EDISON

Cereno Scientific

Long-term EAP data confirms CS1's safety

Clinical data update

Healthcare

31 March 2026

Cereno Scientific has reported encouraging initial observations from the 12-month Expanded Access Program (EAP), reinforcing CS1's favourable safety and tolerability profile across longer-term use. While based on a small dataset (n=10; six completing 12 months), we view the findings as supportive of the upcoming Phase IIb plans,while also contributing to de-risking of the regulatory pathway and supporting ongoing partnering discussions. This is particularly relevant in pulmonary arterial hypertension, where current therapies, including vasodilators (in particular prostacyclins) and newer agents such as activin signalling inhibitors (such as Winrevair), are often limited by tolerability, affecting compliance and treatment persistence. Further EAP data (potentially durability of response and/or other efficacy signals) and results from the Fluidda imaging sub-study are expected in Q226 and should help refine the clinical profile further. Upcoming catalysts include first patient dosing in the Phase IIb study (expected June 2026), which remains the key value driver. We leave our estimates unchanged.

Year end	Revenue (SEKm)	PBT (SEKm)	EPS (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/24	0.0	(98.1)	(0.35)	0.00	N/A	N/A
12/25	0.0	(117.8)	(0.38)	0.00	N/A	N/A
12/26e	0.0	(92.3)	(0.30)	0.00	N/A	N/A
12/27e	0.0	(138.5)	(0.45)	0.00	N/A	N/A

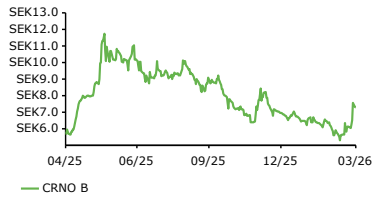
Note: PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

The key takeaway from the recent EAP announcement is the confirmation of CS1's favourable safety and tolerability profile (seen in the earlier Phase IIa study) over a longer-term treatment period (up to 15 months, including three months in Phase IIa). The EAP enroled 10 patients (out of 21 patients who completed Phase IIa) of whom six completed the full 12-month treatment period. Management noted that CS1 was well tolerated, with no unexpected safety concerns observed. Notably, no deaths were reported, and no discontinuations were attributed to CS1; withdrawals were linked to non-drug-related atrial fibrillation events (two patients), withdrawal of consent (one) and loss to follow-up (one). We remind readers that Cereno is also undertaking a sub-study using Fluidda's novel imaging technology to visualise the effect of CS1 on inducing long-term reverse remodelling. Further insights from the EAP and the Fluidda sub-study are expected in Q226 and will be closely watched, particularly for signals on pulmonary vascular structure. However, we emphasise that the small EAP dataset will make it difficult to draw any conclusions on efficacy and larger randomised studies will be required to confirm the findings.

Attention now turns to the planned global Phase IIb study, with first patient enrolment expected in June 2026. The study is designed as a randomised, placebo-controlled, dose-finding trial (n=126), with a 36-week treatment duration intended to better capture potential disease-modifying effects and re-randomisation to ensure all patients receive the treatment at some point during the trial. We expect this to be the next key inflection point for the programme and believe it will be critical in validating the encouraging signals observed in the Phase IIa study, including improvements in right heart function, functional class and quality of life. Overall, we view the latest EAP update as supportive of CS1's investment case, reinforcing confidence in its safety and tolerability profile ahead of Phase IIb. We make no changes to our estimates following this update.

Price	**SEK7.43**
Market cap	**SEK2,388m**
	SEK9.25/$
Pro forma net cash/(debt) at 31 December 2025	SEK(45.4)m
Shares in issue	311.4m
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. Phase IIb is expected to commence in Q226. Second asset CS014, a proprietary NCE and HDACi, is being developed for PH-ILD (Phase II-ready), and preclinical asset CS585 is likely to target rare thrombosis-related indications.

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