EDISON

Cereno Scientific

Clinical update

CS014 achieves another Phase I milestone

Healthcare

13 February 2025

Cereno Scientific's second pipeline asset, CS014, continues to make steady progress through the clinic, with the company successfully completing the single ascending dose (SAD) part of the Phase I study which commenced in June 2024. The SAD part focused on evaluating the safety, tolerability and pharmacokinetics (PK) of CS014 in 30 healthy volunteers; results showcased a favourable safety profile. The second, multiple ascending dose (MAD) part of the study, which commenced in November 2024, is ongoing and management expects results in mid-2025, in line with previous guidance. CS014 is the company's second histone deacetylase inhibitor (HDACi) and has demonstrated anti-fibrotic, reverse remodelling and anti-thrombotic properties in preclinical studies. The target indication for CS014 is idiopathic pulmonary fibrosis (IPF), a rare, progressive disease, with no curative treatments and an average survival of three to five years. Management intends to commence Phase II in H126.

Year end	Revenue (SEKm)	PBT (SEKm)	EPS (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/22	0.0	(27.6)	(0.20)	0.00	N/A	N/A
12/23	0.0	(46.4)	(0.20)	0.00	N/A	N/A
12/24e	0.0	(78.8)	(0.28)	0.00	N/A	N/A
12/25e	0.0	(87.0)	(0.31)	0.00	N/A	N/A

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

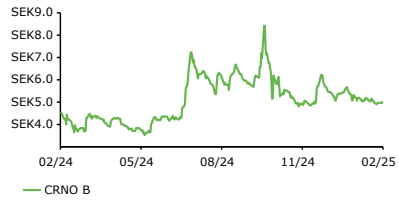
The ongoing Phase I trial is an open-label study designed to explore the safety, tolerability and PK of CS014 in healthy volunteers. A total of 48 subjects are expected to be enrolled in the study, 30 of which have been evaluated as part of the SAD portion. A supportive safety profile was widely expected from this part of the study, particularly following the Safety Monitoring Committee's green light in late 2024. The MAD portion of the study, assessing multiple ascending doses of CS014 over a seven-day period and will also test pharmacodynamics of CS014, commenced in November 2024. Management expects trial completion and topline results in mid-2025 (once the analysis has been conducted).

CS014, a new chemical entity, is a valproic acid analogue and the second candidate from Cereno's HDACi portfolio. It has a similar pharmacological profile to lead asset CS1, which is being developed for pulmonary arterial hypertension (PAH), and reported positive Phase IIa results in September 2024. Following Cereno's strategic repositioning as a rare disease-focused company in October 2024, IPF was selected as the target indication for CS014 (versus the broad label of thrombosis, previously). IPF is a serious chronic lung disease with 30,000–50,000 new cases diagnosed each year in the US alone. Available treatments only aim at managing disease progression and come with serious gastrointestinal side-effects, meaning life expectancy is limited to three to five years (five-year survival rate of c 45%). We foresee significant commercial potential for CS014 if it demonstrates disease-modifying properties in randomised clinical studies. Management has communicated plans to launch a Phase II trial in H126, which we believe will be a key milestone for the company.

In the nearer term, we expect FDA clearance for the CS1 Phase II or Phase IIb/III pivotal study as the most significant potential upcoming catalyst for Cereno (expected from H125). Following the recent SEK250m financing, we estimate the company will be funded into 2026, well beyond this inflection point.

Price	**SEK5.05**
Market cap	**SEK1,408m**
	SEK10.9/US$
Net cash/(debt) at 30 September 2024	SEK(16.6)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 CS1 analogue, will be tested in idiopathic pulmonary fibrosis, and preclinical asset CS585 is likely to target rare thrombosis-related indications.

Analysts

Jyoti Prakash, CFA +44 (0)20 3077 5700

Arron Aatkar, PhD +44 (0)20 3077 5700

healthcare@edisongroup.com

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20 Red Lion Street
London, WC1R 4PS
United Kingdom