EDISON

Cereno Scientific

Clinical update

CS014 completes Phase I, path clears for Phase II

Healthcare

17 April 2025

Cereno Scientific has announced that its second clinical stage asset, CS014, has completed the Phase I safety study, with the conclusion of the second, multiple ascending dose (MAD) part of the trial (which commenced in November 2024). This follows the successful completion of the single ascending dose (SAD) part of the study in February 2025. With the focus now on data management and analysis, management expects to announce top-line results in June 2025. CS014 is Cereno's second histone deacetylase inhibitor (HDACi), a proprietary new chemical entity (NCE), which has demonstrated anti-thrombotic, anti-fibrotic and reverse remodelling properties in preclinical studies. It is currently being developed for idiopathic pulmonary fibrosis (IPF), a rare, progressive disease with no curative treatments and an average survival of three to five years. Phase II is expected to commence in H126.

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
12/24	0.0	(98.1)	(0.35)	0.00	N/A	N/A
12/25e	0.0	(89.2)	(0.32)	0.00	N/A	N/A
12/26e	0.0	(80.0)	(0.28)	0.00	N/A	N/A

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

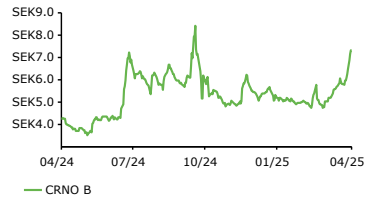
CS014 is a proprietary NCE and a deuterated form of valproic acid. It is Cereno's second HDACi after lead asset CS1. The Phase I study for CS014, which was conducted by the company's contract research organisation partner CTC, was an open-label study designed to test the safety, tolerability, pharmacokinetics and pharmacodynamics of CS014 in healthy volunteers. Of the 48 subjects enrolled in the study, 30 participated in the SAD portion, which was completed in February 2025 and demonstrated a favourable safety profile. The MAD portion, which studied CS014 over a seven-day period in 12 volunteers, began in November 2024. Management has confirmed that the final patient has now received the last dose. Accounting for the time needed for data management and analysis, Cereno expects to release top-line results by June 2025, in line with previously communicated timelines.

Should results be favourable, Cereno plans to commence the Phase II study in H126, targeting IPF as part of its strategic focus on rare diseases. IPF is a serious and fast-progressing lung disease that is estimated to affect around three million people worldwide, with 30,000–50,000 new cases diagnosed annually in the US. Currently, only two drugs are approved for IPF (Esbriet and Ofev), with no new approvals in the past decade. While the approved drugs help slow disease progression, neither halts nor reverses it. Moreover, both these drugs are associated with significant gastrointestinal side effects, such as diarrhoea, nausea, stomach pain and vomiting. We foresee significant commercial potential for CS014 if it were to demonstrate disease-modifying properties in randomised studies.

Looking ahead, we expect the key upcoming catalyst for Cereno to be FDA clearance for the CS1 Phase IIb study, expected in Q225.

Price	**SEK7.16**
Market cap	**SEK1,936m**
Net cash/(debt) at 31 December 2024	SEK(62.8)m
Shares in issue	281.0m
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. Second asset CS014, a proprietary NCE and HDACi, is being developed for idiopathic pulmonary fibrosis, and preclinical asset CS585 is likely to target rare thrombosis-related indications.

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