sequanamedical

FY2019 Financial Results & Business Update

19 March 2020

Today's presenters

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Regulatory disclaimers:

- The **alfa**pump® has not yet received regulatory approval in the US and Canada. Any statement in this presentation about safety and efficacy of the **alfa**pump does not apply to the US and Canada because the device is currently undergoing clinical investigation in these territories.
- Sequana Medical's proprietary DSR therapy is under development and Sequana Medical is developing **alfa**pump DSR (Direct Sodium Removal) to deliver a convenient and fully implanted system for DSR therapy. DSR therapy and **alfa**pump DSR are still in development and it should be noted that any statements in this presentation regarding safety and efficacy arise from pre-clinical and clinical studies and ongoing clinical investigations which have yet to be completed. There is no link between DSR therapy, **alfa**pump DSR and ongoing investigations with the **alfa**pump system in Europe, the US and Canada.

COVID-19 notice

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.

Although it is difficult to draw conclusions at this point on the systemic risk this disease could pose, the Company 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 are expected to **result in delays to execution of clinical studies and impact sales**.

Sequana Medical will **update its guidance** on the expected impact and any material change in the Company's **operations and outlook when the situation is clarified**.

Agenda

- Highlights
- Focus areas and Strategy
- Year in Review
- Financial Results 2019
- Outlook 2020
- Q&A

Highlights 2019 – 2020 YTD

- ✓ FDA Breakthrough Device Designation for **alfa**pump®
- ✓ First patient enrolled in **alfa**pump POSEIDON pivotal study to support approval in North America
- ✓ Expected commercial launch of **alfa**pump in US moved forward to H1 2022

- ✓ Publication of pre-clinical and clinical proof-of-concept of DSR (Direct Sodium Removal) in *Circulation*
- ✓ First patient enrolled in **alfa**pump DSR RED DESERT study
- ✓ Appointment of Heart Failure Scientific Advisors to support **alfa**pump DSR development

- ✓ €27.5 million raised in IPO on Euronext Brussels in February 2019
- ✓ €19.0 million in equity financing in January 2020, extending cash runway into H1 2021
- ✓ Appointment of medtech executive Jason Hannon to the board of directors

Focus on US NASH and global heart failure markets

Large market opportunities with high unmet medical need

Liver (NASH) in US

~145 K patients / year

with refractory ascites due to NASH within next 10-20y[(1)]

> €3 Bn / year

market opportunity

Heart Failure in EU+US

~400 K patients hospitalised / year

for volume overload due to heart failure by 2026[(2)]

> €5 Bn / year

market opportunity

Built upon proven European clinical & commercial experience

NASH: non-alcoholic steatohepatitis

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

Strategy & Key Objectives

- Obtain regulatory approval in North America for the **alfa**pump® in treatment of recurrent and refractory liver ascites and commercialise through our own specialty salesforce
- Advance clinical development of **alfa**pump DSR in the treatment of volume overload due to heart failure and establish a strategic partnership for development and commercialisation
- Explore the use of **alfa**pump DSR in further indications where diuretic-resistant volume overload is a key clinical complication
- Further develop monitoring capabilities of the **alfa**pump to deliver patient management solutions

Year in Review: alfapump® 2019 – 2020 YTD

alfapump **North America**

FDA Breakthrough Device Designation for the treatment of recurrent and refractory liver ascites

FDA approval of POSEIDON pivotal study start

US CMS final ruling on new NTAP pathway for breakthrough devices

First patient enrolled in North American POSEIDON study

Liver Transplantation published North American feasibility study (MOSAIC) in recurrent and refractory liver ascites

alfapump **2019**

alfapump **2020**

alfapump **Europe**

Inclusion in German Society of Gastroenterology Digestive and Metabolic Diseases (DGVS) guidelines for complications of liver cirrhosis

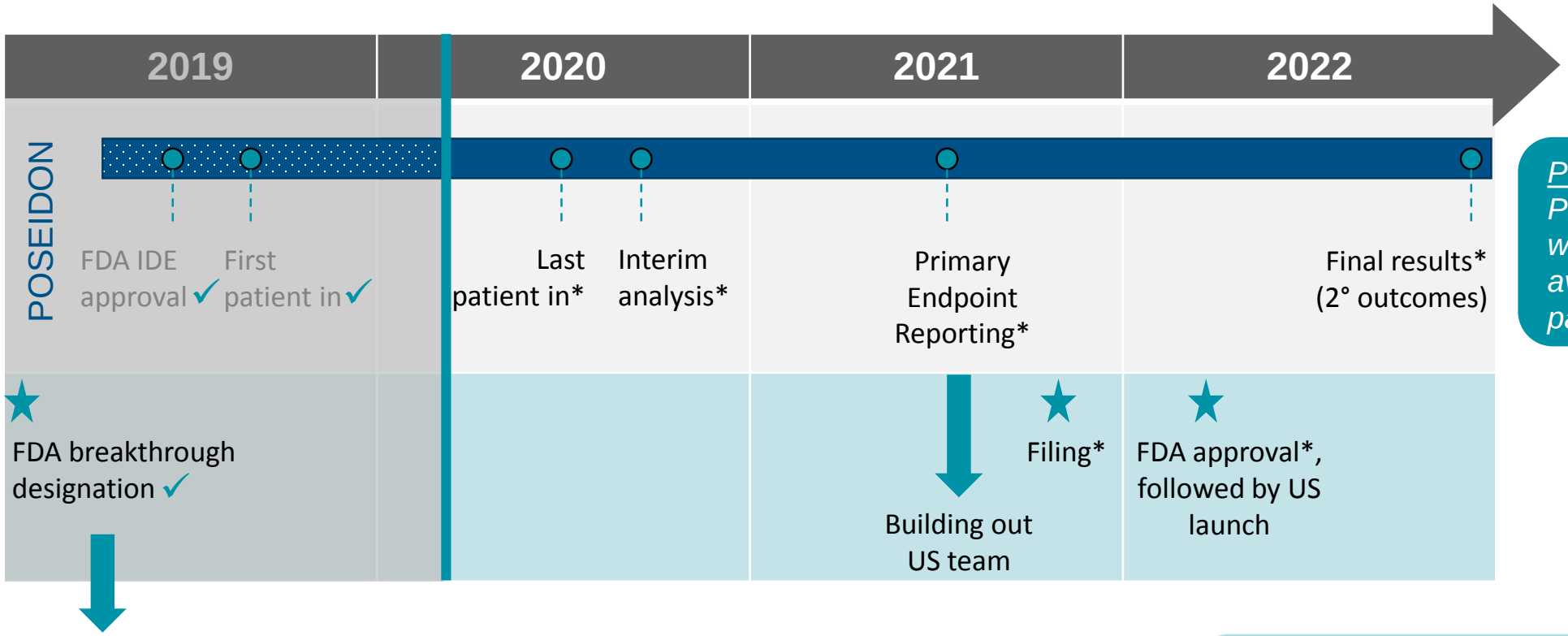
BMC Palliative Care published the retrospective Malignant Ascites study

Annual renewal of German NUB received

Langenbeck's Archives of Surgery published the surgical technique for the implantation of the **alfa**pump

FDA: Food and Drug Administration; CMS: Centers for Medicare and Medicaid Services; NTAP: New Technology Add-on Payment; NUB: Neue Untersuchungs- und Behandlungsmethoden or New Diagnostic and Therapeutic Methods

Strong progress in pursuing US approval



Primary endpoint: *Proportion of patients with a 50% reduction in average number of paracentesis per month*

Final CMS rule for breakthrough devices (NTAP)

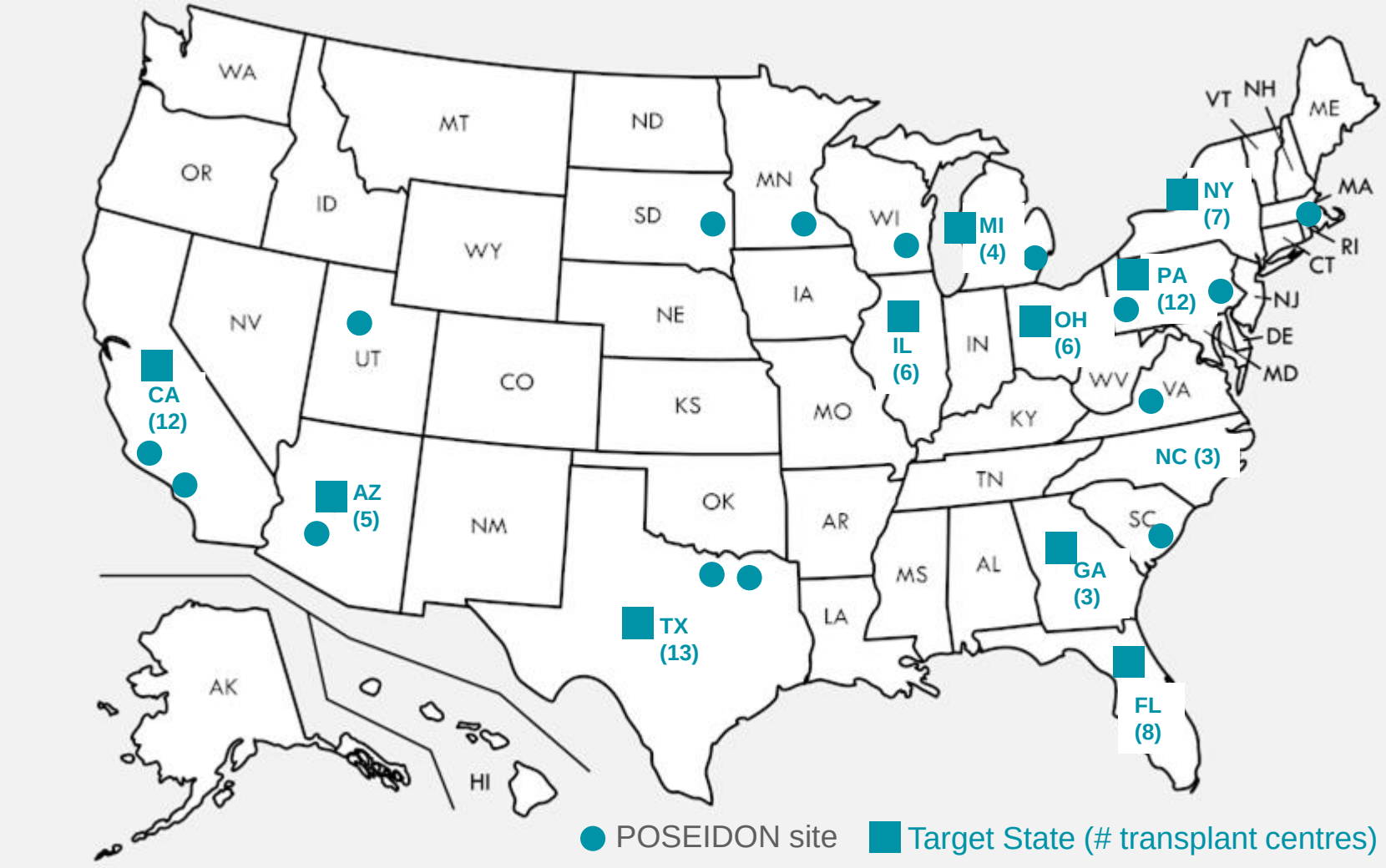
expected to further support reimbursement of alfapump®

- ✓ novel
- ✓ substantial clinical improvement
- ✓ cost criteria

**Note: timings presented in this slide reflect pre-COVID-19 expectations and are likely to be delayed given the current global health crisis*

FDA: Food and Drug Administration (US); IDE: Investigational Device Exemption; NTAP: New Technology Add-on Payment; CMS: Centers for Medicare & Medicaid Services

Self-commercialisation in US through specialty salesforce



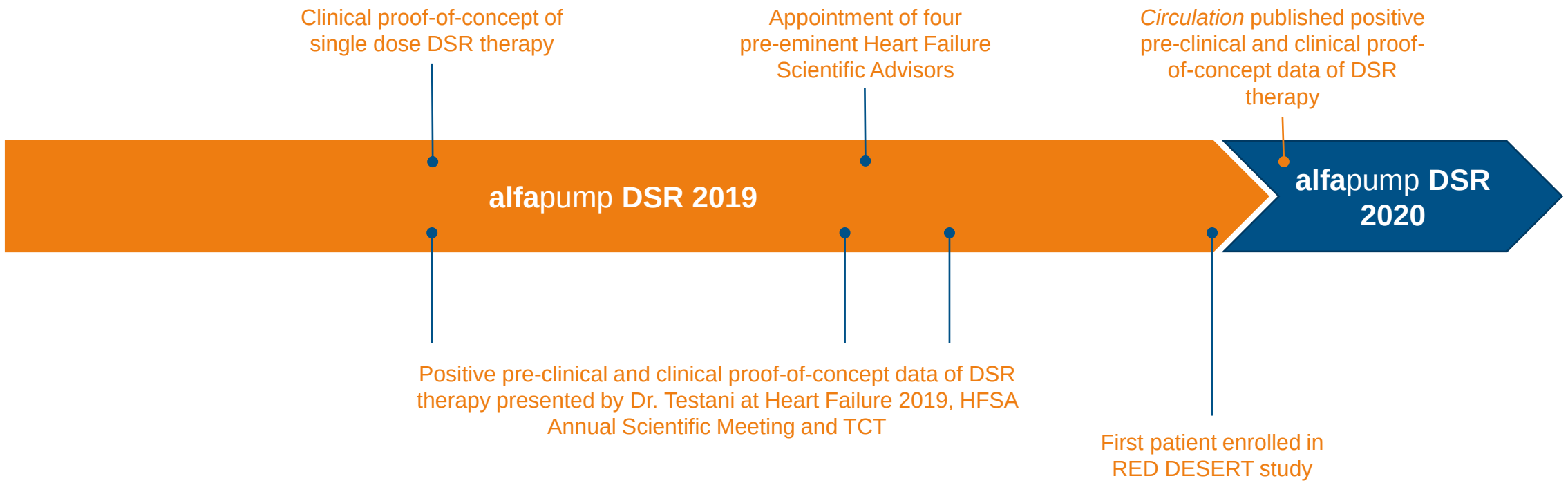
Initial focus on key transplant centres

~50 person team:

35 sales reps, 10 clinical,

5 corporate

Year in Review: alfapump® DSR 2019 – 2020 YTD



Clinical proof-of-concept of single dose DSR therapy

Safe & well-tolerated

No significant discomfort or adverse events

Minimal off-target solute removal

Effective

4-fold greater sodium removal than the strongest commercially available peritoneal dialysis solution

Greater fluid removal

Consistent

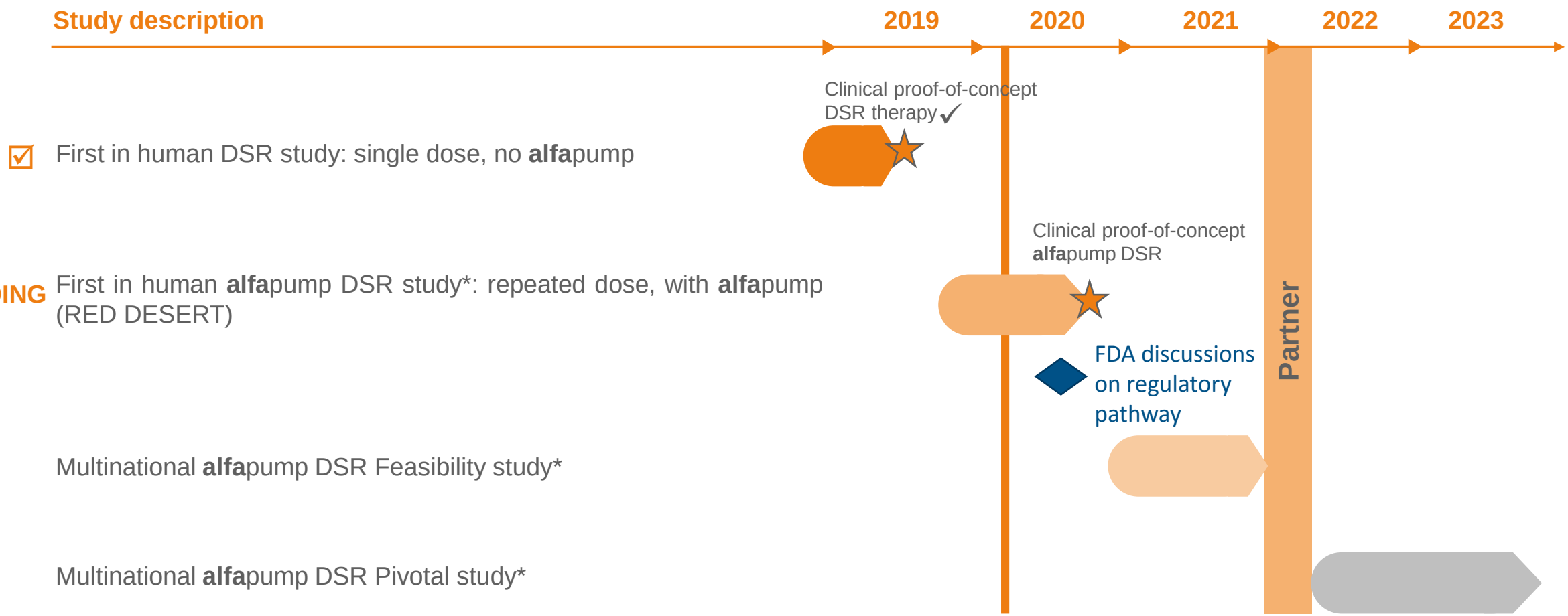
High degree of consistency across patients

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

RED DESERT started – First-In-Human Repeated Dose alfapump® DSR study

- Up to **10 patients** with heart failure on high dose diuretics across 2 centres (Belgium and Georgia)
- Patients put on a low sodium diet without diuretics and **implanted with alfapump DSR system**
- Evaluation of safety and feasibility over a 6-week **alfa**pump DSR treatment
  - **Safety:** absence/rate of device, procedure and/or therapy related serious adverse events
  - **Feasibility:** ability of **alfa**pump DSR to maintain a neutral sodium balance and maintain euvolemia
- Explore potential impact of DSR therapy to **restore response to diuretics**

alfapump® DSR development overview



*Note: study design and timings presented in this slide reflect pre-COVID-19 expectations and are likely to be delayed given the current global health crisis

Financial Results 2019

in Thousand Euros	FY 2019	FY 2018	Variance
Revenue	**971**	**1,029**	**-6%**
Cost of goods sold	(198)	(158)	+25%
Gross margin	**773**	**871**	**-11%**
Sales & Marketing	(2,838)	(2,445)	+16%
Clinical	(3,922)	(1,671)	+135%
Quality & Regulatory	(1,817)	(1,372)	+32%
Supply Chain	(931)	(964)	-3%
Engineering	(983)	(1,808)	-46%
General & Administration	(4,264)	(5,761)	-26%
Other income	18	74	-
Total operating expenses	**(14,736)**	**(13,948)**	**+6%**
Earnings before interest and taxes (EBIT)	**(13,964)**	**(13,077)**	**+7%**
Finance income	53	309	-83%
Finance cost	(931)	(1,192)	-22%
Total net finance expense	**(878)**	**(883)**	**-1%**
Income tax expense	(136)	(24)	-
Net loss for the period	**(14,977)**	**(13,983)**	**+7%**

Outlook 2020 – Focus on POSEIDON and RED DESERT

alfapump

- **POSEIDON study**
  - Recruitment completion (Q2)
  - Interim results (H2)
- **ProMAS study**
  - Start study (H1)
  - Recruitment completion (H2)
- **Step Counter study**
  - Start study (H1)

alfapumpDSR

- **RED DESERT study**
  - Initial results (Q2)
  - Final results (Q3)
- **U.S. Feasibility study**
  - Initiation (Q4)

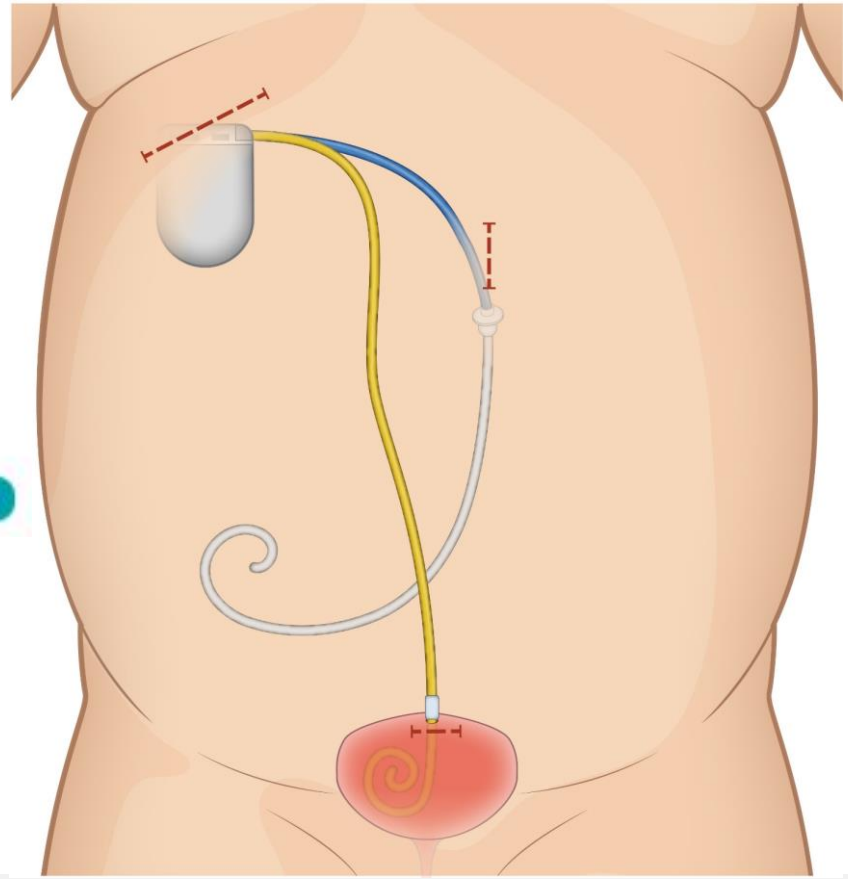
These timings are likely to be delayed given the current global health crisis.

Updated guidance will be provided when the situation is clarified.

Q&A

Back-up

alfapump® – management of liver refractory ascites and malignant ascites



Over 750 implants and hundreds of years of patient experience

CE

EASL
The Home of Hepatology

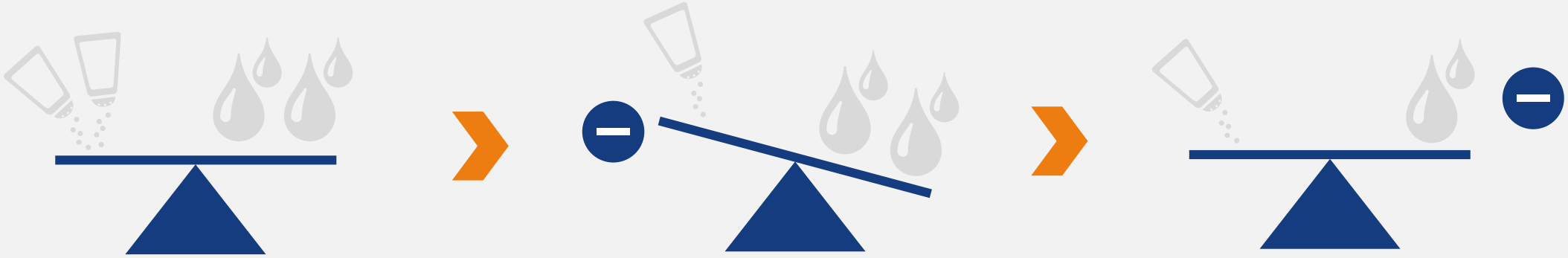
NICE
National Institute for Health and Care Excellence

1913 DGVS
Deutsche Gesellschaft für Gastroenterologie, Verdauungs- und Stoffwechselkrankheiten

FDA **Breakthrough Device** Designation

Direct sodium removal (DSR)

Remove the sodium and the body will eliminate the excess fluid



Too much sodium drives fluid overload

Removing the sodium (DSR)

Elimination of excess fluid

Administer infusate to peritoneal cavity

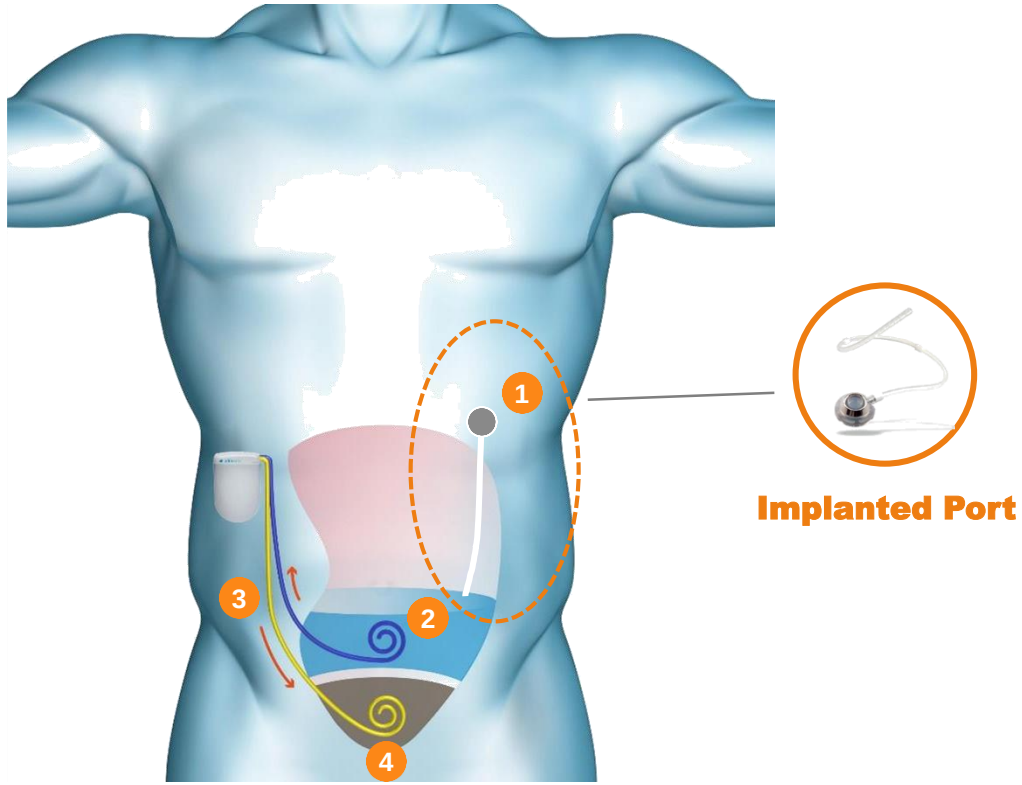
Infusate extracts sodium from the body

alfapump® **removes extracted sodium from peritoneal cavity via bladder**

Body restores balance by eliminating excess fluid

alfapump® DSR

Fully implanted system for DSR therapy leveraging proven elements



- ✓ DSR
- ✓ alfapump
- ✓ Implanted port

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