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FY2020 Financial Results & Business Update

17 March 2021

Today's presenters

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Disclaimers

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Disclaimers

Regulatory disclaimer:

- The **alfa**pump® system has not yet received regulatory approval in the United States and Canada. Any statement in this presentation about safety and efficacy of the **alfa**pump® system does not apply to the United States and 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 visit www.poseidonstudy.com.
- 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.

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 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 Benelux.

2020 – YTD Highlights

- POSEIDON – positive interim results reported; additional interim results expected in Q2 2021
- RED DESERT – positive interim results reported; top-line results expected in Q2 2021
- **alfa**pump DSR® – fundamental patents granted in US and Europe
- Positive data published in two leading peer-reviewed publications: *Circulation* and *Liver Transplantation*
- Strengthened our team:
  - Dr. Oliver Gödje as Chief Medical Officer; Gijs Klarenbeek remains as Senior Medical Advisor
  - Dr. Michael Felker and Dr. James Udelson as additional Heart Failure Scientific Advisors
- Cash runway extended into Q2 2022
  - €19M equity financing (January 2020)
  - €7.3M debt financing (July 2020)
  - €22.5M equity financing (February 2021)

One platform – two products – multi-billion euro opportunities

alfapump®

Liver Disease (NASH)

CE mark / FDA Breakthrough Device
Over 850 devices implanted

> €3 Bn / year market opportunity(1)

POSEIDON pivotal study ongoing

Self-commercialisation

alfapump DSR®

Heart Failure

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

> €5 Bn / year market opportunity(2)

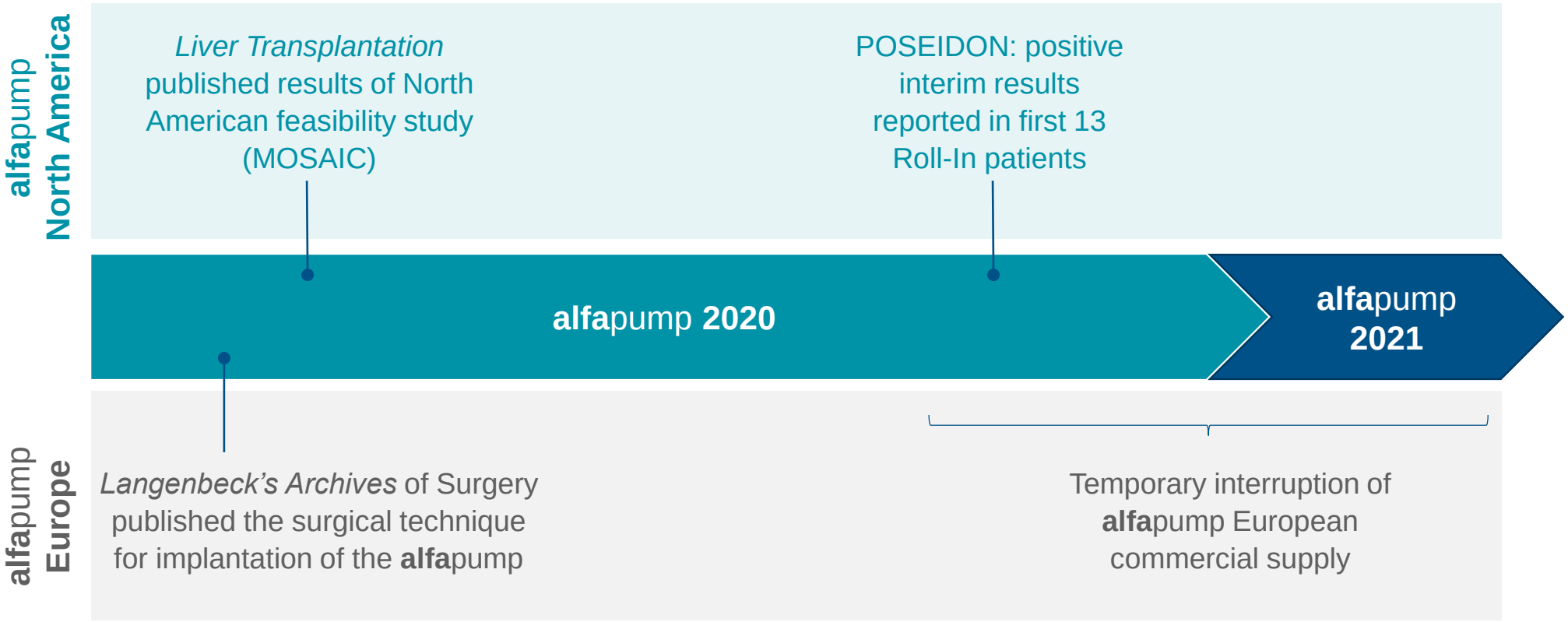
RED DESERT repeated dose study ongoing

Partnering after US efficacy 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)

Year in Review: alfapump® 2020 – YTD



Interim POSEIDON: Positive for primary endpoints

Data from first 13 Roll-In patients implanted with the alfapump®

EFFICACY

- ✓ Over 90% reduction in mean frequency of Therapeutic Paracenthesis (TP) post-implant vs. pre-implant (primary endpoint of >50% reduction)
- ✓ All patients experienced at least a 50% reduction in the mean frequency of TP per month (primary endpoint of >50% of patients)

SAFETY

- ✓ Safety profile in line with expectations

QUALITY OF LIFE

- ✓ Indication of rapid and persistent clinically relevant improvement in patients' quality of life

Note: Pre- and post-implant periods for this analysis of the Roll-In Cohort differ from those that will be used for the Pivotal Cohort analysis

Pursuing North American approval of alfapump®

Targeting primary endpoint read-out in Q2 2022

- POSEIDON – additional upcoming data read-out:
  - Completion of patient enrolment expected in Q2 2021 (small delay due to COVID-19 impact)
  - Interim results of larger Roll-In Cohort (up to 30 patients) expected in Q2 2021
  - Primary endpoint of Pivotal Cohort (up to 50 patients) expected in Q2 2022
- FDA Filing for regulatory approval expected in H2 2022
- Sponsored patient registry (NACSELD) and FDA patient preference study ongoing

*MCIT & NTAP – final CMS rules for breakthrough devices to further support coverage & reimbursement for the **alfa**pump*

CMS: Center for Medicare and Medicaid Services; NACSELD: North American Consortium for the Study of End Stage Liver Disease; MCIT: Medicare Coverage of Innovative Technology; NTAP: New Technology Add-on Payment

Temporary interruption of alfapump® European commercial supply

Low manufacturing yield of alfapump systems

- Prioritisation of POSEIDON and RED DESERT studies
- Limited supply of **alfa**pump systems to European commercial markets
  - No impact on the quality of the **alfa**pump systems that have been supplied to the market
  - No regulatory impact

✓ **POSEIDON and RED DESERT remain on track**

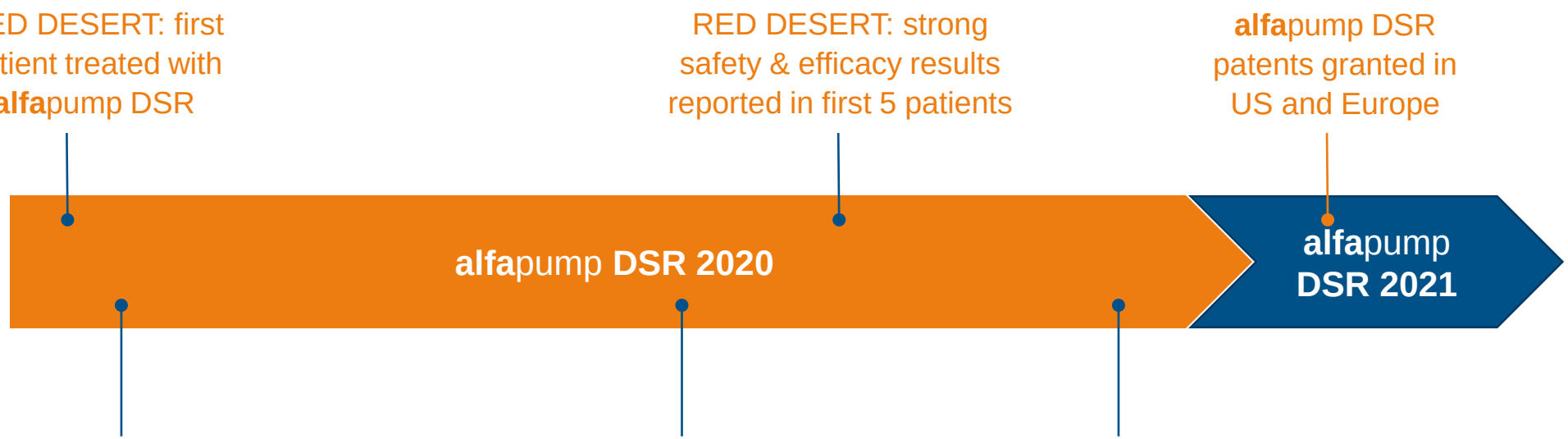
✓ **Addressing manufacturing yield issue**

✓ **Improving manufacturing reliability & stability**

Taking into account ongoing COVID-19 restrictions,

normal commercial activity in Europe is expected to resume in H2 2021

Year in Review: alfapump DSR® 2020 – YTD



Interim RED DESERT: Strong safety & efficacy results

Results from first five patients after 6-week repeated dose alfapump **DSR® therapy**

SAFE & WELL-TOLLERATED

No progressive hyponatremia

Reported adverse events manageable

HIGHLY EFFECTIVE

No diuretics required during the 6-week treatment period

Reduced DSR dosing in majority of patients

RESTORATION OF DIURETIC RESPONSIVENESS

Sodium excretion more than doubled post-study

Dramatic reduction in diuretic dosage post-study

- ***Indicates DSR therapy is more than just a means to remove sodium and water***
- ***Supports intermittent dosing to restore natural kidney response***
- ***Potential expansion into other fluid overload indications***

alfapump DSR®: Upcoming clinical milestones

Building the clinical evidence and experience of DSR in treatment of diuretic-resistant fluid overload

- RED DESERT: Top-line data in up to 10 patients expected in Q2 2021
- SAHARA DESERT:
  - Dose-ranging feasibility study of **alfa**pump DSR in decompensated heart failure patients with residual congestion
  - Submitted for Ethics Committee approval in Georgia
  - First patient expected in Q2 2021
  - Interim data expected in Q4 2021 / Top-line data expected in H1 2022

Ongoing development of proprietary next-generation DSR infusate intended to deliver improved therapeutic profile and recurrent revenue

SAHARA DESERT: Study design

Dose-ranging study to investigate improvement in diuretic response and durability of effect

- 20 decompensated heart failure patients with residual congestion, implanted with **alfa**pump DSR
  - Group 1 (N= 10): DSR treatment plus standard dose of SGLT2-inhibitor
  - Group 2 (N= 10): DSR treatment

Phase 1: Active Treatment phase
- 2 weeks intensive DSR treatment
- Titration of DSR treatment

Inadequate response (1) → **Repeat Phase 1** (maximum 2 times)

Adequate response (2) → **Phase 2: Maintenance phase**
- 16 weeks maintenance DSR treatment

(1) Poor diuretic response / remaining fluid overload
(2) Achieving euvolemia

- Study objectives:
  - Primary: safety and tolerability of **alfa**pump DSR therapy
  - Secondary: feasibility of DSR therapy to restore and maintain euvolemia without the need for additional loop diuretic treatment
  - Exploratory: evaluate potential impact of SGLT-2 inhibitors on DSR treatment

Key Financial Results FY 2020

Revenue: **€963K** (-1%)

- Strong growth in Germany and France in H1 2020
- Delay in supply of **alfa**pump to European commercial markets in Q4 2020

Operating expenses: **- €18,532K** (+26%)

- POSEIDON & RED DESERT studies and operational costs
- Preparation of commercial marketing application in US and Canada

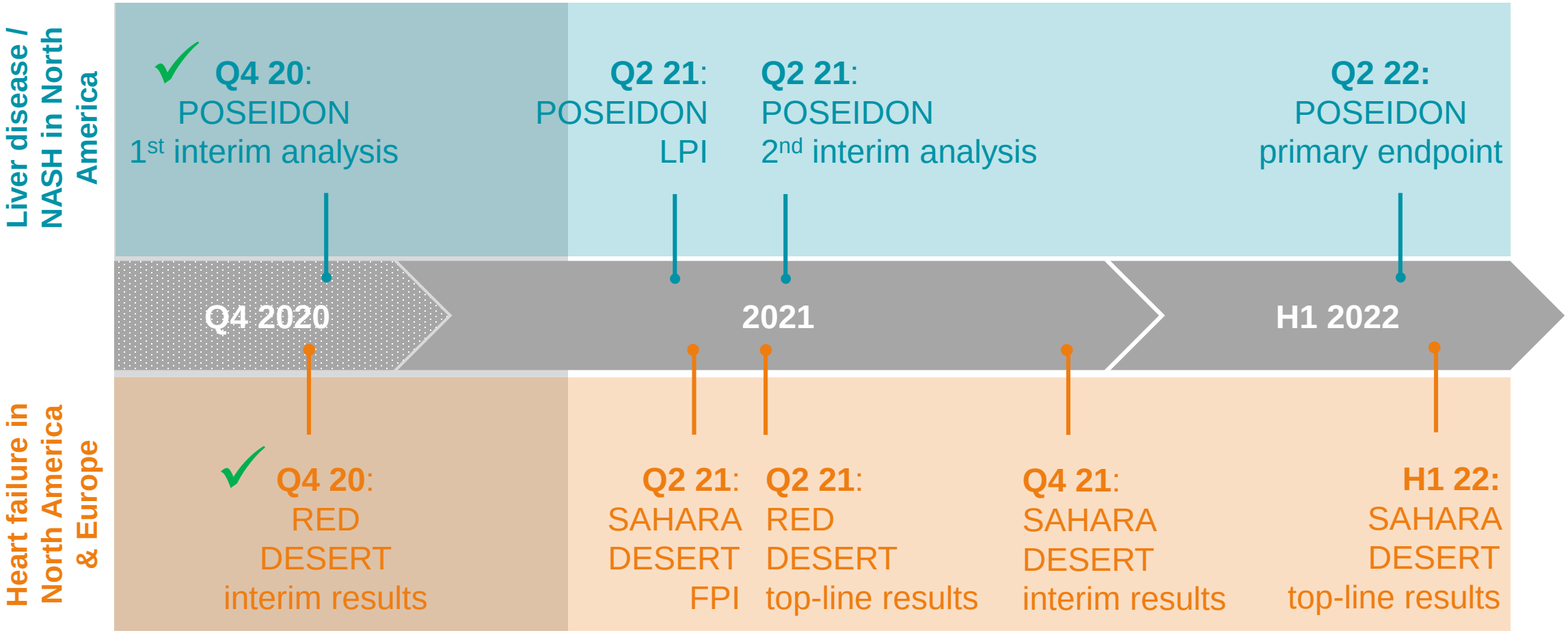
Net result: **- €19,106K**

Cash position of €11.0M at end of December 2020

Post period: ABB Equity Offering (€22.5M)

Cash runway extended into Q2 2022

Expected core value drivers & outlook



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

FPI: First Patient In; LPI: Last Patient In

Q&A