



sequanamedical



2018 Full Year Results & 2019 Outlook

4 April 2019

Today's presenters



Ian Crosbie
Chief Executive Officer



Gijs Klarenbeek
Chief Medical Officer



Kirsten Van Bockstaele
Chief Financial Officer

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Agenda

- ✓ Executive Summary
- ✓ Our Company
- ✓ Major achievements
- ✓ Corporate & Financial highlights
- ✓ Outlook 2019
- ✓ Q&A

Executive Summary



Important third party endorsements

- Included in EASL clinical guidelines
- Improved NICE recommendation
- FDA Breakthrough device designation



Additional clinical evidence presented by leading clinicians

- 2 peer-reviewed publications
- 3 presentations at international conferences



Clinical outcomes continuously better

- **alfapump** therapy exceeding 450 days
- European TOPMOST registry initiated



Significant progress in heart failure programme

- Pre-clinical proof-of-concept achieved
- First-in-human study ongoing



Strengthened team & moved to Belgium

- Kirsten Van Bockstaele as CFO
- Pierre Chauvineau as Chairman and Wim Ottevaere as Non-Executive Director



Much strengthened balance sheet

- €8.5 million in private financing round in '18
- €27.5 million in successful IPO in '19



our company.

Innovators in the management of
liver disease, heart failure,
malignant ascites & other fluid
imbalance disorders

Commercial stage

medtech positioned for long-term growth

Focus

on liver disease and heart failure – large and growing markets

alfapump®

proven step change in the management of liver refractory ascites and malignant ascites; over 700 devices implanted



FDA Breakthrough Device Designation

alfapump® DSR

breakthrough approach to fluid overload in heart failure built on proven device platform

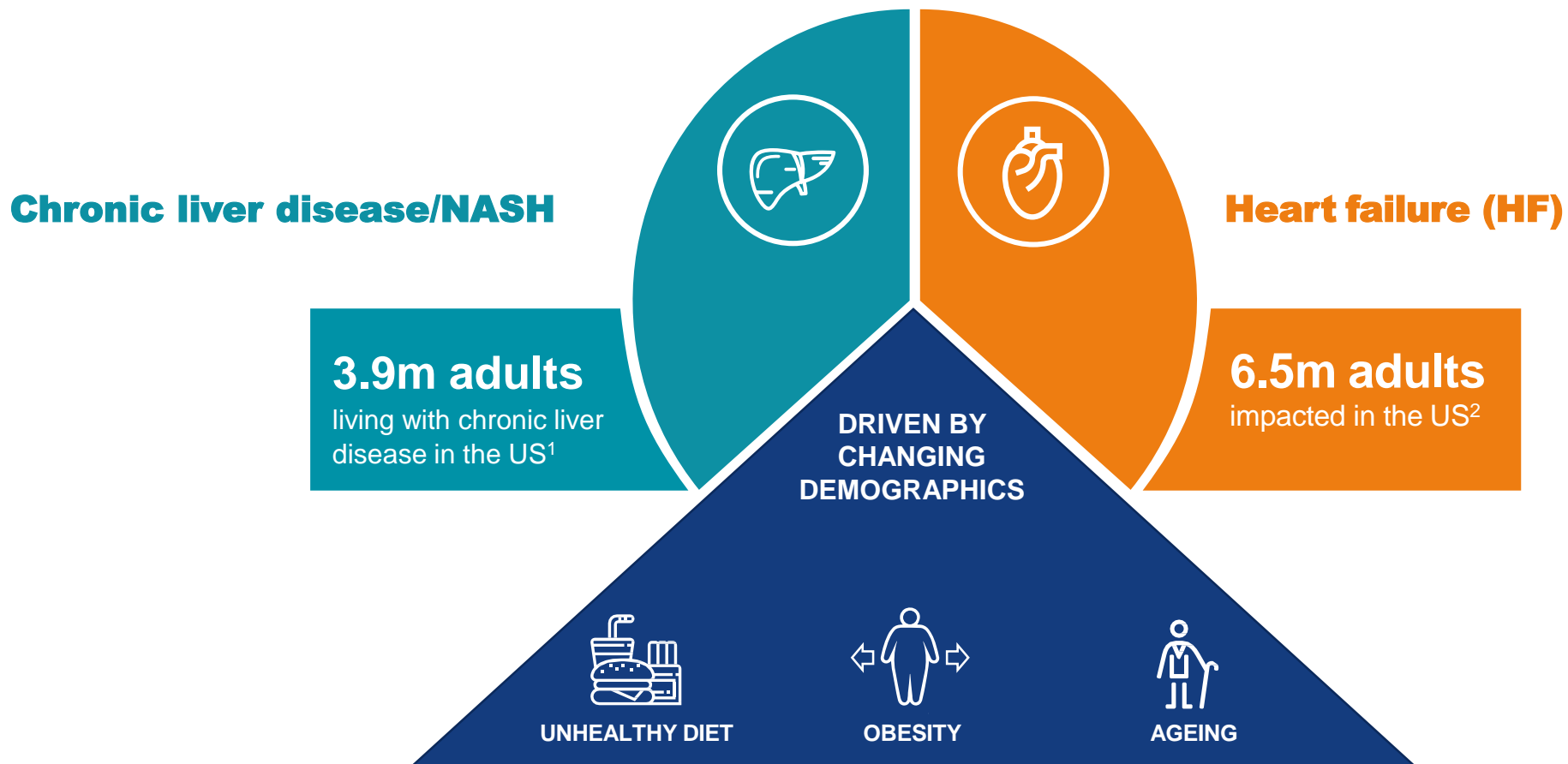
Strong

organisation led by an experienced leadership team ready to execute in the US and EU; strong IP position



Liver disease and heart failure

Large and growing markets driven by unhealthy lifestyles and ageing populations



Source 1: Centres for Disease Control and Prevention (CDC)
 Source 2: Mozzafarian D, Benjamin EJ, Go AS, et al. Heart disease and stroke statistics—2017 update (adults: >=20 years of age)

Key themes of our focus markets

Liver

- Growing prevalence of NASH
- Trend to “mainstream disease” will drive need for novel device therapies

Cancer

- Smaller market but clear patient need
- Untapped patient population to date

Heart Failure

- \$13bn annual cost of US hospitalisations
- Clear unmet need for treatment of diuretic-intolerant patients



major achievements.

alfapump[®] – refractory liver ascites and malignant ascites

Increased awareness and clinical evidence

Important third-party endorsements

- Included in EASL clinical practice guidelines for decompensated cirrhosis
- Updated UK NICE recommendation for treatment of refractory liver ascites under special arrangements
- Granted breakthrough device designation by US FDA for recurrent or refractory liver ascites

Additional clinical evidence presented by leading clinicians

- European Randomised Clinical Trial results published in Quality of Life Research
- Hannover study results published in European Journal of Gastroenterology & Hepatology
- Retrospective Malignant ascites study results presented at 2 international conferences¹
- North American MOSAIC study results presented at AASLD

Continue to build clinical evidence

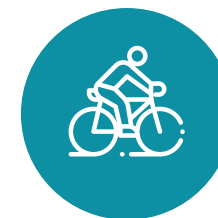
- First patient in TOPMOST European registry
- ARIA pump study initiated by French clinicians to support reimbursement in France



**Drastically reduced
need for drainage**

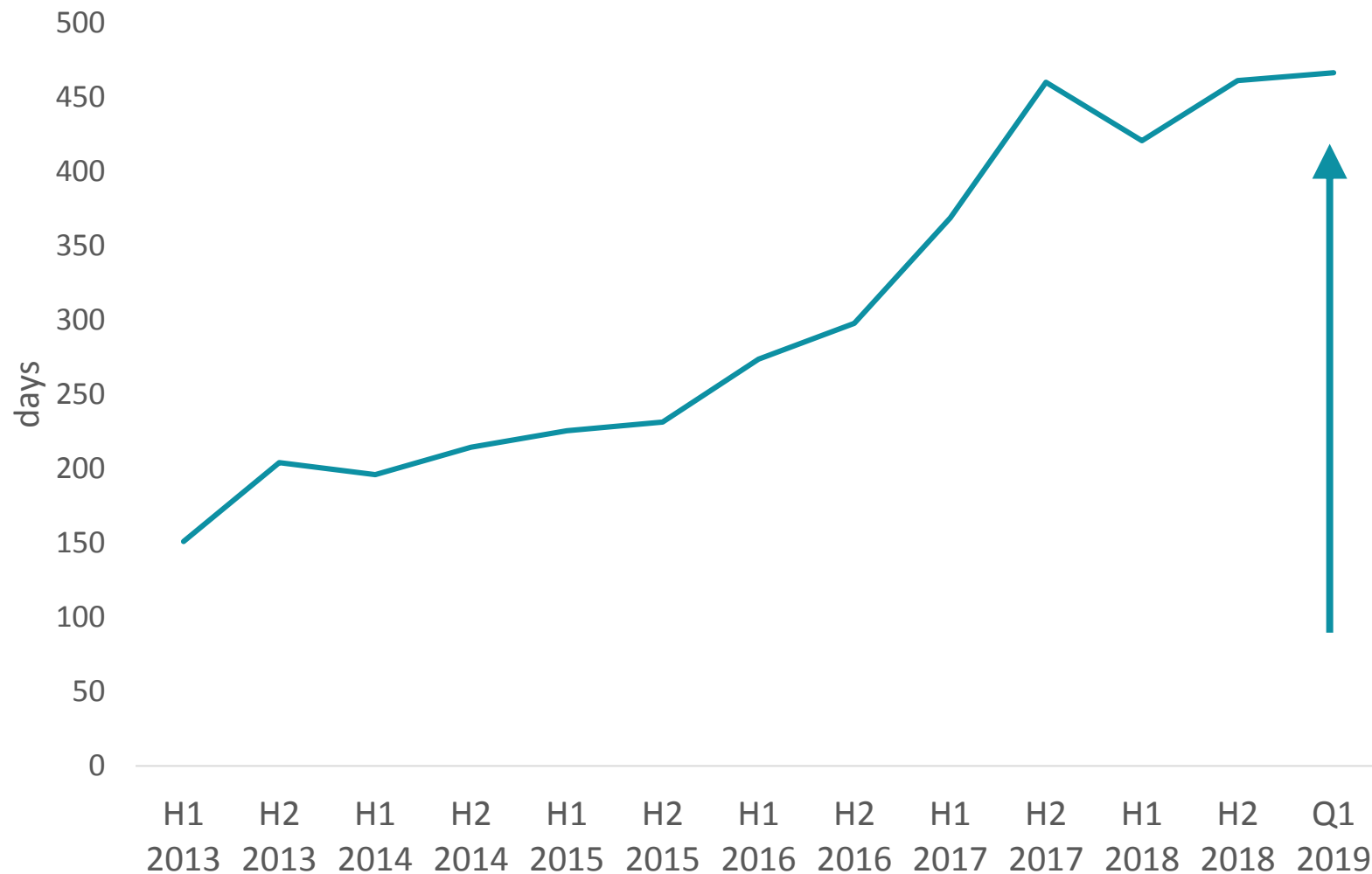


**Improved
nutrition**



**Improved patient
quality of life**

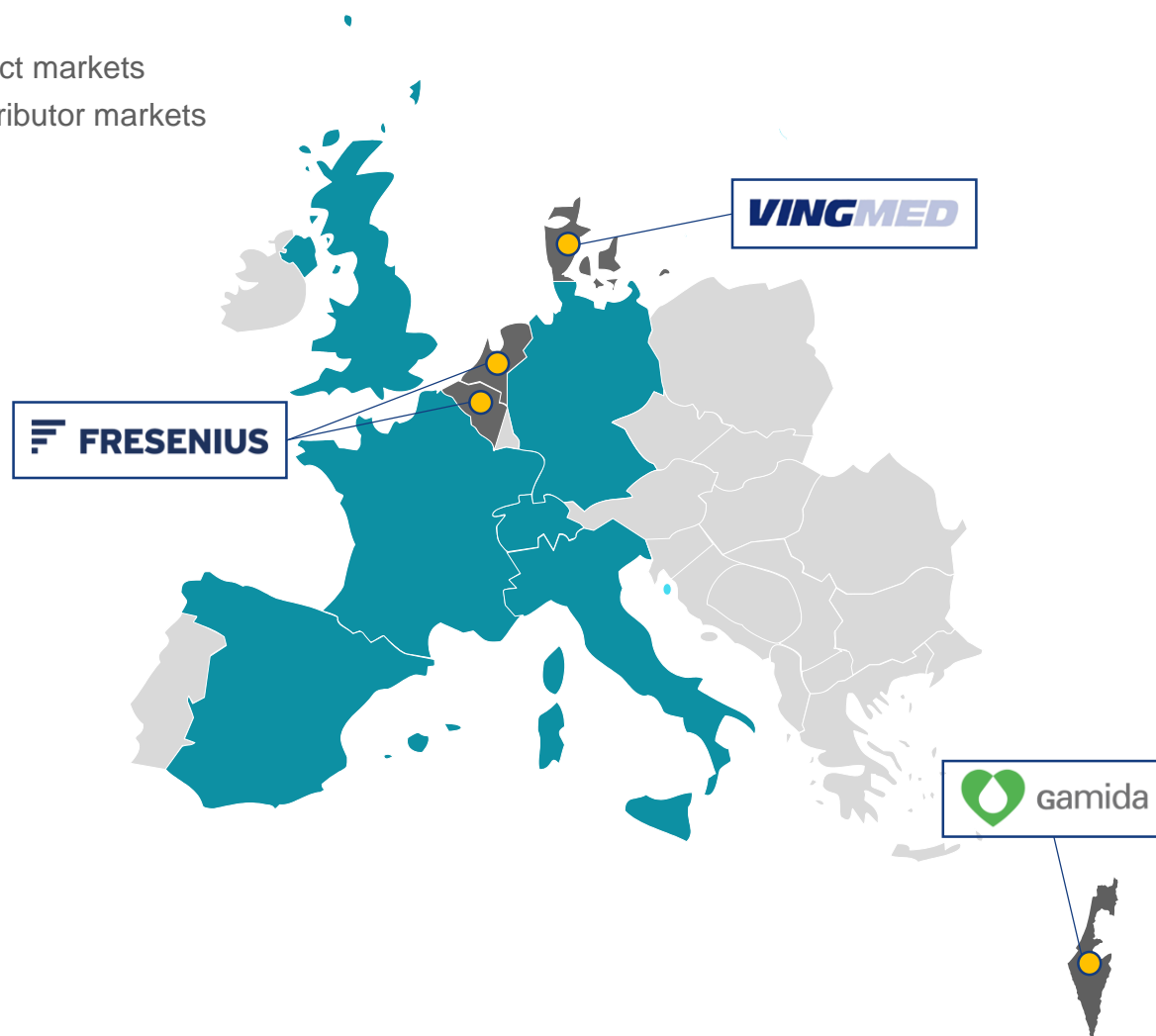
Clear increase in clinical outcomes



Average duration on alfapump therapy exceeding 450 days

Focused European commercial activities

- Direct markets
- Distributor markets



- ✓ Additional clinical evidence
- ✓ Built targeted commercial team
- ✓ Focus on specialist centers
- ✓ Raise awareness at community hospital level

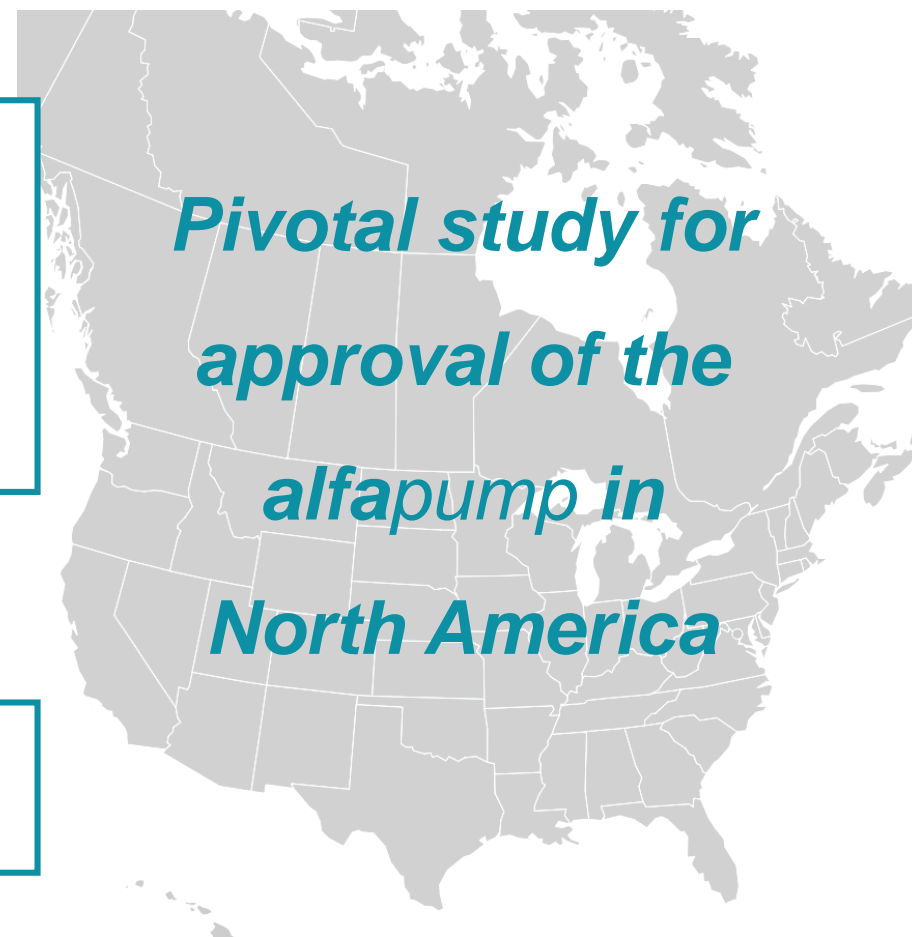
Rapidly moving to POSEIDON kick-off

Strong Progress

- ✓ FDA breakthrough device designation in January '19
- ✓ Several pre-submission meetings with FDA
- ✓ Advanced study design discussions
- ✓ Support from Key Opinion Leaders
- ✓ CRO selected

On Track

- Protocol submission to US FDA and Health Canada in Q2 '19
- Start of study in H2 '19



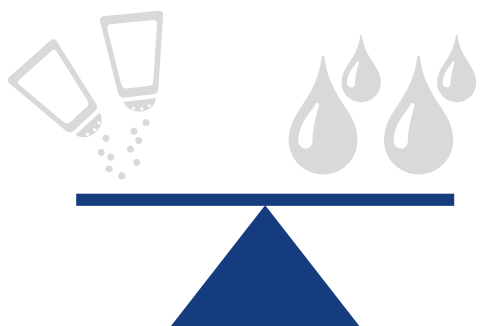


**major
achievements.**

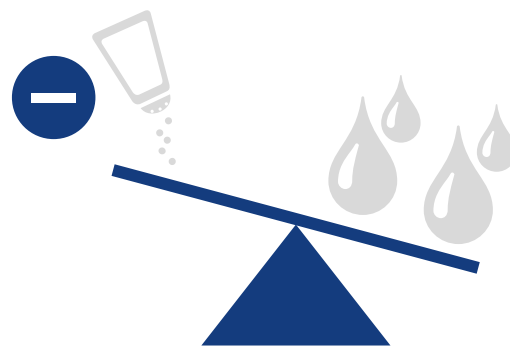
**alfapump[®] DSR – volume
overload in heart failure**

Direct sodium removal (DSR)

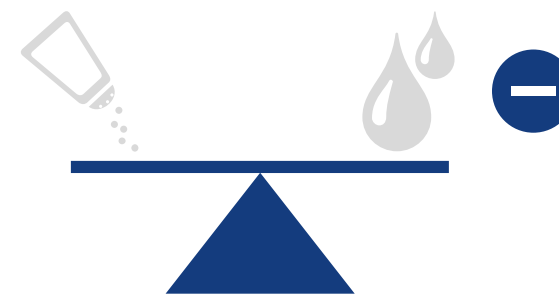
Breakthrough therapy tackling sodium removal directly



Volume overload
in heart failure



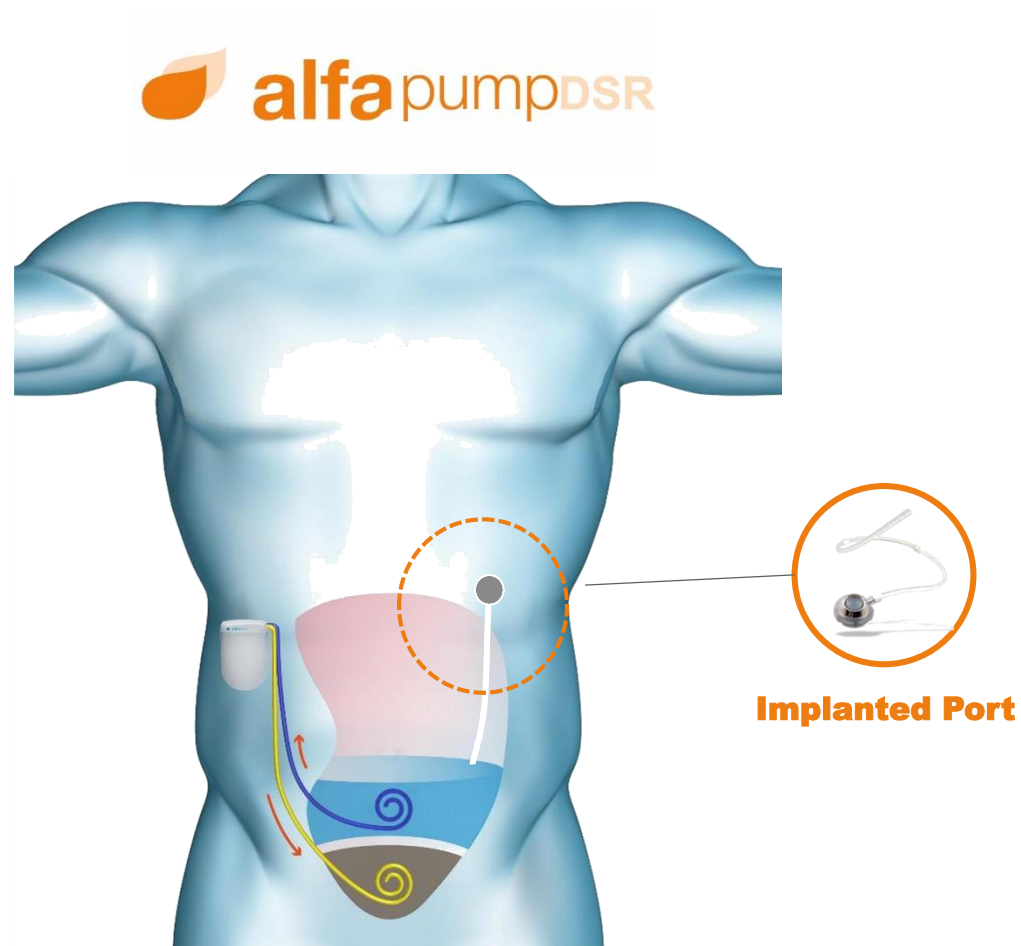
Removing the
sodium (DSR)



Elimination of
excess fluid

alfapump DSR

Fully implanted and convenient system leveraging on the alfapump experience



Administer infusate to the peritoneal cavity



Infusate extracts sodium from the body

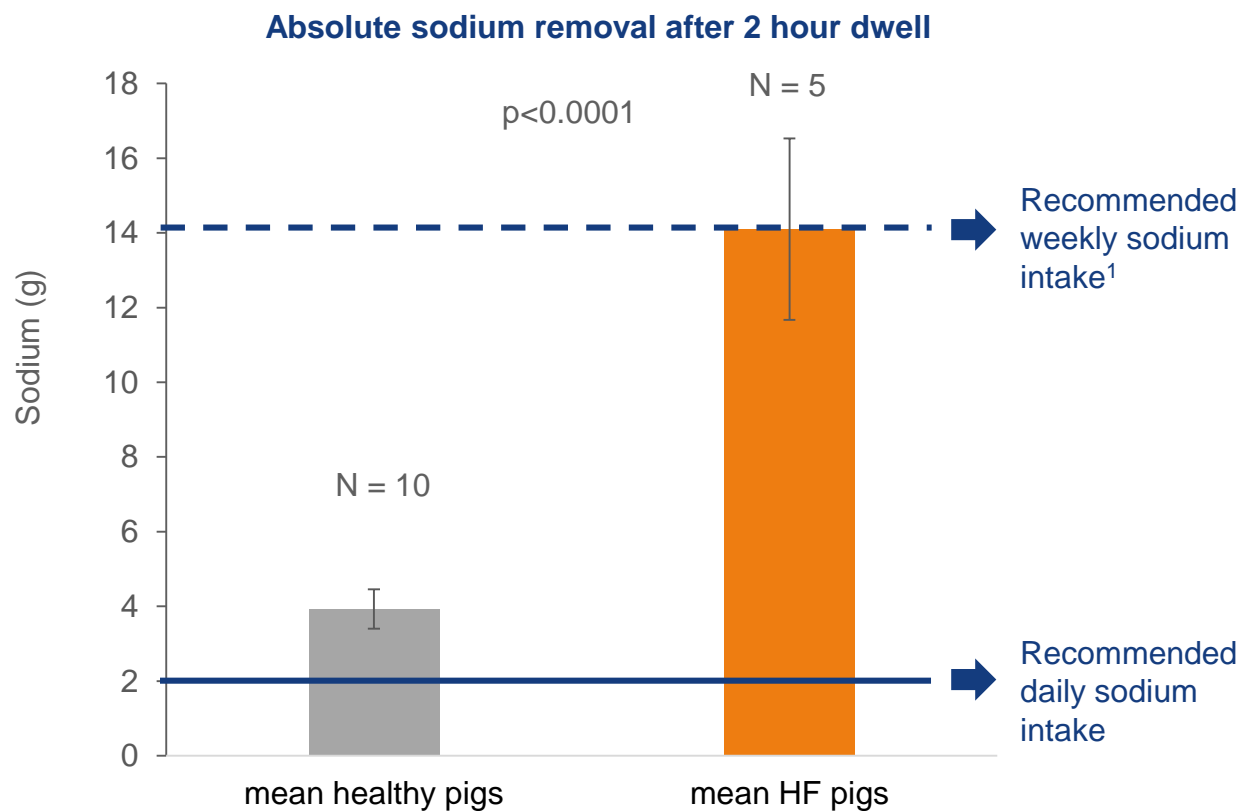


Remove extracted sodium from peritoneal cavity



Body restores balance by eliminating excess fluid

DSR: pre-clinical Proof-of-Concept delivered



*Clinically
relevant
removal of
sodium*

DSR: First-in-Human Proof-of-Concept study underway – On track for initial results in H1 '19

Yale

- Conducted by Dr. Testani at Yale University
- Up to 20 human subjects, peritoneal dialysis (“PD”) patients with peritoneal catheter
- Cross-over design: D10 DSR infusate vs. standard PD solution
- 1 litre infusate administration with 2 hour dwell

Key Objectives

- Safety & tolerability
- “Sodium removal” – efficacy & inter-patient variability (“Does it work and is it repeatable?”)

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. The background is a light, neutral color.

corporate & financial highlights.

Strong organisation

Highly experienced leadership team

Executive team:



Ian Crosbie
Chief Executive Officer



Kirsten Van Bockstaele
Chief Financial Officer



Martijn Blom
Chief Commercial Officer



Gijs Klarenbeek
Chief Medical Officer



Dirk Fengels
Vice President Engineering & Manufacturing



Timur Resch¹
Global VP QM/QA/RA

Board of Directors:



Pierre Chauvineau
Chairman



Ian Crosbie
Chief Executive Officer



Rudy Dekeyser
Director



Wim Ottevaere
Director



Erik Amble
Director

Note 1: position as of May 1st 2019

Move to Belgium

- Headquarters moved to Technologiemarkt in Ghent
- Building the Ghent team rapidly:
 - ⇒ Corporate, Finance, Clinical & Commercial
- Collaborating with Belgian KOLs across all our disease areas



Much strengthened balance sheet

- Q4 2018: €8.5 million through private financing round including existing investors plus Newton Biocapital, PMV and SFPI-FPIM
- Q1 2019: €27.5 million through IPO on Euronext Brussels



Financial results 2018

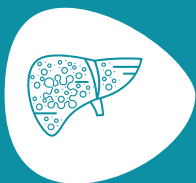
in Thousand Euros	FY 2018	FY 2017	Variance
Revenue	1,029	1,304	-21%
Cost of goods sold	(158)	(212)	-25%
Gross margin	871	1,092	-20%
Sales & Marketing	(2,445)	(1,506)	+62%
Clinical	(1,671)	(1,749)	-4%
Quality & Regulatory	(1,372)	(1,225)	+12%
Supply Chain	(964)	(1,041)	-7%
Engineering	(1,808)	(1,004)	+80%
General & Administration	(5,761)	(1,988)	+190%
Other income	74	4	N.A.
Total operating expenses	(13,948)	(8,510)	+64%
Earnings before interest and taxes (EBIT)	(13,077)	(7,418)	+76%
Finance income	309	107	+189%
Finance cost	(1,192)	(895)	+33%
Total net finance expense	(883)	(788)	+12%
Income tax expense	(24)	(18)	+33%
Net loss for the period	(13,983)	(8,225)	+70%



**outlook & key
catalysts.**

Three platforms for growth

Balancing risk and reward



North American Liver & Cancer

- ✓ Clinical feasibility study (MOSAIC)
- ✓ FDA breakthrough device status
- POSEIDON commencing in H2 2019



North America & Europe Heart Failure

- ✓ Animal studies (Yale University)
- First in human studies: single dose (underway) and repeated dose with **alfapump** (commencing H2 2019)



Europe Liver & Cancer

- ✓ CE mark and EASL clinical practice guidelines
- ✓ Clinical studies (RCT, PMSR, retrospective malignant)
- Prospective study in malignant ascites & registry in liver
- Focused expansion in UK, DE, CH & FR

Upcoming news flow

Key catalysts and development milestones

H2 2018

- ✓ Completion of DSR study in pig heart failure model & presentation of results
- ✓ Presentation of clinical data on 17 malignant ascites patients in retrospective clinical study
- ✓ Outcome of NICE review of **alfapump**[®]
- ✓ Initiation of First in Human clinical study for heart failure, single dose
- ✓ Initiation of TOPMOST: European “Super Registry” (Reporting Data Regularly)

H1 2019

- ✓ Outcome of FDA Breakthrough Device designation
- Presentation of initial results of first-in-human single dose DSR study
- Initiation of prospective malignant ascites study
- Initiation of prospective albumin study in patients with liver ascites

H2 2019

- Initiation of POSEIDON North American pivotal study
- Completion of full results of first-in-human single dose DSR study
- Expected reimbursement of **alfapump** in the Netherlands
- Presentation of initial results of first-in-human repeated dose heart failure study with **alfapump** DSR

Q&A

