

# sequanamedical

Commercial stage medical device company focused on innovative treatment solutions for liver disease, heart failure, malignant ascites and other fluid imbalance disorders

## Fast facts

- Founding in 2006
- Headquarters in Ghent, Belgium
- Manufacturing in Zurich, Switzerland
- 34 employees
- Raised approximately €117 million, including €27.5 million in a successful IPO on Euronext Brussels
- Leading specialist life science investors
- Highly experienced leadership team
- Vast industry and business know-how within the board, which amongst others includes Rudy Dekeyser & Wim Ottevaere
- Strong IP position
- Global network of KOLs in Europe and North America
- Targeted commercial roll-out across Europe



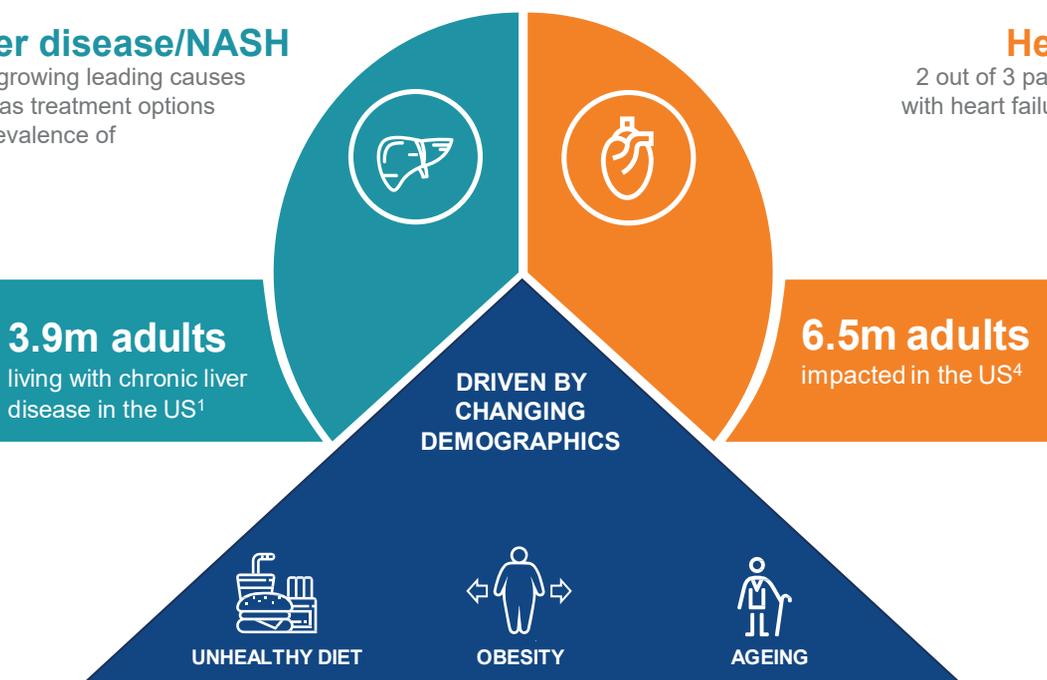
**alfapump®** is being commercialised in Europe for the treatment of liver refractory ascites and malignant ascites. Ascites is the accumulation of excess fluid (up to 15L) in the abdomen due to liver disease or cancer. Over 650 systems have been implanted and a North American pivotal study is planned to commence in the second half of 2019. The US Food and Drug Administration (FDA) has granted Breakthrough Device Designation for the **alfapump** for the treatment of liver recurrent or refractory ascites.

**alfapump** Direct Sodium Removal (DSR) builds upon the proven **alfapump** platform to deliver a convenient and fully implanted system for volume overload in heart failure.

Focus on liver disease and heart failure, large and growing markets driven by unhealthy lifestyles, obesity and an ageing population

## Chronic liver disease/NASH

One of the fastest growing leading causes of death in the US as treatment options are limited<sup>2</sup> and prevalence of NASH increases<sup>3</sup>



## Heart failure

2 out of 3 patients diagnosed with heart failure will die within 5 years<sup>5</sup>

### Liver Cirrhosis:

The market is forecast to grow dramatically due to increasing prevalence of fatty liver disease / NASH (non-alcoholic steatohepatitis) – especially in the US. Approximately three to four million people in the US will be suffering from liver cirrhosis due to NASH in the near- to medium- term.<sup>6</sup>

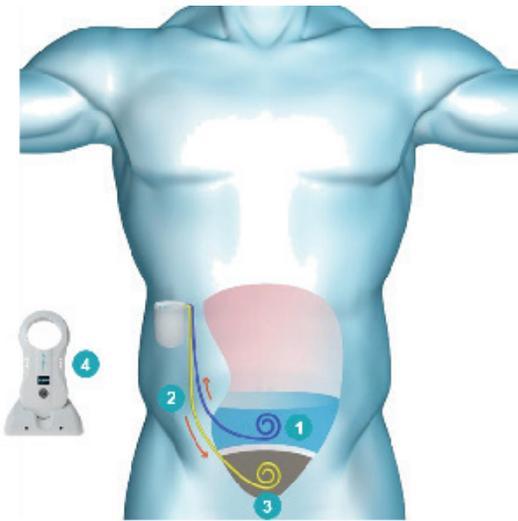
### Volume Overload in Heart Failure:

Volume overload is a major clinical complication of heart failure.

Approximately one million hospitalisations for heart failure occur in the US each year, 90% of which are due to volume overload, costing approximately \$13 billion.<sup>7</sup>

## alfapump: proven step change in the management of liver refractory ascites and malignant ascites

Fully-implanted, wirelessly-charged, CE-marked system that automatically and continuously pumps ascites from the abdominal cavity into the bladder, where the body eliminates the ascites naturally.

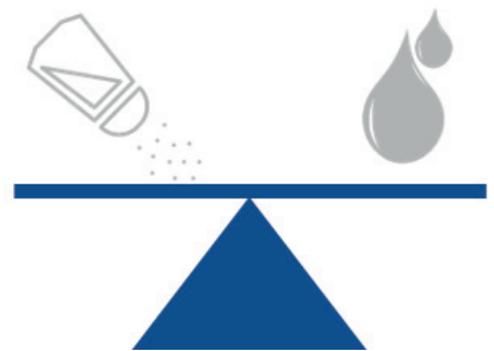


- 1 Automatic and continuous removal of ascites from peritoneal cavity
- 2 Ascites is pumped into bladder
- 3 Ascites leaves the body through normal urination
- 4 Wireless charging and communication for monitoring

Since April 2018, the **alfapump** has been included in the EASL (European Association for the Study of the Liver) clinical practice guidelines for decompensated cirrhosis.

## alfapump DSR: breakthrough development for the management of volume overload due to heart failure

DSR therapy is Sequana Medical's proprietary and breakthrough approach to the management of volume overload in heart failure. The approach focuses on the removal of sodium from the body, and allows the body to naturally remove the excess fluid via urination and osmotic ultrafiltration. **alfapump DSR** is under development and builds on the **alfapump** platform to deliver a convenient and fully implanted system for DSR therapy. Animal studies at Yale have shown DSR therapy to be both safe and effective, and a first-in-human study is ongoing.



## Sequana Medical: Long-term plans



### North American Liver & Cancer

- ✓ Clinical feasibility study (MOSAIC)
- US Pivotal Study in liver recurrent and refractory ascites 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 studies in malignant ascites & albumin
- Focused expansion in UK, DE, CH & FR

For more information, visit [www.sequanamedical.com](http://www.sequanamedical.com) or contact [IR@sequanamedical.com](mailto:IR@sequanamedical.com)

#### Sources

- 1: Centres for Disease Control and Prevention (CDC)
- 2: Big pharma bets billions on 'silent' liver disease, Financial times
- 3: Estes et al. 2018, GlobalData Nash Epidemiology Forecast to 2026
- 4: Mozzafarian D, Benjamin EJ, Go AS, et al. Heart disease and stroke statistics—2017 update (adults: >=20 years of age)

- 5: Mamas (2017) Do patients have worse outcomes in heart failure than in cancer?
- 6: Management estimate based on Estes (2018), GlobalData Nash Epidemiology Forecast to 2026, Nouredin et al. 2013
- 7: Costanzo et al. (2007), Ambrosy et al. 2014, Kilgore et al. 2017

**Important Regulatory Disclaimer:** *alfapump DSR* is under development and neither CE-marked nor available for clinical use.