



Innovators in the treatment of
diuretic-resistant fluid overload
liver disease – malignant ascites – heart failure

Investor presentation – August 2021

Disclaimers

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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 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 **alfapump**® 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:

- **alfapump**® is a registered trademark. DSR® and **alfapump** 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



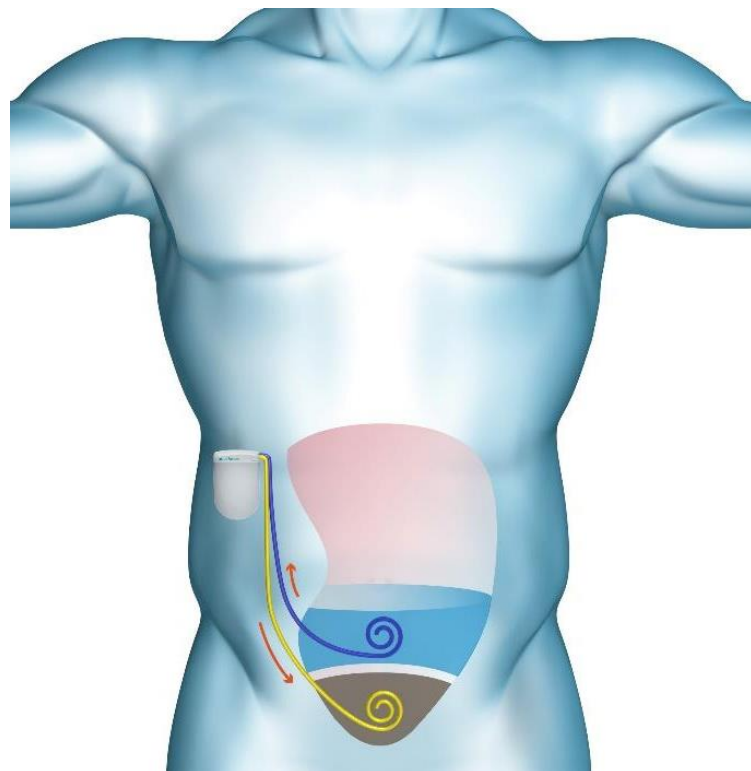
Wireless battery charging



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 sodium and then the body “does the math”, eliminating fluid to restore serum sodium balance

Key Principle



How It Works

Sodium-free DSR infusate administered to peritoneal cavity

1

Sodium diffuses from the body into DSR infusate

2

DSR infusate + extracted sodium removed from the body

3

Body eliminates free water to restore balance

4

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 diuretic-resistant congestion

Proven ability to manage fluid balance, restore diuretic
response & improve cardio-renal function

> €5 Bn / year market opportunity⁽²⁾



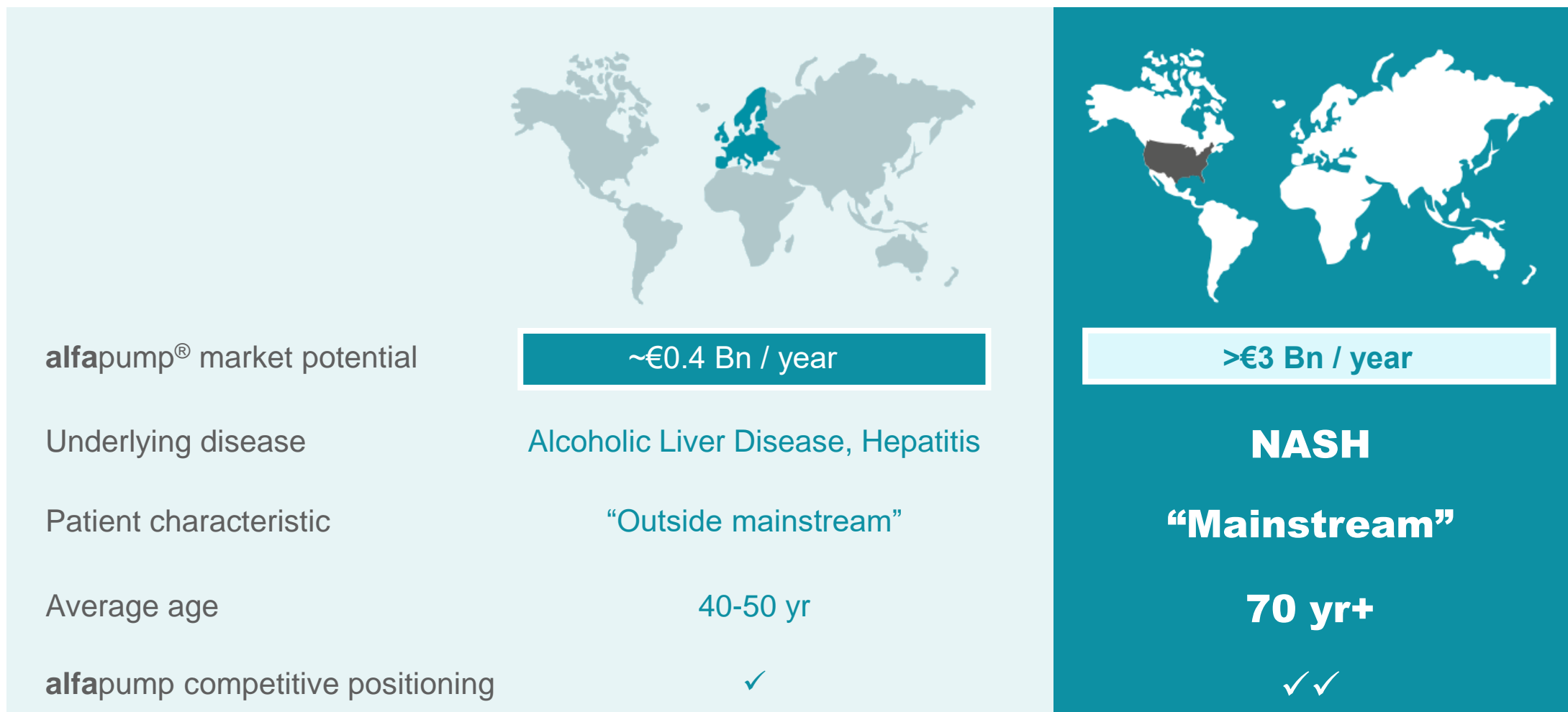
SAHARA DESERT study ongoing

Partnering after US efficacy study

Built upon proven European clinical & commercial experience

NASH drives US liver ascites market attractiveness

Stronger competitive position in a much larger and dynamic market



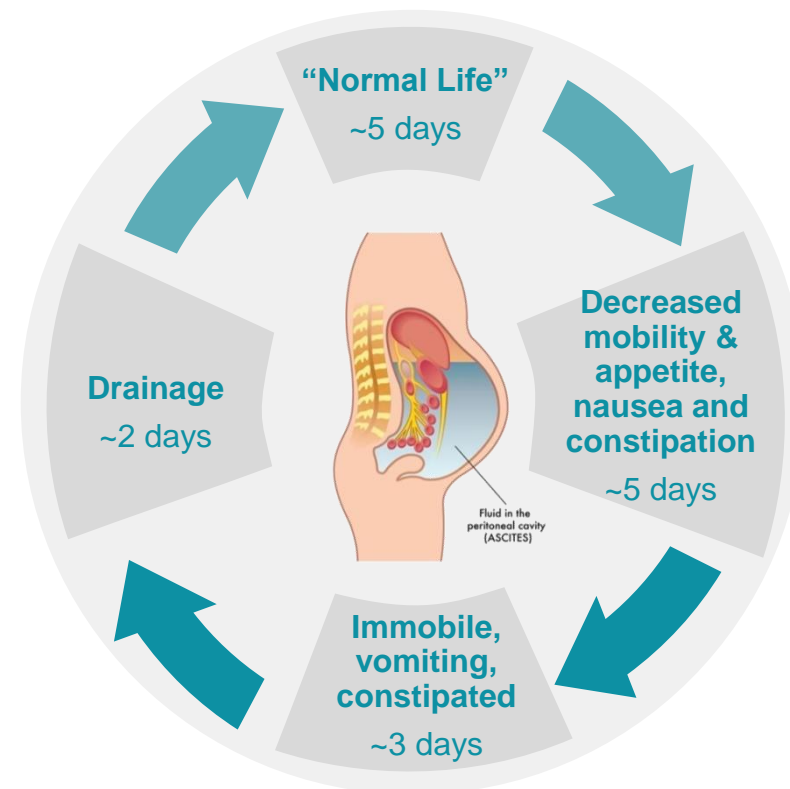


alfapump®

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

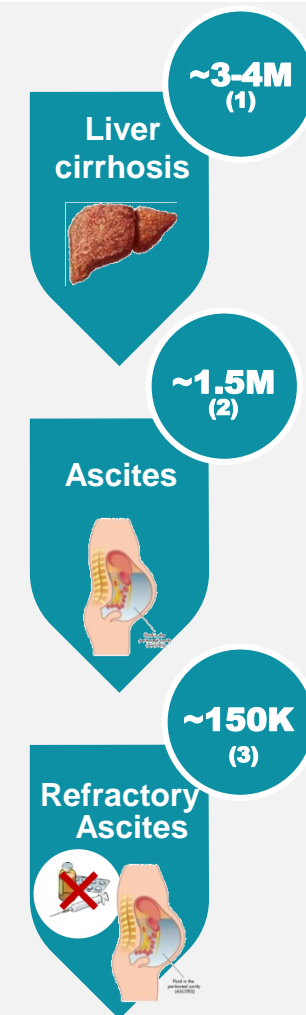
Refractory liver ascites

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



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; Nouredin 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

Malignant ascites

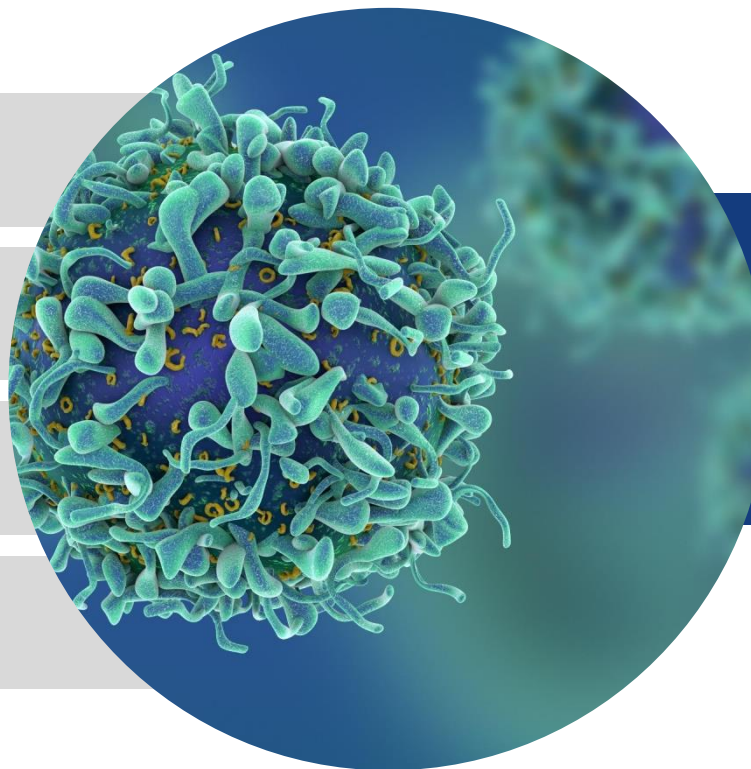
Severe complication of late-stage cancers

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**

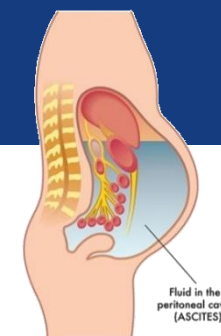
Reduces ability to undergo **anti-cancer treatment**



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

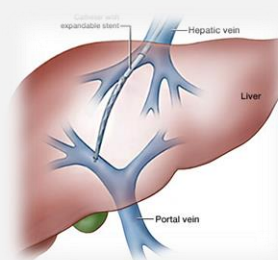
Limitations of existing therapies

Drainage (“Large Volume Paracentesis / LVP”)



Painful, Poor Quality of Life, Short Term Benefit

Transjugular Intrahepatic Portosystemic Shunt (TIPS)



Complications, Contraindications

Permanent Catheter System



External Catheter, Risk for Infections / Blockage

Liver transplantation



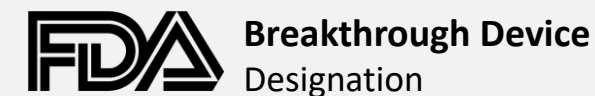
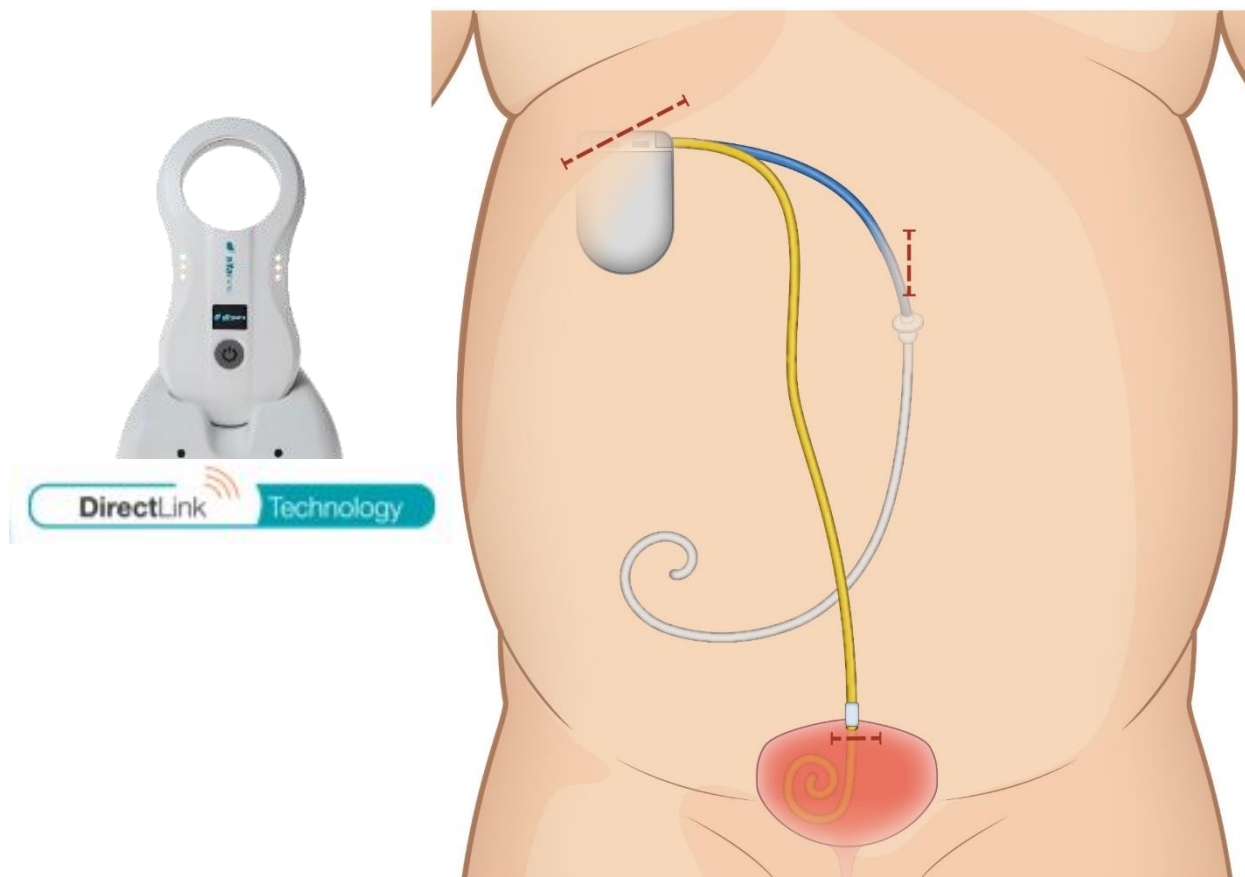
High Cost, Limited Availability

alfapump®



alfapump® for long-term treatment

Over 850 implants and hundreds of years of patient experience



Strong clinical and economic rationale

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

Estimated treatment cost / patient*:

LVP: ~\$54K ↔ **alfapump®: ~\$35K**

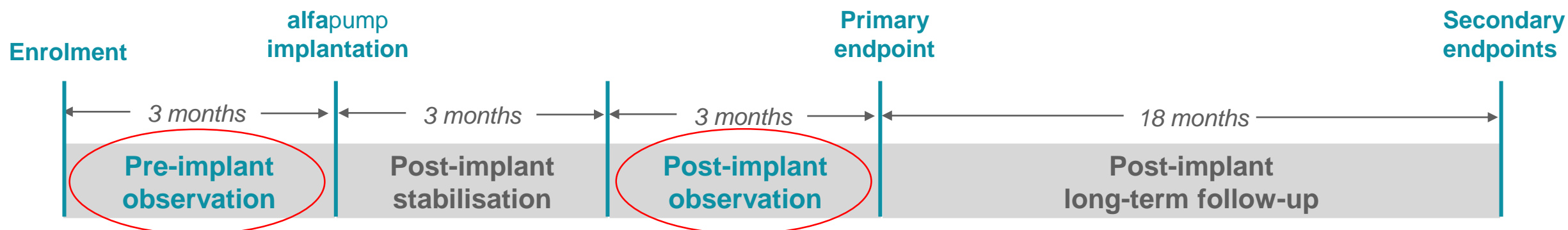
~\$1.8K / LVP⁽¹⁾
2 LVP / month
15 months

~\$25K / alfapump
~\$10K / implantation

* Management estimate of US treatment costs, assuming no complications

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 **alfapump** 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

Interim POSEIDON: Positive for primary endpoints

Data from 26 Roll-In patients implanted with the alfapump®

EFFICACY

- ✓ Substantial and durable reduction in Therapeutic Paracentesis (TP)
- ✓ Over 90% reduction in mean frequency of TP post- 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)

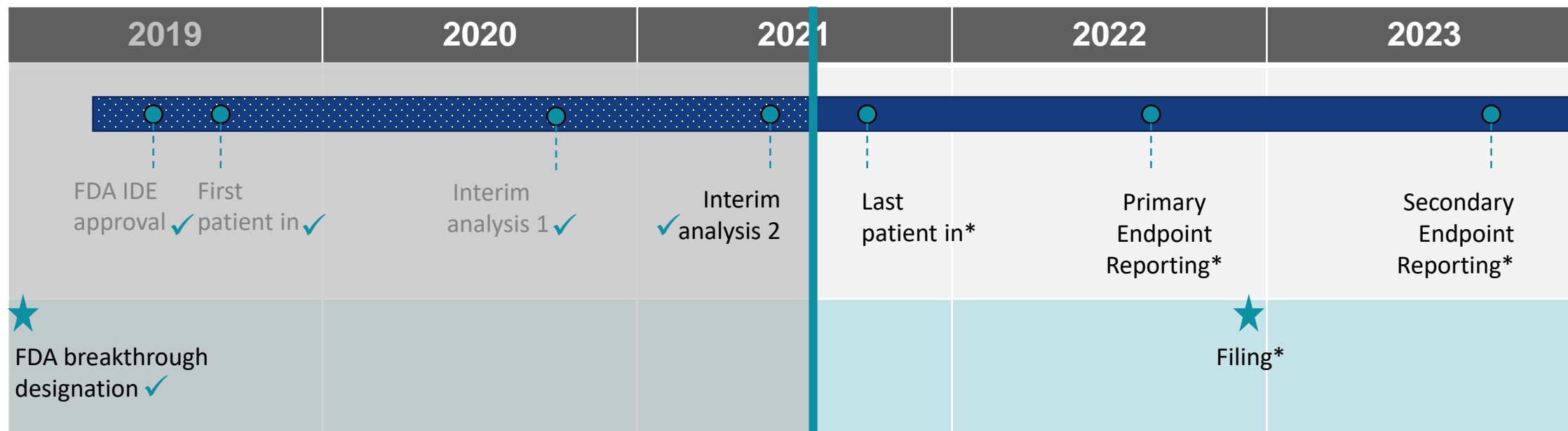
SAFETY

- ✓ Safety profile in line with expectations – 3 out of 26 patients experienced a composite primary safety event

QUALITY OF LIFE

- ✓ Clinically important improvement in quality of life maintained for up to 12 months post-implantation

Targeting announcement of primary endpoint in Q3 '22

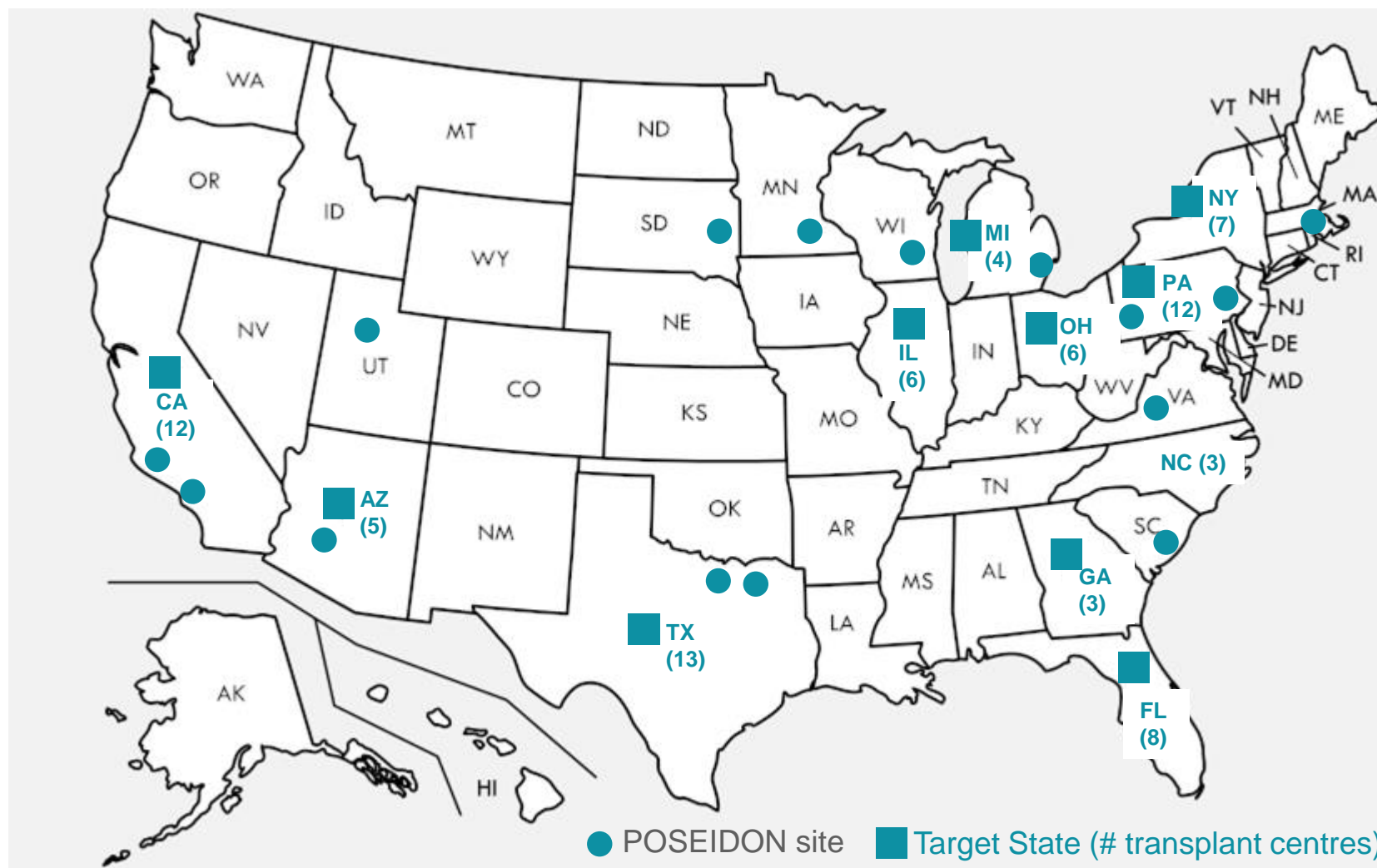


*MCIT & NTAP – CMS initiatives for breakthrough devices to further support coverage & reimbursement for the **alfapump***

* 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

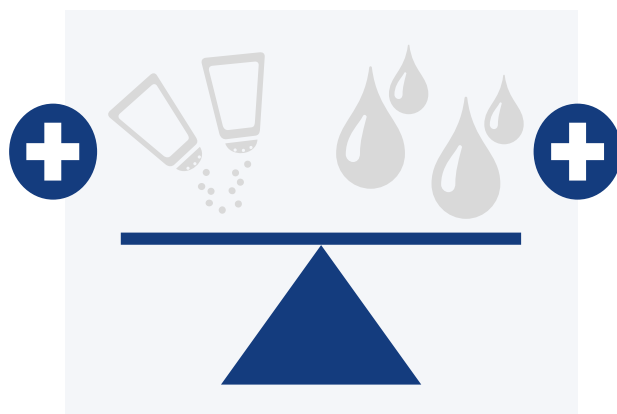


alfapump DSR[®]

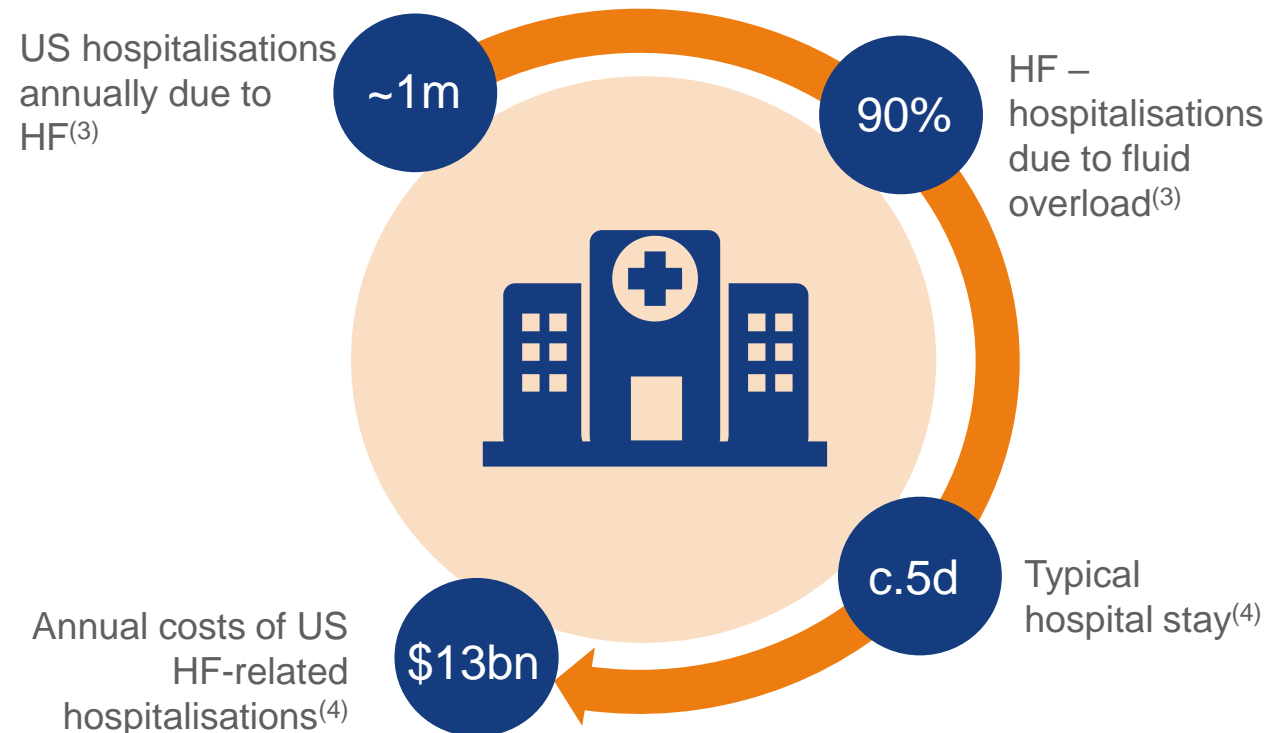
Breakthrough approach to
persistent congestion in heart failure built on proven
alfapump[®] platform

Diuretic-resistant congestion

Key clinical challenge and driver of costs for heart failure patients



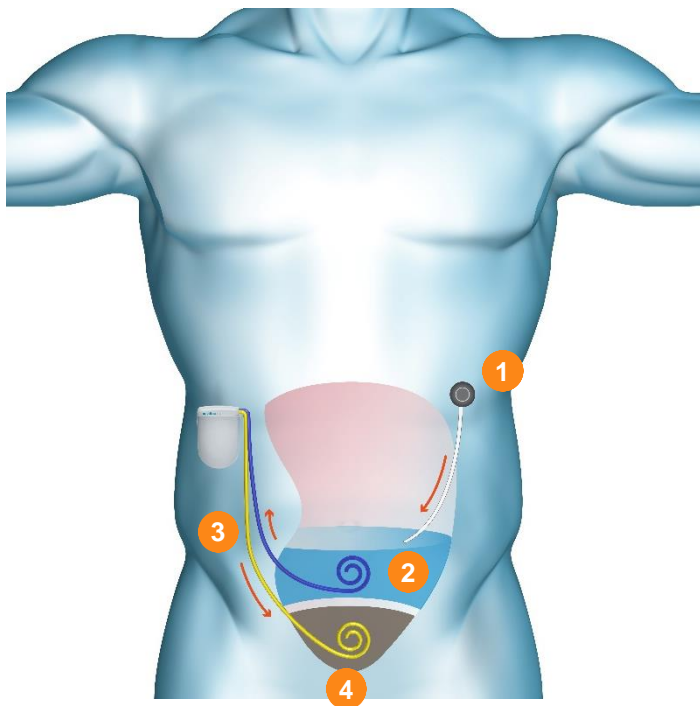
Excess sodium drives
fluid overload



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

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 **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 patients granted in the US and Europe

RED DESERT: repeated dose alfapump DSR® study

Eight euvolemic heart failure patients on high dose diuretics

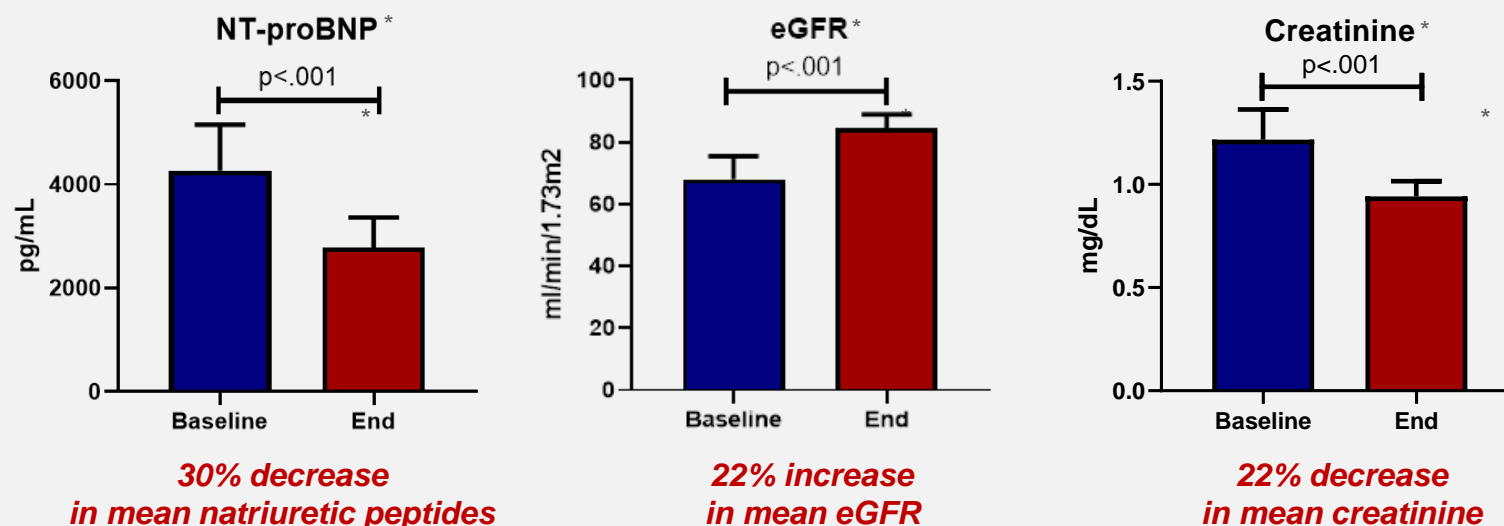
Highly effective replacement of high dose loop diuretics

- DSR treatment 3x per week for up to 6 weeks
- Generally safe and well tolerated; no clinically relevant hyponatremia

Dramatic and long-term improvement in diuretic response

- Over 150% increase in diuretic response**
- 79% reduction in diuretic dose** 10 months after study completion***

Significant improvement in cardio-renal function



Presented as
Late-Breaker and
Highlight at
Heart Failure 2021

“Simultaneous normalisation of diuretic response and improvement in cardio-renal status is a never before seen treatment effect”

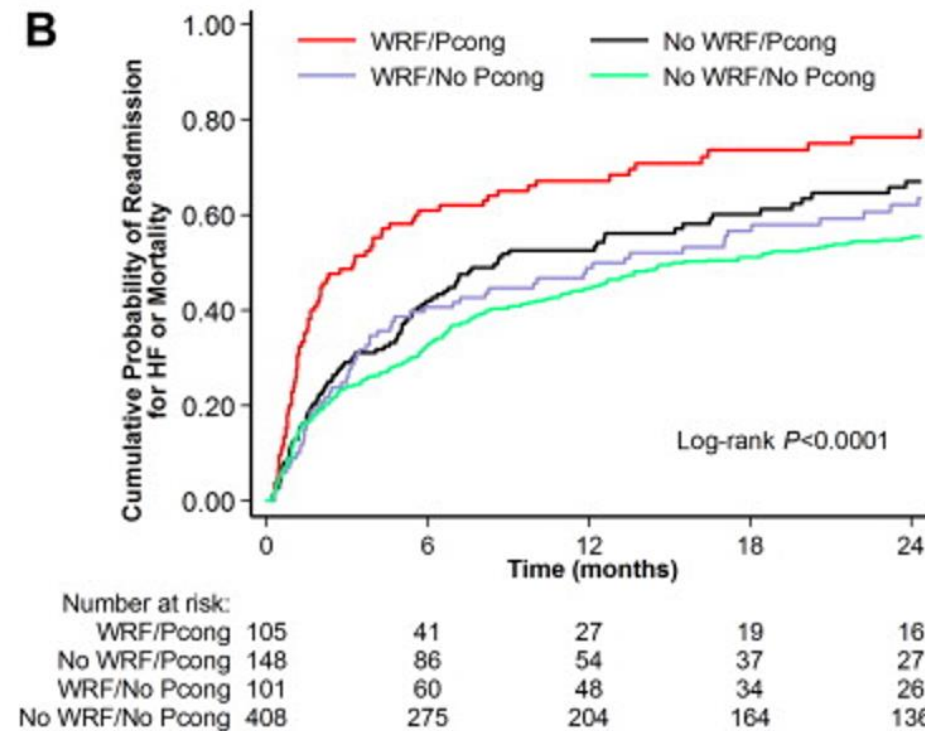
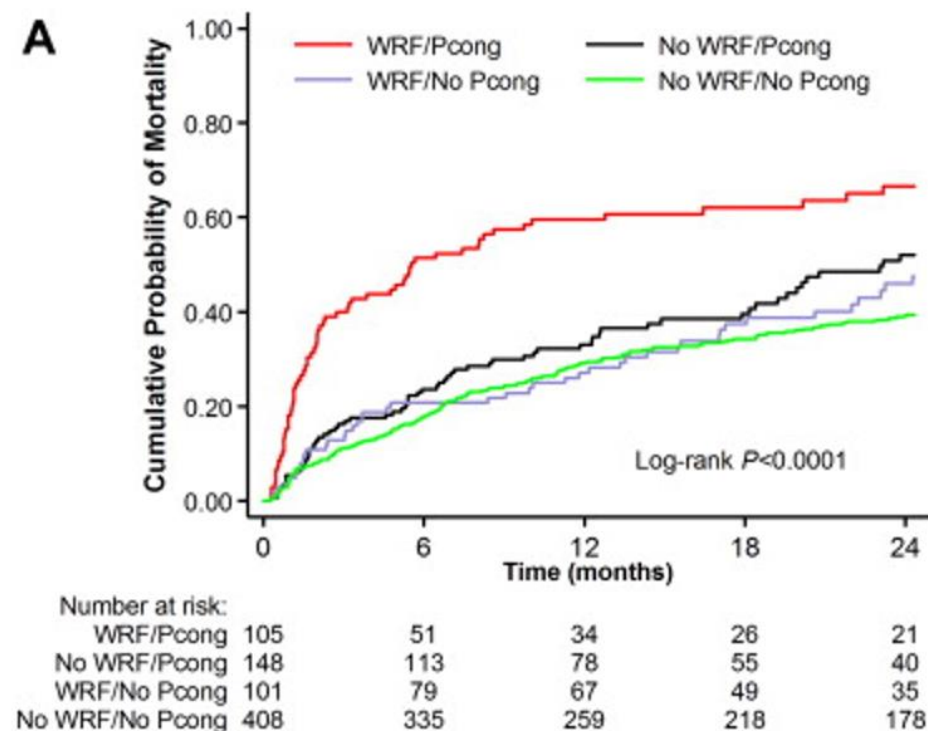
– Dr. Testani, Yale

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

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

Persistent Congestion and WRF are key targets in ADHF

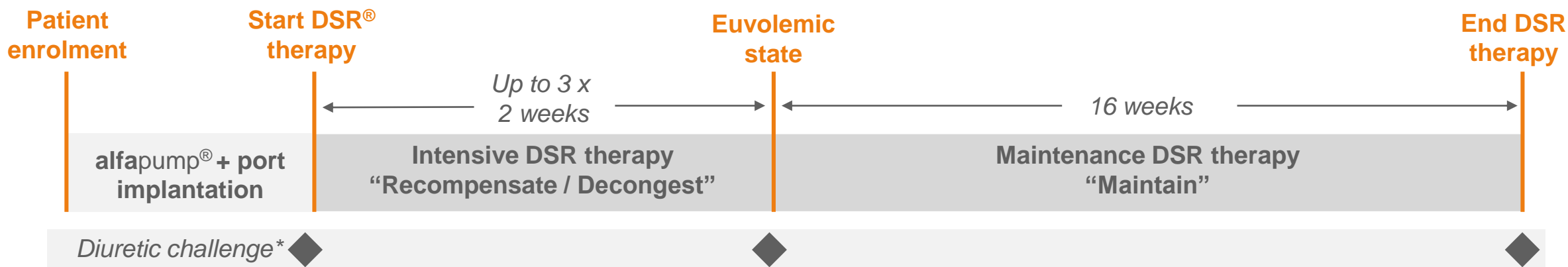
Key drivers of mortality and re-hospitalisation



Wattad et al, American Journal of Cardiology, 2015: interaction between worsening renal function and persistent congestion in acute decompensated heart failure (study of 762 patients)

SAHARA DESERT: Targeting persistent congestion

20 decompensated heart failure patients with persistent congestion on high dose diuretics – ongoing



Study Endpoints

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

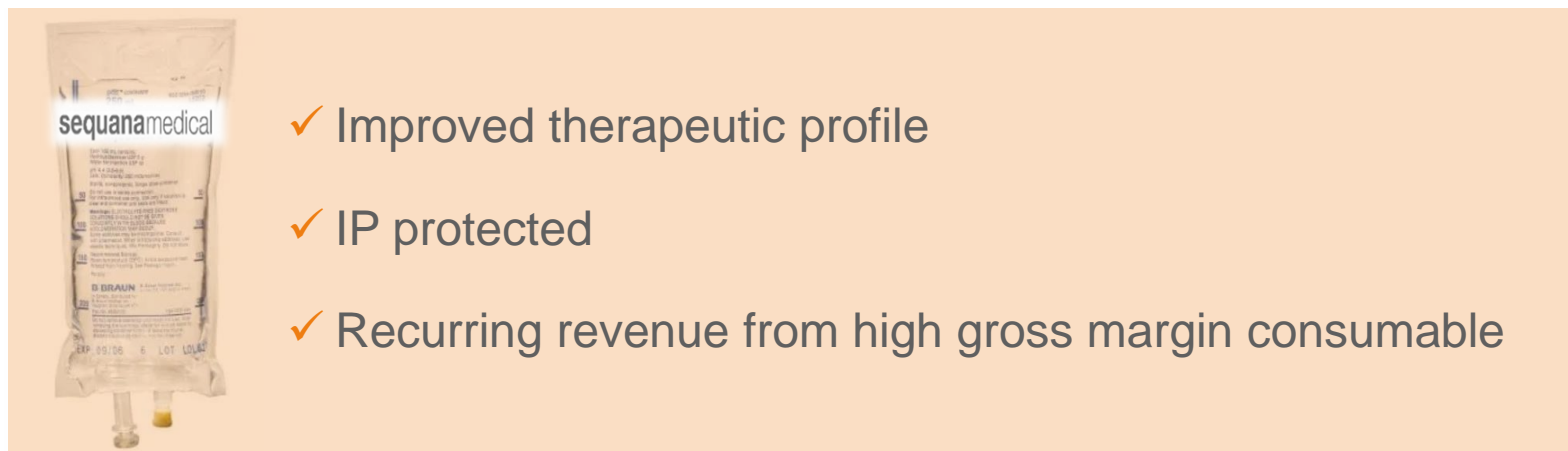
Interim results expected Q4 2021 / Top-line results expected H2 2022

* 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

Developing our proprietary DSR® Infusate 2.0

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



- ✓ Improved therapeutic profile
- ✓ IP protected
- ✓ Recurring revenue from high gross margin consumable

Note: This image is intended for illustration purposes only

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 **alfapump**[®])

Long-term alfapump DSR[®] therapy:

- Intermittent, recurring, intensive DSR treatment
- With **alfapump**



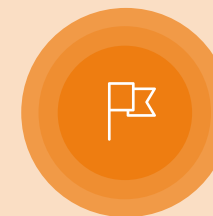
Faster adoption by
clinical community



Support **alfapump** DSR
market entry



Expand potential market
opportunity



Target earlier entry into
the US

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

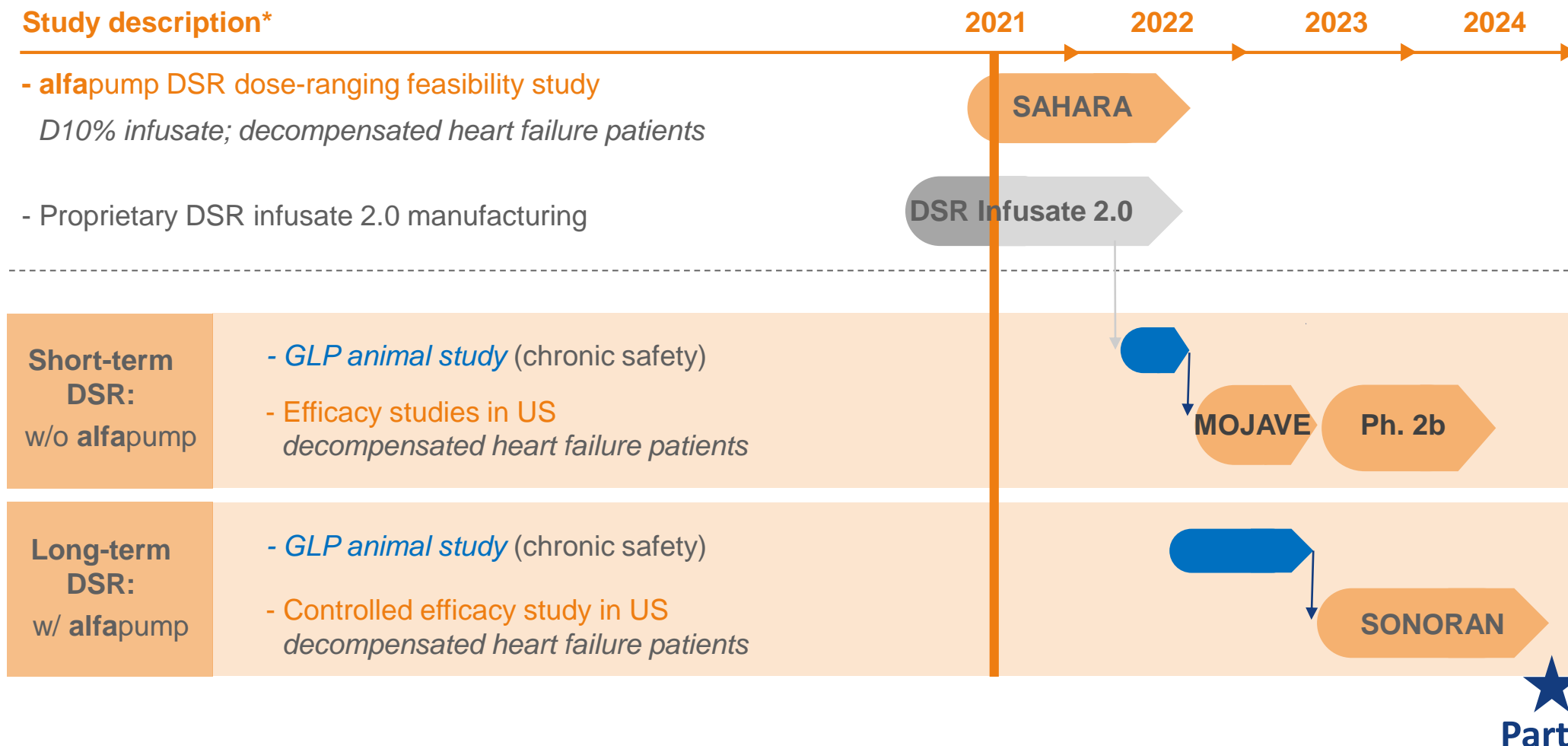
DSR[®] and alfapump DSR[®] development strategy

Short-term DSR therapy extends portfolio

Study description*

- alfapump DSR dose-ranging feasibility study
D10% infusate; decompensated heart failure patients

- Proprietary DSR infusate 2.0 manufacturing



* 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**

Building Sequana Medical on two platforms

Complementary approaches to diuretic-resistant fluid overload

alfapump®

alfapump DSR®

DSR®

Liver Disease /
NASH &
Malignant Ascites

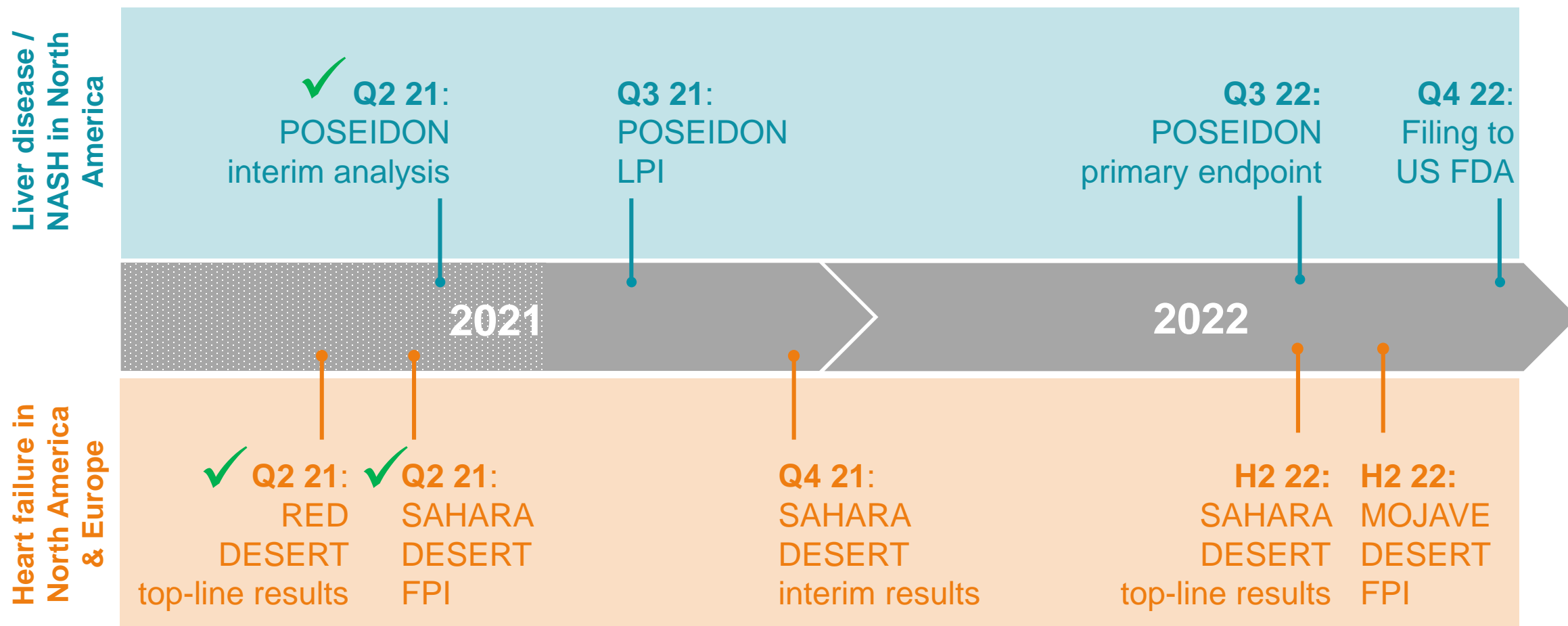
Heart Failure
Decongestion

Long-term
therapy

Short-term
therapy

*Evaluating Renal Failure
Fluid Overload*

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

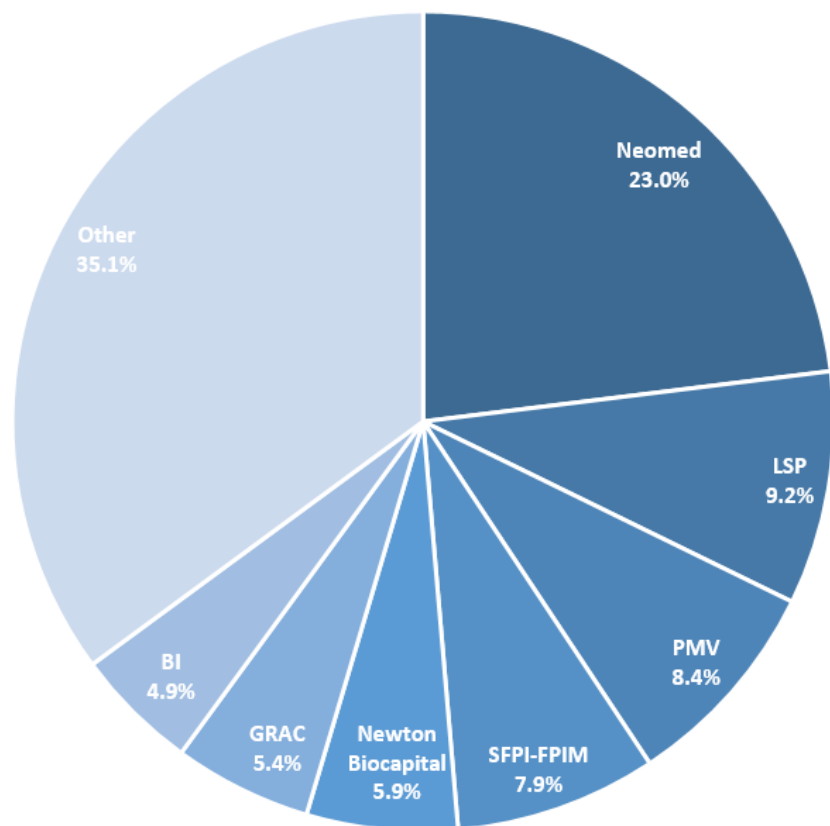


Erik Amble
Director

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 **alfapump**®
- For primary and secondary endpoint analysis

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

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



Recurrent or refractory ascites – patient profile

26 patients from the Roll-In Cohort in the POSEIDON study

Age (mean)	63 y
MELD score (mean \pm SD)	10.3 \pm 3.9
Cirrhosis etiology	
- Alcohol	- 50.0%
- NASH	- 23.1%
- NASH / Alcohol	- 3.8%
- Alcohol / Hepatitis	- 11.5%
- Alcohol / Primary Sclerosing Cholangitis	- 3.8%
- Hepatitis C	- 3.8%
- Budd Chiari Syndrome	- 3.8%
TP per month prior to study (mean \pm SD)	3.8 \pm 1.4

N. American patients are treated early in their disease

NASH is becoming a major driver of ascites market

Higher number of TP compared to Europe



Roll-In Cohort: Substantial and durable reduction in Therapeutic Paracentesis (TP)

Mean values	Primary efficacy endpoint Pivotal Cohort	Interim data Roll-In Cohort (N = 26)
% reduction in monthly frequency of TP	> 50% ⁽¹⁾	> 90% ⁽²⁾
% patients with >50% reduction in TP	> 50% ⁽¹⁾	100% ⁽²⁾

(1) Monthly frequency of TP during 3-month post-implant observation period (month 4 to 6) vs 3-month pre-implant observation period

(2) Monthly frequency of TP during period up to 12 months post-implant vs one month prior to implant (medical history)

Substantial reduction in TP well beyond 6 months post-implantation with alfapump®

* 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

TP: Therapeutic Paracentesis



Roll-In Cohort: Safety in line with expectations

Primary safety endpoint:

- Rate of **alfapump** related re-interventions adjudicated by Clinical Events Committee (CEC)

Interim data Roll-In Cohort (N=26):

- No unanticipated adverse device effects
- Three patients experienced a composite primary safety event as adjudicated by CEC:
 - Hematuria after car accident – **alfapump** explant 1 in 1 patient
 - Wound dehiscence – **alfapump** explant 1 in 1 patient
 - Arterial injury during implantation – patient died 1 in 1 patient

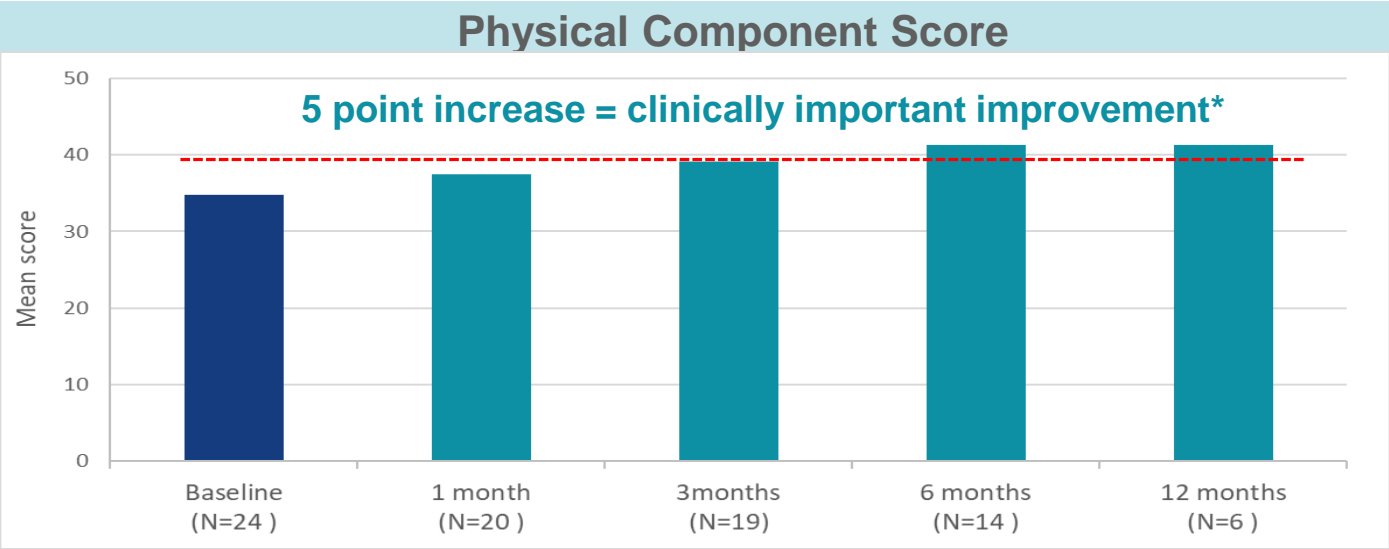
“Safety data reassuring for the potential of the alfapump as a long-term treatment in this fragile patient population” – Prof. Wong, Principal Investigator POSEIDON



Roll-In Cohort: Clinically important improvement in quality of life maintained up to 12 months

SF-36

General health-survey questionnaire

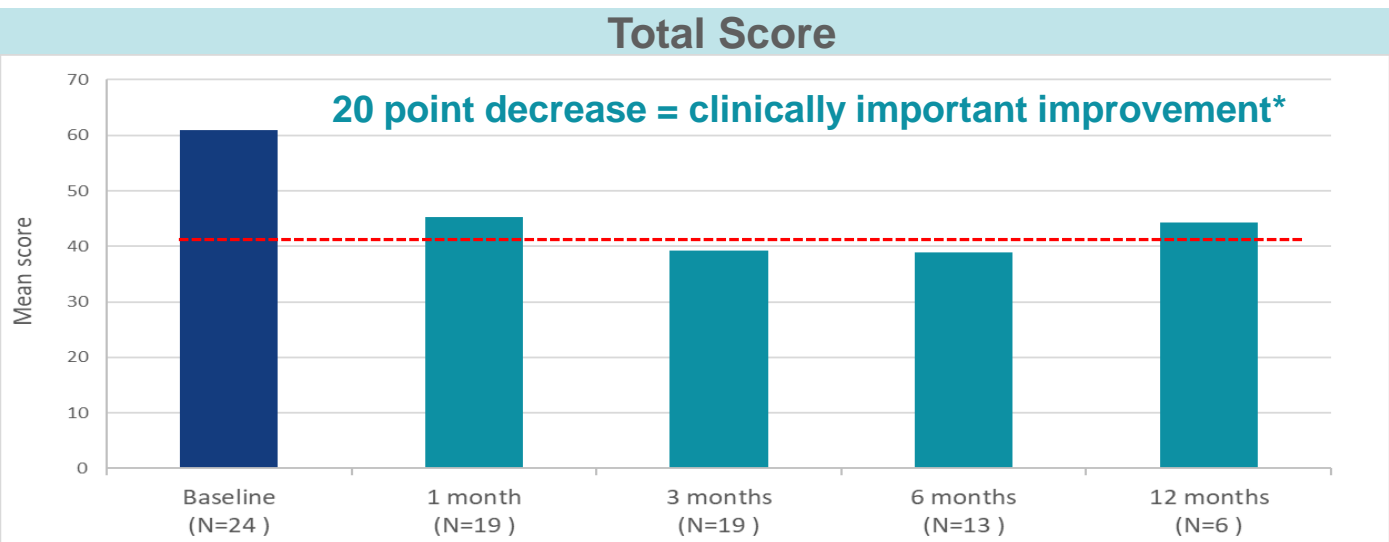


Higher is better



Ascites Q

Specific health-survey questionnaire for ascites



Lower is better



* Clinically important improvement: exceeding the threshold for Minimal Clinically Important Difference



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



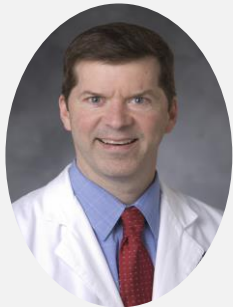
Dr. Javed Butler

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



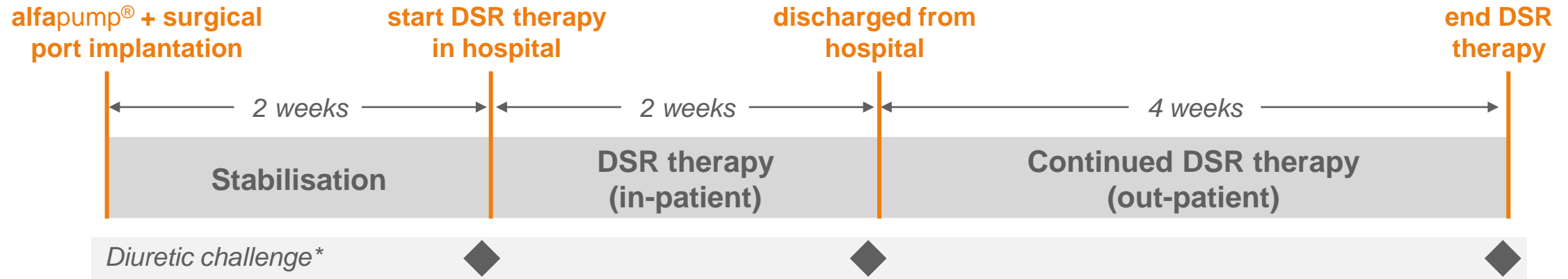
Dr. Udelson

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



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 **alfapump** 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

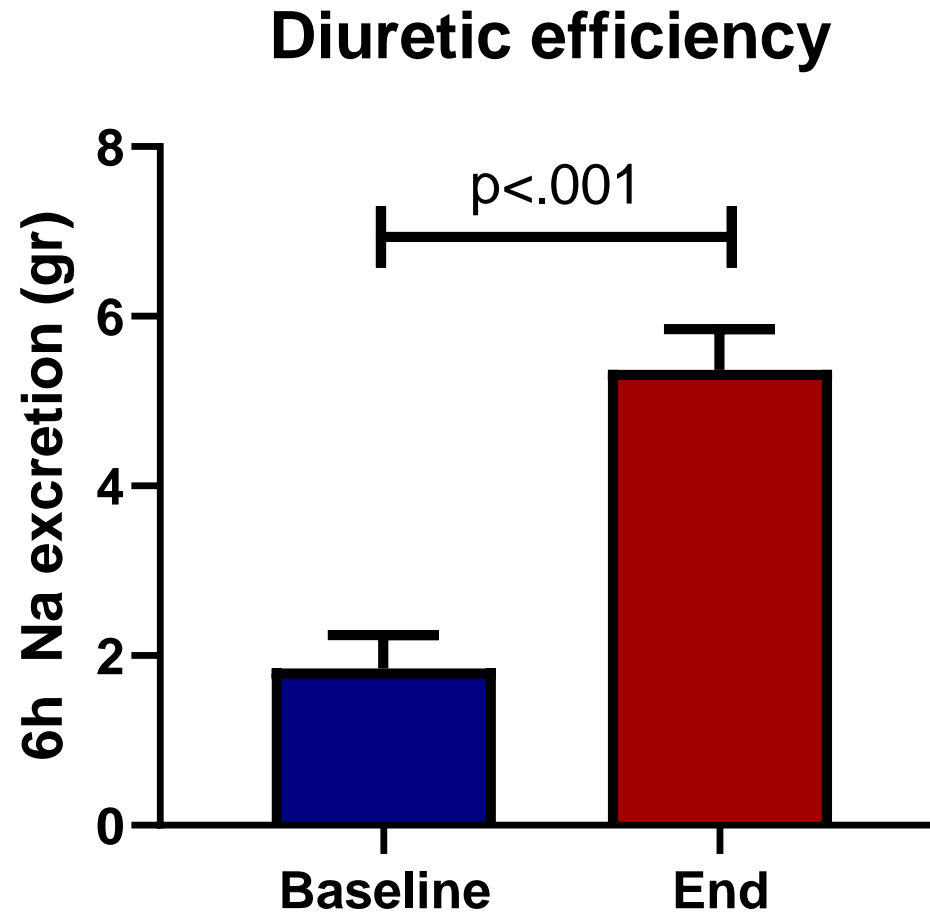
** loop diuretics in furosemide equivalents (mg)

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



RED DESERT – Dramatic improvement in diuretic efficiency

Over 150% 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)***	Time since last DSR study treatment**	Current Daily dose (mg)***	Reduction in diuretic dosage
	At baseline			
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

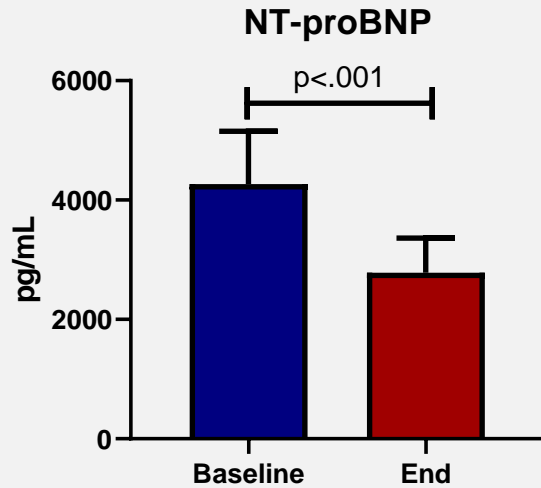
** excluding DSR treatment in follow-up extension

*** loop diuretics in furosemide equivalents (mg)

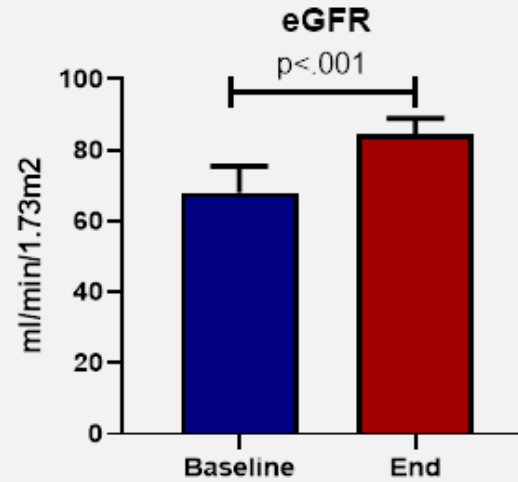
E3D: every third day; BIW: two times per week; TIW: three times per week



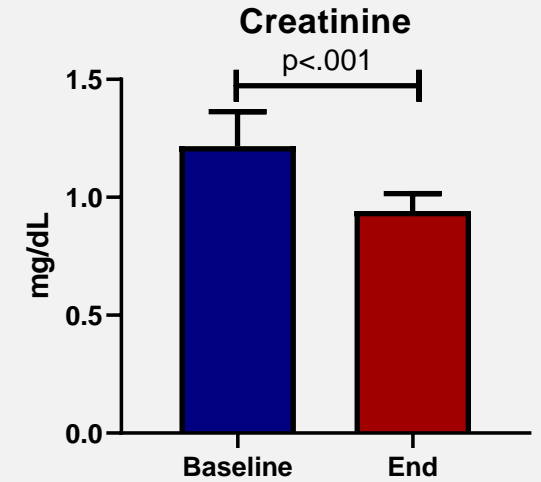
RED DESERT – Significant improvement in cardio-renal function*



**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

Evaluating potential for DSR® in renal failure

Complementary opportunity leveraging heart failure programme capabilities

- Like heart failure, kidney failure / dialysis is one of the leading burdens for healthcare systems and carries a high mortality / morbidity burden
- Hemodialysis seeks to tackle two different challenges – removal of uremic toxins as well as managing the sodium and fluid balance – creating clinical and economic challenges
- DSR therapy has the potential to more effectively manage the fluid and sodium balance of this large patient group
 - ⇒ Leveraging all of our experience from congestion / fluid overload in heart failure
- We are exploring the potential of DSR in this large and important patient group, potentially reducing hospitalisations, the cost and burden of hemodialysis therapy as well as mortality
 - ⇒ Supporting work of Dr McIntyre (Lawson Health Research Institute, Ontario, Canada): evaluating the use of DSR therapy in effective volume management and sodium removal in prevalent hemodialysis patients (NCT04603014)



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