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Innovators in the treatment of diuretic-resistant fluid overload

liver disease – malignant ascites – heart failure

Investor presentation – May 2021

Disclaimers

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Disclaimers

Regulatory disclaimer:

- The **alfa**pump® system has not yet received regulatory approval in the United States and Canada. Any statement in this presentation about safety and efficacy of the **alfa**pump® system does not apply to the United States and Canada. In the United States and Canada, the **alfa**pump® 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 **alfa**pump® 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:

- **alfa**pump® is a registered trademark. DSR® and **alfa**pump DSR® are registered trademarks in Benelux.

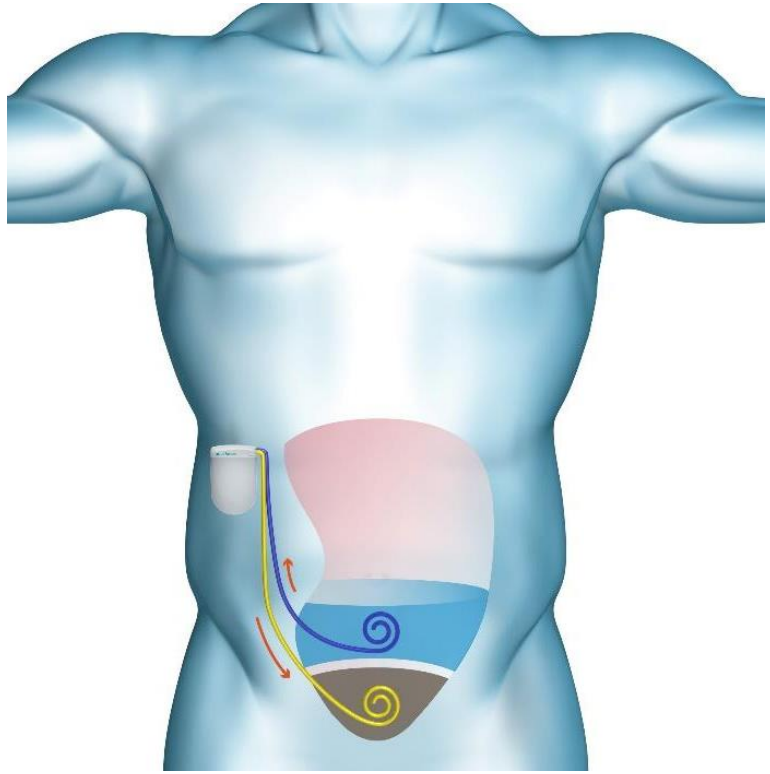
Sequana Medical NV

- Founded in 2006
- Gent, Belgium (HQ): corporate, clinical, commercial
- Zurich, Switzerland: manufacturing, engineering, QA/RA
- ~60 employees
- Euronext Brussels: SEQUA

alfapump® platform

Using the bladder to treat 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

Direct Sodium Removal (DSR®) platform

We remove the sodium and then the body "does the math" to maintain serum sodium balance

Key Principle

DSR therapy directly removes the sodium

Body eliminates excess fluid

DSR therapy

1. Administer sodium-free DSR infusate to peritoneal cavity and allow to dwell
2. Sodium diffuses from the body down a steep diffusion gradient into DSR infusate
3. Remove DSR infusate + extracted sodium from the body
4. Body restores balance & eliminates associated fluid via osmotic ultrafiltration and/or urination

Two pillars of growth – € billion opportunities

alfapump®

Liver Disease (NASH)

Proven step change in liver refractory ascites and malignant ascites

Over 850 devices implanted

> €3 Bn / year market opportunity(1)

POSEIDON pivotal study ongoing

Self-commercialisation

alfapump DSR®

Heart Failure

Breakthrough approach to fluid overload in heart failure

Clinical proof-of-concept achieved

> €5 Bn / year market opportunity(2)

SAHARA DESERT study to start Q2 2021

Partnering after US efficacy study

Built upon proven European clinical & commercial experience

Source 1: Management estimate in US within 10-20 years, that is inclusive of estimated growth in prevalence of NASH for the US based on GlobalData Epidemiology Forecast to 2026
Source 2: Management estimate in US & EU by 2026 based on GlobalData Heart Failure Epidemiology Forecast to 2026; Costanzo et al. (2007). Kiglore et al (2017)

NASH drives US market attractiveness

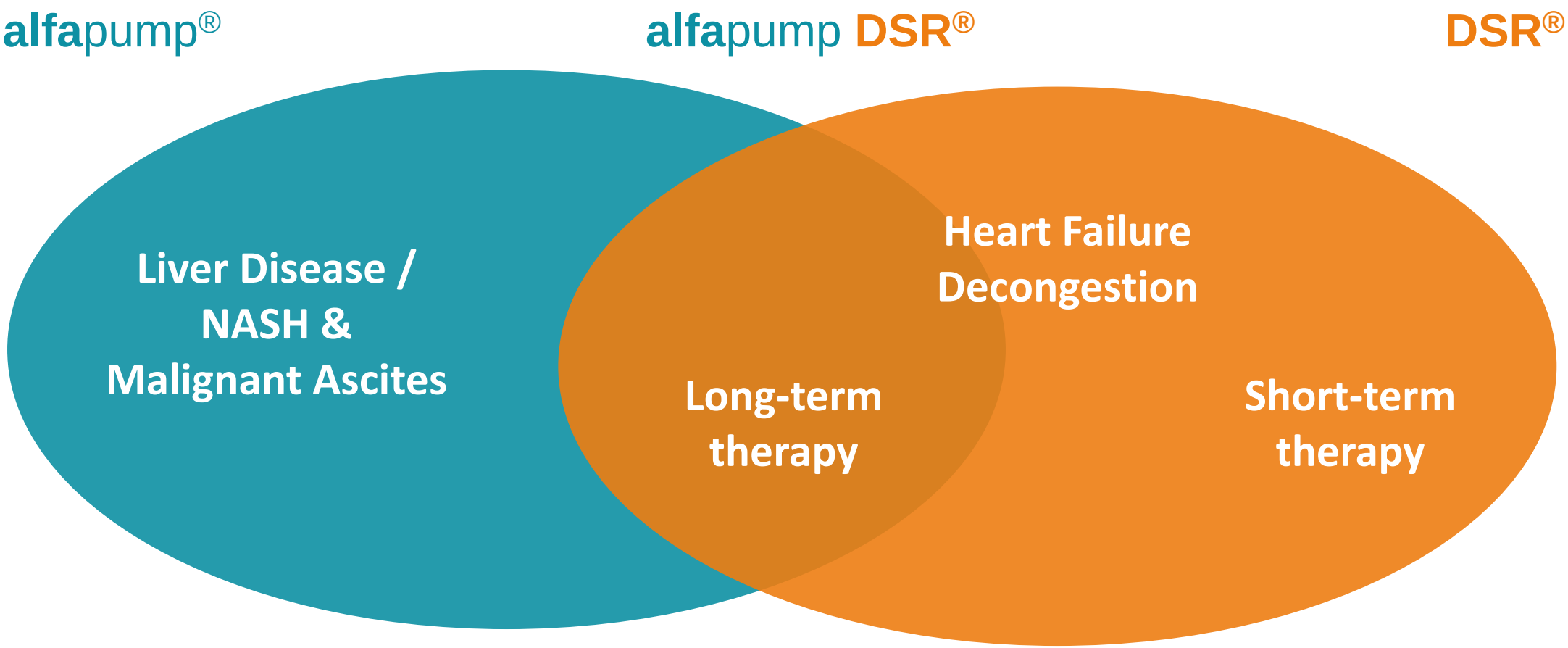
Stronger competitive position in a much larger and dynamic market

alfapump® market potential	~€0.4 Bn / year	>€3 Bn / year
Underlying disease	Alcoholic Liver Disease, Hepatitis	**NASH**
Patient characteristic	“Outside mainstream”	**“Mainstream”**
Average age	40-50 yr	**70 yr+**
alfapump competitive positioning	✓	✓✓

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.

Building Sequana Medical on two platforms

Complementary approaches to diuretic-resistant fluid overload



alfapump®

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

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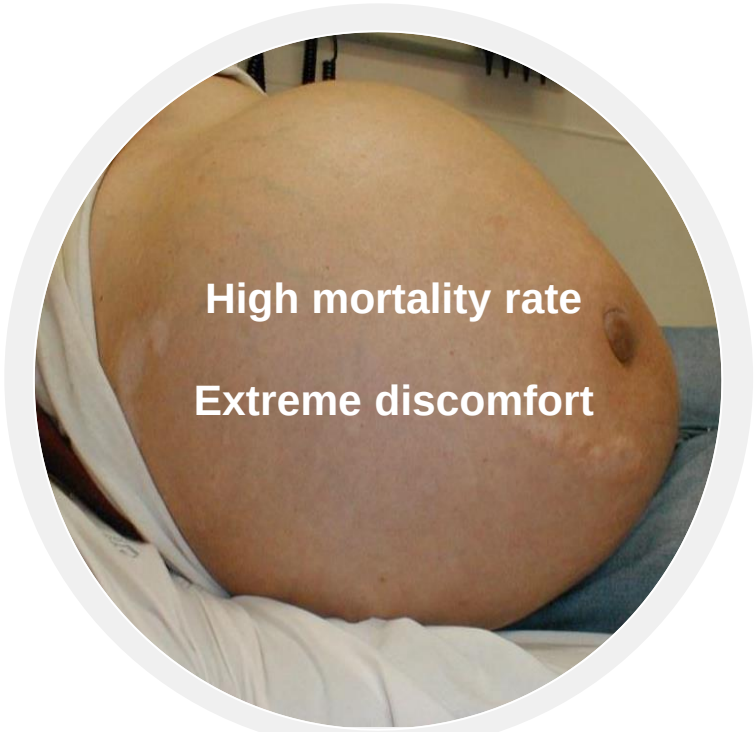
Liver cirrhosis and refractory ascites

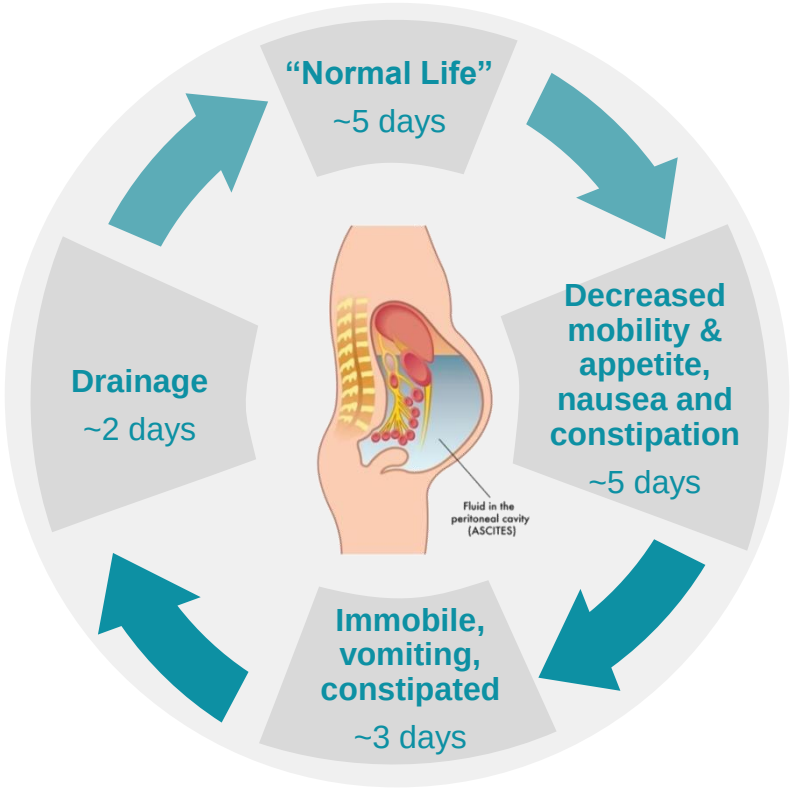
A key complication of liver cirrhosis, with a dramatic impact on quality of life

Viral infections (Hepatitis B & C)

Alcoholic Liver Disease

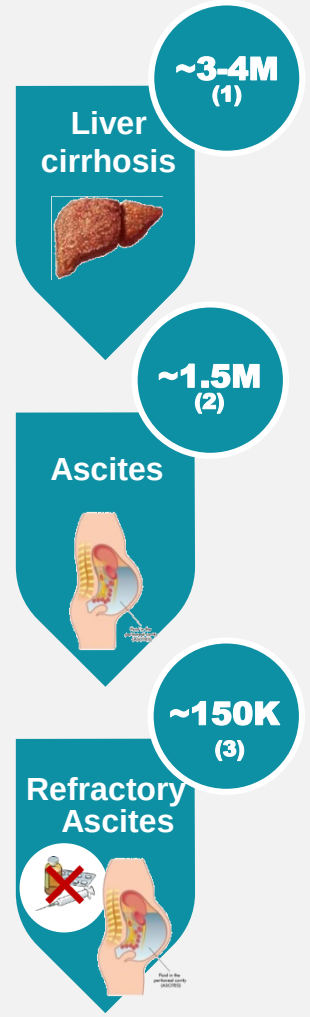
Non-Alcoholic Steatohepatitis (NASH)





Typical patient life[4]

US forecast



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

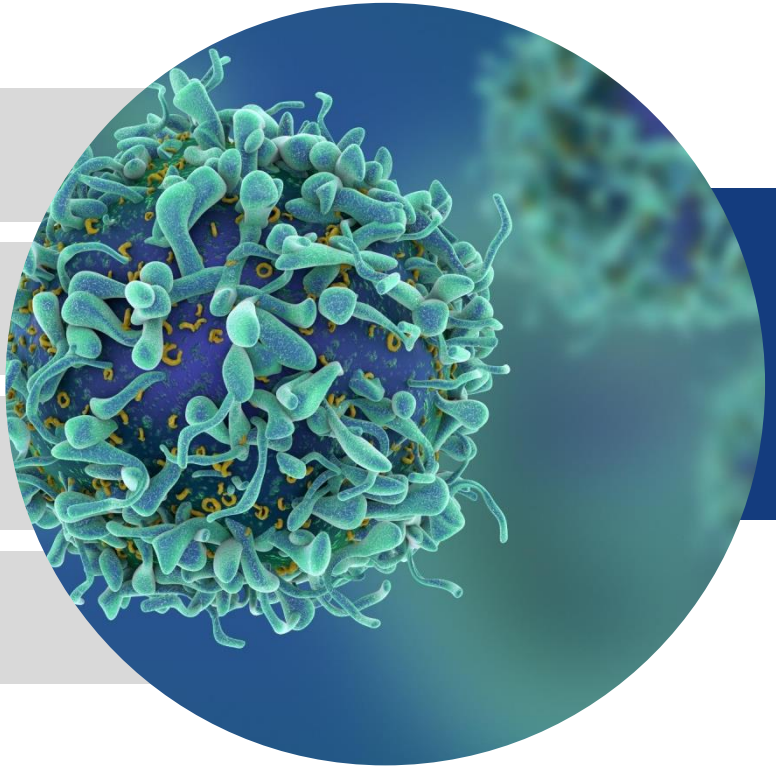
Severe complication of late-stage cancers

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

Breast and ovarian cancer have longest survival with ascites(1)

Severe impact on **quality of life**

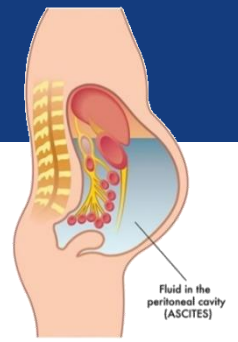
Reduces ability to undergo **anti-cancer treatment**



Malignant ascites due to breast and ovarian cancer(2):

EU5: ~18K

US: ~16K



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

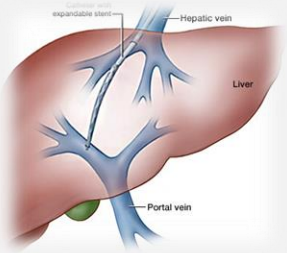
Source 1: Ayantunde & S. L. Parsons. Annals of Oncology 2007
Source 2: Management estimate based on WHO cancer incidence rates (2018) and Ayantunde & S. L. Parsons. Annals of Oncology 2007.

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

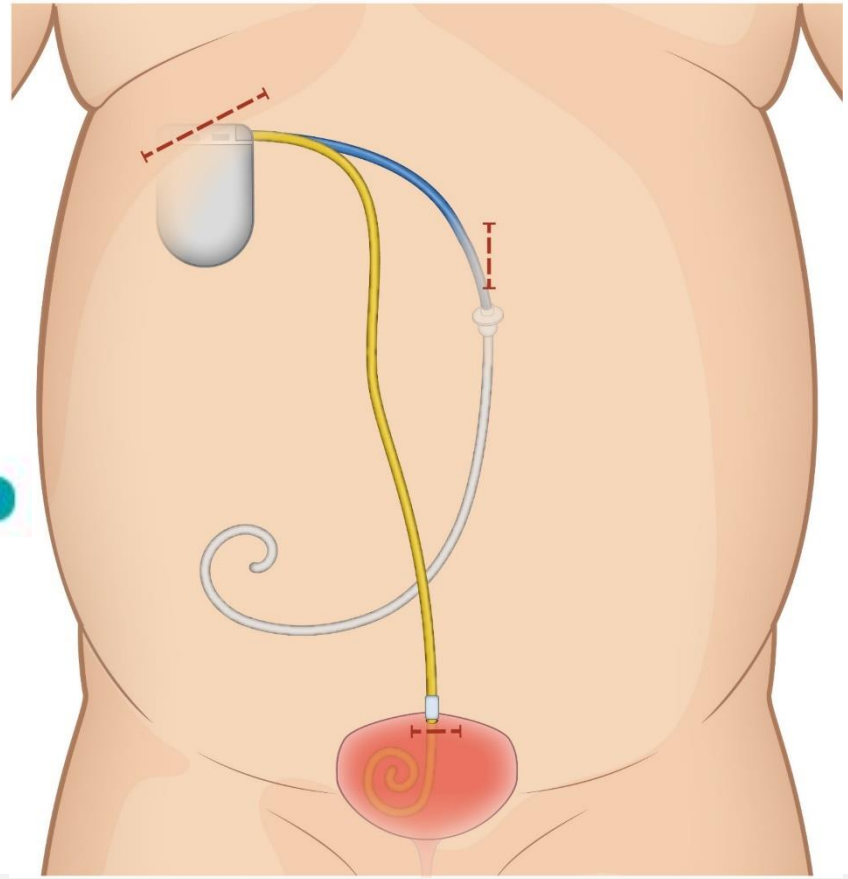
High Cost,
Limited Availability

alfapump®

alfapump® for long-term treatment

Over 850 implants and hundreds of years of patient experience

DirectLink Technology



Breakthrough Device Designation

Strong clinical and economic rationale

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

Estimated treatment cost / patient*:

LVP: ~$54K	⟷	**alfa**pump®**: ~$35K**
~$1,8K / LVP(1)		~$25K / **alfa**pump
2 LVP / month		~$10K / implantation
15 months		

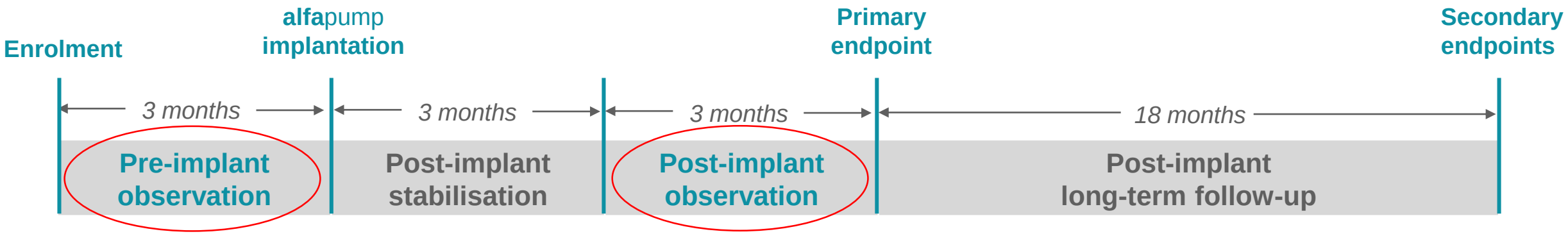
** Management estimate of US treatment costs, assuming no complications*

QoL: Quality of Life; LVP: Large Volume Paracentesis

Source 1: Kwan et al., J Vasc Interv Radiol 2018

North American Pivotal Study (POSEIDON) underway

Pivotal Cohort of up to 50 patients implanted; Roll-In ("training") cohort of up to 30 patients



POSEIDON Study Endpoints	
Primary efficacy:	1) 50% reduction in average monthly frequency of Therapeutic Paracentesis ("TP") post-implant vs. pre-implant
	2) 50% of patients achieve a 50% reduction in the requirement for TP post-implant vs. pre-implant
Primary safety:	Rate of **alfa**pump related re-interventions adjudicated by the Clinical Events Committee (CEC)
Secondary:	QoL (SF36, Ascites-Q), nutritional status, health economics, safety (device and/or procedure-related AEs), survival

***QoL**: Quality of Life; **AE:** Adverse Event*

Interim POSEIDON: Positive for primary endpoints

Data from first 13 Roll-In patients implanted with the alfapump®

EFFICACY

- ✓ Over 90% reduction in mean frequency of Therapeutic Paracenthesis (TP) post-implant vs. pre-implant (primary endpoint of >50% reduction)
- ✓ All patients experienced at least a 50% reduction in the mean frequency of TP per month (primary endpoint of >50% of patients)

SAFETY

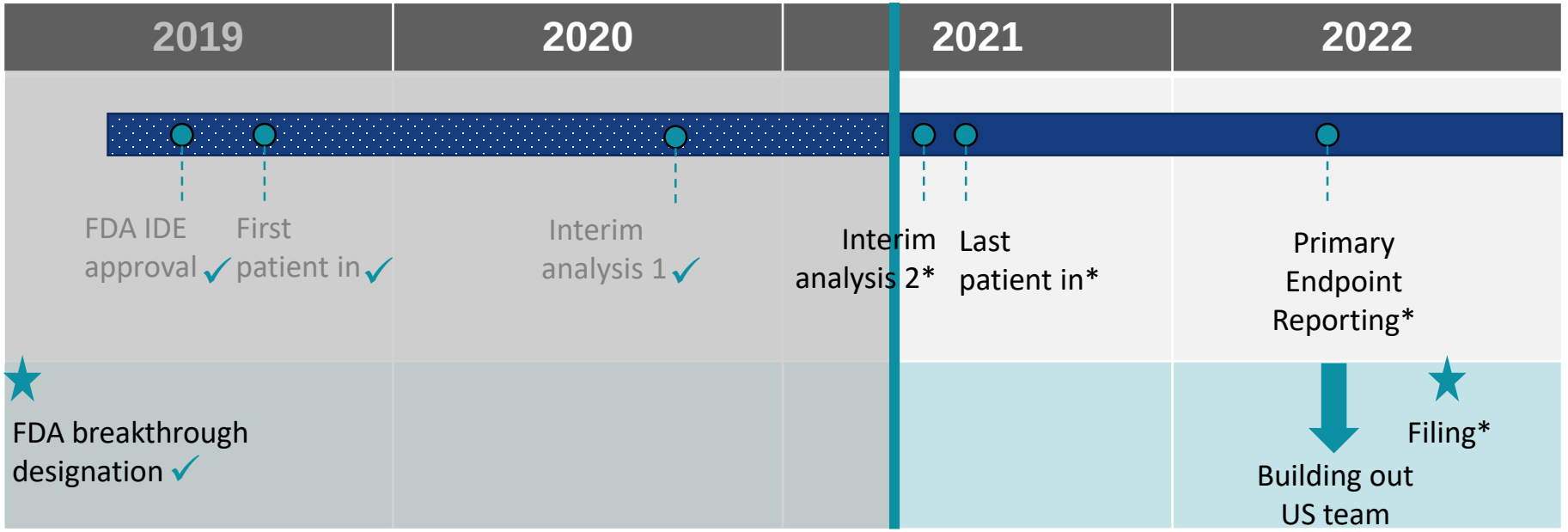
- ✓ Safety profile in line with expectations

QUALITY OF LIFE

- ✓ Indication of rapid and persistent clinically relevant improvement in patients' quality of life

Note: Pre- and post-implant periods for this analysis of the Roll-In Cohort differ from those that will be used for the Pivotal Cohort analysis

Targeting announcement of primary endpoint in Q2 2022

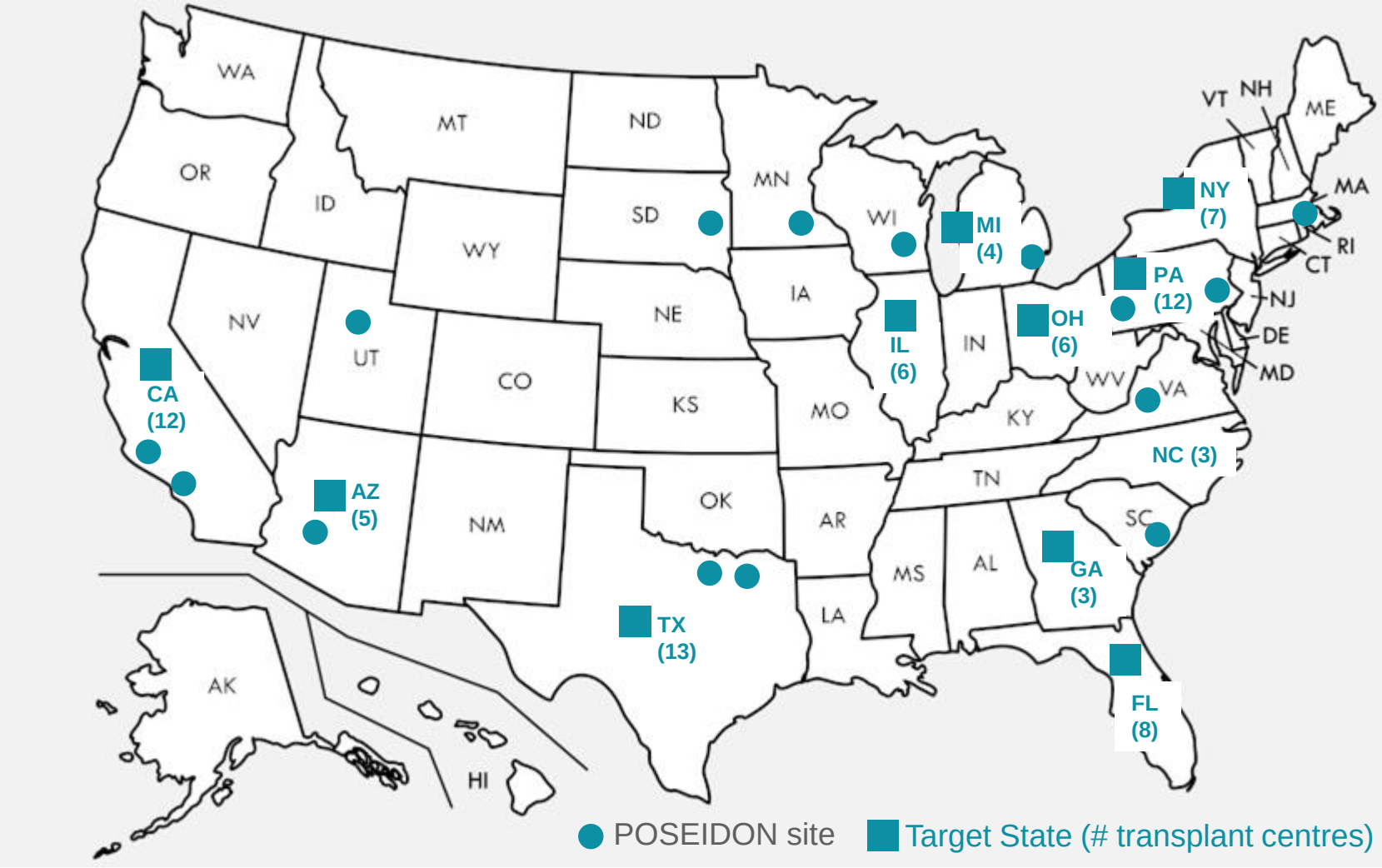


*MCIT & NTAP – CMS initiatives for breakthrough devices to further support coverage & reimbursement for the **alfa**pump*

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

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

US commercialisation through our specialty salesforce



Initial focus on key transplant centres

~50-person team:

35 sales reps, 10 clinical, 5 corporate

alfapump DSR®

Breakthrough approach to **fluid overload in heart failure** built on proven **alfa**pump® platform

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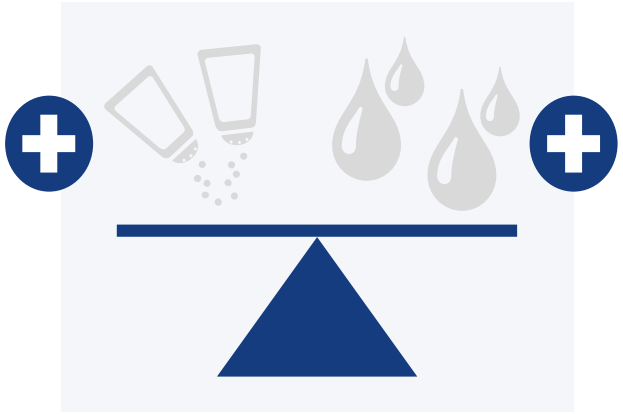
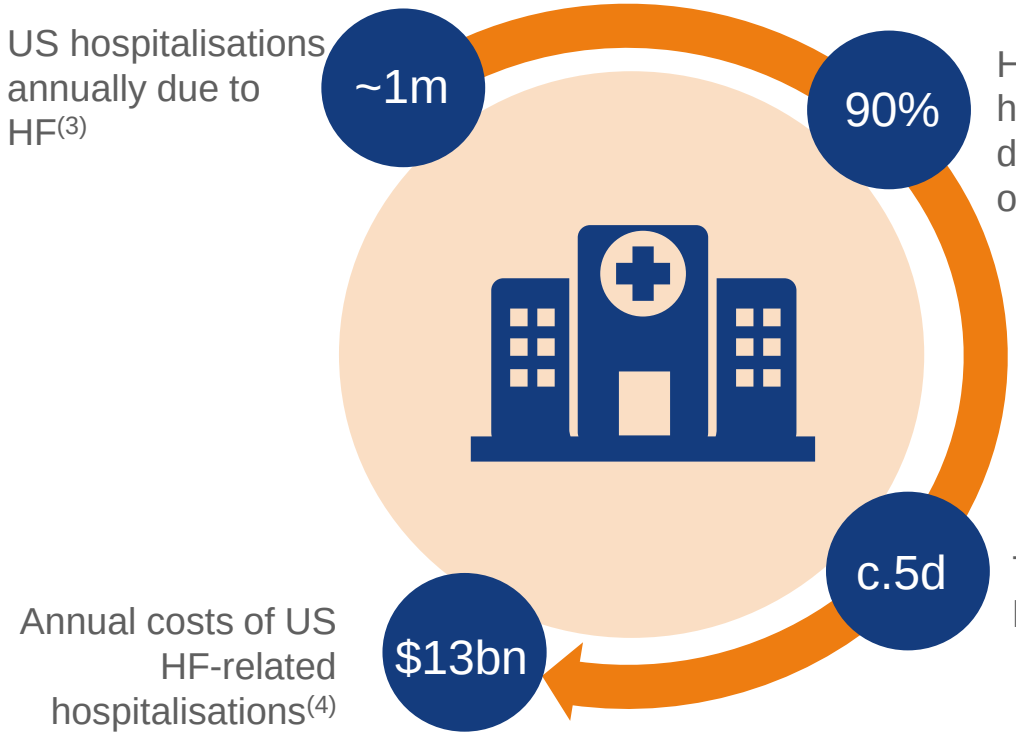
Diuretic-resistant fluid overload in heart failure

Key clinical challenge and driver of costs



Excess sodium drives fluid overload

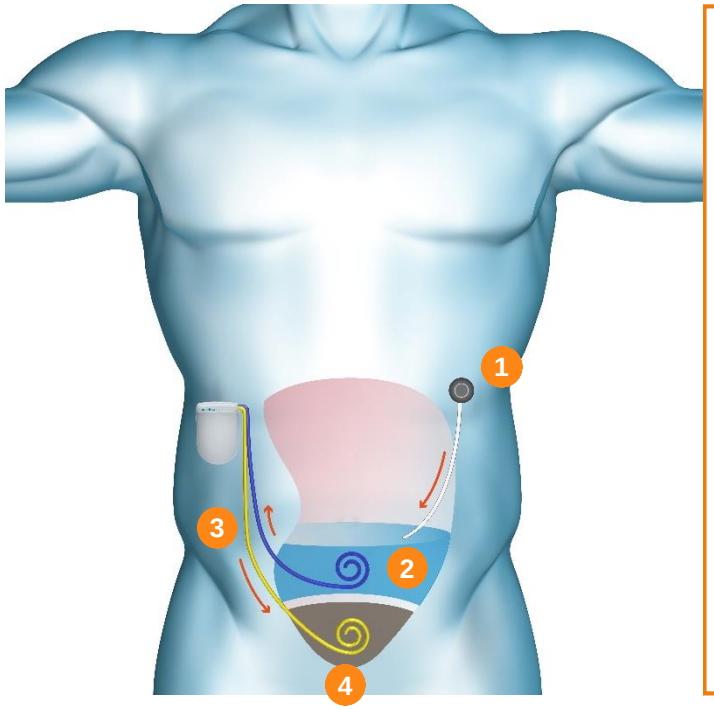


- *40% of heart failure patients on IV loop diuretics have a poor response(1)*
- *24% re-admission rate at 30 days(2)*

Source 1: Testani, Circ Heart Failure, 2014 & 2016; Source 2: Ross et al. (2010); Source 3: Costanzo et al., J. Am. Coll., 2007; Source 4: Kilgore et al. (2017)

alfapump DSR® leveraging proven alfapump® platform

Fully implanted system for long-term DSR® therapy

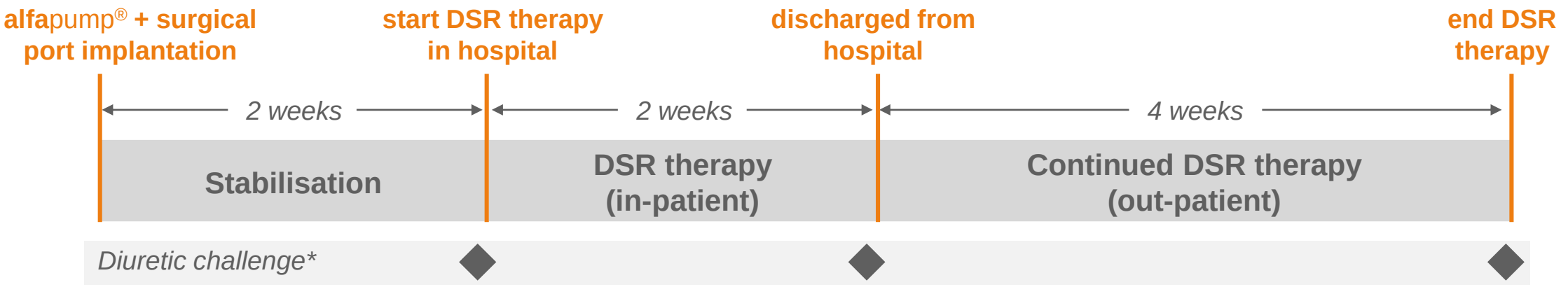


1. Sodium-free DSR infusate administered to peritoneal cavity via implanted port
2. Sodium diffuses into DSR infusate
3. **alfa**pump pumps sodium-rich DSR infusate into the bladder
4. Body eliminates excess fluid through osmotic ultrafiltration and urination

Fundamental patents to reduce fluid overload in heart failure patients granted in the US and Europe

RED DESERT – The first repeated DSR® therapy study

Repeated dose proof-of-concept study of alfapump DSR® in stable heart failure patients on high dose diuretics



Study Endpoints

- **Primary:** absence/rate of device, procedure and/or therapy related serious adverse events
- **Secondary:** ability of the **alfa**pump DSR to maintain a neutral sodium balance in the absence of diuretic therapy and the sustained effect of DSR to maintain euvolemia
- **Exploratory:** impact of DSR to restore response to diuretics following DSR treatment

** 40mg intravenous furosemide to evaluate diuretic response (6 hour sodium and fluid excretion)*

RED DESERT – Highly effective management of fluid & sodium

No loop diuretics required during study despite mean baseline dose of >300 mg/day furosemide equivalents

Subject	Ejection Fraction (%)	NT-proBNP (pg/mL)	Daily Dose of loop diuretics (mg)**	
	At baseline	At baseline	At baseline	During DSR Treatment (D0 - 42)
101-001	26	6,110	80	0
101-002	27	2,863	200	0
101-003	28	1,536	400	0
101-005	25	1,628	120	0
101-006*	23	1,963	80	0
101-007*	26	5,927	300	0
101-008*	20	7,853	600	0
101-009†	20	8,831	800	0
Mean (± SD)	*24 ± 3*	*4,589 ± 2,945*	*323 ± 263*	

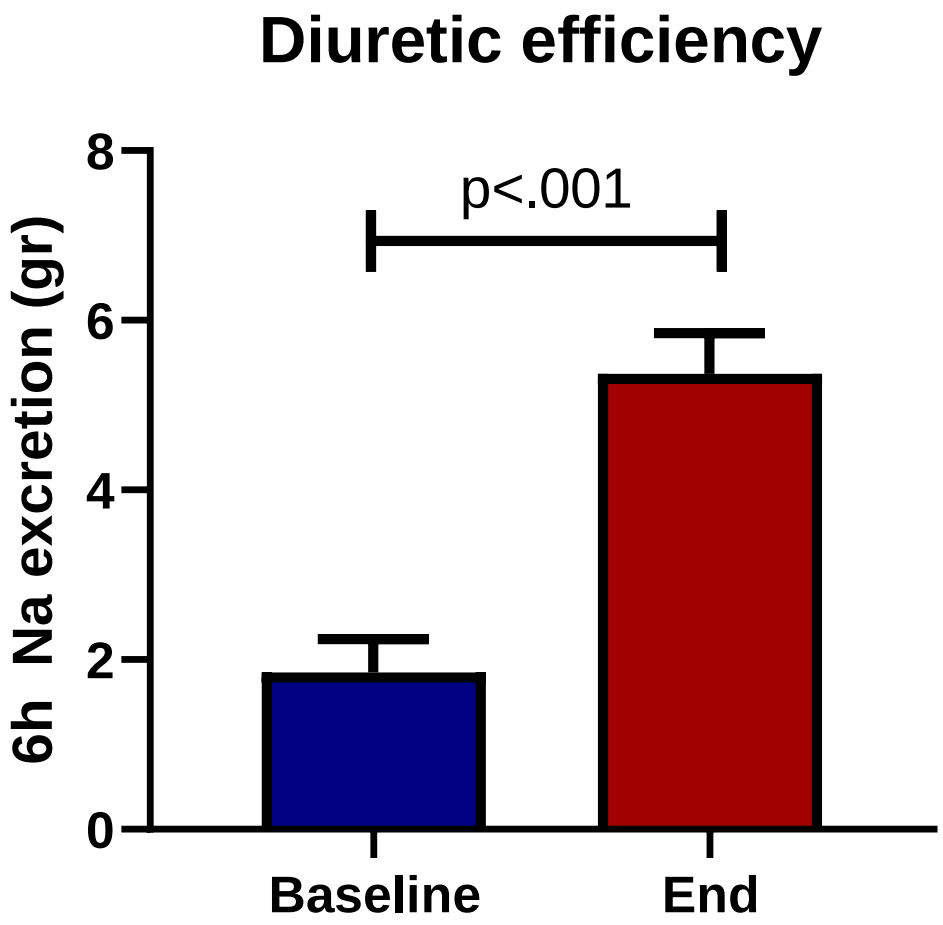
Study recruited severely ill heart failure patients on very high doses of oral loop diuretics

** in follow-up extension with DSR; † subject 101-009 died at D3*
*** loop diuretics in furosemide equivalents (mg)*

***NT-proBNP**: N-terminal-pro hormone B-type Natriuretic Peptide – analysed in local lab*

RED DESERT – Dramatic improvement in diuretic efficiency

Over 250% increase in mean diuretic response*



** 6 hour Na excretion following administration of 40mg intravenous furosemide; paired statistical analysis of patients with baseline and D42 value (N=7)*

RED DESERT – Long term improvement in diuretic response

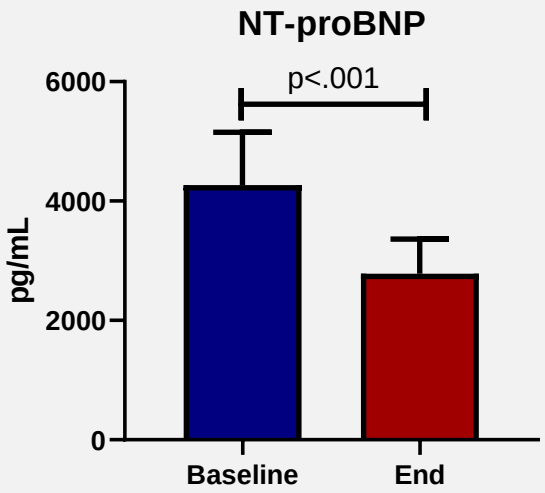
79% reduction in mean diuretic dose at median follow-up of 10 months

Subject	Daily Dose of loop diuretics (mg)*** At baseline	Time since last DSR study treatment**	Current Daily dose (mg)***	Reduction in diuretic dosage
101-001	80	12.5 months	40	**-50 %**
101-002	200	12.5 months	80	**-60 %**
101-003	400	10 months	80	**-80 %**
101-005	120	10.5 months	40 E3D	**-89 %**
101-006*	80	8.5 months	20 BIW	**-93 %**
101-007*	300	2 months	40 TIW	**-94 %**
101-008*	600	2 months	80	**-87 %**
101-009†	800	NA	NA	NA

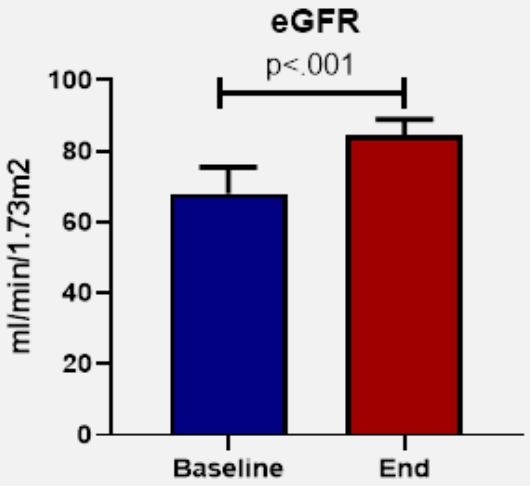
** in follow-up extension with DSR; † subject 101-009 died at D3*
*** excluding DSR treatment in follow-up extension*
**** loop diuretics in furosemide equivalents (mg)*

***E3D:** every third day; **BIW**: two times per week; **TIW:** three times per week*

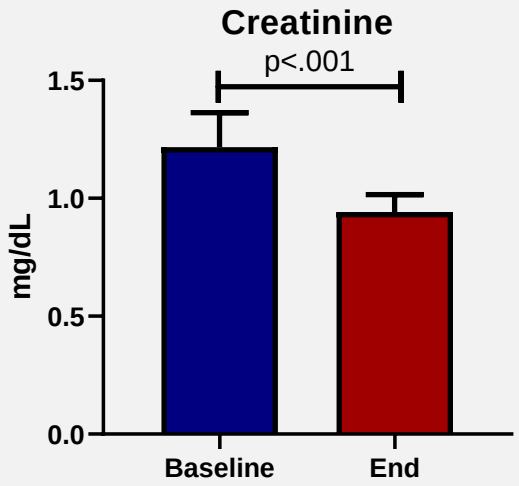
RED DESERT – Significant improvement in cardio-renal function*



30% decrease in mean natriuretic peptides



22% increase in mean eGFR



22% decrease in mean creatinine

"The simultaneous normalisation of diuretic response and improvement in cardio-renal status of the RED DESERT patients is a never before seen treatment effect and could translate into important long-term clinical benefits in heart failure patients" – Dr. Testani

** Paired statistical analysis of patients with baseline and D42 value (N=7)*

***NT-proBNP**: N-terminal-pro hormone B-type Natriuretic Peptide (analysed in local lab); **eGFR**: estimated glomerular filtration rate*

RED DESERT – Adverse event overview

No clinically significant changes in serum sodium levels / no progressive hyponatremia

- Study system related adverse events: 3 in 2 patients
  - 2x SAE blockage of peritoneal catheter in 1 patient
  - 1x site AE hematoma in 1 patient
- Therapy related adverse events: 1 in 1 patient
  - 1x AE abdominal discomfort during pumping phase in 1 patient
- Implant procedure related adverse events: 2 in 2 patients
  - 1x AE site hematoma in 1 patient (see above “Study System related AE”)
  - 1x AE hematuria in 1 patient
- Other SAEs: 2 in 2 patients
  - 1x SAE TIA in 1 patient (D29 - D35)
  - 1x SAE Cardiac Arrest 1 patient (D3)

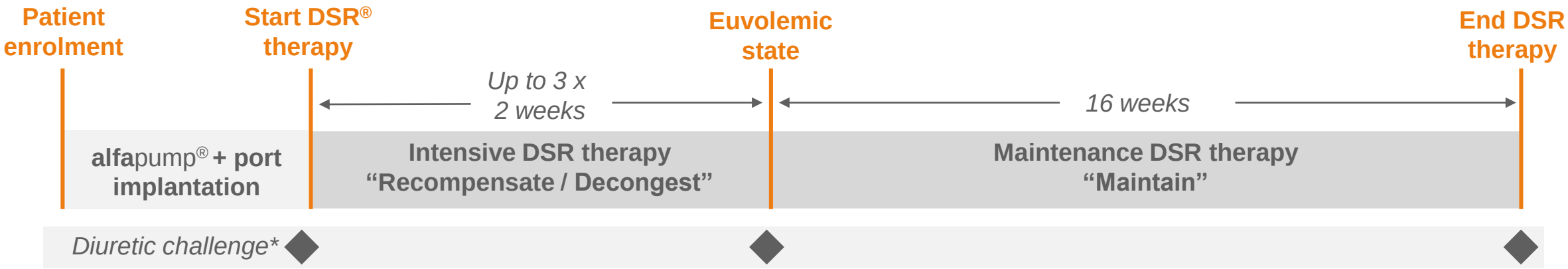
DMC: possibly related to study therapy/procedure but unlikely related to device

Site PI: not related to study therapy, procedure or device

SAE: *Serious Adverse Event;* ***AE:*** *Adverse Event;* ***TIA:*** *Transient Ischemic Attack;* ***DMC****: Data Monitoring Committee;* ***PI:*** *Principal Investigator at site in Georgia*

SAHARA DESERT – On track to start in Q2 2021

20 decompensated heart failure patients with residual congestion on high doses of loop diuretics



Study Endpoints

- **Primary:** safety and tolerability of **alfa**pump DSR® therapy
- **Secondary:** feasibility of DSR therapy to restore and maintain euvolemia without additional loop diuretics
- **Exploratory:** evaluate potential impact of SGLT-2 inhibitors on DSR therapy**

Interim results expected Q4 2021 / Top-line results expected H2 2022

** 40 mg intravenous furosemide to evaluate diuretic response (6 hour sodium and fluid excretion)*

*** patients will be randomised 1:1 to DSR therapy +/- SGLT-2 inhibitor therapy*

Development of proprietary DSR® Infusate 2.0 ongoing

- 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

Note: This image is intended for illustration purposes only

- Pre-clinical development work ongoing & preparing for CMC activities

***CMC**: Chemistry, Manufacturing and Controls*

Short-term DSR® – Expanding development programme

Building upon the success of RED DESERT to extend and strengthen the DSR franchise

Short-term DSR therapy:

- "one off" ~2 weeks intensive DSR treatment
- With peritoneal catheter (w/o **alfa**pump®)

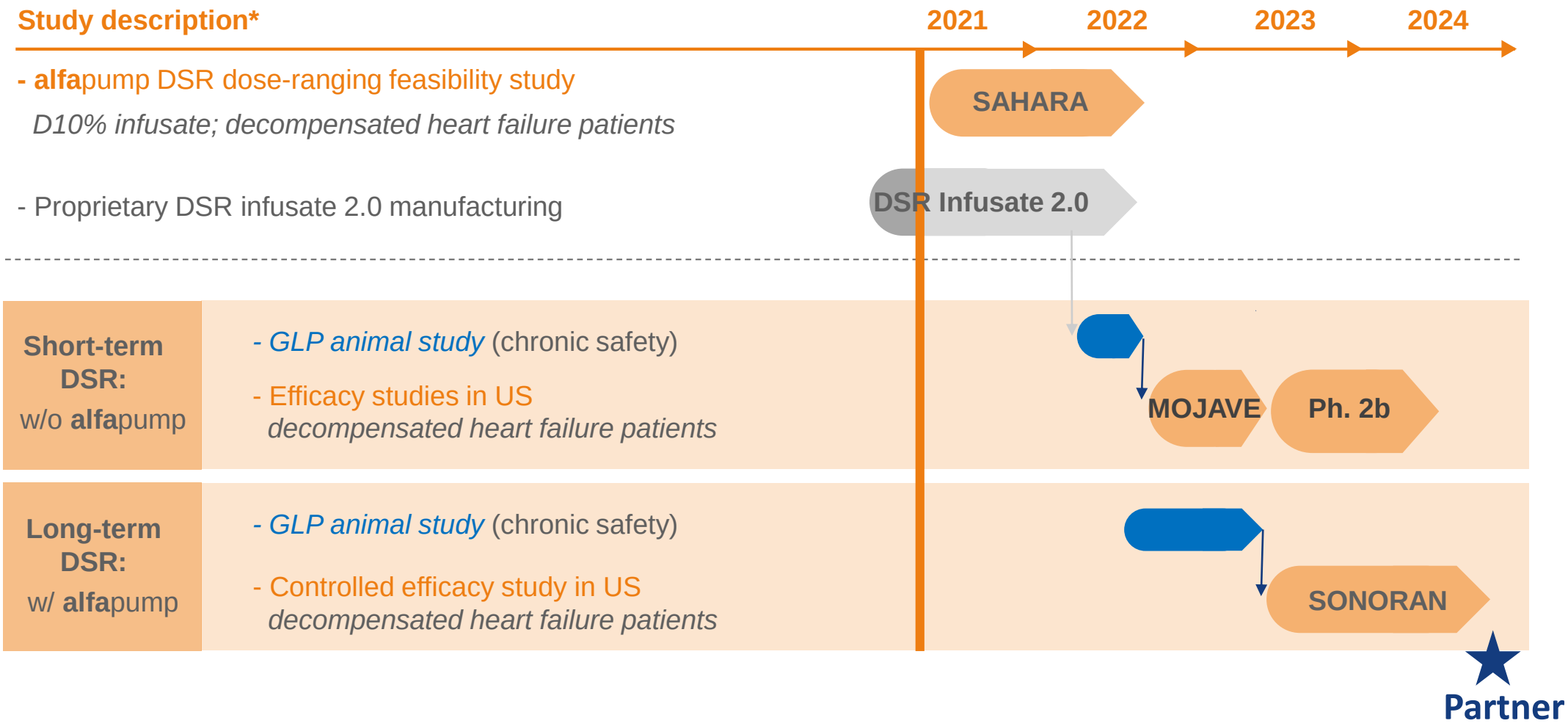
Long-term alfapump DSR® therapy:

- Intermittent, recurring, intensive DSR treatment
- With **alfa**pump

Both DSR therapies will target diuretic-resistant heart failure patients with residual congestion and aim to restore patients' diuretic response and cardio-renal status

DSR® and alfapump DSR® development strategy

Short-term DSR therapy extends portfolio



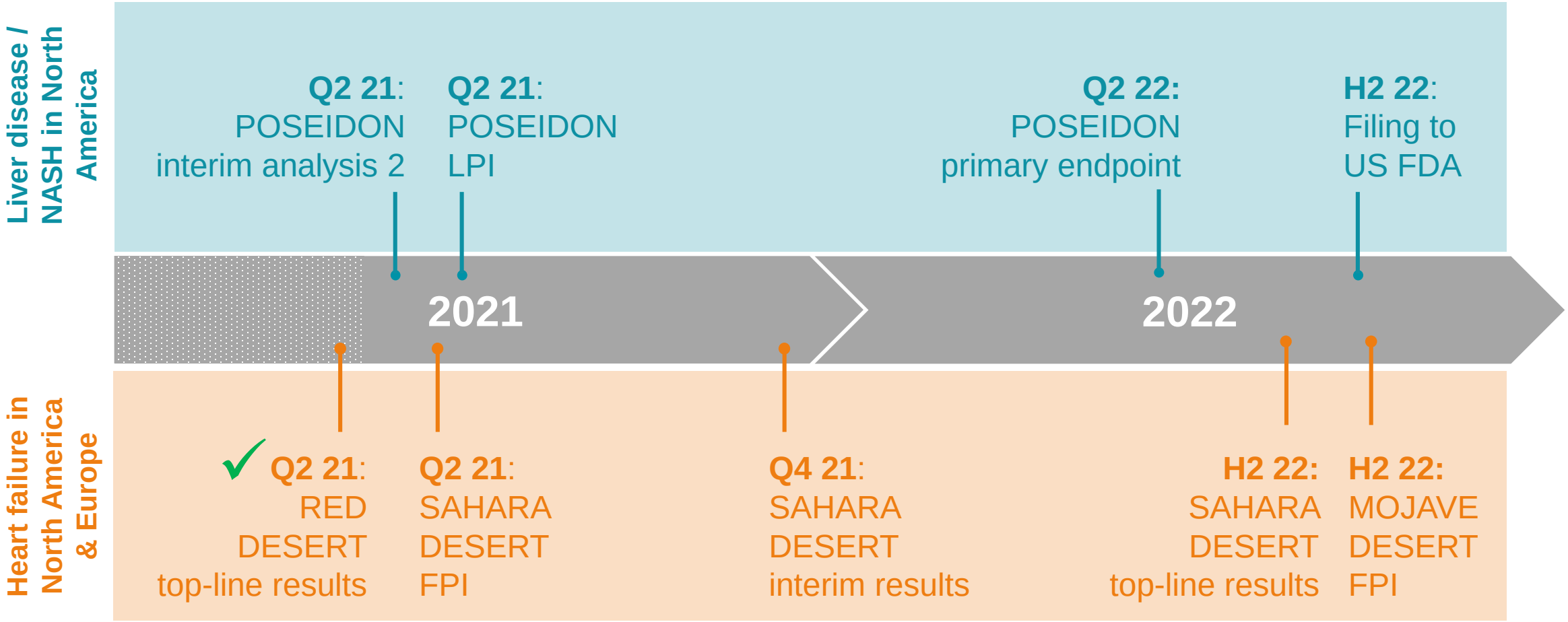
* *Timelines subject to further developments related to the ongoing COVID-19 pandemic*
Description and timing of these studies are subject to change and/or feedback from applicable regulatory authorities

Outlook

Strong **near term value drivers**

with clear **long term potential**

Expected core value drivers & outlook



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

FPI: First Patient In; LPI: Last Patient In

Back-up

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 Gödje
Chief Medical Officer

Dragomir Lakic
VP Manufacturing

Gijs Klarenbeek
Senior Medical Advisor

Martijn Blom
Chief Commercial Officer

Timur Resch
Global VP QM/QA/RA

Andreas Wirth
VP Engineering

Board of Directors:

Pierre Chauvineau
Board Chairman

Ian Crosbie
Chief Executive Officer

Wim Ottevaere
Director

Jason Hannon
Director

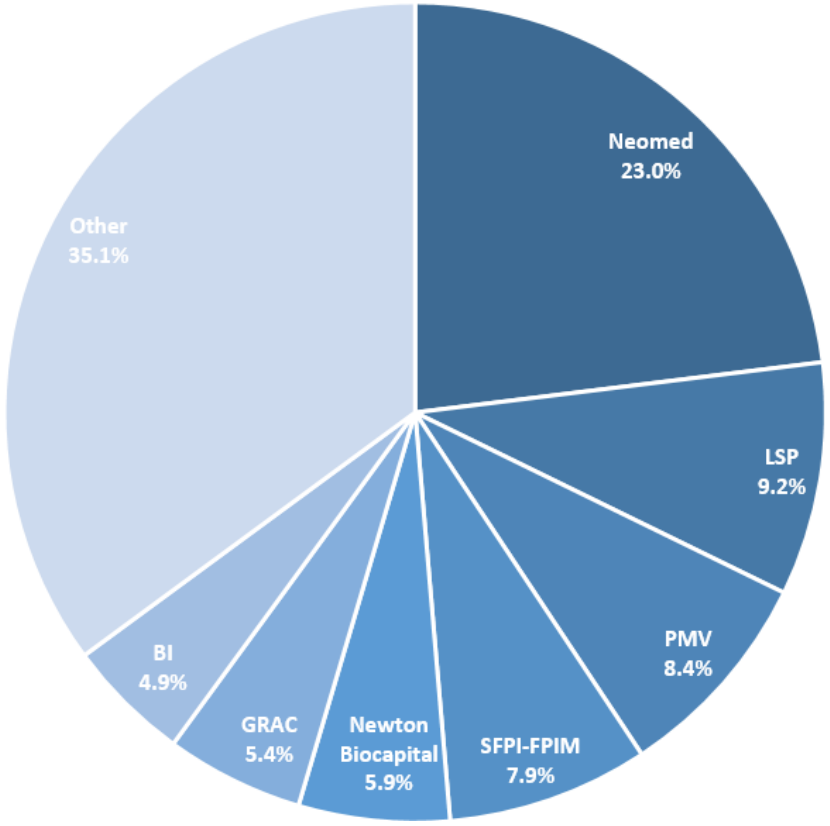
Rudy Dekeyser
Director

Erik Amble
Director

Shareholders base and financial overview

Ticker: SEQUA – Euronext Brussels

- Outstanding shares: 18.5M
- Outstanding share options & warrants: 1.8M



- Analysts:
  - KBC Securities – Lenny Van Steenhuyse
  - Kempen – Ingrid Gafanhão
  - Kepler Cheuvreux – Matthias Maenhaut
  - Mirabaud – Daniel Jelovcan
- Cash (31 December 2020): €11.0M
- Equity financing in February 2021: €22.5M
- Cash runway into Q2 2022

POSEIDON – study cohorts

Patients with recurrent or refractory ascites due to liver cirrhosis in up to 20 centres across US and Canada

Two study cohorts with the same inclusion / exclusion criteria

1 Pivotal Cohort

- Up to 50 patients implanted with the **alfa**pump®
- For primary and secondary endpoint analysis

2 Roll-In Cohort ➡ enables us to report interim data

- Up to 30 patients implanted with the **alfa**pump
- To teach clinicians and medical teams at new centres how to use the **alfa**pump

Cirrhotic patients with recurrent or refractory ascites

First 13 patients in Roll-In Cohort of the POSEIDON study

Age (mean)	65 y
MELD score (mean ± SD)	10.5 ± 4.6
Cirrhosis etiology	
- Alcohol	- 61.5%
- NASH	- 23.1%
- Hepatitis C	- 7.7%
- Alcohol, Hepatitis C, and Hepatitis B	- 7.7%
TP per month prior to study (mean ± SD)	3.4 ± 1.8

MELD: *Model for End-stage Liver Disease;* ***SD:*** *Standard Deviation;* ***NASH:*** *Non-Alcoholic Steatohepatitis;* ***TP:*** *Therapeutic Paracentesis*

Willingness to treat earlier stage patients?

NASH is already an important driver of this market

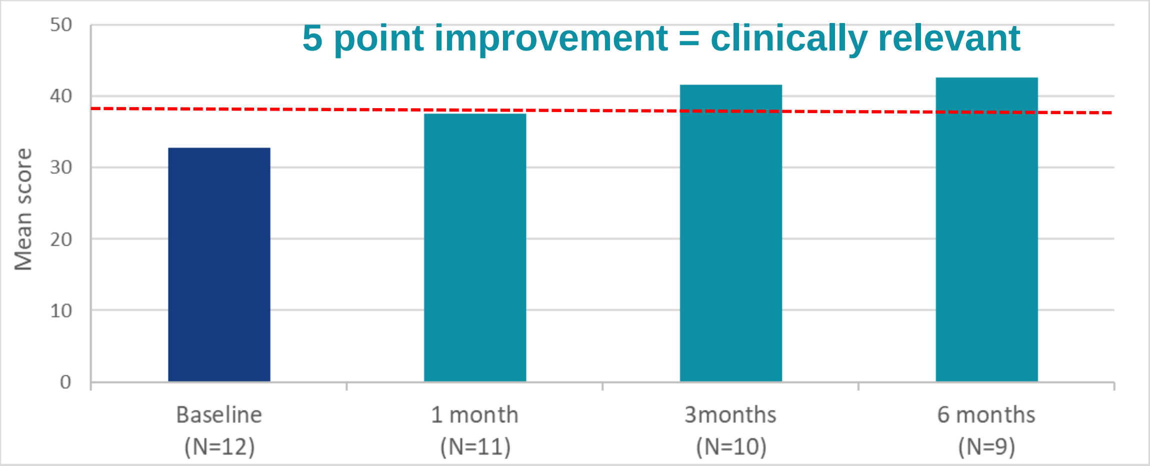
N. American patients appear to have more TP / month compared to Europe

POSEIDON interim: Indication of fast and persistent improvement in Quality of Life

Physical Component Score

SF-36

General health-survey questionnaire

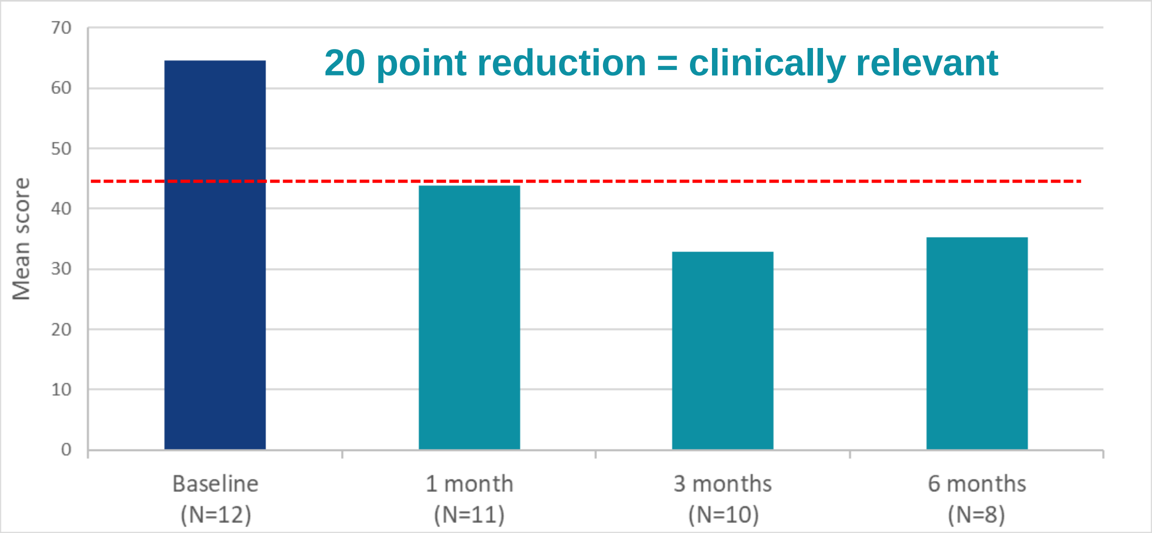


Higher is better

Total Score

Ascites Q

Specific health-survey questionnaire for ascites



Lower is better

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

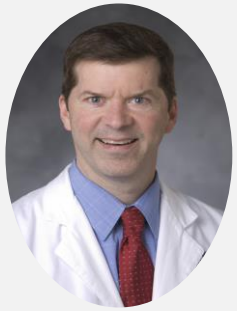
Professor of Medicine at Cleveland Clinic Lerner College of Medicine at Case Western Reserve University

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

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