PRESS RELEASE
REGULATED INFORMATION
17 March 2021 07:00 CET

Sequana Medical announces 2020 Full Year Results and 2021 Outlook

- ***POSEIDON – positive interim results in Q4 2020; additional interim results expected in Q2 2021 and primary endpoint in Q2 2022***
- ***RED DESERT – positive interim results in Q4 2020; top-line data expected in Q2 2021***
- ***Successful equity placements extend cash runway into Q2 2022***

Conference call with live webcast today at 14:00 CET / 08:00 EST

Ghent, BELGIUM – 17 March 2021 – Sequana Medical NV (Euronext Brussels: SEQUA, the "Company"), an innovator in the treatment of diuretic-resistant fluid overload in liver disease, malignant ascites and heart failure, today announces its financial results for the year ended 31 December 2020, and provides a business update and an outlook for the remainder of 2021.

Ian Crosbie, Chief Executive Officer at Sequana Medical, commented: "We made outstanding progress in 2020, delivering very promising clinical data in both our focus areas, liver disease / NASH[1] in North America and heart failure in North America and Europe. We are very encouraged by the interim POSEIDON data, showing positive outcomes against all primary endpoints of the study, indicating a substantial reduction in the need for therapeutic paracentesis, a good safety profile and clinically relevant improvement in patients' quality of life. Data from additional Roll-In patients are expected in Q2 2021 and we look forward to the planned reporting of the primary endpoint in Q2 2022.

"2020 was another breakthrough year for our DSR® heart failure program. The RED DESERT interim results showed, for the first time, that not only could repeated **alfa**pump DSR® therapy in diuretic-resistant heart failure patients safely manage their fluid and sodium balance without the need of loop diuretics, but also restore their diuretic response to near normal levels and dramatically reduce their need for oral diuretics post-study. Granting of key DSR patents in the U.S. and Europe strengthened our intellectual property protection, enabling us to invest with confidence in heart failure as well as other fluid overload indications such as renal failure. We are looking forward to reporting final top-line RED DESERT data in Q2 2021.

"To deliver on our next key inflection points, we reinforced our cash position with two successful equity placements of €19 million in January 2020 and €22.5 million in February 2021. We are grateful for the continued support of our existing investors and are pleased to welcome new high-quality local and international institutional investors as shareholders. With our cash runway extended into Q2 2022, we are well positioned to continue on our strategy and bring value to all our stakeholders."

2020 Operational Highlights

- POSEIDON (North American pivotal study of the **alfa**pump® in recurrent and refractory ascites due to liver cirrhosis) reported positive interim results from the first 13 patients in the Roll-In

[1] NASH: Non-alcoholic steatohepatitis

Cohort. The interim data showed positive outcomes against all primary endpoints of the study[2], as well as indications of clinically relevant improvements in quality of life measures. The mean reduction in frequency of therapeutic parenthesis (TP) post-**alfa**pump implant versus pre-implant was over 90%. All patients had at least a 50% reduction in the average frequency of TP per month and the safety profile was in line with expectations. The study is designed to demonstrate in Pivotal Cohort patients 1) a 50% reduction in average monthly frequency of TP post-alfapump implant versus pre-implant and that 2) at least 50% of patients to achieve a 50% reduction in the requirement for TP post-alfapump implant versus pre-implant.

- RED DESERT (repeated dose proof-of-concept study of the **alfa**pump DSR in diuretic-resistant heart failure patients) reported positive interim results from the first five patients. The results showed that during the course of the six-week therapy, no loop diuretics were required, demonstrating the ability of the **alfa**pump DSR system to remove sodium and fluid from these patients, and there were no clinically significant changes in serum sodium levels or progressive hyponatremia. Following the six-week study, the diuretic response of these patients was restored to near normal levels with the majority of patients requiring low or no diuretics for months after completion of DSR therapy.
- Sequana Medical hosted a Key Opinion Leader (KOL) event on the challenge of diuretic resistance in the management of heart failure patients and the potential for **alfa**pump DSR therapy, featuring a presentation by Dr. Testani, MD, MTR (Yale University School of Medicine).
- Positive data from preclinical and clinical DSR proof-of-concept studies were published in *Circulation,* a top-tier peer-reviewed cardiovascular journal.
- Positive results from MOSAIC (North American feasibility study of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis) were published in the leading peer-reviewed journal *Liver Transplantation.*
- Dr. Oliver Gödje was appointed Chief Medical Officer; Gijs Klarenbeek remains with Sequana Medical as Senior Medical Advisor.
- Dr. Michael Felker and Dr. James Udelson were appointed as new Heart Failure Scientific Advisors.
- Refined the focus of European commercial activities on Germany and France, as part of the Company's focused strategy and continued penetration in these territories. In Q4 2020, there was a limited supply of the **alfa**pump to these markets due to manufacturing problems and the prioritisation of product supply to the POSEIDON and RED DESERT clinical studies. Despite this and the major disruption from COVID-19, revenues from European commercial activities in 2020 were maintained versus 2019.

2020 Financial Highlights

- Raised €19.0 million in an equity placement via an accelerated book building offering from existing investors and new experienced life sciences investors and industry experts.

[2] Pre- and post-implant periods for this analysis of the Roll-In Cohort differ from those that will be used for the Pivotal Cohort analysis

- Entered into subordinated loan agreements with several shareholders (including PMV/z-Leningen) for an aggregate principal amount of €7.3 million, of which €1.4 million can be converted by the lenders into new shares of the Company in the event of a future equity financing or sale of the Company.
- Cash position of €11.0 million at the end of December 2020, compared to €5.6 million at the end of December 2019.

Post-period events

- Key DSR (Direct Sodium Removal) patents were granted in the U.S. and Europe.
- Raised €22.5 million in an equity placement via an accelerated book building offering from existing investors and new local and international life sciences investors and industry experts, extending cash runway into Q2 2022.

Outlook for 2021 – Additional data read-out from POSEIDON and RED DESERT

Patient and physician interest in the POSEIDON study remains extremely high. Enrolment of the Roll-In and Pivotal Cohorts of the North American pivotal POSEIDON study of the **alfa**pump is continuing and the Company is confident of maintaining the strong clinical results that were reported in the Roll-In patients in Q4 2020. Full enrolment of the study is now expected in Q2 2021 due to delays related to the ongoing COVID-19 pandemic, including restrictions on non-essential hospital procedures in some centres in the U.S. and Canada, as well as travel restrictions. This will in turn delay the planned reporting of the primary endpoint from Q1 2022 to Q2 2022. Interim data from the larger Roll-In Cohort remains on track to be reported in Q2 2021. The POSEIDON study is intended to support a future marketing application of the **alfa**pump in the U.S. and Canada, with an FDA submission targeted for H2 2022.

The RED DESERT repeated dose study of the **alfa**pump DSR in diuretic-resistant heart failure patients is enrolling up to five additional patients, with top-line data expected in Q2 2021. Based on the highly encouraging interim safety and efficacy data from the first five RED DESERT patients, Sequana Medical is preparing SAHARA DESERT, a study to evaluate the dosing and frequency of **alfa**pump DSR therapy in decompensated heart failure patients with residual congestion, expected to start in Q2 2021 with interim data expected before year-end. Sequana Medical will continue developing its proprietary next generation DSR infusate which is intended to deliver an improved therapeutic profile, further strengthen its position as a leader in the treatment of diuretic-resistant fluid overload and generate a recurrent revenue stream for the Company.

Sequana Medical continues to make progress in addressing the **alfa**pump manufacturing yield but this, together with ongoing COVID-19 related restrictions on non-essential procedures and access to hospitals in Germany and France, is expected to limit European **alfa**pump sales in H1 2021 while the Company will continue to prioritise **alfa**pump supply to its clinical studies. Depending on further COVID-19 developments, normal commercial activity in Europe is expected to resume in H2 2021.

Detailed financial review

in Thousand Euros	FY 2020	FY 2019	Change
Revenue	**963**	**971**	**-1%**
Cost of goods sold	(202)	(198)	+2%
Gross margin	**761**	**773**	**-2%**
Sales & Marketing	(2,322)	(2,838)	-18%
Clinical	(6,108)	(3,922)	+56%
Quality & Regulatory	(2,232)	(1,817)	+23%
Supply Chain	(1,636)	(931)	+76%
Engineering	(1,859)	(983)	+89%
General & Administration	(4,417)	(4,264)	+4%
Other income	41	18	+134%
Total operating expenses	**(18,532)**	**(14,736)**	**+26%**
Earnings before interest and taxes (EBIT)	**(17,771)**	**(13,964)**	**+27%**
Finance income	170	53	N.M.
Finance cost	(1,348)	(931)	+45%
Total net finance expense	**(1,178)**	**(878)**	**+34%**
Income tax expense	(157)	(136)	+15%
Net loss for the period	**(19,106)**	**(14,977)**	**+28%**
Basic Loss Per Share	**(1.25)**	**(1.22)**	**+2%**
Cash position* at 31 December	**11,016**	**5,586**	**+97%**

N.M.: Not Meaningful (percentage greater than 150%)
* Cash position only includes highly liquid cash and cash equivalents.

Consolidated statements of profit and loss

Revenue

Revenue (€0.96 million) remained at a similar level compared to the same period last year (€0.97 million).

Cost of goods sold

Cost of goods sold (€0.20 million) remained at the same level compared to last year (€0.20 million).

Operating expenses

Total operating expenses increased by 26% to €18.53 million compared to 2019 (€14.74 million).

Sales & Marketing expenses decreased from €2.84 million to €2.32 million primarily as a result of reduced travel and marketing expenses due to COVID-19 restrictions and the focusing of our European commercial activities on Germany and France.

Clinical expenses increased from €3.92 million to €6.11 million mainly as a result of higher costs related to POSEIDON, the North American pivotal study of the alfapump and RED DESERT, the repeated dose proof-of-concept study of the alfapump DSR.

Quality & Regulatory expenses increased from €1.82 million to €2.23 million, mainly driven by costs for external advice for the POSEIDON study and the RED DESERT study, preparations for the new

Medical Devices Regulation (Regulation 2017/745), as well as the preparation for the commercial marketing application of the **alfa**pump in the U.S. and Canada.

Supply chain expenses increased to €1.64 million (FY 2019: €0.93 million), mainly as a result of the increase in clinical expenses and manufacturing yield costs.

Engineering expenses increased from €0.98 million to €1.86 million largely driven by the preparation for the commercial marketing application of the **alfa**pump in the U.S. and Canada.

General & administration expenses (€4.42 million) remained at a similar level to last year (€4.26 million).

EBIT[3]

Earnings before interest and taxes (EBIT) increased from a loss of €13.96 million in 2019 to a loss of €17.77 million in 2020 largely due to increased clinical activities, quality and regulatory expenses, engineering and supply chain expenses partially offset by lower expenses in sales and marketing.

Total net finance expenses

Net finance cost increased from €0.88 million in 2019 to €1.18 million in 2020 and consists mainly of charges related to the Bootstrap loan (repaid on 16 July 2020) and accrued interest on the new subordinated loan agreements concluded at the end of July 2020.

Income tax expense

Income tax expense (€0.16 million) remained at a similar level compared to 2019 (€0.14 million). These expenses largely reflect taxes payable in Switzerland.

Net loss for the period

As a result of the above, the net loss increased from €14.98 million in 2019 to €19.11 million in 2020.

Basic losses per share (LPS)

Basic losses per share for 2020 amounted to €1.25, compared to €1.22 in 2019.

Consolidated balance sheet

Net debt

Net debt[4] at 31 December 2020 improved by €0.79 million, resulting in a positive net cash position of €3.16 million compared to €2.36 million at 31 December 2019, mainly as a result of the proceeds from the equity placement of January 2020.

Working Capital

Working capital[5] improved from 2019 to 2020 by €1.56 million, mainly as a result of an increase in trade payables and accrued liabilities and a decrease in trade and other receivables and inventory.

[3] EBIT is defined as revenue less cost of goods sold and operating expenses.
[4] Net debt is calculated by adding short-term, long-term financial and lease debt and deducting cash and cash equivalents.
[5] 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.

Consolidated statement of cash flows

Net cash outflow from operating activities was €17.01 million compared to €18.48 million in 2019. The decrease was mainly driven by the normalization of the changes in trade and other payables (2019 was mainly impacted by the IPO expenses paid in 2019 and accrued in 2018) partially offset by a general increase in the net loss.

Cash flow from investing activities resulted in a net outflow of €0.14 million similar to the net outflow of €0.11 million in 2019.

Cash flow from financing activities resulted in a net inflow of €22.63 million in 2020, mainly as a result of the proceeds from the equity placement in January 2020 and the new subordinated loan agreements concluded at the end of July 2020, partially offset by the repayment of the Bootstrap loan (on 16 July 2020). In 2019, the net inflow of €22.99 million was mainly a result of the IPO proceeds.

The Company ended 2020 with a total liquidity position of €11.02 million (2019: €5.59 million).

Conference Call and Webcast
Sequana Medical will host a conference call with live webcast presentation today at 14:00 CET / 08:00 EST.

- Registration webcast: please click here
- Registration conference call (only if you wish to participate in the Q&A): please click here. Once registered, you will receive dial-in numbers and a confirmation code.

The webcast and conference call will be conducted in English and a replay will be available on Sequana Medical's website shortly after.

2021 financial calendar

27 April 2021	Online publication of Annual Report 2020
27 May 2021	Annual General Meeting 2021
2 September 2021	Publication half year results 2021

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About Sequana Medical

Sequana Medical is a commercial stage medical device company developing the **alfa**pump® platform for the treatment of fluid overload in liver disease, malignant ascites and heart failure where diuretics are no longer effective. Fluid overload is a frequent complication of many large diseases including advanced liver disease driven by NASH (non-alcoholic steatohepatitis)-related cirrhosis and heart failure, with diuretic resistance being widespread. The U.S. market for the **alfa**pump resulting from NASH-related cirrhosis is forecast to exceed €3 billion annually within the next 10-20 years. The heart failure market for the **alfa**pump DSR (Direct Sodium Removal) is estimated to be over €5 billion annually in the U.S. and EU5 by 2026. Both indications leverage Sequana Medical's **alfa**pump, a unique, fully implanted wireless device that automatically pumps fluid from the abdomen into the bladder, where it is naturally eliminated through urination.

In the U.S., the company's key growth market, the **alfa**pump has been granted breakthrough device designation by the FDA for recurrent or refractory ascites due to liver cirrhosis. Interim data from the ongoing North American pivotal study (POSEIDON) showed positive outcomes against all primary endpoints of the study. This study is intended to support a future marketing application of the **alfa**pump in the U.S. and Canada. In Europe, the **alfa**pump is CE-marked for the management of refractory ascites due to liver cirrhosis and malignant ascites and is included in key clinical practice guidelines. Over 850 **alfa**pump systems have been implanted to date. Building on its proven **alfa**pump platform, Sequana Medical is developing the **alfa**pump DSR®, a breakthrough, proprietary approach to fluid overload due to heart failure. Clinical proof-of-concept was achieved in a first-in-human single dose DSR® study and further supported by strong interim safety and efficacy results from the ongoing repeated dose **alfa**pump DSR study (RED DESERT) in heart failure patients.

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

Important Regulatory Disclaimers

*The **alfa**pump® system is not currently approved in the United States or Canada. In the United States and Canada, the **alfa**pump® 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. The 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. The DSR® therapy is not currently approved for clinical research in the United States or Canada. There is no link between the DSR® therapy and ongoing investigations with the **alfa**pump® system in Europe, the United States or Canada. DSR® and **alfa**pump DSR® are registered trademarks in Benelux.*

Forward-looking statements

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.

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

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 27 April 2021.

As of the date of this press release, the statutory auditor, PricewaterhouseCoopers Bedrijfsrevisoren BV, 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 2020.

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 statement of profit and loss

in Thousand Euros (if not stated otherwise)	Year ended 31 December	
	2020	2019
Revenue	**963**	**971**
Cost of goods sold	(202)	(198)
Gross margin	**761**	**773**
Sales & Marketing	(2,322)	(2,838)
Clinical	(6,108)	(3,922)
Quality & Regulatory	(2,232)	(1,817)
Supply Chain	(1,636)	(931)
Engineering	(1,859)	(983)
General & Administration	(4,417)	(4,264)
Other income	41	18
Total operating expenses	**(18,532)**	**(14,736)**
Earnings before interests and taxes (EBIT)	**(17,771)**	**(13,964)**
Finance income	170	53
Finance cost	(1,348)	(931)
Total net finance expense	**(1,178)**	**(878)**
Income tax expense	(157)	(136)
Net loss for the period	**(19,106)**	**(14,977)**
Basic losses per share (in Euro)	**(1.25)**	**(1.22)**

Consolidated statement of comprehensive income

in Thousand Euros (if not stated otherwise)	Year ended 31 December	
	2020	2019
Net loss for the period	**(19,106)**	**(14,977)**
Components of other comprehensive income (OCI) items that will not be reclassified to profit or loss:		
Remeasurements of defined benefit plans	(15)	209
Items that may be reclassified subsequently to profit or loss:		
Currency translation adjustments	(108)	75
Total other comprehensive income/(loss)-net of tax	**(123)**	**285**
Total comprehensive income	**(19,229)**	**(14,693)**
Attributable to Sequana Medical shareholders	(19,229)	(14,693)

Consolidated balance sheet

in Thousand Euros	As at 31 December	
	2020	2019
ASSETS		
Property, plant and equipment	705	765
Laboratory	66	71
Information Technology	235	159
R&D tools	1	4
Right-of-use assets	393	510
Other tangible fixed assets	11	21
Financial Assets	67	63
Financial assets – rental deposits	67	63
Total non-current assets	**772**	**829**
Trade receivables	24	118
Other receivables	930	1,220
Inventory	1,472	1,598
Cash and cash equivalents	11,016	5,586
Total current assets	**13,441**	**8,522**
Total assets	**14,213**	**9,350**
EQUITY AND LIABILITIES		
Share capital	1,635	1,307
Other equity	-	-
Share premium	119,333	100,661
Reserves	(2,250)	(1,652)
Loss brought forward	(119,080)	(99,974)
Cumulative translation adjustment	476	584
Total equity	**113**	**926**
Long term financial debts	7,473	2,261
Long term lease debts	123	305
Retirement benefit obligation	539	544
Total non-current liabilities	**8,135**	**3,110**
Short term financial debts	-	459
Short term lease debts	264	199
Trade payables	2,802	2,476
Other payables	1,523	1,269
Accrued liabilities	1,376	910
Total current liabilities	**5,966**	**5,315**
Total equity and liabilities	**14,213**	**9,350**

Consolidated statement of cash flows

in Thousand Euros	Year ended 31 December	
	2020	2019
Net loss for the period	**(19,106)**	**(14,977)**
Income tax expense	157	136
Financial result	1,047	878
Depreciation	307	244
Change in defined benefit plan	(22)	(68)
Share-based compensation	256	389
Changes in trade and other receivables	384	(791)
Changes in inventories	126	(362)
Changes in trade and other payables/provisions	(117)	(3,922)
Taxes paid	(36)	(9)
Cash flow used in operating activities	**(17,005)**	**(18,482)**
Investments in tangible fixed assets	(138)	(106)
Investments in financial assets	(4)	(4)
Cash flow used in investing activities	**(142)**	**(110)**
Proceeds from capital increase	19,000	26,165
(Repayments) from leasing debts	(274)	(227)
(Repayments) from financial debts	(3,201)	(1,667)
Proceeds from financial debts	7,300	-
Interest paid	(194)	(1,279)
Cash flow from financing activities	**22,631**	**22,991**
Net change in cash and cash equivalents	**5,483**	**4,399**
Cash and cash equivalents at the beginning of the period	**5,586**	**1,318**
Net effect of currency translation on cash and cash equivalents	(54)	(130)
Cash and cash equivalents at the end of the period	**11,016**	**5,586**

Consolidated statement of changes in equity

in Thousand Euros	Share capital	Other equity	Share premium	Reserves	Loss brought forward	Currency translation differences	Total shareholder equity
Balance at 1 January 2019	**888**	**184**	**64,963**	**(452)**	**(85,003)**	**659**	**(18,760)**
Change in accounting policy					7		7
Restated total equity at 1 January 2019	**888**	**184**	**64,963**	**(452)**	**(84,997)**	**659**	**(18,753)**
Net loss for the period					(14,977)		(14,977)
Other comprehensive income				209		(75)	134
Capital increase IPO (convertible loans)	84		8,533				8,617
Capital increase IPO (contribution in cash)	319		25,846				26,165
Capital increase IPO (contribution in kind)	16		1,319				1,335
Transaction costs for equity instruments				(1,799)			(1,799)
Conversion rights on convertible loans		(184)					(184)
Share-based compensation				389			389
Balance at 31 December 2019	**1,307**	**-**	**100,661**	**(1,652)**	**(99,974)**	**584**	**926**
Balance at 1 January 2020	**1,307**	**-**	**100,661**	**(1,652)**	**(99,974)**	**584**	**926**
Net loss for the period					(19,106)		(19,106)
Other comprehensive income				(15)		(108)	(123)
January 2020 Equity Placement	328		18,672				19,000
Transaction costs for equity instruments				(840)			(840)
Share-based compensation				256			256
Balance at 31 December 2020	**1,635**	**-**	**119,333**	**(2,250)**	**(119,080)**	**476**	**113**