EDISON

Cereno Scientific

Firing on all cylinders

Q125 results

Healthcare

27 May 2025

In Q125, Cereno made tangible progress across both its clinical programmes. The period opened with new data for lead asset CS1 indicating disease-modifying signals, and was capped by FDA endorsement of the Phase IIb plan (May 2025). The next step will be an IND application for Phase IIb and we anticipate data from the extended access programme (EAP, expected by mid-2025) to bolster the regulatory dossier. With Phase I now complete for second asset CS014 and a top-line readout in June, we expect a catalyst-rich period ahead for Cereno. The SEK77m gross cash and anticipated SEK50m from the November 2024 bridge loan should provide a runway into 2026. We expect Cereno to begin partnering talks in advance of trial initiation in H126. We raise our probability of success for CS1 to 45% (from 40%) based on recent developments. We upgrade our valuation to SEK4.5bn (SEK16.0/share) from SEK4.0bn (SEK14.2/share) previously.

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	(94.8)	(0.34)	0.00	N/A	N/A
12/26e	0.0	(83.4)	(0.30)	0.00	N/A	N/A

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

FDA clearance for CS1 Phase IIb in sight

We believe the encouraging data from the Phase IIa study (with disease-modifying signals on exploratory efficacy measures) and recent FDA endorsement of the Phase IIb design and endpoints (post the Type C meeting in April 2025) support the continued development of CS1 in pulmonary arterial hypertension (PAH). We expect an Investigational New Drug application (IND) to be filed in H225, possibly supported by the four-month data from the EAP, which is expected by mid-2025. The Phase IIb trial is planned to commence in H126, and in our view Cereno is likely to engage in partnering discussions in the lead up to the trial.

CS014 on track for Phase I readout in June 2025

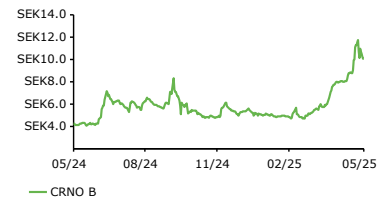
The first quarter of FY25 was also important for CS014, which is being developed to address idiopathic pulmonary fibrosis (IPF). Following the successful completion of the single ascending dose (SAD) portion of the Phase I safety study in February 2025, the second multiple ascending dose (MAD) portion was concluded in April. We look forward to top-line results (expected in June 2025), a key upcoming catalyst for Cereno. If data are supportive (acceptable safety profile in the SAD portion), it plans to initiate the Phase II trial in IPF in H126.

Valuation: SEK4.5bn or SEK16.0 per share

We update our near-term forecasts for the Q125 results, in which R&D and opex dipped y-o-y with the completion of previous trials. We also raise our probability of success for CS1 to 45%, following FDA endorsement of the Phase IIb plans. Accounting for this and latest net debt, our valuation adjusts to SEK16.0/share (vs SEK14.2/share).

Price	**SEK10.74**
Market cap	**SEK3,094m**
	SEK9.7/US$
Net cash/(debt) at 31 March 2025	SEK(103.4)m
Shares in issue	281.0m
Free float	93.0%
Code	CRNO B
Primary exchange	NGM
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	36.1	129.4	195.3
52-week high/low		SEK11.9	SEK3.7

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.

Next events

CS1: EAP update	Mid-2025
CS014: Phase I results	June 2025

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Edison profile page

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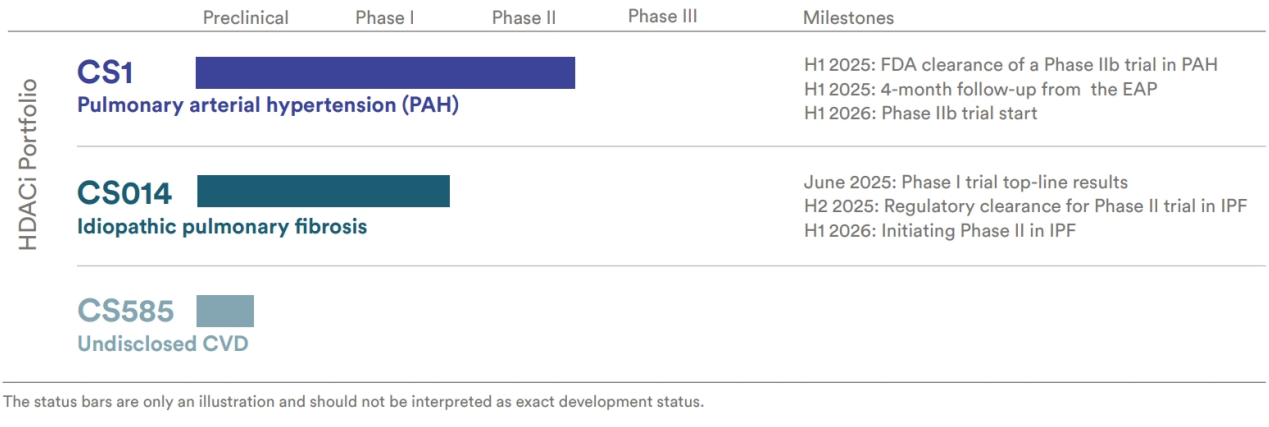
Clinical pipeline offers numerous upcoming milestones

In Q125 Cereno's clinical development focused on the EAP for CS1 (following positive Phase IIa data), the Fluidda sub-study and the Phase I safety study for CS014. Together, CS1 and CS014 form the company's histone deacetylase inhibitor (HDACi) portfolio, which aims to leverage the principles of epigenetic modulation to achieve disease modification across different cardiovascular and pulmonary indications. The third asset, CS585, a selective prostacyclin (IP) receptor agonist, continued to undergo preclinical analysis during the period, in preparation for entering clinical studies.

Exhibit 1: Cereno's clinical development pipeline and upcoming milestones



Source: Cereno Q125 report

CS1: A step closer to Phase IIb

CS1, Cereno's lead asset, is an HDACi designed to leverage the principles of epigenetic modulation to reverse pathological remodelling. It is a delayed immediate release formulation of valproic acid, and holds promise as a potential disease-modifier for PAH. Backed by positive Phase IIa top-line data in September 2024 and subsequent incremental data presented in Q125 specifically related to the drug's potential to produce reverse vascular remodelling and improve right heart function, the focus in recent months has been on preparing to advance CS1 to Phase IIb. We direct readers to our last update note for more details on the Phase IIa trial and subsequent incremental data.

During the quarter, Cereno focused on continued treatment and monitoring of patients enrolled in the EAP, which was available to the 21 patients who completed the 12-week treatment as part of the Phase IIa trial (CS1-003). We understand that as of December 2024, a total of 10 patients had enrolled for the EAP and a four-month follow-up update for these patients is expected by mid-2025, a key upcoming inflection point for Cereno. We believe this long-term data from the EAP is key to establishing continued benefits from the treatment with CS1. We also remind readers that in February 2025, a sub-study to the EAP, using novel imaging technology developed by Fluidda, was initiated, to visualise the effect of CS1 on inducing long-term reverse remodelling in PAH. We understand that the sub-study will enrol five to seven of the 10 patients in the EAP and results are expected in H126.

In April 2025, Cereno successfully completed its planned Type C meeting with the FDA, noting the regulator's alignment with the Phase IIb study design and planned steps for clinical development. This was confirmed by the meeting minutes released recently, with the FDA reported to have endorsed Cereno's Phase IIb plans. 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 agreement on study objectives, design and endpoints. This may support the likelihood of a successful outcome.

We expect the next step for Cereno will be the filing of the IND application for the planned Phase IIb trial and believe that the additional data from the EAP may be used as part of the regulatory dossier for this next stage of development. While the Phase IIb study design has not been disclosed as yet, we anticipate it to be a placebo-controlled trial designed to further evaluate the encouraging efficacy signs seen in the CS1-003 trial (including reverse vascular remodelling and improvement of right heart function). We also see the possibility of the trial being increased duration (around 24 weeks as compared to the 12-week CS1-003 study) which may potentially be driven by insights from the longer-term data from the EAP. Cereno 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 distinct possibility.

We note that while other products have been approved for PAH (notably the FDA approved Merck's sotatercept, brand name Winrevair, in March 2024), the established safety profile of VPA and potential for oral administration of CS1 could offer a competitive edge, especially if further clinical development efforts provide further evidence of its disease-modifying properties.

CS014: closing in on Phase I readouts

CS014 is the second candidate in Cereno's HDACi portfolio, and is a proprietary new chemical entity and deuterated valproic analogue of VPA. IPF was nominated as the target indication for CS014 at the company's capital markets day in 2024, whereby it announced a strategic pivot to specialise in the rare disease space. The Phase I study (designed to evaluate safety, tolerability, pharmacokinetics/PK and pharmacodynamics/PD of CS014 in 48 healthy volunteers) commenced in June 2024 and was recently concluded. The SAD part of the study, which evaluated safety, tolerability and PK of CS014 in 30 participants, was completed in February 2025 and showed no safety concerns. More recently, the MAD part of the study, which also assessed PD of CS014 in 18 participants over a seven-day period, concluded in April 2025. Data management and analysis is currently ongoing, and the Q125 update confirmed that the top-line results are on-track to be reported in June 2025, another near-term catalyst for Cereno.

Should the Phase I results be favourable, Cereno intends to undertake a Phase II study in H126, which will include IPF patients as part of its strategic focus on rare diseases. We believe that toxicology studies required prior to the initiation of the Phase II study have already commenced. Currently, there are only two drugs approved for IPF, Esbriet (pirfenidone) and Ofev(nintedanib), with no new approvals in the past decade. While the approved drugs help slow disease progression, neither halts nor reverses it. Moreover, these drugs are associated with severe side effects and tolerability issues. This offers a potentially sizeable opportunity for Cereno, should CS014 demonstrate disease modification in IPF patients.

CS585: bolstering the preclincial data package

The company's third asset, CS585, is an oral, selective and potent inhibitor of the prostacyclin (IP) receptor, in the preclinical stages of development. A precise indication is yet to be determined for CS585, but early-stage research has showcased its promise as a potential treatment to prevent thrombosis without increased risk of bleeding, aiming to address a key limitation of current anti-thrombotic medications. The promise it has shown in preclinical studies has been recognised with a publication in the high-impact factor journal *Blood*. The latest updates demonstrated that CS585 inhibits platelet activation and clot formation for up to 24 hours after being administered, and showed that it is highly selective for the IP receptor, providing sustained prevention of thrombus formation. We understand the drug continues to be evaluated in the preclinical setting, and we await further information from management on the plans to progress to the clinic.

Financials

Lower opex offset by higher interest expenses

Being a clinical stage company, Cereno does not have a recurring revenue stream and does not report sales. In Q125, the company reported total operating expenses of SEK34.0m, down 4.2% y-o-y (Q124: SEK35.5m) and 12.5% q-o-q (Q424: SEK38.8m). This included external costs of SEK24.9m (Q124: SEK28.7m and Q424: SEK30.1m) and personnel expenses of SEK8.9m (up 41.5% y-o-y and 13.3% q-o-q). Cereno capitalises its R&D on the basis of which we estimate the Q125 R&D expenses (which are a part of external costs) to be SEK16.1m, materially lower than the Q124 figure of SEK21.6m. We attribute the decline to be driven by the completion and subsequent readout of the Phase IIa CS1 study in Q324 and estimate the remaining costs to be related to the ongoing EAP for CS1, the Phase I study for CS014 (which was completed in April 2025 with top-line data expected in June 2025), toxicology studies to prepare for the CS014 Phase II study and preclinical activities on the third pipeline asset, CS585. Given the completion of the CS014 phase I study and expected H126 timeline for the initiation of the CS1 Phase IIb and CS014 Phase II studies, we expect the R&D costs to decline over the remaining quarters of FY25. The Q125 operating loss was SEK17.5m (including other income of SEK0.3m), up 26.7% from the Q124 figure of SEK13.8m. Note that this does not reflect the impact from the lowered R&D expenses, given these expenses are capitalised on the balance sheet. Net loss in Q125 rose 62% y-o-

y to SEK25.0m (Q124: SEK15.4m) due to the increased interest expenses (SEK7.5m in Q125 vs SEK1.6m in Q124) related to the SEK SEK250m financing arrangement announced in November 2024. This was reflected in the free cash outflows, which increased to SEK40.6m (+6.8% y-o-y) despite the lower R&D costs.

Funded into Q126 with current cash and SEK50m in available debt drawdown

Cereno ended Q125 with a gross cash balance of SEK77m and debt outstanding of SEK180.4m (maturing on 30 April 2026). This includes the repayment of SEK10m of debt in Q125. As a reminder, Cereno had raised SEK250m in short-term financing in November 2024, from Fenja Capital and Arena Investors. The financing included a cash loan of SEK175m across two tranches and SEK75m in convertible debt. While the first cash tranche of SEK125m and the SEK75m convertible debt (total SEK200m) was made available to Cereno immediately, the pending SEK50m payout was conditional on CS1 receiving FDA approval for the next clinical phase as well as certain other financial conditions. While details on the covenants for the latter are not available, we believe that the recent FDA endorsement (following the successful EoP2 meeting) paves the way for the IND filing and subsequent regulatory clearance, meaning that these funds could be made available to the company as early as Q325. Accounting for these inflows, we believe that Cereno is funded into 2026 as it approaches the next clinical development stages for both CS1 and CS014.

Estimates revision

Based on the Q125 results, We have made modest reductions to our FY25 and FY26 R&D estimates - SEK55m and SEK170m, respectively, from SEK65m and SEK182.5m previously. This, however, has been largely offset by the higher personnel costs we now assume to reflect the Q125 trend (SEK32.3m and SEK33.9m in FY25 and FY26, respectively vs SEK27.1m and SEK28.5m previously). As a result, our operating loss estimates for FY25 and FY26 stay largely unchanged at SEK71.0m and SEK73.0m (from SEK70.5m and SEK72.2m previously).

Valuation

Our valuation for Cereno is based on a risk-adjusted net present value (rNPV) approach, using appropriate probabilities of success for the respective phases of development and a flat discount rate of 12.5%. The calculated enterprise value reflects contributions from the company's clinical candidates CS1 (completed Phase IIa) and CS014 (completed Phase I). Note that our valuation excludes CS585, which is currently undergoing preclinical development, and should add to the upside potential on successful clinical transition. Based on the Q125 results, we keep our underlying assumptions for future sales and market potential for CS1 unchanged but raise our probability of success to 45%, from 40% previously, given the recent FDA endorsement of the Phase IIb design, objectives and endpoints. For CS014, we maintain our estimates for now but will revisit our assumptions (including PoS) following the Phase I readout in June 2025.

Based on the aforementioned updates and incorporating the latest net debt figure (SEK103.4mn at end-Q125, including SEK77.0m in gross cash and SEK180.4m of debt), our valuation for Cereno upgrades to SEK4.5bn or SEK16.0/share, from SEK4.0bn or SEK14.2/share (Exhibit 2).

Exhibit 2: Cereno's rNPV valuation

Asset	Indication	Development phase	Launch	Peak sales ($m)	Peak sales year	NPV (SEKm)	Probability	rNPV (SEKm)	rNPV/share (SEK)
CS1	PAH	Phase IIb-ready	2031	2,043	2038	9,077.7	45%	4,085.0	14.5
CS014	IPF	Phase I	2032	2,123	2042	5,107.3	10%	510.7	1.8
Total						14,185.0		4,595.7	16.4
Net debt at 31 March 2025								(103.4)	(0.4)
Valuation								**4,492.3**	**16.0**

Source: Edison Investment Research. Note: The per share valuation is calculated on shares outstanding of 281m

While we note that Cereno may already be readying for talks with potential licensing partners for CS1 and potentially CS014 (as reflected in the proposed new board composition with members with M&A, partnering and business development backgrounds) our model assumes that the company will undertake the Phase IIb trial for CS1 on its own before licensing it out to a partner for Phase III development and subsequent commercialisation. We reflect this deal happening in 2028, with a total deal value of US$2bn, including an upfront licensing payment of US$100m. Note that the deal value is likely to be proportionally lower, should the partnering agreement take place prior to Phase IIb.

As an added sensitivity, however, if we were to assume no partnering deal, with Cereno opting to self-develop and

self-commercialise the asset, we estimate the company would need to raise SEK500m in FY26 to fund operations and service outstanding debt and a further SEK1.5bn between FY27 and FY30, until the commercial launch of CS1 in 2031 (a total of SEK2bn between FY26 and FY30). If these funds are raised through equity issues, we estimate Cereno would need to issue c 198.2m shares (assuming the current share price of SEK10.09), which would result in our per-share valuation diluting to SEK13.5/share, from SEK16.0/share currently.

Exhibit 3: Financial summary

Accounts: K3, Yr end: December 31, SEK:000s	2022	2023	2024	2025e	2026e
PROFIT & LOSS					
Net sales	**0**	**0**	**0**	**0**	**0**
Capitalised work for own account	57,538	49,277	80,903	55,000	170,000
Total revenues	57,538	49,277	80,903	55,000	170,000
Total operating expenses	(85,037)	(93,927)	(156,739)	(126,041)	(243,003)
R&D and other expenses	(76,620)	(71,152)	(128,675)	(93,405)	(208,789)
Of which - R&D expenses	*(57,538)*	*(49,277)*	*(80,903)*	*(55,000)*	*(170,000)*
Of which - other expenses	*(18,899)*	*(21,658)*	*(46,880)*	*(37,504)*	*(37,879)*
Personnel costs	(7,514)	(18,763)	(26,108)	(32,636)	(34,213)
Other operating items	(903)	(4,012)	(1,956)	0	0
Operating income (reported)	(27,499)	(44,650)	(75,836)	(71,041)	(73,003)
EBITDA (normalized)	(27,485)	(44,636)	(75,549)	(70,681)	(72,679)
Finance income/(expense)	(149)	(3,456)	(23,690)	(23,752)	(10,374)
Profit before tax (reported)	(27,649)	(48,106)	(99,526)	(94,792)	(83,377)
Profit before tax (normalised)	(27,649)	(46,436)	(98,106)	(94,792)	(83,377)
Income tax expense (includes exceptionals)	(6)	0	0	0	0
Net income (reported)	(27,654)	(48,106)	(99,526)	(94,792)	(83,377)
Net income (normalised)	(27,654)	(46,436)	(98,106)	(94,792)	(83,377)
End of period number of shares, '000	137,515	233,775	281,702	281,702	281,702
Basic EPS (SEK)	(0.20)	(0.21)	(0.35)	(0.34)	(0.30)
Adjusted EPS (SEK)	(0.20)	(0.20)	(0.35)	(0.34)	(0.30)
BALANCE SHEET					
Intangible Assets	146,987	196,264	277,167	332,167	502,167
Fixtures, tools and installation	29	14	3,599	3,239	2,915
Other long-term receivables	10	9	10	10	10
Total non-current assets	147,025	196,287	280,775	335,415	505,092
Other receivables	1,248	1,124	2,880	2,202	2,795
Prepaid expenses and accrued income	335	407	2,540	2,540	2,540
Cash and bank balance	67,046	87,169	127,578	16,091	32,855
Total current assets	68,629	88,699	132,997	20,832	38,189
Accounts Payable	9,411	6,930	13,951	11,218	21,628
Other Current Liabilities	4,331	16,231	17,495	17,495	17,495
Short-term Debt	0	0	0	0	0
Total current liabilities	13,742	23,162	31,446	28,713	39,124
Long-term Debt	0	45,000	190,000	230,000	490,000
Other debt	400	400	400	400	400
Total non-current liabilities	400	45,400	190,400	230,400	490,400
Equity attributable to company	201,511	216,424	191,926	97,134	13,757
CASH FLOW STATEMENT					
Net profit	(27,654)	(48,106)	(99,526)	(94,792)	(83,377)
Depreciation	14	14	287	360	324
Translation difference	(90)	34	0	0	0
Accrued costs	450	777	6	0	0
Share based payments	0	1,671	1,420	0	0
Taxes paid	(4)	0	0	0	0
Movements in working capital	8,669	8,695	(5,609)	(2,055)	9,817
Cash from operations (CFO)	(18,615)	(36,915)	(103,422)	(96,487)	(73,236)
Purchase of intangible assets	(57,538)	(49,277)	(80,903)	(55,000)	(170,000)
Purchase of PPE	0	0	(3,871)	0	0
Cash used in investing activities (CFIA)	(57,538)	(49,277)	(84,774)	(55,000)	(170,000)
Loans received	0	45,000	245,000	50,000	500,000
Loan repayments	(5,000)	0	(90,000)	(10,000)	(240,000)
Equity issued	58,791	61,315	73,605	0	0
Other Financing Cash Flows	(226)	0	0	0	0
Cash from financing activities (CFF)	53,564	106,315	228,605	40,000	260,000
Cash and equivalents at beginning of period	89,635	67,046	87,169	127,578	16,091
Increase/(decrease) in cash and equivalents	(22,589)	20,123	40,409	(111,487)	16,764
Cash and equivalents at end of period	67,046	87,169	127,578	16,091	32,855
Net (debt)/cash	66,646	41,769	(62,822)	(214,309)	(457,545)

Source: Company documents, Edison Investment Research

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