PRESS RELEASE
REGULATED INFORMATION – INSIDE INFORMATION
2 September 2021, 07:00 CET

Sequana Medical announces H1 2021 results and provides business update

- ***alfa**pump® – Positive results from second interim analysis of POSEIDON pivotal study; awaiting FDA approval on POSEIDON pivotal study expansion*
- ***alfa**pump® – FDA regulatory submission now expected in mid-2023 due to worldwide supply shortage of electronic components; European commercial activities and clinical studies unaffected*
- ***alfa**pump **DSR®** – Strong top-line results from RED DESERT; interim results of SAHARA DESERT study in heart failure patients with persistent congestion expected in Q4 2021*
- ***DSR® – Key patents granted in U.S. and Europe; expansion of DSR development programme with short-term DSR therapy; proprietary DSR Infusate 2.0 development ongoing***
- ***Total liquidity position of €21.8 million provides cash runway into Q2 2022***

Conference call with live webcast presentation today at 03:00 pm CET / 09:00 am ET

Ghent, Belgium – 2 September 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 business highlights and financial results for the six-month period ending 30 June 2021 and its outlook for the remainder of the year and beyond.

Ian Crosbie, Chief Executive Officer at Sequana Medical, commented: *"We have continued to deliver outstanding clinical results in H1 2021 with promising data from our POSEIDON and RED DESERT studies demonstrating the potential of our two technology platforms, **alfa**pump and Direct Sodium Removal (DSR).*

*"We believe that the strong interim results from the POSEIDON Roll-In Cohort significantly de-risk our North American liver programme and demonstrate the potential of the **alfa**pump to provide a safe and efficacious treatment that can dramatically improve the quality of life for patients with recurrent or refractory liver ascites. While we have made strong progress in POSEIDON patient recruitment, we continue to work with the FDA on expanding the number of patients to be enrolled and look forward to updating the market on timing. The delay in planned submission of the PMA due to subcomponent shortages is frustrating but reflects the growing issues facing many high-tech companies in sourcing complex electronic components and we are working tirelessly with our long-term suppliers to further minimise the delay on **alfa**pump PMA submission in the U.S.*

*"RED DESERT demonstrated that **alfa**pump DSR could not only replace high doses of loop diuretics but also improve the diuretic response and cardio-renal status in patients with diuretic-resistant heart failure. These results indicate the unique capabilities of DSR, which we are further evaluating in the SAHARA DESERT study in decompensated heart failure patients. We expect to report interim results from this trial before the end of the year.*

"The continued growth of the NASH-related ascites and decompensated heart failure markets validates our focus on delivering innovative treatments for when diuretics are no longer an effective option in these patients."

Outlook for the remainder of 2021 and for 2022

POSEIDON – The North American pivotal study of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis is ongoing. As previously reported, the Company submitted a protocol amendment to the U.S. FDA to extend the patient enrolment due to the higher rate of attrition. Our discussions with the agency on the expansion of patient enrolment are ongoing and the Company will update the market once it has clarity from the FDA on study expansion and expected end of patient enrolment and subsequent primary endpoint read-out.

As a result of recent detailed planning involving discussions with the Company's suppliers in connection with the verification and validation activities supporting the submission of the Pre-Market Approval (PMA) to the U.S. FDA, it has become clear that the worldwide shortage of electronic components will result in an expected six-months delay of the PMA submission.

SAHARA DESERT – The study of the **alfa**pump DSR in diuretic-resistant heart failure patients with persistent congestion is ongoing and intends to enrol 20 patients. The study will evaluate the ability of **alfa**pump DSR therapy to eliminate persistent congestion, restore correct fluid status (euvolemia) and improve cardio-renal condition for up to 22 weeks. Interim results are expected in Q4 2021 and top-line results in H2 2022.

European commercial production and activities resumed in August 2021. Assuming no further COVID-19 related restrictions, the Company expects to generate 2021 revenues, on a *pro rata* basis, in line with the periods before the reduced manufacturing supply.

The Company continues to monitor the impact of COVID-19 on its activities, particularly in respect to POSEIDON and its European commercial business. While the situation has improved dramatically over the past 12 months, the recent increase in infections due to the delta variant is a potential cause for concern and may impact the Company's forecasts for milestones.

H1 2021 Operational Highlights

- POSEIDON – The ongoing North American pivotal study of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis reported the second positive interim analysis. Data from 26 patients in the Roll-In Cohort reconfirmed positive outcomes against all primary endpoints[1] and demonstrated (i) over 90% reduction in mean frequency of therapeutic paracentesis (TP) versus baseline, (ii) all patients having at least a 50% reduction in mean frequency of TP per month versus baseline, (iii) clinically important improvement in quality of life maintained even up to 12 months post-

[1] 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

implantation and (iv) safety profile in line with expectations. These data substantially exceed the primary endpoints as defined for the Pivotal Cohort in the POSEIDON study.

- RED DESERT – Positive clinical data were reported in this repeated dose proof-of-concept study of the **alfa**pump DSR in diuretic-resistant heart failure patients. The study demonstrated that **alfa**pump DSR (i) is highly effective at replacing high-dose loop diuretics, (ii) dramatically improved diuretic response and the benefit was maintained in long-term follow-up and (iii) significantly improved cardio-renal function. Results were presented as a late-breaker at European Society of Cardiology's *Heart Failure 2021* and selected as one of the congress highlights.
- SAHARA DESERT – Initiated the dose-ranging feasibility study in 20 decompensated heart failure patients with persistent congestion despite high-dose diuretics. Interim results are expected at the end of 2021 and top-line results in H2 2022.
- Key patents for the **alfa**pump DSR granted in the U.S and European Union. The patents cover the **alfa**pump DSR and its method of operation.
- Continued pre-clinical development of the proprietary DSR Infusate 2.0 intended to deliver a superior therapeutic profile as well as a high margin recurring revenue flow to accompany **alfa**pump DSR sales.
- Expanded DSR development programme with Short-Term DSR to support faster adoption of the DSR therapy in the clinical community, support **alfa**pump DSR market entry, expand potential market opportunity and target earlier entry into the U.S. market.
- Resolved the **alfa**pump manufacturing yield issues and brought production volumes back to normal levels. Sequana Medical resumed commercial activity in Europe in August 2021. Due to the limited supply in H1 2021, the Company prioritised the supply of the **alfa**pump to the POSEIDON and RED DESERT clinical studies. This together with the COVID-19 related restrictions on non-essential procedures and access to hospitals in Germany and France, limited the European **alfa**pump sales in H1 2021.

H1 2021 Financial Highlights

- Raised €22.5 million in gross proceeds by means of a private placement via an accelerated bookbuild offering from existing investors and new experienced life sciences investors and industry experts, extending the Company's cash runway into Q2 2022.
- Total liquidity position of €21.8 million at the end of June 2021 compared to €11.0 million at the end of December 2020.

Post Period Events

- Hosted a Key Opinion Leader webinar with two leading KOLs from the Mayo Clinic, Arizona, Dr. Vargas and Dr. Knuttinen, on "*the impact of liver ascites on patients and healthcare systems and the potential of **alfa**pump therapy in NASH-related ascites*".
- Appointed Jackie Fielding, a former Vice President of medical technology company Medtronic with more than 30 years of experience in the healthcare industry, as independent Non-Executive Director of the Company, effective as of 1 September 2021.

Financial review – Six months ended 30 June 2021

in Thousand Euros	HY 2021	HY 2020	Variance
Revenue	**23**	**595**	**-96%**
Cost of goods sold	(4)	(126)	-96%
Gross margin	**18**	**469**	**-96%**
Sales & Marketing	(1,069)	(1,373)	-22%
Clinical	(3,652)	(3,138)	+16%
Quality & Regulatory	(1,558)	(1,023)	+52%
Supply Chain	(1,107)	(806)	+37%
Engineering	(1,539)	(771)	+100%
General & Administration	(2,593)	(2,313)	+12%
Other income	17	27	-35%
Total operating expenses	**(11,501)**	**(9,397)**	**+22%**
Earnings before interest and taxes (EBIT)[2]	**(11,483)**	**(8,928)**	**+29%**
Finance income	156	47	N.M.
Finance cost	(434)	(570)	-24%
Total net finance expense	**(278)**	**(523)**	**-47%**
Income tax expense	(129)	(103)	+25%
Net loss for the period	**(11,890)**	**(9,554)**	**+24%**
Basic Loss Per Share	**(0.66)**	**(0.62)**	**+6%**
Cash position* at 30 June	**21,772**	**14,882**	**+46%**

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

Condensed Consolidated Income Statement

Revenue

Revenue limited to €0.02 million compared to the same period last year (€0.59 million) as a result of the reduced supply of the **alfa**pump for the European commercial activities due to lower manufacturing yield and

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

the prioritisation of product supply for the POSEIDON and RED DESERT clinical trials, as well as the impact of COVID-19 on **alfa**pump procedures in France and Germany.

Cost of goods sold

Cost of goods sold of €0.04 million compared to the same period last year (€0.13 million) in line with the decrease in revenue.

Operating expenses

Total operating expenses increased to €11.50 million (HY 2020: €9.40 million) mainly due to i) the preparations for the submissions for marketing approval of the **alfa**pump in the U.S. and Canada, and ii) DSR pre-clinical and clinical development.

Sales and marketing expenses of €1.07 million decreased by 22% compared to the same period last year (€1.37 million) due to reduced European commercial activities.

Clinical expenses increased from €3.14 million to €3.65 million mainly as a result of 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), the start of the SAHARA DESERT study and DSR infusate pre-clinical development.

Quality and regulatory expenses increased from €1.02 million to €1.56 million, mainly driven by certification costs for the new Medical Devices Regulation (Regulation 2017/745) and Medical Device Single Audit Program (MDSAP) as well as external advice costs for the preparation of the submissions for marketing approval of the **alfa**pump in the U.S. and Canada.

Supply chain expenses increased to €1.11 million (HY 2020: €0.81 million) largely driven by the additional staffing for the preparations for the submissions for marketing approval of the **alfa**pump in the U.S. and Canada.

Engineering expenses increased from €0.77 million to €1.54 million largely driven by external advice and staffing for the preparations for the submissions for marketing approval of the **alfa**pump in the U.S. and Canada.

General and administration expenses increased from €2.31 million to €2.59 million mainly due to the costs related to the equity placement in H1 2021.

EBIT[3]

As a result of the above, earnings before interest and taxes (EBIT) evolved from a loss of €8.93 million in HY 2020 to a loss of €11.48 million in HY 2021.

Total net finance expenses

Net finance cost (€0.28 million) decreased compared to the same period last year (€0.52 million), mainly resulting from the repayment of the Bootstrap loan in 2020.

Income tax expense

Income tax expense remained at a similar level for HY 2021 (€0.13 million) compared to HY 2020 (€0.10 million).

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

Net loss for the period

As a result of the above, the net loss increased from €9.55 million in HY 2020 to €11.89 million in HY 2021.

Basic losses per share (LPS)

Basic losses per share remained at a similar level for HY 2021 (€0.66) compared to HY 2020 (€0.62).

Condensed Consolidated Statement of Financial Position

Net debt

Net debt[4] at 30 June 2021 improved by €11.18 million, resulting in a positive net cash position of €14.34 million compared to €3.16 million at 31 December 2020, mainly as a result of the proceeds from the February 2021 equity placement.

Working Capital

Working capital[5] at 30 June 2021 improved by €0.28 million compared to 31 December 2020, mainly as a result of an increase in trade payables and accrued liabilities.

Condensed Consolidated Statement of Cash Flows

Net cash outflow from operating activities was €11.87 million in HY 2021 compared to a net cash outflow of €9.24 million in HY 2020. The difference mainly relates to an increase in cash relating to working capital primarily due to the increase in the net loss and inventory.

Cash flow from investing activities resulted in a net outflow of €0.07 million in HY 2021 compared to a net outflow of €0.03 million in HY 2020.

Cash flow from financing activities resulted in a net inflow of €22.63 million in HY 2021, mainly as a result of the proceeds from the equity placement in February 2021, compared to a net inflow of €18.67 million in HY 2020 (equity placement in January 2020).

The Company ended the period with a total liquidity position of €21.77 million (2020: €14.89 million).

[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.

Conference Call and Webcast

Sequana Medical will host a conference call with live webcast presentation today at 15:00 CET / 09:00 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.

2022 Financial Calendar

17 March 2022	Publication Full Year Results 2021
27 April 2022	Online publication of Annual Report 2021
27 May 2022	Annual General Meeting 2022
8 September 2022	Publication Half Year results 2022

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About Sequana Medical

Sequana Medical is a commercial stage medical device company utilizing its proprietary **alfa**pump® and DSR® (Direct Sodium Removal) technologies to develop innovative treatments for 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 DSR and the **alfa**pump DSR® is estimated to be over €5 billion annually

in the U.S. and EU5 by 2026.

The **alfa**pump is a unique, fully implanted wireless device that automatically pumps fluid from the abdominal cavity into the bladder, where it is naturally eliminated through urination. DSR is Sequana Medical's proprietary approach to managing sodium and fluid overload through use of a sodium-free infusate administered into the abdominal cavity.

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 and a rapid and persistent clinically important improvement in quality of life. 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.

Sequana Medical has combined its proven **alfa**pump and proprietary DSR therapy, and is developing the **alfa**pump DSR, a breakthrough approach to fluid overload due to heart failure. RED DESERT, the repeated dose **alfa**pump DSR study in diuretic-resistant heart failure patients has demonstrated that repeated DSR therapy is able to both manage the fluid and sodium balance of these patients as well as restore their diuretic response and improve their cardio-renal status. The SAHARA DESERT study of **alfa**pump DSR in decompensated heart failure patients is ongoing.

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.*

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

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 2021 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	
	2021	2020
Revenue	**23**	**595**
Cost of goods sold	(4)	(126)
Gross margin	**18**	**469**
Sales & Marketing	(1,069)	(1,373)
Clinical	(3,652)	(3,138)
Quality & Regulatory	(1,558)	(1,023)
Supply Chain	(1,107)	(806)
Engineering	(1,539)	(771)
General & Administration	(2,593)	(2,313)
Other income	17	27
Total operating expenses	**(11,501)**	**(9,397)**
Earnings before interests and taxes (EBIT)[6]	**(11,483)**	**(8,928)**
Finance income	156	47
Finance cost	(434)	(570)
Total net finance expense	**(278)**	**(523)**
Income tax expense	(129)	(103)
Net loss for the period	**(11,890)**	**(9,554)**
Basic losses per share (in Euro)	**(0.66)**	**(0.62)**

[6] 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	
	2021	2020
Net loss for the period	**(11,890)**	**(9,554)**
Components of other comprehensive income (OCI) items that will not be reclassified to profit or loss:		
Remeasurements of defined benefit plans	-	-
Items that may be reclassified subsequently to profit or loss:		
Currency translation adjustments	(9)	78
Total other comprehensive income/(loss)-net of tax	**(9)**	**78**
Total comprehensive income	**(11,899)**	**(9,476)**
Attributable to Sequana Medical shareholders	(11,899)	(9,476)

Condensed Consolidated Statement of Financial Position

in Thousand Euros	As at period ended	
	30 June 2021	31 December 2020
ASSETS		
Property, plant and equipment	666	705
Laboratory	64	66
Information Technology	239	235
R&D tools	-	1
Right-of-use assets	357	393
Other tangible fixed assets	6	11
Assets under construction	-	-
Financial Assets	79	67
Financial assets – rental deposits	79	67
Total non-current assets	**745**	**772**
Trade receivables	-	24
Other receivables	1,225	930
Inventory	1,963	1,472
Cash and cash equivalents	21,772	11,016
Total current assets	**24,960**	**13,441**
Total assets	**25,705**	**14,213**
EQUITY AND LIABILITIES		
Share capital	1,925	1,635
Share premium	142,430	119,333
Reserves	(2,951)	(2,250)
Loss brought forward	(130,970)	(119,080)
Cumulative translation adjustment	485	476
Total equity	**10,919**	**113**
Long term financial debts	7,089	7,473
Long term lease debts	138	123
Retirement benefit obligation	612	539
Total non-current liabilities	**7,839**	**8,135**
Short term financial debts	-	-
Short term lease debts	205	264
Trade payables	3,107	2,802
Other payables	1,640	1,523
Accrued liabilities	1,995	1,376
Total current liabilities	**6,947**	**5,966**
Total equity and liabilities	**25,705**	**14,213**

Condensed Consolidated Statement of Cash Flows

in Thousand Euros	Half Year ended 30 June	
	2021	2020
Net loss for the period	**(11,890)**	**(9,554)**
Income tax expense	129	103
Financial result	299	390
Depreciation	52	145
Change in defined benefit plan	73	-
Share-based compensation	350	69
Changes in trade and other receivables	(271)	63
Changes in inventories	(492)	214
Changes in trade and other payables/provisions	(31)	(667)
Taxes paid	(85)	(6)
Cash flow used in operating activities	**(11,866)**	**(9,244)**
Investments in tangible fixed assets	(56)	(26)
Investments in financial assets	(13)	-
Cash flow used in investing activities	**(69)**	**(26)**
Proceeds from capital increase	22,768	19,000
(Repayments)/Proceeds from leasing debts	(138)	(131)
(Repayments)/Proceeds from financial debts	-	-
Interest paid	-	(194)
Cash flow from financing activities	**22,630**	**18,675**
Net change in cash and cash equivalents	**10,695**	**9,405**
Cash and cash equivalents at the beginning of the period	**11,016**	**5,586**
Net effect of currency translation on cash and cash equivalents	60	(110)
Cash and cash equivalents at the end of the period	**21,772**	**14,882**

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 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**	**(2,251)**	**(119,080)**	**476**	**113**
Balance at 1 January 2021	**1,635**	**-**	**119,333**	**(2,251)**	**(119,080)**	**476**	**113**
Net loss for the period					(11,890)		(11,890)
Other comprehensive income						9	9
February 2021 Capital increase Placement	274	-	22,226				22,500
Capital increase ESOP	6		263				268
Capital increase convertible loan to shares	10		609				619
Transaction costs for equity instruments				(1,050)			(1,050)
Share-based compensation				350			350
Balance at 30 June 2021	**1,925**	**-**	**142,430**	**(2,951)**	**(130,970)**	**485**	**10,919**