

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 **alfapump**® and **alfapump**® 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 **alfapump** 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 **alfapump** for treatment of refractory ascites caused by cirrhosis under special arrangements.
- Two peer-reviewed **alfapump** 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 **alfapump** 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 **alfapump** was effective in treating palliative patients and improving their QoL.
- Enrolled first patient in TOPMOST European registry study in cirrhosis patients implanted with the **alfapump** for the management of refractory liver ascites.
- Maintained clear improvement in clinical outcomes with average duration of **alfapump** 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 **alfapump** 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 **alfapump** 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 **alfapump** 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 **alfapump** 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 **alfapump** 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 **alfapump** 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 **alfapump**.”

Detailed operational review

alfapump – proven step change in the management of ascites in liver disease and cancer

[Since April 2018](#), the **alfapump** 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 **alfapump**.

To support French reimbursement of the **alfapump**, 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 **alfapump** in 58 patients with refractory liver ascites were published in [Quality of Life Research](#), demonstrating an improved patient QoL in the **alfapump** group compared to the standard of care group.

In September 2018, results from the retrospective study of the **alfapump** 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 **alfapump** 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 **alfapump** 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 **alfapump** 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 **alfapump** for the treatment of refractory ascites caused by liver cirrhosis under special arrangements. This improved guidance is important to support market adoption of the **alfapump** 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 **alfapump** patients with refractory liver ascites. These real-world data will be important for healthcare providers and payers, and to increase awareness of the **alfapump**.

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

alfapump 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 **alfapump** experience and is developing **alfapump** 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 **alfapump** 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 debt¹ at December 31, 2018 amounted to €13.34 million, compared to €2.89 million in 2017, as a result of several new convertible loan agreements² 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 capital³ 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.

Belgium:	+32 2 789 8603
The Netherlands:	+31 20 794 8426
Switzerland:	+41 43 456 9986
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:

Sequana Medical

Lies Vanneste

Director IR

Tel: +32 (0) 498 05 35 79

Email: IR@sequanamedical.com

Consilium Strategic Communications

Alexandra Harrison, Marieke Vermeersch, Sukaina Virji

Tel: +44 (0) 203 709 5000

Email: sequanamedical@consilium-comms.com

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 **alfapump** 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 **alfapump** 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 **alfapump** systems have been implanted to date and since April 2018, the **alfapump** 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 **alfapump** for the treatment of recurrent or refractory liver ascites. The **alfapump** 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 the second half of 2019 to support approval of the **alfapump** in recurrent or refractory liver ascites.

The **alfapump** 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 **alfapump** prevents fluid build-up and its possible complications, improving patient quality of life and nutrition, and potentially reducing hospital visits and healthcare costs. The **alfapump** DirectLink technology allows clinicians to receive pump performance information and more effectively manage patients treated by the **alfapump**.

Sequana Medical is developing the **alfapump** DSR, built upon the proven **alfapump** 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 **alfapump** 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)