sequanamedical

Innovators in the management of fluid overload

liver disease – malignant ascites – heart failure

VFB Happening – 19 September 2020

Ian Crosbie, CEO

Forward-Looking Statements

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Disclaimers

Regulatory disclaimer:

- The **alfa**pump® system is not currently approved in the United States or 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 see 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 **alfa**pump® system in Europe.

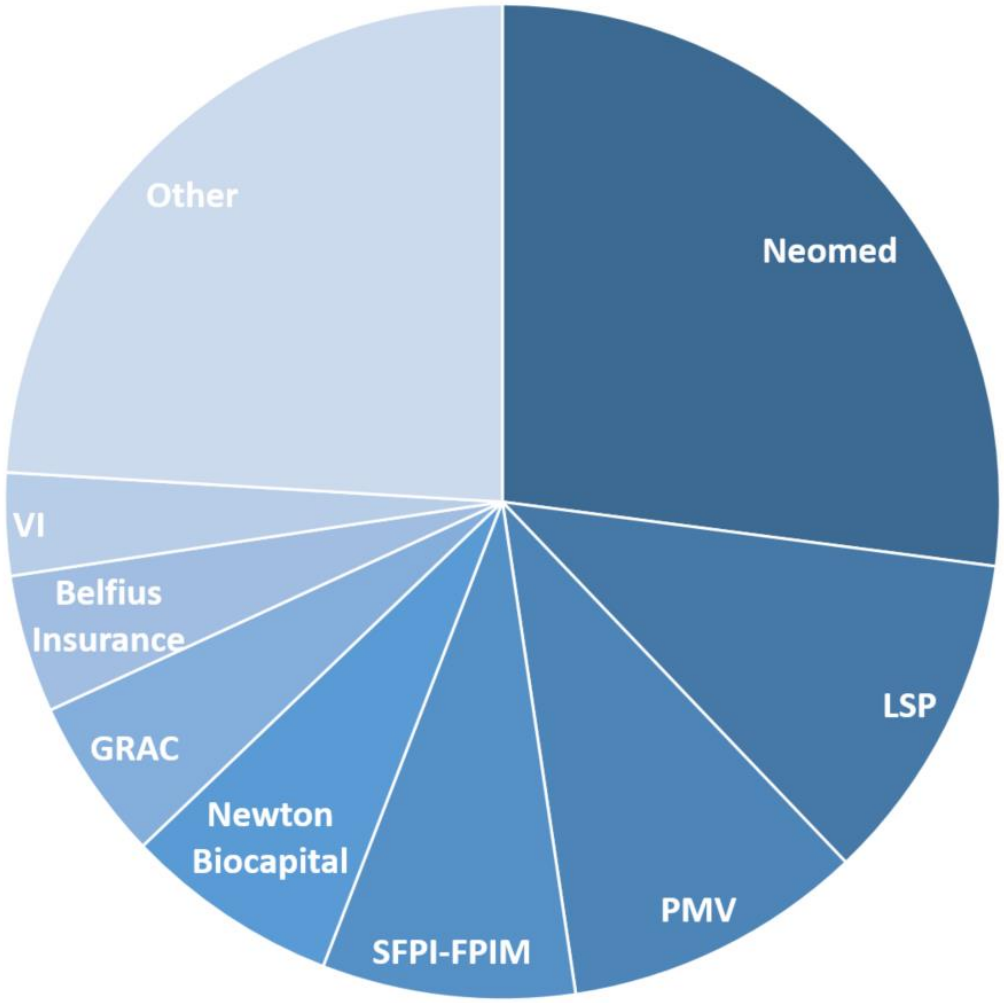
COVID-19 disclaimer:

- 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

Shareholders base and financial overview

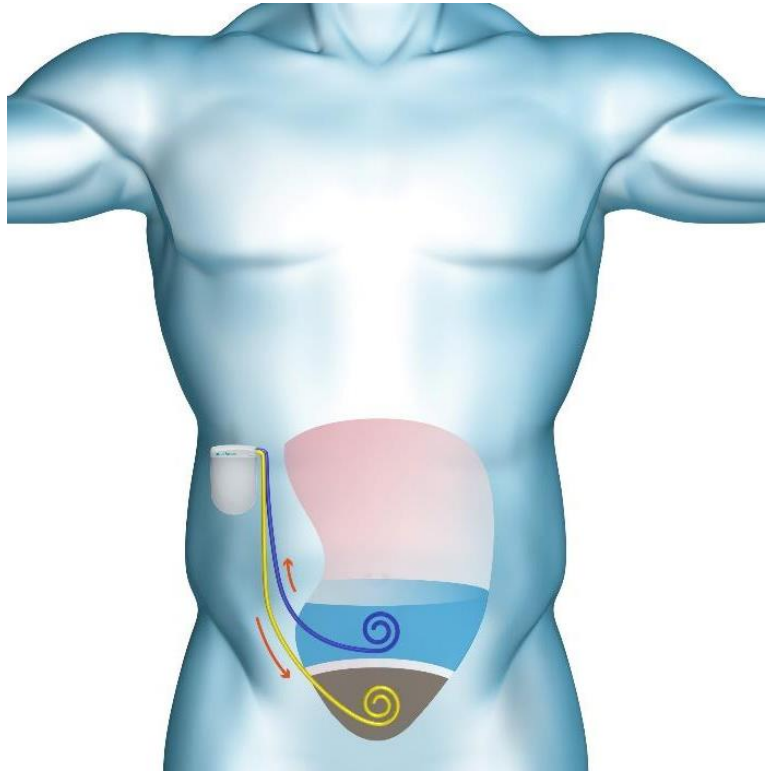


- Cash at 30 June 2020: €14.9M
- Debt financing in July 2020: €7.3M
- **Cash runway into H2 2021**

Unique alfapump® 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

> €3 Bn / year

market opportunity(1)

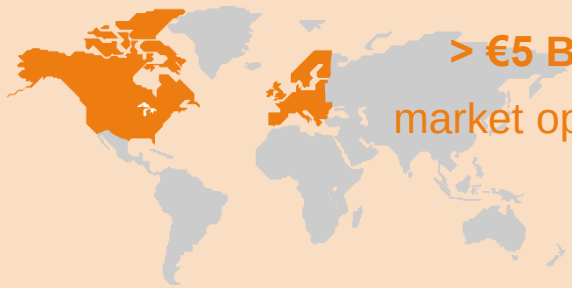
- **POSEIDON pivotal study ongoing**
- **Self-commercialisation**

alfapump® DSR

Heart Failure

Breakthrough approach to fluid overload in heart failure

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



> €5 Bn / year

market opportunity(2)

- **RED DESERT repeated dose study ongoing**
- **Partnering after US feasibility 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)

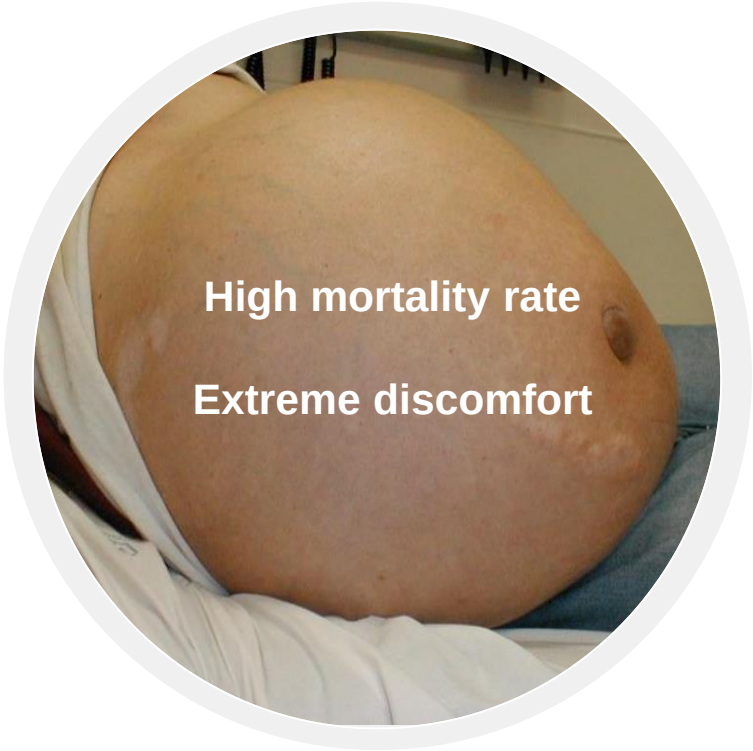
NASH drives US market attractiveness

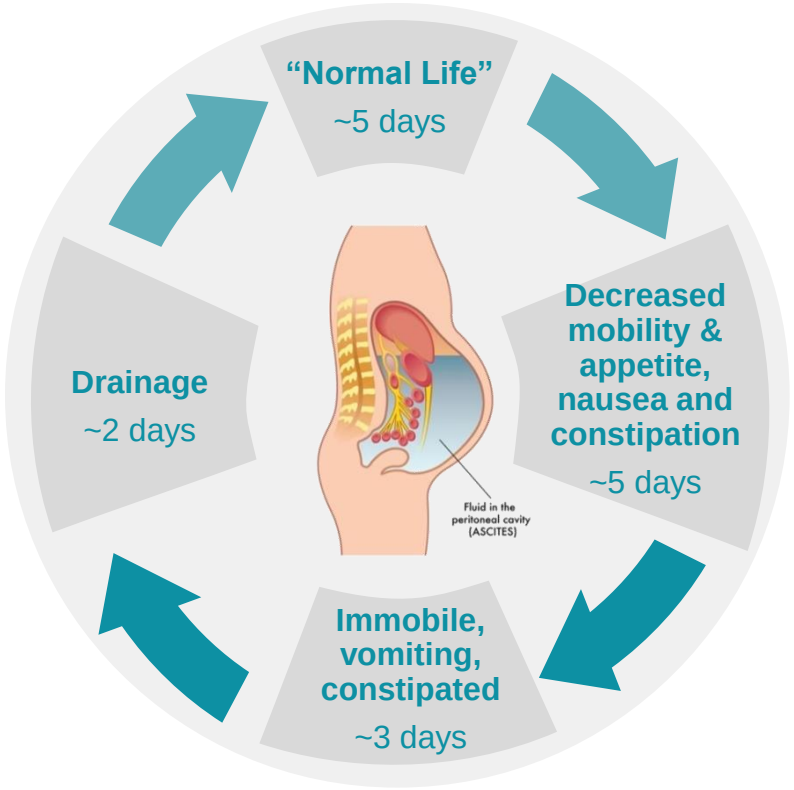
Stronger competitive position in a much larger and dynamic market

alfapump® market potential	~€0.4 Bn / year (1)	**>€3 Bn / year** (2)
Underlying disease	Alcoholic Liver Disease, Hepatitis	**NASH**
Patient characteristic	“Outside mainstream”	**“Mainstream”**
Average age	40-50 yr	**70 yr+**
alfapump competitive positioning	✓	✓✓

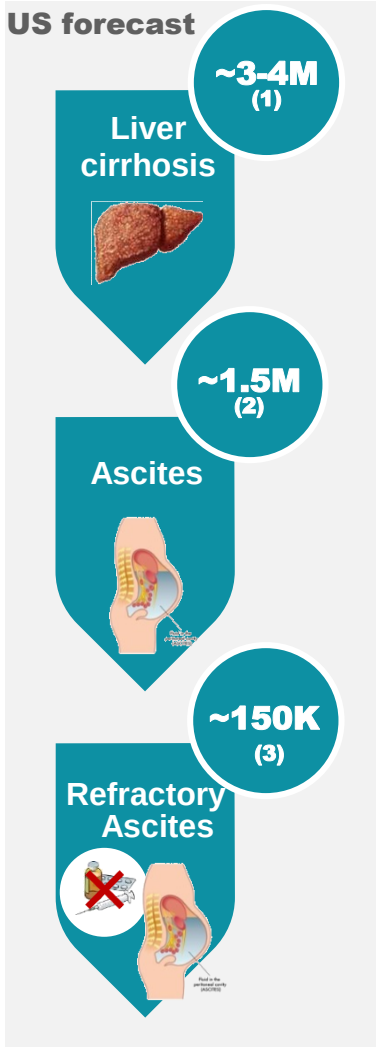
Note 1: Current estimated EU Liver market; Source: Data from 1980-2010, death rates between 9-12.4 per 100,000; Mokdad et al., 2014, Management estimates of 7.5% cirrhosis patients that die per year based on experts feedback.
Note 2: Forecast US Liver market within 10-20 years; Source: Management estimate that is inclusive of estimated growth in prevalence of NASH for the US based on GlobalData Epidemiology Forecast to 2026.

Refractory ascites – a key complication of liver cirrhosis with a dramatic impact on quality of life





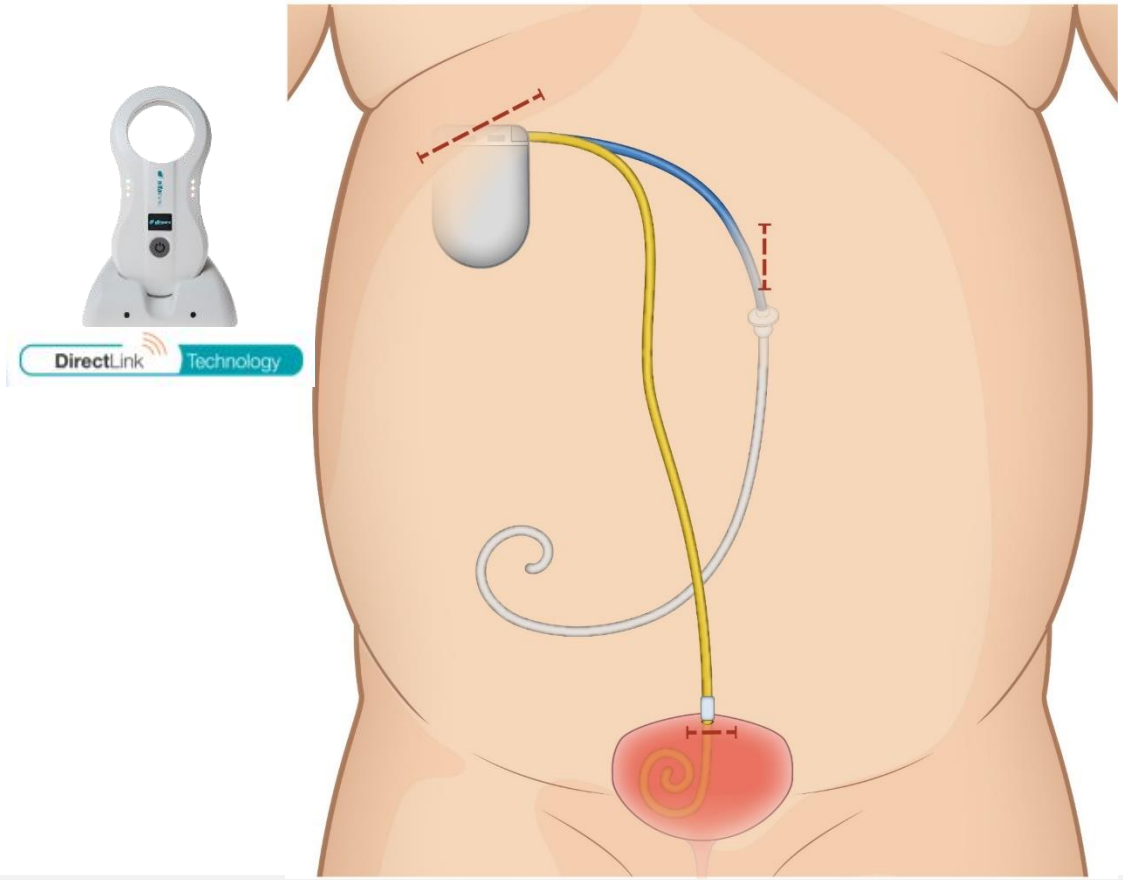
Typical patient life[4]



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

alfapump® for long-term treatment

Over 800 implants and hundreds of years of patient experience



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

CE

EASL The Home of Hepatology

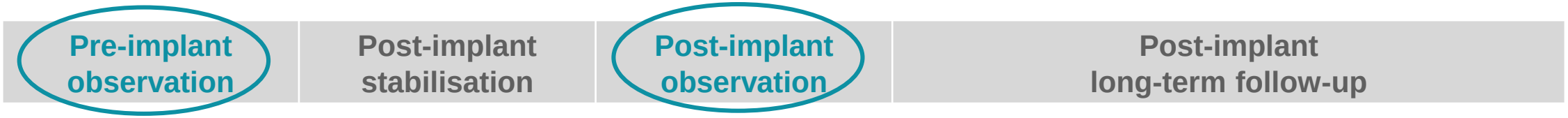
NICE National Institute for Health and Care Excellence

1913 DGVS Deutsche Gesellschaft für Gastroenterologie, Verdauungs- und Stoffwechselkrankheiten

FDA **Breakthrough Device** Designation

POSEIDON – key value inflection points

North American pivotal study of the alfapump® in recurrent and refractory ascites due to liver cirrhosis



T-3M — **Enrollment in the study**

T0 — **alfapump implantation**

T+3M

T+6M — **Primary endpoint**

Proportion of patients with a 50% reduction in average number of paracentesis per month post-implant vs pre-implant

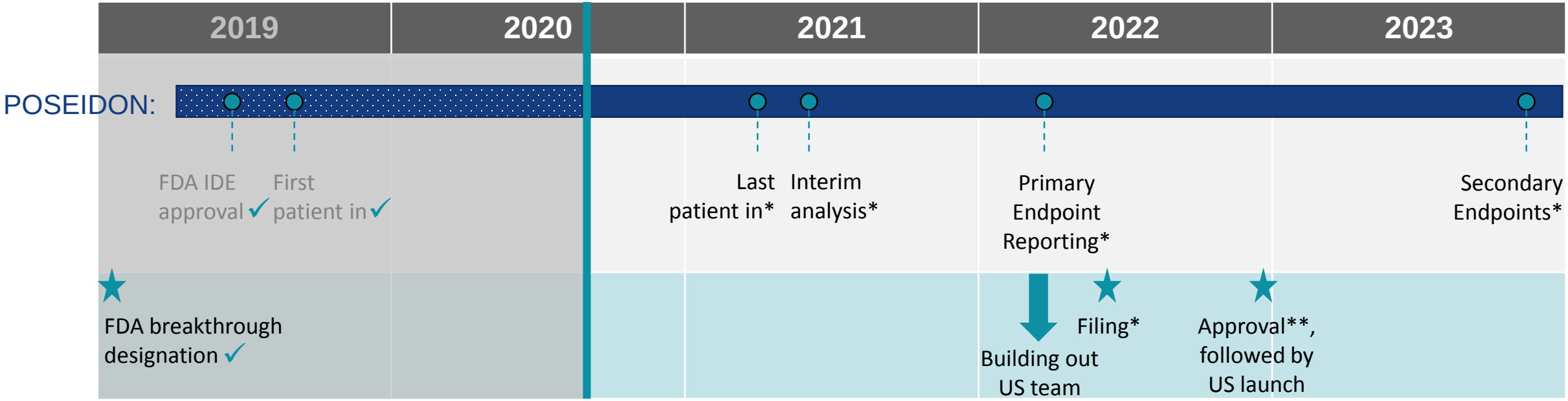
T+24M — **Secondary endpoints**

- Roll-in cohort: up to 30 patients ⇨ interim results expected in H1 2021
- Study cohort: up to 50 patients ⇨ primary endpoint read-out expected in Q1 2022

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

alfapump® US approval roadmap

Key anticipated milestones

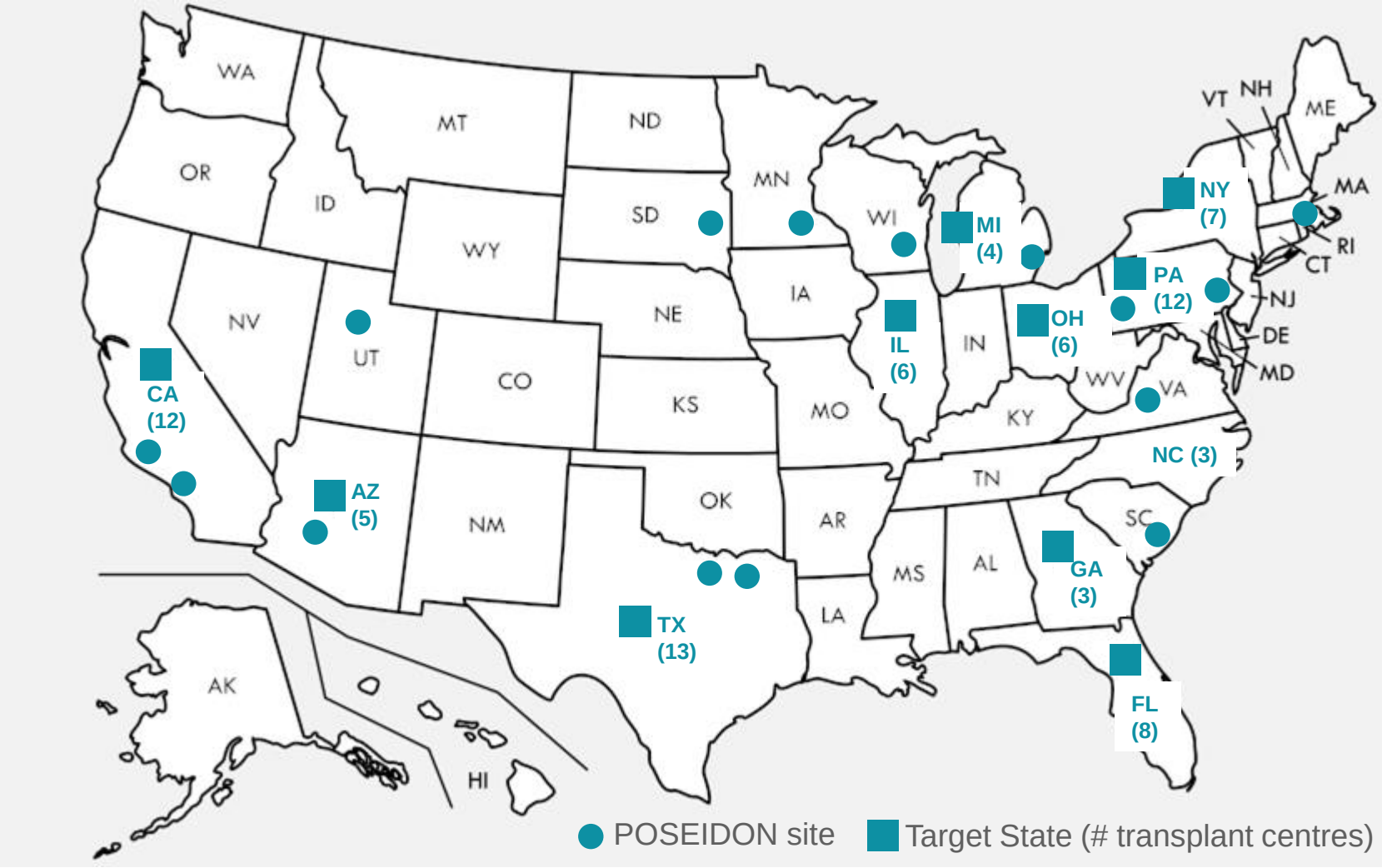


*Final CMS rule on reimbursement for breakthrough devices expected to further support reimbursement for the **alfa**pump*

* *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; CMS: Centers for Medicare & Medicaid Services

Self-commercialisation in US through specialty salesforce



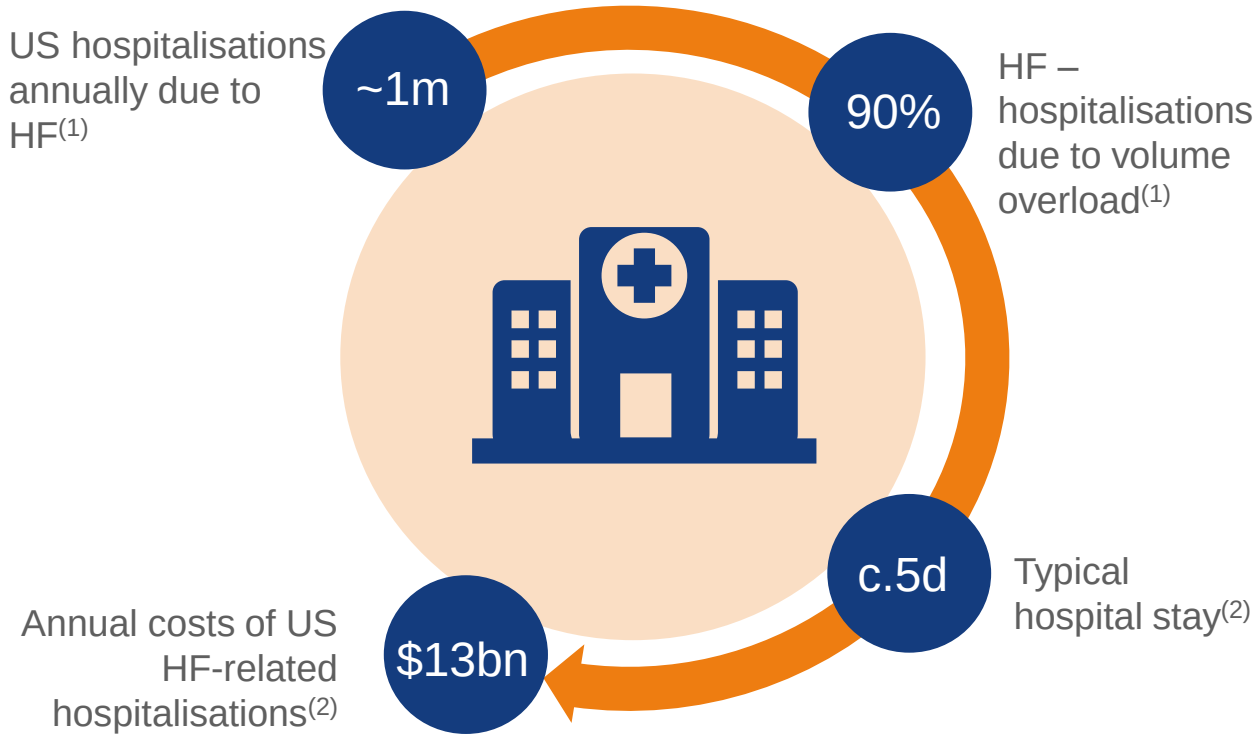
Initial focus on key transplant centres

~50-person team:

35 sales reps, 10 clinical, 5 corporate

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

Excess sodium drives fluid overload



Source 1: Costanzo et al., J. Am. Coll., 2007; Source 2: Kilgore et al. (2017)

Limitations of Diuretic Therapy in Heart Failure

High unmet need for safe and effective chronic treatment solution to treat volume overload

Diuretics primarily remove hypotonic urine

Body retains water and cuts back on urination to restore homeostasis

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

Source 1: Testani, Circ Heart Failure, 2014 & 2016; Source 2: Ross et al. (2010)

Direct Sodium Removal (DSR)

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

DSR therapy directly removes the sodium

Body eliminates excess fluid

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

Circulation

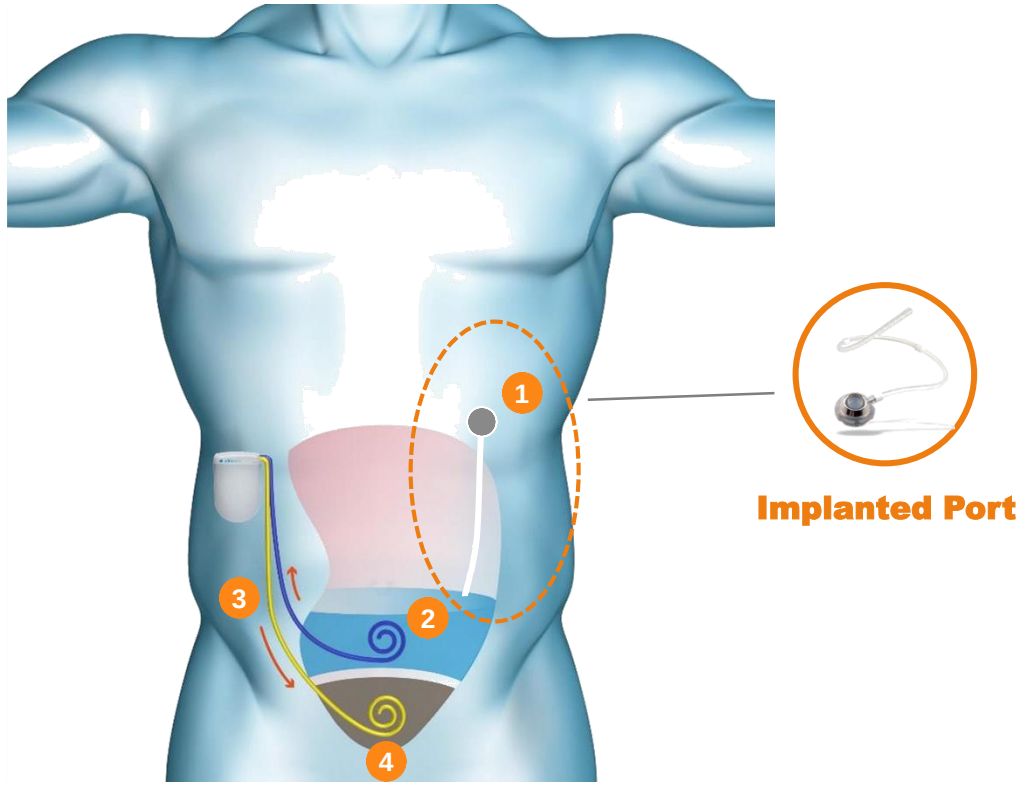
First in Human Experience with Peritoneal Direct Sodium Removal Using a Zero Sodium Solution: A New Candidate Therapy for Volume Overload

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® DSR

Fully implanted system for DSR therapy leveraging proven elements

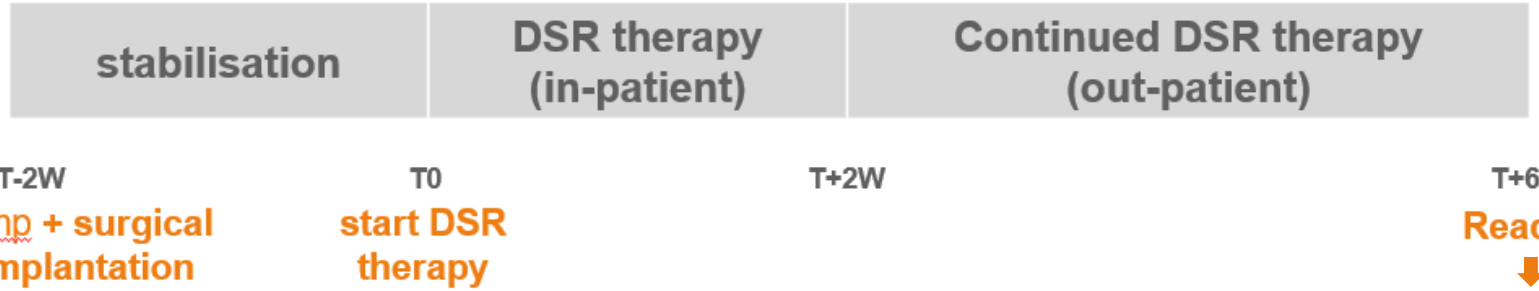


- ✓ Direct Sodium Removal
- ✓ alfapump
- ✓ Implanted port

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

RED DESERT – key value inflection points

Repeated dose alfapump® DSR study for treatment of diuretic-resistant heart failure patients

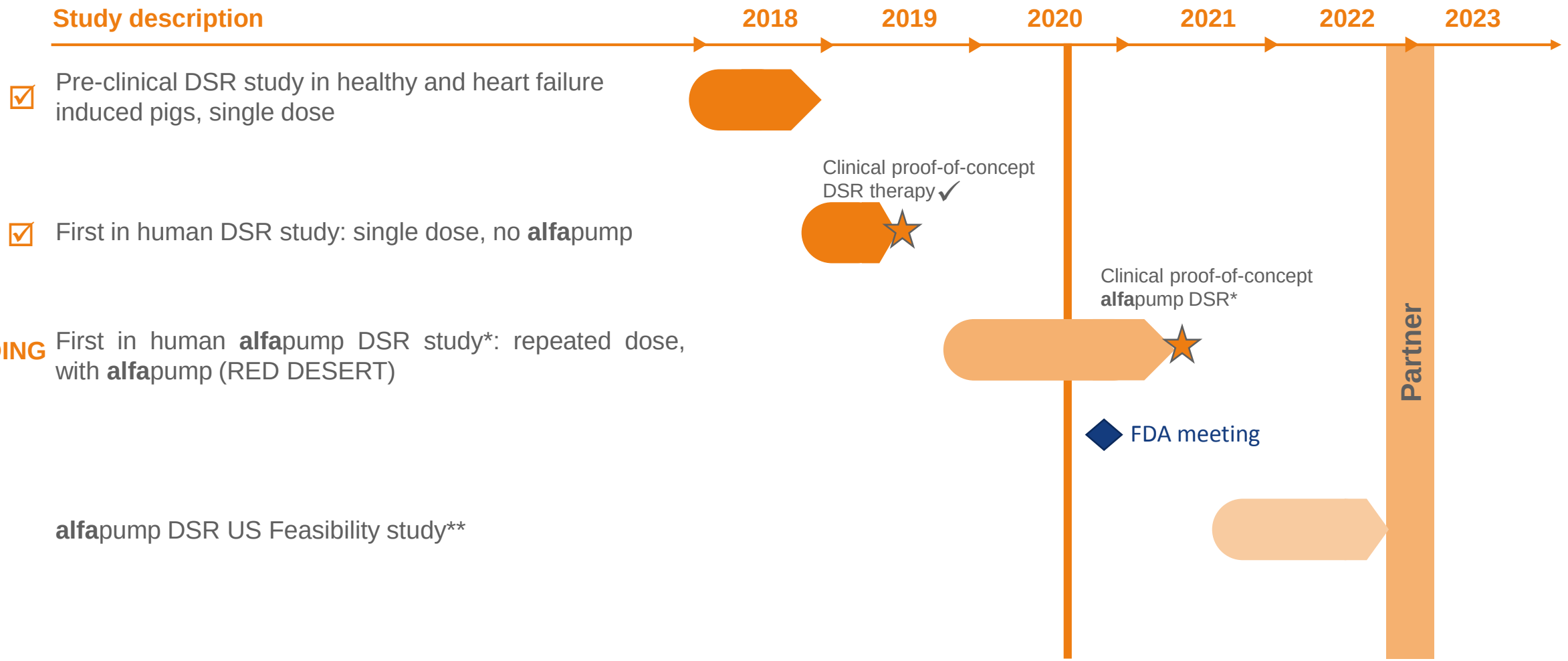


- ***Safety:*** *absence/rate of device, procedure and/or therapy related serious adverse events*
- ***Feasibility:*** *ability of the* ***alfa****pump DSR to maintain a neutral sodium balance and maintain euvolemia*
- ***Exploratory:*** *impact of DSR to restore response to diuretics*

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

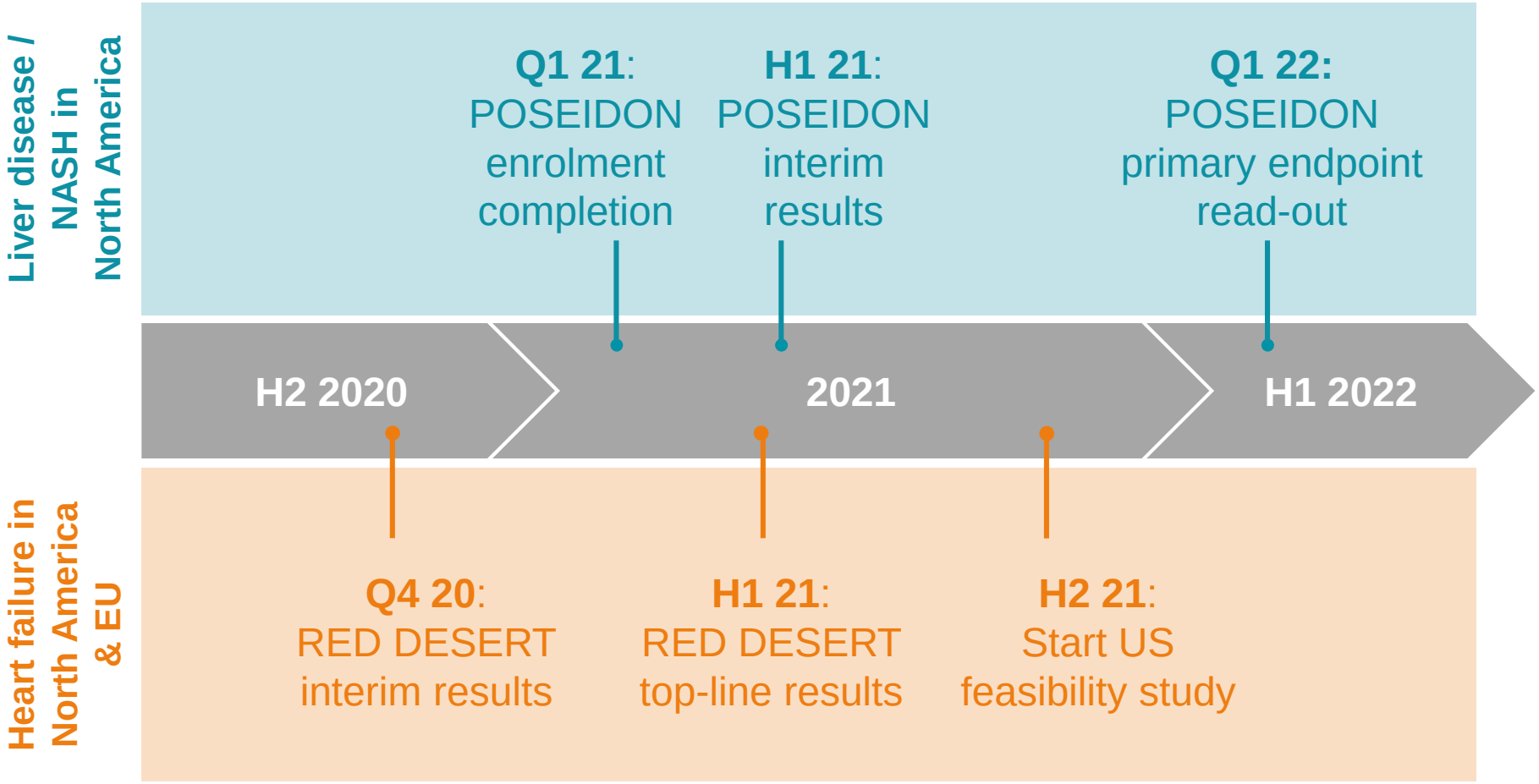
Note: Presented timelines are subject to further developments related to the COVID-19 pandemic

alfapump® DSR development strategy



** Subject to further developments related to the ongoing COVID-19 pandemic*
*** Subject to change and/or feedback from applicable regulatory authorities*

Expected Core Value Drivers & Outlook



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Thank You

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