EDISON

Cereno Scientific

CS1 takes another step towards Phase IIb

Healthcare

23 April 2025

Cereno Scientific has successfully completed its planned Type C meeting with the FDA for lead asset CS1. The minutes from the meeting will be available after 30 days, but Cereno has indicated that the regulators looked to be in alignment with the Phase IIb study design and planned steps for clinical development. Note that unlike Type A and Type B meetings, Type C meetings are not strictly required, although they offer the opportunity to engage with the regulators to ensure alignment with study objectives, design and endpoints, which supports the likelihood of a successful outcome. Following receipt of the official minutes of the meeting and outcome of the subsequent IND, management plans to commence the Phase IIb trial in H126. As indicated in our previous note, we expect Cereno to self-sponsor Phase IIb, before seeking a licensing partner for the Phase III registrational study and subsequent commercialisation.

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.

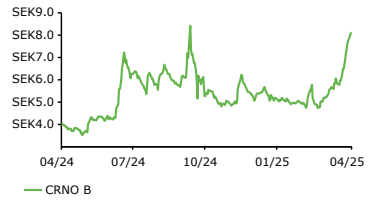
CS1 is a histone deacetylase inhibitor (HDACi) being developed as a potentially disease-modifying treatment for the rare condition, pulmonary arterial hypertension (PAH). Afflicting c 100,000 people in the US and Europe, PAH has average survival of seven to 10 years. Given the small patient populations, treatments for rare diseases often received incentives like research grants, tax credits, lower regulatory fees and longer market exclusivity. More recently, the new FDA Commissioner Marty Makary proposed an accelerated approval pathway for drugs targeting rare diseases based on 'plausible mechanism' of action, on a conditional basis, without requiring randomised control trials. If ratified, this should materially lower time to market for such treatments, which should benefit Cereno.

Compared to other drugs for PAH (eg Winrevair), CS1 offers more convenient oral administration and a relatively benign safety profile. Top-line data from the Phase IIa study, showed the drug's favourable tolerability and positive impact on exploratory clinical efficacy parameters. More detailed analysis, presented in March 2025, provided further support of CS1's ability to reverse vascular remodelling. Disease modification is the holy grail for therapeutics under development, particularly for progressive conditions like PAH. In this context, the latest data release from Cereno's Phase IIa CS1-003 trial was particularly encouraging, although we advise that this relates to a small cohort of c 21 patients.

Based on the Type C meeting, management believes the FDA is in alignment with the Phase IIb study design and plans, and further validation of this is expected with the release of the meeting minutes in May 2025. We believe this, along with the four-month follow-up data from the expanded access programme in June 2025, will be key upcoming catalysts for Cereno. If the observations are supportive, management plans to commence the Phase IIb trial in H126 and we assume this will be self-sponsored. However, should Cereno receive interest from a prospective partner and have shareholder support, a licensing deal prior to the Phase IIb initiation is also a possibility. This would require an adjustment to our projections.

Price	**SEK7.62**
Market cap	**SEK2,141m**
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.

Analysts

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

healthcare@edisongroup.com
Edison profile page

General disclaimer and copyright

This report has been commissioned by Cereno Scientific and prepared and issued by Edison, in consideration of a fee payable by Cereno Scientific. Edison Investment Research standard fees are £60,000 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or sol icitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

London | New York | Frankfurt
20 Red Lion Street
London, WC1R 4PS
United Kingdom