EDISON

Sequana Medical

Clinical trial update

POSEIDON enrolment completed on schedule

Pharma & biotech

Meeting its recent Q421 guidance, Sequana has completed patient enrolment for the POSEIDON North American pivotal study assessing the alfapump system for the treatment of recurrent or refractory ascites (RRA) due to liver cirrhosis. 70 patients have been enrolled in the pivotal cohort, with Sequana expecting to implant 50 of these with the alfapump by the end of Q122. This should allow Sequana to meet its pre-defined target of having 40 evaluable patients for the primary efficacy analysis at six months post-implantation, which continues to be expected in Q422. The company expects to submit a US pre-market approval (PMA) application in mid-2023, which we believe could lead to a US launch in mid-2024.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	DPS (%)	Yield (%)
12/19	1.0	(14.9)	(1.22)	0.0	N/A	N/A
12/20	1.0	(19.0)	(1.25)	0.0	N/A	N/A
12/21e	0.5	(22.7)	(1.25)	0.0	N/A	N/A
12/22e	1.2	(22.8)	(1.22)	0.0	N/A	N/A

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

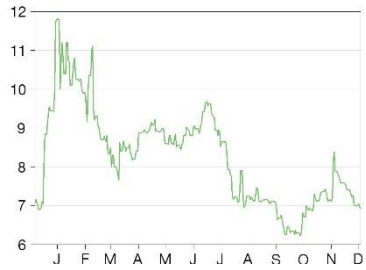
Sequana reported its second interim results in July from the POSEIDON study roll-in cohort. As outlined in our prior note, this second interim analysis showed that subjects in the roll-in cohort had a greater than 90% reduction in mean frequency of therapeutic paracentesis (TP) versus baseline. Furthermore, all patients experienced at least a 50% reduction in mean TP frequency per month versus baseline. As these trends substantially exceed the primary endpoints as defined for the pivotal cohort, we anticipate that the POSEIDON study would meet the primary endpoint if trends shown in the roll-in cohort are maintained. Provided alfapump receives North American approval, we expect sales prospects to be driven by the rising prevalence of non-alcoholic steatohepatitis, which we project will contribute to the US incidence of RRA rising by c 7% pa through 2030.

We continue to expect that Sequana's funds on hand should be sufficient for it to maintain operations into Q222 and model that the company will raise €20m in 2022 (modelled as illustrative debt). Our unchanged financial assumptions are described in our most recent update note.

6 December 2021

Price	**€6.92**
Market cap	**€129m**
Net cash (€m) at 30 June 2021 (excluding €0.3m lease liabilities)	14.7
Shares in issue	18.58m
Free float	50%
Code	SEQUA
Primary exchange	Euronext
Secondary exchange	N/A

Share price performance



Business description

Based in Belgium, Sequana Medical develops devices based on its alfapump platform for the treatment of diuretic-resistant fluid overload in liver disease, malignant ascites and heart failure. Alfapump is CE marked for refractory ascites and is in a pivotal North American study for this indication.

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