sequanamedical

Innovators in the treatment of diuretic-resistant fluid overload

liver disease – malignant ascites – heart failure

H.C. Wainwright 23rd Annual Global Investment Conference

September 13-15, 2021 – Ian Crosbie, CEO

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.

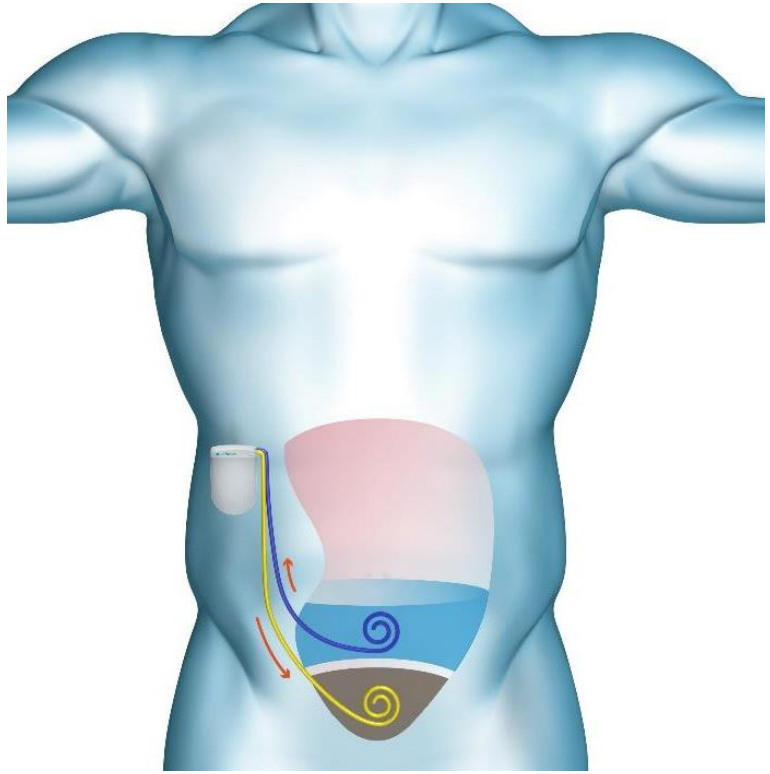
Note:

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

alfapump® platform

Eliminating fluid from the peritoneal cavity – working in partnership with the bladder

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



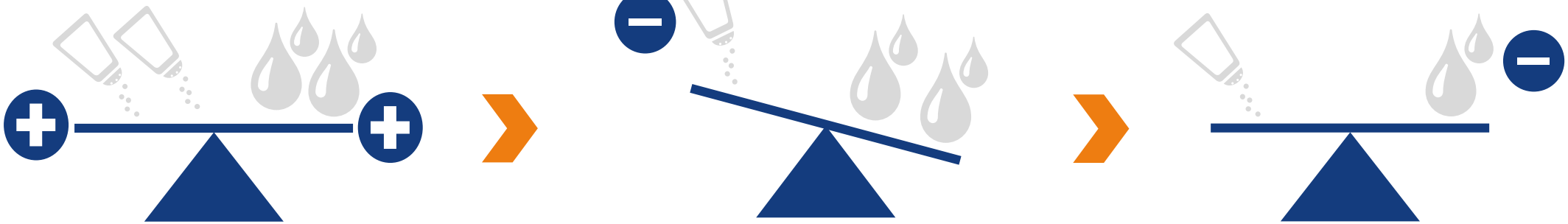
- Easy implantation
- Long-term implantation & catheter patency
- Moves up to 4 litres / day
- Virtually non-clogging
- No significant heating during charging and operation

Strong IP barriers through extensive patent portfolio & know-how

Direct Sodium Removal (DSR®) platform

Eliminating fluid spread across the body – working in partnership with the kidneys

Key Principle



Excess fluid in balance with excess sodium

DSR removes the sodium – disrupts the equilibrium

Body eliminates excess fluid to restore the balance

How It Works

1. Sodium-free DSR infusate administered to peritoneal cavity
2. Sodium diffuses from the body into DSR infusate
3. DSR infusate + extracted sodium removed from the body
4. Body eliminates free water to restore balance

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

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 liver ascites 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.

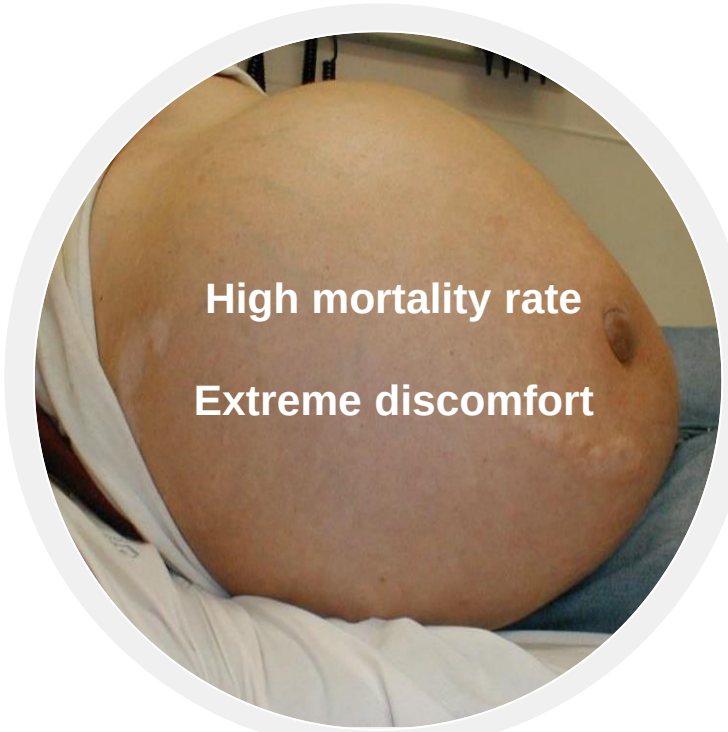
Refractory liver ascites

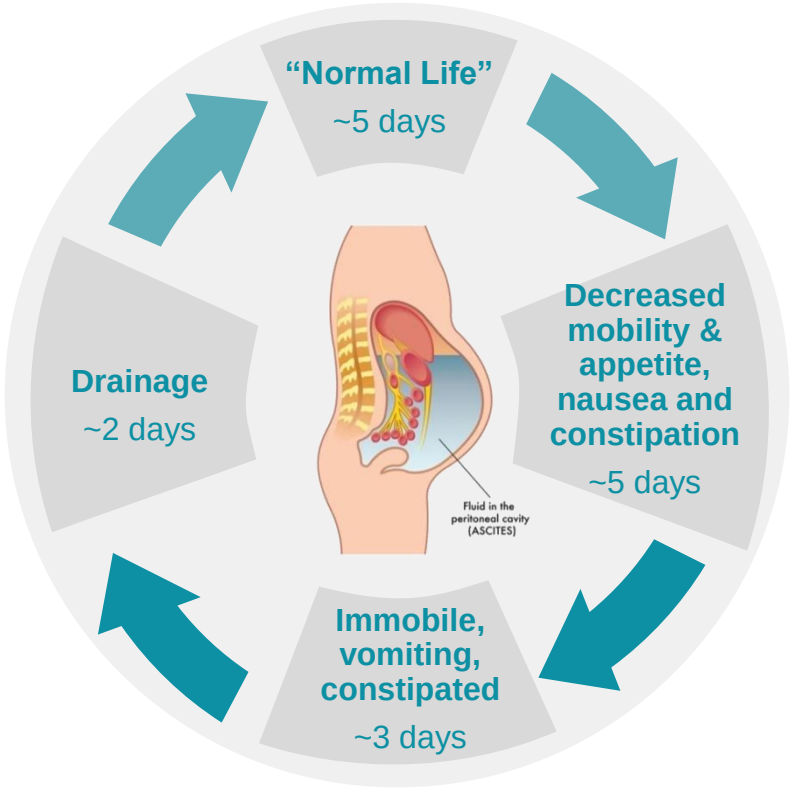
A key complication of liver cirrhosis, with a dramatic impact on quality of life

Viral infections (Hepatitis B & C)

Alcoholic Liver Disease

Non-Alcoholic Steatohepatitis (NASH)





Typical patient life(4)

US forecast

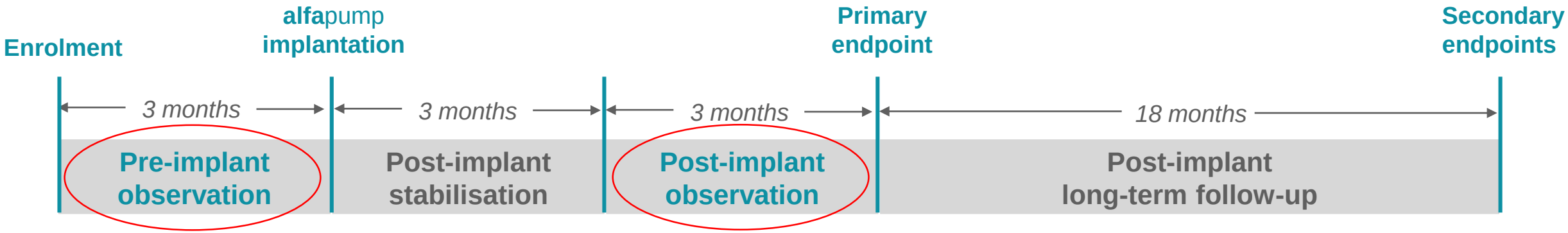
- Liver cirrhosis — ~3-4M (1)
- Ascites — ~1.5M (2)
- Refractory Ascites — ~150K (3)

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

North American Pivotal Study (POSEIDON) underway

Pivotal Cohort of up to 50 implanted patients; 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 26 Roll-In patients

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)
- ✓ 100% patients with > 50% reduction in mean TP frequency per month (primary endpoint >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

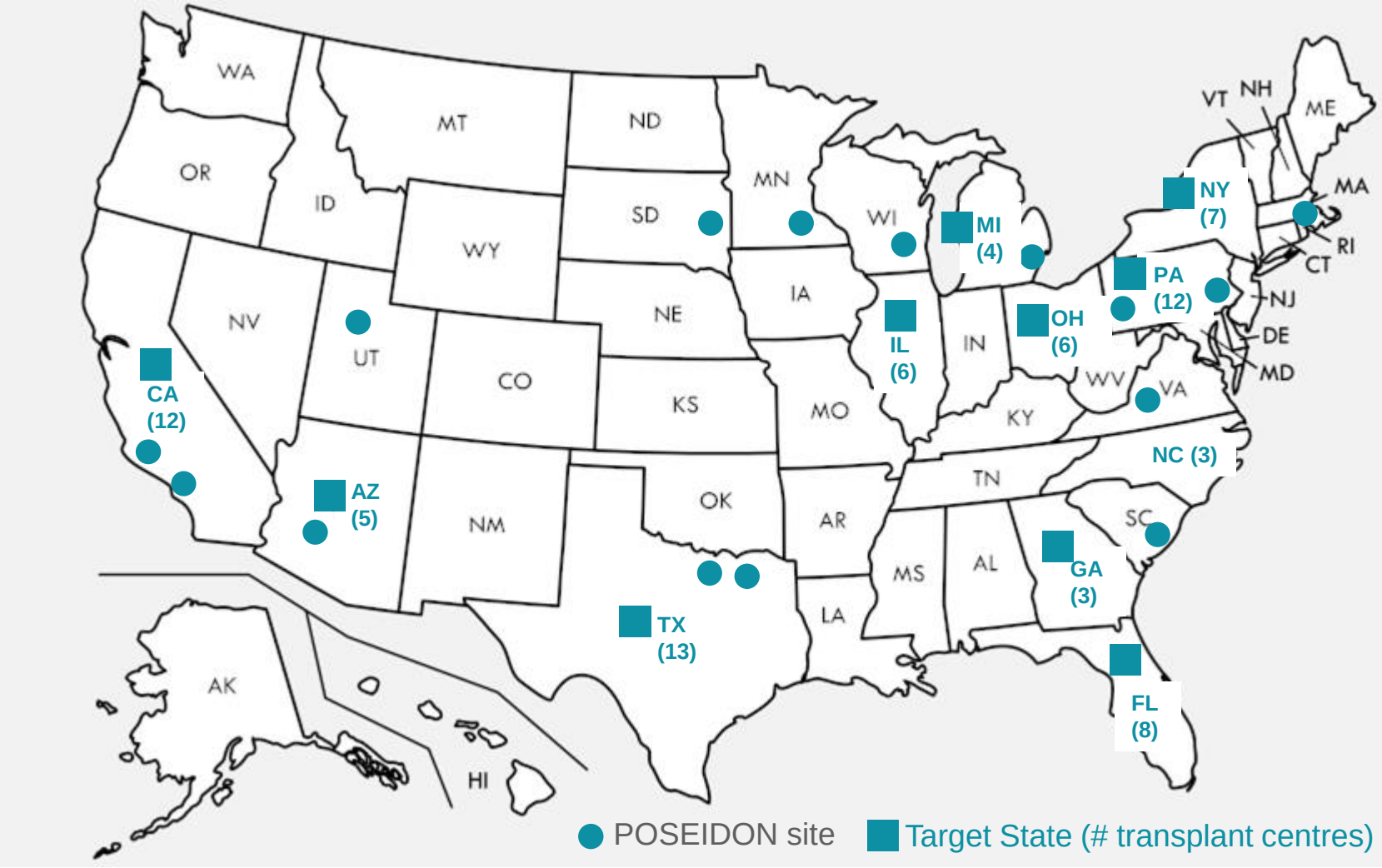
Note: Pre- and post-implant periods for this analysis of the Roll-In Cohort differ from those that will be used for the Pivotal Cohort analysis

Pursuing North American alfapump® approval

- POSEIDON – Submitted protocol amendment to FDA to extend patient enrolment due to the higher attrition rate between enrolment and implantation
- PMA – Submission for regulatory approval expected mid-2023
- Reimbursement – CMS support for breakthrough devices (MCIT, NTAP) derisks coverage and reimbursement for the **alfa**pump

PMA: *Pre-Market Approval*
MCIT: *Medicare Coverage of Innovative Technology;* ***NTAP:*** *New Technology Add-On Payment*

US commercialisation through our specialty salesforce



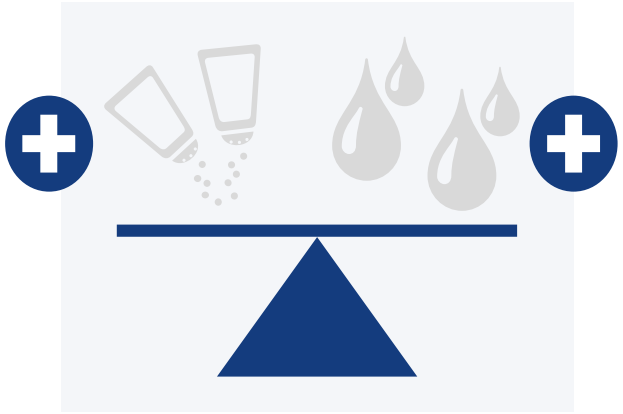
Initial focus on key transplant centres

~50-person team:

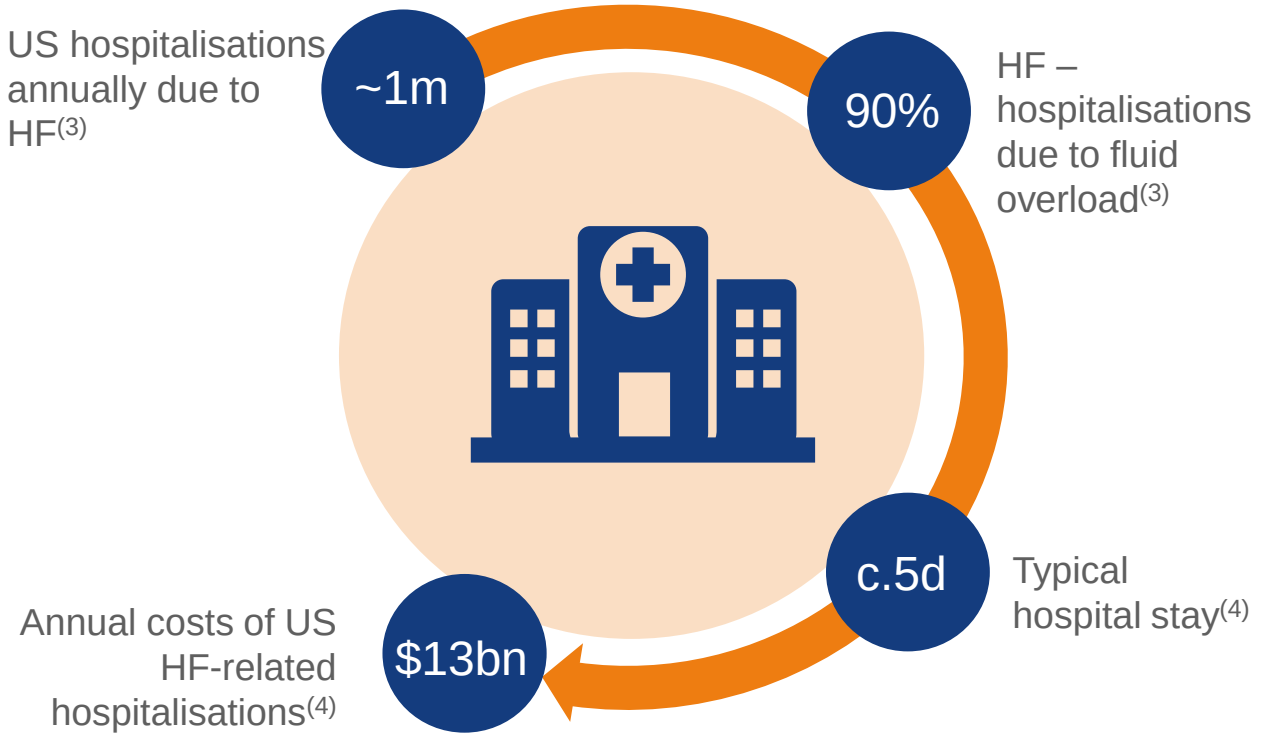
35 sales reps, 10 clinical, 5 corporate

Targeting diuretic-resistant congestion

Clear unmet need and driver of costs for heart failure patients



Excess sodium drives fluid overload

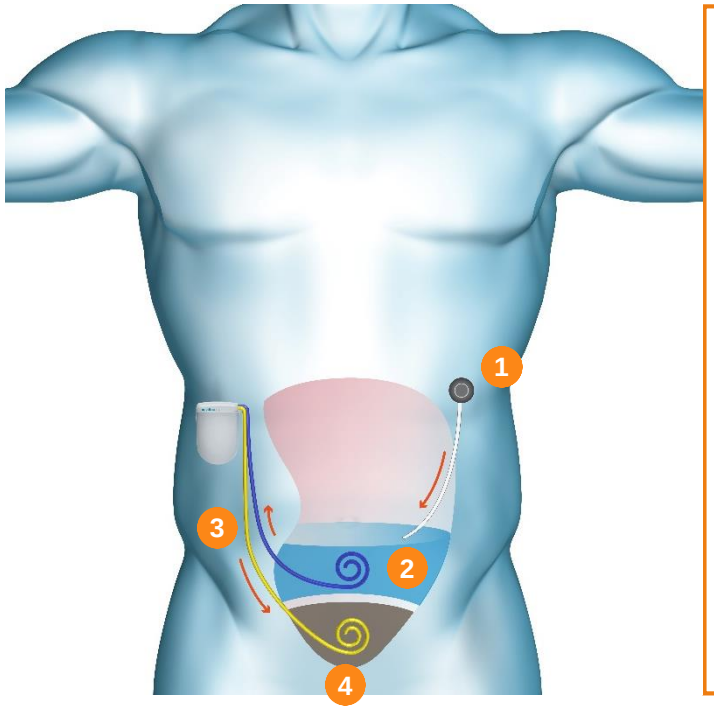


- *40% of heart failure patients on IV loop diuretics have a poor response(1)*
- *24% re-admission rate at 30 days(2)*

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: repeated dose alfapump DSR® study

Eight euvolemic heart failure patients on high dose diuretics

Highly effective management of fluid and sodium balance

- 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

- 30% decrease* in NT-proBNP** (p<0.001)
- 22% increase* in eGFR** (p<0.001)
- 22% decrease* in creatinine** (p<0.001)

Presented as Late-Breaker and Highlight at Heart Failure 2021

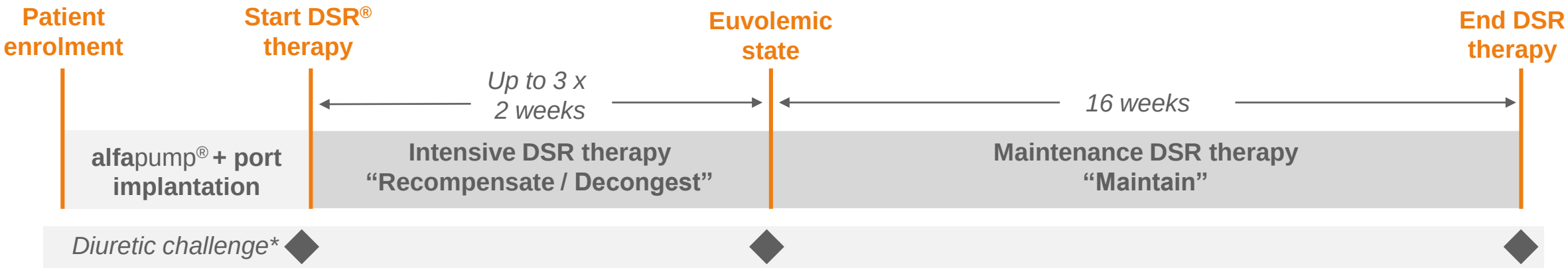
"Simultaneous normalisation of diuretic response and improvement in cardio-renal status is a never before seen treatment effect" – Dr. Testani, Yale

** Paired statistical analysis of patients with baseline and D42 value (N=7); ** mean value ***median follow-up*

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

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 **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*

Proprietary DSR® Infusate 2.0 drives value model

- 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® – Derisking & extending franchise

Simplifying Regulatory Process and Preparing for alfapump DSR market entry

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

Faster adoption by clinical community

Support **alfa**pump DSR market entry

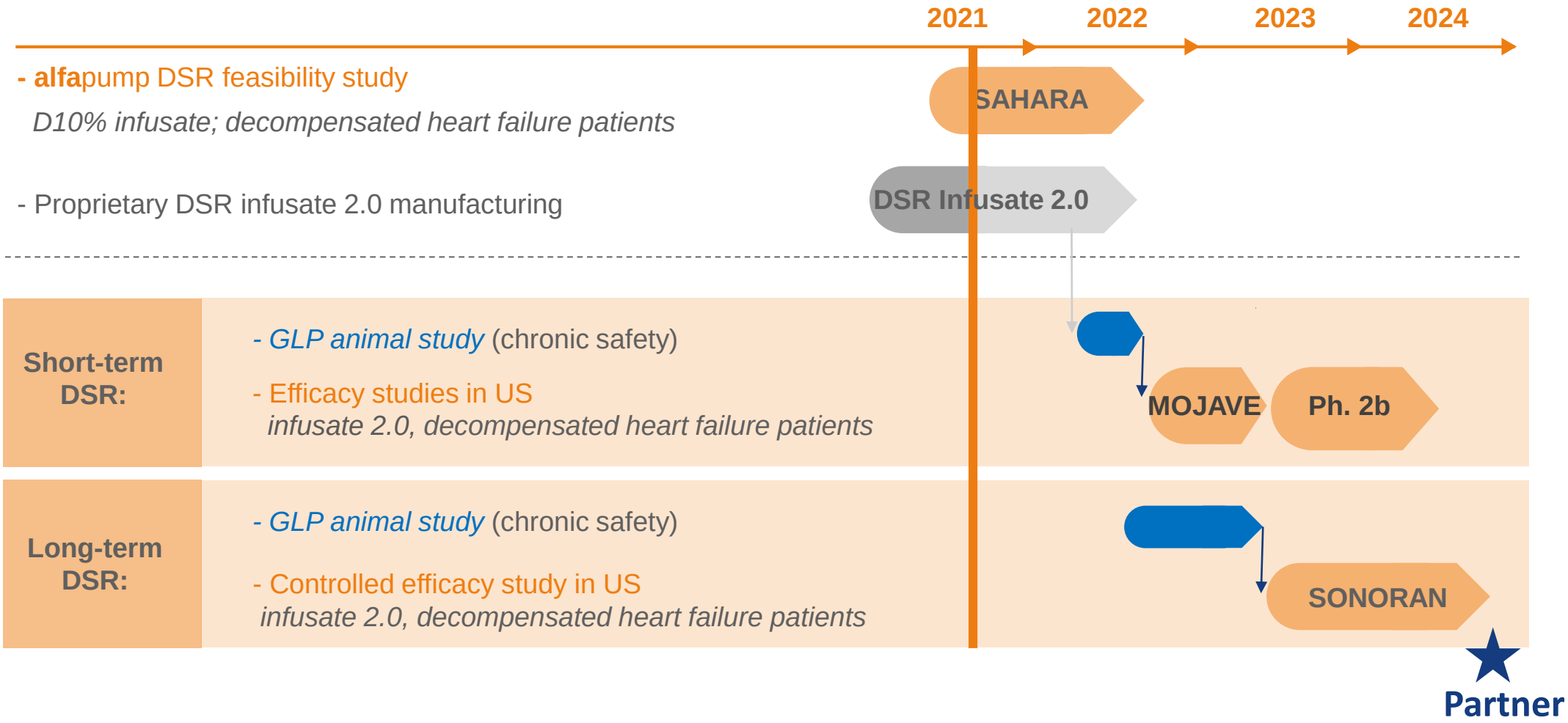
Expand potential market opportunity

Target earlier entry into the US

Tackling residual congestion and restoring diuretic response and cardio-renal status in diuretic-resistant heart failure patients

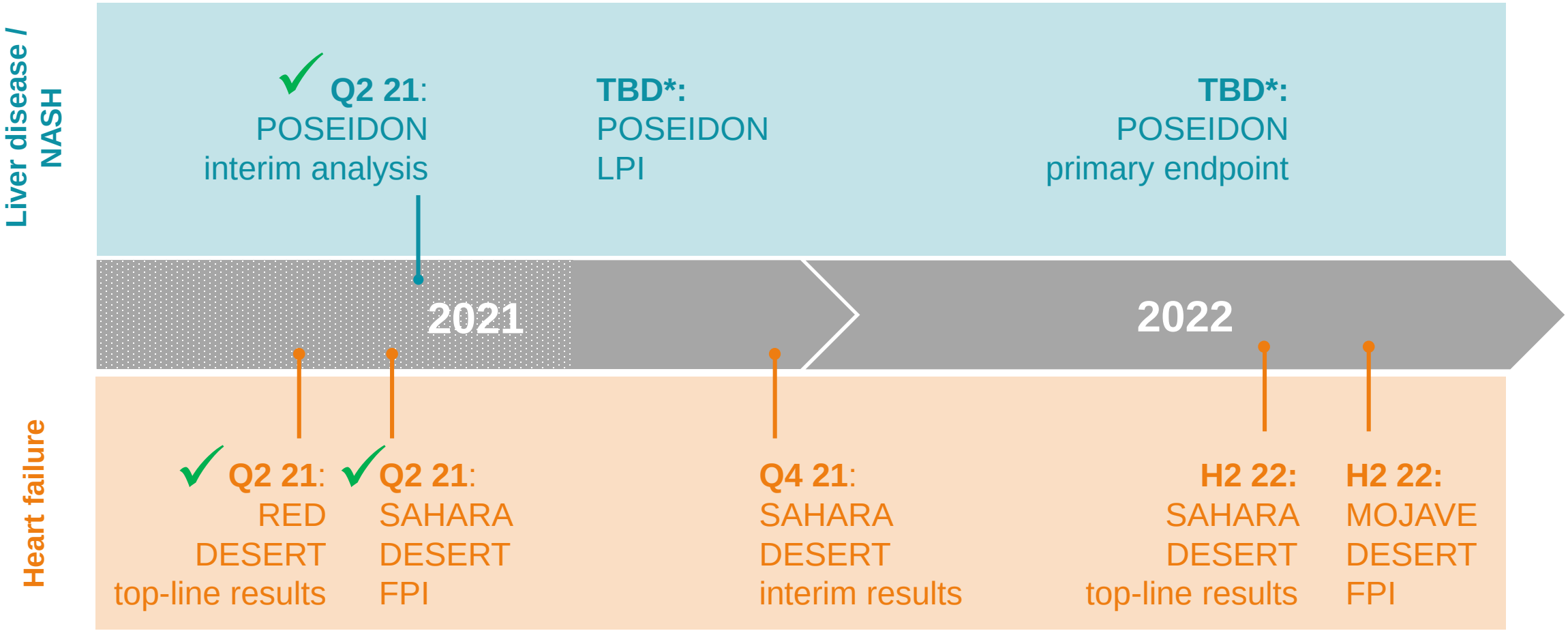
DSR® - robust development program*

Step-by-step approach to introduction of breakthrough therapy



** 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

Strong outlook for value drivers



** Pending further clarity from the FDA on study expansion – the Company will update the market as soon as possible*

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

***FPI:** First Patient In; **LPI:** Last Patient In*

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