sequanamedical

Webcast presentation – 7 December 2021

# alfapump DSR®

# SAHARA DESERT

# Interim Results

# Today's presenters

**Ian Crosbie**
Chief Executive Officer

**Oliver Gödje**
Chief Medical Officer

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- 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.

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- 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 the Benelux, China, the EU, United Kingdom, and Hong Kong.

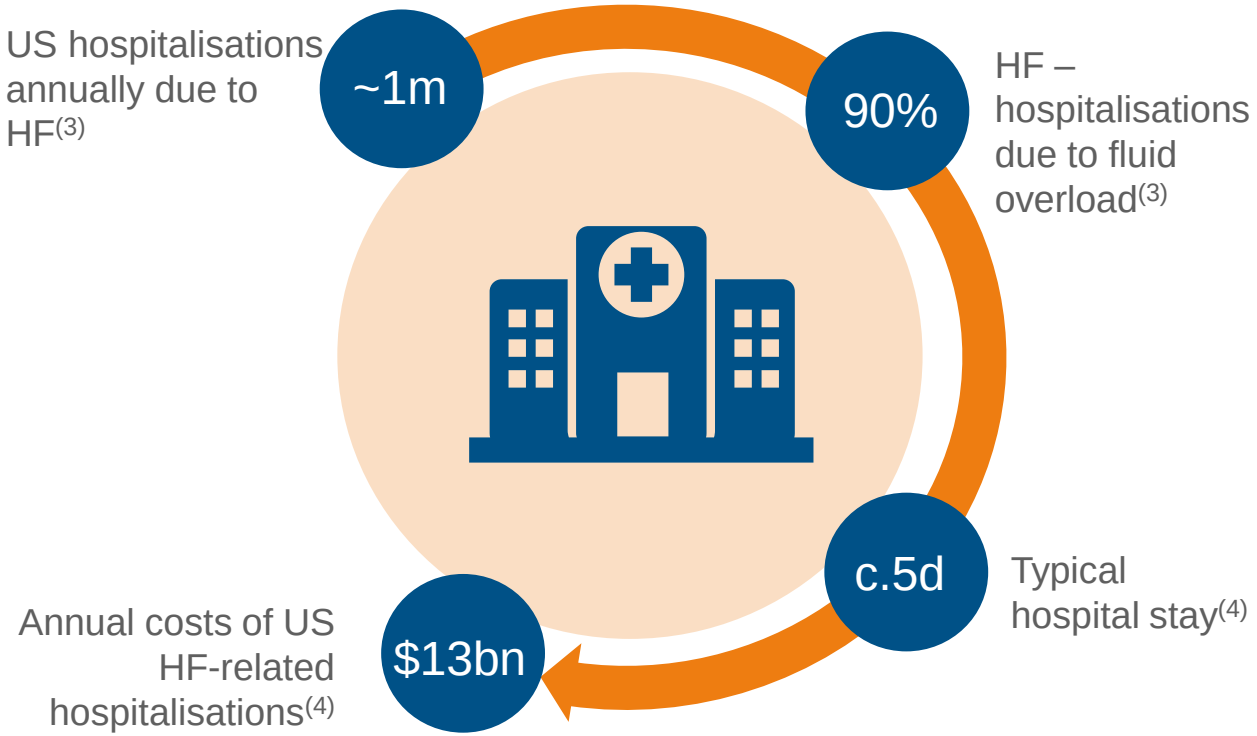
# SAHARA DESERT: Strong interim results

**Six diuretic-resistant heart failure patients with persistent congestion treated with alfapump DSR®**

- ✓ Indication of the ability of repeated DSR® therapy to
  - ✓ Safely, effectively and rapidly eliminate persistent congestion and restore euvolemia
  - ✓ Considerably benefit cardio-renal status
  - ✓ Dramatically improve diuretic responsiveness for months post-treatment
- ✓ Recruitment on-track to report top-line data in H2 2022
- ✓ Long-term follow-up of RED DESERT patients shows durable improvement in diuretic response
- ✓ Proprietary DSR Infusate 2.0 development on track to start MOJAVE DESERT in H2 2022

# Diuretic-resistant congestion in heart failure

**Clear unmet clinical need and driver of costs for heart failure patients**




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

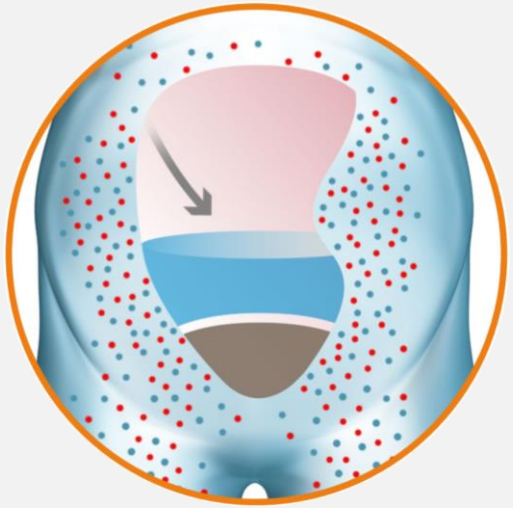


*Source 1: Testani, Circ Heart Failure, 2014 & 2016; Source 2: Ross et al. (2010); Source 3: Costanzo et al., J. Am. Coll., 2007; Source 4: Kilgore et al. (2017)*

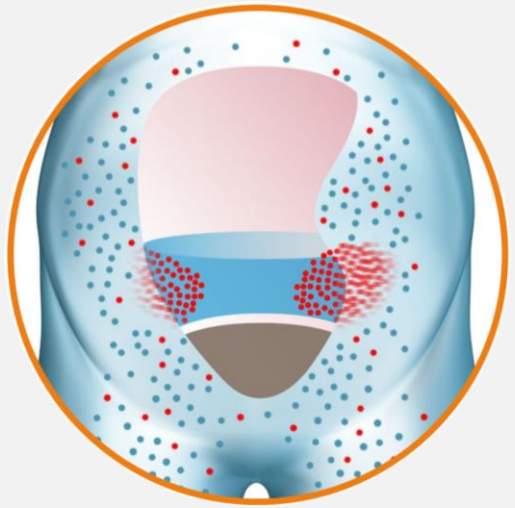
# Direct Sodium Removal (DSR®) platform

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

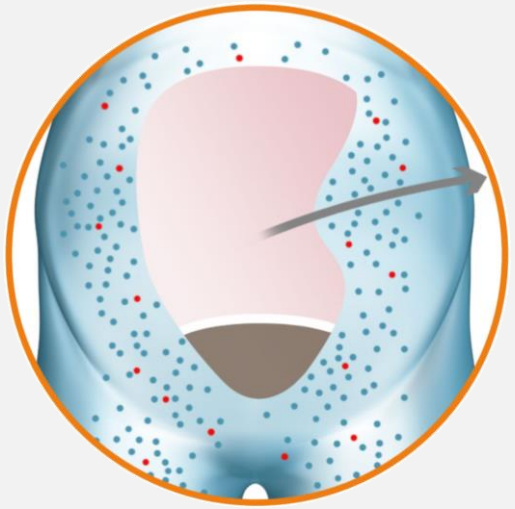
1. **Sodium-free DSR infusate administered to peritoneal cavity**



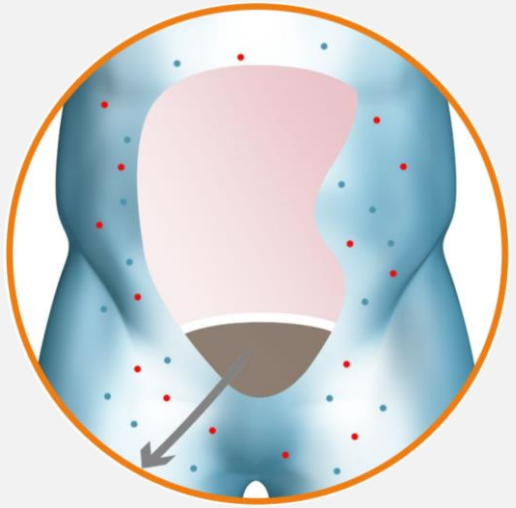
2. **Sodium diffuses from body into DSR infusate**



3. **DSR infusate + extracted sodium removed from the body**



4. **Body eliminates free water to restore sodium balance, reducing the fluid overload**

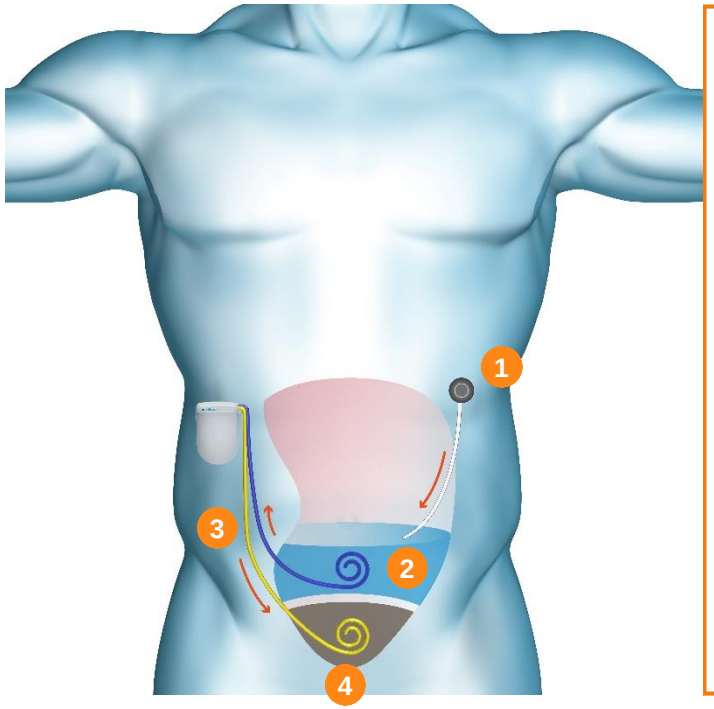


- water
- sodium

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

# alfapump DSR® leveraging proven alfapump® platform

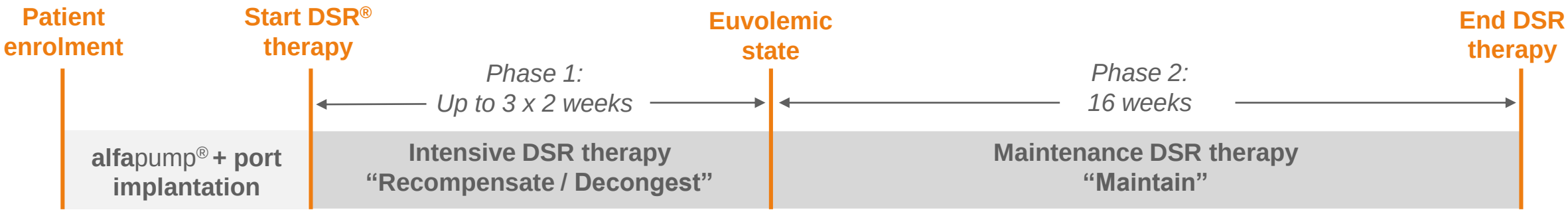
**Fully implanted system for long-term DSR® therapy**




1. Sodium-free DSR infusate administered to peritoneal cavity via implanted subcutaneous 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

# SAHARA DESERT: Targeting persistent congestion

**20 decompensated heart failure patients with persistent congestion on high dose 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*

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

# Interim analysis: 6 severe heart failure patients with persistent congestion on high dose diuretics

| Mean values at baseline of 6 patients in interim analysis | |
|---|---|
| Left ventricular ejection fraction: | low 20% |
| NT-proBNP: | >6,000 pg/mL |
| Furosemide equivalent dose: (standard of care) | ~250 mg/day |

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

| Study status of 6 patients in interim analysis | |
|---|---|
| Phase 1: | n = 2 (1 complete, 1 ongoing) |
| Phase 2: | n = 4 (1 complete, 3 ongoing) |

# Interim analysis: Strong efficacy results

**Interim data from six patients indicate that alfapump DSR® therapy can:**

- Safely, effectively and rapidly eliminate persistent congestion and restore euvolemia without any loop diuretics
  - ⇨ Weight loss* of ~6kg (=7% of body weight) vs. baseline
  - ⇨ 3 patients required 1 x 2 weeks dosing in phase 1; 3 patients required 2 x 2 weeks dosing in phase 1
    - ➢ All patients only required reduced dosing intensity after first week of therapy
- Considerably benefit cardio-renal status
  - ⇨ Reduction* in NT-proBNP of more than 30% vs. baseline
  - ⇨ eGFR* and creatinine* similar to baseline; remarkable result since worsening in kidney function during significant volume removal is the expectation in such severely ill diuretic-resistant heart failure patients
- Dramatically improve diuretic responsiveness for months post-treatment
  - ⇨ End of phase 1 (n=6***): more than doubling* of sodium excretion** (near normal levels)
  - ⇨ 3 months* after end of Phase 1 (n=4): less than 10% of their baseline loop diuretic dose

***"These interim results are highly encouraging and could potentially provide a course of therapy for severely ill diuretic-resistant heart failure patients with persistent congestion where alternative treatment options are currently exceedingly limited" – Dr. Testani***

**mean value; ** assessed by 6-hour excretion of sodium after IV administration of 40mg furosemide *** one patient has completed first 2-week dosing in phase 1 and is about to enter repeat 2-week dosing in phase 1*
***NT-proBNP**: N-terminal-pro hormone B-type Natriuretic Peptide (analysed in local lab); **eGFR**: estimated glomerular filtration rate*

# Interim analysis: Repeated alfapump® DSR therapy was safe and well-tolerated

- No clinically significant changes in serum sodium levels or other electrolytes after intensive DSR therapy

- Reported adverse events were manageable:
  - ⇨ Diarrhea (1 patient)
  - ⇨ Catheter blockage (1 patient)
  - ⇨ Smart charger communication error (2 patients)

# SAHARA DESERT: Enrolment

- Overall, 9 patients have been enrolled and implanted with **alfa**pump DSR® across 2 sites
  - 6 patients were evaluated for interim analysis
  - 2 further patients just started study treatment*
  - 1 further patient was enrolled but died due to a cardiac arrest three days after study initiation*
    - ⇨ Study site: not related to study therapy, procedure or device
    - ⇨ Data Monitoring Committee: possibly related to study therapy; not related to procedure or device
- Completion of patient enrolment expected in H1 2022
- Reporting of top-line data expected in H2 2022

** excluded from interim analysis*

# RED DESERT: Long-term follow-up of patients

## Durable improvement in diuretic response following alfapump DSR® therapy

| Subject | Daily dose of loop diuretics** | | Time since last DSR treatment in the study | Current known daily dose*** | Currrent known reduction in diuretic dose |
|---|---|---|---|---|---|
| | At screening | During DSR treatment (D0 – D42) | | | |
| 101-001 | 80 | 0 | 19 months | 40 | **-50%** |
| 101-002 | 200 | 0 | 19 months | 120 | **-40%** |
| 101-003 | 400 | 0 | 16 months | 160 | **-60%** |
| 101-005 | 120 | 0 | 16 months | 40 | **-67%** |
| *101-006 | 80 | 0 | 14 month | 20 EOD | **-88%** |
| *101-007 | 300 (400 EOD + 200 EOD) | 0 | 9 month | 40 BIW | **-96%** |
| *101-008† | 600 | 0 | 9 month | 80 | **-87%** |
| 101-009† | 800 | 0 | NA | NA | **NA** |

** in follow-up extension with DSR; † subject 101-008 died in follow-up extension (9 months after end of study), subject 101-009 died at D3*
*** loop diuretics in furosemide equivalents (mg)*
**** loop diuretics in furosemide equivalents (mg) – status 5 Nov 2021*

***EOD:** every other day; **BIW**: two times per week*

# Strong progress in development of proprietary DSR® Infusate 2.0 for first US DSR study in H2 2022

- CMC activities ongoing & pre-clinical development work on track
- MOJAVE DESERT – first US study of short-term DSR therapy planned to start in H2 2022
  - Diuretic resistant chronic heart failure patients with persistent congestion
  - Treatment algorithm built upon learnings from SAHARA DESERT
  - Infusate 2.0 with peritoneal catheter
  - Creates a more valuable clinical and economic package for partnering

Developing DSR Infusate 2.0 with:

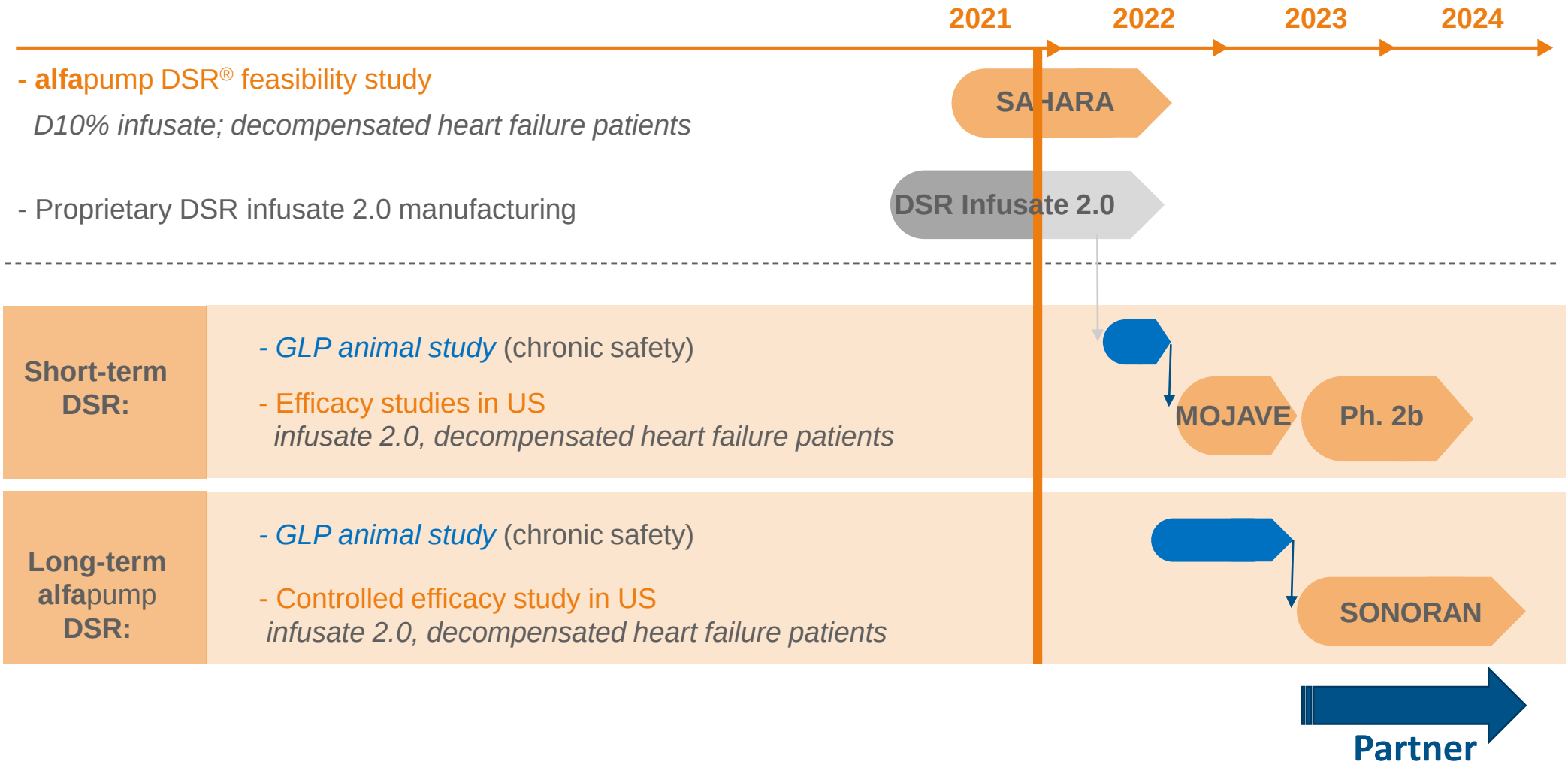
✓ Improved therapeutic profile

✓ IP protection

✓ Recurring revenue from high gross margin consumable

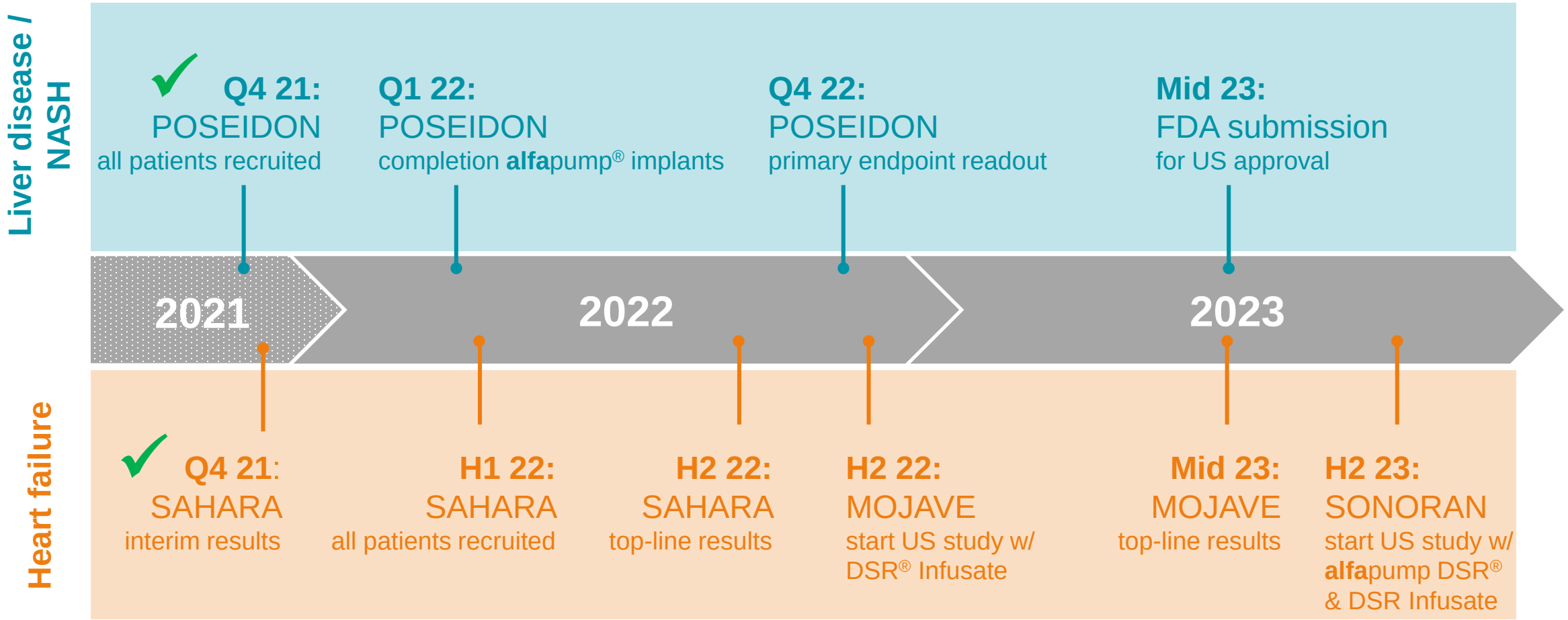
# DSR® – Robust development program*

## 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




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

# Q&A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