sequanamedical

Vernieuwers in de behandeling van vochtophoping

leveraandoening – maligne ascites – hartfalen

VFB Dag van de Tips, Gent – 28 september 2019

Wim Ottevaere – Lies Vanneste

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Regulatory disclaimers:

- The **alfa**pump® has not yet received regulatory approval in the US and Canada. Any statement in this presentation about safety and efficacy of the **alfa**pump 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 **alfa**pump 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 **alfa**pump system in Europe, the US and Canada.

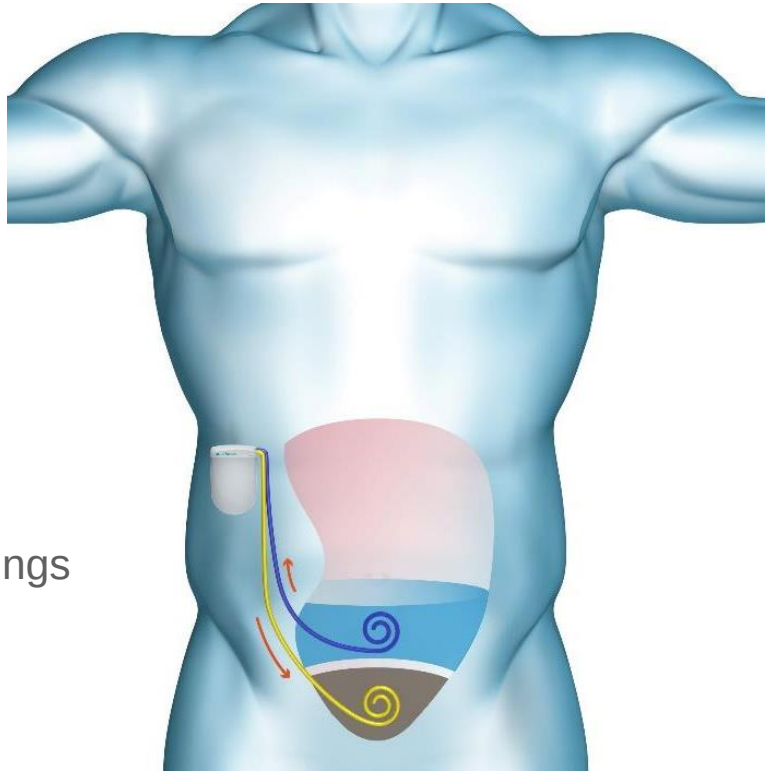
Bedrijfsoverzicht

- Opgericht in 2006
- Hoofdkantoor in Gent, België
- ~40 werknemers
- Uniek **alfa**pump® platform
  - ⇨ >700 pompen geïmplanteerd
  - ⇨ toepassingen in leverziekte, kanker en hartfalen
- Euronext Brussels: SEQUA
- €12,9M in cash op 30 juni 2019

alfapump® platform

Gebruik makend van de blaas om vochtophoping te behandelen

- 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 ascites door levercirrose en maligne ascites;

meer dan 700 pompen geïmplanteerd

alfapump® DSR

breakthrough aanpak voor vochtophoping in hartfalen;

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

CE

FDA **Breakthrough Device** Designation

EASL The Home of Hepatology

NICE National Institute for Health and Care Excellence

1913 DGVS Deutsche Gesellschaft für Gastroenterologie, Verdauungs- und Stoffwechselkrankheiten

euro PCR 21 - 24 May, 2019, Paris Palais des Congrès - Porte Maillot

SAN FRANCISCO, CA September 25-29, 2019 tct2019

Focus op NASH in de VS en hartfalen markten

Grote marktopportuniteiten 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+US

~400 K patiënten gehospitaliseerd / jaar

voor vochtophoping door hartfalen tegen 2026(2)

> €5 Bn / jaar

markt opportuniteit

Gebouwd op bewezen Europese klinische & commerciële ervaring

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

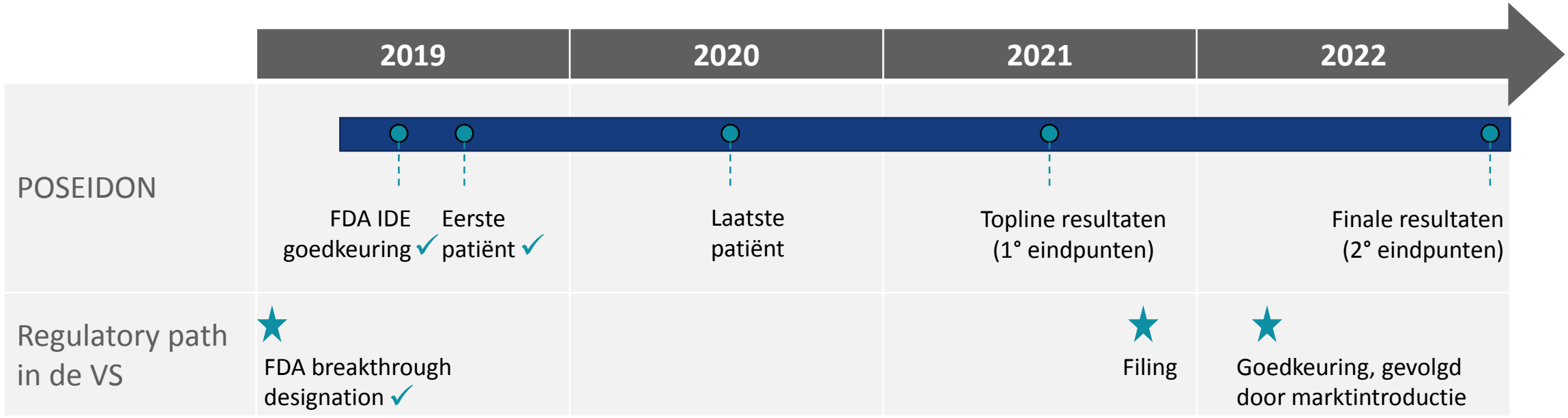
Sterkere concurrentiepositie in een veel grotere en meer dynamische markt

	EU	VS
alfapump® markt potentieel	~€0.4 Bn / jaar	**> €3 Bn / jaar**
Onderliggende ziekte	Alcoholische Leverziekte, Hepatitis	**NASH**
Patiënten karakteristiek	“Outside mainstream”	**“Mainstream”**
Gemiddelde leeftijd	40-50 j	**70 j+**
alfapump concurrentiepositie	✓	✓✓

Notes: EU Lever markt: Data van 1980-2010, sterftecijfers tussen 9-12.4 per 100,000; Mokdad et al., 2014, Management inschatting dat 7.5% cirrhosis patiënten jaarlijks sterven, dit gebaseerd op feedback van experten.
US Lever markt: Management inschatting inclusief de geschatte groei in prevalentie van NASH voor de VS gebaseerd op GlobalData Epidemiology Forecast to 2026.

alfapump® roadmap voor goedkeuring in de VS

Belangrijke verwachte mijlpalen

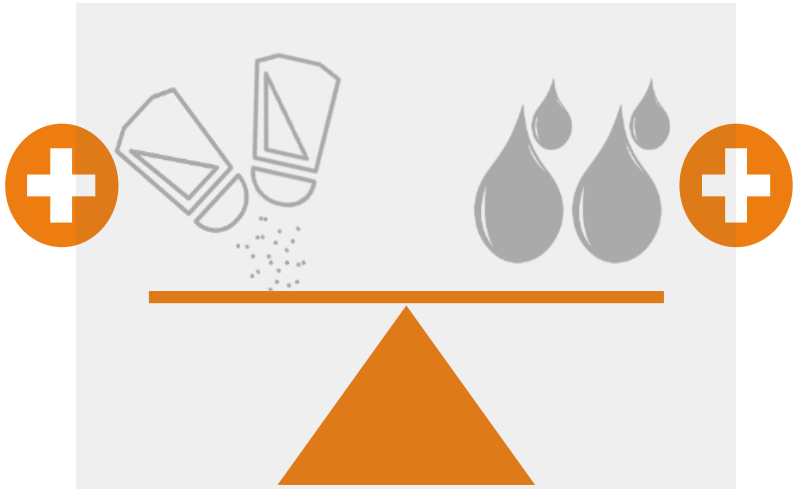


Voorgestelde CMS-regel inzake terugbetaling voor breakthrough devices

*Positieve ontwikkeling voor de **alfa**pump*

FDA: Food and Drug Administration (VS); IDE: Investigational Device Exemption

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



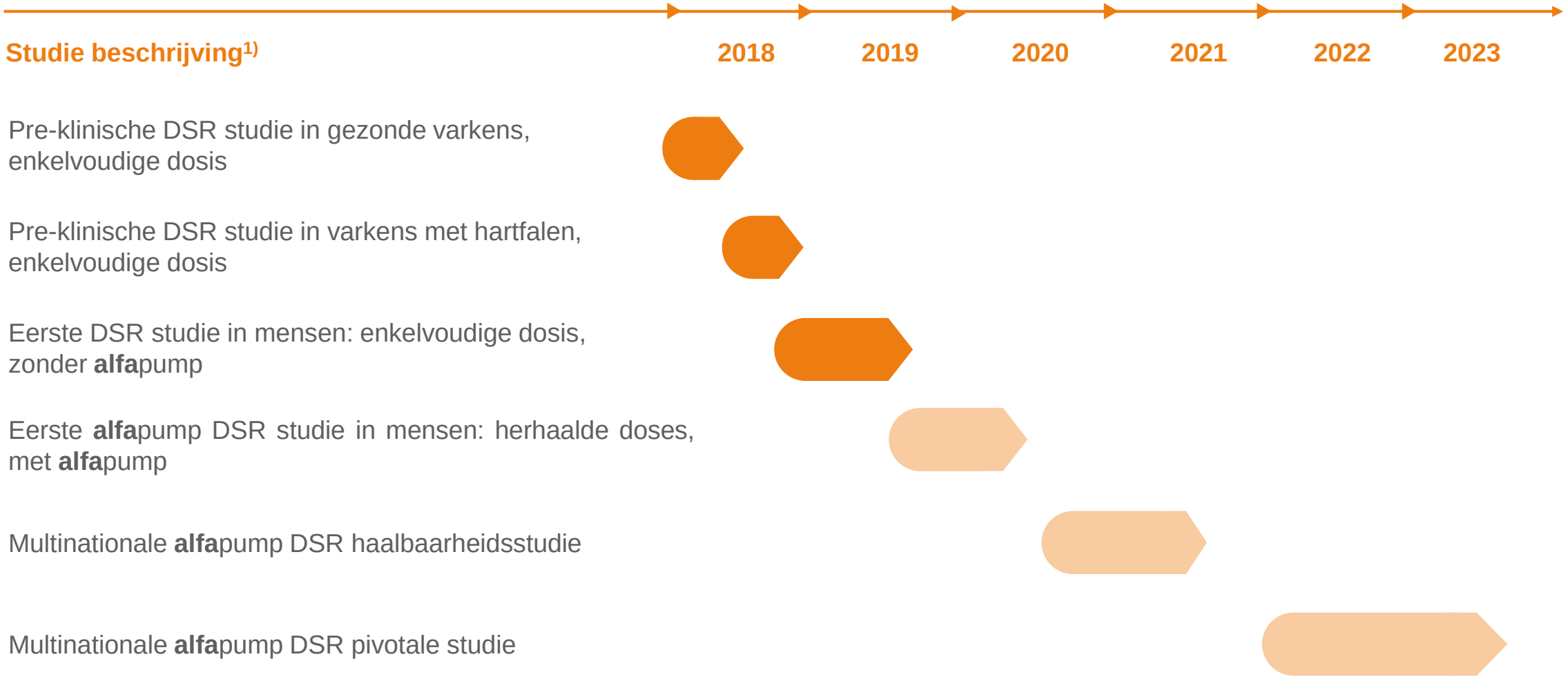
Overtollig natrium stimuleert vochtophoping

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

Bronnen: Testani, Circ Heart Failure, 2014 & 2016; Costanzo et al., J. Am. Coll., 2007; Kilgore et al. (2017)

alfapump® DSR ontwikkeling – overzicht



Note 1: studie design en tijdslijnen kunnen wijzigen

Sterke news flow / potentiële mijlpalen

H1 2019

- **alfa**pump® kreeg van FDA status van Breakthrough Device
- **alfa**pump opgenomen in Duitse behandelingsrichtlijnen (DGVS) voor complicaties van levercirrose
- Positieve resultaten gepubliceerd van eerste DSR studie in mensen voor behandeling van vochtophoping in hartfalen
- Kreeg onvoorwaardelijke goedkeuring van de FDA om de Noord-Amerikaanse pivotale studie (POSEIDON) te starten in patiënten met terugkerende en refractaire ascites door levercirrose

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 **alfa**pump DSR studie in patiënten met vochtophoping door hartfalen
- Initiële resultaten van eerste **alfa**pump DSR studie in patiënten met vochtophoping door hartfalen

H1 2020

- Te verwachten finale Duitse(1) terugbetaling van de **alfa**pump
- **Voltooiing van recrutering van patiënten met terugkerende en refractaire lever ascites in POSEIDON studie**
- **Presentatie van finale resultaten van eerste alfa**pump **DSR studie in patiënten met vochtophoping door hartfalen**

IDE: Investigational Device Exemption; DSR: Direct Sodium Removal of directe natrium verwijdering
Note 1: finale Duitse terugbetaling = DRG + ZE ("Zusatzentgelt"); ZE = DRG specifieke additionele terugbetaling dat permanent wordt verleend voor specifieke gevallen en vervangt NUB; ZE beslissingen worden één keer per jaar genomen, in het begin van ieder jaar

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