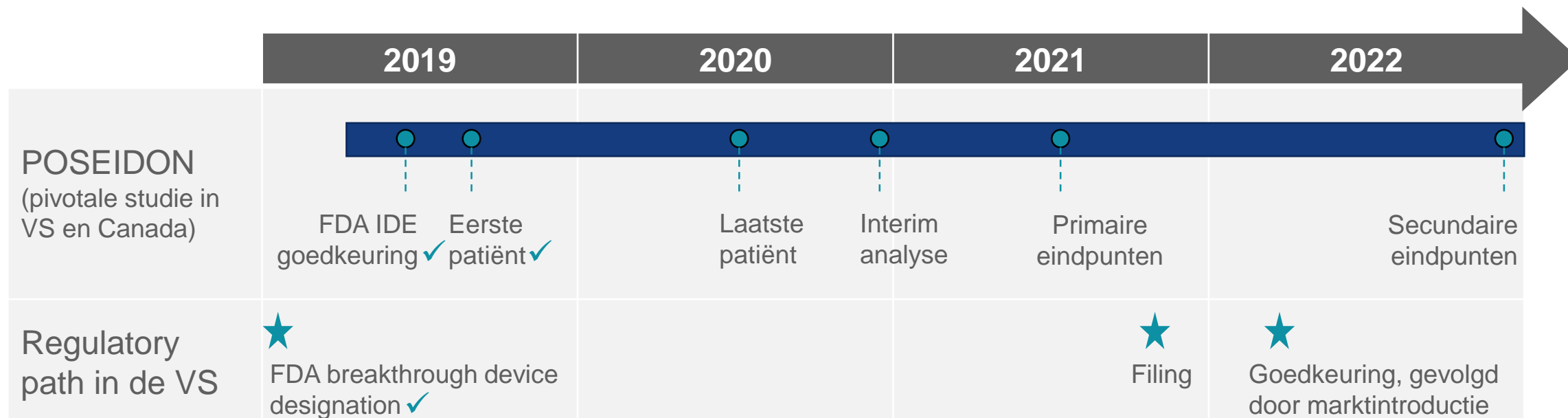
**Betere
klinische
resultaten**



Sequana Medical data

alfapump® roadmap voor goedkeuring in de VS

Belangrijke verwachte mijlpalen



Voorgestelde CMS-regel inzake terugbetaling voor breakthrough devices

Positieve ontwikkeling voor de alfapump

Praktijkervaring in Europa is belangrijk voor de Amerikaanse levermarkt en de hartfalenmarkt



“ De **alfapump** is een fantastische nieuwe techniek. Patiënten moeten niet meer zo vaak naar het ziekenhuis. De patiënt is vrij, mobiel en kan voor zichzelf zorgen.

14 sales 

Focus op gespecialiseerde centra

Terugbetaling in:

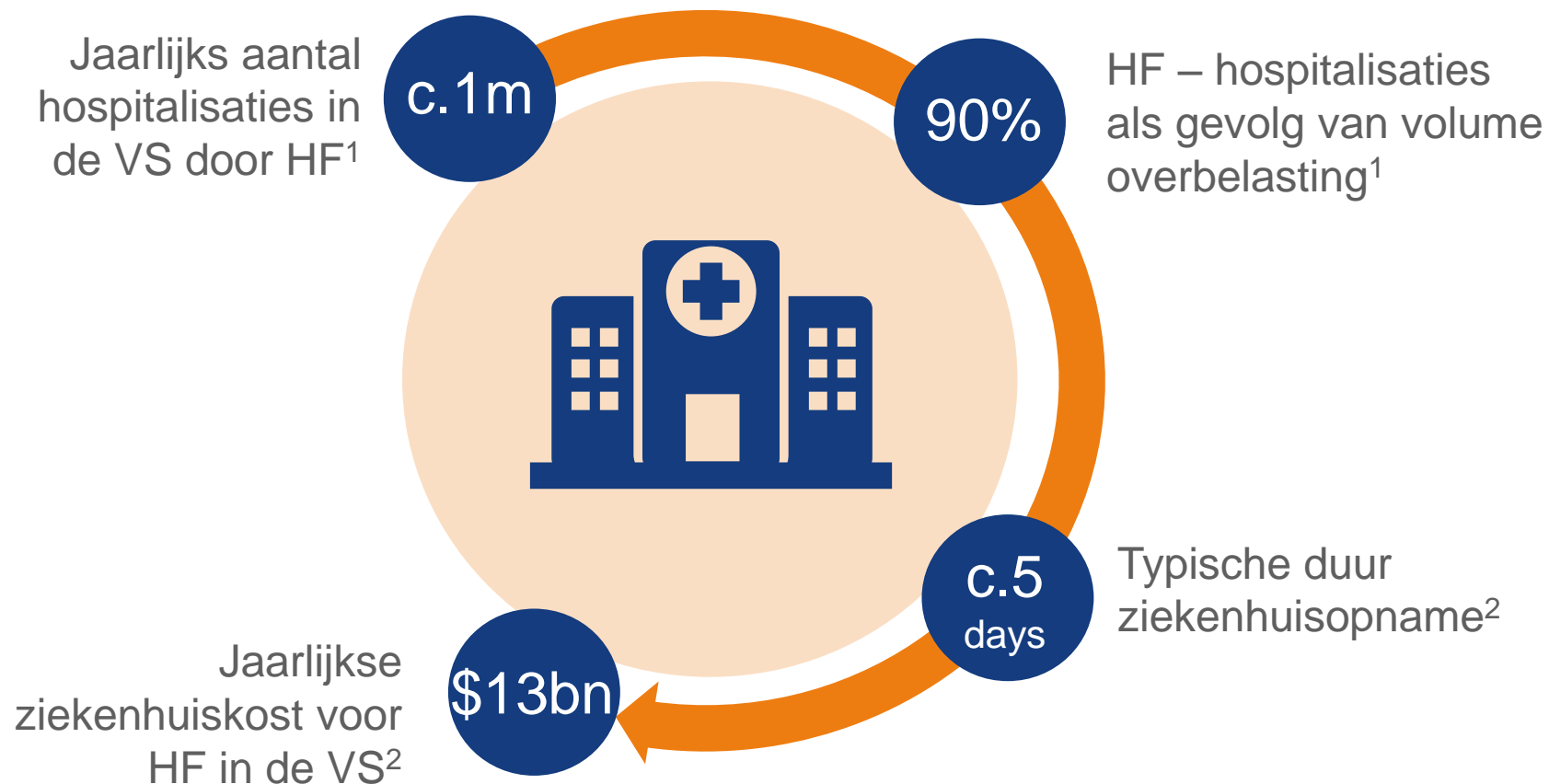
- ✓ **Zwitserland**
- ✓ **Duitsland** (voorlopige terugbetaling)
- ✓ **VK** (aanbevolen door NICE onder speciale regeling)



alfapump[®] DSR

Potentieel chronische behandeling
voor vochtophoping bij hartfalen

Vochtophoping bij hartfalen is een groot probleem



40% van hartfalen patiënten zijn moeilijk te behandelen met diuretica⁴

24% terug opgenomen binnen de 30 dagen³

Direct sodium removal of directe natrium verwijdering (DSR)



Toediening
zoutloze
oplossing
in buikholte

Extractie
van het zout
uit het
lichaam

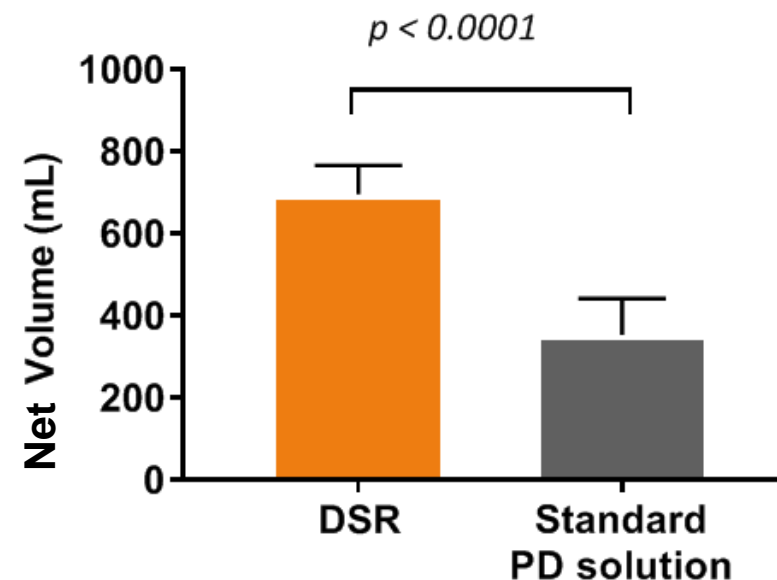
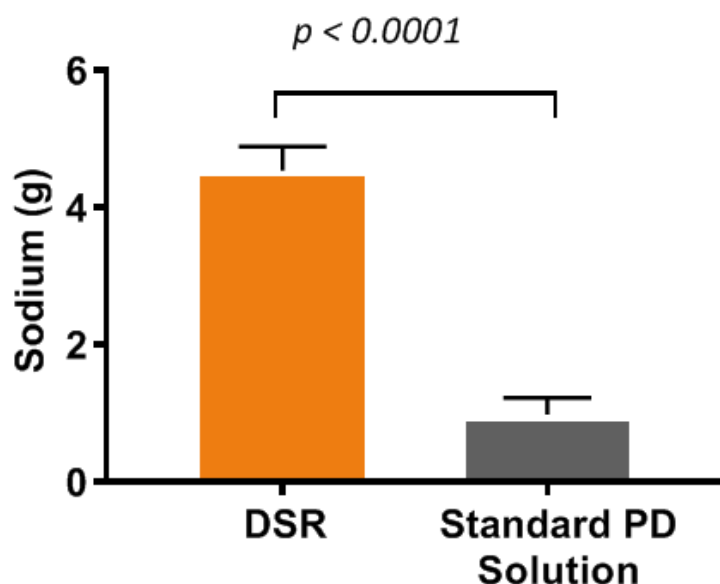
Oplossing met
zout wordt
verwijderd

Lichaam herstelt
evenwicht en
verwijderd
overtollig vocht

DSR heeft klinische proof-of-concept

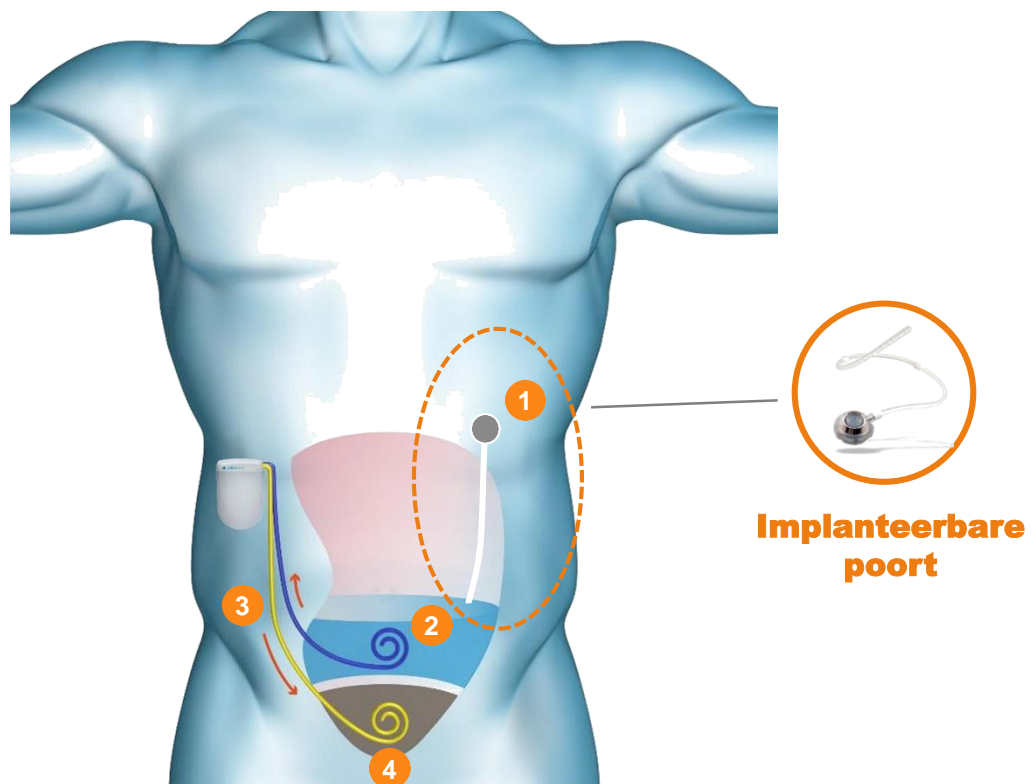
Primaire en secundaire eindpunten behaald in eerste studie in mensen

- ✓ 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

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



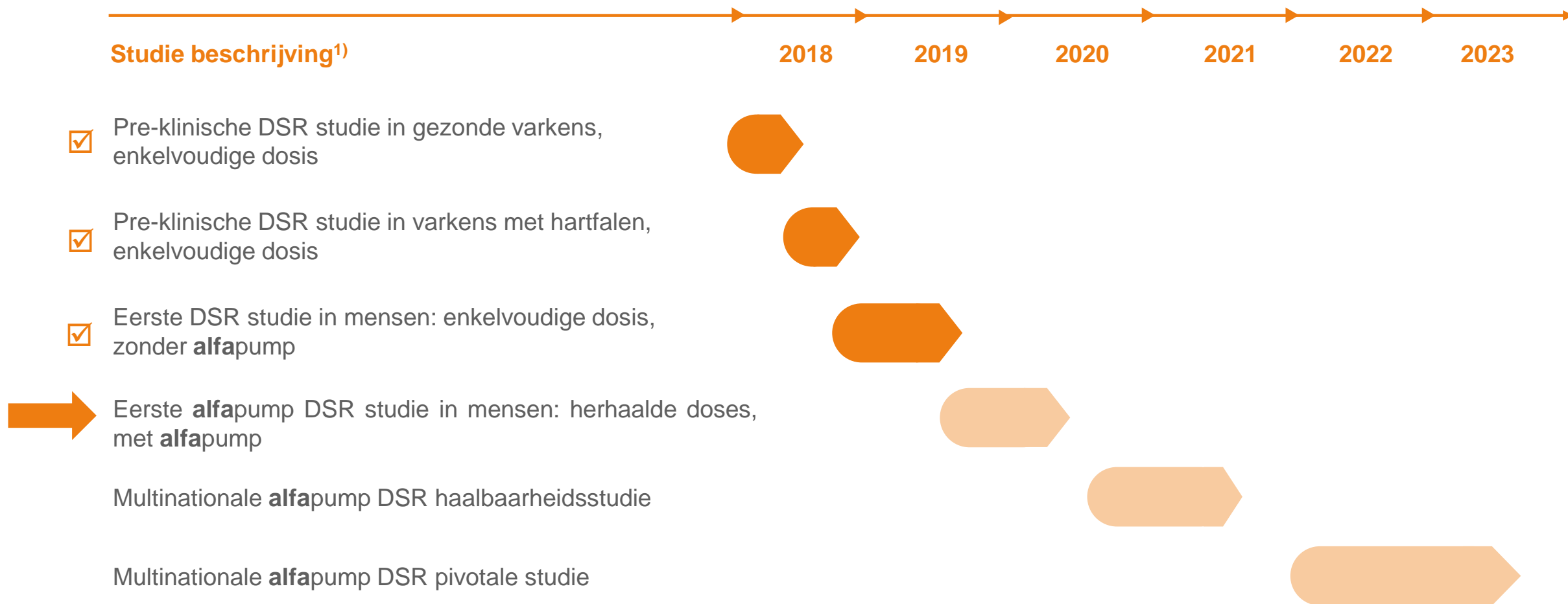
✓ DSR

✓ alfapump

✓ Implanteerbare poort

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

alfapump[®] DSR ontwikkeling – overzicht



Wetenschappelijke adviseurs voor hartfalen:



Dr. Butler



Dr. Costanzo



Dr. Tang



Dr. Testani



Waardecreatie op korte termijn

Vooruitzichten / potentiële mijlpalen

H2 2019

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

H1 2020

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

Veelzijdig alfapump® platform met waardecreatie op korte termijn

Besluit

- Eén platform – twee producten: **alfapump**[®] & **alfapump**[®] DSR
- **alfapump** platform is klinisch en commercieel gevalideerd: >700 implantaties
- Praktijkervaring in Europa is belangrijk voor de Amerikaanse levermarkt en hartfalen markt
- Lever (NASH) in de VS en Hartfalen zijn onze 2 belangrijkste pijlers van groei met waardecreatie op korte termijn:
 - ⇒ alle patiënten opgenomen in de POSEIDON studie verwacht tegen midden 2020
 - ⇒ eerste **alfapump** DSR study verwacht te starten in H2 2019 met resultaten in H1 2020



“Mijn levensstijl is 100% veranderd. We kunnen opnieuw mee darts spelen, kaarten en dansen, opnieuw genieten van dat deel van het leven.



“Ik heb mijn vrijheid terug. We kunnen opnieuw afspreken met vrienden. Het is fantastisch, hij danst zelfs opnieuw met mij.



contact info



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