PRESS RELEASE
REGULATED INFORMATION – INSIDE INFORMATION
14 September 2023, 07:00 CEST

Sequana Medical announces H1 2023 results and provides business update

- ***alfapump® – strong pivotal POSEIDON data presented at leading international liver congress / on track to file Pre-Market Approval (PMA) application to US FDA in Q4 2023***
- ***DSR® – safety of single dose DSR 2.0 demonstrated / Phase 1/2a US MOJAVE study in heart failure ongoing with initial data expected in Q4 2023***
- ***Total liquidity position of €17.1 million and cash runway into Q1 2024***

Conference call with live webcast presentation today at 03:00 pm CEST / 09:00 am EST

Ghent, Belgium – 14 September 2023 – Sequana Medical NV (Euronext Brussels: SEQUA) (the "**Company**" or "**Sequana Medical**"**)**, a pioneer in the treatment of 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 2023 and its outlook for the remainder of the year.

Ian Crosbie, Chief Executive Officer at Sequana Medical, commented: "*During the first half of this year, we made strong progress in both our **alfa**pump and DSR programs.*

*"Our **alfa**pump liver program is advancing towards North American commercialization with filing of the PMA with the FDA planned by year end. Data from our landmark POSEIDON study was presented at the prestigious international EASL liver congress and reaffirms **alfa**pump's strong clinical profile – virtually eliminating the need for needle paracentesis and significantly improving patients' quality of life. Although not powered for survival, the study's one-year survival probability of 70% is encouraging in a patient population where 50% survival after one year is typically reported. We are pleased to see the progress of TCET[1] in the US and applaud CMS[2] intent to support patient care and innovation by providing a new national coverage pathway for promising FDA-designated breakthrough devices such as the **alfa**pump.*

"We are excited to have the MOJAVE study of our second-generation DSR product in diuretic-resistant heart failure patients underway in the US, with first patients enrolled. In this Phase 1/2a randomized controlled study, we are seeking to build upon the strong results of our SAHARA study where we demonstrated DSR's disease-modifying profile – safe, effective and rapid elimination of persistent congestion, important improvements in cardiovascular and renal health, and the restoration of diuretic response of the kidney. We look forward to reporting initial safety and efficacy data from the non-randomized cohort by year end, and are planning for enrollment of up to 30 patients into the randomized cohort next year.

"Despite challenging market conditions, we've secured additional financing, extending our cash runway into the first quarter of 2024. We're delighted to welcome Ken Macleod to our Board, whose wealth of experience in healthcare companies and life science fund management will be invaluable to our journey."

[1] TCET: Transitional Coverage of Emerging Technologies
[2] CMS: Center for Medicare and Medicaid Services

Highlights from year 2023 to date

North American alfapump liver program

- POSEIDON – data presented by Principal Investigator Prof. Wong at EASL 2023 Congress from successful pivotal study in patients with recurrent or refractory ascites due to liver cirrhosis, supports strong clinical profile of **alfa**pump
    - Effective control of ascites, virtually eliminating needle paracentesis
    - Safety in line with expectations
    - Clinically meaningful and statistically significant improvement in patients' quality of life at six months post-implantation compared to baseline
    - One year survival of 70% compares favorably to literature citing 50% in this patient population[3]
- On track to file PMA application to the US FDA in Q4 2023

DSR heart failure program

- Successful completion of IND[4]-enabling pre-clinical and Phase 1 studies of second-generation DSR product (DSR 2.0)
    - Data from GLP[5] studies in mice and sheep showed there was no difference in systemic and local toxic effects in animals treated repeatedly with DSR 2.0 compared to animals in the control group, concluding that DSR 2.0 had consistent safety with the standard peritoneal dialysis solution used in the control group.
    - Data from the Phase 1 CHIHUAHUA study in stable peritoneal dialysis patients demonstrated that a single dose of DSR 2.0 was safe and well-tolerated and indicated a compelling dosing profile.
- MOJAVE – US randomized controlled Phase 1/2a study of DSR 2.0 for treatment of congestive heart failure underway
    - First patients enrolled in non-randomized cohort of three patients. Progress to the randomized cohort of up to 30 additional patients planned for H1 2024, subject to approval from the independent Data and Safety Monitoring Board following their review of these first three patients.
- Additional DSR patents granted in the US and China

[3] Biggins et al., Hepatology, Vol. 74, No. 2, 2021, AASLD Practice Guidance; Moreau R et al., Liver International 2004: 24: 457-464; Bureau et al., Gastroenterology 2017
[4] IND: Investigational New Drug
[5] GLP: Good Laboratory Practice

- Additional US patents granted covering among other, the expansion of the composition of matter and method for Sequana Medical's DSR therapy, including additional oncotic and osmotic agents and the use of an implantable pump system.
- A key composition of matter patent was granted in China.

Corporate

- Expanded Board of Directors with the appointment of Dr. Kenneth Macleod as non-executive director. Dr. Macleod is a partner at Rosetta Capital and brings more than 35 years' experience in the life science sector from his senior operating roles in healthcare companies and life science fund management.
- Raised €15.8 million in gross proceeds by means of an equity placement via an accelerated book building offering, extending the Company's cash runway into Q1 2024.
- Total liquidity position of €17.1 million at the end of June 2023 compared to €18.9 million at the end of December 2022.

Outlook for the remainder of 2023

- North American **alfa**pump liver program – on track to file PMA application to the US FDA in Q4 2023
  - Top-line data from the US patient preference study expected in H2 2023
  - Data from propensity matched interim analysis of NACSELD[6] registry vs POSEIDON pivotal cohort expected in H2 2023

- DSR heart failure program – continue US Phase 1/2a randomized controlled MOJAVE study
  - Data from three patients in non-randomized cohort expected in Q4 2023

[6] NACSELD: North American Consortium for the Study of End-stage Liver Disease

Financial review – Six months ended 30 June 2023

in Thousand Euros	HY 2023	HY 2022	Variance
Revenue	**384**	**464**	**(17%)**
Cost of goods sold	(88)	(103)	(14%)
Gross margin	**296**	**361**	**(17%)**
Sales & Marketing	(1,100)	(1,149)	(4%)
Clinical	(3,714)	(4,279)	(13%)
Quality & Regulatory	(3,186)	(1,660)	92%
Supply Chain	(2,372)	(1,478)	61%
Engineering	(2,095)	(1,761)	19%
General & Administration	(3,455)	(3,538)	(2%)
Total operating expenses	**(15,922)**	**(13,865)**	**15%**
Other income	210	217	(3%)
Earnings before interest and taxes (EBIT)[7]	**(15,417)**	**(13,287)**	**16%**
Finance income	1,316	113	N.M.
Finance cost	(2,108)	(1,425)	48%
Total net finance cost	**(792)**	**(1,311)**	**(40%)**
Income tax expense	(255)	(257)	(1%)
Net loss for the period	**(16,464)**	**(14,855)**	**11%**
Basic Loss Per Share	**(0.65)**	**(0.68)**	**(5%)**
Cash position* at 30 June	**17,122**	**23,802**	**(28%)**

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

Condensed Consolidated Income Statement

Revenue

Revenue decreased from €0.46 million in H1 2022 to €0.38 million in H1 2023 due to the decision to scale back European commercial activities.

Cost of goods sold

Cost of goods sold decreased from €0.10 million in H1 2022 to €0.09 million in H1 2023 in line with the decrease in revenue.

Operating expenses

Total operating expenses increased from €13.87 million in H1 2022 to €15.92 million in H1 2023 mainly due to the preparations of the submissions for marketing approval of the **alfa**pump in the US and Canada.

Sales and Marketing expenses remained stable at €1.15 million in H1 2022 and €1.10 million in H1 2023.

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

Clinical expenses decreased from €4.28 million in H1 2022 to €3.71 million in H1 2023 mainly as a result of lower costs related to the North American pivotal POSEIDON study of the **alfa**pump and the SAHARA DSR proof-of-concept study, partially compensated by pre-clinical and clinical development work required for the Company's IND filing for its proprietary DSR product and commencement of the MOJAVE study in the US.

Quality and Regulatory expenses increased from €1.66 million in H1 2022 to €3.19 million in H1 2023, mainly driven by external advice solicited for the preparation of the submissions for marketing approval of the **alfa**pump in the US and Canada.

Supply chain expenses increased from €1.48 million in H1 2022 to €2.37 million in H1 2023 largely driven by additional staffing and external advice for the preparation of the submissions for marketing approval of the **alfa**pump in the US and Canada.

Engineering expenses increased from €1.76 million in H1 2022 to €2.10 million in H1 2023, largely driven by test samples required for the preparation of the submissions for marketing approval of the **alfa**pump in the US and Canada.

General and Administration expenses remained stable at €3.54 million in H1 2022 and €3.45 million in H1 2023.

Other income remained stable at €0.22 million in H1 2022 and €0.21 million in H1 2023 and includes recognized income from Belgian Research & Development (R&D) incentives with regard to incurred R&D expenses.

EBIT

As a result of the above, earnings before interest and taxes (EBIT) evolved from a loss of €13.29 million in H1 2022 to a loss of €15.42 million in H1 2023.

Total net finance cost

Net finance cost decreased from €1.31 million in H1 2022 to €0.79 million in H1 2023, mainly resulting from the impact of the valuation of the Bootstrap Warrants and Kreos Subscription Rights partially compensated by the initial valuation of the Investor Warrants (issued as part of the April 2023 equity placement). All of these items are non-cash items.

Income tax expense

Income tax expense remained stable at €0.26 million in H1 2022 and H1 2023 and are a result of the activities in Switzerland.

Net loss for the period

As a result of the above, the net loss increased from €14.86 million in H1 2022 to €16.46 million in H1 2023.

Basic losses per share (LPS)

Basic losses per share decreased from €0.68 in H1 2022 to €0.65 in H1 2023.

Condensed Consolidated Statement of Financial Position

Net debt

Net debt[8] at 30 June 2023 increased by €1.80 million compared to 31 December 2022, mainly as a result of slightly lower cash position compared to 31 December 2022.

Working Capital

Working capital[9] at 30 June 2023 remained stable at -€4.57 million compared to 31 December 2022.

Condensed Consolidated Statement of Cash Flows

Net cash outflow from operating activities was €16.36 million in H1 2023 compared to €13.66 million in H1 2022. The higher outflow was mainly driven by higher net loss of the period.

Cash flow from investing activities resulted in a net outflow of €0.08 million in H1 2023, compared to a net outflow of €0.44 million in H1 2022.

Cash flow from financing activities resulted in a net inflow of €14.72 million in H1 2023, mainly as a result of the proceeds from the April 2023 equity placement. In H1 2022, the net inflow of €28.22 million was mainly a result of the March 2022 equity placement.

The Company ended H1 2023 with a total liquidity position of €17.12 million (end 2022: €18.87 million).

Conference Call and Webcast

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

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

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About Sequana Medical

Sequana Medical NV is a pioneer in treating fluid overload, a serious and frequent clinical complication in patients with liver disease, heart failure and cancer. 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, difficulty breathing and restricted mobility that severely impacts daily life. Although diuretics are standard of care, the problem is that in many patients they are no longer effective and / or tolerable. There are limited effective treatment options for these patients, resulting in poor clinical outcomes, high costs and a major impact on their quality of life. Sequana Medical is seeking to provide innovative treatment options for this large and growing "diuretic-resistant" patient population.

alfapump® and DSR® are Sequana Medical's proprietary platforms that work with the body to treat diuretic-resistant fluid overload, delivering major clinical and quality of life benefits for patients and reducing costs for healthcare systems. The Company has reported positive primary endpoint data from the North American pivotal POSEIDON trial of the **alfa**pump in recurrent or refractory ascites due to liver cirrhosis, enabling the filing of a Pre-Market Approval (PMA) application with the FDA, planned for Q4 2023. Having delivered clinical proof-of-concept for DSR as a disease-modifying drug program for the treatment of heart failure, the Company has commenced MOJAVE, a US randomized controlled multi-center Phase 1/2a clinical trial of DSR 2.0, with initial data expected in Q4 2023.

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 Trial) and is being studied in adult patients with refractory or recurrent ascites due to liver cirrhosis. 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. 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® and DSR® are registered trademarks.*

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 2023 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	
	2023	2022
Revenue	**384**	**464**
Cost of goods sold	(88)	(103)
Gross margin	**296**	**361**
Sales & Marketing	(1,100)	(1,149)
Clinical	(3,714)	(4,279)
Quality & Regulatory	(3,186)	(1,660)
Supply Chain	(2,372)	(1,478)
Engineering	(2,095)	(1,761)
General & Administration	(3,455)	(3,538)
Total operating expenses	**(15,922)**	**(13,865)**
Other income	210	217
Earnings before interests and taxes (EBIT)	**(15,417)**	**(13,287)**
Finance income	1,316	113
Finance cost	(2,108)	(1,425)
Total net finance cost	**(792)**	**(1,311)**
Income tax expense	(255)	(257)
Net loss for the period	**(16,464)**	**(14,855)**
Basic losses per share (in Euro)	**(0.65)**	**(0.68)**

Condensed Consolidated Statement of Comprehensive Income

in Thousand Euros (if not stated otherwise)	Half Year ended 30 June	
	2023	2022
Net loss for the period	**(16,464)**	**(14,855)**
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	95	(559)
Total other comprehensive income/(loss)-net of tax	**95**	**(559)**
Total comprehensive income	**(16,368)**	**(15,415)**
Attributable to Sequana Medical shareholders	(16,368)	(15,415)

Condensed Consolidated Statement of Financial Position

in Thousand Euros	As at period ended	
	30 June 2023	31 December 2022
ASSETS		
Property, plant and equipment	2,185	2,068
Financial Assets	88	86
Other non-current assets	954	782
Total non-current assets	**3,227**	**2,936**
Trade receivables	112	114
Other receivables and prepaid expenses	1,888	1,479
Inventory	2,778	2,621
Cash and cash equivalents	17,122	18,875
Total current assets	**21,900**	**23,089**
Total assets	**25,127**	**26,025**
EQUITY AND LIABILITIES		
Share capital	2,921	2,460
Share premium	185,644	170,324
Reserves	(3,104)	(2,426)
Loss brought forward	(189,922)	(173,458)
Cumulative translation adjustment	851	946
Total equity	**(3,610)**	**(2,153)**
Long term financial debts	13,909	12,193
Long term lease debts	573	609
Retirement benefit obligation	385	228
Total non-current liabilities	**14,867**	**13,030**
Short term financial debts	2,882	4,483
Short term lease debts	280	307
Other current financial liabilities	1,358	1,569
Trade payables and contract liabilities	2,876	3,392
Other payables	2,085	1,812
Accrued liabilities and provisions	4,389	3,586
Total current liabilities	**13,870**	**15,148**
Total equity and liabilities	**25,127**	**26,025**

Condensed Consolidated Statement of Cash Flows

in Thousand Euros	Half Year ended 30 June	
	2023	2022
Net loss for the period	**(16,464)**	**(14,855)**
Income tax expense	255	257
Financial result	67	1,184
Depreciation	144	100
Change in defined benefit plan	156	156
Share-based compensation	(0)	379
Changes in trade and other receivables	(407)	(146)
Changes in inventories	(156)	(746)
Changes in trade and other payables/provisions	173	200
Taxes paid	(130)	(188)
Cash flow used in operating activities	**(16,362)**	**(13,659)**
Investments in tangible fixed assets	(80)	(455)
Investments in financial assets	-	13
Cash flow used in investing activities	**(80)**	**(442)**
Proceeds from capital increase	15,780	28,427
(Repayments)/Proceeds from leasing debts	(222)	(203)
(Repayments)/Proceeds from financial debts	(522)	-
Interest paid	(318)	-
Cash flow from financing activities	**14,718**	**28,224**
Net change in cash and cash equivalents	**(1,725)**	**14,124**
Cash and cash equivalents at the beginning of the period	**18,875**	**9,600**
Net effect of currency translation on cash and cash equivalents	(28)	77
Cash and cash equivalents at the end of the period	**17,122**	**23,802**

Condensed Consolidated Statement of Changes in Equity

in Thousand Euros	Share capital	Share premium	Reserves	Loss brought forward	Cumulative translation adjustment	Total shareholder equity
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**
Balance at 1 January 2023	**2,460**	**170,324**	**(2,426)**	**(173,458)**	**946**	**(2,153)**
Net loss for the period				(16,464)		**(16,464)**
Other comprehensive income					(95)	**(95)**
April 2023 Equity Placement	461	15,320				**15,780**
Transaction costs for equity instruments			(678)			**(678)**
Share-based compensation			(0)			**(0)**
Balance at 30 June 2023	**2,921**	**185,644**	**(3,104)**	**(189,922)**	**851**	**(3,610)**