

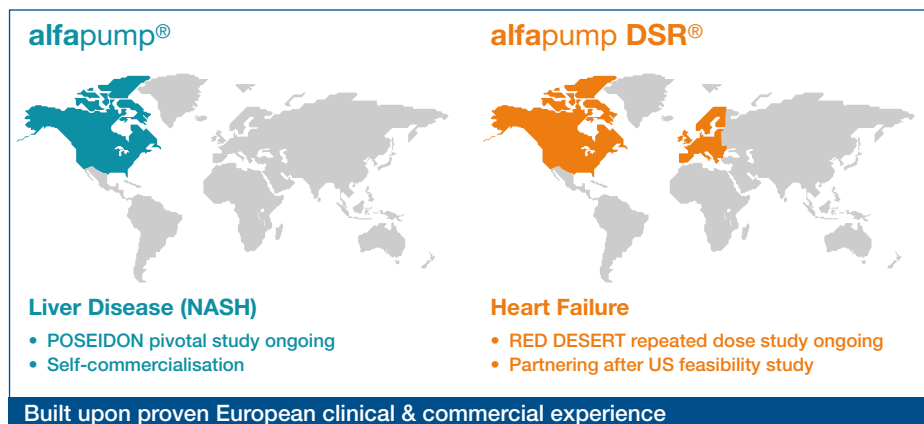
# sequanamedical

Commercial stage medical device company developing the **alfapump®** platform for the treatment of fluid overload in liver disease, malignant ascites and heart failure where diuretics are no longer effective.

## Fast facts

- Founded in 2006
- Headquarters in Ghent, Belgium
- Manufacturing in Zurich, Switzerland
- ~50 employees
- Listed on Euronext Brussels: SEQUA
- Unique **alfapump®** platform
- Strong IP position
- Global network of KOLs in Europe and North America

## Strategic focus



### Liver Disease / NASH

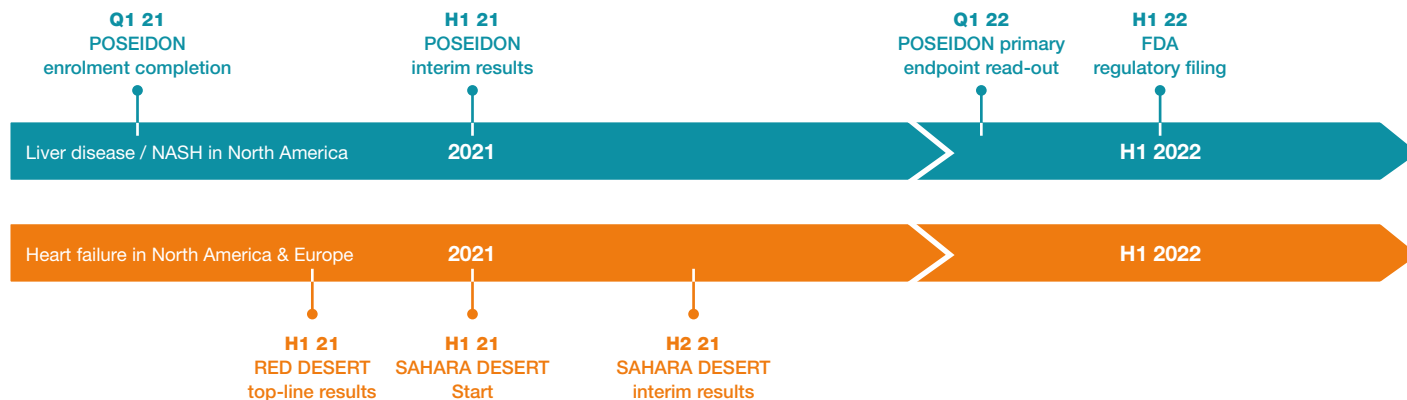
Fluid overload is a fast-growing complication of advanced liver disease driven by NASH-related cirrhosis which is forecast to grow dramatically, in particular in the US.



### Heart Failure

Fluid overload is a major clinical complication of heart failure and 40% of heart failure patients on IV loop diuretics are poorly controlled with diuretics.

## Expected Core Value Drivers & Outlook



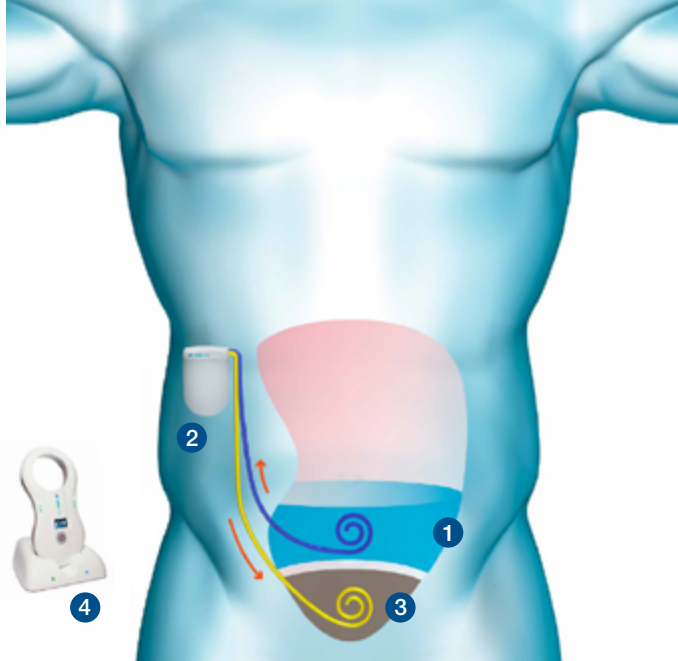
Presented timelines are subject to further developments related to the COVID-19 pandemic.

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

**Regulatory disclaimer:** The **alfapump®** system is currently not approved in the United States or Canada. In the United States and Canada, the **alfapump®** system is currently under clinical investigation (POSEIDON Study) and is being studied in adult patients with refractory or recurrent ascites due to cirrhosis. For more information regarding the POSEIDON clinical study see [www.poseidonstudy.com](http://www.poseidonstudy.com). DSR® therapy is still in development and it should be noted that any statements regarding safety and efficacy arise from ongoing pre-clinical and clinical investigations which have yet to be completed. DSR® therapy is currently not approved for clinical research in the United States or Canada. There is no link between the DSR® therapy and ongoing investigations with the **alfapump®** system in Europe, the United States or Canada.

**Source:** Testani, Circ Heart Failure, 2014 & 2016 **DSR:** Direct Sodium Removal; **NASH:** Non-alcoholic steatohepatitis

**Note:** **alfapump®** is a registered trademark. DSR® and **alfapump DSR®** are registered trademarks in the Benelux.



### alfapump platform: using the bladder to manage fluid overload

The **alfapump** is a subcutaneously implanted battery-powered pump that automatically and continuously pumps fluid from the abdominal cavity into the bladder, where the body eliminates the fluid naturally. The patient charges the **alfapump** wirelessly through the skin using a hand-held device.

- 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: proven step change for treatment of refractory liver ascites and malignant ascites

In the US, the company's key growth market, the **alfapump** has been granted **breakthrough device designation by the FDA** for recurrent or refractory liver ascites.

The attractiveness of the US market for the **alfapump** is driven by the increasing prevalence of NASH-related cirrhosis, creating a much larger and more dynamic market opportunity for the **alfapump** than the traditional cirrhosis markets caused by alcoholic liver disease and hepatitis.

The North American pivotal study (POSEIDON) in recurrent and refractory ascites due to liver cirrhosis is currently underway, and is intended to support a commercial marketing application of the **alfapump** in the US and Canada. Interim data reported in Nov '20 showed positive outcomes against all primary endpoints of the study.

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 800 **alfapump** devices have been implanted to date.



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

The **alfapump DSR** is built upon the proven **alfapump** platform, to deliver a fully implanted system for Direct Sodium Removal (DSR) therapy, the company's proprietary therapy for the management of fluid overload in heart failure.

DSR therapy involves the use of the peritoneal cavity for the removal of sodium via diffusion into a sodium-free solution (DSR infusate). The **alfapump** pumps the sodium-rich fluid into the bladder where it is urinated away.

**Clinical proof-of-concept** data from a first-in-human single dose DSR study have been published in the high impact cardiovascular journal, *Circulation*.

A repeated dose **alfapump DSR** study (RED DESERT) in diuretic-resistant heart failure patients is ongoing. Interim data reported in Oct '20 showed strong safety and efficacy results.

