

# sequanamical

Commercial stage medical device company developing the **alfapump**® platform for the management of fluid overload in liver disease, malignant ascites and heart failure.



## Fast facts

- Founded in 2006
- Headquarters in Ghent, Belgium
- Manufacturing in Zurich, Switzerland
- ~45 employees
- Listed on Euronext Brussels: SEQUA
- Unique **alfapump**® platform
- Strong IP position
- Global network of KOLs in Europe and North America

Sequana Medical's **alfapump** is a unique, fully implanted wireless device that automatically pumps fluid from the abdomen into the bladder, where it is urinated away.

In the US, the company's key growth market, the **alfapump** has been granted breakthrough device designation by the FDA. The North-American pivotal POSEIDON study has started in H2 2019 in patients with recurrent or refractory ascites due to liver cirrhosis, with US approval expected in H1 2022.

In the EU, the **alfapump** is CE-marked for the treatment of refractory ascites due to liver cirrhosis and malignant ascites and is included in key clinical practice guidelines. Over 750 **alfapump** devices have been implanted to date.

**alfapump** DSR (Direct Sodium Removal) is in clinical development for treatment of fluid overload due to heart failure. Clinical proof-of-concept of single dose DSR therapy was achieved and a repeated dose **alfapump** DSR study started in H2 2019, with results expected in Q2 and Q3 2020.

Focus on NASH<sup>1</sup> and heart failure, large and growing markets driven by unhealthy lifestyles, obesity and an ageing population

## NASH in US

~145k patients / year with refractory ascites due to NASH within next 10-20y<sup>2</sup>

>€3bn / year  
market opportunity



UNHEALTHY DIET

OBESITY

AGEING

NASH:

Fluid overload is a fast-growing complication of advanced liver disease driven by NASH (non-alcoholic steatohepatitis) related cirrhosis which is forecast to grow dramatically, in particular in the US.

## Heart failure in EU & US

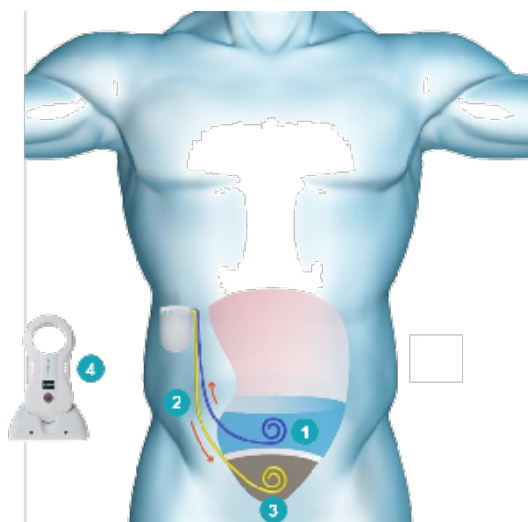
~400 K patients hospitalised / year for volume overload due to heart failure by 2026<sup>3</sup>

>€5bn / year  
market opportunity

Heart Failure:

Volume overload is a major clinical complication of heart failure and 40% of heart failure patients on IV loop diuretics are poorly controlled with diuretics.<sup>4</sup>

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

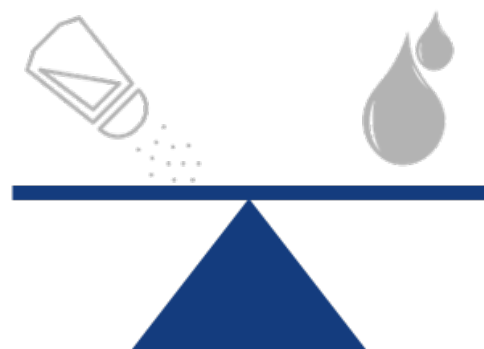


- 1 Automatic and continuous removal of fluid from the abdomen
- 2 Fluid is pumped into bladder
- 3 Fluid leaves the body through normal urination
- 4 Wireless charging and communication for monitoring

alfapump DSR: potential chronic therapy for heart failure patients not well controlled on diuretics

DSR therapy focuses on the removal of excess sodium from the body, and allows the body to naturally remove the excess fluid via urination and osmotic ultrafiltration.

alfapump DSR builds on the proven alfapump and is in development to deliver a fully implanted and automated system for DSR therapy.



alfapump and alfapump DSR: near-term value drivers

**North America Liver (NASH)**

- Pivotal alfapump study (POSEIDON) started H2 2019 with interim results expected H2 2020 and primary outcome readout mid-2021

**Heart Failure**

- Repeated dose alfapump DSR study (RED DESERT) started H2 2019 with results expected Q2 and Q3 2020

**Europe Liver & Cancer**

- alfapump study in malignant ascites & alfapump registry in liver
- Focused commercial expansion of alfapump in UK, Germany, Switzerland & France

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

Sources

- 1: Non-alcoholic steatohepatitis
- 2: Management estimate based on GlobalData Epidemiology Forecast to 2026
- 3: Management estimate based on GlobalData Epidemiology Forecast to 2026; Constanzo et al. (2007), Kiglore et al (2017)
- 4 : Testani, Circ Heart Failure, 2014 & 2016

*Important Regulatory Disclaimer: The alfapump has not yet received regulatory approval in the US and Canada. DSR therapy and alfapump DSR are still in development and there is no link between DSR therapy, alfapump DSR and ongoing investigations with the alfapump system in Europe, the US and Canada.*

*Timings presented on this document are likely to be delayed given the COVID-19 global health crisis. Updated guidance will be provided when the situation is clarified.*