

sequana**medical**



2019 Half Year Results & Year-to-date Business Update

25 September 2019

Today's presenters



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Chief Executive Officer



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Chief Medical Officer



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Chief Financial Officer

Disclaimers

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Regulatory disclaimers:

- The **alfapump**[®] has not yet received regulatory approval in the US and Canada. Any statement in this presentation about safety and efficacy of the **alfapump** 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 **alfapump** DSR (Direct Sodium Removal) to deliver a convenient and fully implanted system for DSR therapy. DSR therapy is 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 and ongoing investigations with the **alfapump** system in Europe, the US and Canada.

Agenda

- ✓ Executive Summary
- ✓ Our Company
- ✓ Update on **alfapump**[®] and **alfapump**[®] DSR
- ✓ Corporate & Financial Highlights
- ✓ Outlook & Value Drivers
- ✓ Q&A

Executive Summary

Strong progress across both liver disease and heart failure, our two pillars of growth



alfapump® North America

- ✓ Breakthrough Device Designation from US FDA
- ✓ First patient enrolled in POSEIDON pivotal study to support marketing approval in US and Canada



alfapump® DSR

- ✓ Clinical proof-of-concept of DSR (Direct Sodium Removal) for volume overload due to heart failure
- ✓ Appointment of Dr. Butler, Dr. Costanzo, Dr. Tang and Dr. Testani as Heart Failure Scientific Advisors



alfapump® Europe

- ✓ Inclusion in German treatment guidelines (DGVS)



Corporate

- ✓ Appointment of medtech executive Jason Hannon to the board of directors
- ✓ €27.5 million raised in IPO on Euronext Brussels



Our Company

Innovators in the management of
fluid overload

liver disease - malignant ascites - heart failure

One platform – two products

alfapump platform



alfapump[®]

proven step change in liver refractory ascites and malignant ascites;

over 700 devices implanted



alfapump[®] **DSR**

breakthrough approach to fluid overload in heart failure;

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



Breakthrough Device Designation



NICE
National Institute for Health and Care Excellence



1913 DGVS
Deutsche Gesellschaft für Gastroenterologie, Verdauungs- und Stoffwechselkrankheiten



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



alfapump® North America



NASH drives US market attractiveness

Stronger competitive position in a much larger and dynamic market

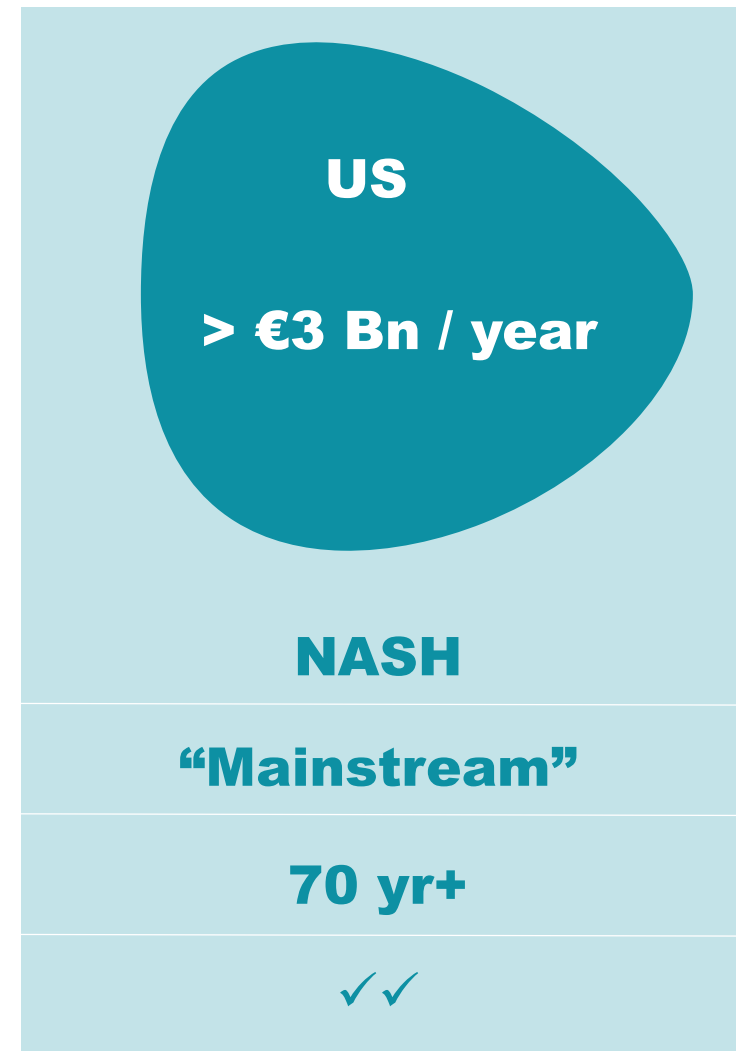
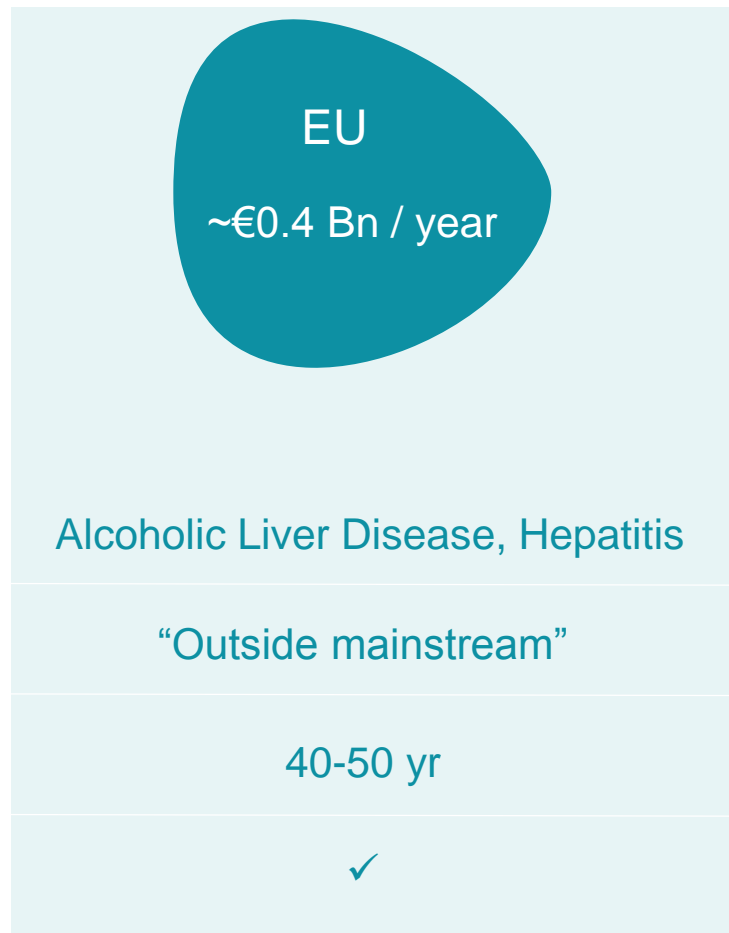
| **alfapump**[®] market potential |

| Underlying disease |

| Patient characteristic |

| Average age |

| **alfapump** competitive positioning |



Notes: EU Liver market: 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.
 US Liver market: Management estimate that is inclusive of estimated growth in prevalence of NASH for the US and EU5 based on GlobalData Epidemiology Forecast to 2026.



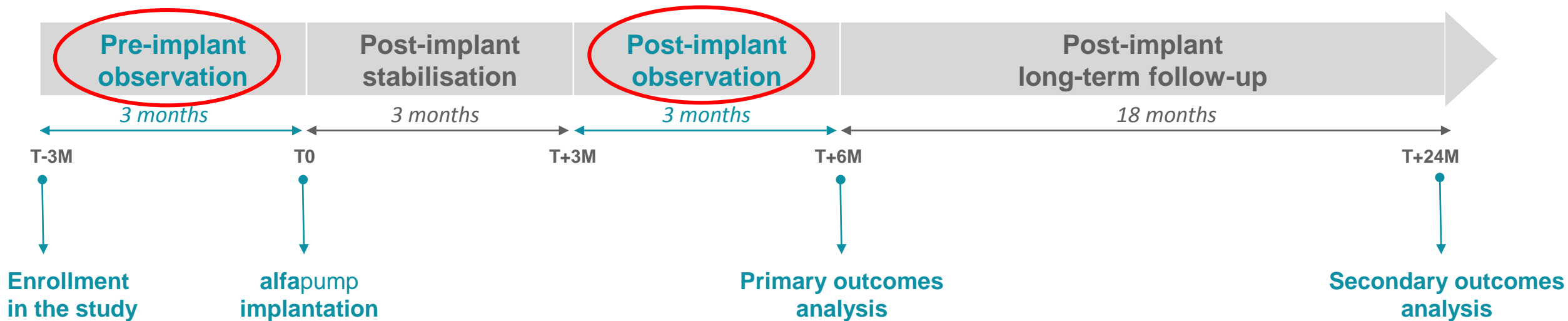
Clear progress in pursuit of North American approval

- ✓ Received Breakthrough Device Designation from the U.S. FDA for the **alfapump**[®] for the treatment of recurrent or refractory liver ascites
- ✓ Received unconditional IDE approval from the US FDA and ITA approval from Health Canada to start North American pivotal study (POSEIDON) using an optimised clinical trial design
- ✓ First patient enrolled in POSEIDON in September 2019
- ✓ Received approval from Institutional Review Board from 5 centres



First patient enrolled in POSEIDON study

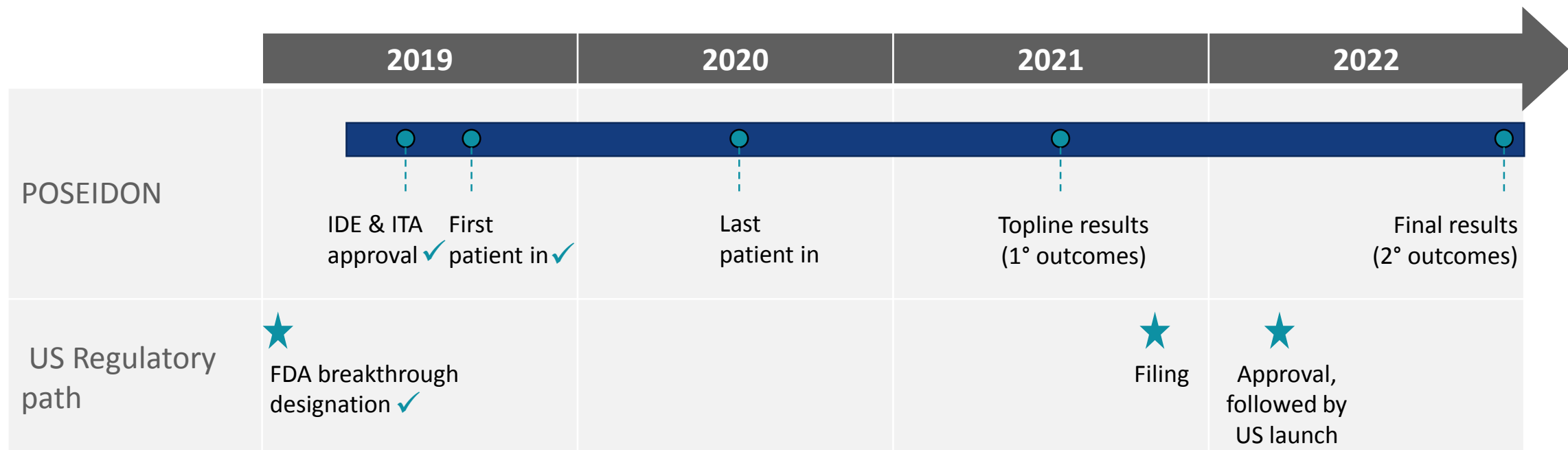
- Up to **50 patients** implanted with the **alfapump**⁽¹⁾ across 15 centres
- Primary endpoint at **9 months after enrollment**:
 - ⇒ proportion of patients with a 50% reduction in average number of paracentesis per month post-implant vs pre-implant





alfapump[®] US approval roadmap

Key anticipated milestones



Proposed CMS rule on reimbursement for breakthrough devices (NTAP)

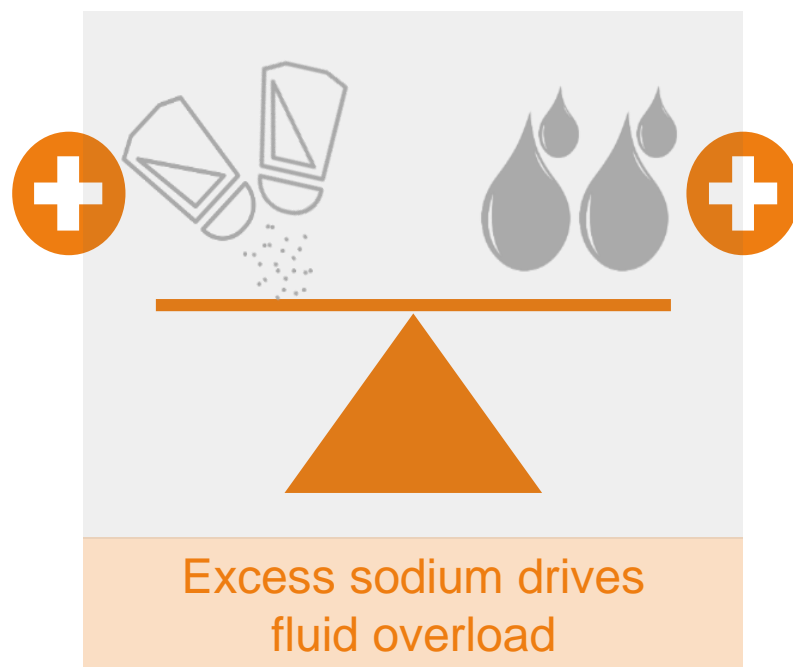
*Positive development for the **alfapump***



alfapump[®] DSR



Volume overload in heart failure is a major problem and a key driver of costs



40% of heart failure patients are poorly controlled with diuretics

\$13 billion annual US cost of heart failure related hospitalisations of which ~90% due to volume overload



Clinical proof-of-concept of DSR paves the way for our breakthrough approach

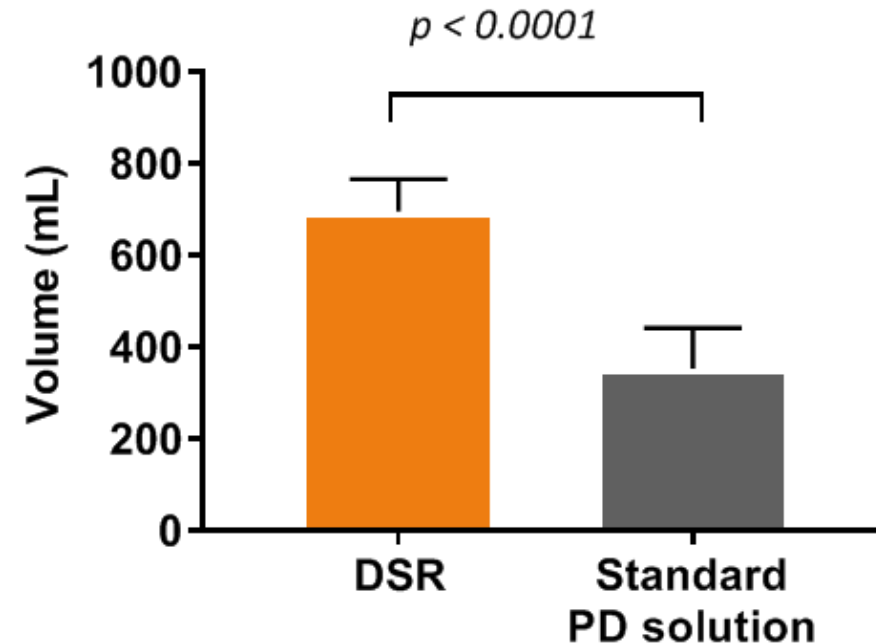
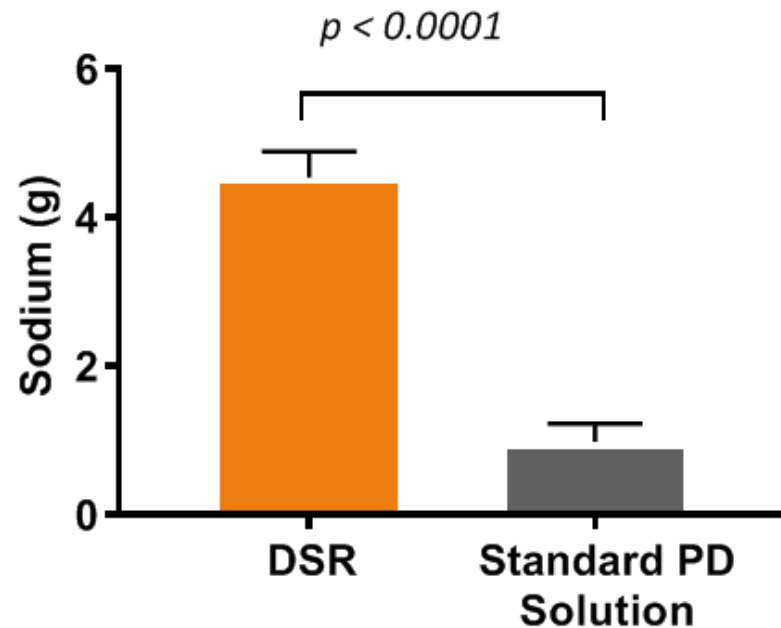
- ✓ Primary and secondary endpoints met in first-in-human single dose DSR proof-of-concept study
 - ⇒ Results selected for late-breaking abstract session and highlights plenary session at Heart Failure 2019
- ✓ Preparations underway to start repeated dose **alfapump**[®] DSR study in H2 2019
- ✓ Appointment of leading experts Dr. Butler, Dr. Costanzo, Dr. Tang and Dr. Testani as Heart Failure Scientific Advisors





First-in-human single dose DSR proof-of-concept study

- ✓ DSR therapy was safe & well-tolerated with no adverse events or significant discomfort
- ✓ Substantially higher sodium removal with DSR vs standard Peritoneal Dialysis (PD) solution
- ✓ Minimal inter-patient variability





alfapump[®] DSR leverages proven elements

Combining clinical proof-of-concept of DSR with validated alfapump platform

✓ DSR

- Safe & well-tolerated
- Clinically relevant removal of sodium
- Minimal patient inter-variability



✓ alfapump

- Validated technical performance
- Extensive clinical experience
- Deep understanding of implementation



✓ Implanted port

- Many years of clinical experience

Preparations underway for repeated dose alfapump DSR study to commence in H2 2019



alfapump®

Europe



Continued scale up of our commercial activities in focus European territories

- ✓ Inclusion in German treatment guidelines (DGVS) for complications of liver cirrhosis
- ✓ Created referral networks of centres of excellence in Germany, Switzerland, France and UK
- ✓ Hired Therapy Development Managers
- ✓ Discussions with Dutch reimbursement institutions ongoing following new regulation Promising Care



Expanding clinical evidence in Europe

- 
- ✓ Preparing for patient enrolment in Prospective Malignant Ascites Study (ProMAS)

- ⇒ Impact of **alfapump**[®] on quality of life in patients with malignant ascites

- ⇒ Up to 40 patients across sites in Belgium, the UK and Switzerland

- ⇒ First patient enrolled expected in Q4 2019

- ⇒ Top line results planned for H1 2021

- 
- ✓ Preparations ongoing for Step Counter Study

- ⇒ Impact of **alfapump** on patient activity, stress and sleep quality using fitness loggers

- ⇒ Continuous enrollment with interim readouts at regular time points

A grid of white medical devices, possibly infusion pumps, arranged on shelves. Each device has a small screen and a handle. The devices are illuminated with a soft blue and green glow from below. The background is a light, neutral color.

Corporate & Financial Highlights

Strengthened leadership team and balance sheet

- ✓ Appointment of Medtech executive Jason Hannon to Board of Directors



Pierre Chauvineau
Board Chairman



Ian Crosbie
Chief Executive Officer



Rudy Dekeyser
Director



Wim Ottevaere
Director



Erik Amble
Director



Jason Hannon
Director

- ✓ €27.5 million through IPO on Euronext Brussels in February 2019



2019 half year results

in Thousand Euros	HY 2019	HY 2018	Variance
Revenue	413	447	-8%
Cost of goods sold	(86)	(96)	-10%
Gross margin	327	352	-7%
Sales & Marketing	(1,306)	(977)	+34%
Clinical	(1,451)	(749)	+94%
Quality & Regulatory	(930)	(564)	+65%
Supply Chain	(368)	(514)	-28%
Engineering	(534)	(548)	-3%
General & Administration	(2,582)	(1,763)	+46%
Other income	6	-	N.A.
Total operating expenses	(7,166)	(5,115)	+40%
Earnings before interest and taxes (EBIT)	(6,838)	(4,763)	+44%
Finance income	13	134	-90%
Finance cost	(471)	(391)	+20%
Total net finance expense	(458)	(258)	+78%
Income tax expense	(7)	(24)	-71%
Net loss for the period	(7,303)	(5,045)	+45%
Cash position	12,877	1,223	N.A.

A person wearing a white lab coat and white gloves is working in a laboratory. They are holding a small, green electronic component with a red circular sticker. The background shows laboratory equipment, including a microscope and various tubes and containers. The scene is brightly lit, with a soft glow from the right side.

Outlook & Value Drivers

Strong news flow

Key anticipated milestones

H1 2019

- ✓ **alfapump**® received FDA Breakthrough Device designation
- ✓ **alfapump** included in German treatment guidelines (DGVS) for complications of liver cirrhosis
- ✓ Presented positive results of first-in-human single dose DSR study for volume overload in heart failure
- ✓ Received unconditional IDE approval from FDA to start North-American pivotal study (POSEIDON) in recurrent and refractory liver ascites patients

H2 2019

- ✓ Initiation of POSEIDON study in recurrent and refractory liver ascites patients
 - Initiation of Prospective Malignant Ascites Study (ProMAS)
 - Initiation of Step Counter study in refractory liver ascites patients
 - Initiation of first-in-human repeated dose **alfapump** DSR study in heart failure patients with volume overload
 - Initial results of first-in-human repeated dose **alfapump** DSR study in heart failure patients with volume overload

H1 2020

- Expected final German⁽¹⁾ reimbursement of **alfapump**
- **Completion of enrollment of POSEIDON study in recurrent and refractory liver ascites patients**
- **Final results of first-in-human repeated dose alfapump DSR study in heart failure patients with volume overload**

Q&A

