EDISON

Sequana Medical

SAHARA results

SAHARA results pave the way for DSR 2.0

Pharma and biotech

Sequana Medical reported positive top-line results from its SAHARA Phase IIa study of DSR 1.0, involving 10 evaluable patients with diuretic-resistant heart failure. Results from these patients, who had completed the 16-week follow-up period (the second phase of the study, see our recent outlook note for details on study phases and design) following intensive DSR therapy, were largely consistent with the interim data reported in July. These patients reported a mean 33% reduction in NT-proBNP at this time point versus baseline (indicating improved cardio-renal status) and stable renal function (no significant change in eGFR versus baseline). Importantly, the need for loop diuretics medication was substantially reduced for many (at least six to 15) months following the first phase (intensive DSR therapy) of SAHARA, with nine out of 10 patients having had a reduction of more than 90% of their required dosing. Sequana is now advancing its second-generation DSR 2.0 product, designed to provide improved therapeutic and safety profiles and a longer dwell time. It has successfully dosed the first patient with DSR 2.0 in the Canadian Phase I study (YUKON), and aims to start the multi-centre randomised US MOJAVE Phase I/IIa study in DSR 2.0 in H123.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/20	1.0	(19.0)	(1.25)	0.0	N/A	N/A
12/21	0.4	(24.4)	(1.36)	0.0	N/A	N/A
12/22e	0.8	(26.3)	(1.12)	0.0	N/A	N/A
12/23e	0.8	(25.4)	(1.07)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

The YUKON single-arm open-label study will provide a single treatment of DSR 2.0 in patients on peritoneal dialysis, with results expected to help determine DSR 2.0 dosing for the MOJAVE study. An additional Phase I DSR 2.0 study, CHIHUAHUA, will enrol patients in Mexico. Both studies are designed to enrol up to 10 patients each, and are intended to support the US Investigational New Drug (IND) application for MOJAVE, which the company expects to submit in Q123. They replace the previously planned DSR 2.0 extension arm of SAHARA. Sequana anticipates receiving IND approval and starting MOJAVE in H123.

The MOJAVE study will have two study cohorts. In the safety cohort, three heart failure patients will receive DSR 2.0 via a peritoneal catheter on top of usual care for up to four weeks. An independent data safety monitoring board will then determine whether the study can proceed to the efficacy cohort. The efficacy cohort is then designed to enrol 30 diuretic-resistant chronic heart failure patients with persistent congestion, with 20 patients randomised to DSR 2.0 administered via a peritoneal catheter on top of usual care for congestive heart failure for up to four weeks, and 10 patients randomised to usual care alone. There will also be a three-month safety follow-up period after the four weeks of DSR therapy. Sequana expects to report interim data from MOJAVE in H223, and top-line results in mid-2024. If results are positive, we believe the company could be in an enviable position to seek favourable terms for commercial partnership or licensing transactions.

18 November 2022

Price	**€6.62**
Market cap	**€157m**
Net cash (€m) at 30 June 2022	16.2
Shares in issue	23.75m
Free float	45%
Code	SEQUA
Primary exchange	Euronext
Secondary exchange	N/A

Share price performance

Business description

Based in Belgium, Sequana Medical develops products to treat diuretic-resistant fluid overload, a frequent complication of liver disease and heart failure. Its proprietary alfapump and DSR approaches aim to provide significant clinical and quality-of-life benefits in these fluid overload conditions.

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