

Message from the Chairman and the CEO

Dear Shareholders, Colleagues and Business Partners,

2020 was another very positive year for Sequana Medical where, despite the impact of COVID, we delivered outstanding clinical progress in both our focus areas, liver disease/non-alcoholic steatohepatitis (NASH) in North America and heart failure in North America and Europe. This growing body of clinical evidence supports our strategy of concentrating on these two large and growing markets where we intend to bring the unique benefits of our **alfapump**-based therapies to address the clear unmet needs of patients, physicians and healthcare systems.

We have a clear focus on innovative treatments for diuretic-resistant fluid overload. Excess fluid in the body is a major problem in many large diseases, such as chronic heart, kidney and liver failure as well as cancer. In most cases, the fluid overload is treated with diuretics but for many patients these drugs stop becoming effective. When this happens, there are often limited alternative treatments available. We believe the novel treatment options we are developing will improve clinical outcomes and quality of life for these patients, and reduce the costs and burdens on healthcare systems and payers.

We were delighted to present the strong interim efficacy and safety data from POSEIDON, our ongoing North American pivotal study of the **alfapump** in patients with recurrent or refractory ascites due to liver cirrhosis. In the first 13 patients from the Roll-In Cohort, we achieved a reduction of more than 90% in the average number of therapeutic paracenteses (TP) post-**alfapump** implant versus pre-implant, with all patients having at least a 50% reduction in the average frequency of TP per month. In addition, we were able to show clinically relevant improvements in quality of life and we believe this clear benefit will be crucial in driving physician and patient acceptance. We look forward to presenting data from a larger group of Roll-In patients in Q2 of this year, ahead of the planned reporting of the primary endpoint data in Q2 2022, with the PMA (premarket approval) filing to the FDA scheduled for H2 2022.

Heart failure has advanced in two key areas this year and this has significantly strengthened the programme. First, we reported impressive interim results from our RED DESERT study where, for the first time, we evaluated repeated use of **alfapump** DSR therapy in patients with diuretic-resistant heart failure. Data from the first five patients showed that **alfapump** DSR therapy was safe and effective, maintaining the sodium and fluid balance in these patients without the need for any loop diuretics. Following the six-week study, the diuretic response of these patients was restored to near normal levels, with them requiring substantially lower diuretic doses even months after completion of DSR therapy. This indicates that DSR therapy is more than just a means to remove sodium and water but also has the potential to restore normal kidney response.



This key finding will be further explored in both heart failure and other disease areas where diuretic-resistance is a problem, such as renal failure. In Q2 2021, we plan to report top-line data from all the RED DESERT patients and start SAHARA DESERT, in which we intend to evaluate the dosing and frequency of **alfapump** DSR therapy in decompensated heart failure patients with residual congestion. Secondly, the key **alfapump** DSR patents were granted in U.S. and Europe providing a strong intellectual property platform that establishes Sequana Medical as a leader in the treatment of diuretic-resistant fluid overload. Following receipt of these patents, we have commenced development of our own DSR infusate that we expect to deliver an improved therapeutic profile as well as the potential for a high value recurring revenue stream.

We would like to take this opportunity to thank all our employees for their commitment and dedication to make Sequana Medical a success, and our shareholders and partners for their continued support. Despite the challenging circumstances over the past year, we can look back on our successes with pride. Together, we have enhanced the position of Sequana Medical and significantly strengthened the development of our ground-breaking treatments. We look forward to keeping you up to date on the exciting times ahead.

Pierre Chauvineau,
Chairman

Ian Crosbie,
CEO