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Cereno Scientific

Regulatory update

CS1 granted OMPD, complementing FDA ODD

Pharma and biotech

Cereno Scientific's lead asset CS1 has been granted the Orphan Medicinal Product Designation (OMPD) from the European Commission as a potential treatment for pulmonary arterial hypertension (PAH). The OMPD provides 10 years of market exclusivity, assuming CS1 receives EU regulatory approval, in addition to fee waivers during the development process. Further, this regulatory designation complements the FDA Orphan Drug Designation (ODD) granted in 2020, bolstering the value proposition of the candidate. We expect this news will be viewed positively as investors await the Phase II CS1 trial's topline results in PAH, expected in September 2024.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/22	0.0	(27.6)	(0.20)	0.0	N/A	N/A
12/23	0.0	(46.4)	(0.20)	0.0	N/A	N/A
12/24e	0.0	(58.9)	(0.21)	0.0	N/A	N/A
12/25e	0.0	(56.0)	(0.20)	0.0	N/A	N/A

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

In advance of the Phase II results in PAH (anticipated in Q324), management has announced the receipt of the OMPD for CS1 from the European Commission in the PAH indication and covering all 27 EU countries. The orphan medicinal product label is granted to drug candidates with the potential to diagnose, prevent or treat life-threatening or chronically debilitating conditions affecting up to five in 10,000 people in the EU, and provides a host of benefits, including fee waivers and 10 years of market exclusivity post-approval. This designation further strengthens Cereno's commercial strategy for CS1, and follows the US FDA ODD granted in March 2020. The company also has a robust patent portfolio for the CS1 drug candidate, with granted patents in major markets, which was augmented with new patents in New Zealand (second family), the US (third family) and Brazil (third family) in the prior quarter.

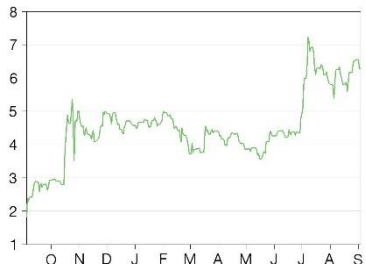
The near-term inflection point for Cereno will be the results of the Phase II trial for CS1 in PAH, expected in September 2024. This is a randomised, open-label, blinded endpoint study, primarily assessing the safety and tolerability of the candidate, with additional exploratory efficacy parameters focused on various functional, hemodynamic and structural measures and biomarkers. The study also aims to inform the design of the next study of CS1. Cereno recently announced (30 August 2024) that the first patient had been dosed in the Expanded Access Program (EAP), an initiative prompted by requests from trial investigators to enable patients from the Phase II trial to continue taking CS1 after completing the study. The EAP will allow Cereno to obtain longer-term safety and efficacy data, which may facilitate future discussions with regulators. We view the EAP as an encouraging sign of perceived patient benefit, although we acknowledge that detailed conclusions rest on the results of the full analysis.

Last week, Cereno reported its Q224 results, and management highlighted the progress of its three pipeline candidates targeting cardiovascular diseases with high unmet needs. For a more detailed discussion of the recent results, we direct readers to our update note.

4 September 2024

Price	**SEK6.30**
Market cap	**SEK1,770m**
	SEK10.21/US$
Net cash at 30 June 2024	SEK40.2m
Shares in issue	281.0m
Free float	93%
Code	CRNO B
Primary exchange	First North Growth Market
Secondary exchange	N/A

Share price performance



Business description

Cereno Scientific is a clinical-stage biotech based in Sweden, focused on the development of innovative, effective and safe treatments for cardiovascular diseases with unmet medical needs. Lead asset CS1 is an HDAC inhibitor that acts as an epigenetic modulator. It is currently being investigated in a Phase II clinical trial for the treatment of pulmonary arterial hypertension.

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