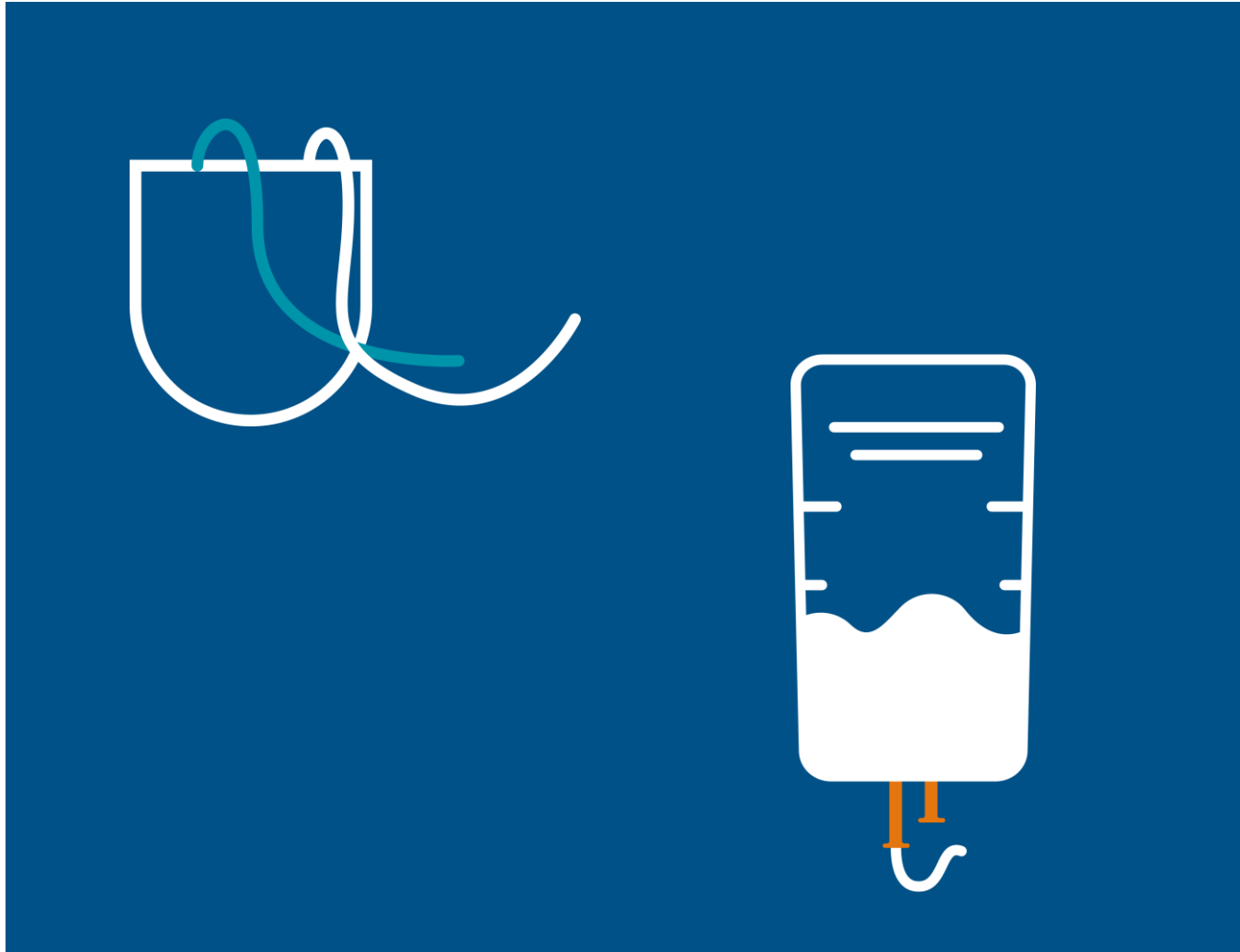


**sequana**medical



## **POSEIDON**

### **Primary endpoint results**

Webcast presentation – 25 October 2022

# Today's presenters



**Ian Crosbie**  
Chief Executive Officer



**Gijs Klarenbeek**  
Sr Medical Advisor

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- The **alfapump**<sup>®</sup> 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**<sup>®</sup> system does not apply to the United States and Canada. In the United States and Canada, the **alfapump**<sup>®</sup> 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](http://www.poseidonstudy.com).
- DSR<sup>®</sup> 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<sup>®</sup> therapy is currently not approved for clinical research in the United States or Canada. There is no link between DSR<sup>®</sup> therapy and ongoing investigations with the **alfapump**<sup>®</sup> 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:

- alfapump**<sup>®</sup> is a registered trademark. DSR<sup>®</sup> and **alfapump DSR**<sup>®</sup> are registered trademarks in the Benelux, China, the EU, United Kingdom, and Hong Kong.

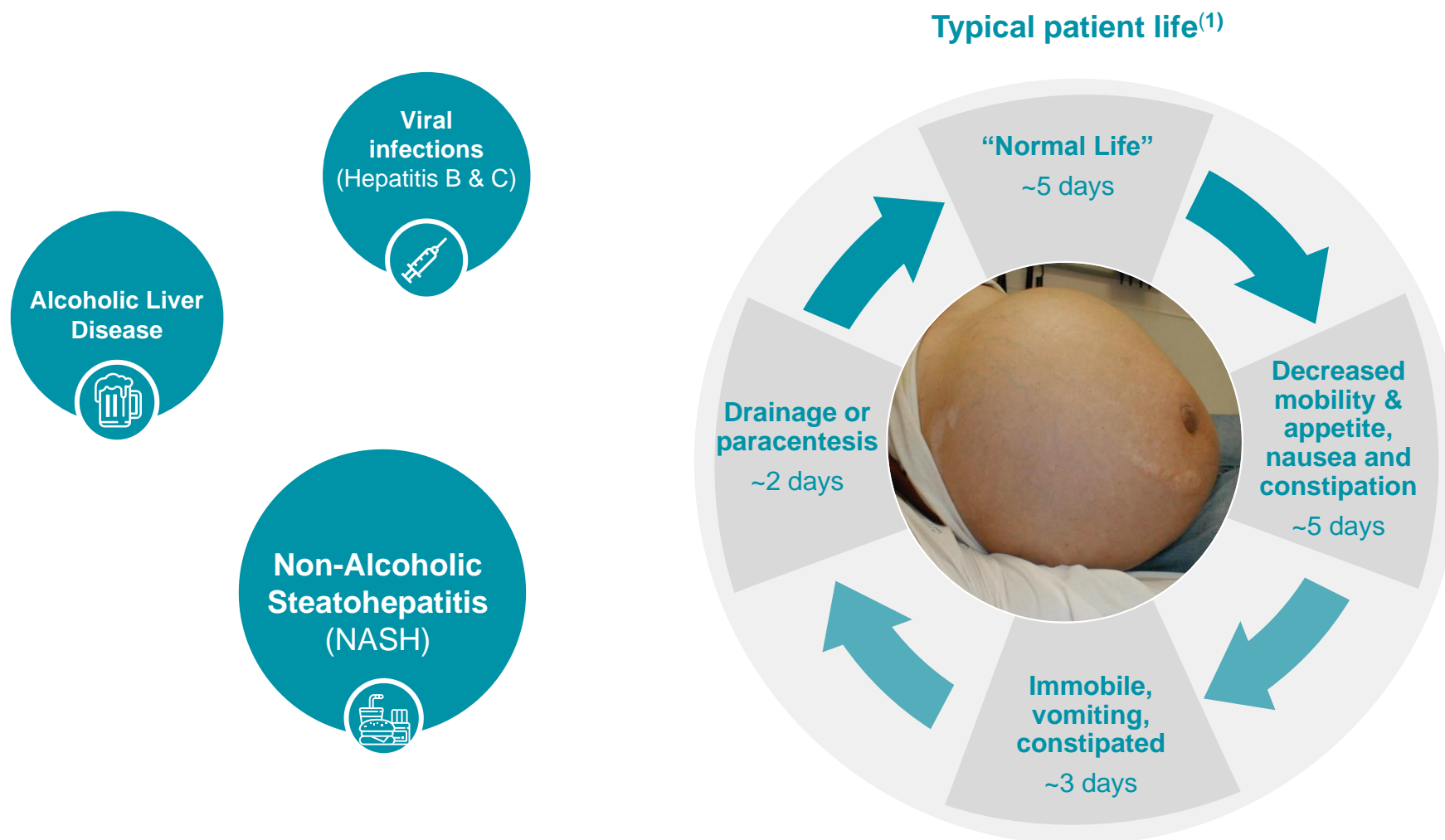
# Positive top-line results from POSEIDON

North American pivotal study of the alfapump®

- alfapump **achieves pre-specified primary effectiveness endpoints** with statistical significance at six months post-implantation:
  - **100% median per-patient reduction** in therapeutic paracentesis (TP) post- vs pre-implantation ( $p<0.001$ )
  - **77% of patients with at least 50% reduction** in number of TP post- vs pre-implantation ( $p<0.001$ )
- alfapump primary safety endpoint data **in line with expectations**
- On track to file **Pre-Market Approval (PMA) application** with FDA in **H2 2023**
- Third party market analysis estimates prevalence of recurrent or refractory liver ascites in North America at over **60,000 patients in 2022**, growing at **6-7% annually**
- Management to attend **AASLD The Liver Meeting®** from November 4-6 in Washington, DC

# Refractory ascites – key complication of liver cirrhosis

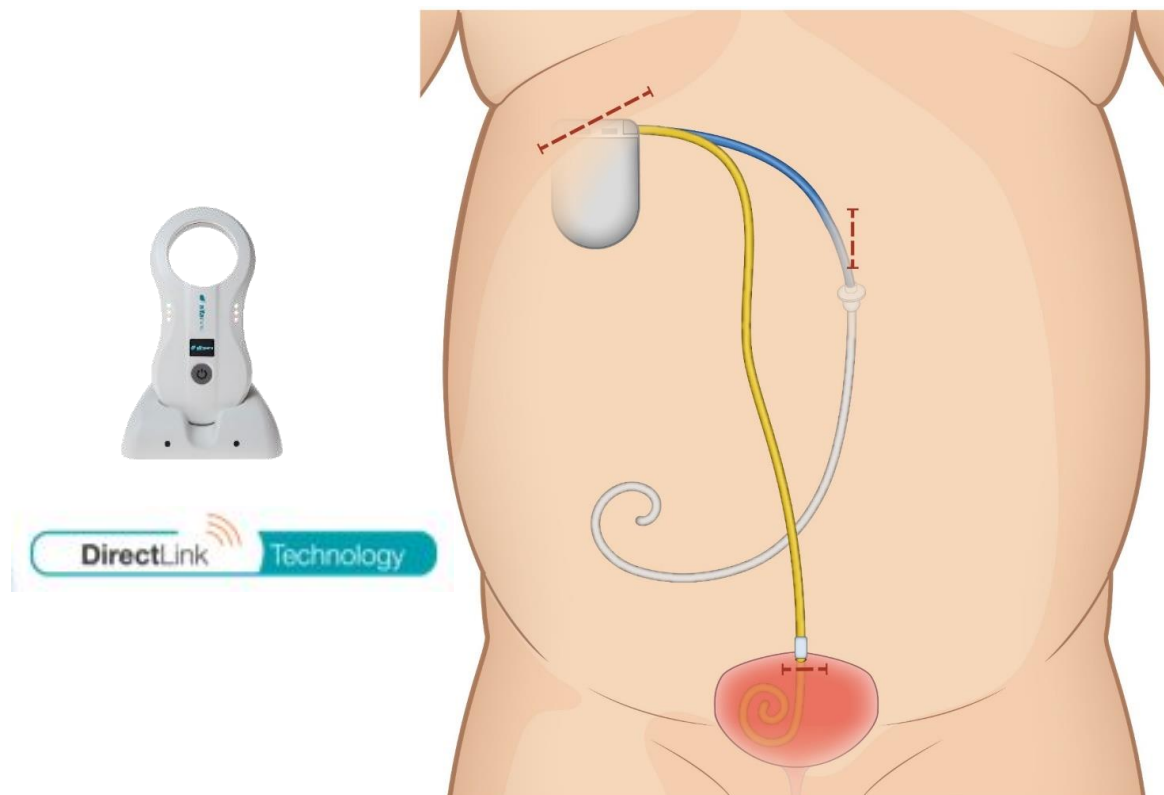
Fatty liver disease / NASH is driving dramatic growth and change in attitudes to liver cirrhosis patients








Source 1: Presentation of Dr. Rajiv Jalan at EASL in 2018, Large Volume Paracentesis (LVP) treatment cycle for refractory ascites

# alfapump® – strong clinical and economic rationale

Strong IP, over 950 implants and hundreds of years of patient experience

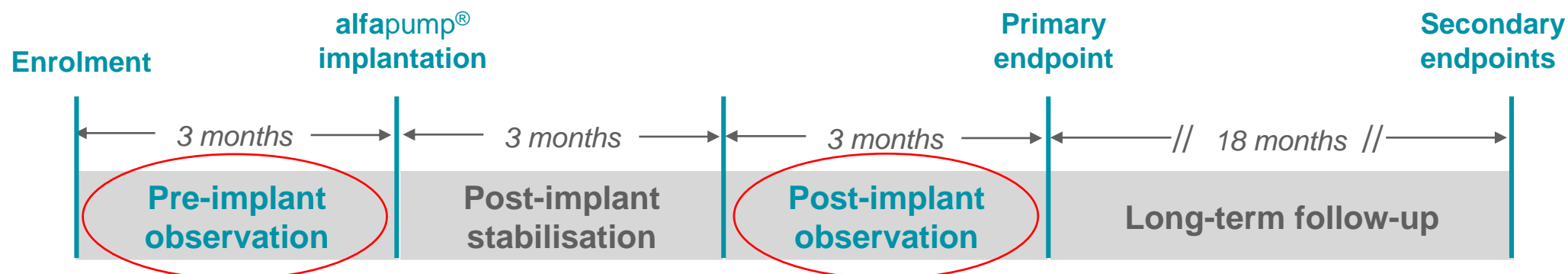


-  Fully-implanted system for automatic and continuous removal of ascites
-  Wireless battery charging and remote data monitoring
-  Reducing the need for paracentesis
-  Improving patients' quality of life
-  Reducing hospital visits and potentially healthcare costs



# POSEIDON – North American pivotal study

Pivotal Cohort of 40 implanted patients; Roll-In (“training”) Cohort of 29 implanted patients

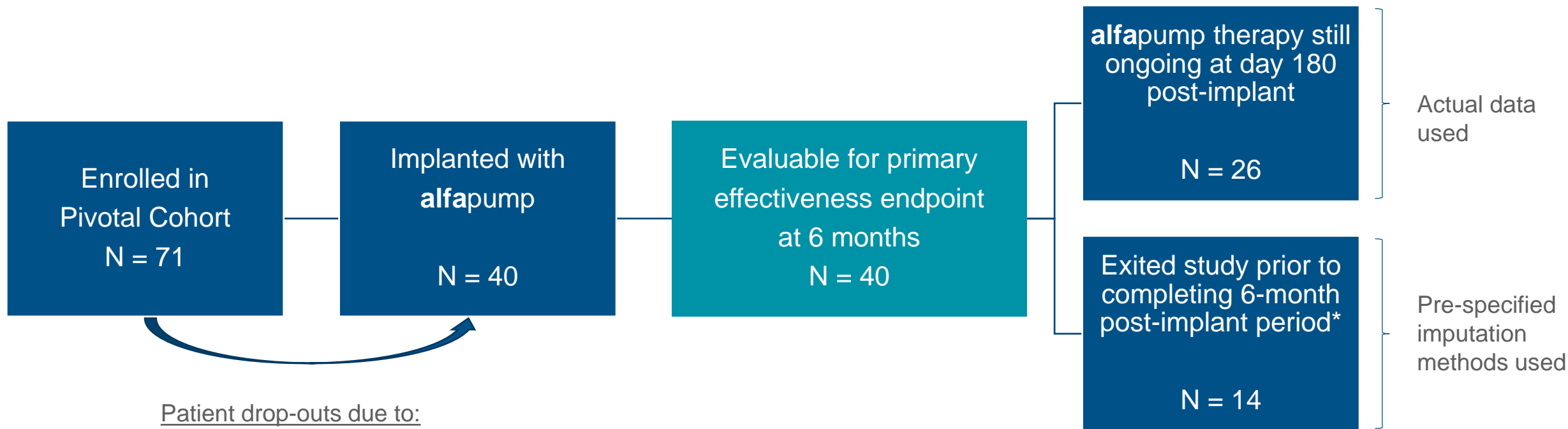


## POSEIDON primary effectiveness endpoint hypotheses:

- 1) median per-patient ratio of post-implant three-month observation period to the pre-implant three-month observation period with respect to number of therapeutic paracentesis (TP) is less than 0.5 (or a median reduction of at least 50%)
- 2) at least 50% of patients achieve a 50% reduction in the requirement for TP in the same period

# POSEIDON – Pivotal cohort

More than 1/3 of patients implanted with the alfapump® had NASH or combined NASH etiology



Patient drop-outs due to:

- COVID-19 related delays in elective surgery
- Not meeting inclusion criteria at time of implant decision

\* Reasons for exiting study:

- death or withdrawal due to unrelated AE, liver transplant (N=8)
- **alfapump** system, procedure or therapy related AE (N=6)



# Primary effectiveness endpoints met

Data from the Pivotal Cohort patients substantially exceeded the predefined thresholds for study success

Pivotal Cohort N = 40	%*	p-value**
1. Frequency of Therapeutic Paracentesis (TP)		
a. median per-patient ratio	100% reduction	P<0.001
b. mean per-patient ratio	82% reduction	-
2. Proportion of patients with a 50% reduction in number of TP post- vs pre-implantation	77% of patients	P<0.001

***“These positive top-line results are very encouraging, indicating that the alfapump® could provide great benefits to patients with cirrhosis and ascites, and dramatically reduce their visits to the hospital for paracentesis.” – Dr. Wong, Principal Investigator POSEIDON***

\* Using pre-specified imputation methods for 14 patients that had exited the study prior to completing the 6-month post-implantation period.

\*\* As per primary effectiveness endpoint hypotheses. Per protocol, testing conducted using nonparametric methods for data that is not normally distributed.

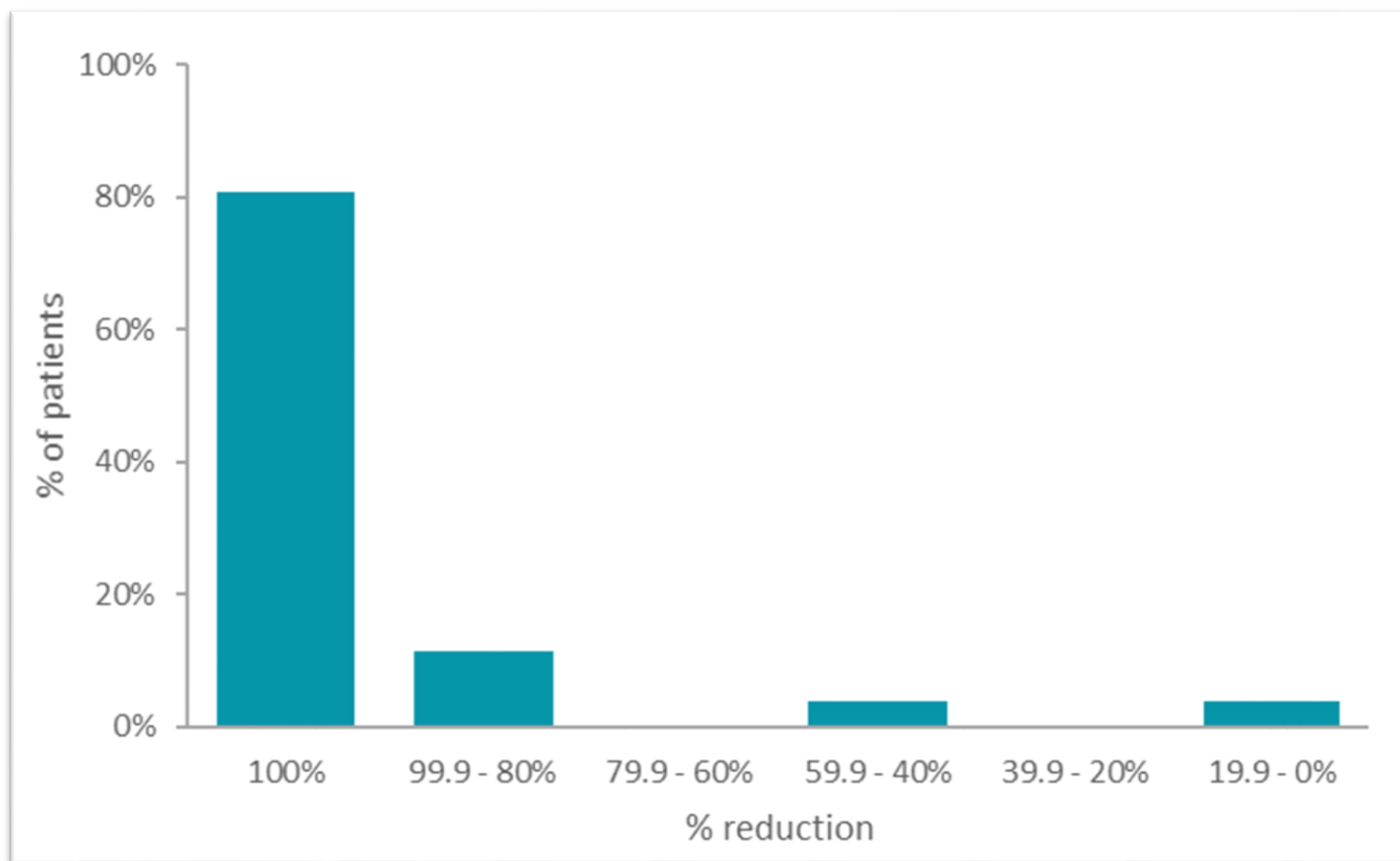
# **Observed data from patients completing alfapump<sup>®</sup> therapy through day 180 post-implant\* (1/2)**

<b>N = 26</b>	<b>%</b>
1. Frequency of TP	
a. median per-patient ratio	100% reduction
b. mean per-patient ratio	93% reduction
2. Proportion of patients with a 50% reduction in number of TP post- vs pre-implantation	92% of patients

\* These observed patient data are not part of the main primary effectiveness endpoint analysis.

# **Observed data from patients completing alfapump<sup>®</sup> therapy through day 180 post-implant\* (2/2)**

Distribution of reduction in Therapeutic Paracentesis post-implant vs pre-implant (N = 26)



\* These observed patient data are not part of the main primary effectiveness endpoint analysis.

# Primary safety endpoint in line with expectations

## Primary safety endpoint:

- Combined rate of i) open surgical re-intervention due to pump system related AE or to restore pump functionality, ii) pump explant (without replacement) due to pump system related AE, or iii) pump system related death from time of pump implant through 6 months post-implantation as adjudicated by the CEC

## Pivotal Cohort:

- No unanticipated adverse device effects
- Six primary safety events – in line with expectations:
  - Wound erosion – **alfapump** explant 3 in 3 patients
  - Patient-reported discomfort – **alfapump** explant 3 in 3 patients → CEC: moderate severity

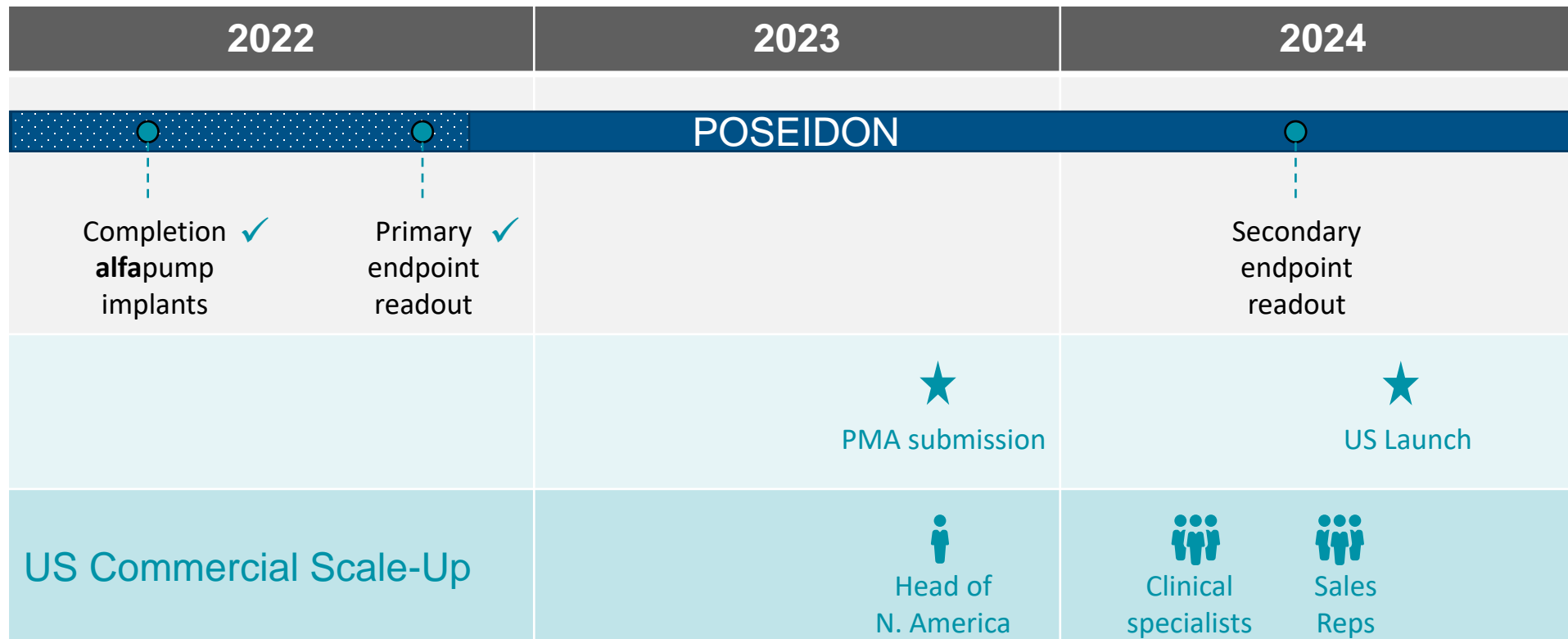
*“The safety data regarding the primary safety endpoint are in line with expectations and reassuring for the potential of the alfapump as a long-term treatment in this patient population”*  
 – Dr. Wong, Principal Investigator POSEIDON

## Next steps

- Poster presentation of data from the Roll-In Cohort\* at [AASLD The Liver Meeting®](#) by Dr. Wong, on November 6<sup>th</sup> between 1:00-2:00 pm EST
- Complete [secondary efficacy and safety endpoint analysis](#) (e.g., SAE / AE, quality of life)
- Present data at upcoming [medical liver meeting](#) in 2023 and submit to a [peer-reviewed journal](#)
- Prepare [PMA application](#) with US FDA, filing planned in [H2 2023](#)
- Continue to follow patients for up to [two years post-implant](#) for analysis of secondary outcome measurements (e.g., safety, quality of life, nutritional status, health economics and overall survival)
- Step-up preparations for [commercialization of alfapump®](#) in North America

\* Results from a secondary interim analysis from the Roll-In Cohort of the POSEIDON study were announced in a press release on 1 July 2021

# North American alfapump approval expected for 2024



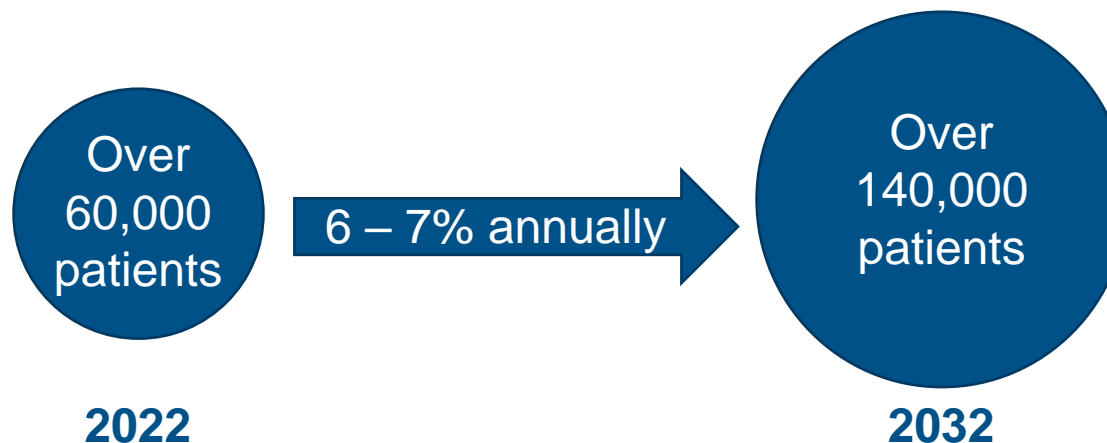
*NTAP for breakthrough devices de-risks reimbursement in key Medicare population\**

*\*On the basis of existing ICD-10 codes issued for the alfapump, the likely DRG coding will be 423, 424 and 425 "OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES"*

*PMA: Pre-Market Approval; NTAP: New Technology Add-On Payment*

# Large and growing North American patient population

NASH is forecast to drive significant growth in patient numbers for many years to come



- Patients in North America with recurrent or refractory ascites due to liver cirrhosis
- NASH is a key driver of growth, with alcohol continuing to play an important role
- Estimated incidence of 60%
- Represents market potential growing to **over \$2 billion by 2032\***
- US and Canada market assessment conducted by highly experienced international consulting group
  - Claims analysis for commercial and CMS patients requiring paracentesis procedure with liver disease diagnosis codes



\*Based on price of *alfapump* of \$25K

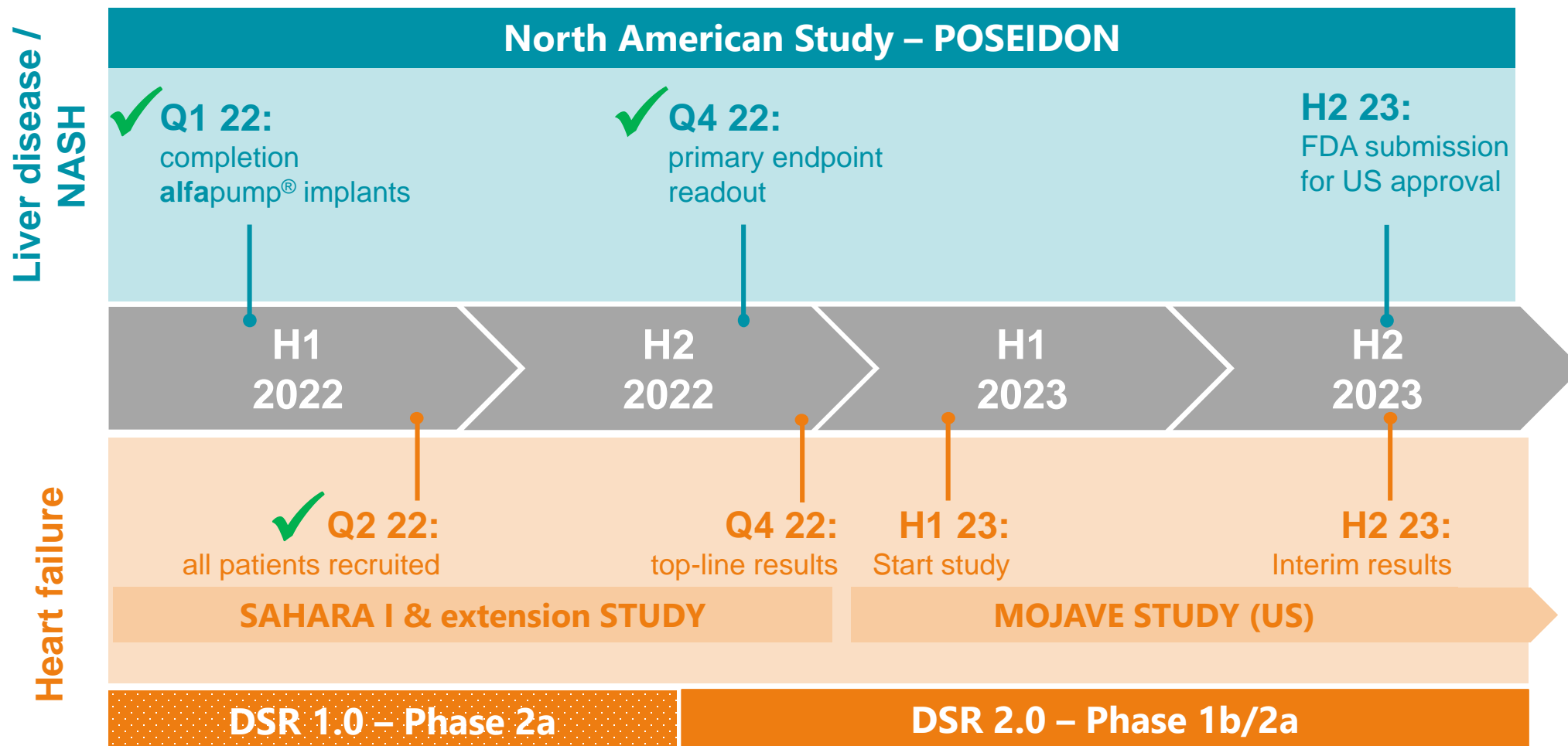
# US – Go direct to 140 liver transplant centres

Highly efficient approach to target doctors and patients – driven by treatment guidelines





# Strong Outlook for Value Drivers



**Notes:**

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

# Q&A

[IR@sequanamedical.com](mailto:IR@sequanamedical.com)

+32 498 053579

[www.sequanamedical.com](http://www.sequanamedical.com)

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