PRESS RELEASE
REGULATED INFORMATION – INSIDE INFORMATION
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Sequana Medical announces H1 2025 results and provides business update

- ***alfapump® US commercialisation underway; Strengthened US reimbursement with CMS approval of NTAP "top-up" reimbursement;***
- ***On track for at least 70 US commercial alfapump implants during "Soft Launch" – "Full Launch" on track for Q2 2026***
- ***Debt reduction of EUR 2 million through partial conversion of Kreos loan and 2025 convertible loan***
- ***Total liquidity position of EUR 7.3 million as per 30 June 2025***

Ghent, Belgium – 25 September 2025 – 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, announces today its business highlights and financial results for the six-month period ending 30 June 2025 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 with the commencement of **alfa**pump commercialisation in the United States. We have put in place the US infrastructure to support this launch, including a team of ten focused on this key activity for Sequana Medical. We are delighted with the strong interest among the US clinical and patient community for the **alfa**pump as a breakthrough in the treatment of a condition that has been overlooked for far too long. Reimbursement is a key aspect of our commercialisation plans, and we are delighted to have received approval for the NTAP "top-up" reimbursement of up to $21,450 from CMS.*

Our team is working intensively with the target sites to complete necessary approvals and contracting to enable US commercial implants to take place. We are in advanced discussions with multiple highly regarded sites and anticipate first implants early in the fourth quarter. We remain confident of our goals for both the Soft Launch and Full Launch phases.

*Despite challenging market conditions, we were able to secure €13.6m of financing in the first half of the year and anticipate this, together with the anticipated proceeds from the GEM share subscription facility will extend our financing runway to at least the first quarter of 2026. 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 2025 to date

US alfapump liver program

- US Commercial:
    - US Commercialisation Underway: Following the PMA approval of the **alfa**pump in late December 2024, the Company made the necessary preparations for US commercialization that commenced during Q3. Formal transfer to manufacturing was completed and the **alfa**pump systems for the Soft Launch have been manufactured. The initial US team of seven individuals has been recruited and they are supported by three further European team members dedicated to the US. The Company is very pleased with the strong interest from US clinicians for **alfa**pump as a new treatment option for their patients and discussions are underway with more than ten US hospitals to complete the necessary approvals and contracting to commence **alfa**pump implants. Seven hospitals have completed **alfa**pump training for hepatologists, interventional radiologists and their teams. Awareness is spreading among both the hepatology and interventional radiology communities in the US and the **alfa**pump has been or will be imminently profiled in three podium presentations at clinical conferences.
    - US Reimbursement – NTAP: In August 2025 CMS (the Centers for Medicare and Medicaid Services), published the Final Rule for Fiscal Year 2026 Hospital Inpatient Prospective Payment System (IPPS), approving a NTAP (new technology add-on payment) for the **alfa**pump system when performed in the hospital inpatient setting. The NTAP will be in effect from October 1, 2025 and provides "top-up" reimbursement of up to $21,450, in addition to the hospital's Medicare Severity Diagnosis Related Group (MS-DRG) payment.
    - The Company forecasts completing at least 70 US commercial implants in eight hospitals during the "Soft Launch" (up to the end of Q1 2026), prior to commencing the "Full Launch" with approximately five additional centers opening per quarter starting Q2 2026.
- Publications & Presentations:
    - January 2025 – Publication of "The Effects of **alfa**pump on Ascites Control and Quality of Life in Patients with Cirrhosis and Recurrent or Refractory Ascites" in the prestigious peer-reviewed journal, *American Journal of Gastroenterology*. The publication covered the six month data for the forty implanted patients in the pivotal cohort of the POSEIDON study, the multicenter, open-label, single arm study with a within-subject crossover design conducted in patients with cirrhosis and recurrent or refractory ascites. The authors reported that the **alfa**pump system effectively controlled ascites, which improved quality of life[1,2]. Results from the literature

[1] as defined by subjective physical health (assessed by SF-36 PCS) and ascites symptoms (assessed by Ascites Q)
[2] Data on file; statements from "The Effects of **alfa**pump on Ascites Control and Quality of Life in Patients with Cirrhosis and Recurrent or Refractory Ascites" A*merican Journal of Gastroenterology [January 2025]*

indicate that the overall survival of patients with the **alfa**pump was higher than reported for standard of care (LVP)[3].

- January 2025 – The Company hosted a Key Opinion Leader (KOL) Webinar to discuss **alfa**pump US Commercial Roll-Out following FDA approval of the **alfa**pump system. Sequana Medical management, together with Dr Saab, Professor of Medicine and Surgery, David Geffen School of Medicine, UCLA and Dr Pagadala, Transplant Hepatologist, Methodist Dallas Medical Center, discussed i) the clinical need in recurrent and refractory ascites due to liver cirrhosis, including current treatment options, ii) the results of the **alfa**pump POSEIDON and Patient Preference studies, and what this means for US patients and physicians, and iii) **alfa**pump US commercial roll-out plans and market opportunity.
- July 2025 – Publication of "Using the **alfa**pump to control ascites enabling elective umbilical hernia repair: A case report" in the prestigious peer-reviewed journal, *Hernia*. The case study presented a patient from the POSEIDON study that received an **alfa**pump for control of his ascites and subsequently underwent a robotic repair of his umbilical hernia.

Corporate

- Financing
  - Conversion outstanding indebtedness into equity. In January 2025, the Company announced the conversion of EUR 0.53 million under the Sensinnovat 2020 loan, EUR 1.28 million under the 2024 convertible loan with various shareholders, and EUR 2.68 million under the Kreos 2022 loan into equity, reducing net debt by EUR 4.50 million. Today, the Company announced a further EUR 2.0 million reduction of net debt through the conversion into equity of EUR 1.8 million of the Kreos 2022 loan and EUR 0.2 million of the 2025 Convertible Loan.
  - EUR 4.0 million convertible loan investment and GEM Committed Share Subscription Facility of up to EUR 60 million. In March 2025, the Company announced a financing package comprising i) the granting of an unsecured subordinated convertible loan of EUR 4.0 million by certain of its major shareholders, namely Partners in Equity V B.V. and EQT Health Economics 3 Coöperatief U.A. and ii) entering into a share subscription facility agreement with GEM Global Yield LLC SCS ("**GEM**"), a $3.4 billion, Luxembourg based alternative investment group with offices in Paris, New York and Bahamas. Pursuant to the Facility, GEM agreed to commit, subject to certain conditions, an amount of up to EUR 20 million in cash (with Sequana Medical's option to increase the commitment to up to EUR 60 million in cash, once the aforementioned EUR 20 million has been drawn down) (the "**Capital Commitment**"), within a maximum term of three years in exchange for new ordinary shares in Sequana Medical and subject to certain share lending arrangements being in place. In addition, the Company agreed with its existing debt providers to restructure several features of the Company's debt, subject

[3] a) Tan HK, James PD, Wong F. Albumin may prevent the morbidity of paracentesis-induced circulatory dysfunction in cirrhosis and refractory ascites: A pilot study. Dig Dis Sci 2016;61:3084-3092; b) Salerno F, Cammà C, Enea M, Rössle M, Wong F. Transjugular intrahepatic portosystemic shunt for refractory ascites: a meta-analysis of individual patient data. Gastroenterology 2007;133:825-834.

to certain conditions. The Company subsequently made subscription requests under the Subscription Share Facility in May, August and September 2025.

- Additional EUR 6.3 million convertible loan financing. In May 2025, the Company announced that SFPIM (previously known as SFPI-FPIM) and other existing shareholders had invested a further EUR 6.3 million in the 2025 Convertible Loan announced on 18th March 2025.

Outlook for the remainder of 2025

- US **alfa**pump liver program – US Commercialisation on Track
  - As a result of the extensive discussions with target centers, the Company anticipates significant US commercial implants in several top tier US hospitals.
  - The Company forecasts completion of at least 70 commercial implants at up to eight centers in the US before the end of Q1 2026, following which the "Full Launch" is planned to commence with the addition of approximately five new centers per quarter.

- DSR heart failure program
  - The Company continues to explore financing of DSR either as part of the Company or as a separate entity. The start of MOJAVE randomized cohort is approved by the independent DSMB, and subject to additional fundraising.

Financial review – Six months ended 30 June 2025

in Thousand Euros	HY 2025	HY 2024	Variance
Revenue	**-**	**106**	**-100%**
Cost of goods sold	-	(26)	-96%
Gross margin	**-**	**79**	**-101%**
Sales & Marketing	(709)	(370)	91%
Clinical	(541)	(1,628)	-67%
Quality & Regulatory	(1,188)	(1,771)	-33%
Supply Chain	(1,927)	(1,626)	18%
Engineering	(784)	(982)	-20%
General & Administration	(3,817)	(3,438)	11%
Total operating expenses	**(8,966)**	**(9,816)**	**-9%**
Other income	383	142	N.M
Earnings before interest and taxes (EBIT)[4]	**(8,582)**	**(9,595)**	**-11%**
Finance income	3,193	3,172	1%
Finance cost	(12,763)	(4,512)	183%
Total net finance cost	**(9,570)**	**(1,340)**	**N.M.**
Income tax expense	(126)	(146)	-13%
Net loss for the period	**(18,278)**	**(11,080)**	**65%**
Basic Loss Per Share	**(0.35)**	**(0.34)**	**2%**
Cash position* at 30 June	**7,314**	**4,153**	**76%**

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 €0.11 million in H1 2024 to €0.00 million in H1 2025 due to the decision to terminate European commercial activities in Q1 2024 .

Cost of goods sold

Cost of goods sold decreased from €0.03 million in H1 2024 to €0.00 million in H1 2025 in line with the decrease in revenue.

Operating expenses

Total operating expenses decreased from €9.82 million in H1 2024 to €8.97 million in H1 2025 due to the measures taken to substantially reduce the cash burn.

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

Sales and Marketing expenses increased from €0.37 million in H1 2024 to €0.71 million in H1 2025 due to the preparation for the US **alfa**pump commercial launch.

Clinical expenses decreased from €1.63 million in H1 2024 to €0.54 million in H1 2025, mainly as a result of lower costs related to the North American pivotal POSEIDON study of the **alfa**pump and the decision to postpone the start of the randomized phase of the MOJAVE DSR study in the US.

Quality and Regulatory expenses decreased from €1.77 million in H1 2024 to €1.19 million in H1 2025, mainly due to the lower expenses in 2025 following the successful completion of the submission for marketing approval of the **alfa**pump in the US and the measures taken to reduce the cash burn.

Supply chain expenses increased from €1.63 million in H1 2024 to €1.93 million in H1 2025, largely driven by the preparation for the US **alfa**pump commercial launch.

Engineering expenses decreased from €0.98 million in H1 2024 to €0.78 million in H1 2025, largely driven by the measures taken to reduce the cash burn.

General and Administration expenses remained broadly stable at €3.44 million in H1 2024 versus €3.82 million in H1 2025.

Other income increased from €0.14 million in H1 2024 to €0.38 million in H1 2025 and includes recognized income from Belgian Research & Development (R&D) incentives with regard to incurred R&D expenses and the capitalization effect of 2025 Development costs following the application of IFRS IAS 38 para 57.

EBIT

As a result of the above, earnings before interest and taxes (EBIT) evolved from a loss of €9.59 million in H1 2024 to a loss of €8.58 million in H1 2025.

Total net finance cost

Net finance cost increased from €1.34 million in H1 2024 to €9.57 million in H1 2025, mainly resulting from the impact of the valuation of the warrants and the March 2025 loan amendments. All of these items are non-cash items.

Income tax expense

Income tax expense remained stable at €0.15 million in H1 2024 versus €0.13 million in H1 2025.

Net loss for the period

As a result of the above, the net loss increased from €11.08 million in H1 2024 to €18.28 million in H1 2025, of which the majority of the increase is due to the increase in non-cash net finance cost.

Basic losses per share (LPS)

Basic losses per share remained broadly stable at €0.34 in H1 2024 and €0.35 in H1 2025.

Condensed Consolidated Statement of Financial Position

Net debt

Net debt[5] at 30 June 2025 decreased by €2.2 million compared to 31 December 2024, mainly as a result of the improvement of the cash position.

Working Capital

Working capital[6] at 30 June 2025 dropped €1.83 million compared to 31 December 2024. The decrease is largely driven by measures taken to reduce cash burn.

Condensed Consolidated Statement of Cash Flows

Net cash outflow from operating activities was €9.72 million in H1 2025 compared to €12.36 million in H1 2024. The lower outflow was driven by the measures taken to further reduce the cash burn.

Cash flow from investing activities resulted in no outflow in H1 2025, compared to a net outflow of €0.03 million in H1 2024.

Cash flow from financing activities was €13.26 million in H1 2025, comprising the proceeds from the financing announced in March 2025, compared to €13.96 million in H1 2024, comprising the proceeds from the March 2024 equity placement and the Convertible Loan provided by major shareholders in February 2024.

The Company ended H1 2025 with a total liquidity position of €7.31 million (end 2024: €3.81 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 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

[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.

platforms that work with the body to treat diuretic-resistant fluid overload, and are intended to deliver major clinical and quality of life benefits for patients, while reducing costs for healthcare systems.

The Company received US FDA approval for the **alfa**pump System for the treatment of recurrent or refractory ascites due to liver cirrhosis in December 2024, following the grant of FDA Breakthrough Device Designation in 2019. Sequana Medical has commenced US commercialisation through its specialty commercial team that will target the 90 US liver transplant centers that perform more than 90% of liver transplants. In August 2025, CMS announced that it approved the New Technology Add-on Payment for the **alfa**pump when performed in the hospital inpatient setting as of October 1, 2025.

Results of the Company's RED DESERT and SAHARA proof-of-concept studies in heart failure published in European Journal of Heart Failure in April 2024 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[7]. The independent Data Safety Monitoring Board approved the start of the randomized MOJAVE cohort of up to a further 30 patients, which is dependent on securing additional financing.

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 Safety Information:

Indication for Use: The **alfa**pump® System is intended for single patient use only in adult patients with refractory or recurrent ascites due to liver cirrhosis. It is indicated for the removal of excess peritoneal fluid from the peritoneal cavity into the bladder, where it can be eliminated through normal urination.

Contraindications: MRI Safety Information: The **alfa**pump® System is MRI unsafe. This diagnostic procedure is contraindicated due to possible movement of the **alfa**pump®, damage to the pump circuitry, tissue damage in the vicinity of the **alfa**pump® and/or catheter dislocation. Hyperbaric oxygen therapy is contraindicated because the environmental conditions entailed in this therapy are out of the defined range of use for the **alfa**pump® System.

Warnings, Risks, and Precautions: The implantation of the **alfa**pump® may result in infection that could delay liver transplant or impact transplant listing status. Additional risks associated with implanting the **alfa**pump® System including risk of peritoneal cavity infections/peritonitis, Coagulopathy, Small bladder capacity and/or obstructive uropathy. The following procedures or therapies could impact the **alfa**pump® System function: Supersonic therapy and high-frequency heat therapy, Transcutaneous Electrical Nerve Stimulation (TENS), Lithotripsy, Defibrillation, Radiation therapy, Electrocautery, or use of other implantable medical devices and wearable devices.

Adverse Events: In addition to procedure related risks the following Adverse Events may occur: pump pocket hematoma, skin erosion, infection, pump migration, catheter clogging or other catheter complications resulting in tissue damage or loss of or change in therapy, genito-urinary complications, reduced kidney function, hepatic encephalopathy, progression of liver disease, and other systemic effects.

[7] Data reported in press release of March 25, 2024; mean increase of 326% in six-hour urinary sodium excretion at 3 months follow up vs baseline, and 95% reduction of loop diuretics over same period

Caution: the law restricts the sale by or on the order of a physician. Refer to package insert provided with the product for complete Instructions for Use, Contraindications, Potential Adverse Effects, Warnings and Precautions prior to using this product.

The **alfa**pump® System is currently not approved in Canada.

DSR® therapy is still in development and is currently not approved in any country. The safety and effectiveness of DSR® therapy has not been established.

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 2025 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	
	2025	2024
Revenue	**-**	**106**
Cost of goods sold	-	(26)
Gross margin	**-**	**79**
Sales & Marketing	(709)	(370)
Clinical	(541)	(1,628)
Quality & Regulatory	(1,188)	(1,771)
Supply Chain	(1,927)	(1,626)
Engineering	(784)	(982)
General & Administration	(3,817)	(3,438)
Total operating expenses	**(8,966)**	**(9,816)**
Other income	383	142
Earnings before interests and taxes (EBIT)	**(8,582)**	**(9,595)**
Finance income	3,193	3,172
Finance cost	(12,763)	(4,512)
Total net finance cost	**(9,570)**	**(1,340)**
Income tax expense	(126)	(146)
Net loss for the period	**(18,278)**	**(11,080)**
Basic losses per share (in Euro)	**(0.35)**	**(0.34)**

Condensed Consolidated Statement of Comprehensive Income

in Thousand Euros (if not stated otherwise)	Half Year ended 30 June	
	2025	2024
Net loss for the period	**(18,278)**	**(11,080)**
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	(62)	14
Total other comprehensive income/(loss)-net of tax	**(62)**	**14**
Total comprehensive income	**(18,341)**	**(11,066)**
Attributable to Sequana Medical shareholders	(18,341)	(11,066)

Condensed Consolidated Statement of Financial Position

in Thousand Euros	As at period ended	
	30 June 2025	31 December 2024
ASSETS		
R&D	264	-
Property, plant and equipment	1,866	1,774
Financial Assets	105	104
Other non-current assets	1,757	1,649
Total non-current assets	**3,992**	**3,527**
Trade receivables	-	-
Other receivables and prepaid expenses	816	563
Inventory	2,449	2,046
Cash and cash equivalents	7,314	3,807
Total current assets	**10,579**	**6,417**
Total assets	**14,571**	**9,944**
EQUITY AND LIABILITIES		
Share capital	5,927	4,604
Share premium	208,981	201,565
Reserves	13,960	(721)
Loss brought forward	(268,954)	(250,676)
Cumulative translation adjustment	911	849
Total equity	**(39,175)**	**(44,379)**
Long term financial debts	-	-
Long term lease debts	725	358
Retirement benefit obligation	864	754
Total non-current liabilities	**1,589**	**1,112**
Short term financial debts	40,426	39,698
Short term lease debts	251	55
Other current financial liabilities	6,586	7,387
Trade payables and contract liabilities	1,123	1,889
Other payables	1,682	1,693
Accrued liabilities and provisions	2,089	2,488
Total current liabilities	**52,156**	**53,211**
Total equity and liabilities	**14,571**	**9,944**

Condensed Consolidated Statement of Cash Flows

in Thousand Euros	Half Year ended 30 June	
	2025	2024
Net loss for the period	**(18,278)**	**(11,080)**
Income tax expense	126	146
Financial result	9,340	1,310
Depreciation	575	141
Change in defined benefit plan	104	(0)
Share-based compensation	257	(109)
Changes in trade and other receivables	(129)	294
Changes in inventories	(384)	143
Changes in trade and other payables/provisions	(981)	(3,044)
Taxes paid	(352)	(155)
Cash flow used in operating activities	**(9,723)**	**(12,355)**
Investments in tangible fixed assets	-	(29)
Investments in financial assets	-	-
Cash flow used in investing activities	**-**	**(29)**
Proceeds from capital increase	2,827	11,500
(Repayments)/Proceeds from leasing debts	(179)	(233)
(Repayments)/Proceeds from financial debts	10,820	2,884
Interest paid	(210)	(188)
Cash flow from financing activities	**13,258**	**13,962**
Net change in cash and cash equivalents	**3,535**	**1,578**
Cash and cash equivalents at the beginning of the period	**3,807**	**2,584**
Net effect of currency translation on cash and cash equivalents	(28)	(9)
Cash and cash equivalents at the end of the period	**7,314**	**4,153**

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 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)**
Balance at 1 January 2025	**4,604**	**201,565**	**(721)**	**(250,676)**	**849**	**(44,379)**
Net loss for the period				(18,278)		(18,278)
Other comprehensive income					62	62
Capital increase convertible loans to shares	955	4,558	14,141			19,654
Capital increase share subscription facility (contribution in kind)	47	353	283			683
Capital increase share subscription facility (cash)	321	2,506				2,827
Share-based compensation			257			257
Balance at 30 June 2025	**5,927**	**208,981**	**13,960**	**(268,954)**	**911**	**(39,175)**