PRESS RELEASE
REGULATED INFORMATION – INSIDE INFORMATION
28 March 2024, 08:00 a.m. CET

Sequana Medical announces 2023 Full Year Results and 2024 Outlook

- ***alfapump® – PMA[1] submitted to US FDA and accepted for substantive review, extensive feedback just received from FDA which is currently under review by the Company***
- ***DSR® – potential treatment for cardiorenal syndrome in heart failure presented at international heart failure conference, strong data from non-randomized cohort of US MOJAVE study***

Ghent, Belgium – 28 March 2024 – 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 financial results for the year ended 31 December 2023, and provides a business update and outlook for 2024 and beyond.

Ian Crosbie, Chief Executive Officer of Sequana Medical, commented: *"Securing PMA approval is a major value inflection point and the team is navigating through the approval process. Last night we received extensive feedback from the FDA on our PMA application and we will update the market as soon as we have completed the review thereof together with our external advisors. Subject to PMA approval, we believe US commercialization is derisked given our focus on the liver transplant centers that address the large majority of our target patients. Furthermore, the **alfa**pump can benefit from attractive pricing and leverage its FDA breakthrough device designation to enhance its reimbursement position.*

*We are excited by DSR as a potential treatment in cardiorenal syndrome, where there is a clear unmet need for therapies to effectively and durably address congestion and cardiorenal dysfunction. The data from our RED DESERT and SAHARA clinical studies demonstrate that DSR can not only completely replace loop diuretics during therapy but also deliver a dramatic and durable improvement in their diuretic responsiveness and reduction in chronic loop diuretic requirements. Looking ahead, we plan to initiate the randomized phase of the US MOJAVE study post **alfa**pump PMA approval and expect interim data in the second half of 2025."*

2023 highlights

North American alfapump liver program

- POSEIDON – one-year follow-up data from successful pivotal study in patients with recurrent or refractory ascites due to liver cirrhosis, confirms strong clinical profile of **alfa**pump
    - Virtual elimination of needle paracentesis
    - Robust safety profile despite disease progression
    - Clinically meaningful improvement in patients' quality of life maintained
    - Survival probability of 70% at 12 and 18 months post-implant

[1] PMA: Pre-Market Approval

- Patient preference study indicates that US patients have a strong preference for the **alfa**pump vs large volume paracentesis[2]
- Matched interim analysis of patients from NACSELD[3] registry indicates that **alfa**pump safety profile is comparable to standard of care[4]
- PMA application submitted to the US FDA in December 2023

DSR heart failure program

- Successful completion of IND[5]-enabling pre-clinical and Phase 1 studies of second-generation DSR product (DSR 2.0)
    - Data from GLP[6] 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 – all three patients from the non-randomized cohort in the US Phase 1/2a study of DSR 2.0 for treatment of congestive heart failure successfully treated with DSR 2.0, confirming the strong clinical outcomes seen in the RED DESERT and SAHARA proof-of-concept studies
    - Safe and effective maintenance of euvolemia without the need for loop diuretics
    - Durable improvement in cardio-renal health
    - Dramatic improvement in diuretic response and at least 95% reduction in loop diuretic requirements up to almost four months after last DSR therapy
- Additional DSR patents granted in the US and China
    - Additional US patents granted in February 2023 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
    - Key composition of matter patent was granted in China in March 2023

[2] Patient preference study using discrete-choice experiment methodology to elicit patient preference for attributes of an implantable pump as a novel interventional treatment for ascites, N=125 US patients with comparable patient profile to pivotal cohort in POSEIDON study
[3] NACSELD: North American Consortium for the Study of End stage Liver Disease
[4] Comparing outcomes in terms of death, hospitalization rate and liver transplant of POSEIDON pivotal cohort (6 months post-implant) to matched patient group from NACSELD registry with POSEIDON
[5] IND: Investigational New Drug
[6] GLP: Good Laboratory Practice

Corporate

- Established Sequana Medical US Inc. with an office in Boston which has been certified according to ISO 13485:2016 and MDSAP[7] (USA and Canada) by BSI[8], in preparation of the US commercial launch of the **alfa**pump
- Expanded Board of Directors with the appointment of Dr. Kenneth Macleod in June 2023 and Ids van der Weij in November 2023 as non-executive directors
    - 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
    - Mr. van der Weij is managing partner of Partners in Equity and brings more than 25 years' corporate investment experience
- Raised €15.8 million in gross proceeds in April 2023 by means of an equity placement via an accelerated book building offering
- Cash position of €2.6 million at the end of December 2023, compared to €18.9 million at the end of December 2022

Post-period events

North American alfapump liver program

- The American Medical Association granted six new CPT[9] category III reimbursement codes in January 2024, available for use by healthcare professionals and payors as of July 1st, 2024, for procedures related to the **alfa**pump system, including implantation, revision, removal and programming of the pump system, replacement of the pump and the catheters
- PMA application for **alfa**pump accepted by the US FDA for substantive review in January 2024, ahead of anticipated timing

DSR heart failure program

- The independent Data Safety Monitoring Board approved the start of the MOJAVE randomized cohort of up to 30 additional patients following review of data from non-randomized cohort in January 2024
- Three-month follow-up data from all three patients in the MOJAVE non-randomized cohort confirmed dramatic improvement in diuretic response and virtual elimination of loop diuretics following DSR therapy

[7] MDSAP: Medical Device Single Audit Program
[8] BSI: British Standards Institution
[9] CPT: Current Procedural Terminology

- Strong data supporting DSR's role as potential treatment for cardiorenal syndrome based on results of RED DESERT and SAHARA proof-of-concept DSR studies presented during late-breaking session at leading international heart failure conference, THT 2024

Corporate

- Company's cash runway extended to end of Q3 2024
    - In February 2024, the Company announced a significantly reduced cash burn through 1) the focus on obtaining **alfa**pump PMA approval, 2) postponing the start of the randomized cohort of the DSR MOJAVE study to after reaching **alfa**pump PMA approval, and 3) halting all European commercial activities for **alfa**pump
    - In February 2024, the Company's lenders agreed to defer all debt service payments until after **alfa**pump PMA approval decision
    - In March 2024, the Company raised €11.5 million in gross proceeds by means of an equity placement via an accelerated book building offering. Following this equity placement, the €3.0 million convertible loan agreement entered in February 2024 by Partners in Equity and Rosetta Capital will be mandatorily converted into new shares.

Outlook for 2024 and beyond

The Company is currently reviewing the extensive feedback which was received from the FDA yesterday (day-90 after PMA filing) on its **alfa**pump PMA application together with its external advisors and will update the market in due course. A day-100 meeting is scheduled with the FDA on April 9th 2024.

For the DSR heart failure program, the Company will start the randomized cohort of the US Phase 1/2a MOJAVE study after reaching PMA approval for its **alfa**pump. The start of the randomized phase is currently anticipated in Q1 2025, including up to 30 additional diuretic-resistant heart failure patients, with up to 20 patients treated with DSR 2.0 and up to 10 patients treated with intravenous loop diuretics, and interim data are expected in H2 2025.

Detailed financial review

in Thousand Euros (if not stated otherwise)	FY 2023	FY 2022	Change
Revenue	**712**	**923**	**-23%**
Cost of goods sold	(164)	(205)	-20%
Gross margin	**548**	**718**	**-24%**
Sales & Marketing	(1,799)	(2,240)	-20%
Clinical	(6,947)	(9,773)	-29%
Quality & Regulatory	(5,586)	(3,632)	+54%
Supply Chain	(4,724)	(3,158)	+50%
Engineering	(4,041)	(3,853)	+5%
General & Administration	(6,943)	(6,687)	+4%
Total operating expenses	**(30,040)**	**(29,343)**	**+2%**
Other income	629	530	+19%
Earnings before interest and taxes (EBIT[10])	**(28,862)**	**(28,094)**	**+3%**
Finance income	1,052	451	+133%
Finance cost	(4,288)	(2,733)	+57%
Total net finance expense	**(3,236)**	**(2,282)**	**+42%**
Income tax expense	(466)	(387)	+20%
Net loss for the period	**(32,564)**	**(30,763)**	**+6%**
Basic Loss Per Share (in Euros)	**(1.22)**	**(1.35)**	**-10%**
Cash position* at 31 December	**2,584**	**18,875**	**-86%**

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

Consolidated statements of profit and loss

Revenue

Revenue decreased from €0.92 million in 2022 to €0.71 million in 2023 due to the decision to scale back European commercial activities in April 2023.

Cost of goods sold

Cost of goods sold decreased from €0.21 million in 2022 to €0.16 million in 2023 in line with the decrease in revenue.

Operating expenses

Total operating expenses remained broadly unchanged from €29.34 million in 2022 to €30.04 million in 2023, and are mainly related to the preparations of the submissions for marketing approval of the **alfa**pump in the US.

[10] EBIT is defined as revenue less cost of goods sold and operating expenses.

Sales and marketing expenses decreased from €2.24 million in 2022 to €1.80 million in 2023 due to the decision to scale back European commercial activities.

Clinical expenses decreased from €9.77 million in 2022 to €6.95 million in 2023 mainly as a result of lower costs related to the North American pivotal POSEIDON study of the **alfa**pump and the completion of the SAHARA DSR proof-of-concept study in 2022, 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 €3.63 million in 2022 to €5.59 million in 2023, mainly driven by external advice and testing solicited for the preparation of the submissions for marketing approval of the **alfa**pump in the US.

Supply chain expenses increased from €3.16 million in 2022 to €4.72 million in 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 higher production costs.

Engineering expenses increased from €3.85 million in 2022 to €4.04 million in 2023, largely driven by test samples required for the preparation of the submissions for marketing approval of the **alfa**pump in the US.

General and Administration expenses remained broadly unchanged, from €6.69 million in 2022 to €6.94 million in 2023.

Other income remained broadly unchanged from €0.53 million in 2022 to €0.63 million in 2023.

EBIT

Earnings before interest and taxes (EBIT) remained broadly unchanged from a loss of €28.09 million in 2022 to a loss of €28.86 million in 2023.

Total net finance expenses

Net finance cost increased from €2.28 million in 2022 to €3.24 million in 2023, mainly resulting from the valuation of the Investor Warrants (non-cash item) and debt related interest expenses compensated by the valuation of the Bootstrap Warrants and Kreos Subscription Rights (both non-cash items).

Income tax expense

Income tax expense remained broadly unchanged from €0.39 million in 2022 to €0.47 million in 2023.

Net loss for the period

As a result of the above, the net loss increased from €30.76 million in 2022 to €32.56 million in 2023.

Basic losses per share (LPS)

Basic losses per share decreased from €1.35 in 2022 to €1.22 in 2023.

Consolidated balance sheet

Net debt

Net debt[11] at 31 December 2023 increased by €16.22 million compared to 31 December 2022.

Working Capital

Working capital[12] in 2023 decreased by €0.32 million compared to 2022, mainly as a result of a decrease in trade payables and other payables.

Liquidity

The Company is still in its development phase and conducting clinical trials in order to achieve regulatory marketing approvals, which incurs various risks and uncertainties, including but not limited to the uncertainty of the development process and the timing of achieving profitability. The Company's ability to continue operations also depends on its ability to raise additional capital and to refinance existing debt, in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows.

The impact of macroeconomic conditions and geopolitical situation in Ukraine and the Middle East on the Company's ability to secure additional financing rounds or undertake capital market transactions remains unclear at this point in time and will remain under review by the Executive Management and the Board of Directors.

The above conditions indicate the existence of material uncertainties, which may also cast significant doubt about the Company's ability to continue as a going concern.

The Company will continue to require additional financing in the near future and in that respect already entered a €3.0 million mandatory convertible loan agreement in February 2024 with Partners in Equity and Rosetta Capital and successfully raised €11.5 million gross proceeds in March 2024 in a private equity placement via an accelerated bookbuild offering. Together with existing cash resources, the net proceeds from this financing round are expected to extend the current cash runway of the Company to the end of Q3 2024. The Company continues to evaluate equity and other financing options, including discussions with existing as well as new investors.

The Executive Management and the Board of Directors remain confident about the strategic plan, which comprises additional financing measures including equity and/or other financing sources, and therefore consider the financial information in this press release on a going concern basis as appropriate.

Consolidated statement of cash flows

Net cash outflow from operating activities was €29.06 million in 2023 compared to €27.48 million in 2022. The outflow was mainly driven by higher net loss of the period.

[11] Net debt is calculated by adding short-term, long-term financial and lease debt and deducting cash and cash equivalents.
[12] The components of working capital are inventory + trade receivables + other receivables and prepaid expenses - trade payables - other payables - accrued liabilities and provisions.

Cash flow from investing activities resulted in a net outflow of €0.72 million in 2023, compared to a net outflow of €0.65 million in 2022.

Cash flow from financing activities resulted in a net inflow of €13.46 million in 2023, mainly as a result of the proceeds from the equity placement in H1 2023 partially compensated by repayments of financial debt and interest. In 2022, the net inflow of €37.32 million was mainly a result of the proceeds from the equity placement in H1 2022, and the €10 million loan facility with Kreos Capital secured in H2 2022.

The Company ended 2023 with a total cash and cash equivalents amount of €2.58 million (2022: €18.87 million).

2024 Financial Calendar

23 April 2024	Online publication of Annual Report 2023
23 May 2024	Annual General Meeting 2024

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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. This causes major medical issues including increased mortality, repeated hospitalizations, severe pain, difficulty breathing and restricted mobility. Although diuretics are standard of care, they become ineffective, untolerable or exacerbate the problem in many patients. There are limited effective treatment options, 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. **alfa**pump® 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's Premarket Approval (PMA) application for the **alfa**pump was submitted to the US FDA in December 2023 and accepted for substantive review in January 2024, having reported positive primary and secondary endpoint data from the North American pivotal POSEIDON study in recurrent or refractory ascites due to liver cirrhosis.

Results of the Company's RED DESERT and SAHARA proof-of-concept studies in heart failure support DSR's mechanism of action as breaking the vicious cycle of cardiorenal syndrome. All three patients from the non-randomized cohort of MOJAVE, a US randomized controlled multi-center Phase 1/2a clinical study, have been

successfully treated with DSR, resulting in a dramatic improvement in diuretic response and virtual elimination of loop diuretic requirements. The independent Data Safety Monitoring Board approved the start of the randomized MOJAVE cohort of up to a further 30 patients, which is planned after **alfa**pump US PMA approval.

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 financial statements have been prepared in accordance with IFRS, as adopted by the EU. The financial information included in this press release is an extract from the full IFRS consolidated financial statements which will be published on 23 April 2024.

As of the date of this press release, the statutory auditor, PricewaterhouseCoopers Bedrijfsrevisoren BV, with registered office at Culliganlaan 5, 1831 Machelen, Belgium, represented by Peter D'hondt, auditor, has not yet completed his audit procedures on the IFRS consolidated statements as of and for the year ended 31 December 2023.

The statutory auditor has confirmed that the audit, which is substantially complete, has not to date revealed any material misstatement in the draft consolidated accounts, and that the accounting data reported in the press release is consistent, in all material respects, with the draft consolidated accounts from which it has been derived.

Consolidated statement of profit and loss

in Thousand Euros (if not stated otherwise)	Year ended 31 December	
	2023	2022
Revenue	**712**	**923**
Cost of goods sold	(164)	(205)
Gross margin	**548**	**718**
Sales & Marketing	(1,799)	(2,240)
Clinical	(6,947)	(9,773)
Quality & Regulatory	(5,586)	(3,632)
Supply Chain	(4,724)	(3,158)
Engineering	(4,041)	(3,853)
General & Administration	(6,943)	(6,687)
Total operating expenses	**(30,040)**	**(29,343)**
Other income	629	530
Earnings before interests and taxes (EBIT)	**(28,862)**	**(28,094)**
Finance income	1,052	451
Finance cost	(4,288)	(2,733)
Total net finance expense	**(3,236)**	**(2,282)**
Income tax expense	(466)	(387)
Net loss for the period	**(32,564)**	**(30,763)**
Basic losses per share (in Euro)	**(1.22)**	**(1.35)**

Consolidated statement of comprehensive income

in Thousand Euros (if not stated otherwise)	Year ended 31 December	
	2023	2022
Net loss for the period	**(32,564)**	**(30,763)**
Components of other comprehensive income (OCI) items that will not be reclassified to profit or loss:		
Remeasurements of defined benefit plans	(356)	413
Items that may be reclassified subsequently to profit or loss:		
Currency translation adjustments	(64)	727
Total other comprehensive income/(loss)-net of tax	**(420)**	**1,140**
Total comprehensive income	**(32,984)**	**(29,623)**
Attributable to Sequana Medical shareholders	(32,984)	(29,623)

Consolidated balance sheet

in Thousand Euros (if not stated otherwise)	As at 31 December	
	2023	2022
ASSETS		
Property, plant and equipment	2,316	2,068
Financial Assets	100	86
Other non-current assets	1,388	782
Total non-current assets	**3,805**	**2,936**
Trade receivables	43	114
Other receivables and prepaid expenses	1,373	1,479
Inventory	2,296	2,621
Cash and cash equivalents	2,584	18,875
Total current assets	**6,296**	**23,089**
Total assets	**10,101**	**26,025**
EQUITY AND LIABILITIES		
Share capital	2,926	2,460
Share premium	185,644	170,324
Reserves	(2,896)	(2,426)
Loss brought forward	(206,022)	(173,458)
Cumulative translation adjustment	882	946
Total equity	**(19,465)**	**(2,153)**
Long term financial debts	8,969	12,193
Long term lease debts	464	609
Retirement benefit obligation	668	228
Total non-current liabilities	**10,101**	**13,030**
Short term financial debts	7,818	4,483
Short term lease debts	269	307
Other current financial liabilities	2,767	1,569
Trade payables and contract liabilities	2,907	3,392
Other payables	2,257	1,812
Accrued liabilities and provisions	3,448	3,586
Total current liabilities	**19,466**	**15,148**
Total equity and liabilities	**10,101**	**26,025**

Consolidated statement of cash flows

in Thousand Euros (if not stated otherwise)	Year ended 31 December	
	2023	2022
Net loss for the period	**(32,564)**	**(30,763)**
Income tax expense	466	387
Financial result	3,271	1,923
Depreciation	661	312
Change in defined benefit plan	(50)	(102)
Share-based compensation	564	564
Changes in trade and other receivables	(543)	(457)
Changes in inventories	483	42
Changes in trade and other payables/provisions	(905)	990
Taxes paid	(446)	(378)
Cash flow used in operating activities	**(29,063)**	**(27,482)**
Investments in tangible fixed assets	(711)	(677)
Investments in financial assets	(11)	24
Cash flow used in investing activities	**(721)**	**(653)**
Proceeds from capital increase	15,786	28,420
(Repayments) from leasing debts	(414)	(407)
(Repayments) from financial debts	(982)	-
Proceeds from financial debts	-	9,626
Interest paid	(929)	(315)
Cash flow from financing activities	**13,461**	**37,324**
Net change in cash and cash equivalents	**(16,324)**	**9,189**
Cash and cash equivalents at the beginning of the period	**18,875**	**9,600**
Net effect of currency translation on cash and cash equivalents	33	85
Cash and cash equivalents at the end of the period	**2,584**	**18,875**

Consolidated statement of changes in equity

in Thousand Euros (if not stated otherwise)	Share capital	Share premium	Reserves	Loss brought forward	Currency translation differences	Total shareholder equity
Balance at 1 January 2022	**1,925**	**142,433**	**(2,669)**	**(142,695)**	**220**	**(787)**
Net loss for the period				(30,763)		(30,763)
Other comprehensive income			413		727	1,140
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			564			564
Balance at 31 December 2022	**2,460**	**170,324**	**(2,426)**	**(173,458)**	**946**	**(2,153)**
Balance at 1 January 2023	**2,460**	**170,324**	**(2,426)**	**(173,458)**	**946**	**(2,153)**
Net loss for the period				(32,564)		(32,564)
Other comprehensive income			(356)		(64)	(420)
April 2023 Equity Placement	461	15,320				15,780
Capital increase 10/23	5	0				6
Transaction costs for equity instruments			(678)			(678)
Share-based compensation			564			564
Balance at 31 December 2023	**2,926**	**185,644**	**(2,896)**	**(206,022)**	**882**	**(19,465)**