

Message from the Chairman and the CEO

Dear Shareholders, Colleagues and Business Partners,

We are very pleased to report on the significant achievements Sequana Medical has made during 2021, which demonstrate our progress towards our goal of developing innovative treatments for diuretic-resistant fluid overload in liver disease, cancer and heart failure. 2022 promises to be another busy year for us with a number of exciting milestones coming up, as we continue to demonstrate the power and versatility of our proprietary **alfapump** and DSR technology platforms, and move closer to market launch.

Sequana Medical remains focussed on two strategic programmes in liver disease and heart failure. Our first is the commercialisation of the **alfapump** in North America, our key growth market. During 2021, we made important progress in POSEIDON, our North American pivotal study of the **alfapump** in recurrent and refractory ascites due to liver cirrhosis, which is the last clinical step in bringing the **alfapump** to market in the U.S. and Canada. In mid-year, we reported strong data from the second interim analysis, which reaffirmed the previous positive efficacy results and provided longer-term evidence that the **alfapump** dramatically improves the quality of life for patients. In December, we completed patient enrolment and more recently, completed **alfapump** implantations, an important milestone that confirms our timing for reporting the primary endpoint by the end of this year. The **alfapump** comes with a strong package of evidence, including a European market approval for refractory ascites due to liver cirrhosis, more than 900 systems already implanted to date, Breakthrough Device designation granted by the U.S. FDA, and strong interim data reported in

North America. We look forward to submission of our Pre-Market Approval to the U.S. FDA in mid-2023 and moving another step closer to launch in the U.S.

Our second strategic focus is the clinical development of DSR therapy for congestive heart failure in North America and Europe, which was bolstered by further strong clinical results in 2021. Our RED DESERT study showed that **alfapump** DSR is highly effective at not only safely managing the fluid and sodium balance in diuretic-resistant heart failure patients, but also dramatically improving their diuretic response and cardio-renal function, a treatment effect not seen before and one that holds great potential. With this initial strong clinical evidence, we progressed into heart failure patients with fluid overload (decompensated patients) with our phase 2a SAHARA DESERT study. We reported positive interim results from this study in December 2021, demonstrating the ability to safely, effectively and rapidly remove the fluid overload in these patients, as well as again improving their cardio-renal function and restoring the diuretic response of their kidneys. We look forward to reporting top-line data in all patients from this study in the second half of this year.

A key element and value driver of our DSR platform is our proprietary DSR Infusate 2.0, and this is progressing well through pre-clinical and CMC development. It is due to enter the clinic in the second half of this year in MOJAVE DESERT, a phase 1b/2a trial in the U.S. evaluating short-term DSR therapy in decompensated heart failure patients. The objective of DSR Infusate 2.0 is to develop a proprietary drug with a superior therapeutic

and safety profile, that can deliver a high margin recurring revenue stream to accompany **alfapump** DSR sales.

The outstanding clinical data Sequana Medical delivered throughout 2021 helped us secure our latest round of financing to cover our next stage of development, including the POSEIDON and SAHARA DESERT read-outs, the start of the MOJAVE DESERT trial, and the preparations for the submission of the **alfapump** for Pre-Market Approval in the U.S.

The tremendous developments in 2021 reinforce our belief in the potential of our proprietary **alfapump** and DSR technology platforms to offer better treatment solutions for the clinically and commercially important market of diuretic-resistant fluid overload. Our employees are the bedrock of our success, and we are deeply grateful for all their hard work and commitment. We would also like to thank our shareholders, clinical investigators and other partners for their continued support.

Pierre Chauvineau

Ian Crosbie

