**PRESS RELEASE**
**REGULATED INFORMATION**

# Sequana Medical announces 2018 Full Year Results and 2019 Outlook

***Successfully raised €27.5 million in an Initial Public Offering on Euronext Brussels***

***Clear progress on plans to make the alfa*pump® *and alfa*pump® *DSR available to a broader patient group, addressing large and growing markets with unmet medical needs***

***Sequana Medical NV (the "Company") will host a conference call with live webcast presentation today at 14:00 CET / 08:00 ET. Details provided below.***

**Ghent, BELGIUM – 4 April 2019 – Sequana Medical NV (Euronext Brussels: SEQUA)**, a commercial stage medical device company focused on innovative treatment solutions for the management of liver disease, heart failure, malignant ascites and other fluid imbalance disorders, today announces its business highlights and financial results for the year ended 31 December 2018, prepared in accordance with IFRS as endorsed by the European Union, as well as post-period highlights and an outlook for the remainder of the year.

## 2018 Highlights

- Inclusion of the **alfa**pump in the European Association for the Study of the Liver (EASL) clinical practice guidelines for decompensated cirrhosis.
- Recommendation by the U.K. National Institute for Health and Care Excellence (NICE) for use of the **alfa**pump for treatment of refractory ascites caused by cirrhosis under special arrangements.
- Two peer-reviewed **alfa**pump publications highlighting the improvement in patient quality of life (QoL) compared to standard of care in the European Randomised Controlled Trial (RCT) and the improvement in clinical outcomes in routine clinical practice from the use of the new peritoneal catheter.
- Presentation of the North American MOSAIC **alfa**pump feasibility study demonstrating a significant reduction in large volume paracentesis (LVP) as well as improved nutritional status and QoL of the patient during at least one year follow-up.
- Presentation of the retrospective Malignant Ascites study demonstrating that the **alfa**pump was effective in treating palliative patients and improving their QoL.
- Enrolled first patient in TOPMOST European registry study in cirrhosis patients implanted with the **alfa**pump for the management of refractory liver ascites.
- Maintained clear improvement in clinical outcomes with average duration of **alfa**pump therapy exceeding 450 days.
- Presentation of the pre-clinical proof-of-concept data for Direct Sodium Removal (DSR) therapy in the management of volume overload due to heart failure demonstrating the removal of clinically relevant amounts of sodium and fluid.
- First-in-human single dose DSR study commenced at Yale University, U.S.
- Established new corporate headquarters in Ghent, Belgium.
- Raised €8.5 million in private financing rounds from leading Belgian investors including Newton Biocapital, PMV and SFPI-FPIM, as well as existing shareholders.
- Appointed Kirsten Van Bockstaele as Chief Financial Officer and Lies Vanneste as Director, Investor Relations.

**Post-period events**

- Raised €27.5 million in a successful Initial Public Offering (IPO) on Euronext Brussels.
- Appointed Pierre Chauvineau as Independent Chairman and Wim Ottevaere as an Independent Non-Executive Director.
- Received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) for the **alfa**pump for the treatment of recurrent or refractory liver ascites, demonstrating the potential to bring much-needed improvement to the treatment of this important medical condition.

**Outlook for the remainder of 2019**

The North American POSEIDON pivotal study in recurrent or refractory liver ascites to support approval of the **alfa**pump in the U.S. and Canada is planned to begin in the second half of 2019. Filing of the clinical trial application with the FDA and Health Canada is planned for later this month.

The Company expects to start two prospective **alfa**pump clinical studies in the second quarter of 2019, i) a study in malignant ascites patients and ii) a study in refractory liver ascites patients to evaluate the impact of albumin replacement therapy. Furthermore, in the second half of 2019, the Company expects to receive reimbursement of the **alfa**pump in the Netherlands.

Interim results from the single dose first-in-human DSR therapy study are expected to be reported during the second quarter of 2019. Final results from this study are expected in the second half of 2019. The repeated dose first-in-human study of **alfa**pump DSR in patients with volume overload due to heart failure is planned to begin in the second half of this year, with initial results expected by the year-end.

The Company expects the results of the investments in the European commercial team to result in growth of revenues versus 2018.

**Ian Crosbie, Chief Executive Officer at Sequana Medical, commented:**
"We are very excited about our progress in 2018 and our plans for 2019 and beyond. Our successful IPO on Euronext Brussels has provided the funds to progress our growth strategy across the three pillars of our business. 2018 built upon the successes from previous years, marked by improved clinical outcomes, additional clinical evidence and third party clinical endorsement. In addition, it was the year that we expanded beyond liver disease and cancer to deliver pre-clinical proof-of-concept for our breakthrough DSR therapy in heart failure. So far in 2019, as well as completing the IPO, the **alfa**pump has received Breakthrough Device designation from the FDA for the treatment of recurrent or refractory liver ascites in a further recognition of the potential of the **alfa**pump."

**Detailed operational review**

**alfa**pump **– proven step change in the management of ascites in liver disease and cancer**

Since April 2018, the **alfa**pump has been included in the EASL clinical practice guidelines for the management of patients with decompensated cirrhosis. The Company considers this a key step in the potential widespread commercial acceptance of the **alfa**pump.

To support French reimbursement of the **alfa**pump, a study in patients with refractory liver ascites (the ARIA pump study) was initiated in 2018. This study is funded by the French government and is being conducted and sponsored by leading clinicians in France.

In June 2018, results from the multicentre RCT of the **alfa**pump in 58 patients with refractory liver ascites were published in Quality of Life Research, demonstrating an improved patient QoL in the **alfa**pump group compared to the standard of care group.

In September 2018, results from the retrospective study of the **alfa**pump in 21 patients with refractory liver ascites in a real-world setting at Hannover Medical School were published in the European Journal of Gastroenterology & Hepatology.

Also in September 2018, results from the retrospective Malignant Ascites study of the **alfa**pump in 17 patients with malignant ascites were presented at the International Gynaecologic Cancer Society congress in Kyoto and the Pelvic Surgeons Annual Meeting in Romania, by Principal Investigator Prof. Dr. Fotopoulou from Imperial College in London. The study demonstrated that the **alfa**pump was effective in treating palliative patients with malignant ascites and improving their QoL.

In November 2018, results from the North American MOSAIC study, an IDE (Investigational Device Exemption) feasibility study, of the **alfa**pump in 30 patients with recurrent or refractory liver ascites were presented at the American Association for the Study of Liver Disease (AASLD) by Principal Investigator Prof. Wong from the University of Toronto. Results demonstrated a significant reduction in LVP, the current standard of care, as well as improved nutritional status and patient QoL during at least one year follow-up.

Furthermore, in November 2018, the U.K. NICE recommended use of the **alfa**pump for the treatment of refractory ascites caused by liver cirrhosis under special arrangements. This improved guidance is important to support market adoption of the **alfa**pump in the U.K.

In December 2018, the first patient was enrolled in the TOPMOST registry, a European registry to collect data from prospectively enrolled **alfa**pump patients with refractory liver ascites. These real-world data will be important for healthcare providers and payers, and to increase awareness of the **alfa**pump.

By the end of 2018, the average duration of **alfa**pump therapy exceeded 450 days. This is the result of continuous work to further improve the design and use of the **alfa**pump including pre- and post- implant care based on feedback from Key Opinion Leaders (KOLs) and clinical experience.

**alfa**pump **DSR – potential breakthrough treatment of volume overload in patients with heart failure**

Direct Sodium Removal (DSR) is Sequana Medical's proprietary therapy for the management of volume overload in heart failure patients. The Company has leveraged its **alfa**pump experience and is developing **alfa**pump DSR, a fully implanted system to deliver a commercially attractive approach to implement DSR therapy.

In September 2018, results from the DSR pre-clinical proof-of-concept study in 15 healthy and 5 experimentally induced heart failure pigs were presented at the Annual Scientific Meeting of the Heart Failure Society of America (HFSA) by Principal Investigator Dr. Testani from Yale University. These data demonstrated that DSR therapy resulted in the removal of clinically relevant amounts of sodium and fluid in the studied pigs. The stable serum sodium concentration is an encouraging signal for the safety of DSR therapy.

By the end of 2018, the first patient was enrolled in the first-in-human Single Dose DSR study to demonstrate the safety, tolerability and efficacy of a single dose of DSR therapy in approximately 20 human subjects. Interim results are expected to be reported in the second quarter of 2019 and full results in the second half of 2019.

## Detailed financial review

| in Thousand Euros | FY 2018 | FY 2017 | Variance |
|---|---|---|---|
| **Revenue** | **1,029** | **1,304** | **-21%** |
| Cost of goods sold | (158) | (212) | -25% |
| **Gross margin** | **871** | **1,092** | **-20%** |
| Sales & Marketing | (2,445) | (1,506) | +62% |
| Clinical | (1,671) | (1,749) | -4% |
| Quality & Regulatory | (1,372) | (1,225) | +12% |
| Supply Chain | (964) | (1,041) | -7% |
| Engineering | (1,808) | (1,004) | +80% |
| General & Administration | (5,761) | (1,988) | +190% |
| Other income | 74 | 4 | N.A. |
| **Total operating expenses** | **(13,948)** | **(8,510)** | **+64%** |
| **Earnings before interest and taxes (EBIT)** | **(13,077)** | **(7,418)** | **+76%** |
| Finance income | 309 | 107 | +189% |
| Finance cost | (1,192) | (895) | +33% |
| **Total net finance expense** | **(883)** | **(788)** | **+12%** |
| Income tax expense | (24) | (18) | +33% |
| **Net loss for the period** | **(13,983)** | **(8,225)** | **+70%** |
| | | | |
| **Basic LPS*** | **(1.40)** | **(0.88)** | **+59%** |
| **Cash position** at 31 December** | **1,318** | **1,684** | **-22%** |

* Losses per share

** Cash position only includes highly liquid cash and cash equivalents.

## Consolidated statements of profit and loss

### Revenue

Total revenues decreased by 21% to €1.03 million (2017: €1.30 million), mainly as a result of a strategic decision to focus principally on Sequana Medical's focus markets in Europe (Switzerland, Germany, France and the U.K.).

### Cost of goods sold

Cost of goods sold decreased from €0.21 million to €0.16 million in line with the decrease in revenue.

### Operating expenses

Total operating expenses increased to €13.95 million (2017: €8.51 million).

*Sales and marketing* expenses increased from €1.51 million to €2.45 million mainly as a result of the expansion of the commercial team and increased marketing activities.

*Clinical* expenses decreased from €1.75 million to €1.67 million principally as a result of lower expenses for the MOSAIC (North American IDE feasibility) study in 2018 versus 2017, due to completion of the study, partly offset by higher expenses for the DSR proof-of-concept animal studies.

*Quality and regulatory* expenses increased from €1.23 million to €1.37 million, principally as a result of external advice regarding the POSEIDON (North American pivotal) study and the preparation for the new Medical Devices Regulation (Regulation 2017/745).

*Supply chain* expenses decreased from €1.04 million to €0.96 million, mainly as a result of the decrease in revenue.

*Engineering* expenses increased from €1.00 million to €1.81 million largely as a result of the costs related to the further development of the **alfa**pump and costs related to the preparation for the new Medical Device Regulation.

*General and administration* expenses increased from €1.99 million to €5.76 million mainly as a result of the costs related to the preparation of the Initial Public Offering (IPO) and relocation to Belgium.

**EBIT**
As a result of the above, earnings before interest and taxes (EBIT) increased from a loss of €7.42 million in 2017 to a loss of €13.08 million in 2018 largely due to costs related to the preparation of the IPO and relocation to Belgium, increased marketing activities and a lower gross profit due to a decrease in sales (partially offset by lower expenses in clinical affairs).

**Total net finance expenses**
Net finance cost increased from €0.79 million to €0.88 million mainly as a result of the interest expense related to the convertible loans received in 2018. The remainder of the costs relate to the Bootstrap loan.

**Income tax expense**
Income tax expense was €0.02 million for 2018 and was broadly flat compared to 2017. These expenses largely reflect taxes payable in Germany.

**Net loss for the period**
As a result of the above, the net loss increased from €8.23 million in 2017 to €13.98 million in 2018.

**Basic losses per share (LPS)**
Basic losses per share for 2018 amounted to €1.40, compared to €0.88 in 2017.

## Consolidated balance sheet

**Net debt**
Net debt[1] at December 31, 2018 amounted to €13.34 million, compared to €2.89 million in 2017, as a result of several new convertible loan agreements[2] entered into in 2018.

[1] Net debt is calculated by adding short-term and long-term financial debt and deducting cash and cash equivalents.

[2] The following conversion option was foreseen in the convertible loan agreements, in the event of an IPO:
There will be a mandatory conversion where the entire outstanding convertible loan amounts shall automatically be converted into shares of the Company in the event of, and simultaneously with the initial closing of, the next increase of the Company's share capital .

**Working Capital**
Working capital[3] from 2017 to 2018 decreased with €3.73 million, which was a result of an increase in trade payables and accrued liabilities.

## Consolidated statements of cash flows

Net cash outflow from operating activities was €9.88 million compared to a net outflow of €8.38 million in 2017. The difference mainly relates to a general increase in the net loss partly offset by the decrease in working capital.

Cash flow from investing activities resulted in a net outflow of €0.05 million compared to a net outflow of €0.01 million in 2017. The net cash outflow mainly relates to the down payment for the new office lease in Ghent, Belgium.

Cash flow from financing activities remained broadly flat. In 2018, cash inflow amounted to €9.47 million, as a result of the proceeds of several convertible loans, compared to a net inflow of €9.50 million in 2017, resulting from the issuance of shares in 2017.

The Company ended the period with a total liquidity position of €1.32 million (2017: €1.68 million) which consists fully of highly liquid cash and cash equivalents.

**Conference Call and Webcast**

Sequana Medical will host a conference call with live webcast presentation today at 14:00 CET / 8:00 ET. The webcast can be accessed by clicking here. To participate in the Q&A, please dial one of the numbers below ten minutes in advance, using confirmation code **5731205**. The webcast and conference call will be conducted in English and a replay will be available on Sequana Medical's website shortly after.

| | |
|---|---|
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| U.K.: | +44 20 3003 2666 |
| U.S.: | +1 866 966 5335 |

**Financial calendar**

| | |
|---|---|
| 23 April 2019 | Online publication annual report 2018 |
| 23 May 2019 | Annual General Meeting 2019 |
| 4 September 2019 | Publication half year results 2019 |

[3] The components of working capital are inventories plus trade receivables and other receivables minus trade payables (including contract liabilities) and other payables, and accrued liabilities.

**For more information, please contact:**

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**About Sequana Medical**

Sequana Medical is a commercial stage medical device company focused on innovative treatment solutions for the management of liver disease, heart failure, malignant ascites and other fluid imbalance disorders.

Sequana Medical's technology is based on its proprietary **alfa**pump platform, a fully implantable, programmable, wirelessly-charged, battery-powered system for automatic and continuous removal of fluid from the abdomen, which is applicable across multiple life-threatening disorders. The **alfa**pump is being commercialised in Europe for the management of refractory ascites (chronic fluid build-up in the abdomen) due to liver cirrhosis and malignant ascites. The number of patients with refractory liver ascites is forecast to increase dramatically due to the growing prevalence of NASH (Non-alcoholic Steatohepatitis).

Over 700 **alfa**pump systems have been implanted to date and since April 2018, the **alfa**pump has been included in the EASL (European Association for the Study of the Liver) clinical practice guidelines for decompensated cirrhosis. In January 2019, the FDA has granted Breakthrough Device designation for the **alfa**pump for the treatment of recurrent or refractory liver ascites. The **alfa**pump has not yet received regulatory approval in the U.S. and Canada and the Company expects to start POSEIDON, the North American pivotal study in in the second half of 2019 to support approval of the **alfa**pump in recurrent or refractory liver ascites.

The **alfa**pump is one of the first safe and effective, long-term alternatives to large-volume paracentesis (LVP) for the management of ascites, offering major advantages to patients, clinicians and healthcare systems. By automatically and continuously moving ascites to the bladder, where the body eliminates it naturally through urination, the **alfa**pump prevents fluid build-up and its possible complications, improving patient quality of life and nutrition, and potentially reducing hospital visits and healthcare costs. The **alfa**pump DirectLink technology allows clinicians to receive pump performance information and more effectively manage patients treated by the **alfa**pump.

Sequana Medical is developing the **alfa**pump DSR, built upon the proven **alfa**pump platform, to deliver a convenient and fully implanted system for Direct Sodium Removal (DSR) therapy, a novel and proprietary approach for the management of volume overload in heart failure. A first-in-human study for DSR therapy is ongoing. Treatment of volume overload in diuretic-resistant heart failure patients is a major clinical challenge. There are an estimated one million hospitalisations due to heart failure in the U.S. each year, of which 90% are due to symptoms of volume overload. The estimated cost of heart failure-related hospitalisations in the U.S. is $13 billion a year.

Sequana Medical is headquartered in Ghent, Belgium. For further information, please visit www.sequanamedical.com.

**Important Regulatory Disclaimer**
Any statement in this press release about safety and efficacy of the **alfa**pump does not apply to the U.S. and Canada because the device is currently undergoing clinical investigation in these territories.

**Disclaimer**

This press release may contain predictions, estimates or other information that might be considered forward-looking statements. Such forward-looking statements are not guarantees of future performance. These forward-looking statements represent the current judgment of Sequana Medical on what the future holds, and are subject to risks and uncertainties that could cause actual results to differ materially. Sequana Medical expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release, except if specifically required to do so by law or regulation. You should not place undue reliance on forward-looking statements, which reflect the opinions of Sequana Medical only as of the date of this press release.

Certain monetary amounts and other figures included in this press release have been subject to rounding adjustments. Accordingly, any discrepancies in any tables between the totals and the sums of amounts listed are due to rounding.

**Financial information**

The financial statements have been prepared in accordance with IFRS, as adopted by the EU. The financial information included in this press release is an extract from the full IFRS consolidated financial statements which will be published on 23 April 2019.

As of the date of this press release, the statutory auditor, PricewaterhouseCoopers Bedrijfsrevisoren BV CVBA, with registered office at Woluwedal 18, 1932 Sint-Stevens-Woluwe, Belgium , represented by Peter D'hondt, auditor , has not yet completed his audit procedures on the IFRS consolidated statements as of and for the year ended 31 December 2018.

The statutory auditor has confirmed that the audit, which is substantially complete, has not to date revealed any material misstatement in the draft consolidated accounts, and that the accounting data reported in the press release is consistent, in all material respects, with the draft accounts from which it has been derived.

## Consolidated statements of profit and loss

| in Thousand Euros (if not stated otherwise) | Year ended 31 December | |
|---|---|---|
| | 2018 | 2017 |
| **Revenue** | **1,029** | **1,304** |
| Cost of goods sold | (158) | (212) |
| **Gross margin** | **871** | **1,092** |
| | | |
| Sales & Marketing | (2,445) | (1,506) |
| Clinical | (1,671) | (1,749) |
| Quality & Regulatory | (1,372) | (1,225) |
| Supply Chain | (964) | (1,041) |
| Engineering | (1,808) | (1,004) |
| General & Administration | (5,761) | (1,988) |
| Other income | 74 | 4 |
| **Total operating expenses** | **(13,948)** | **(8,510)** |
| | | |
| **Earnings before interests and taxes (EBIT)** | **(13,077)** | **(7,418)** |
| | | |
| Finance income | 309 | 107 |
| Finance cost | (1,192) | (895) |
| **Total net finance expense** | (883) | (788) |
| | | |
| Income tax expense | (24) | (18) |
| **Net loss for the period** | **(13,983)** | **(8,225)** |
| | | |
| **Basic losses per share (in Euro)** | **(1.40)** | **(0.88)** |

## Consolidated balance sheet

| in Thousand Euros | As at 31 December | |
|---|---|---|
| | 2018 | 2017 |
| **ASSETS** | | |
| Property, plant and equipment | 184 | 206 |
| Laboratory | 6 | 10 |
| Information Technology | 138 | 186 |
| R&D tools | 7 | 10 |
| Assets under construction | 32 | - |
| Financial Assets | | |
| Financial assets – rental deposits | 58 | 42 |
| Loans to related parties | - | - |
| **Total non-current assets** | **242** | **248** |
| Trade and other receivables | 546 | 317 |
| Inventory | 1,235 | 1,271 |
| Cash and cash equivalents | 1,318 | 1,684 |
| **Total current assets** | **3,099** | **3,272** |
| **Total assets** | **3,341** | **3,519** |
| **EQUITY AND LIABILITIES** | | |
| Share capital | 888 | 955 |
| Other equity | 184 | - |
| Own shares | - | (193) |
| Share premium | 64,963 | 65,157 |
| Reserves | (452) | (183) |
| Loss brought forward | (85,003) | (71,082) |
| Cumulative translation adjustment | 659 | 736 |
| **Total equity** | **(18,760)** | **(4,611)** |
| Long term financial debts | 2,582 | 1,757 |
| Retirement benefit obligation | 792 | 819 |
| **Total non-current liabilities** | **3,374** | **2,576** |
| Short term financial debts | 12,073 | 2,820 |
| Trade and other payables | 3,848 | 2,283 |
| Accrued liabilities | 2,806 | 451 |
| **Total current liabilities** | **18,727** | **5,554** |
| **Total equity and liabilities** | **3,341** | **3,519** |

## Consolidated statement of cash flows

| in Thousand Euros | Year ended 31 December | |
|---|---|---|
| | 2018 | 2017 |
| **Net loss for the period** | **(13,983)** | **(8,225)** |
| Income tax expense | 24 | 18 |
| Financial result | 883 | 788 |
| Depreciation | 81 | 78 |
| Change in defined benefit plan | 43 | 64 |
| Share-based compensation | 241 | 23 |
| Changes in trade and other receivables | (77) | 146 |
| Changes in inventories | 80 | 556 |
| Changes in trade and other payables/provisions | 2,839 | (1,807) |
| Taxes paid | (5) | (18) |
| **Cash flow used in operating activities** | **(9,875)** | **(8,378)** |
| Investments in tangible fixed assets | (39) | (7) |
| Investments in financial assets | (16) | (4) |
| **Cash flow used in investing activities** | **(55)** | **(10)** |
| Proceeds from capital increase | 2 | 9,815 |
| Proceeds from financial debts | 9,583 | - |
| Interest paid | (115) | (314) |
| **Cash flow from financing activities** | **9,469** | **9,500** |
| **Net change in cash and cash equivalents** | **(461)** | **1,112** |
| **Cash and cash equivalents at the beginning of the period** | **1,684** | **797** |
| Net effect of currency translation on cash and cash equivalents | 95 | (226) |
| **Cash and cash equivalents at the end of the period** | **1,318** | **1,684** |

## Consolidated statement of changes in equity

| in Thousand Euros | Share capital | Other equity | Own shares | Share premium | Reserves | Loss brought forward | Currency translation differences | Total shareholder equity |
|---|---|---|---|---|---|---|---|---|
| **Balance at 31 December 2016** | **860** | **-** | **-** | **55,438** | **(335)** | **(62,857)** | **226** | **(6,668)** |
| Net loss | | | | | | (8,225) | | (8,225) |
| Other comprehensive income | | | | | 129 | | 510 | 639 |
| Capital increase (net of costs) | 95 | | | 9,719 | | | | 9,813 |
| Acquisition of own shares (non-cash transaction) | | | (193) | | | | | (193) |
| Share-based compensation | | | | | 23 | | | 23 |
| **Balance at 31 December 2017** | **955** | **-** | **(193)** | **65,157** | **(183)** | **(71,082)** | **736** | **(4,611)** |
| Net loss | | | | | | (13,983) | | (13,983) |
| Other comprehensive income | | | | | 102 | | (76) | 26 |
| Capital increase (net of costs) | 2 | | | | | | | 2 |
| Liquidation own shares | | | 193 | (193) | | | | - |
| Conversion share capital into EUR | (68) | | | | | | | (68) |
| Transaction costs for equity instruments | | | | | (612) | | | (612) |
| Conversion rights on convertible loans | | 184 | | | | | | 184 |
| Share-based compensation | | | | | 241 | 62 | | 302 |
| **Balance at 31 December 2018** | **888** | **184** | **-** | **64,963** | **(452)** | **(85,003)** | **659** | **(18,760)** |