PRESS RELEASE
REGULATED INFORMATION – INSIDE INFORMATION
30 September 2024, 24:00 CEST

Sequana Medical announces H1 2024 results and provides business update

- ***alfapump® - US FDA approval anticipated Q1 2025 and US launch planned for H2 2025; Strong progress with US reimbursement - CPT III codes issued & NTAP Application filed***
- ***DSR® – Publication of RED DESERT and SAHARA data in peer-reviewed "European Journal of Heart Failure" highlights potential as treatment for Cardiorenal Syndrome; Positive data from non-randomized cohort in US MOJAVE study and DSMB approval to start randomized phase***
- ***Total liquidity position of EUR 4.2m as per 30 June 2024***
- ***Shareholder financing of up to EUR 6.1m announced today extends runway towards planned alfapump FDA approval; exploring direct financing into each of alfapump® and DSR® businesses***

Ghent, Belgium – 30 September 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 business highlights and financial results for the six-month period ending 30 June 2024 and its outlook for the remainder of the year.

Ian Crosbie, Chief Executive Officer at Sequana Medical, commented*: "This is an exciting time for Sequana Medical as we prepare for launch of the alfapump in the United States. We are very pleased with our positive interactions with the FDA and look forward to finalising the remaining topics over the coming months. Regular meetings with US hepatologists have reaffirmed our belief in the clear demand for improved treatment options for this large patient universe driven by NASH / MASH and alcoholic liver disease – we estimate the North American alfapump market at $2.4 billion in 2025, growing at 9% per year. We are making good progress with our US reimbursement preparations with the receipt of CPT III codes and the filing of our application for the NTAP program. With these reimbursement steps in place, we are confident that our direct commercialisation strategy through a small specialty team will enable a successful launch through liver transplant centers, where 90 hospitals cover more than 95% of the US market.*

For our DSR heart failure program, we were delighted to see the publication of the RED DESERT and SAHARA data in the prestigious peer-reviewed European Journal of Heart Failure, and presented at the leading international heart failure conference THT 2024 DSR as a potential treatment for cardiorenal syndrome. Following the positive DSMB decision as well as the strong data from the first patients in MOJAVE, we look forward to commencing the randomized cohort of this US Phase 1/2a study once funding is available.

*Despite challenging market conditions, we were able to secure €14.5m of financing in the first half of the year and today announced additional support of up to €6.1m from our existing investors. We continue to explore all financing options for the company, including direct investments into each of the **alfa**pump® and DSR® activities which we anticipate to expand the universe of potential investors and therefore benefit all Sequana Medical shareholders."*

Highlights from H1 2024 to date

US alfapump liver program

- US Commercial:
    - Submission of Premarket Approval (PMA): The PMA application for the alfapump system was accepted for substantive review on 29 January 2024. Following a review of this application by the FDA, the Company received a "Day 90" major deficiency letter and a "Day 100" meeting was held with the FDA to align on key findings. The FDA confirmed completion of the substantive review and no further new questions on the clinical study or the pre-clinical data, unless related to the Company's response to the "Day 90" Letter. The FDA had a number of non-clinical questions that required additional work and the Company will submit this additional information today and continues to plan for approval before the end of Q1 2025.
    - US Reimbursement – CPT III: In January 2024, the American Medical Association (AMA) approved the issuance of six new Category III Current Procedural Terminology (CPT III) codes for the **alfa**pump system. This is a key step in facilitating reimbursement and the US commercialization strategy, augmenting the existing ICD-10 procedure codes. Upon FDA approval, this will allow healthcare institutions to submit claims for the **alfa**pump system, paving the way for broader adoption and supporting commercial rollout in the US.
    - US Reimbursement – NTAP: The Company has submitted the application for the US NTAP (new technology add-on payment) program. CMS established this program to ensure that Medicare beneficiaries have access to emerging technologies, recognizing that the cost of such new technologies often exceeds the existing payments under the relevant DRGs (diagnostics related groups). The Company believes that it meets all criteria for NTAP given alfapump's FDA breakthrough device designation and the anticipated device cost of $30,000.
- Posters and presentations:
    - Presentation at the EASL Congress 2024[1] of data from the North American pivotal POSEIDON study of the **alfa**pump®, announced 6 June 2024. The data demonstrated similar safety outcomes but significantly improved quality of life compared to baseline, which is not seen in refractory ascites patients enrolled contemporaneously in the prospective NACSELD3 (North American Consortium for Study of End-Stage Liver Disease) cohort.

DSR heart failure program

- MOJAVE – US randomized controlled Phase 1/2a study of DSR 2.0 for treatment of congestive heart failure

[1] Europe's largest event in this domain.

- Approval to commence randomised phase: The independent Data and Safety Monitoring Board (DSMB) approved the start of the randomized cohort in MOJAVE, following review of the safety data reported from the non-randomized cohort, announced in January 2024.
- Study results from non-randomised cohort: On 25 March 2024, the three-month follow-up data from all three patients in the non-randomized cohort of MOJAVE were announced, confirming the dramatic and durable improvement in their diuretic response and virtual elimination of loop diuretic requirements. These final data support DSR's mechanism of action as breaking the vicious cycle of cardiorenal syndrome.

- Posters and presentations:
  - On 28 February 2024, presentation at the THT 2024 conference[2], a leading international heart failure conference, of a late-breaking abstract including data from the RED DESERT and SAHARA proof-of-concept studies of the Company's DSR therapy in patients with diuretic-resistant heart failure.
  - On 3 April 2024, the Company announced publication of the results from two proof-of-concept studies, RED DESERT and SAHARA, in the prestigious peer-reviewed journal *European Journal of Heart Failure*. This publication highlights the potential for DSR as a novel treatment for diuretic resistance and cardiorenal syndrome in heart failure.

Corporate

- Financing
  - February Shareholder Financing: On 8 February 2024, announcement of the granting of an unsecured subordinated convertible loan of EUR 3.0 million by two major shareholders, Partners in Equity and Rosetta Capital , and the agreement from its lenders to defer the debt service payments, alongside the decision of the board of directors to prioritize its resources towards US FDA PMA approval of the **alfa**pump as a key value inflection point for the Company.
  - March Equity Financing: On 21 March 2024, announcement of a successful equity raise of EUR 11.5 million in gross proceeds by means of a private placement allowing continuing towards FDA PMA approval of the **alfa**pump, preparing its US commercial launch, implementing CMC activities for DSR 2.0[3], as well as extending the cash runway of the Company to the end of Q3 2024.
  - September Shareholder Financing: Today, the Company announced the strong support of up to €6.1m from existing shareholders, with an initial tranche of €3.05m (with the second tranche at the discretion of each lender). The Company is exploring the possibility to expand this financing through including additional experienced investors. The announced financing extends the cash runway into Q1 2025 if the full €6.1m is received.
  - Exploring direct financing into each of the alfapump and DSR programs: As a result of the success of the DSR development program and the data from the RED DESERT and SAHARA

2 Technology and Heart failure Therapeutics conference held in March 2024 in Boston, US
3 Including a Quality Management System and preparations to start the randomized phase of the US MOJAVE study post- **alfa**pump PMA approval

studies demonstrating the durability of the treatment effect, it was decided to pursue development of the DSR program without the alfapump. As a result, there is little synergy between the DSR and alfapump programs. Furthermore, based on feedback from potential investors, the Company is exploring how to enable investments into each of the DSR drug and the alfapump device programs separately which may expand the pool of potential investors and enable more effective financing of the Company's business. The Company believes that such an approach may be beneficial to Sequana Medical investors through expanding the pool of potential experienced investors, while retaining the ability to invest in Sequana Medical through the EuroNext Brussels listing.

Outlook for the remainder of 2024

- North American **alfa**pump liver program – on track for US commercial launch in H2 2025
  - Working with the FDA to complete PMA review – the Company's responses to the outstanding points raised by the FDA in the Day 90 letter will be submitted today
  - US commercial launch planned in H2 2025 – ongoing engagement with target launch centers, and further preparations for reimbursement and market entry

- DSR heart failure program – start of MOJAVE randomized cohort is approved by the independent DSMB, and subject to additional fundraising.

Financial review – Six months ended 30 June 2024

in Thousand Euros	HY 2024	HY 2023	Variance
Revenue	**106**	**384**	**-73%**
Cost of goods sold	(26)	(88)	-71%
Gross margin	**79**	**296**	**-73%**
Sales & Marketing	(370)	(1,100)	-66%
Clinical	(1,628)	(3,714)	-56%
Quality & Regulatory	(1,771)	(3,186)	-44%
Supply Chain	(1,626)	(2,372)	-31%
Engineering	(982)	(2,095)	-53%
General & Administration	(3,438)	(3,455)	0%
Total operating expenses	**(9,816)**	**(15,922)**	**-38%**
Other income	142	210	-32%
Earnings before interest and taxes (EBIT)[4]	**(9,595)**	**(15,417)**	**-38%**
Finance income	3,172	1,316	141%
Finance cost	(4,512)	(2,108)	114%
Total net finance cost	**(1,340)**	**(792)**	**69%**
Income tax expense	(146)	(255)	-43%
Net loss for the period	**(11,080)**	**(16,464)**	**-33%**
Basic Loss Per Share	**(0.34)**	**(0.65)**	**-47%**
Cash position* at 30 June	**4,153**	**17,122**	**N.M**

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 €0.38 million in H1 2023 to €0.11 million in H1 2024 due to the decision to terminate European commercial activities in Q1 2024.

Cost of goods sold

Cost of goods sold decreased from €0.09 million in H1 2023 to €0.03 million in H1 2024 in line with the decrease in revenue.

Operating expenses

Total operating expenses decreased from €15.92 million in H1 2023 to €9.82 million in H1 2024 due to the higher expenses in 2023 related to preparations of the submission for marketing approval of the **alfa**pump in the US and the measures taken to substantially reduce the cash burn in 2024.

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

Sales and Marketing expenses decreased from €1.10 million in H1 2023 to €0.37 million in H1 2024 due to the decision to terminate European commercial activities in Q1 2024.

Clinical expenses decreased from €3.71 million in H1 2023 to €1.63 million in H1 2024, mainly as a result of lower costs related to the North American pivotal POSEIDON study of the **alfa**pump and the decision to pause the start of the randomized phase of the MOJAVE study in the US.

Quality and Regulatory expenses decreased from €3.19 million in H1 2023 to €1.77 million in H1 2024, mainly due to the higher expenses in 2023 for external advice solicited for the preparation of the submissions for marketing approval of the **alfa**pump in the US.

Supply chain expenses decreased from €2.37 million in H1 2023 to €1.63 million in H1 2024, largely driven by the measures taken to reduce the cash burn in 2024 and higher spend in 2023 for additional staffing and external advice for the preparation of the submissions for marketing approval of the **alfa**pump in the US.

Engineering expenses decreased from €2.10 million in H1 2023 to €0.98 million in H1 2024, largely driven by the measures taken to reduce the cash burn in 2024 and the one off costs for test samples in 2023 required for the preparation of the submissions for marketing approval of the **alfa**pump in the US.

General and Administration expenses remained stable at €3.45 million in H1 2023 and €3.44 million in H1 2024.

Other income decreased from €0.21 million in H1 2023 to €0.14 million in H1 2024 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 €15.42 million in H1 2023 to a loss of €9.59 million in H1 2024.

Total net finance cost

Net finance cost increased from €0.79 million in H1 2023 to €1.34 million in H1 2024, mainly resulting from the impact of the valuation of the warrants and the February 2024 loan amendments. All of these items are non-cash items.

Income tax expense

Income tax expense decreased from €0.26 million in H1 2023 to €0.15 million in H1 2024 as a result of the lower activities in Switzerland.

Net loss for the period

As a result of the above, the net loss decreased from €16.46 million in H1 2023 to €11.08 million in H1 2024.

Basic losses per share (LPS)

Basic losses per share decreased from €0.65 in H1 2023 to €0.34 in H1 2024.

Condensed Consolidated Statement of Financial Position

Net debt

Net debt[5] at 30 June 2024 increased by €3.24 million compared to 31 December 2023, mainly as a result of the Convertible Loan provided by major shareholders (€3.00 million).

Working Capital

Working capital[6] at 30 June 2024 dropped €2.64 million compared to 31 December 2023.

Condensed Consolidated Statement of Cash Flows

Net cash outflow from operating activities was €12.36 million in H1 2024 compared to €16.36 million in H1 2023. The lower outflow was mainly driven by lower net loss of the period, partially offset by higher working capital needs.

Cash flow from investing activities resulted in a net outflow of €0.03 million in H1 2024, compared to a net outflow of €0.08 million in H1 2023.

Cash flow from financing activities resulted in a net inflow of €13.96 million in H1 2024, mainly as a result of the proceeds from the March 2024 equity placement and the Convertible Loan provided by major shareholders (€3.00 million) in February 2024. In H1 2023, the net inflow of €14.72 million was mainly a result of the April 2023 equity placement.

The Company ended H1 2024 with a total liquidity position of €4.15 million (end 2023: €2.58 million).

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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, intolerable or exacerbate the problem in many patients. There

[5] Net debt is calculated by adding short-term, long-term financial and lease debt and deducting cash and cash equivalents.
[6] 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.

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. 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's Premarket Approval (PMA) application for the alfapump 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. US market approval of the alfapump is anticipated before the end of Q1 2025 with US commercial launch planned for H2 2025.

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 alfapump US PMA approval.

Sequana Medical is listed on the regulated market of 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 alfapump 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 alfapump 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 2024 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	
	2024	2023
Revenue	**106**	**384**
Cost of goods sold	(26)	(88)
Gross margin	**79**	**296**
Sales & Marketing	(370)	(1,100)
Clinical	(1,628)	(3,714)
Quality & Regulatory	(1,771)	(3,186)
Supply Chain	(1,626)	(2,372)
Engineering	(982)	(2,095)
General & Administration	(3,438)	(3,455)
Total operating expenses	**(9,816)**	**(15,922)**
Other income	142	210
Earnings before interests and taxes (EBIT)	**(9,595)**	**(15,417)**
Finance income	3,172	1,316
Finance cost	(4,512)	(2,108)
Total net finance cost	**(1,340)**	**(792)**
Income tax expense	(146)	(255)
Net loss for the period	**(11,080)**	**(16,464)**
Basic losses per share (in Euro)	**(0.34)**	**(0.65)**

Condensed Consolidated Statement of Comprehensive Income

in Thousand Euros (if not stated otherwise)	Half Year ended 30 June	
	2024	2023
Net loss for the period	**(11,080)**	**(16,464)**
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	14	95
Total other comprehensive income/(loss)-net of tax	**14**	**95**
Total comprehensive income	**(11,066)**	**(16,368)**
Attributable to Sequana Medical shareholders	(11,066)	(16,368)

Condensed Consolidated Statement of Financial Position

in Thousand Euros	As at period ended	
	30 June 2024	31 December 2023
ASSETS		
Property, plant and equipment	1,991	2,317
Financial Assets	98	100
Other non-current assets	1,552	1,388
Total non-current assets	**3,641**	**3,805**
Trade receivables	-	43
Other receivables and prepaid expenses	959	1,373
Inventory	2,036	2,296
Cash and cash equivalents	4,153	2,584
Total current assets	**7,148**	**6,296**
Total assets	**10,789**	**10,101**
EQUITY AND LIABILITIES		
Share capital	3,721	2,926
Share premium	196,350	185,644
Reserves	(3,399)	(2,896)
Loss brought forward	(217,102)	(206,022)
Cumulative translation adjustment	868	882
Total equity	**(19,561)**	**(19,465)**
Long term financial debts	11,869	8,969
Long term lease debts	386	464
Retirement benefit obligation	642	668
Total non-current liabilities	**12,897**	**10,101**
Short term financial debts	9,903	7,818
Short term lease debts	175	269
Other current financial liabilities	2,120	2,767
Trade payables and contract liabilities	1,986	2,907
Other payables	1,060	2,257
Accrued liabilities and provisions	2,209	3,448
Total current liabilities	**17,454**	**19,466**
Total equity and liabilities	**10,789**	**10,101**

Condensed Consolidated Statement of Cash Flows

in Thousand Euros	Half Year ended 30 June	
	2024	2023
Net loss for the period	**(11,080)**	**(16,464)**
Income tax expense	146	255
Financial result	1,310	67
Depreciation	141	144
Change in defined benefit plan	(0)	156
Share-based compensation	(109)	(0)
Changes in trade and other receivables	294	(407)
Changes in inventories	143	(156)
Changes in trade and other payables/provisions	(3,044)	173
Taxes paid	(155)	(130)
Cash flow used in operating activities	**(12,355)**	**(16,362)**
Investments in tangible fixed assets	(29)	(81)
Investments in financial assets	-	-
Cash flow used in investing activities	**(29)**	**(81)**
Proceeds from capital increase	11,500	15,780
(Repayments)/Proceeds from leasing debts	(233)	(222)
(Repayments)/Proceeds from financial debts	2,884	(522)
Interest paid	(188)	(318)
Cash flow from financing activities	**13,962**	**14,718**
Net change in cash and cash equivalents	**1,578**	**(1,725)**
Cash and cash equivalents at the beginning of the period	**2,584**	**18,875**
Net effect of currency translation on cash and cash equivalents	(9)	(28)
Cash and cash equivalents at the end of the period	**4,153**	**17,122**

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 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)**
Balance at 1 January 2024	**2,926**	**185,644**	**(2,896)**	**(206,022)**	**882**	**(19,465)**
Net loss for the period				(11,080)		(11,080)
Other comprehensive income					(14)	(14)
March 2024 Equity Placement	794	10,706				11,500
Transaction costs for equity instruments			(393)			(393)
Share-based compensation			(109)			(109)
Balance at 30 June 2024	**3,721**	**196,350**	**(3,399)**	**(217,102)**	**868**	**(19,561)**