

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

- Founded 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 refractory ascites due to liver cirrhosis and malignant ascites due to cancer. Ascites is the accumulation of excess fluid (up to 15L) in the abdomen due to liver disease or cancer. Over 700 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 DSR (Direct Sodium Removal) 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 limited² and prevalence of NASH increases³

3.9m adults

living with chronic liver disease in the US¹



Heart failure

2 out of 3 patients diagnosed with heart failure will die within 5 years⁵

6.5m adults

impacted in the US⁴

DRIVEN BY
CHANGING
DEMOGRAPHICS



UNHEALTHY DIET



OBESITY



AGEING

Liver Cirrhosis:

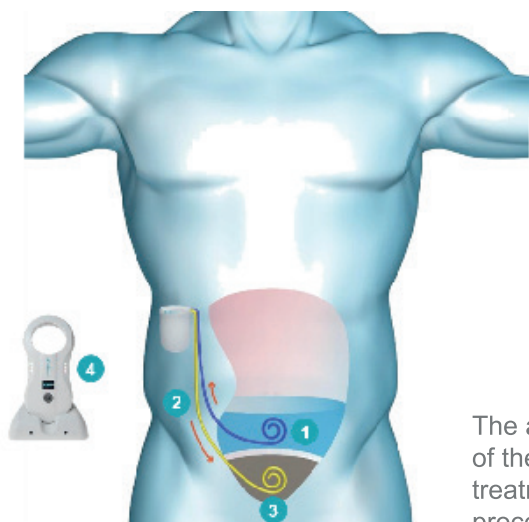
The market is forecast to grow dramatically due to increasing prevalence of fatty liver disease / NASH (non-alcoholic steatohepatitis) – especially in the US. Approximately three to four million people in the US will be suffering from liver cirrhosis due to NASH in the near- to medium- term.⁶

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.⁷

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 the abdomen
- 2 Ascites is pumped into bladder
- 3 Ascites leaves the body through normal urination
- 4 Wireless charging and communication for monitoring

The **alfapump** has been included in the EASL (European Association for the Study of the Liver) clinical practice guidelines for decompensated cirrhosis, the German treatment guidelines for complications of liver cirrhosis and the UK NICE interventional procedure guidance for treatment of refractory ascites caused by 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 and a first-in-human study at Yale University have shown that DSR can result in the removal of large quantities of sodium and fluid from the body in a safe and tolerable manner. A first clinical study with **alfapump DSR** is planned to start in H2 2019.



Sequana Medical: Three platforms for growth

North American Liver & Cancer

- POSEIDON commencing in H2 2019 – study to support approval of **alfapump** in US & Canada

North America & Europe Heart Failure

- First study with **alfapump DSR** commencing in H2 2019

Europe Liver & Cancer

- Prospective study in malignant ascites & registry in liver
- Focused expansion in UK, DE, CH & FR

For more information, visit www.sequanamedical.com or contact 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:** The **alfapump** has not yet received regulatory approval in the US and Canada. DSR therapy is still in development and there is no link between DSR therapy and ongoing investigations with the **alfapump** system in Europe, the US and Canada.