PRESS RELEASE
REGULATED INFORMATION

Sequana Medical announces 2019 Half Year Results and Year-to-date Business Update

Continued strong progress since IPO in February 2019:

- ***Commenced POSEIDON pivotal study to support approval of the alfa*pump® *in the U.S. & Canada***
- ***Achieved clinical proof-of-concept of Direct Sodium Removal (DSR), potential breakthrough therapy for volume overload due to heart failure***

Conference call with live webcast presentation today at 14:00 CET / 08:00 ET.

Ghent, BELGIUM – 25 September 2019 – Sequana Medical NV (Euronext Brussels: SEQUA), 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 2019, prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the European Union, and an outlook for the remainder of the year.

Operational Highlights Year-to-Date

- Received Breakthrough Device Designation from the U.S. FDA for the **alfa**pump for the treatment of recurrent and refractory liver ascites.
- First patient enrolled in the POSEIDON pivotal study to support approval and reimbursement of the **alfa**pump in the U.S. and Canada for the treatment of recurrent and refractory ascites due to liver cirrhosis. Study completion expected by mid-2021 and launch in the U.S. anticipated in the first half of 2022, ahead of expectation.
- Positive clinical proof-of-concept data from the first-in-human single-dose Direct Sodium Removal (DSR) study demonstrating that single dose DSR therapy was safe and well-tolerated and resulted in a clinically relevant removal of sodium with consistent results across all treated patients. The repeated dose **alfa**pump DSR study is expected to commence in Q4 2019 with results expected in the first half of 2020.
- Appointed Dr. Butler, Dr. Costanzo, Dr. Tang and Dr. Testani as Heart Failure Scientific Advisors.
- **alfa**pump included in the German treatment guidelines (DGVS) for complications of liver cirrhosis.
- Appointed experienced Medtech executive, Jason Hannon, as Independent Non-Executive Director.

Financial Highlights

- Raised €27.5 million in a successful Initial Public Offering (IPO) on Euronext Brussels in February 2019.
- Total liquidity position of €12.9 million at the end of June 2019 compared to €1.2 million at the end of June 2018.

Ian Crosbie, Chief Executive Officer at Sequana Medical, commented: "2019 has already seen significant progress in the development of our unique **alfa**pump platform for liver disease and heart failure, our two pillars of growth."

"A step change for the Company will be the introduction of the **alfa**pump into North America, a much larger and more dynamic market where the **alfa**pump is expected to have a stronger adoption and competitive position due to the increasing prevalence of NASH-related cirrhosis. The hard work to develop the **alfa**pump in this key market is beginning to pay off. The FDA breakthrough device designation for the **alfa**pump in the U.S. and the start of POSEIDON, our North American pivotal study in recurrent and refractory liver ascites, are key milestones towards achieving our North American ambitions."

"We have also been encouraged by the recently proposed ruling from the CMS regarding the new technology add-on payment (NTAP) pathway for breakthrough devices, which could further support reimbursement and market adoption of the **alfa**pump in the U.S."

"We have also continued to rapidly advance our heart failure program, the second pillar in our strategy, where the **alfa**pump DSR is in development as a potential breakthrough therapy for chronic management of volume overload. Following clinical proof-of-concept for the single dose DSR therapy, preparations are well underway to start the first-in-human repeated dose **alfa**pump DSR study in Q4 2019, with results anticipated in the first half of 2020."

"Beyond our R&D focus, we continue to invest in the European commercialisation of the **alfa**pump in the key markets of Germany, Switzerland, France and the U.K, where we expect consistent revenue growth. This real-world experience is invaluable as we continue to prepare for the **alfa**pump North American market launch as well as the **alfa**pump DSR clinical development program."

Year-to-date operational update

alfa**pump – clear progress toward North American approval for treatment of recurrent and refractory ascites due to liver cirrhosis

- Received Breakthrough Device Designation from the U.S. FDA for the **alfa**pump for the treatment of recurrent and refractory liver ascites, demonstrating the potential to bring much-needed improvement to the treatment of this important medical condition.
- Received unconditional IDE approval from the U.S. FDA and ITA approval from Health Canada to start POSEIDON, the North American pivotal study, using an optimised clinical trial design to include up to 50 patients implanted with the **alfa**pump for primary endpoint analysis at nine months after enrolment.
    - 15 centres selected for inclusion in the study
    - First patient enrolled in September 2019
- The planned U.S. launch of the **alfa**pump has been brought forward to H1 2022, thanks to the optimised clinical trial design and Breakthrough Device Designation.

alfa**pump **DSR – clinical proof-of-concept for Direct Sodium Removal (DSR) paves the way for our breakthrough approach to volume overload in heart failure

- Dr. Testani, Associate Professor at Yale University, presented positive clinical proof-of-concept results from the first-in-human single dose DSR study for volume overload due to heart failure at the Heart Failure 2019 congress. The study met its primary and secondary endpoints, demonstrating that single dose DSR therapy was safe and well-tolerated and resulted in a clinically relevant removal of sodium with consistent results across treated patients. The presentation was selected for inclusion in the highlights plenary session presented by Dr. Lyon, Board Member of the Heart Failure Association of the ESC (European Society of Cardiology).
- Preparations are underway to start the first-in-human repeated dose **alfa**pump DSR study in Europe, with Dr. Bartunek, Interventional Cardiologist at Cardiovascular Research Center Aalst (Belgium) as the principal investigator. This is a single-arm feasibility study in up to 10 patients with volume overload due to heart failure and will evaluate the safety of repeated dose DSR therapy and the clinical relevance of sodium removal in this patient population. Enrolment of the first patient is expected in Q4 2019.
- Appointment of Heart Failure Scientific Advisors. Dr. Butler, Dr. Costanzo and Dr. Tang are all current or past members of the Board of Directors of the HFSA (Heart Failure Society of America) and pre-eminent figures in the heart failure clinical community.
- Preparations are underway for a meeting with the FDA to discuss the start of clinical studies to support the regulatory pathway of the **alfa**pump DSR in the U.S.

alfa**pump* **– *continued scale-up of our commercial activities in key European territories; expanding clinical evidence and recommendations from key third parties

- Inclusion of the **alfa**pump in the DGVS ("German Society of Gastroenterology Digestive and Metabolic Diseases") guidelines for complications of liver cirrhosis. These guidelines are considered the reference treatment guidelines in Germany and provide evidence-based key recommendations for diagnosis and therapy of complications of liver cirrhosis.
- Preparing to enrol patients in the Prospective Malignant Ascites Study (ProMAS). Up to 40 patients with various malignancies will be recruited across clinical sites in Belgium, the U.K. and Switzerland. This single-arm, post-marketing study will evaluate the efficacy of the **alfa**pump and its impact on quality of life in patients with malignant ascites. First patient expected to be enrolled in Q4 2019 with top line results planned for H1 2021.
- Started preparations for the Step Counter study in patients with refractory ascites due to liver cirrhosis to measure the impact of the **alfa**pump on patient activity, stress and sleep quality using fitness loggers.
- In light of the ongoing discussion in the hepatology community regarding optimal albumin replacement therapy, the **alfa**pump prospective albumin study will be deferred until further consultation has been completed with the Key Opinion Leader (KOL) group.
- As a result of the new regulation Promising Care in the Netherlands intended to accelerate patient access to new treatment options, discussions with the Dutch reimbursement institutions are ongoing regarding reimbursement of the **alfa**pump.
- Created a referral network of centres of excellence in our core markets, Germany, Switzerland, France and the U.K., and hired Therapy Development Managers to further strengthen the commercial team. The ongoing progress on clinical outcomes and inclusion in the DGVS guidelines continue to support increased interest from potential customers in these markets.

Outlook for the remainder of 2019

The second half of 2019 will be a period of intensive clinical activity with a key focus on the careful execution of the North American POSEIDON and European ProMAS studies as well as the start of the first-in-human repeated dose **alfa**pump DSR study. In addition, enrolment is expected to commence in the Step Counter study.

The Company reiterates its previous guidance and expects the results of the investment in the European commercial team to result in revenue growth versus 2018.

Financial review – First half ended 30 June 2019

in Thousand Euros	HY 2019	HY 2018	Variance
Revenue	**413**	**447**	**-8%**
Cost of goods sold	(86)	(96)	-10%
Gross margin	**327**	**352**	**-7%**
Sales & Marketing	(1,306)	(977)	+34%
Clinical	(1,451)	(749)	+94%
Quality & Regulatory	(930)	(564)	+65%
Supply Chain	(368)	(514)	-28%
Engineering	(534)	(548)	-3%
General & Administration	(2,582)	(1,763)	+46%
Other income	6	-	N.A.
Total operating expenses	**(7,166)**	**(5,115)**	**+40%**
Earnings before interest and taxes (EBIT)	**(6,838)**	**(4,763)**	**+44%**
Finance income	13	134	-90%
Finance cost	(471)	(391)	+20%
Total net finance cost	**(458)**	**(258)**	**+78%**
Income tax expense	(7)	(24)	-71%
Net loss for the period	**(7,303)**	**(5,045)**	**+45%**
Basic LPS*	**(0.61)**	**(0.50)**	**+21%**
Cash position**	**12,877**	**1,223**	**N.A.**

* Losses per share

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

Consolidated statement of profit and loss

Revenue

Revenues (€0.41 million) remained relatively at a similar level compared to the same period last year (€0.45 million).

Cost of goods sold

Cost of goods sold (€0.09 million) remained relatively at a similar level compared to the same period last year (€0.10 million).

Operating expenses

Total operating expenses increased to €7.17 million (HY 2018: €5.11 million).

Sales and marketing expenses increased from €0.98 million to €1.31 million primarily due to the expansion of the commercial team and increased marketing activities in Europe.

Clinical expenses increased from €0.75 million to €1.45 million, mainly as a result of costs related to preparations for the North American pivotal study (POSEIDON) and the Prospective Malignant Ascites Study (ProMAS).

Quality & regulatory expenses increased from €0.56 million to €0.93 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 decreased from €0.51 million to €0.37 million, mainly as a result of the completion of the **alfa**pump development project.

Engineering expenses remained stable at €0.53 million (HY 2018: €0.55 million).

General and administration expenses increased from €1.76 million to €2.58 million mainly as a result of the Euronext listing.

EBIT
As a result of the above, earnings before interest and taxes (EBIT) evolved from a loss of €4.76 million in HY 2018 to a loss of €6.84 million in HY 2019 largely due to costs related to the IPO, increased commercial activities, and increased clinical and quality & regulatory expenses.

Total net finance expenses
Net finance cost increased from €0.26 million to €0.46 million mainly as a result of the interest expense related to the loan and the net foreign exchange result.

Income tax expense
Income tax expense was €0.01 million for HY 2019 and was broadly flat compared to HY 2018. These expenses largely reflect taxes payable in Germany.

Net loss for the period
As a result of the above, the net loss increased from €5.05 million in HY 2018 to €7.30 million in HY 2019.

Basic losses per share (LPS)
Basic losses per share for HY 2019 amounted to €0.61, compared to €0.50 in HY 2018.

Consolidated balance sheet

Net debt
Net debt[1] at 30 June 2019 improved by €23.64 million, resulting in a positive net cash situation of €10.30 million compared to a net debt of €13.34 million at 31 December 2018, mainly as a result of the proceeds from the IPO in February 2019.

Working Capital
Working capital[2] from 31 December 2018 to 30 June 2019 increased by €3.34 million, mainly a result of a decrease in trade payables and accrued liabilities for IPO expenses end of 2018.

Consolidated cash flow statement

Net cash outflow from operating activities amounted to €12.19 million compared to a net outflow of €4.08 million in HY 2018. The difference mainly relates to a general increase in the net loss and the increase in working capital primarily due to the decrease in trade payables and accrued liabilities (mainly IPO outstanding liabilities and accruals at the end of 2018 that led to a cash outflow at the time of the IPO).

Cash flow from investing activities resulted in a net outflow of €0.14 million. The net cash outflow mainly relates to the investment in leasing of cars and buildings (IFRS 16 applied) and the purchase of a new test system for production.

Cash flow from financing activities resulted in a net inflow of €23.88 million in HY 2019, mainly as a result of the IPO proceeds, compared to a net inflow of €3.71 million in HY 2018, resulting from the proceeds of several convertible loans.

The Company ended the period with a total liquidity position of €12.88 million (HY 2018: €1.22 million) which consists fully of highly liquid cash and cash equivalents.

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

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

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 **475648**. The webcast and conference call will be conducted in English and a replay will be available on Sequana Medical's website shortly after the call.

Belgium:	+32 2 792 0434
Switzerland:	+41 43 456 9986
The Netherlands:	+31 20 794 8426
U.K.:	+44 20 3003 2666
U.S.:	+1 212 999 6659

Glossary

CMS	Centers for Medicare and Medicaid Services
DGVS	German Society of Gastroenterology Digestive and Metabolic Diseases
DSR	Direct Sodium Removal
ESC	European Society of Cardiology
FDA	Food and Drug Administration
HFSA	Heart Failure Society of America
IDE	Investigational Device Exemption
IPO	Initial Public Offering
IRB	Institutional Review Board
ITA	Investigational Testing Authorisation
KOL	Key Opinion Leader
NASH	Non-Alcoholic Steatohepatitis
NTAP	New Technology Add-on Payment
R&D	Research & Development

For more information, please contact:

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

Consilium Strategic Communications
Amber Fennell, Sukaina Virji, 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. 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 within the next 10-20 years. The heart failure market for the **alfa**pump DSR (Direct Sodium Removal) is estimated to be over €5 billon in 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 started in H2 2019 and a commercial launch in the U.S. is planned for H1 2022. 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 700 **alfa**pump systems have been implanted to date.

Building on its proven **alfa**pump platform, Sequana Medical is developing **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 in heart failure patients is planned to start in H2 2019, with results expected in H1 2020.

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

Important Regulatory Disclaimers

*The **alfa**pump has not yet received regulatory approval in the U.S. and Canada. 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.*

*DSR therapy is still in development and it should be noted that any statements in this press release regarding safety and efficacy arise from pre-clinical studies and ongoing clinical investigations which have yet to be completed. There is no link between DSR therapy and ongoing investigations with the **alfa**pump system in Europe, the U.S. and Canada.*

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 this press release is an extract from the condensed consolidated financial statements.

The condensed consolidated financial statements six months ending 30 June 2019 are available on the website of Sequana Medical: https://www.sequanamedical.com/investors/financial-information/

Condensed consolidated statements of profit and loss

in Thousand Euros (if not stated otherwise)	Half Year ended 30 June	
	2019	2018
Revenue	**413**	**447**
Cost of goods sold	(86)	(96)
Gross margin	**327**	**352**
Sales & Marketing	(1,306)	(977)
Clinical	(1,451)	(749)
Quality & Regulatory	(930)	(564)
Supply Chain	(368)	(514)
Engineering	(534)	(548)
General & Administration	(2,582)	(1,763)
Other income	6	-
Total operating expenses	**(7,166)**	**(5,115)**
Earnings before interests and taxes (EBIT)	**(6,838)**	**(4,763)**
Finance income	13	134
Finance cost	(471)	(391)
Total net finance cost	**(458)**	**(258)**
Income tax expense	(7)	(24)
Net loss for the period	**(7,303)**	**(5,045)**
Basic losses per share (in Euro)	**(0.61)**	**(0.50)**

Condensed consolidated balance sheet

in Thousand Euros	As at period end	
	HY 2019	FY 2018
ASSETS		
Property, plant and equipment	510	184
Laboratory	71	6
Information Technology	129	138
R&D tools	6	7
Right-of-use assets	304	-
Assets under construction	-	32
Financial Assets	58	58
Financial assets – rental deposits	58	58
Loans to related parties	-	-
Total non-current assets	**568**	**242**
Trade and other receivables	1,177	546
Inventory	1,519	1,235
Cash and cash equivalents	12,877	1,318
Total current assets	**15,573**	**3,099**
Total assets	**16,142**	**3,341**
EQUITY AND LIABILITIES		
Share capital	1,307	888
Other equity	-	184
Own shares	-	-
Share premium	100,661	64,963
Reserves	(1,784)	(452)
Loss brought forward	(92,300)	(85,003)
Cumulative translation adjustment	668	659
Total equity	**8,552**	**(18,760)**
Long term financial debts	2,282	2,582
Long term lease debts	154	-
Retirement benefit obligation	494	792
Total non-current liabilities	**2,929**	**3,374**
Short term financial debts	295	12,073
Short term lease debts	137	-
Trade and other payables	3,020	3,848
Accrued liabilities	1,208	2,806
Total current liabilities	**4,661**	**18,727**
Total equity and liabilities	**16,142**	**3,341**

Condensed consolidated statement of cash flows

in Thousand Euros	Half Year ended 30 June	
	2019	2018
Net loss for the period	**(7,303)**	**(5,045)**
Income tax expense	7	24
Financial result	42	263
Depreciation	111	5
Change in defined benefit plan	(91)	-
Share-based compensation	248	18
Changes in trade and other receivables	(631)	(201)
Changes in inventories	(284)	64
Changes in trade and other payables/accrued liabilities	(4,281)	821
Taxes paid	(7)	(24)
Cash flow from operating activities	**(12,189)**	**(4,075)**
Investments in tangible fixed assets	(138)	-
Investments in financial assets	(0)	-
Cash flow for investing activities	**(138)**	**-**
Proceeds from capital increase	26,165	-
(Repayments)/ Proceeds from financial debts	(1,375)	3,714
Interest paid	(912)	-
Cash flow from financing activities	**23,878**	**3,714**
Net change in cash and cash equivalents	**11,551**	**(361)**
Cash and cash equivalents at the beginning of the period	**1,318**	**1,684**
Net effect of currency translation on cash and cash equivalents	9	(100)
Cash and cash equivalents at the end of the period	**12,877**	**1,223**

Condensed 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 1 January 2018	**955**	**-**	**(193)**	**65,157**	**(183)**	**(71,082)**	**736**	**(4,611)**
Net loss for the period						(5,045)		(5,045)
Other comprehensive income							(100)	(100)
Transaction costs for equity instruments					(93)			(93)
Conversion rights on convertible loans		184						184
Share-based compensation					18			18
Balance at 30 June 2018	**955**	**184**	**(193)**	**65,157**	**(257)**	**(76,127)**	**636**	**(9,646)**
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)**