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Cereno Scientific

Regulatory update

Runway clears for Phase IIb with FDA nod

Healthcare

11 December 2025

Cereno Scientific has announced that it has been granted FDA clearance for its global Phase IIb trial for CS1 in pulmonary arterial hypertension (PAH), clearing the way for trial initiation in Q226. Management also provided details on the study design, which will be a 126-patient, double-blind, placebo-controlled, dose-finding trial, assessing two dose levels of CS1 versus placebo in combination with background therapy. We note the 60-week total treatment duration (including screening and follow-up) with a re-randomisation after 36-weeks, ensuring all participants receive active treatment at some point during the trial. We believe this to be strategic, allowing the company to confirm previously observed disease-modifying signals in a larger, controlled cohort. Study endpoints include change in pulmonary vascular resistance (PVR) and six-minute walk distance (6MWD) at week 36 (well-validated regulatory benchmarks in PAH), with top-line readouts expected in Q428. We will review our estimates to reflect this news and will present our updated valuation in a forthcoming note.

Year end	Revenue (SEKm)	PBT (SEKm)	EPS (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/23	0.0	(46.4)	(0.20)	0.00	N/A	N/A
12/24e	0.0	(98.1)	(0.35)	0.00	N/A	N/A
12/25e	0.0	(95.4)	(0.33)	0.00	N/A	N/A
12/26e	0.0	(73.6)	(0.25)	0.00	N/A	N/A

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

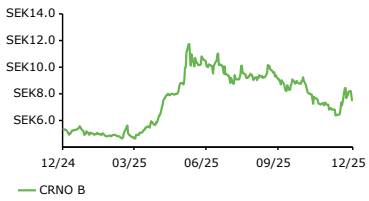
CS1 is an orally available HDAC inhibitor (HDACi) acting through epigenetic modulation to target vascular remodelling, fibrosis and inflammation, mechanisms believed to underlie PAH progression. We see the FDA clearance for the Phase IIb design as a key de-risking event for CS1's development plans, with positive implications for ongoing and planned partnering discussions. The Phase IIb study, Cereno's largest undertaking to date, will be a double-blind, placebo-controlled study, evaluating two dose levels of CS1 to establish the optimal Phase III dose. The study will recruit 126 patients across 65 sites in the US, Europe and South America and will evaluate CS1's efficacy in combination with background therapy (versus placebo). The key study endpoints will be change in PVR tested via right-heart catheterisation, change in 6MWD, biomarker changes, other measures of heart function, pharmacokinetics and patient-reported outcomes.

A notable feature of the upcoming study is the 36-week core treatment period, which is materially longer than the c 24-week duration typically employed in mid-stage PAH studies (eg sotatercept, seralutinib; CS1 Phase IIa was 12 weeks). The total trial duration will be 60 weeks, including re-randomisation at 36 weeks with the placebo group receiving CS1 and the treated patients either continuing on CS1 or switching to placebo . In our view, this study design is a deliberate strategic choice, permitting all trial participants to be dosed with CS1 at some point during the trial and allowing the company to evaluate previously observed disease-modifying signals (reverse vascular remodelling and improved right-heart function) in a broader, controlled cohort.

Management expects the trial to commence in Q226 with top-line readouts likely in Q428. With the recent fund-raise of up to SEK665m, the company has financial runway into Q427. We will revisit our model to incorporate the Phase IIb design and will provide revised estimates and valuation in our forthcoming update note.

Price	**SEK7.64**
Market cap	**SEK2,370m**
	SEK9.46/$
Pro forma net cash/(debt) at 30 September 2025 (including SEK4m from warrants conversion and SEK100 from a directed equity issue in November 2025)	SEK(2.2)m
Shares in issue (including the 14.3m shares issued as part of the November 2025 directed issue)	310.2m
Free float	93.0%
Code	CRNO B
Primary exchange	NGM
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 indications with high unmet needs. Lead asset CS1 is an HDAC inhibitor that acts as an epigenetic modulator. Cereno reported positive top-line results from the Phase IIa study in pulmonary arterial hypertension in September 2024 and FDA clearance for the Phase IIb trial in December 2025. Second asset CS014, a proprietary NCE and HDACi, is being developed for idiopathic pulmonary fibrosis (Phase II-ready), and preclinical asset CS585 is likely to target rare thrombosis-related indications.

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