The ALFApump® System

A breakthrough in Ascites Management
Dedicated to improving patient lives through development, manufacture & commercialisation of innovative implantable pump systems to manage fluid balance within the body.
Sequana Medical
Company History

- 2000: Concept (American physician)
- 2006: Company founded in Switzerland
- 2007: Series A funding - 13.5 million CHF
- 2008: First implant
- 2010: Pioneer Study - 40 patients
- 2011: Series B funding - 26.6 million CHF
  - for liver disease
- 2012: Commercial Launch in DE, A, CH & UK
  - for cancer
Ascites

- Accumulates in abdominal cavity
- Up to 2.5 litres every day
- Most common complication and main reason for hospitalisation
- Symptoms are painful, distressing and impact negatively quality of life

QUELLE: www.patient.co.uk/doctor/ascites.htm
**STANDARD CURRENT TREATMENT**

**LARGE VOLUME PARACENTESIS**

- Large bore needle drains up to 15 litres of Ascites over several hours
- Repeated every 7 to 10 days; often requiring overnight stay
- Highly unpopular with patients & physicians
- Expensive infusion of human Albumin to offset risk of renal failure (PICD)
The ALFAPump® System
New Revolutionary Treatment Option

- Implanted into abdominal cavity
- Automatically and continually collects Ascites; moving it to the bladder
- Reduces need for large volume Paracentesis
- Reduces economic burden of Refractory Ascites
- Significantly improves quality of life
Implantation Procedure

Minimally invasive (> 1 hour)
- General anaesthesia

Procedure
- Place Bladder Catheter
- Place Peritoneal Catheter
- Create standard pump pocket
- Tunnel and connect Catheters

Post Procedure
- Program daily volume
AUTOMATED LOW-FLOW
ASCITES PUMP

• Custom designed & engineered

• Fully implanted
  • No external or visible components

• Individualised programming

• Wireless recharging by patient

• Unique mechanism
  • Unidirectional flow
  • Anti-blockage system
  • No pumping in absence of Ascites or when Bladder full
LIFE HAS CHANGED

PATIENT’S PERSPECTIVE

“I’m very satisfied with my pump.

I enjoy my new life and like to be active. Now I can go swimming again and I take a walk every day. I have started to work again and I’m writing a new book with a friend of mine.”

Patient P1, implanted March 2009
SMART CHARGER & REMOTE PATIENT MONITORING SYSTEM

- Performance Data on ALFApump®
  - All events including all fluid cycles

- Data Transfer
  - Logs transferred to Charger
  - Logs uploaded to Server overnight
  - Logs analysed & alerts generated

- Launch Q1 2013
## SOLID CLINICAL RESEARCH PLAN

<table>
<thead>
<tr>
<th>Year</th>
<th>Study Type</th>
<th>Patients</th>
<th>Location</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>2009</td>
<td>Feasibility Study</td>
<td>9 patients</td>
<td>CZE, SWE</td>
<td></td>
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<tr>
<td>2010</td>
<td>Non randomised (Pioneer)</td>
<td>40 patients, safety and performance</td>
<td>(Prof. Such, Alicante)</td>
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<tr>
<td>2011</td>
<td>Non randomised</td>
<td>12 patients, Hemodynamic &amp; renal effect</td>
<td>(Prof. Gines, Hospital Clinic Barcelona)</td>
<td>Post Market Surveillance Registry</td>
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<td>2012</td>
<td>Randomised</td>
<td>ALFApump® vs. Paracentesis, 60 patients</td>
<td>(Prof. Jalan, Royal Free London)</td>
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<tr>
<td>2013</td>
<td>Randomised</td>
<td>50 patients, malignant Ascites</td>
<td>(Prof. Gabra, Imperial College London)</td>
<td>FDA Feasibility Study, 10 patients</td>
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</tbody>
</table>
PIONEER STUDY
40 Patients, 9 Centres, 4 Countries (EU)

Median days between Paracentesis procedures

Mean volume of Ascites removed per paracentesis
Economic Benefits

- Costs of Paracentesis can exceed €40,000 per year
- Cost of ALFApump® recovered after approx. 6 – 9 months
- NHS (UK) independent report
  - Paracentesis cost ca. £78,000 per year
  - ALFApump® could save £50 mio. per year

“Sequana Medical’s ALFApump® system is a revolutionary fluid management solution for patients with Ascites which could save the NHS significant amounts of money by eliminating the costs associated with repeat medical interventions whilst significantly improving patients’ Quality of Life.”

Head of the National Innovation Centre, October 2011

❖ One time cost of alfapump and surgery
❖ Cumulated cost of paracentesis and albumin
SUSTAINABILITY

- The ALFApump® System reduces number of patient hospital visits, reducing risk of hospital-acquired infection and burden on patient
- Frees up doctor and nurse time that can be put to use more efficiently
- Frees up hospital beds & resources
ALFAPUMP® Market

Refractory Ascites in EU
- Cirrhosis ~ 30'000 patients
- Cancer ~ 12'000 patients

Refractory Ascites in US
- All types ~ 75'000 patients
BEYOND ASCITES MANAGEMENT
LEVERAGING TECHNOLOGY INTO NEW MARKETS

Management of Refractory Pleural Effusion
- Only minor modification required
- Over 50,000 patients in the EU suffering from
  - Trapped lungs, length of hospitalisation
  - Complications, quality of life, body image

Removal of excess fluid caused by late-stage renal disease or congestive heart failure
- Pump delivers osmotic agent into the peritoneal cavity, causing fluid to move from the circulation into the peritoneal cavity due to the osmotic gradient
- Over 500,000 patients with fluid overload
  - Most Swiss patients hospitalised due to fluid overload
# Market & Product Expansion

## ALFApump® System
- **2012**: Refractory Ascites due to Liver Cirrhosis
  - EU Market ~ 30'000 patients
- **2013**: Refractory Ascites due to Cancer
  - EU Market ~ 12'000 patients
- **2014**: Chronic Pleural Effusion
  - EU Market ~ 10’000 patients
- **US Market**: All Applications ~ 100’000 patients

## Osmotic System
- **2012**: Congestive Heart Failure with Fluid Overload
  - EU & US Markets ~ 500’000 patients
- **2014**: End Stage Renal Disease
  - Automated Peritoneal Dialysis
  - EU & US Markets ~ 70’000 patients

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THE ALFAPUMP® SYSTEM

The ALFAPump® System
- Battery (rechargeable) powered implantable pump
- Smart Charger
- Catheters
- ALFAPump® programmer

Designed & Manufactured in Switzerland
- World recognised engineering talent, especially with motors, gears, microelectronics, sensors and battery powered devices
- Partnering with several Swiss companies
  - Art of Technology, Intersema, Maxon Motor, Microdul

Generating sustainable economic growth & jobs in Switzerland
BEITRAG VON AOT

- Redesigned Electronics and Firmware for new Pump generation for Human Clinical Trials (based on working prototype used for animal studies)
- Software Development for Motor Controller (including recovery algorithm in case of Hall sensor failures)
- Design and Development of Wireless Charger (first 2 generations)
- Revision of Wireless Communication Protocol
- Optimisation of overall Energy Transfer System
- Generation of initial Technical Documentation for CE Submission
- As of today - punctual support (as and when required)