Cereno Scientific

Clinical update

Successful bridge clears CS014's path to Phase IIb

Healthcare

25 September 2026

Cereno Scientific has reported positive top-line results from the Phase I pharmacokinetic (PK) bridging study of CS014 (n=14), clearing an important development hurdle for its second clinical-stage HDAC inhibitor (HDACi). The results showed that CS014's PK relationship with valproic acid (VPA) was consistent with the assumptions underpinning Cereno's bridging strategy. This could enable Cereno to leverage the extensive clinical safety and PK experience with VPA to streamline CS014's development pathway, potentially reducing development timelines and funding requirements. Cereno plans to file an Investigational New Drug (IND) application with the FDA in Q426 and, subject to regulatory acceptance, could progress directly into a placebo-controlled Phase IIb study in PH-ILD, bypassing Phase IIa and additional non-clinical safety studies. We expect planned Phase IIb initiation in Q327 to strengthen Cereno's broader investment case, with two HDACi assets in concurrent Phase IIb development.

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	(113.4)	(0.35)	0.00	N/A	N/A
12/27e	0.0	(124.5)	(0.38)	0.00	N/A	N/A

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

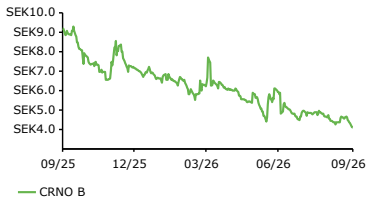
The PK study was designed following FDA feedback and enroled 14 healthy volunteers in a randomised, open-label, two-period crossover study comparing seven days of repeat oral dosing with CS014 and VPA. All participants completed both treatment periods, with Cereno noting that the relationship between plasma concentration profiles was consistent across the 14 sampling points assessed. No serious adverse events or withdrawals were reported. This builds on the favourable safety and tolerability profile in the initial Phase I study and, in our view, makes a direct Phase IIb route more credible, although formal acceptance remains dependent on FDA review of the full IND package, to be submitted in Q426.

We see FDA acceptance of the IND application as the key near-term de-risking event, determining whether CS014 can move directly into Phase IIb without a Phase IIa study or non-clinical safety work. Subject to clearance, initiation is targeted for Q327, with chemistry, manufacturing and controls activities progressing in parallel. While bypassing Phase IIa materially shortens the route to market, we note that it also places increased importance on the Phase IIb plan (including patient and dose selection, study size, duration, endpoints and powering), given that this will be the first test of clinical efficacy for the asset in a controlled setting.

The pulmonary hypertension associated with interstitial lung disease (PH-ILD) commercial opportunity remains attractive given the limited treatment landscape, with inhaled treprostinil the only approved therapy in the US and no approved PH-ILD-specific treatments in Europe. Cereno estimates c 200,000 diagnosed patients across the US and Europe and a market exceeding $6bn by 2032. We see CS014's differentiation resting on its oral administration, favourable safety and tolerability profile and multimodal mechanism, targeting underlying disease-driving processes across several cardiopulmonary diseases. While clinical validation remains the key catalyst, progression into Phase IIb would give Cereno two HDACi programmes in concurrent mid-stage development, strengthening its investment proposition.

Price	**SEK4.08**
Market cap	**SEK1,321m**
Pro forma net cash/(debt) at 30 June 2026	SEK(76.0)m
Shares in issue	323.9m
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. Patient randomisation in the Phase IIb study in PAH is expected to commence in September 2026. Second asset CS014, a proprietary NCE and HDACi, is being developed for PH-ILD, and preclinical asset CS585 has chosen antiphospholipid syndrome, a rare autoimmune condition, as its lead target indication.

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