PRESS RELEASE
REGULATED INFORMATION – INSIDE INFORMATION
8 September 2022, 07:00 CET

Sequana Medical announces H1 2022 results and provides business update

- ***alfapump® – strong interim data / on track to report primary endpoint data of North American pivotal POSEIDON study in Q4 2022***
- ***DSR® – clinical evidence of disease-modifying heart failure drug therapy / preparations ongoing to start US phase 1b/2a MOJAVE study in H1 2023***
- ***Total liquidity position of €23.8 million and cash runway into Q3 2023***

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

Ghent, Belgium – 8 September 2022 – Sequana Medical NV (Euronext Brussels: SEQUA) (the "**Company**" or "**Sequana Medical**"**)**, a pioneer in the treatment of drug-resistant fluid overload in liver disease, heart failure and cancer, today announces its business highlights and financial results for the six-month period ending 30 June 2022 and its outlook for the remainder of the year and beyond.

Ian Crosbie, Chief Executive Officer at Sequana Medical, commented: *"We have made important progress with both our liver disease and heart failure programs during this reporting period. Our POSEIDON study for the **alfa**pump in patients with liver disease continues to report strong interim results, including 70% 12 month survival for the Roll-In cohort, and we look forward to reporting primary endpoint data for the Pivotal cohort by year end. We are excited to see the continued strong clinical evidence of a disease-modifying profile for our DSR program for diuretic-resistant heart failure patients. In addition to no congestion-related re-hospitalizations during their study follow-up, which is remarkable given that typically one in four of these patients is re-admitted within a month of discharge, the 75% reduction in predicted 12 month mortality is highly promising for this patient group in need of improved clinical options. The evidence from our proof-of-concept studies show the long-term clinical benefits delivered by Short Term DSR therapy and we look forward to further demonstrating DSR's potential in MOJAVE, our upcoming US phase 1b/2a multi-centred, randomized, controlled study with DSR 2.0, our second-generation DSR product.*

*"Finally, the two highly experienced US medtech executives that we have added to our Board bring important expertise as we prepare for US commercialization of the **alfa**pump, and we are well capitalised into Q3 2023 having successfully raised additional finance."*

Operational Highlights – 2022 year to date

- POSEIDON – North American pivotal study of **alfa**pump in patients with recurrent and refractory ascites due to liver cirrhosis on track to report top-line data in Q4 2022
    - Completion of **alfa**pump implantations in Roll-In and Pivotal cohorts.

  - A preliminary interim analysis[1] of patient survival in the Roll-In cohort reported 70% survival at one year post-implantation, comparing favorably to published literature of only 50% survival for refractory ascites patients after one year.[2]

- SAHARA – Phase 2a study of DSR therapy in decompensated heart failure patients reports strong interim data
  - Interim results from 10 patients treated with our first-generation DSR product ("DSR 1.0") show safe, rapid and effective decongestion, clear improvements in cardio-renal health and a large and long-lasting reduction in the need for loop diuretic drugs.
  - Enrollment in SAHARA I[3] with DSR 1.0 completed.
  - Study to be extended to treat a small number of patients with our second-generation DSR product ("DSR 2.0") to support US IND[4] filing.
- Strong clinical observations from RED DESERT and SAHARA studies in diuretic-resistant heart failure patients support heart failure disease-modifying profile of DSR therapy
  - No heart failure congestion-related re-hospitalizations during study follow-up.
  - Clinical benefits result in a 75% reduction in predicted one-year mortality pre- vs. post-intensive DSR therapy based on the Seattle Heart Failure Model[5].
  - An intensive treatment period of three to four weeks of DSR therapy delivers six to twelve months of important clinical benefits.
- Focus on Short Term DSR therapy with proprietary DSR 2.0
  - As a result of the strong, durable clinical signals observed, the Company will focus the heart failure development program on Short Term DSR with its proprietary DSR 2.0 administered via a peritoneal catheter.
  - DSR 2.0 is expected to have an improved therapeutic and favourable safety profile.
  - Preparations for US IND filing continue, including good progress in product development and GLP[6] animal studies.
- European MDR certification
  - Medical Device Regulation (MDR) certification received, confirming that the Company's quality management system (QMS) and **alfa**pump are compliant with the latest regulatory

[1] Date of analysis 25 March 2022, as part of a general safety assessment
[2] Biggins et al., Hepatology, Vol. 74, No. 2, 2021, AASLD Practice Guidance; Moreau R et al., Liver International 2004: 24: 457-464
[3] SAHARA I: SAHARA study using DSR 1.0
[4] IND: Investigational New Drug
[5] Predicted one-year survival analysis using Seattle Heart Failure Model of seven patients from RED DESERT and eight patients from SAHARA pre- and post-intensive DSR therapy. Analysis includes physician-assessed data collected *post hoc*
[6] GLP: Good Laboratory Practice

standards required for medical devices in Europe. **alfa**pump was one of the first novel Class III active implantable medical devices to be certified. In 2021, the Company also received Medical Device Single Audit Program (MDSAP) certification, thereby expanding its QMS towards the US and Canada.

- Expanding the Board of Directors with seasoned US medtech executives
    - The Company appointed two highly experienced medtech leaders from the US as independent Non-Executive Directors. Doug Kohrs brings more than 40 years' experience from his many roles as a founder and executive of leading medical technology companies. Alexandra Clyde brings more than 30 years' experience and has an exceptional understanding and track record of successfully navigating health economics and reimbursement in the medical device industry.
    - Erik Amble announced to step down as a member of the Board after the September board meeting but will remain involved as a Board observer in a non-voting capacity. Mr. Amble has contributed tremendously to the Company's development activities for more than 15 years and is happy to now pass the torch to new expertise to help guide the Company's commercial readiness activities.

Financial Highlights

- H1 2022
    - Raised €28.4 million in gross proceeds by means of an equity placement via an accelerated book building offering from a new investor, Partners in Equity V B.V. and existing shareholders.
    - Total liquidity position of €23.8 million at the end of June 2022 compared to €9.6 million at the end of December 2021.
- Post period:
    - Secured €10 million loan facility with Kreos Capital, a leading growth debt provider for life sciences and healthcare companies. The loan facility is available for drawdown until 30 September 2022 and extends the Company's cash runway into Q3 2023.

Outlook for the remainder of 2022 and beyond

- Towards approval of **alfa**pump in North America
    - Reporting primary endpoint data from POSEIDON Pivotal cohort planned for Q4 2022.
    - Submission of the Premarket Approval (PMA) to the US FDA expected in H2 2023.
- DSR heart failure drug development
    - Reporting top-line data from SAHARA, using DSR 1.0 and 2.0, expected by year end.

- Start of MOJAVE, a phase 1b/2a multi-centre, randomised, controlled study in the US in decompensated heart failure patients using DSR 2.0, following approval of the US IND, expected in H1 2023.

Financial review – Six months ended 30 June 2022

in Thousand Euros	HY 2022	HY 2021	Variance
Revenue	**464**	**23**	**N.M.**
Cost of goods sold	(103)	(4)	N.M.
Gross margin	**361**	**18**	**N.M.**
Sales & Marketing	(1,149)	(1,069)	7%
Clinical	(4,279)	(3,652)	17%
Quality & Regulatory	(1,660)	(1,558)	7%
Supply Chain	(1,478)	(1,107)	34%
Engineering	(1,761)	(1,539)	14%
General & Administration	(3,538)	(2,593)	36%
Other income	217	17	N.M.
Total operating expenses	**(13,648)**	**(11,501)**	**19%**
Earnings before interest and taxes (EBIT)[7]	**(13,287)**	**(11,483)**	**16%**
Finance income	113	156	(27%)
Finance cost	(1,425)	(434)	N.M.
Total net finance expense	**(1,311)**	**(278)**	**N.M.**
Income tax expense	(257)	(129)	99%
Net loss for the period	**(14,855)**	**(11,890)**	**25%**
Basic Loss Per Share	**(0.68)**	**(0.66)**	**3%**
Cash position* at 30 June	**23,802**	**21,772**	**9%**

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

Condensed Consolidated Income Statement

Revenue

Revenue increased from €0.02 million in H1 2021 to €0.46 million in H1 2022 as a result of resumed commercial activity in Europe as the impact of COVID declines.

Cost of goods sold

Cost of goods sold increased from €0.00 million in H1 2021 to €0.10 million in H1 2022 in line with the increase in revenue.

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

Operating expenses

Total operating expenses increased from €11.50 million in H1 2021 to €13.65 million in H1 2022 mainly due to i) the preparations of the submissions for marketing approval of the **alfa**pump in the US and Canada, and ii) pre-clinical and clinical development work for Sequana Medical's proprietary DSR therapy.

Sales and Marketing expenses increased from €1.07 million in H1 2021 to €1.15 million in H1 2022 due to the resumption of European commercial activities.

Clinical expenses increased from €3.65 million in H1 2021 to €4.28 million in H1 2022 mainly as a result of costs related to the North American pivotal POSEIDON study of the **alfa**pump, the SAHARA DSR proof-of-concept study and pre-clinical and clinical development work for the Company's proprietary DSR therapy.

Quality and Regulatory expenses increased from €1.56 million in H1 2021 to €1.66 million in H1 2022, mainly driven by external advice for the preparation of the submissions for marketing approval of the **alfa**pump in the US and Canada.

Supply chain expenses increased from €1.11 million in H1 2021 to €1.48 million in H1 2022 largely driven by additional staffing for the preparation of the submissions for marketing approval of the **alfa**pump in the US and Canada.

Engineering expenses increased from €1.54 million in H1 2021 to €1.76 million in H1 2022, largely driven by external advice and additional staffing for the preparations of the submissions for marketing approval of the **alfa**pump in the US and Canada.

General and Administration expenses increased from €2.59 million in H1 2021 to €3.54 million in H1 2022 mainly due to costs relating to the equity placement in H1 2022 and additional staffing.

Other income increased from €0.02 million in H1 2021 to €0.22 million in H2 2022 largely driven by recognized income from Belgian Research & Development (R&D) incentives with regard to incurred R&D expenses.

EBIT[8]

As a result of the above, earnings before interest and taxes (EBIT) evolved from a loss of €11.48 million in H1 2021 to a loss of €13.29 million in H1 2022.

Total net finance expenses

Net finance cost increased from €0.28 million in H1 2021 to €1.31 million in H1 2022, mainly resulting from valuation of the Bootstrap Warrants (a non-cash item) issued at the extraordinary shareholders meeting of 27 May 2022.

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

Income tax expense

Income tax expense increased from €0.13 million in H1 2021 to €0.26 million in H1 2022 largely due to the increased activities in Switzerland.

Net loss for the period

As a result of the above, the net loss increased from €11.89 million in H1 2021 to €14.86 million in H1 2022.

Basic losses per share (LPS)

Basic losses per share increased from €0.66 in H1 2021 to €0.68 in H1 2022.

Condensed Consolidated Statement of Financial Position

Net debt

Net debt[9] at 30 June 2022 improved by €13.63 million compared to 31 December 2021, mainly as a result of the proceeds from the March 2022 equity placement.

Working Capital

Working capital[10] at 30 June 2022 increased by €0.22 million compared to 31 December 2021, mainly as a result of an increase in inventory partly compensated by trade payables and accrued liabilities.

Condensed Consolidated Statement of Cash Flows

Net cash outflow from operating activities was €13.66 million in H1 2022 compared to €11.87 million in H1 2021. The higher outflow was mainly driven by higher net loss of the period.

Cash flow from investing activities resulted in a net outflow of €0.44 million in H1 2022, compared to a net outflow of €0.07 million in H1 2021.

Cash flow from financing activities resulted in a net inflow of €28.22 million in H1 2022, mainly as a result of the proceeds from the March 2022 equity placement. In H1 2021, the net inflow of €22.63 million was mainly a result of the February 2021 equity placement.

The Company ended H1 2022 with a total liquidity position of €23.80 million (end 2021: €9.60 million).

[9] Net debt is calculated by adding short-term, long-term financial and lease debt and deducting cash and cash equivalents.
[10] 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.

H1 2023 Financial Calendar

9 February 2023	Publication Full Year Results 2022
25 April 2023	Online publication of Annual Report 2022
25 May 2023	Annual General Meeting 2023

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About Sequana Medical

Sequana Medical NV is a pioneer in treating drug-resistant fluid overload, a serious and frequent clinical complication in patients with liver disease, heart failure and cancer. Fluid overload is a well-recognized problem in these growing diseases, causing severe problems for the large number of patients for whom current medicines are no longer effective. These patients can have up to 15 liters of extra fluid in their bodies, causing major medical issues including increased mortality, repeated hospitalizations, severe pain, difficult breathing and restricted mobility that severely impacts daily life.

alfapump® and DSR® are Sequana Medical's proprietary platforms that work with the body to remove this excess fluid, delivering major clinical and quality of life benefits for patients and reducing costs for healthcare systems. Sequana Medical is listed on Euronext Brussels (Ticker: SEQUA.BR) and headquartered in Ghent, Belgium. For further information, please visit www.sequanamedical.com.

Important Regulatory Disclaimers

*The **alfa**pump® system is currently not 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. 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. DSR therapy is currently not approved for clinical research in the United States or Canada. There is no link between 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, China, the EU, United Kingdom, and Hong Kong.*

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 2022 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	
	2022	2021
Revenue	**464**	**23**
Cost of goods sold	(103)	(4)
Gross margin	**361**	**18**
Sales & Marketing	(1.149)	(1,069)
Clinical	(4,279)	(3,652)
Quality & Regulatory	(1,660)	(1,558)
Supply Chain	(1,478)	(1,107)
Engineering	(1,761)	(1,539)
General & Administration	(3,538)	(2,593)
Other income	217	17
Total operating expenses	**(13,648)**	**(11,501)**
Earnings before interests and taxes (EBIT)[11]	**(13,287)**	**(11,483)**
Finance income	113	156
Finance cost	(1,425)	(434)
Total net finance expense	**(1,311)**	**(278)**
Income tax expense	(257)	(129)
Net loss for the period	**(14,855)**	**(11,890)**
Basic losses per share (in Euro)	**(0.68)**	**(0.66)**

[11] 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	
	2022	2021
Net loss for the period	**(14,855)**	**(11,890)**
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	(559)	(9)
Total other comprehensive income/(loss)-net of tax	**(559)**	**(9)**
Total comprehensive income	**(15,415)**	**(11,899)**
Attributable to Sequana Medical shareholders	(15,415)	(11,899)

Condensed Consolidated Statement of Financial Position

in Thousand Euros	As at period ended	
	30 June 2022	31 December 2021
ASSETS		
Property, plant and equipment	2,040	1,268
Financial Assets	88	82
Other non-current assets	584	464
Total non-current assets	**2,712**	**1,815**
Trade receivables	96	82
Other receivables and prepaid expenses	1,201	1,069
Inventory	2,885	2,139
Cash and cash equivalents	23,802	9,600
Total current assets	**27,983**	**12,891**
Total assets	**30,696**	**14,705**
EQUITY AND LIABILITIES		
Share capital	2,460	1,925
Share premium	170,324	142,433
Reserves	(3,025)	(2,669)
Loss brought forward	(157,551)	(142,695)
Cumulative translation adjustment	779	220
Total equity	**12,988**	**(787)**
Long term financial debts	7,582	7,325
Long term lease debts	756	477
Retirement benefit obligation	665	510
Total non-current liabilities	**9,002**	**8,312**
Short term financial debts	-	-
Short term lease debts	318	283
Other current financial liabilities	824	
Trade payables and contract liabilities	2,783	2,367
Other payables	1,715	1,925
Accrued liabilities and provisions	3,067	2,605
Total current liabilities	**8,706**	**7,180**
Total equity and liabilities	**30,696**	**14,705**

Condensed Consolidated Statement of Cash Flows

in Thousand Euros	Half Year ended 30 June	
	2022	2021
Net loss for the period	**(14,855)**	**(11,890)**
Income tax expense	257	129
Financial result	1,184	299
Depreciation	100	52
Change in defined benefit plan	156	73
Share-based compensation	379	350
Changes in trade and other receivables	(146)	(271)
Changes in inventories	(746)	(492)
Changes in trade and other payables/provisions	200	(31)
Taxes paid	(188)	(85)
Cash flow used in operating activities	**(13,659)**	**(11,866)**
Investments in tangible fixed assets	(455)	(56)
Investments in financial assets	13	(13)
Cash flow used in investing activities	**(442)**	**(69)**
Proceeds from capital increase	28,427	22,768
(Repayments)/Proceeds from leasing debts	(203)	(138)
(Repayments)/Proceeds from financial debts	-	-
Interest paid	-	-
Cash flow from financing activities	**28,224**	**22,630**
Net change in cash and cash equivalents	**14,124**	**10,695**
Cash and cash equivalents at the beginning of the period	**9,600**	**11,016**
Net effect of currency translation on cash and cash equivalents	77	60
Cash and cash equivalents at the end of the period	**23,802**	**21,772**

Condensed Consolidated Statement of Changes in Equity

in Thousand Euros	Share capital	Share premium	Reserves	Loss brought forward	Currency translation differences	Total shareholder equity
Balance at 1 January 2021	**1,635**	**119,333**	**(2,250)**	**(119,080)**	**476**	**113**
Net loss for the period				(23,615)		(23,615)
Other comprehensive income			96		(256)	(160)
February 2021 Equity Placement	274	22,226				22,500
Capital increase Share Options	6	265				271
Capital increase convertible loan to shares	10	609				619
Transaction costs for equity instruments			(1,051)			(1,051)
Share-based compensation			536			536
Balance at 31 December 2021	**1,925**	**142,433**	**(2,669)**	**(142,695)**	**220**	**(787)**
Balance at 1 January 2022	**1,925**	**142,433**	**(2,669)**	**(142,695)**	**220**	**(787)**
Net loss for the period				(14,855)		(14,855)
Other comprehensive income					559	559
March 2022 Equity Placement	535	27,885				28,420
Capital increase Share Options	0	7				7
Transaction costs for equity instruments			(735)			(735)
Share-based compensation			379			379
Balance at 30 June 2022	**2.460**	**170,324**	**(3,025)**	**(157,551)**	**779**	**12,988**