EDISON

Sequana Medical

POSEIDON results

POSEIDON pivotal study meets primary endpoint

Pharma and biotech

Sequana Medical reported that the POSEIDON North American pivotal study of its implantable alfapump device in patients with recurrent and refractory ascites (RRA) due to liver cirrhosis met the primary efficacy endpoint, and that safety results were in line with expectations. These positive results should pave the way for the company to file a US premarket approval application with the FDA in H223, in line with prior guidance, which we estimate can lead to US market launch in mid-2024. The alfapump device was shown to lead to significant reductions in the need for RRA patients to undergo burdensome therapeutic paracentesis (TP) procedures, which should lead to improved patient independence and quality of life, given the limitations of current treatments as discussed in our Outlook report. We expect the rising prevalence of non-alcoholic steatohepatitis will result in the target market for RRA patients in North America increasing at an upper single-digit CAGR over the next decade, providing a robust commercialisation opportunity for alfapump in RRA.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/2020	1.0	(19.0)	(1.25)	0.0	N/A	N/A
12/2021	0.4	(24.4)	(1.36)	0.0	N/A	N/A
12/2022e	0.8	(26.3)	(1.12)	0.0	N/A	N/A
12/2023e	0.8	(25.1)	(1.05)	0.0	N/A	N/A

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

Data from the 40 enrolled patients in the pivotal cohort of the POSEIDON study met the key primary efficacy outcomes. Notably, 77% of evaluable patients experienced a 50% reduction in the frequency of TP in the post-implant observation period (reflecting month four to month six after implantation) as compared to the three-month pre-implant observation period ($p<0.001$); the study's aim was to show at least a 50% reduction. There was also a 100% median per-patient reduction in TP post- versus pre-implantation ($p<0.001$). We believe the results exceeded the efficacy thresholds required for approval by a reasonable margin.

The company noted that of the 40 implantations, 14 patients exited the study prior to completing the 180-day post-implantation period, with eight discontinuations due to reasons such as death or withdrawal due to an unrelated adverse event or for liver transplant. These discontinuations are not surprising given the high burden of disease in the RRA population; the 12-month survival rate is only c 50%. There were six discontinuations due to primary safety events, which were in line with company expectations. Three of these events were due to wound or skin erosion, and three were explants due to patient-reported discomfort (which were all determined by the Clinical Events Committee as moderate severity). No unanticipated adverse device effects occurred during the POSEIDON study, and the company expects to report additional secondary efficacy and safety endpoints at a medical liver meeting in 2023.

We expect Sequana to ramp up its regulatory and pre-commercialisation activities over the coming months as it aims to position the alfapump in the highly unmet North American market of RRA relating to liver ascites.

25 October 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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