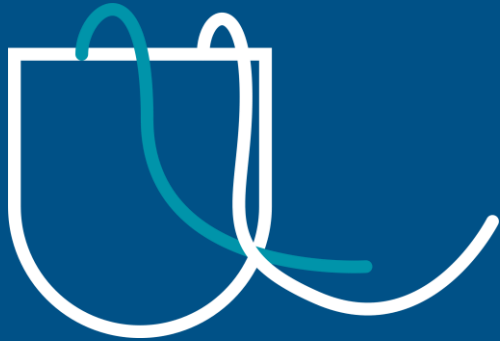


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HY 2023 Financial Results & Business Update

Webcast presentation – 14 September 2023

Today's presenters



Ian Crosbie
Chief Executive Officer



Kirsten Van Bockstaele
Chief Financial Officer

Disclaimers

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- The **alfapump**[®] 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**[®] system does not apply to the United States and Canada. In the United States and Canada, the **alfapump**[®] system is currently under clinical investigation (POSEIDON Study) and is being studied in adult patients with refractory or recurrent ascites due to liver cirrhosis.
- 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. There is no link between DSR[®] therapy and ongoing investigations with the **alfapump**[®] system in Europe, the United States or Canada.

General disclaimer:

- Sequana Medical is closely following the evolution of macroeconomic conditions, the geopolitical situation in Ukraine and 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**[®] and DSR[®] are registered trademarks.

Strong progress in both programs

alfapump advancing towards US and Canadian launch and Phase 1/2a US MOJAVE DSR study underway

alfapump[®] – US approval in liver disease expected in 2024



- ✓ Additional POSEIDON data reported, reaffirming strong clinical profile of **alfapump**
- ✓ Data from POSEIDON presented by Prof. Wong at leading international EASL liver congress
- ✓ On track to file PMA application to US FDA in Q4 2023
- ✓ Proposed TCET continues to look good for automatic coverage of the **alfapump**

DSR[®] – Phase 1/2a US MOJAVE study expected to report initial data by year end



- ✓ Additional DSR patents granted in the US and China
- ✓ Safety of single dose DSR 2.0 demonstrated in IND-enabling pre-clinical and Phase 1 studies
- ✓ First patients with congestive heart failure enrolled in Phase 1/2a US MOJAVE study

Total liquidity position of €17.1 million at end June 2023 and cash runway into Q1 2024

- ✓ Equity placement of €15.8 million in April 2023



POSEIDON – strong clinical profile of alfapump

Primary and key secondary endpoints presented by Prof. Wong, PI, at leading international liver congress

- ✓ Effective in control of ascites, “virtually eliminating needle paracentesis”
- ✓ NASH is already a key driver of decompensated cirrhosis
- ✓ Safety in line with expectations
 - Six pumps were explanted: three due to skin erosion & three due to moderate bladder discomfort
 - Despite disease progression:
 - Similar number of Major Adverse Events (MAEs) in pre- and post-implant period
 - Comparable number of serious infections in pre- and post-implant period
 - Stable kidney function over long-term follow-up
- ✓ Clinically meaningful and statistically significant improvement in quality of life*
- ✓ One-year survival probability of 70%, comparing favorably to literature citing 50%⁽¹⁾

PMA filing planned for Q4 2023 / FDA approval anticipated in H2 2024

* At six months post-implantation compared to baseline

Source 1: Biggins et al., *Hepatology*, Vol. 74, No. 2, 2021, AASLD Practice Guidance; Moreau R et al., *Liver International* 2004; 24: 457-464; Bureau et al., *Gastroenterology* 2017; Note: POSEIDON study not powered for survival



Attractive pricing with derisked reimbursement

Existing DRG payment and breakthrough device designation de-risk reimbursement of alfapump

Coding – Strong existing position with potential for further upside

- Existing US hospital DRG payment for **alfapump** procedure of \$60-70K in target hospitals*
- Supports **alfapump** price of **at least \$25K** (gross margin of over 75%)
- Potential for higher payments via NTAP
- Physician CPT III coding process underway

Coverage – Breakthrough designation brings clear benefits

- Proposed TCET provides automatic coverage for 4 years with pathway to permanent coverage

Medicare will be dominant payer
Additional potential from Veterans Affairs

*On the basis of existing ICD-10 codes issued for the **alfapump**, the likely DRG coding will be 423 “OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES”, payments adjusted with Medicare inflation rates to 2025



US – Go direct to 90 liver transplant centers

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



125 adult centres, of which 90 cover 95% of transplants



~50 commercial team initially



DSR 2.0 improves therapeutic and safety profile

Strong granted IP drives high margin recurring revenue stream

- ✓ **Additional DSR patents granted in the US and China**
 - Expansion of composition of matter and method patent in the US, including oncotic and osmotic agents and the use of an implantable pump system
 - Key composition of matter patent in China
- ✓ **Successful completion of IND-enabling pre-clinical and Phase 1 studies**
 - No difference in systemic and local toxic effects in animals treated repeatedly with DSR 2.0, compared to standard peritoneal dialysis solution used in the control group
 - Single dose of DSR 2.0 was safe and well-tolerated and indicated a compelling dosing profile in stable peritoneal dialysis patients (Phase 1 CHIHUAHUA study)

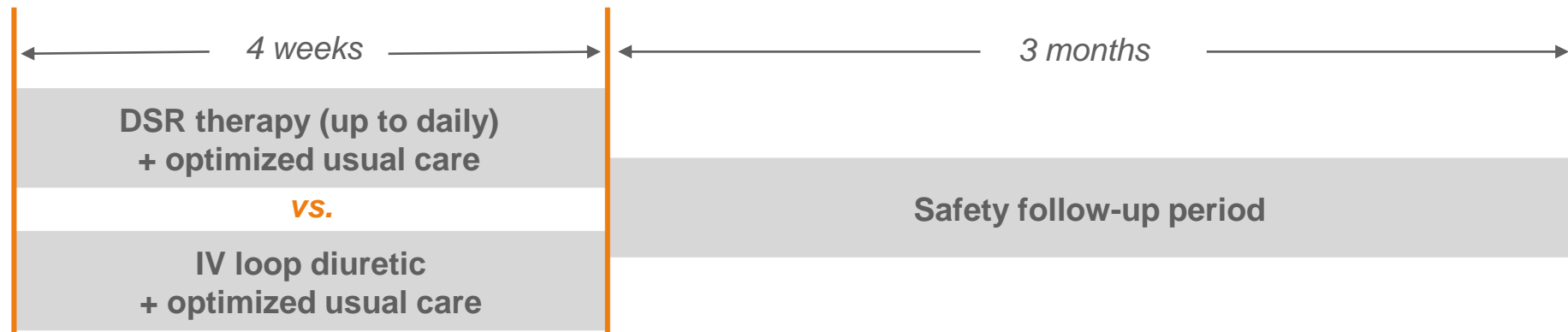


***US FDA cleared IND application for DSR 2.0 in a timely manner
Enabled the start of the US MOJAVE study***



MOJAVE – Phase 1/2a randomized controlled US study

Seeking to replicate SAHARA outcomes in US study of heart failure patients with persistent congestion



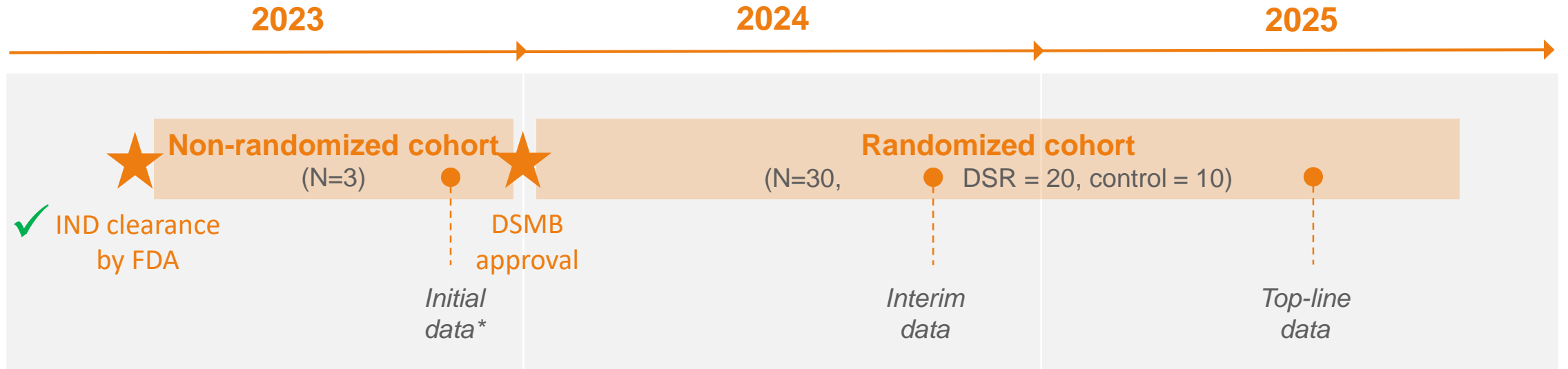
Endpoints

- **Safety:** rate of adverse and serious adverse events
- **Efficacy:** improvement in diuretic response (6-hour urine sodium output)
- **Exploratory:** change in weight (volume status), creatinine (renal function), natriuretic peptides (heart function), NYHA functional class, number of HF-related re-hospitalizations



MOJAVE – initial data expected in Q4 2023

First patients enrolled in non-randomized cohort



Top-line data in mid 2025 intended to deliver the clinical data package for partnering

* Data from three patients in non-randomized cohort

Key financial results H1 2023

Equity placement of €15.8 M in April 2023 extended cash runway into Q1 2024

Revenue: €384 K

- Commercial activities in Europe scaled back

Operating expenses: - €15.9 M

- Preparation of submissions for marketing approval of **alfapump** in US and Canada
- IND filing for DSR 2.0 and commencement of US MOJAVE study

Net result: - €16.5 M

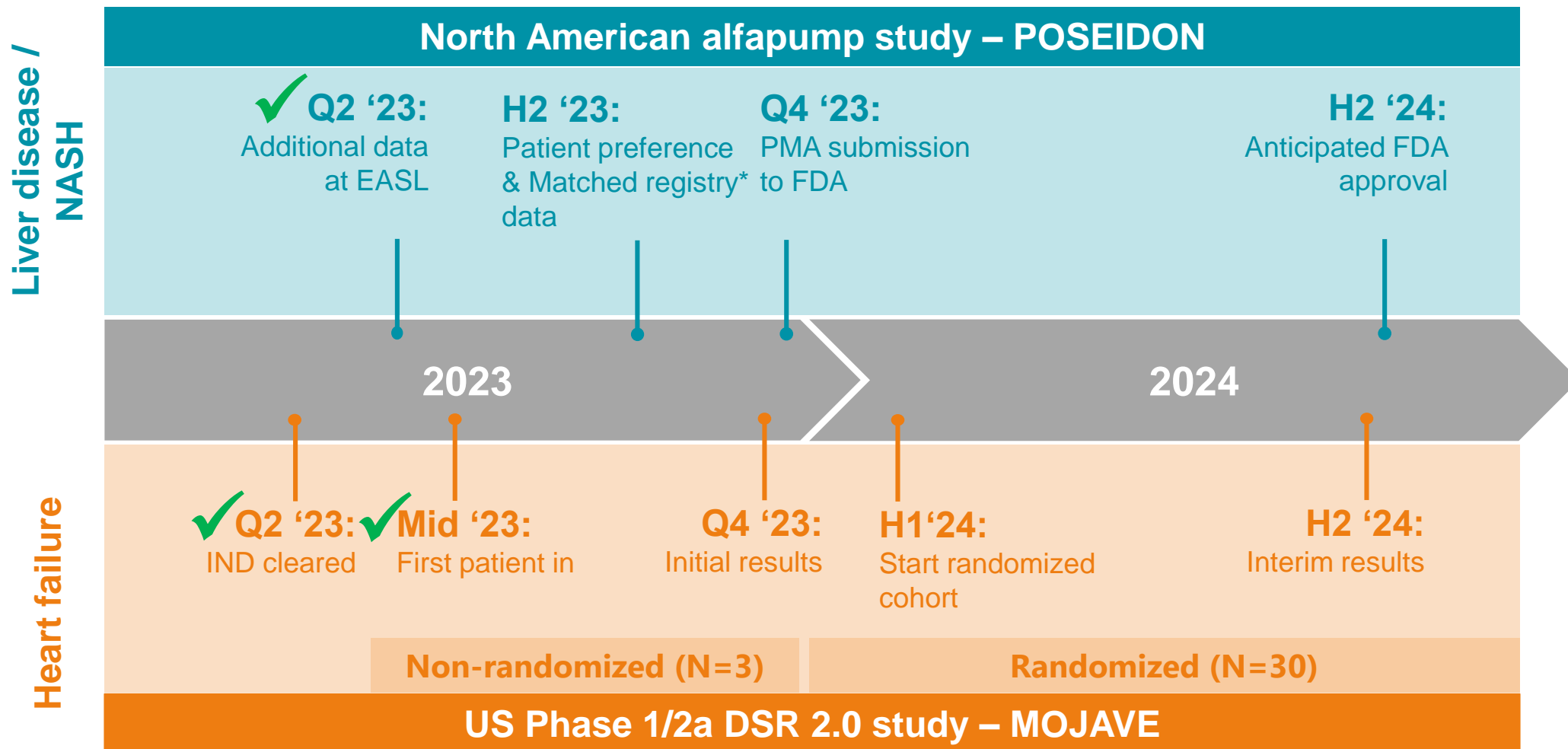
Cash position of €17.1 M at 30 June 2023

Kenneth Macleod appointed to our Board of Directors



- Partner at **Rosetta Capital**
- **Over 35 years** in life sciences sector
 - Healthcare companies: Abbott Laboratories, Serono SA
 - Life science fund management: SV Health Investors, Paul Capital Partners, Visium Healthcare Partners
- Board member of JenaValve Technology Inc., Oxular Limited

Strong outlook for key value drivers



* Data from propensity matched interim analysis of NACSELD (North American Consortium for the Study of End-stage Liver Disease) registry vs POSEIDON pivotal cohort

Leader in large markets with unmet needs

Near term liver opportunity with visibility into heart failure



alfapump in liver disease

- Market growing to over \$2.5 billion by 2035⁽¹⁾
- FDA breakthrough device / Approved in EU
- Successful North American POSEIDON pivotal study – primary endpoints met, strong clinical profile
- PMA filing planned for Q4 '23 with FDA approval anticipated in H2 '24
- Direct sales in US
- Strong reimbursement profile – existing DRGs, NTAP and TCET opportunity



DSR in heart failure

- Multi-billion commercial opportunity – 400K patients in the US & EU
- Clinical proof-of-concept as disease-modifying heart failure drug therapy
- Transitioning to DSR 2.0; low development risk, improved profile & strong IP
- US Ph. 1/2a randomized controlled study (MOJAVE) started; initial data planned for Q4 '23
- Partnering based on MOJAVE readout in '25

Growth in liver cirrhosis due to NASH and breakthrough DSR innovation drives tremendous commercial opportunity for Sequana Medical

Source 1: Based on US and Canada market assessment conducted by highly experienced international consulting group, estimating over 170,000 patients with recurrent or refractory ascites in North America by 2035, with estimated incidence of 60% and based on \$25K for price of **alfapump**

PMA: Pre-Market Approval; **DRG:** Diagnosis Related Group (hospital payment code); **NTAP:** New Technology Add-on Payment; **TCET:** Transitional Coverage of Emerging Technologies

Q&A

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