PRESS RELEASE
REGULATED INFORMATION – INSIDE INFORMATION
03 September 2020, 07:00 CEST

Sequana Medical announces H1 2020 results and provides business update

- ***POSEIDON – Implants in Canada continue; interim results expected H1 2021***
- ***RED DESERT – Implants continue; interim results expected Q4 2020***
- ***DSR (Direct Sodium Removal) – Fundamental patents allowed in U.S. and Europe***
- ***Continued growth in European commercial implants***
- ***Secured additional funding extending cash runway into H2 2021***

Conference call with live webcast presentation today at 14:00 CEST / 08:00 am EST

Ghent, BELGIUM – 03 September 2020 – Sequana Medical NV (Euronext Brussels: SEQUA) (the "**Company**" or "**Sequana Medical**"), an innovator in the management of fluid overload in liver disease, malignant ascites and heart failure, today announces its business highlights and financial results for the six-month period ending 30 June 2020 and its outlook for the remainder of the year and into 2021.

Ian Crosbie, Chief Executive Officer of Sequana Medical, commented: "We have continued to make good progress towards key milestones in our two areas of strategic focus, liver disease / NASH in North America and heart failure in North America and Europe, despite the impact of COVID-19. Our POSEIDON pivotal study and RED DESERT repeated dose proof-of-concept study have both resumed and interim results are expected in H1 2021 and Q4 2020 respectively. Whilst not a core strategic focus, we are pleased to see the strong increase in European **alfa**pump® revenue compared to the same period last year, underlining the patient need and demonstrating the positive impact of our targeted commercial strategy.

"Since the start of this year, we have successfully secured additional funding that extends our cash runway into H2 2021. This enables us to reach key value inflection points and execute on our strategy of bringing the **alfa**pump to more patients in two significant areas of medical need."

H1 2020 Operational Highlights

- POSEIDON (North American pivotal study of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis) – despite the ongoing impact of COVID-19, implants and patient enrolment have resumed in Canada; although U.S. sites continue to screen for patients, restrictions on travel and non-essential hospital visits and procedures have prevented the resumption of implants and enrolment in this region. Assuming such restrictions are lifted in Q4 2020, enrolment is expected to be completed in Q1 2021 with interim results in H1 2021 and primary endpoint read-out in Q1 2022.
- RED DESERT (repeated dose proof-of-concept study of the **alfa**pump DSR in diuretic-resistant heart failure patients) – following a delay due to COVID-19, patient enrolment has resumed and the Company expects to report interim results in Q4 2020 and top-line results in H1 2021.
- DSR – fundamental patents allowed in the U.S. and Europe to reduce fluid overload in heart failure.
- European **alfa**pump studies: TOPMOST (European registry study in cirrhosis patients implanted with the **alfa**pump for the management of refractory liver ascites) continues to enroll patients and the first patient has been enrolled in the Step Counter study (registry to measure the impact of the **alfa**pump on activity, stress and sleep quality using fitness loggers in patients with refractory ascites due to liver cirrhosis). ProMAS (prospective study of efficacy and clinical impact of the **alfa**pump in patients with malignant ascites) has been delayed to enable focus of operational and financial resources on the

POSEIDON and RED DESERT studies; timing for conducting the ProMAS study will be reviewed at a later stage.
- Publication of positive data from preclinical and clinical DSR proof-of-concept studies in *Circulation,* a top-tier peer-reviewed cardiovascular journal.
- Publication of positive results from MOSAIC (North American feasibility study of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis) in leading peer-reviewed journal *Liver Transplantation.*
- Appointed Dr Oliver Gödje as Chief Medical Officer; Gijs Klarenbeek remains with Sequana Medical as Senior Medical Advisor.
- Further refined the focus of European commercial activities for the **alfa**pump on Germany and France, as part of the Company's focused strategy and continued market penetration in these territories.

H1 2020 Financial Highlights

- Raised €19.0 million in a successful private equity placement via an accelerated book building offering from existing investors and new experienced life sciences investors and industry experts.
- Total liquidity position of €14.9 million at the end of June 2020 compared to €5.6 million at the end of 2019.

Post Period Events

- Repayment of the Bootstrap loan for a total consideration of €3.2 million.
- 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. This funding extends the Company's cash runway into H2 2021.

Outlook for the Remainder of 2020 and beyond

Assuming that U.S. implants can resume in Q4 2020, and subject to no further COVID-19-related delays, the Company expects to complete enrolment in the POSEIDON study in Q1 2021 and report interim results in H1 2021 with primary endpoint read-out in Q1 2022. The POSEIDON study aims to support the approval of the **alfa**pump in the U.S. and Canada, with an FDA submission expected in H1 2022.

The Company expects to report interim results from the RED DESERT study in Q4 2020 and top-line results in H1 2021. The RED DESERT interim results are intended to support the discussions with the U.S. FDA to reach agreement on the plans for a U.S. feasibility study of the **alfa**pump DSR in patients with volume overload due to heart failure, which is expected to start in H2 2021. Sequana Medical plans to hold a key opinion leader (KOL) event on the **alfa**pump DSR programme in Q4 2020 and will communicate more details nearer the time.

Financial review – Six months ended 30 June 2020

in Thousand Euros	HY 2020	HY 2019	Variance
Revenue	**595**	**413**	**44%**
Cost of goods sold	(126)	(86)	+46%
Gross margin	**469**	**327**	**+43%**
Sales & Marketing	(1,373)	(1,306)	+5%
Clinical	(3,138)	(1,451)	+116%
Quality & Regulatory	(1,023)	(930)	+10%
Supply Chain	(806)	(368)	+119%
Engineering	(771)	(534)	+44%
General & Administration	(2,313)	(2,582)	-10%
Other income	27	6	N.M.
Total operating expenses	**(9,397)**	**(7,166)**	**+31%**
Earnings before interest and taxes (EBIT)[1]	**(8,928)**	**(6,838)**	**+31%**
Finance income	47	13	N.M.
Finance cost	(570)	(471)	+21%
Total net finance expense	**(523)**	**(458)**	**+14%**
Income tax expense	(103)	(7)	N.M.
Net loss for the period	**(9,554)**	**(7,303)**	**+31%**
Basic Loss Per Share	**(0.62)**	**(0.61)**	**+2%**
Cash position* at 30 June	**14,882**	**12,877**	**+16%**

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

Condensed Consolidated Income Statement

Revenue

Revenue (€0.59 million) increased +44% compared to the same period last year (€0.41 million) as a result of growth in Germany and France.

Cost of goods sold

Cost of goods sold (€0.13 million) increased +46% compared to the same period last year (€0.09 million) in line with the increase in revenue.

Operating expenses

Total operating expenses increased to €9.40 million (HY 2019: €7.17 million).

Sales and marketing expenses (€1.37 million) remained relatively at a similar level compared to the same period last year (€1.31 million).

Clinical expenses more than doubled from €1.45 million to €3.14 million mainly as a result of higher costs related to the North American pivotal study of the **alfa**pump (POSEIDON) and the repeated dose proof-of-concept study of the **alfa**pump DSR (RED DESERT).

[1] EBIT is defined as Revenue less Cost of goods sold and Operating Expenses.

Quality and regulatory expenses increased from €0.93 million to €1.02 million, mainly driven by costs linked to external advice for the POSEIDON study and the preparations for the new Medical Devices Regulation (Regulation 2017/745).

Supply chain expenses increased to €0.81 million (HY 2019: €0.37 million) in line with the increase in both revenue and clinical expenses.

Engineering expenses increased from €0.53 million to €0.77 million largely driven by the preparation for the commercial marketing application of the **alfa**pump in the U.S. and Canada.

General and administration expenses decreased from €2.58 million to €2.31 million mainly due to the costs related to the IPO in H1 2019 offset by higher public company costs and the costs related to the accelerated book building in H1 2020.

EBIT[2]
As a result of the above, earnings before interest and taxes (EBIT) evolved from a loss of €6.84 million in 2019 to a loss of €8.93 million in 2020.

Total net finance expenses
Net finance cost (€0.46 million) remained at a similar level to the same period last year (€0.52 million) and consists mainly of interest expenses related to the Bootstrap loan.

Income tax expense
Income tax expense increased from €0.01 million in 2019 to €0.10 million in 2020. These expenses largely reflect taxes payable in Switzerland.

Net loss for the period
As a result of the above, the net loss increased from €7.30 million in HY 2019 to €9.55 million in HY 2020.

Basic losses per share (LPS)
Basic losses per share remained at a similar level for HY2020 (€0.62) compared to (€0.61) HY 2019.

Condensed Consolidated Statement of Financial Position

Net debt
Net debt[3] at 30 June 2020 improved by €9.12 million, resulting in a positive net cash position of €11.48 million compared to €2.36 million at 31 December 2019, mainly as a result of the proceeds from the January 2020 Equity Placement.

Working Capital
Working capital[4] at 30 June 2020 improved by €0.45 million compared to 31 December 2019, mainly as a result of a decrease in inventories and an increase in accrued liabilities.

[2] EBIT is defined as Revenue less Cost of goods sold and Operating Expenses.

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

[4] 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.

Condensed Consolidated Statement of Cash Flows

Net cash outflow from operating activities was €9.24 million in HY 2020 compared to a net cash outflow of €12.19 million in HY 2019. The difference mainly relates to a decrease in cash relating to working capital primarily due to the decrease in trade and other payables related to the IPO in 2019, partially offset by a general increase in the net loss.

Cash flow from investing activities resulted in a net outflow of €0.03 million in HY 2020 compared to a net outflow of €0.14 million in HY 2019.

Cash flow from financing activities resulted in a net inflow of €18.67 million in HY 2020, mainly as a result of the proceeds from the private equity placement in January 2020, compared to a net inflow of €23.88 million in HY 2019, as a result of the IPO proceeds.

The Company ended the period with a total liquidity position of €14.89 million (2019: €12.88 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.

For more information, please contact:

Sequana Medical
Lies Vanneste, Director Investor Relations
Tel: +32 498 05 35 79
Email: IR@sequanamedical.com

Consilium Strategic Communications
Amber Fennell, Ashley Tapp, Melissa Gardiner
Tel: +44 203 709 5000
Email: sequanamedical@consilium-comms.com

LifeSci Advisors
Chris Maggos
Tel: +41 79 367 6254
Email: chris@lifesciadvisors.com

About Sequana Medical

Sequana Medical is a commercial stage medical device company developing the **alfa**pump platform for the management of fluid overload in liver disease, malignant ascites and heart failure where diuretics are no longer effective. Fluid overload is a fast growing complication of advanced liver disease driven by NASH (non-alcoholic steatohepatitis) related cirrhosis and a common complication in heart failure. 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. 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 **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 800 **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 a repeated dose **alfa**pump DSR study (RED DESERT) in heart failure patients is currently underway.

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.*

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.

Financial information

The condensed consolidated financial statements have been prepared in accordance with IAS 34, as adopted by the EU. The financial information included in the press release is an extract from the Condensed Consolidated Financial Statements.

The Condensed Consolidated Financial Statements for the six months ending 30 June 2020 are available on the website of Sequana Medical: https://www.sequanamedical.com/investors/financial-information/

Condensed Consolidated Income Statement

in Thousand Euros (if not stated otherwise)	Half Year ended 30 June	
	2020	2019
Revenue	**595**	**413**
Cost of goods sold	(126)	(86)
Gross margin	**469**	**327**
Sales & Marketing	(1,373)	(1,306)
Clinical	(3,138)	(1,451)
Quality & Regulatory	(1,023)	(930)
Supply Chain	(806)	(368)
Engineering	(771)	(534)
General & Administration	(2,313)	(2,582)
Other income	27	6
Total operating expenses	**(9,397)**	**(7,166)**
Earnings before interests and taxes (EBIT)[5]	**(8,928)**	**(6,838)**
Finance income	47	13
Finance cost	(570)	(471)
Total net finance expense	**(523)**	**(458)**
Income tax expense	(103)	(7)
Net loss for the period	**(9,554)**	**(7,303)**
Basic losses per share (in Euro)	**(0.62)**	**(0.61)**

[5] EBIT is defined as Revenue less Cost of goods sold and Operating Expenses.

Condensed Consolidated Statement of Comprehensive Income

in Thousand Euros (if not stated otherwise)	Half Year ended 30 June	
	2020	2019
Net loss for the period	**(9,554)**	**(7,303)**
Components of other comprehensive income (OCI) items that will not be reclassified to profit or loss:		
Remeasurements of defined benefit plans	-	218
Items that may be reclassified subsequently to profit or loss:		
Currency translation adjustments	78	(9)
Total other comprehensive income/(loss)-net of tax	**78**	**209**
Total comprehensive income	**(9,476)**	**(7,094)**
Attributable to Sequana Medical shareholders	(9,476)	(7,094)

Condensed Consolidated Statement of Financial Position

in Thousand Euros	As at period ended	
	30 June 2020	31 December 2019
ASSETS		
Property, plant and equipment	702	765
Laboratory	66	71
Information Technology	159	159
R&D tools	2	4
Right-of-use assets	458	510
Other tangible fixed assets	16	21
Assets under construction	-	-
Financial Assets	64	63
Financial assets – rental deposits	64	63
Total non-current assets	**765**	**829**
Trade receivables	131	118
Other receivables	1,144	1,220
Inventory	1,384	1,598
Cash and cash equivalents	14,882	5,586
Total current assets	**17,540**	**8,522**
Total assets	**18,306**	**9,350**
EQUITY AND LIABILITIES		
Share capital	1,635	1,307
Share premium	119,333	100,661
Reserves	(2,423)	(1,652)
Loss brought forward	(109,528)	(99,974)
Cumulative translation adjustment	506	584
Total equity	**9,523**	**926**
Long term financial debts	-	2,261
Long term lease debts	221	305
Retirement benefit obligation	554	544
Total non-current liabilities	**774**	**3,110**
Short term financial debts	2,946	459
Short term lease debts	234	199
Trade payables	2,405	2,476
Other payables	1,217	1,269
Accrued liabilities	1,206	910
Total current liabilities	**8,008**	**5,315**
Total equity and liabilities	**18,306**	**9,350**

Condensed Consolidated Statement of Cash Flows

in Thousand Euros	Half Year ended 30 June	
	2020	2019
Net loss for the period	**(9,554)**	**(7,303)**
Income tax expense	103	7
Financial result	390	42
Depreciation	145	111
Change in defined benefit plan	-	(91)
Share-based compensation	69	248
Changes in trade and other receivables	63	(631)
Changes in inventories	214	(284)
Changes in trade and other payables/provisions	(667)	(4,281)
Taxes paid	(6)	(7)
Cash flow used in operating activities	**(9,244)**	**(12,189)**
Investments in tangible fixed assets	(26)	(138)
Investments in financial assets	-	-
Cash flow used in investing activities	**(26)**	**(138)**
Proceeds from capital increase	19,000	26,165
(Repayments)/Proceeds from leasing debts	(131)	
(Repayments)/Proceeds from financial debts	-	1,375
Interest paid	(194)	(912)
Cash flow from financing activities	**18,675**	**23,878**
Net change in cash and cash equivalents	**9,405**	**11,551**
Cash and cash equivalents at the beginning of the period	**5,586**	**1,318**
Net effect of currency translation on cash and cash equivalents	(110)	9
Cash and cash equivalents at the end of the period	**14,882**	**12,877**

Condensed 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 31 December 2018	**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					(7,303)		(7,303)
Other comprehensive income				218		9	227
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				248			248
Balance at 30 June 2019	**1,307**	**-**	**100,661**	**(1,784)**	**(92,300)**	**668**	**8,552**
Balance at 31 December 2019	**1,307**	**-**	**100,661**	**(1,652)**	**(99,974)**	**584**	**926**
Net loss for the period					(9,554)		(9,554)
Other comprehensive income						(78)	(78)
January 2020 Equity Placement	328	-	18,672				19,000
Transaction costs for equity instruments				(840)			(840)
Share-based compensation				69			69
Balance at 30 June 2020	**1,635**	**-**	**119,333**	**(2,423)**	**(109,528)**	**506**	**9,523**