

## Sequana Medical announces 2022 Full Year Results and 2023 Outlook

- **alfapump® – successful primary endpoint read-out of North American pivotal POSEIDON study / PMA<sup>1</sup> filing planned for H2 2023**
- **DSR® (Direct Sodium Removal) – clinical evidence of disease-modifying heart failure drug therapy, on track to start US Phase 1/2a MOJAVE study in Q2 2023**
- **Total cash position of €18.9 million at end 2022 and cash runway into mid-2023**

Conference call with [live webcast](#) today at 03:00 pm CEST / 09:00 am EST

Ghent, Belgium – 09 February 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 financial results for the year ended 31 December 2022, and provides a business update and outlook for 2023.

**Ian Crosbie, Chief Executive Officer of Sequana Medical, commented:** "2022 was a landmark year for Sequana Medical achieving excellent results in both our **alfapump** liver and DSR heart failure programs. All primary endpoints were met in POSEIDON, our pivotal North American **alfapump** study, allowing us to prepare for PMA filing and US commercial launch planned for 2024. We believe that there is a clear need for improved treatment options for the large and growing number of patients suffering from recurrent or refractory ascites due to liver cirrhosis. The North American market is forecast to grow between 6-7% annually reaching over 170,000 patients in 2035, representing a total addressable market for the **alfapump** of over US \$2.5bn<sup>2</sup>."

"Our DSR therapy demonstrated substantial long-lasting clinical benefits in decompensated heart failure patients. Top-line data from our SAHARA study showed the 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 are very excited by the great potential of DSR as a disease-modifying therapy that could help the estimated 200,000 US heart failure patients suffering from diuretic-resistant congestion. We have moved swiftly with our second-generation DSR product, successfully completing GLP pre-clinical safety studies, dosing the first patients in our Phase 1 single-dose studies and we are looking forward to starting MOJAVE, our US Phase 1/2a randomized controlled multi-center study in patients with congestive heart failure in Q2 2023."

"As we prepare for commercialization of the **alfapump** in North America, we have continued to strengthen our Board with the addition of Doug Kohrs and Alexandra Clyde, two seasoned US medtech executives who bring with them invaluable knowledge and expertise in light of the next stage of Sequana Medical's development."

"We are also pleased to welcome Rosetta Capital, an experienced long-term life sciences investor, as shareholders following the purchase of the shares held by Neomed V."

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<sup>1</sup> PMA: Pre-Market Approval

<sup>2</sup> Based on US and Canada market assessment conducted by highly experienced international consulting group, using claims analysis for commercial and CMS (Center for Medicare and Medicaid Services) patients requiring paracentesis procedure with liver disease diagnosis codes.

## 2022 highlights

### **alfapump in liver disease**

- POSEIDON – North American pivotal study of the **alfapump** in patients with recurrent or refractory ascites due to liver cirrhosis successfully met primary endpoint data:
  - Reported positive top-line results in [October 2022](#) from 40 patients of the Pivotal Cohort at six months post-implantation, including primary effectiveness endpoints substantially exceeding the predefined thresholds for study success and safety in line with expectations:
    - 100% median per-patient reduction in therapeutic paracentesis (TP) post- vs pre-implantation ( $p < 0.001$ ), vs hypothesis of at least 50% reduction.
    - 77% of patients with at least 50% reduction in number of TP post- vs pre-implantation ( $p < 0.001$ ), vs hypothesis of at least 50% of patients.
    - Six primary safety events of which three involved explants due to wound or skin erosion, and three explants due to patient-reported discomfort (all patient-reported discomfort events were adjudicated by the Clinical Events Committee as moderate severity), in line with expectations.
  - Reported results of a preliminary interim analysis<sup>3</sup> of patient survival from the Roll-In Cohort in [April 2022](#) including 70% survival rate at one year post-implantation, comparing favorably to published literature of 50% survival rate for refractory ascites patients after one year<sup>4</sup>.
  - Prof. Wong presented safety, efficacy and quality of life data from the Roll-In Cohort at the AASLD The Liver Meeting® in [November 2022](#).
- US patient preference study initiated:
  - Survey study to quantify patients' preferences for the **alfapump** including treatment effectiveness and risks of treatment-related adverse events. The results of this study are expected to be presented in H2 2023.
- European PMSR data published in Liver International<sup>5</sup>:
  - Final safety and efficacy results of the Post Marketing Surveillance Registry (PMSR) study of the **alfapump** published in [Liver International](#), the peer-reviewed publication of the International Association for the Study of the Liver.

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<sup>3</sup> Date of analysis 25 March 2022, as part of a general safety assessment

<sup>4</sup> Biggins et al., Hepatology, Vol. 74, No. 2, 2021, AASLD Practice Guidance; Moreau R et al., Liver International 2004: 24: 457-464

<sup>5</sup> Liver International promotes all aspects of the science of hepatology from basic research to applied clinical studies and provides an international forum for the publication of high quality original research in hepatology.

## DSR in heart failure

- SAHARA – Phase 2a study of DSR 1.0 in diuretic-resistant heart failure patients with persistent congestion showed important and long-lasting clinical benefits:
  - Reported positive top-line data from ten evaluable patients with its first-generation DSR product (DSR 1.0) in [November 2022](#), including i) safe, effective and rapid elimination of fluid overload and restoration of euvolemia, ii) improvement of cardiovascular and renal health, iii) restoration of the diuretic-response of the kidney, and iv) dramatic reduction in the need for oral loop diuretics up to 15 months post-therapy – demonstrating a durable improvement in the heart failure status of these patients.
- Strong clinical observations from RED DESERT and SAHARA studies in diuretic-resistant heart failure patients support heart failure disease-modifying profile of DSR therapy:
  - No heart failure congestion-related re-hospitalizations during study follow-up.
  - All patients improved their NYHA<sup>6</sup> status by at least one class.
  - Clinical benefits result in a 75% reduction in predicted one-year mortality pre- vs. post-intensive DSR therapy based on the Seattle Heart Failure Model<sup>7</sup>.
- Focus on Short Term DSR therapy with proprietary DSR 2.0:
  - Based on the results of RED DESERT and SAHARA, the Company expects that an intensive treatment period of three to four weeks of DSR therapy may deliver at least twelve months of important clinical benefits.
  - As a result of the strong, durable clinical signals observed, the Company will focus the heart failure development program on Short Term DSR with its proprietary second-generation DSR product (DSR 2.0) administered via a peritoneal catheter.
  - DSR 2.0 is expected to have an improved therapeutic and favorable safety profile with robust intellectual property protection.
- MOJAVE – US Phase 1/2a randomized controlled multi-center study of DSR 2.0 in diuretic-resistant chronic heart failure patients with persistent congestion, on track to start in Q2 2023:
  - Good progress of DSR 2.0 in product development and GLP<sup>8</sup> animal studies.
  - Approval to start two Phase 1 single-arm, open-label, single-dose studies in Canada (YUKON) and Mexico (CHIHUAHUA) to evaluate the safety, tolerability and efficacy of DSR 2.0, with first patient dosed successfully in YUKON.

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<sup>6</sup> NYHA: New York Heart Association classification, data collected outside study protocols of RED DESERT and SAHARA

<sup>7</sup> Predicted one-year survival analysis using Seattle Heart Failure Model of seven patients from RED DESERT and eight patients from SAHARA pre- and post-intensive DSR therapy. Analysis includes physician-assessed data collected *post hoc*

<sup>8</sup> GLP: Good Laboratory Practice

- Data from the GLP animal and Phase 1 CHIHUAHUA studies are intended to support the US IND<sup>9</sup> application filing of DSR 2.0, planned for Q1 2023.
- Preparations ongoing to start the MOJAVE study, planned for Q2 2023, assuming FDA approval of the US IND application. The intention is to enroll 30 diuretic-resistant chronic heart failure patients with persistent congestion, with 20 patients randomized to DSR 2.0 administered via a peritoneal catheter on top of usual care for congestive heart failure (CHF) for up to four weeks and ten patients randomized to usual care for CHF alone.

### **Corporate**

- European Medical Device Regulation (MDR) certification:
  - Received MDR certification from the Company's Notified Body, BSI, in [February 2022](#), confirming that its QMS<sup>10</sup> and **alfapump** system are compliant with the latest regulatory standards required for medical devices in Europe. **alfapump** is one of the first novel Class III active implantable medical devices to receive such certification.
- Expanding the Board of Directors with seasoned US medtech executives:
  - Appointed two highly experienced US medtech leaders as independent Non-Executive Directors. Doug Kohrs brings more than 40 years of experience from his many roles as a founder and executive of leading medical technology companies. Alexandra Clyde brings more than 30 years of experience and has an exceptional understanding and track record of successfully navigating health economics and reimbursement in the medical device industry.
- Extending the Company's cash runway into mid-2023:
  - Raised €28.4 million in gross proceeds in [March 2022](#) by means of an equity placement via an accelerated bookbuild offering from a new investor, Partners in Equity V B.V., and existing shareholders.
  - Secured €10 million loan facility with Kreos Capital, a leading growth debt provider for life sciences and healthcare companies, in [July 2022](#).
- Cash position of €18.9 million at the end of December 2022, compared to €9.6 million at the end of December 2021.

### **Post-period events**

- Granting of additional DSR patent in the US:
  - Additional US patent granted in [January 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.

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<sup>9</sup> IND: Investigational New Drug

<sup>10</sup> QMS: Quality Management System

- Successful completion of pre-clinical studies of DSR 2.0:
  - Reported data from two GLP animal studies in mice and sheep in [February 2023](#) demonstrating safety of DSR 2.0. No difference in systemic and local toxic effects were observed 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.
- First patient dosed successfully in CHIHUAHUA study – Phase 1 single-arm, open-label, single-dose study of DSR 2.0 in Mexico
  - The first patient has been treated successfully and the results of this study will be used to determine dosing of DSR 2.0 in MOJAVE.
  - Data from this study, together with the data from the GLP animal studies are intended to support the filing of the US IND application, planned for Q1 2023.

### **Outlook for 2023**

2023 is a pivotal year for Sequana Medical as it builds upon the successful clinical data published for both programs in 2022. The Company is working towards the PMA submission for the **alfapump** program to the US FDA planned for H2 2023. For the DSR heart failure program, the key next step is the Phase 1/2a MOJAVE randomized controlled study expected to commence in Q2 2023, with Short Term DSR therapy using DSR 2.0.

- North American liver program of the **alfapump** – PMA filing to US FDA planned for H2 2023:
  - Analysis of additional secondary efficacy and safety endpoints from the North American pivotal POSEIDON study and submit for presentation at a forthcoming medical liver meeting in 2023.
  - Top-line data from the US patient preference study expected in H2 2023.
- Heart failure program of DSR 2.0 – on track to start US Phase 1/2a MOJAVE study in Q2 2023:
  - Top-line results from Phase 1 single-arm, open-label, single-dose study in Mexico (CHIHUAHUA) expected in Q1 2023.
  - IND application filing to US FDA expected in Q1 2023.
  - First patient enrolled in US Phase 1/2a randomized controlled MOJAVE study expected in Q2 2023. and interim data expected in H2 2023.

**Detailed financial review**

in Thousand Euros (if not stated otherwise)	FY 2022	FY 2021	Change
<b>Revenue</b>	<b>923</b>	<b>371</b>	<b>+149%</b>
Cost of goods sold	(205)	(77)	N.M.
<b>Gross margin</b>	<b>718</b>	<b>294</b>	<b>+144%</b>
Sales & Marketing	(2,240)	(2,079)	+8%
Clinical	(9,773)	(7,798)	+25%
Quality & Regulatory	(3,632)	(3,215)	+13%
Supply Chain	(3,158)	(2,716)	+16%
Engineering	(3,853)	(3,206)	+20%
General & Administration	(6,687)	(5,098)	+31%
<b>Total operating expenses</b>	<b>(29,343)</b>	<b>(24,112)</b>	<b>+22%</b>
Other income	530	1,205	-56%
<b>Earnings before interest and taxes (EBIT<sup>11</sup>)</b>	<b>(28,094)</b>	<b>(22,614)</b>	<b>+24%</b>
Finance income	451	246	+83%
Finance cost	(2,733)	(855)	N.M.
<b>Total net finance expense</b>	<b>(2,282)</b>	<b>(608)</b>	<b>N.M.</b>
Income tax expense	(387)	(393)	-2%
<b>Net loss for the period</b>	<b>(30,763)</b>	<b>(23,615)</b>	<b>+30%</b>
<b>Basic Loss Per Share (in Euros)</b>	<b>(1.35)</b>	<b>(1.30)</b>	<b>+4%</b>
<b>Cash position* at 31 December</b>	<b>18,875</b>	<b>9,600</b>	<b>+97%</b>

N.M.: Not Meaningful (percentage greater than 150%)

\* Cash position only includes cash and cash equivalents.

**Consolidated statements of profit and loss**

**Revenue**

Revenue increased from €0.37 million in 2021 to €0.92 million in 2022 as a result of resumed commercial activity in Europe as the impact of COVID declines.

**Cost of goods sold**

Cost of goods sold increased from €0.08 million in 2021 to €0.21 million in 2022 in line with the increase in revenue.

**Operating expenses**

Total operating expenses increased from €24.11 million in 2021 to €29.34 million in 2022 mainly due to i) the preparations of the submissions for marketing approval of the **alfapump** in the US and Canada, and ii) pre-clinical and clinical development work for Sequana Medical's proprietary DSR therapy.

<sup>11</sup> EBIT is defined as revenue less cost of goods sold and operating expenses.

*Sales and marketing* expenses increased from €2.08 million in 2021 to €2.24 million in 2022 due to the resumption of European commercial activities.

*Clinical* expenses increased from €7.80 million in 2021 to €9.77 million in 2022 mainly as a result of costs related to the POSEIDON North American pivotal study of the **alfapump**, the SAHARA Phase 2a study of DSR and pre-clinical and clinical development work for the Company's proprietary DSR therapy.

*Quality and Regulatory* expenses increased from €3.22 million in 2021 to €3.63 million in 2022, mainly driven by external advice for the preparation of the submissions for marketing approval of the **alfapump** in the US and Canada.

*Supply chain* expenses increased from €2.72 million in 2021 to €3.16 million in 2022 largely driven by additional staffing for the preparation of the submissions for marketing approval of the **alfapump** in the US and Canada.

*Engineering* expenses increased from €3.21 million in 2021 to €3.85 million in 2022, largely driven by external advice and additional staffing for the preparations of the submissions for marketing approval of the **alfapump** in the US and Canada.

*General and administration* expenses increased from €5.10 million in 2021 to €6.69 million in 2022 mainly due to costs relating to the equity and debt financings in 2022, and additional staffing.

*Other income* decreased from €1.21 million in 2021 to €0.53 million in 2022 related to the one-off termination of a distribution agreement by mutual agreement in 2021.

#### **EBIT**

As a result of the above, earnings before interest and taxes (EBIT) evolved from a loss of €22.61 million in 2021 to a loss of €28.09 million in 2022.

#### **Total net finance expenses**

Net finance cost increased from €0.61 million in 2021 to €2.28 million in 2022, mainly resulting from valuation of the Bootstrap Warrants and Kreos Subscription Rights (to be approved by the extraordinary shareholders meeting of 10 February 2023), both non-cash items, as well as, the increased realized foreign exchange losses following the weakening of the EUR compared to CHF and USD.

#### **Income tax expense**

Income tax expense remained stable at €0.39 million in 2022 compared to 2021.

#### **Net loss for the period**

As a result of the above, the net loss increased from €23.62 million in 2021 to €30.76 million in 2022.

#### **Basic losses per share (LPS)**

Basic losses per share increased from €1.30 in 2021 to €1.35 in 2022.

## Consolidated balance sheet

### Net debt

Net debt<sup>12</sup> at 31 December 2022 increased by €0.23 million compared to 31 December 2021.

### Working Capital

Working capital<sup>13</sup> decreased by €0.99 million in 2022 compared to 2021, mainly as a result of an increase in trade payables and accrued liabilities, partially compensated by an increase in inventory and other receivables and prepaid expenses.

### 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 the geopolitical situation in Ukraine 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.

With the existing cash resources, the current cash runway is sufficient into mid-2023. 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 €27.48 million in 2022 compared to €23.62 million in 2021. The outflow was mainly driven by higher net loss of the period.

Cash flow from investing activities resulted in a net outflow of €0.65 million in 2022, compared to a net outflow of €0.34 million in 2021.

Cash flow from financing activities resulted in a net inflow of €37.32 million in 2022, mainly as 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. In 2021, the net inflow of €22.44 million was mainly a result of the February 2021 equity placement.

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<sup>12</sup> Net debt is calculated by adding short-term, long-term financial and lease debt and deducting cash and cash equivalents.

<sup>13</sup> The components of working capital are inventory + trade receivables + other receivables and prepaid expenses - trade payables - other payables - accrued liabilities and provisions.



The Company ended 2022 with a total cash and cash equivalents amount of €18.88 million (2021: €9.60 million).

**Conference Call and Webcast**

Sequana Medical will host a conference call with live webcast presentation today at 03:00 pm CEST / 09:00 am 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.

**2023 financial calendar**

25 April 2023	Online publication of Annual Report 2022
25 May 2023	Annual General Meeting 2023

**For more information, please contact:**

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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, difficult 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 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**<sup>®</sup> and **DSR**<sup>®</sup> 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 study of the **alfapump** in recurrent or refractory ascites due to liver cirrhosis, enabling the filing of a Pre-Market Approval (PMA) application with the FDA, planned for H2 2023. Having delivered clinical proof-of-concept for **DSR** as a disease-modifying drug program for the treatment of heart failure, the Company is planning to commence **MOJAVE**, a US multi-centered randomized controlled Phase 1/2a clinical study of **DSR** 2.0, in Q2 2023.

Sequana Medical is listed on Euronext Brussels (Ticker: SEQUA.BR) and headquartered in Ghent, Belgium. For further information, please visit [www.sequanamedical.com](http://www.sequanamedical.com).

### **Important Regulatory Disclaimers**

*The **alfapump**<sup>®</sup> 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 Study) and is being studied in adult patients with refractory or recurrent ascites due to cirrhosis. For more information regarding the POSEIDON clinical study see [www.poseidonstudy.com](http://www.poseidonstudy.com). **DSR**<sup>®</sup> therapy is still in development and it should be noted that any statements regarding safety and efficacy arise from ongoing pre-clinical and clinical investigations which have yet to be completed. **DSR** therapy is currently not approved for clinical research in the United States or Canada. There is no link between **DSR** therapy and ongoing investigations with the **alfapump** system in Europe, the United States or Canada.*

*Note: **alfapump**<sup>®</sup> is a registered trademark. **DSR**<sup>®</sup> is a registered trademark in the Benelux, China, the EU, United Kingdom, and Hong Kong.*

### **Forward-looking statements**

*This press release may contain predictions, estimates or other information that might be considered forward-looking statements. Such forward-looking statements are not guarantees of future performance. These forward-looking statements represent the current judgment of Sequana Medical on what the future holds, and are subject to risks and uncertainties that could cause actual results to differ materially. Sequana Medical expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release, except if specifically required to do so by law or regulation. You should not place undue reliance on forward-looking statements, which reflect the opinions of Sequana Medical only as of the date of this press release.*

**Financial information**

The 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 25 April 2023.

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 2022.

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	
	2022	2021
<b>Revenue</b>	<b>923</b>	<b>371</b>
Cost of goods sold	(205)	(77)
<b>Gross margin</b>	<b>718</b>	<b>294</b>
Sales & Marketing	(2,240)	(2,079)
Clinical	(9,773)	(7,798)
Quality & Regulatory	(3,632)	(3,215)
Supply Chain	(3,158)	(2,716)
Engineering	(3,853)	(3,206)
General & Administration	(6,687)	(5,098)
<b>Total operating expenses</b>	<b>(29,343)</b>	<b>(24,112)</b>
Other income	530	1,205
<b>Earnings before interests and taxes (EBIT)</b>	<b>(28,094)</b>	<b>(22,614)</b>
Finance income	451	246
Finance cost	(2,733)	(855)
<b>Total net finance expense</b>	<b>(2,282)</b>	<b>(608)</b>
Income tax expense	(387)	(393)
<b>Net loss for the period</b>	<b>(30,763)</b>	<b>(23,615)</b>
<b>Basic losses per share (in Euro)</b>	<b>(1.35)</b>	<b>(1.30)</b>

Consolidated statement of comprehensive income

in Thousand Euros (if not stated otherwise)	Year ended 31 December	
	2022	2021
<b>Net loss for the period</b>	<b>(30,763)</b>	<b>(23,615)</b>
Components of other comprehensive income (OCI) items that will not be reclassified to profit or loss:		
Remeasurements of defined benefit plans	413	96
Items that may be reclassified subsequently to profit or loss:		
Currency translation adjustments	727	(256)
<b>Total other comprehensive income/(loss)-net of tax</b>	<b>1,140</b>	<b>(160)</b>
<b>Total comprehensive income</b>	<b>(29,623)</b>	<b>(23,775)</b>
Attributable to Sequana Medical shareholders	(29,623)	(23,775)

Consolidated balance sheet

in Thousand Euros (if not stated otherwise)	As at 31 December	
	2022	2021
<b>ASSETS</b>		
Property, plant and equipment	2,068	1,268
Financial Assets	86	82
Other non-current assets	782	464
<b>Total non-current assets</b>	<b>2,936</b>	<b>1,815</b>
Trade receivables	114	82
Other receivables and prepaid expenses	1,479	1,069
Inventory	2,621	2,139
Cash and cash equivalents	18,875	9,600
<b>Total current assets</b>	<b>23,089</b>	<b>12,891</b>
<b>Total assets</b>	<b>26,025</b>	<b>14,705</b>
<b>EQUITY AND LIABILITIES</b>		
Share capital	2,460	1,925
Share premium	170,324	142,433
Reserves	(2,426)	(2,669)
Loss brought forward	(173,458)	(142,695)
Cumulative translation adjustment	946	220
<b>Total equity</b>	<b>(2,153)</b>	<b>(787)</b>
Long term financial debts	12,193	7,325
Long term lease debts	609	477
Retirement benefit obligation	228	510
<b>Total non-current liabilities</b>	<b>13,030</b>	<b>8,312</b>
Short term financial debts	4,483	-
Short term lease debts	307	283
Other current financial liabilities	1,569	-
Trade payables and contract liabilities	3,392	2,367
Other payables	1,812	1,925
Accrued liabilities and provisions	3,586	2,605
<b>Total current liabilities</b>	<b>15,148</b>	<b>7,180</b>
<b>Total equity and liabilities</b>	<b>26,025</b>	<b>14,705</b>

Consolidated statement of cash flows

in Thousand Euros (if not stated otherwise)	Year ended 31 December	
	2022	2021
<b>Net loss for the period</b>	<b>(30,763)</b>	<b>(23,615)</b>
Income tax expense	387	393
Financial result	1,923	613
Depreciation	312	409
Change in defined benefit plan	(102)	(40)
Share-based compensation	564	536
Changes in trade and other receivables	(457)	(163)
Changes in inventories	42	(865)
Changes in trade and other payables/provisions	990	(662)
Taxes paid	(378)	(222)
<b>Cash flow used in operating activities</b>	<b>(27,482)</b>	<b>(23,617)</b>
Investments in tangible fixed assets	(677)	(326)
Investments in financial assets	24	(12)
<b>Cash flow used in investing activities</b>	<b>(653)</b>	<b>(338)</b>
Proceeds from capital increase	28,420	22,771
(Repayments) from leasing debts	(407)	(335)
(Repayments) from financial debts	-	-
Proceeds from financial debts	9,626	-
Interest paid	(315)	-
<b>Cash flow from financing activities</b>	<b>37,324</b>	<b>22,435</b>
<b>Net change in cash and cash equivalents</b>	<b>9,189</b>	<b>(1,520)</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>9,600</b>	<b>11,016</b>
Net effect of currency translation on cash and cash equivalents	85	104
<b>Cash and cash equivalents at the end of the period</b>	<b>18,875</b>	<b>9,600</b>

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
<b>Balance at 1 January 2021</b>	<b>1,635</b>	<b>119,333</b>	<b>(2,250)</b>	<b>(119,080)</b>	<b>476</b>	<b>113</b>
Net loss for the period				(23,615)		(23,615)
Other comprehensive income			96		(256)	(160)
February 2021 Equity Placement	274	22,226				22,500
Capital increase Share Options	6	265				271
Capital increase convertible loan to shares	10	609				619
Transaction costs for equity instruments			(1,051)			(1,051)
Share-based compensation			536			536
<b>Balance at 31 December 2021</b>	<b>1,925</b>	<b>142,433</b>	<b>(2,669)</b>	<b>(142,695)</b>	<b>220</b>	<b>(787)</b>

<b>Balance at 1 January 2022</b>	<b>1,925</b>	<b>142,433</b>	<b>(2,669)</b>	<b>(142,695)</b>	<b>220</b>	<b>(787)</b>
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
<b>Balance at 31 December 2022</b>	<b>2,460</b>	<b>170,324</b>	<b>(2,426)</b>	<b>(173,458)</b>	<b>946</b>	<b>(2,153)</b>