

# sequana**medical**



Innovators in the management  
of **fluid overload**

liver disease – malignant ascites – heart failure

Investor presentation – October 2020

# Disclaimers

## Important Notice

IMPORTANT: You must read the following before continuing. The following applies to this document, the oral presentation of the information in this document by Sequana Medical NV (the "Company") or any person on behalf of the Company, and any question-and-answer session that follows the oral presentation:

- This presentation has been prepared by the management of the Company. It does not constitute or form part of, and should not be construed as, an offer, solicitation or invitation to subscribe for, underwrite or otherwise acquire, any securities of the Company or any member of its group nor should it or any part of it form the basis of, or be relied on in connection with, any contract to purchase or subscribe for any securities of the Company or any member of its group, nor shall it or any part of it form the basis of or be relied on in connection with any contract or commitment whatsoever. Prospective investors are required to make their own independent investigations and appraisals of the business and financial condition of the Company and the nature of its securities before taking any investment decision with respect to securities of the Company. This presentation is not a prospectus or offering memorandum.
- The information included in this presentation has been provided to you solely for your information and background and is subject to updating, completion, revision and amendment and such information may change materially. No person is under any obligation or undertaking to update or keep current the information contained in this presentation and any opinions expressed in relation thereto are subject to change without notice. No representation or warranty, express or implied, is made as to the fairness, accuracy, reasonableness or completeness of the information contained herein. Neither the Company nor any other person accepts any liability for any loss howsoever arising, directly or indirectly, from this presentation or its contents.
- The presentation also contains information from third parties. Third party industry publications, studies and surveys may also contain that the data contained therein have been obtained from sources believed to be reliable, but that there is no guarantee of the accuracy or completeness of such data. While the Company reasonably believes that each of these publications, studies and surveys has been prepared by a reputable source, the Company, or any of their respective parent or subsidiary undertakings or affiliates, or any of their respective directors, officers, employees, advisers or agents have independently verified the data contained therein. Thus, while the information from third parties has been accurately reproduced with no omissions that would render it misleading, and the Company believes it to be reliable, the Company cannot guarantee its accuracy or completeness. In addition, certain of the industry and market data contained in this presentation comes from the Company's own internal research and estimates based on the knowledge and experience of the Company's management in the market in which the Company operates. While the Company reasonably believes that such research and estimates are reasonable and reliable, they, and their underlying methodology and assumptions, have not been verified by any independent source for accuracy or completeness and are subject to change without notice. Accordingly, undue reliance should not be placed on any of the industry, market or competitive position data contained in this presentation.
- This presentation includes forward-looking statements that reflect the Company's intentions, beliefs or current expectations concerning, among other things, the Company's results, condition, performance, prospects, growth, strategies and the industry in which the Company operates. These forward-looking statements are subject to risks, uncertainties and assumptions and other factors that could cause the Company's actual results, condition, performance, prospects, growth or opportunities, as well as those of the markets it serves or intends to serve, to differ materially from those expressed in, or suggested by, these forward-looking statements. These statements may include, without limitation, any statements preceded by, followed by or including words such as "target," "believe," "expect," "aim," "intend," "may," "anticipate," "estimate," "plan," "project," "will," "can have," "likely," "should," "would," "could" and other words and terms of similar meaning or the negative thereof. The Company cautions you that forward-looking statements are not guarantees of future performance and that its actual results and condition and the development of the industry in which the Company operates may differ materially from those made in or suggested by the forward-looking statements contained in this presentation. In addition, even if the Company's results, condition, and growth and the development of the industry in which the Company operates are consistent with the forward-looking statements contained in this presentation, those results or developments may not be indicative of results or developments in future periods. The Company and each of its directors, officers and employees expressly disclaim any obligation or undertaking to review, update or release any update of or revisions to any forward-looking statements in this presentation or any change in the Company's expectations or any change in events, conditions or circumstances on which these forward-looking statements are based, except as required by applicable law or regulation.
- This document and any materials distributed in connection with this document are not directed to, or intended for distribution to or use by, any person or entity that is a citizen or resident of, or located in, any locality, state, country or other jurisdiction where such distribution, publication, availability or use would be contrary to law or regulation or which would require any registration or licensing within such jurisdiction. The distribution of this document in certain jurisdictions may be restricted by law and persons into whose possession this document comes should inform themselves about, and observe any such restrictions.
- The Company's securities have not been and will not be registered under the US Securities Act of 1933, as amended (the "Securities Act"), and may not be offered or sold in the United States absent registration under the Securities Act or exemption from the registration requirement thereof.
- 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.

# Disclaimers

## 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 see [www.poseidonstudy.com](http://www.poseidonstudy.com).
- The DSR therapy is still in 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. The DSR therapy is not currently approved for clinical research in the United States or Canada. There is no link between the DSR therapy and ongoing investigations with the **alfapump**® system in Europe.

## 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 its operations as necessary.
- Sequana Medical has put in place mitigation plans to minimise delays. The impact of increased demands on the healthcare systems, restrictions 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.

# Company Overview

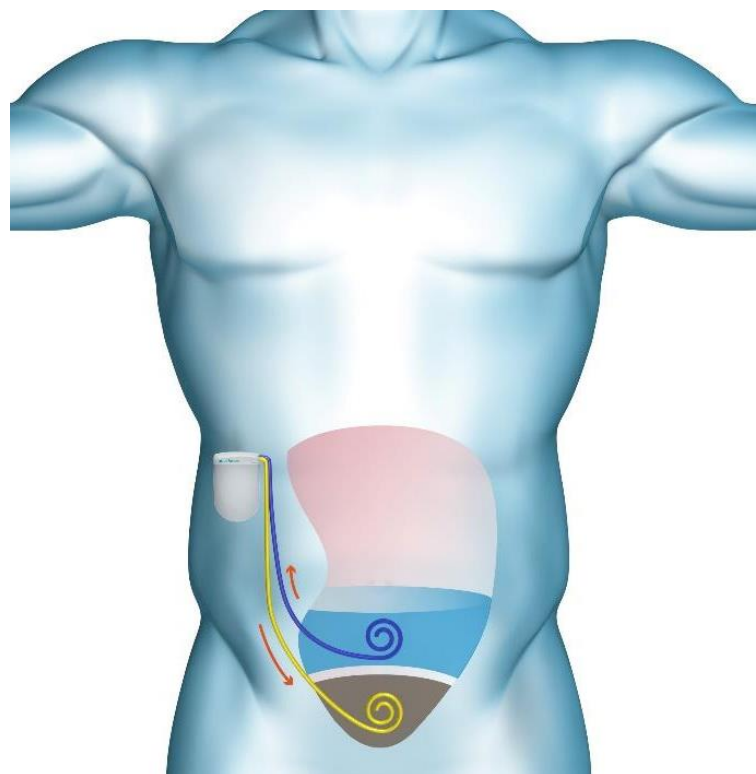
- Founded in 2006
- Gent, Belgium (HQ): corporate, clinical, commercial
- Zurich, Switzerland: manufacturing, engineering, QA/RA
- ~50 employees
- Euronext Brussels: SEQUA



# alfapump<sup>®</sup> platform

Using the bladder to manage fluid overload

- ✓ Fully implanted
- ✓ Automatic operation
- ✓ Wireless battery charging
- ✓ Settings wirelessly adjusted
- ✓ Remote data monitoring



- ✓ Easy implantation
- ✓ Long-term implantation & catheter patency
- ✓ Moves up to 4 litres / day
- ✓ Virtually non-clogging
- ✓ No significant heating during charging and operation

***Strong IP barriers through extensive patent portfolio & know-how***

# One platform – two products



**alfapump®**

## Liver Disease (NASH)

Proven step change in liver refractory ascites  
and malignant ascites

Over 800 devices implanted



**~145 K**

patients / year with refractory ascites due to  
NASH within next 10-20y<sup>(1)</sup>

**> €3 Bn / year**  
market opportunity



**alfapump® DSR**

## Heart Failure

Breakthrough approach to fluid overload in  
heart failure

Clinical proof-of-concept of  
Direct Sodium Removal (DSR)



**~400 K**

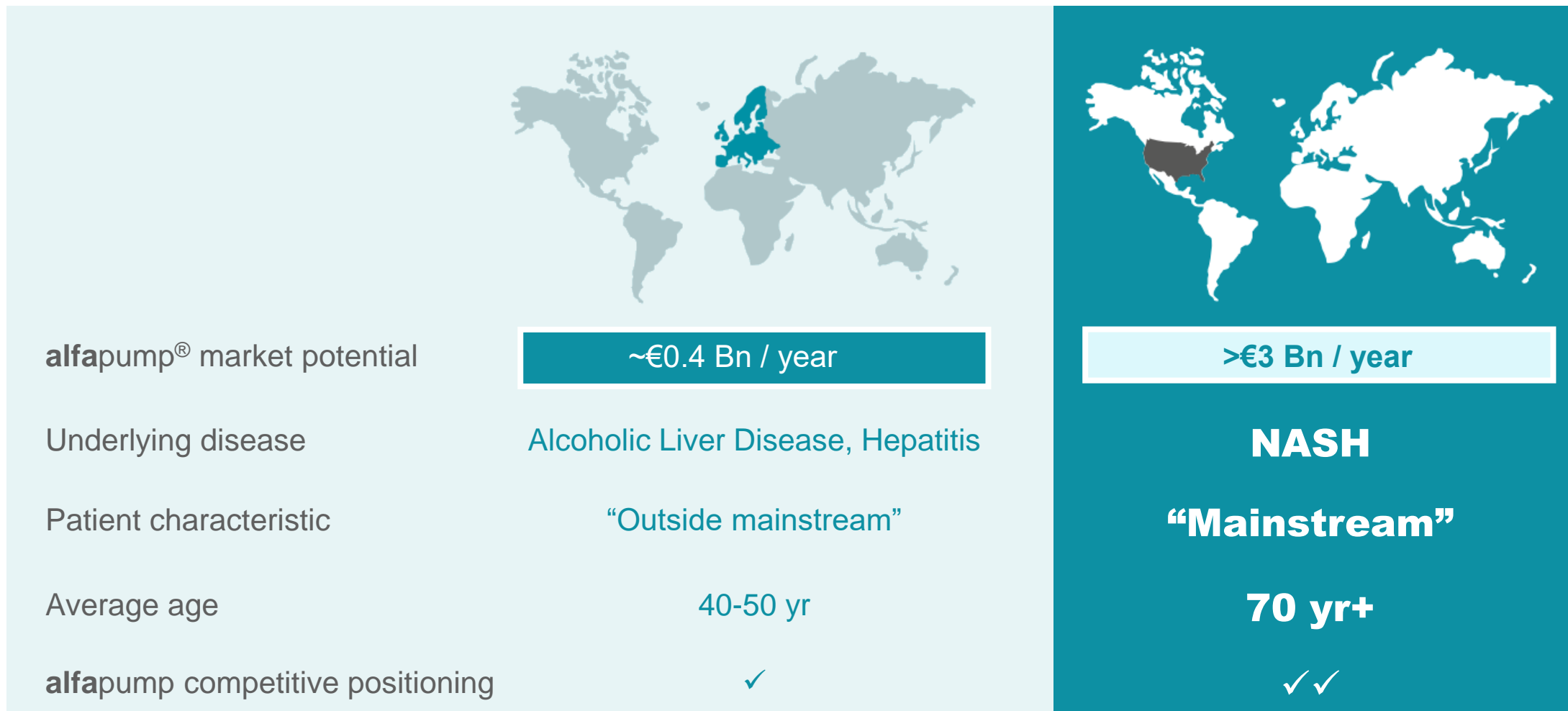
patients / year hospitalised for fluid overload  
due to heart failure by 2026<sup>(2)</sup>

**> €5 Bn / year**  
market opportunity

**Built upon proven European clinical & commercial experience**

# NASH drives US market attractiveness

Stronger competitive position in a much larger and dynamic market



Notes: current estimated EU Liver market: Data from 1980-2010, death rates between 9-12.4 per 100,000; Mokdad et al., 2014, Management estimates of 7.5% cirrhosis patients that die per year based on experts feedback. forecast US Liver market: Management estimate that is inclusive of estimated growth in prevalence of NASH for the US based on GlobalData Epidemiology Forecast to 2026.



# alfapump®

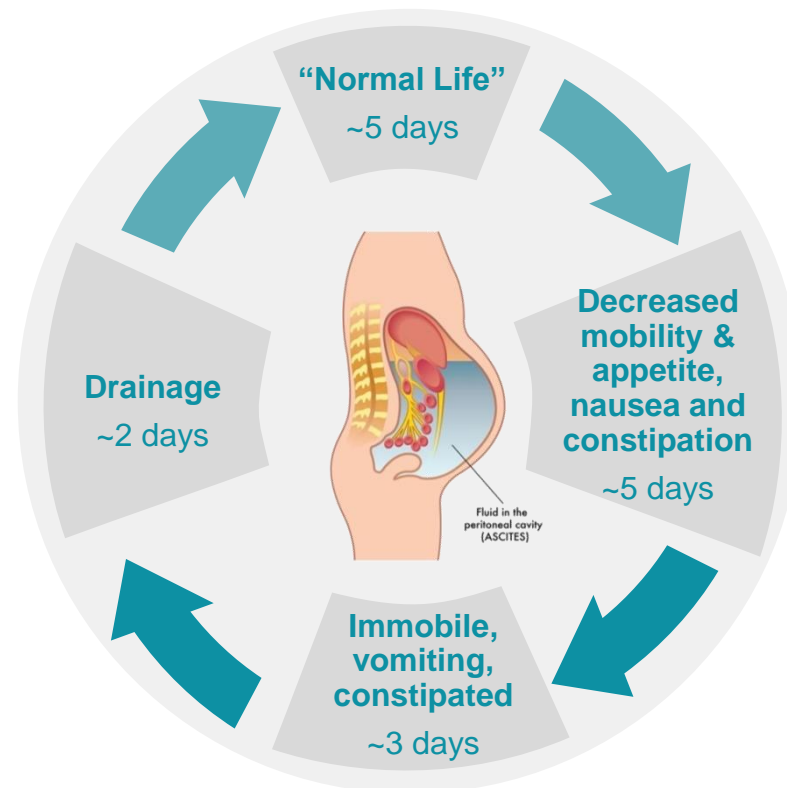
Proven step change in the management of liver refractory ascites and malignant ascites



# Liver cirrhosis and refractory ascites

A key complication of liver cirrhosis, with a dramatic impact on quality of life

- Viral infections**  
(Hepatitis B & C)
- Alcoholic Liver Disease**
- Non-Alcoholic Steatohepatitis (NASH)**



Typical patient life<sup>(4)</sup>

## US forecast

- Liver cirrhosis**  
~3-4M<sup>(1)</sup>
- Ascites**  
~1.5M<sup>(2)</sup>
- Refractory Ascites**  
~150K<sup>(3)</sup>

Note : Prevalence of NASH in US is expected to increase by 63% between 2015-2030; Estes et al., 2018

Source 1 Management estimate in US based on Estes et al; GlobalData Nash Epidemiology Forecast to 2026; Noureddin et al., 2013

Source 2: Runyon 2009: approximately 50% of cirrhotic patients develop ascites within 10 years of diagnosis of cirrhosis

Source 3: Ginès et al., NEJM 2004: refractory ascites occurs in 5-10% patients with ascites

Source 4: Presentation of Dr. Rajiv Jalan at EASL in 2018, Large Volume Paracentesis (LVP) treatment cycle for refractory ascites

# Cancer and malignant ascites

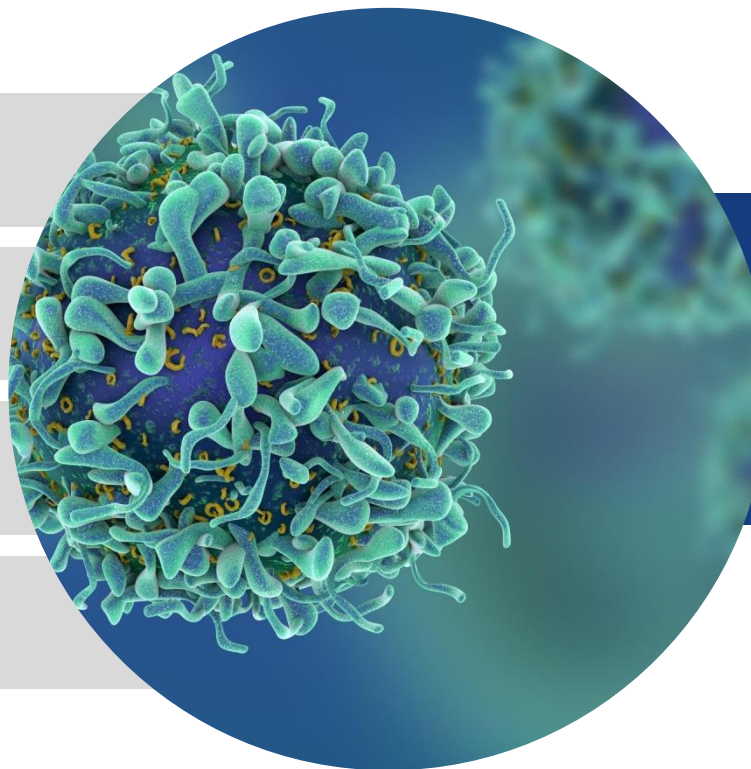
Severe complication of late-stage cancers

Fluid accumulation in the abdomen due to **drainage of lymph system**

**Breast and ovarian cancer** have longest survival with ascites<sup>(1)</sup>

Severe impact on **quality of life**

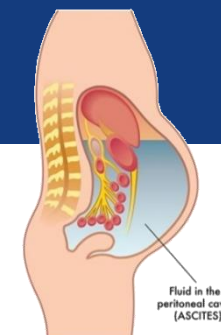
Reduces ability to undergo **anti-cancer treatment**



Malignant ascites due to breast and ovarian cancer<sup>(2)</sup>:

EU5: ~18K

US: ~16K



*Clear unmet need for improving Quality of Life and the ability to increase cancer treatment intensity*

Source 1: Ayantunde & S. L. Parsons. Annals of Oncology 2007

Source 2: Management estimate based on WHO cancer incidence rates (2018) and Ayantunde & S. L. Parsons. Annals of Oncology 2007.

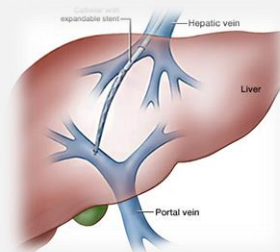
# Severe limitations of existing therapies

## Diet / Diuretics



Resistance,  
Complications

## Transjugular Intrahepatic Portosystemic Shunt (TIPS)



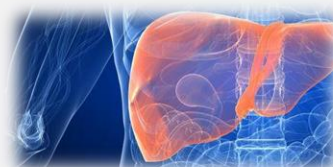
Complications,  
Contraindications

## Drainage (“Large Volume Paracentesis / LVP”)



Painful, Poor Quality of  
Life, Short Term Benefit

## Liver transplantation



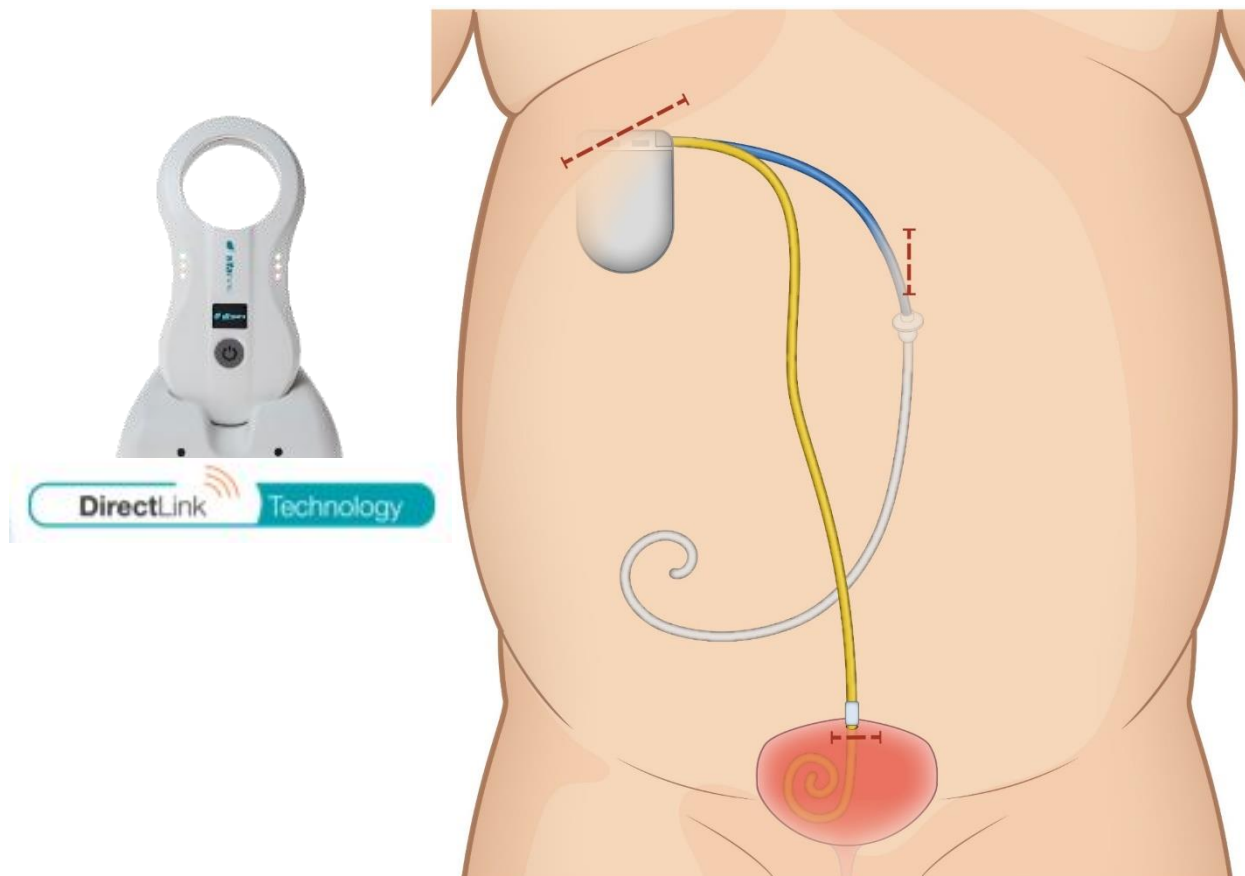
High Cost,  
Limited Availability

**alfapump®**






# alfapump® for long-term treatment

Over 800 implants and hundreds of years of patient experience



# Strong health economics rationale

## Significant reduction in regular drainage leads to:

-  Reduced burden of disease
-  Improved patient QoL
-  Cost savings for hospitals and payers

Estimated treatment cost / patient\*:

**LVP: ~\$54K** ↔ **alfapump®: ~\$35K**

~\$1,8K / LVP<sup>(1)</sup>

2 LVP / month

15 months

~\$25K / alfapump

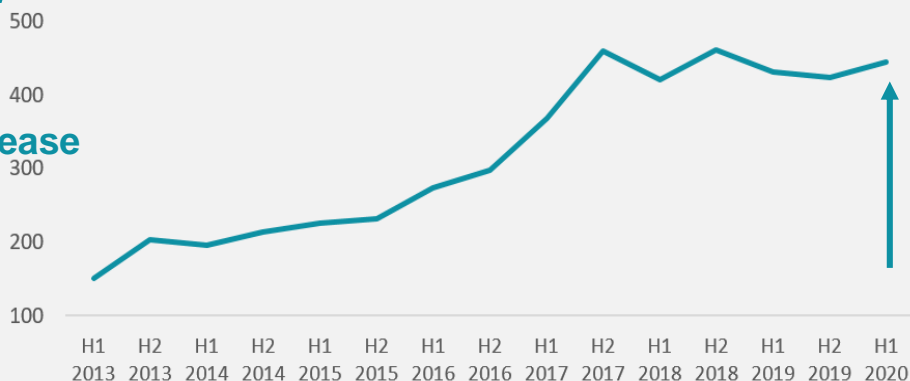
~\$10K / implantation

# Strong clinical validation



**Clear increase in clinical outcomes**

Avg days of alfapump therapy / patient

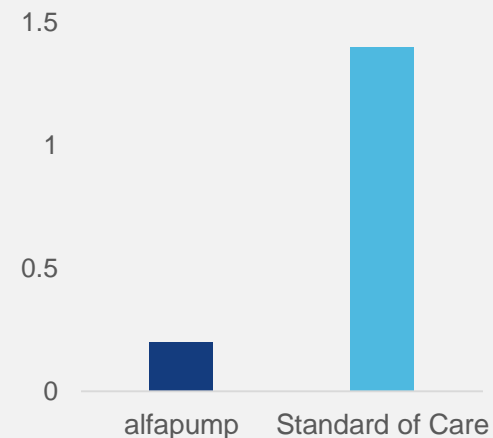


Sequana Medical data

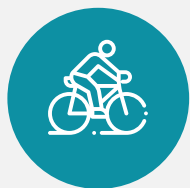


**Drastically reduced need for drainage**

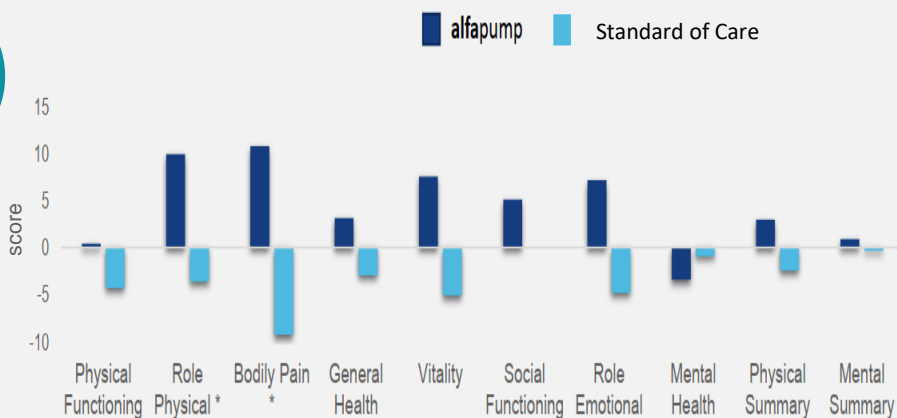
Mean # drainages / patient / 28 days



Results RCT study



**Improved quality of life**



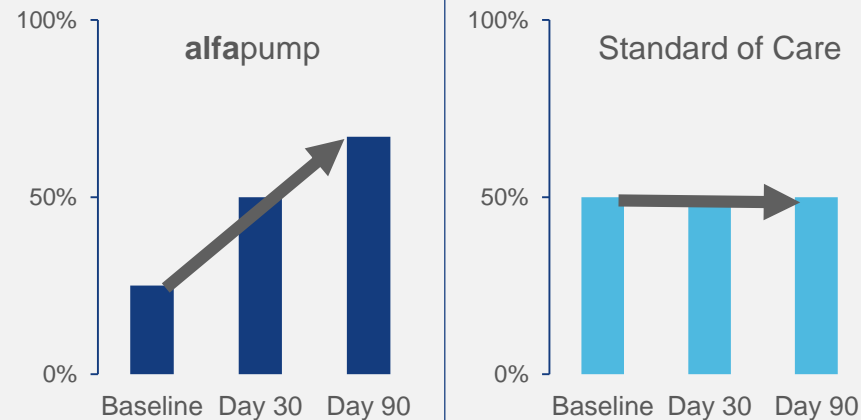
Results RCT study

\* p<0.05



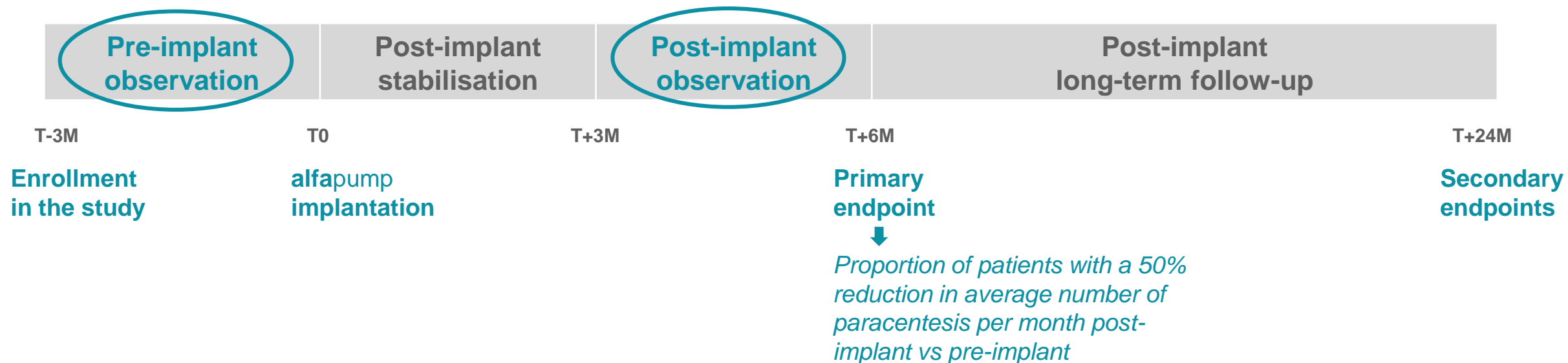
**Improved nutrition**

% patients adequately nourished



Results RCT study

# North American Pivotal Study (POSEIDON) underway

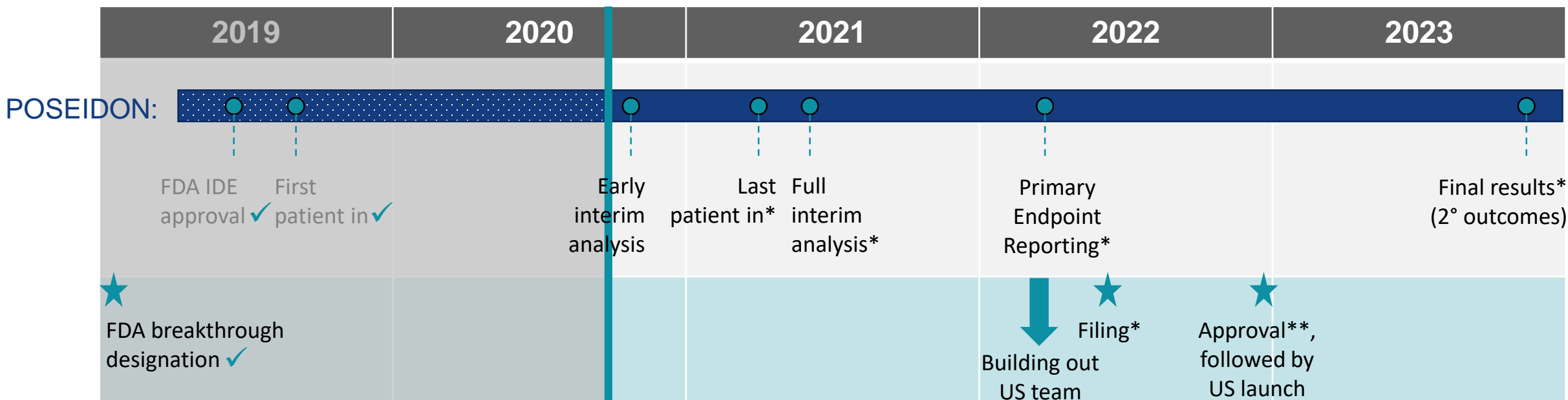


- Roll-in cohort: up to 30 patients ⇒ early interim data expected in Q4 2020 / full interim data expected in H1 2021
- Study cohort: up to 50 patients ⇒ primary endpoint read-out expected in Q1 '22

*Note: Presented timelines are subject to further developments related to the COVID-19 pandemic*

# alfapump® US approval roadmap

Key anticipated milestones\*



*Final CMS rule on reimbursement for breakthrough devices (NTAP)*

*expected to further support reimbursement for the alfapump*

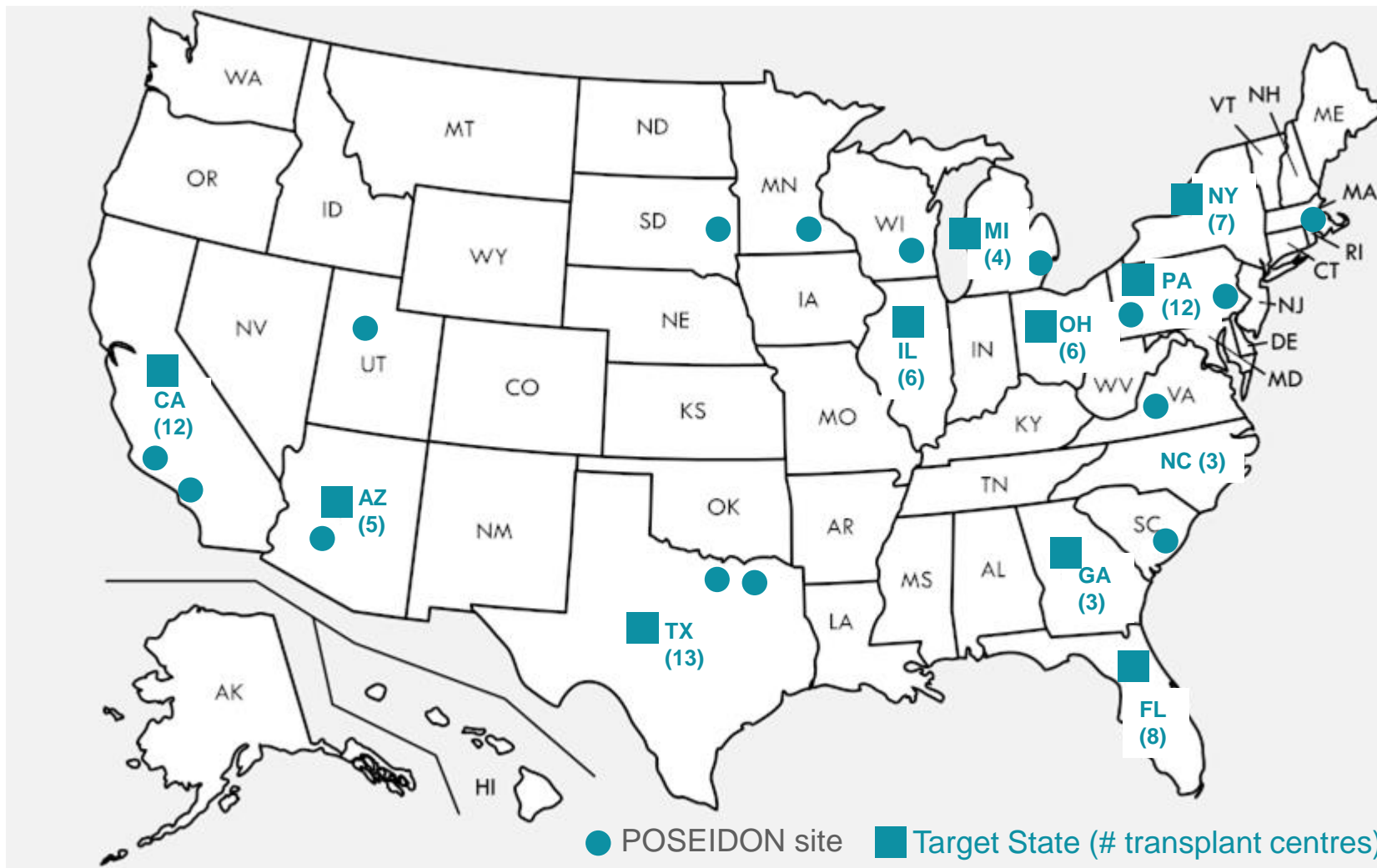
\* Subject to further developments related to the ongoing COVID-19 pandemic

\*\* Subject to FDA review timelines

FDA: Food and Drug Administration (US); IDE: Investigational Device Exemption; NTAP: New Technology Add-on Payment



# Self-commercialisation in US through specialty salesforce



Initial focus on key  
transplant centres

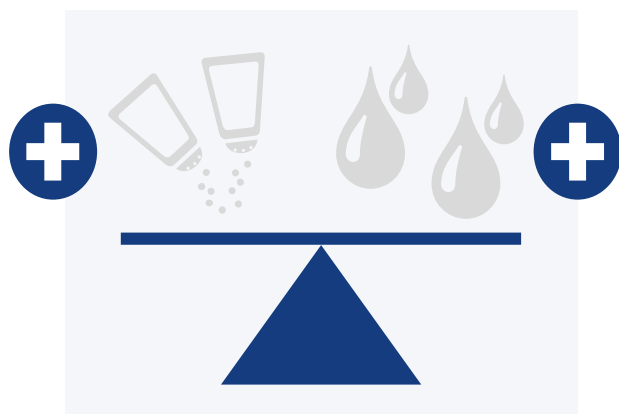
~50-person team:  
35 sales reps, 10 clinical,  
5 corporate



# alfapump<sup>®</sup> DSR

Breakthrough approach to **fluid overload in heart failure** built on proven **alfapump** platform

# Fluid overload in heart failure – major clinical problem and key driver of costs



Excess sodium drives fluid overload

US hospitalisations annually due to HF<sup>(3)</sup>

~1m

90%

HF – hospitalisations due to fluid overload<sup>(3)</sup>



c.5d

Typical hospital stay<sup>(4)</sup>

Annual costs of US HF-related hospitalisations<sup>(4)</sup>

\$13bn

- *40% of heart failure patients on IV loop diuretics have a poor response<sup>(1)</sup>*
- *24% re-admission rate at 30 days<sup>(2)</sup>*

# Direct Sodium Removal (DSR)

Sequana Medical's breakthrough approach to volume overload in heart failure



**“DSR represents a new potential therapy for non-renal sodium and fluid removal in edematous disorders such as heart failure”**

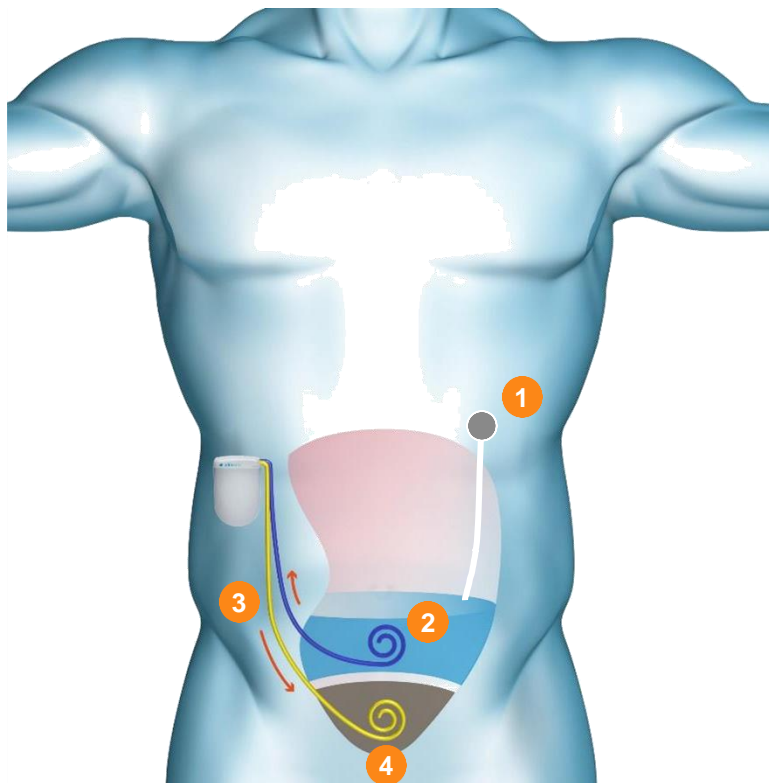
**Circulation** First in Human Experience with Peritoneal Direct Sodium Removal Using a Zero Sodium Solution: A New Candidate Therapy for Volume Overload

Veena S. Rao, Jeffrey M. Turner, Matthew Griffin, Devin Mahoney, Jennifer Asher, Sangchoon Jeon, Peter S. Yoo, Nabil Boutagy, Attila Feher, Albert Sinusas, F. Perry Wilson, ... [Show all Authors](#) ▾

Originally published 8 Jan 2020 | <https://doi.org/10.1161/CIRCULATIONAHA.119.043062> | Circulation .0.null

# alfapump<sup>®</sup> DSR

Potential chronic therapy for heart failure patients with fluid overload that are not well controlled on diuretics

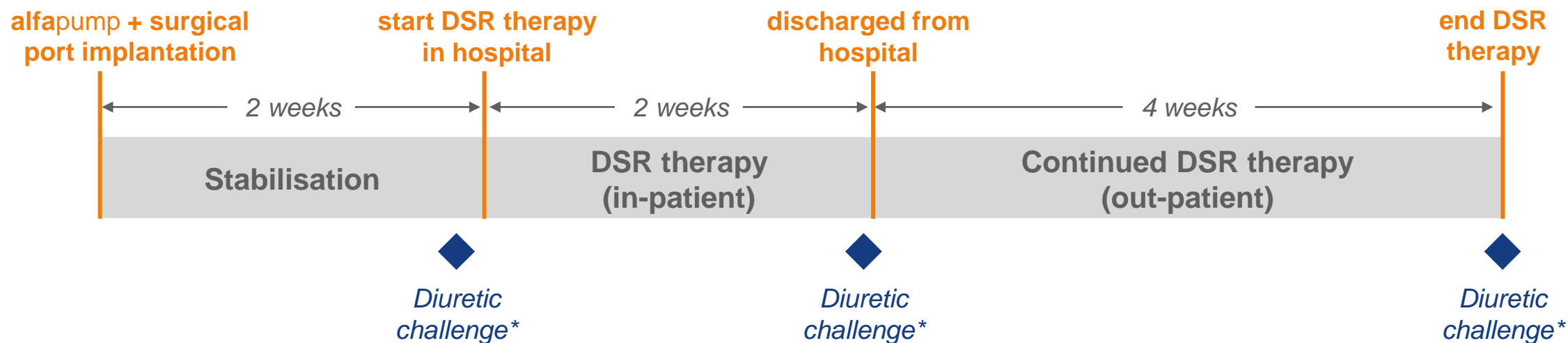


- 1 Administration of sodium-free DSR infusate to peritoneal cavity via implanted port
- 2 Sodium diffuses into DSR infusate
- 3 **alfapump** pumps sodium-rich DSR infusate into the bladder
- 4 Body eliminates excess fluid through osmotic ultrafiltration and urination

*Fundamental patents to reduce fluid overload in heart failure allowed in US and Europe*

# RED DESERT: Study design

Repeated dose proof-of-concept study of alfapump<sup>®</sup> DSR in up to 10 diuretic-resistant heart failure patients

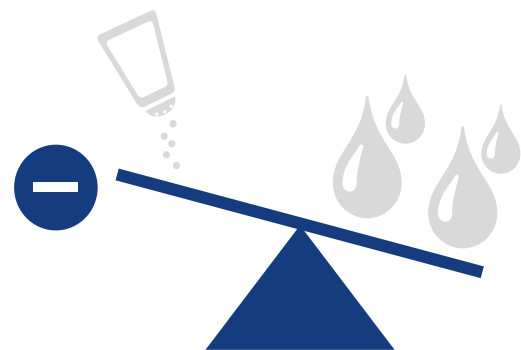


- **Safety:** absence/rate of device, procedure and/or therapy related serious adverse events
- **Feasibility:** ability of the alfapump DSR to maintain a neutral sodium balance and maintain euvolemia
- **Exploratory:** impact of DSR to restore response to diuretics (diuretic challenge)

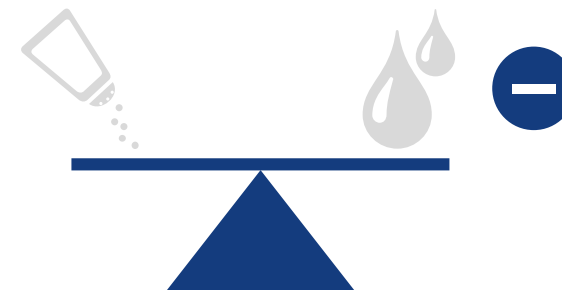
Interim results (5 patients) reported in Q4 2020 / Top-line results (up to 10 patients) expected in H1 2021

\* intravenous dose of 40mg dose furosemide

# Interim RED DESERT data support DSR hypothesis



**DSR therapy directly  
removes the sodium**



**Body eliminates  
excess fluid**

- DSR removes the sodium and then the body responds to quickly and accurately eliminate the free water to maintain the sodium concentration in the blood
- No clinically significant changes in serum sodium levels / no progressive hyponatremia

# Interim RED DESERT: Strong safety & efficacy results from first 5 patients

## SAFETY

- Implant procedure of **alfapump**<sup>®</sup> DSR and repeated dosing of DSR therapy were **well-tolerated**
- No clinically significant changes in serum sodium levels / no progressive hyponatremia
- Reported **adverse events were manageable**

## EFFICACY

- **No diuretics required** in any of the patients during 6-week **alfapump** DSR treatment
- Reduced doses of DSR therapy and / or less frequent DSR dosing in majority of patients
  - ⇒ maintaining stable to lower weight and NT-proBNP compared to baseline



# Interim RED DESERT: Restoring kidney response


Loop diuretic responsiveness restored to near normal levels in all 5 patients

- Diuretic response assessed by 6-hour excretion of fluid and sodium following intravenous administration of 40mg furosemide
  - ⇒ Baseline: objectively poor diuretic response
  - ⇒ End of 6-week study period: more than doubling of sodium excretion (near normal levels)
- Long-lasting diuretic responsiveness after completion of **alfapump**<sup>®</sup> DSR therapy
  - ⇒ dramatic reduction in loop diuretics requirements in majority of patients

*Based on these interim data, it appears that DSR therapy is not just an alternative means to remove sodium and water, it restores kidney response to near normal levels – opening up whole new ways it can be used*

# Developing our proprietary DSR infusate

- D10% was chosen as the initial DSR infusate for fastest proof-of-concept
- We are developing our **proprietary next-generation DSR infusate**:



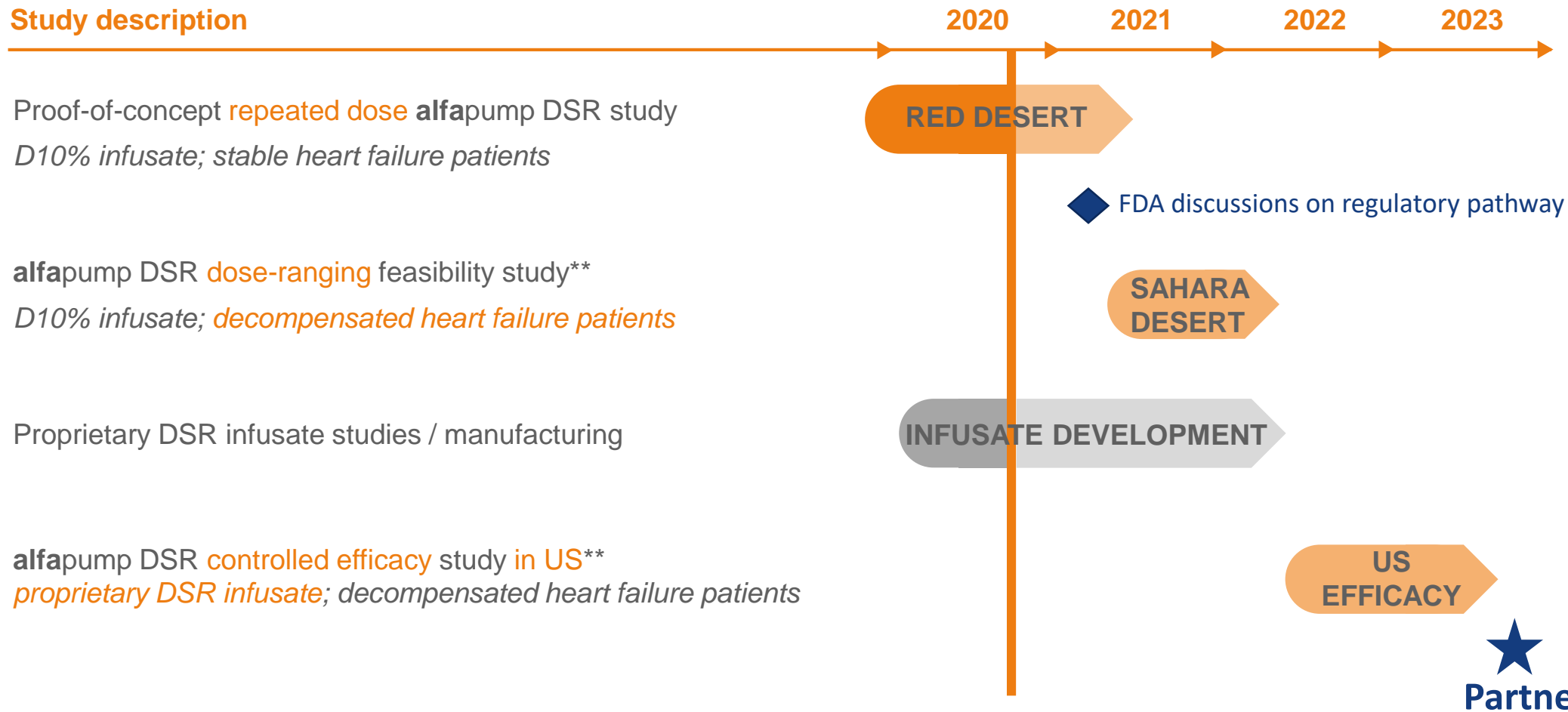
- ✓ Improved therapeutic profile compared to D10%
- ✓ IP protected
- ✓ Recurring revenue from high gross margin consumable

⇒ studies ongoing at Yale University

⇒ pharmaceutical manufacturing development initiated

# alfapump<sup>®</sup> DSR development strategy\*

## Study description



\* Timelines subject to further developments related to the ongoing COVID-19 pandemic

\*\* Subject to change and/or feedback from applicable regulatory authorities



# Conclusion

Experienced **leadership team**

**Value creation** in the short term



# Strong organisation

Highly experienced leadership team supported by committed and well-reputed shareholders

---

## Executive team:



**Ian Crosbie**  
Chief Executive Officer



**Kirsten Van Bockstaele**  
Chief Financial Officer



**Oliver Gødje**  
Chief Medical Officer



**Martijn Blom**  
Chief Commercial Officer



**Gijs Klarenbeek**  
Senior Medical Advisor



**Dirk Fengels**  
VP Engineering & Manufacturing



**Timur Resch**  
Global VP QM/QA/RA

---

## Board of Directors:



**Pierre Chauvineau**  
Board Chairman



**Ian Crosbie**  
Chief Executive Officer



**Wim Ottevaere**  
Director



**Jason Hannon**  
Director

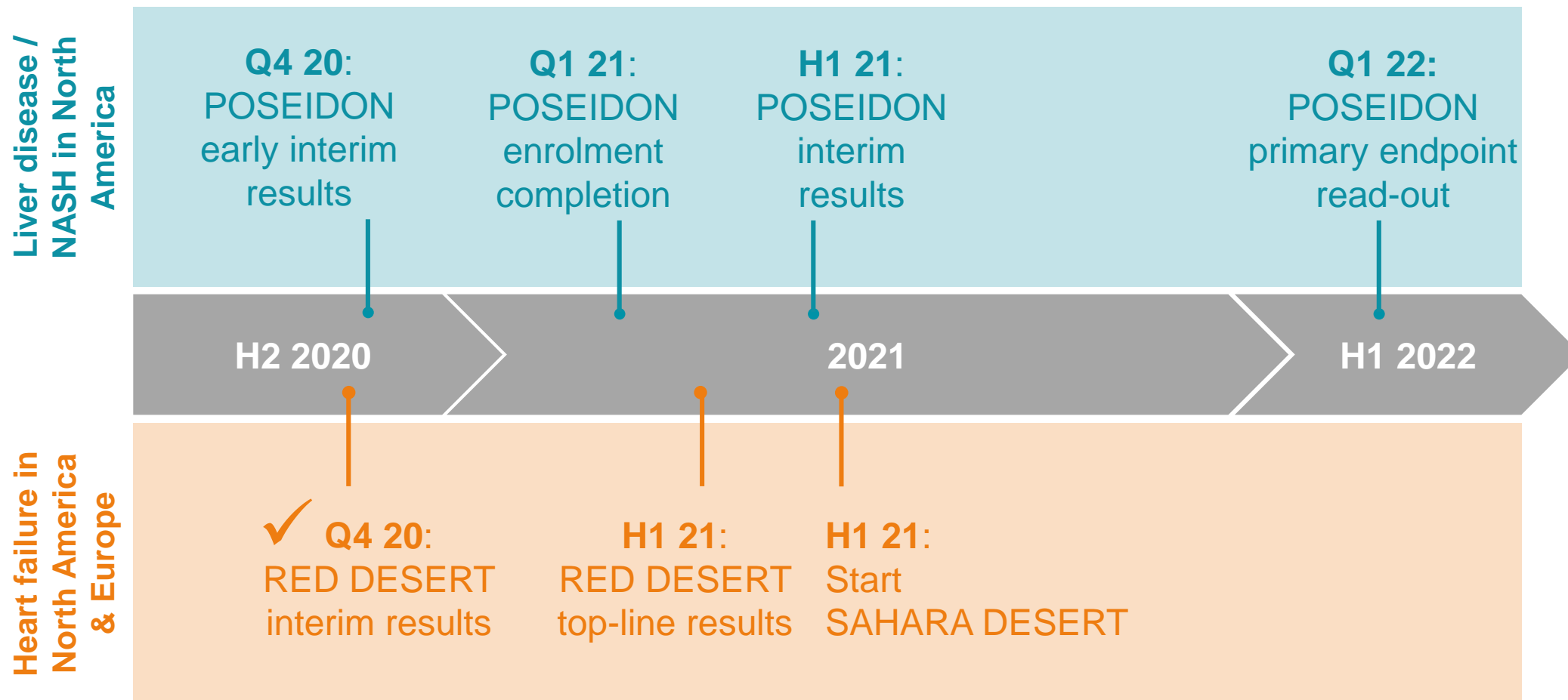


**Rudy Dekeyser**  
Director



**Erik Amble**  
Director

# Expected Core Value Drivers & Outlook



Note: Presented timelines are subject to further developments related to the COVID-19 pandemic

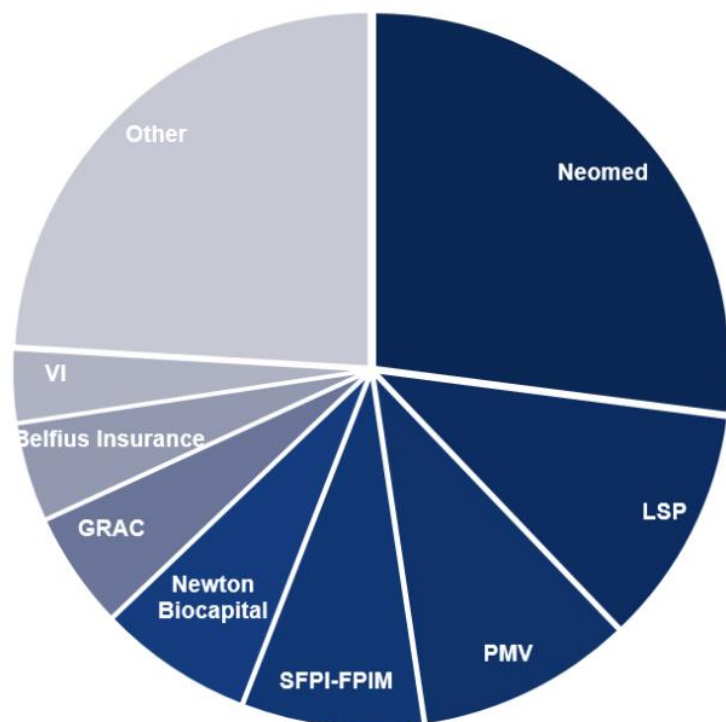
# Back-up



# Shareholders base and financial overview

Ticker: SEQUA – Euronext Brussels

- Outstanding shares: 15.8M
- Outstanding share options & warrants: 1.9M authorised of which 0.9M granted



- Analysts:
  - KBC Securities – Sandra Cauwenberghs & Lenny Van Steenhuyse
  - Kempen – Ingrid Gafanhão
  - Kepler Cheuvreux – Matthias Maenhaut
  - Mirabaud – Daniel Jelovcan
- Cash (30 June 2020): €14.9M
- Debt financing in July 2020: €7.3M
- Cash runway into H2 2021





# Leading experts as Heart Failure Scientific Advisors



**Dr. Maria Rosa Costanzo**

Medical Director of the Edward Center for Advanced Heart Failure  
Medical Director Heart Failure Research for the Advocate Heart Institute



**Dr. Wilson Tang**

Professor of Medicine at Cleveland Clinic Lerner College of Medicine at Case Western Reserve University



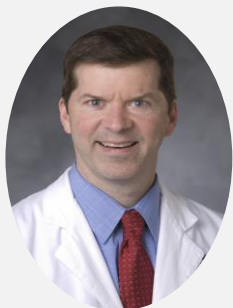
**Dr. Javed Butler**

Professor and Chairman of the Department of Medicine at the University of Mississippi Medical Center



**Dr. Jeffrey Testani**

Associate Professor of Medicine and Director of Heart Failure Research at Yale University School of Medicine



**Dr. Michael Felker**

Professor of Medicine in the Division of Cardiology at Duke University School of Medicine  
Director of Cardiovascular Research at the Duke Clinical Research Institute and Vice-Chief for Clinical Research in the Division of Cardiology



**Dr. Udelson**

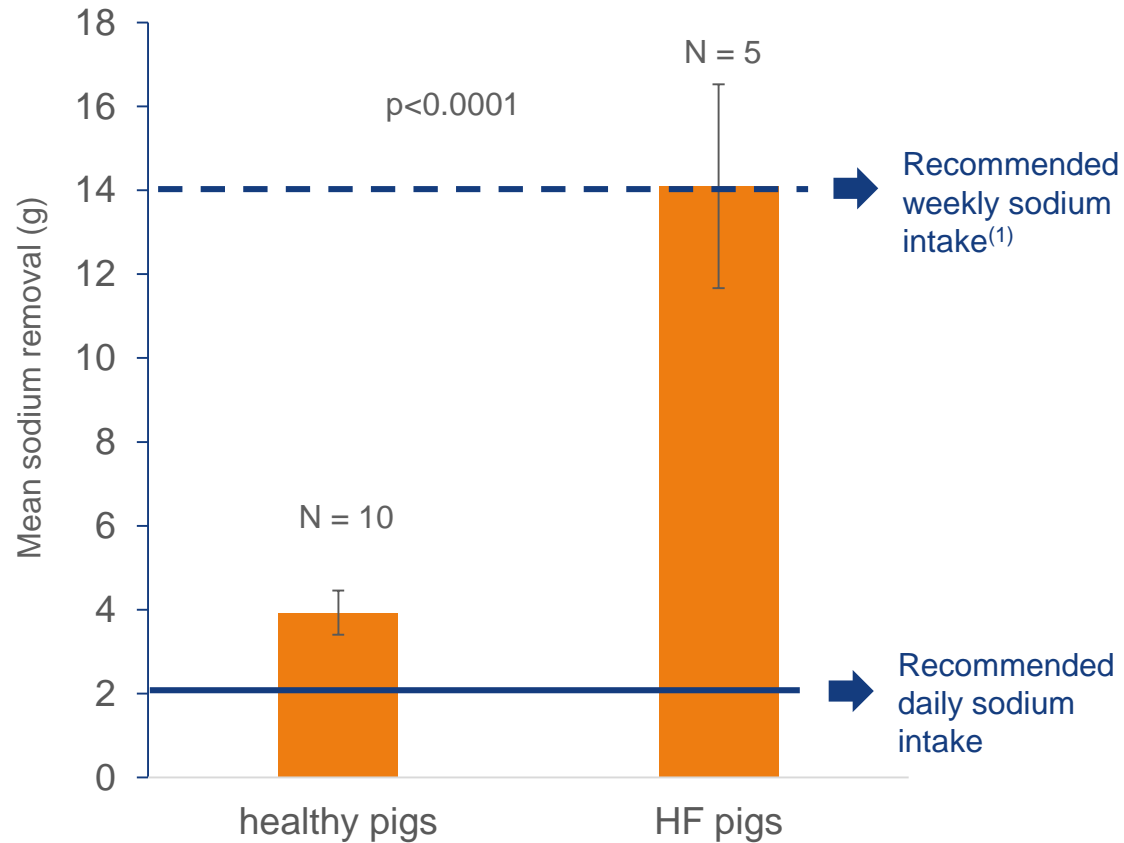
Chief of the Division of Cardiology at Tufts Medical Center  
Professor of Medicine and Radiology at Tufts University School of Medicine



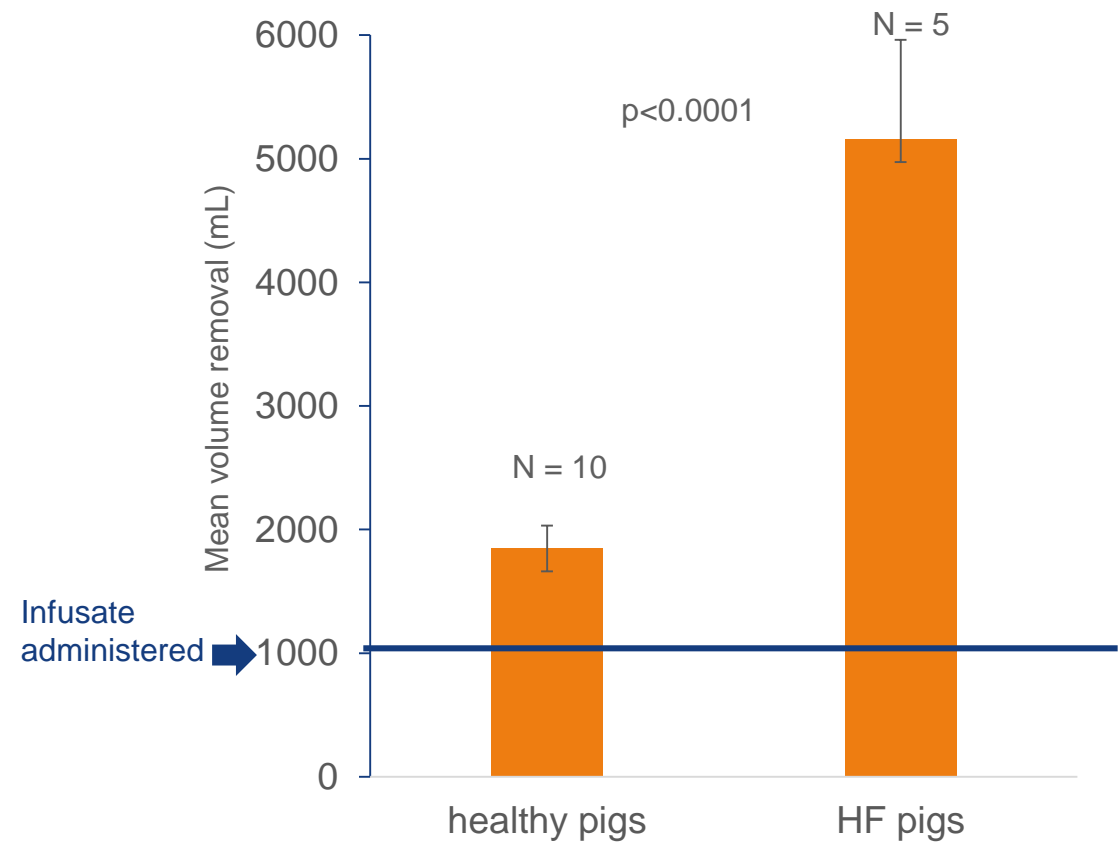
# DSR pre-clinical Proof-of-Concept

Clinically relevant sodium and fluid removal

## Clinically relevant removal of sodium



## Effective fluid removal

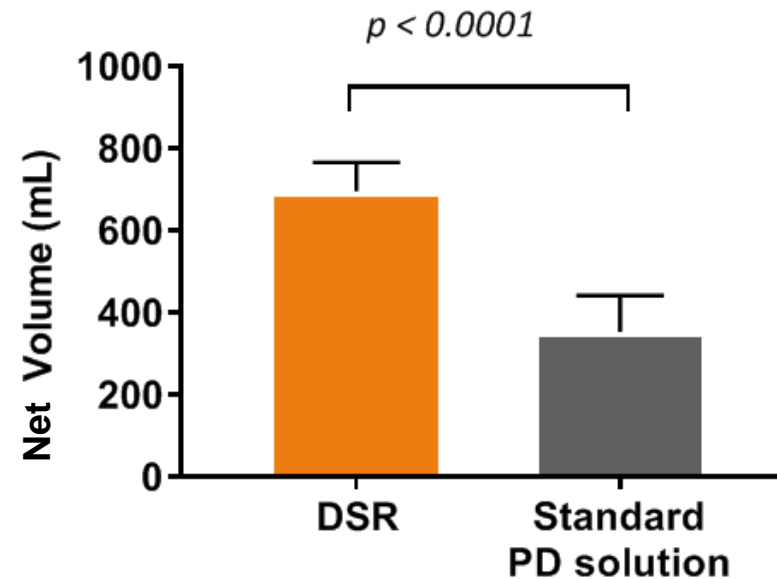
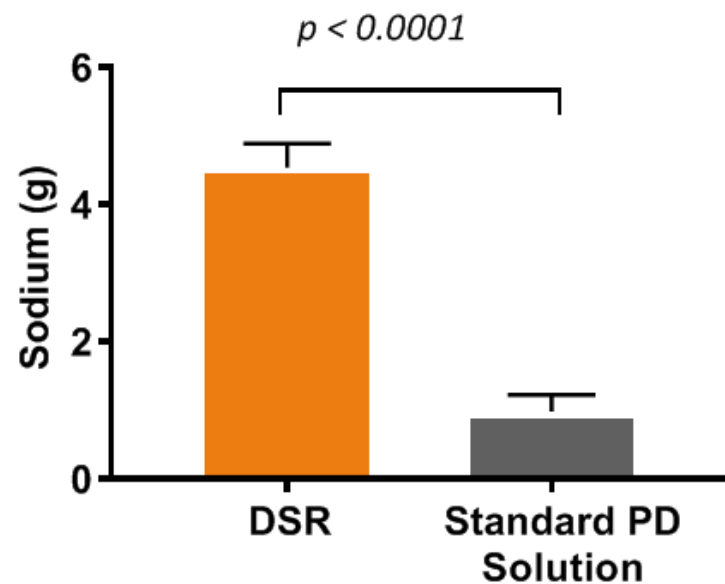


Source 1: Weekly recommended intake for humans equals 14 grams ([www.cdc.gov](http://www.cdc.gov))



# DSR first-in-human study met primary and secondary endpoints

- ✓ DSR therapy was safe & well-tolerated with no adverse events or significant discomfort
- ✓ Substantially higher sodium removal with DSR vs standard Peritoneal Dialysis (PD) solution
- ✓ Minimal inter-patient variability



*Results presented at  
key Cardiac  
Conferences and  
published in  
Circulation*



# Clinical development strategy

Exciting impact on diuretic response requires additional investigation to support value of DSR therapy

## RED DESERT

- Enrol up to five additional patients, with top-line data expected in H1 2021

## SAHARA DESERT – dose-ranging study in decompensated heart failure patients

- Move into decompensated heart failure patients with residual congestion
- Dose ranging to learn more about improvement in diuretic response and durability of effect
- Key learnings to be taken into US controlled efficacy study
- D10% as DSR infusate

## US efficacy study with proprietary DSR infusate

- Controlled efficacy study versus standard of care
- Treatment algorithm built upon learnings from SAHARA DESERT
- Paves the way and de-risks FDA pivotal study
- Creates a more valuable clinical and economic package for partnering



# contact info



[IR@sequanamedical.com](mailto:IR@sequanamedical.com)



+32 498 053579

[www.sequanamedical.com](http://www.sequanamedical.com)