Cereno Scientific

Sector: Biotech

Clinical-stage orphan opportunity

Redeye initiates coverage of Cereno Scientific, a biotech company developing drugs to treat both rare and common cardiovascular diseases. Cereno is about to initiate a phase II clinical trial with lead candidate CS1 in pulmonary arterial hypertension, a commercially attractive orphan disease.

Pulmonary arterial hypertension: Paradigm shift

Cereno will start its phase II clinical trial with lead candidate CS1 in pulmonary arterial hypertension (PAH) during H2 2021. PAH is a commercially attractive orphan disease with no disease-modifying treatments on the market. CS1 has a unique mechanism of action and is the only epigenetic modulator in clinical development for PAH. Cereno has secured orphan drug designation for CS1 in the US, providing seven years of market exclusivity following approval for PAH treatment. Recently approved drugs for PAH treatment cost approximately USD 150,000 to USD 200,000 per patient per year in the US, indicating substantial pricing power.

Besides PAH, label expansions of CS1 to other cardiovascular diseases could be possible due to CS1's antithrombotic, antifibrotic, anti-inflammatory, and pressure reducing properties.

Attractive for big pharma players

United Therapeutics and Johnson & Johnson have established themselves as leaders on the PAH drug market. If successful in phase II (and phase III) clinical trials, we believe CS1 will be highly attractive for licensing to these or other actors in the PAH/cardiovascular disease (CVD) field. Further, we do not exclude the possibility of Cereno becoming an acquisition target in such a scenario.

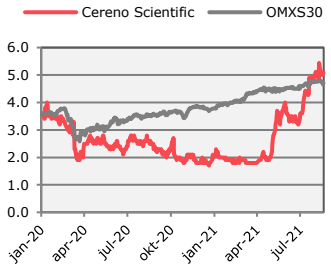
Valuation

Our valuation model suggests a Base Case at SEK 6.0 per share taking into account the approaching warrant exercise in September 2021. Further, our Bull Case and Bear Case project fair value at SEK 11.0 and SEK 2.3, respectively. If Cereno presents strong phase II data with CS1, we see potential for the stock to rally towards our current Bull Case in H2 2022.

FAIR VALUE RANGE

BEAR	BASE	BULL
2.3	6.0	11.0

CERENO VERSUS OMXS30



REDEYE RATING

KEY STATS

Ticker	CRNO B
Market	Spotlight Stock Market
Share Price (SEK)	5.1
Market Cap (SEKm)	366
Net Debt (SEKm)	-46
Free Float	90.4%
Avg. daily volume ('000)	481.6

SEKm (Risk-adjusted)	2019	2020	2021E	2022E	2023E
Net sales	-	-	-	-	-
EBITDA	(13)	(16)	(42)	(45)	(33)
EBIT	(13)	(16)	(42)	(45)	(33)

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Investment thesis

Commercially attractive PAH market

The pulmonary arterial hypertension (PAH) market is a commercially attractive space with high profit potential. Cereno is about to initiate a phase II clinical trial in PAH with lead candidate CS1, together with collaboration partner Abbott using Abbott's CardioMEMS™ HF System. Today's available PAH treatments only improve function and delay disease progression somewhat, with lung transplantation being the only curative treatment available. However, the vast majority of patients are not eligible for transplantation, given their precarious state. Therefore, there exists a large unmet need for a disease-modifying treatment. We judge CS1 has potentially disease-modifying properties with its unique mechanism of action. Drugs approved for PAH treatment tend to have high pricing power, and we estimate CS1's price at c. USD 160,000 per patient per year in the US, where over 70% of PAH patients in the major markets (US, EU5, JP) reside. Our sales model projects peak CS1 sales in PAH at some USD 750m in 2033 (not risk-adjusted).

Besides PAH, label expansions of CS1 to other cardiovascular diseases could be possible due to its antithrombotic, antifibrotic, anti-inflammatory, and pressure-reducing properties. Estimates project global CVD drug sales to grow at 4% CAGR from c. USD 92b in 2021 to c. USD 108b in 2025 (Research and Markets). In addition to CS1, the company has two preclinical candidates (CS014 and CS585), aiming to transition them to clinical trials within two years.

Near-term capital raises secure financing

Upcoming warrant exercises in September 2021 and September 2022 could raise up to SEK 98.4m and SEK 114.8m before costs, respectively. We project that this will fund Cereno's operations into 2024, reducing near-term financing risk. Further, we believe phase II PAH trials with CS1 starting in H2 2021 and topline data in H2 2022 will generate interest in Cereno's stock, allowing the company to exercise these warrants at attractive valuations.

Valuation

Adjusting for increased cash and dilution from the upcoming September 2021 warrant exercise, our Base Case amounts to SEK 6.0 per share. Similarly, our Bull Case and Bear Case come in at SEK 11.0 and SEK 2.3 per share, respectively. If CS1 phase II trials in PAH deliver strong topline data, we believe the stock price could rally to our current Bull Case and beyond in H2 2022.

We judge that CS1 being an advanced controlled-release formulation of valproic acid (an API used in, e.g., epilepsy treatment) and favorable phase I data de-risk CS1 development. We believe safety and tolerability issues are unlikely, and our investment thesis mainly rests on future clinical trials proving CS1's efficacy in PAH treatment.

Counter thesis

Crowded PAH development pipeline

There are four classes of approved PAH drugs on the market. Further, we identified some 25 drug candidates in clinical development for PAH. Therefore, Cereno's lead candidate CS1 faces broad competition. Today, all approved PAH drugs merely treat symptoms but do not prevent disease progression. If clinical trials show that CS1 has similar efficacy as existing treatments but is not disease-modifying, market share may be lower than expected, negatively impacting its potential.

Development risk

CS1's clinical efficacy in PAH is yet unproven. Phase I studies have shown good safety and tolerability in healthy volunteers. However, failure to show CS1's efficacy in upcoming clinical trials would be a substantial setback for Cereno. Other phase II trials with CS1 could be run in further CVD indications if unsuccessful in PAH. However, this would likely require several new share issues. We estimate a 20% likelihood of approval (LoA) for CS1. Cereno aims to transition its two preclinical drug candidates into the clinic within two years. This would diversify its clinical pipeline and thus spread risk over several assets.

Patent challenges

Physicians have treated epilepsy and bipolar disorder with valproic acid for many years. Thus, Cereno does not have a patent on the molecule itself. CS1 is an advanced controlled-release formulation of valproic acid. Cereno secured IP protection/market exclusivity with clinical use patents, formulation patents, and ODD until 2035, with potential extension of up to five years. However, there is still a risk that some generic manufacturers may try to challenge Cereno's patent protection for CS1 in indications not protected by ODD. Notably, we think a patent challenge would likely fail. However, the legal process could be expensive in case of a patent dispute, even if Cereno successfully defends its IP.

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Company description

Located in Gothenburg, Cereno Scientific is a biotech company developing drugs to treat both rare and common cardiovascular diseases. Prof. Sverker Jern, Dr. Niklas Bergh, and Dr. Pia Larsson founded Cereno in 2012 with seed financing from GU Ventures AB.

In 2015, Cereno developed an advanced controlled-release formulation of valproic acid named CS1, tailored explicitly for thrombotic CVD treatment to mimic diurnal thrombosis risk. In 2016, the company went public on Spotlight Stock Market and raised c. SEK 22m before costs at SEK 7.5 per share. The following year Cereno started a phase I study with CS1 in healthy volunteers (Bergh et al. 2018).

In 2019, the company received approval to start a phase II study with CS1 to prevent venous thromboembolism (VTE) after total knee replacement. The intended main indications at the time were deep vein thrombosis (DVT) and stroke prevention in atrial fibrillation (SPAF). However, the COVID-19 pandemic prevented this trial from commencing, and development for these indications is now on hold until phase II studies with CS1 in PAH are completed.

In early 2020, the FDA granted Cereno an ODD for CS1 in PAH treatment. The company chose to refocus development on this indication and established a US subsidiary in Boston, Massachusetts. Moreover, Cereno took in SEK 60m in a directed share issue.

Cereno plans to start phase II trials with CS1 for PAH treatment in H2 2021. Results are expected in H2 2022 and will be an important milestone to establish epigenetic modulation in PAH treatment, we judge.

Cereno Scientific: Historical Highlights

2009	- Prof. Sverker Jern et al. discover HDAC inhibitors' anti-thrombotic effects.
2012	- Seeded by GU Ventures AB, Prof. Sverker Jern, Dr. Niklas Bergh, and Dr. Pia Larsson incorporate Cereno Scientific AB. - Cereno initiates preclinical animal studies with valproic acid in pigs.
2013	- Clinical studies with valproic acid in healthy volunteers and patients commences.
2014	- Preclinical and clinical results show valproic acid's anti-thrombotic effects (Svennerholm et al. 2014, Saluveer et al. 2014).
2015	- Study published showing that valproic acid lowers PAI-1 blood levels in human stroke patients (Svennerholm et al. 2015).
2016	- Cereno enters agreement with Galenica AB to develop CS1, an advanced extended-release formulation of valproic acid. - IPO on Aktietorget (now Spotlight Stock Market). - Cereno receives approval for their phase I clinical trial application with CS1.
2017	- Cereno initiates phase I clinical trial with CS1 in healthy volunteers.
2018	- Positive clinical results from phase I trial with CS1 in healthy volunteers (Bergh et al. 2018).
2019	- Cereno acquires CS014 from Emeriti Bio AB, a preclinical drug candidate for treatment of CVD.
2020	- Cereno reorients CS1's development for treatment of the orphan disease PAH. FDA grants ODD in PAH treatment for CS1. - Planned and approved phase II study with CS1 in VTE is suspended due to COVID-19 pandemic. - Cereno establishes US subsidiary in Boston. - The company takes in SEK 60m before costs in directed share issue.
2021	- Cereno signs option agreement with University of Michigan to in-license CS585. - Collaboration with the University of Michigan for CS014/CS585 preclinical development initiated, to be completed H2 2023. - September: Phase II study with CS1 in PAH to be initiated in the US.

Source: Cereno Scientific, Redeye Research

People

Management all have ample experience in their respective tasks, bringing a broad spectrum of knowledge that enables them to perform their functions competently. The CEO, CFO, CMO, CSO, and Chief IP Officer hold decent stock positions (c. 1-2% of shares outstanding), aligning their interests with shareholders. Further, certain management and board members have been issued warrants as part of an incentive program in 2019 (see appendix 1). Members of management and the board who own shares also hold warrants of series TO1 and TO2 allocated to shareholders in Cereno's directed share during September 2020 (not listed in appendix 1). For a more detailed description of the management and board of directors, see appendix 1.

Ownership

Cereno's stock remains undiscovered by institutional capital. Shareholders are mainly private investors, insiders, and retail investors. A share ownership is restricted to founders/early employees. Collectively, management and board members own some 9.6% of share capital. We believe institutional ownership will increase if Cereno can present positive phase II and phase III results, de-risking lead candidate CS1. Cereno currently does not have any controlling shareholder(s).

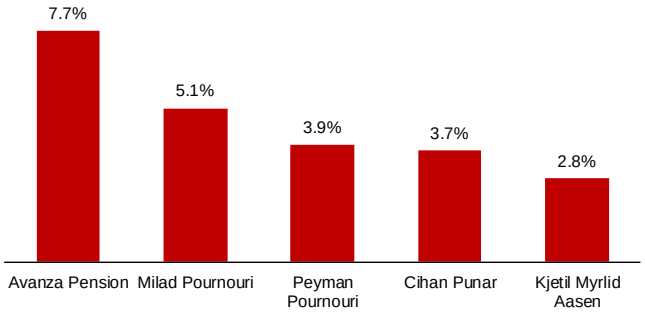
Cereno Scientific: Share ownership

Ownership

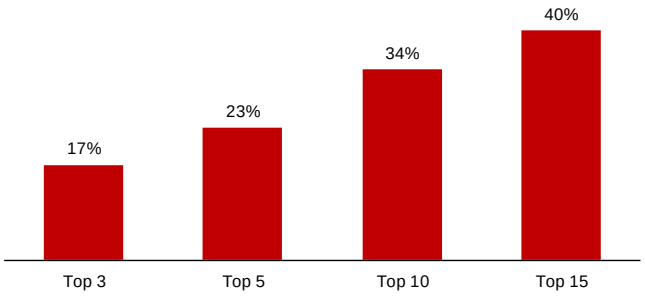
Rank	Shareholder	A-Shares	B-Shares	Total Shares	Share Capital	Voting Rights
1	Avanza Pension	0	5,532,828	5,532,828.0	7.7%	7.1%
2	Milad Pournouri	0	3,684,000	3,684,000.0	5.1%	4.7%
3	Peyman Pournouri	0	2,816,200	2,816,200.0	3.9%	3.6%
4	Cihan Punar	0	2,658,300	2,658,300.0	3.7%	3.4%
5	Kjetil Myrlid Aasen	0	2,000,000	2,000,000.0	2.8%	2.6%
6	Ivar Nordqvist	0	1,813,053	1,813,053.0	2.5%	2.3%
7	Dory Gevryie	0	1,600,000	1,600,000.0	2.2%	2.0%
8	GU Ventures	0	1,556,497	1,556,497.0	2.2%	2.0%
9	Sverker Jern	232,760	988,567	1,221,327.0	1.7%	4.2%
10	Niklas Bergh	230,128	964,995	1,195,123.0	1.7%	4.2%
11	Nordnet Pensionsförsäkring	0	1,097,016	1,097,016.0	1.5%	1.4%
12	Mie Usuda	0	1,058,468	1,058,468.0	1.5%	1.4%
13	Hadi Ghafori	0	962,143	962,143.0	1.3%	1.2%
14	Björn Dahlöf	123,920	832,815	956,735.0	1.3%	2.6%
15	Jonas Säljö	135,440	736,174	871,614.0	1.2%	2.7%
	Total 15 Largest Shareholders	**722,248**	**28,301,056**	**29,023,304**	**40.4%**	**45.4%**
	Others		42,796,008	42,796,008	59.6%	54.6%
	Total Number of Shares	**722,248**	**71,097,064**	**71,819,312**	**100.0%**	**100.0%**
				Free Float	90.4%	

Source: Modular Finance AB as of 2021-08-20

Top 5 Shareholders



Ownership Concentration



Source: Modular Finance, Redeye Research

Share performance

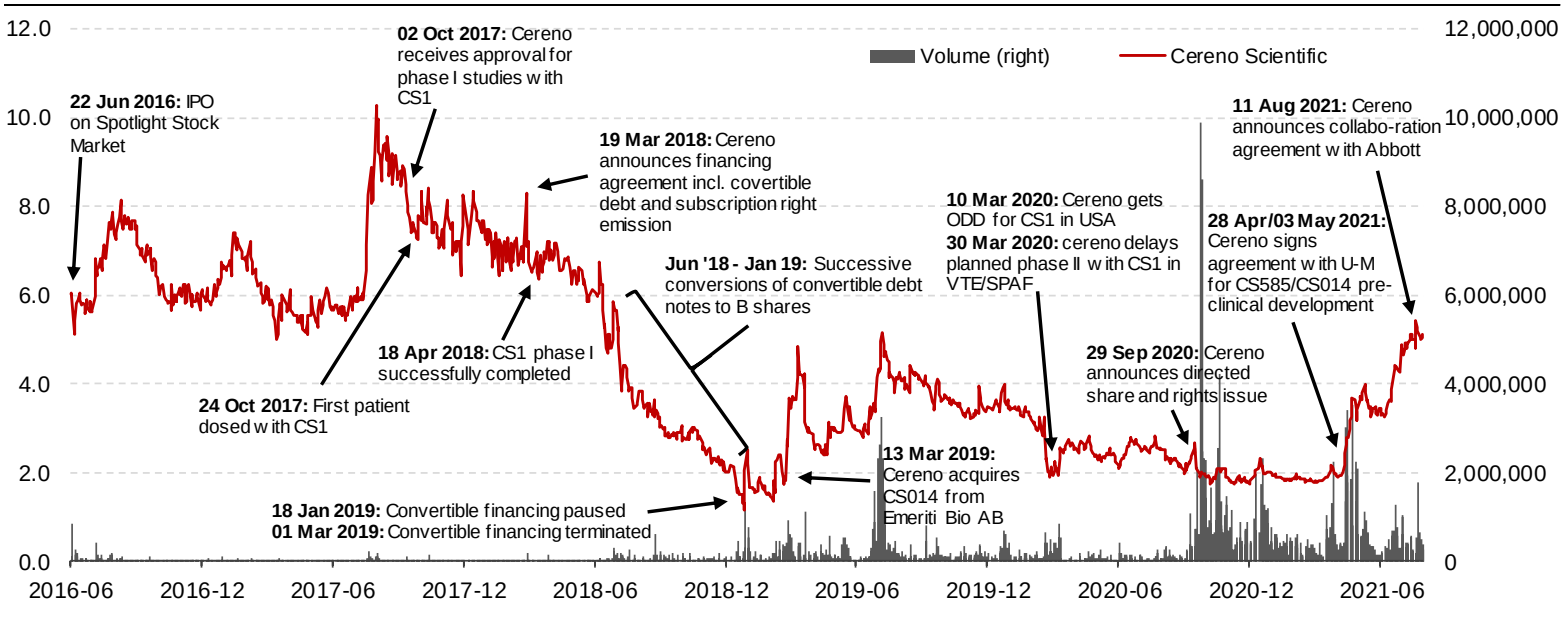
While volatile throughout, Cereno's stock price did not change much from its initial SEK 6 price between June 2016 and June 2018. Following a financing agreement with European High Growth Opportunities Securitization Fund (EHGOSF), Cereno issued convertible notes and subscription rights to the issuer in 2018. EHGOSF converted issued notes to B shares throughout the second half of 2018. We judge EHGOSF selling its newly printed shares negatively pressured Cereno's share price, declining from SEK 6 in June 2018 to some SEK 1.5 in January 2019.

Terminating the EHGOSF financing agreement and announcing CS014's acquisition in Q1 2020 made the share rally to around SEK 4. We suspect that terminating the financing agreement and therefore reducing selling pressure from EHGOSF likely contributed to the share price rally. The COVID crash and dilution from a directed share & warrant issue put negative pressure on the stock price in 2020, ending the year at some SEK 2.

Cereno entering a preclinical development agreement with U-M seems to have improved sentiment around the share, which rallied above SEK 4 during Q2 2021. Additionally, Cereno's share rallied to over SEK 5 following the announcement that it will collaborate with Abbott in its upcoming phase II trial in PAH and use Abbott's CardioMEMS™ HF System.

In the coming year, we believe presenting phase II topline data in H2 2022 will be the major catalyst. We estimate that timely trial initiation and topline data presentation will generate interest and obtain favorable exercise prices for the coming rights issues. In contrast, dilution from rights exercises in September 2021 and September 2022 could put some short-term selling pressure on the stock. If Cereno can present strong phase II data in H2 2022, we believe the stock can re-rate to our current Bull Case at SEK 11.0.

Cereno Scientific: Share price development



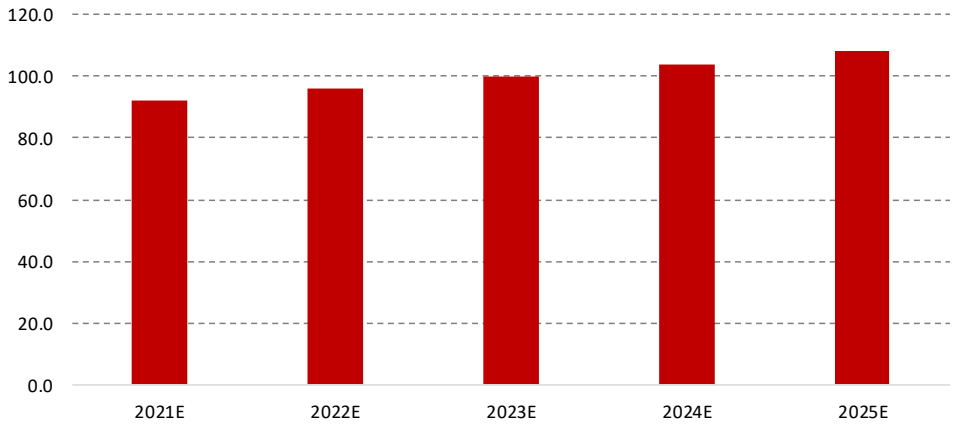
Source: Yahoo Finance, Cereno Scientific, Redeye Research

Project description

Cardiovascular diseases

Experts estimate global CVD deaths at some 17.9 million annually, constituting the largest cause of death globally. Strokes and heart attacks feature most prominently, with 80% of CVD deaths (World Health Organization). *Research and Markets* projects the global CVD drug market to grow at 4% CAGR from c. USD 92b in 2021 to c. USD 108b in 2025. While many different underlying pathologies can cause CVDs, thrombotic complications are the most common. The market's sheer size illustrates the sales potential drugs targeting this disease category may have. A major risk factor for developing CVDs is hypertension, i.e., high blood pressure. Evidence suggests that over 1.5 billion people will suffer from hypertension by 2025 (Lackland and Weber 2015).

Global CVD drugs market (USDb)



Source: Research and Markets, Redeye Research

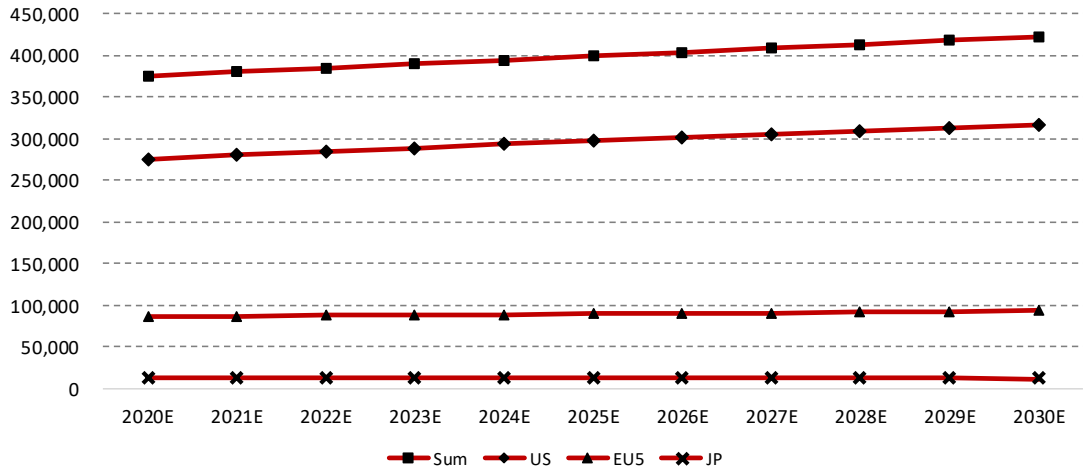
Pulmonary hypertension

Pulmonary hypertension (PH) is a chronic progressive cardiovascular disease commonly divided into five clinical subgroups (Yaghi et al. 2020, Mandras et al. 2020):

- Group 1: Pulmonary arterial hypertension (PAH)
- Group 2: PH due to left-sided heart disease (PH-LHD)
- Group 3: PH due to chronic lung disease/hypoxia (PH-CLD)
- Group 4: PH due to pulmonary artery obstruction (also known as chronic thromboembolic PH or CTEPH)
- Group 5: PH with unclear/multifactorial mechanisms

PH is life-threatening and eventually fatal in many patients. Datamonitor estimates PH prevalence in the US, EU5 (Germany, France, Spain, Italy, the UK), and Japan at c. 375,000 in 2020, growing at some 1.2% CAGR to c. 422,000 in 2030. Notably, the US has a disproportionate share with an estimated 276,000 patients in 2020 (Datamonitor). Combining high disease prevalence and drug pricing has made the US the commercial focus among companies developing PH therapies.

Pulmonary Hypertension est. Diagnosed Prevalence 2020-2030

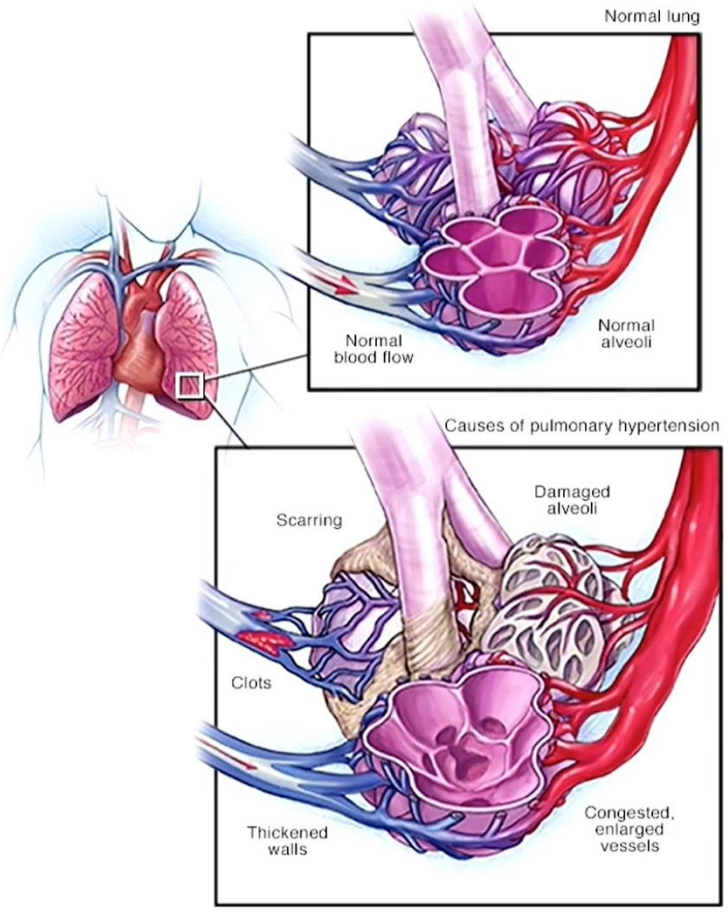


Source: Datamonitor, Redeye Research

Pulmonary arterial hypertension

PAH (pulmonary hypertension group 1) is an orphan disease in itself, with incidence estimates ranging from 2.0 to 7.6 cases per million adults and prevalence between 11 and 26 cases per million adults (Thenappan et al. 2018). PAH features progressive adverse remodeling of lung vasculature, especially in small pulmonary arterioles. Pulmonary blood vessels become progressively narrower, resulting from increased artery contractility, endothelial dysfunction, endothelial + smooth muscle cell proliferation, and *in situ* thrombosis (Lai et al. 2014). Simply stated, abnormal cell growth in the blood vessels leading from the right side of the heart to the lungs results in progressive thickening of the vessel walls. This, in turn, leads to progressively increasing pulmonary artery pressure. As the disease progresses, blood clots frequently occur in the same blood vessels, further hindering blood flow.

Comparison healthy pulmonary vasculature vs. PAH pulmonary vasculature

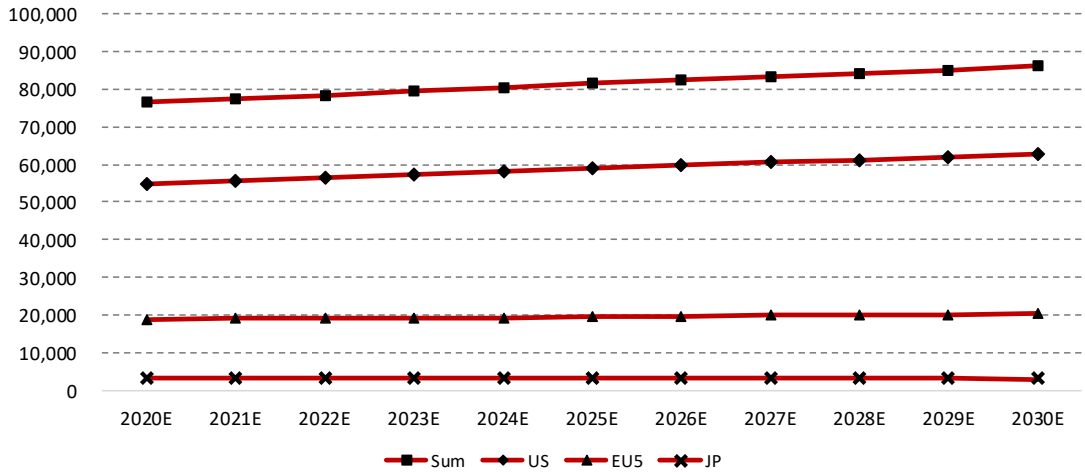


Source: Cereno Scientific, Hibiscus BioVenture

These changes result in progressive dysfunction and eventual failure of the heart's right ventricle, as it must pump blood against increasing resistance. PAH patients face a poor prognosis, with some reported five-year survival rates as low as 39% (Mandras et al. 2020). Almost 50% of PAH cases have an idiopathic origin, i.e., their cause is unknown. The next largest group constitutes PAH associated with connective tissue diseases, making up around 15% to 25% of PAH patients. Remaining PAH categories include heritable PAH (<5%), drug/toxin-induced PAH (5-10%), chronic congenital heart disease-associated PAH (c. 12%), and HIV infection-associated PAH (some 2-3%; Lai et al. 2014).

Notably, while PAH patients constitute c. 20% of PH patients, PAH is the commercial focus among pharmaceutical companies in the PH space. Groups 2-5 are relatively abandoned, leading to frequent off-label use of PAH drugs in these cohorts. According to Datamonitor, PAH prevalence in the US, EU5, and Japan was some 77,000 in 2020, growing at c. 1.2% CAGR to 86,000 in 2030. Datamonitor estimates worldwide PAH prevalence of around c. 218,500 in 2018 to grow at a modest 0.5% CAGR to c. 241,800 in 2040. US PAH prevalence is estimated to grow at 1.4% CAGR between 2020 and 2030, ahead of EU5 at 0.7% CAGR and Japan at -0.4% CAGR (Datamonitor).

Pulmonary Arterial Hypertension est. Diagnosed Prevalence 2020-2030



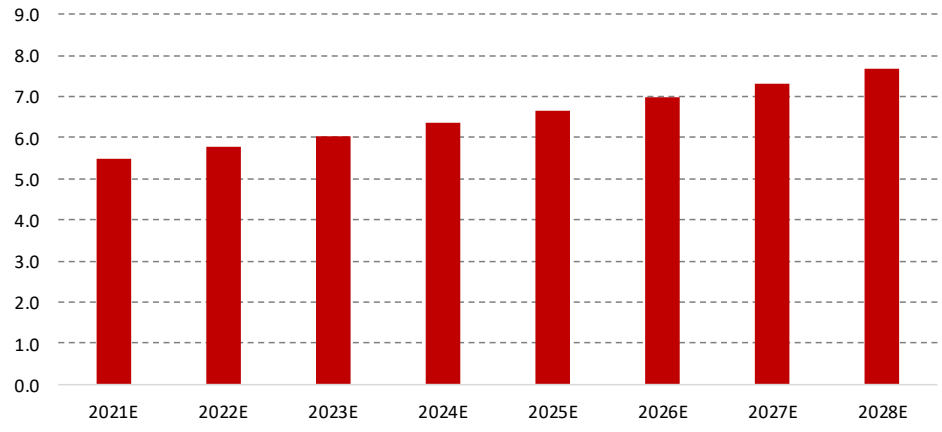
Source: Datamonitor, Redeye Research

Grand View Research estimates the global PAH market to grow from USD 5.5b in 2021 to 7.7b in 2028 (4.9% CAGR). Today, all available PAH drugs treat symptoms but not disease progression. Lack of disease-modifying drugs represents an unmet need with considerable commercial potential. PAH-specific treatment commonly involves four drug classes (Thenappan et al. 2018):

- Prostacyclin receptor (IP) agonists
- Phosphodiesterase type 5 (PDE5) inhibitors
- Endothelin receptor (ER) antagonists
- Soluble guanylate cyclase (sGC) stimulators

Further, evidence suggests that non-specific treatments like calcium channel blockers and anticoagulants benefit subgroups of PAH patients.

Global Pulmonary Arterial Hypertension market (USDb)



Source: Grand View Research, Redeye Research

IP agonists effective in PAH therapy first came on the market in 1995 (epoprostenol, Barst et al. 1996). We have identified seven IP agonists approved for PAH treatment (Biomedtracker). Importantly, reduced prostacyclin levels occur commonly in PAH patient lungs. IP agonist therapy compensates for reduced prostacyclin levels and induces non-selective pulmonary vasodilation (widening of pulmonary arteries) (Thenappan et al. 2018).

Older agents like Remodulin (intravenous/subcutaneous treprostinil, US approval 2002) are starting to face generic competition. More recently approved originator drugs like Uptravi (oral selexipag, US approval 2015), Orenitram (oral treprostinil, US approval 2013), and Tyvaso (inhaled treprostinil, US approval 2009) still enjoy market exclusivity. Johnson & Johnson and United Therapeutics are the dominant players in the IP agonist market, with three approved IP agonists for PAH treatment each.

PAH patients' lungs often feature reduced nitric oxide production and increased PDE5 levels. Nitric oxide is a potent vasodilator, while PDE5 promotes vasoconstriction, which counteracts nitric oxide signaling. **PDE5 inhibitors** promote nitric oxide-induced vasodilation (widening of arteries) and prevent PED5-associated adverse vascular remodeling (thickening of arterial wall; Lai et al. 2014). Adcirca (tadalafil, same API as Cialis) and Revatio (sildenafil, same API as Viagra) are PED5 inhibitors approved for PAH treatment. Both face generic competition, causing declining originator sales.

Nitric oxide-mediated signaling induces sGC signaling, ultimately resulting in vasodilation. Therefore, one way to tackle low nitric oxide levels in PAH patient lungs is pharmacological sGC stimulation (Lai et al. 2014, Thenappan et al. 2018). To our best knowledge, Adempas (riociguat) is the only **sGC stimulator** approved for PAH treatment.

Lastly, **endothelin receptor (ER) antagonists** counteract endothelin signaling. Endothelin is a potent vasoconstrictor and smooth muscle cell mitogen. Endothelin tends to be overexpressed in PAH patient lungs and plasma, contributing to blood vessel narrowing and arterial wall thickening. Opsumit (macitentan, US approval 2013) is the only ER antagonist which does not face generic competition yet. In contrast, Letairis (ambrisentan, US approval 2007) and Tracleer (bosentan, US approval 2001) both have generic competitors.

United Therapeutics and Johnson & Johnson dominate the PAH-specific drug market with four and five pharmaceuticals, respectively. Burger et al. (2018) investigated PAH-specific therapy among 13,633 patients in the US. Between 2010 to 2015, they observed that 22.0% of patients received IP agonist therapy, 74.2% received PDE5 inhibitor treatment, and 41.6% took ER antagonists. Bayer received FDA approval for PAH treatment with Adempas in 2013, and the study does not clearly state what percentage of all surveyed patients received sGC treatment between 2013 to 2015.

Drugs marketed for PAH treatment

Drug Name	API	Lead Company	Molecule	Class	Administration	US approval	Generic competition	2020 lead company sales (USDm)
Uptravi	selexipag	Johnson & Johnson	Small Molecule	IP agonist	oral	2015	no	1,161
Orenitram	treprostinil diolamine	United Therapeutics	Small Molecule	IP agonist	oral	2013	no*	293
Tyvaso	treprostinil sodium	United Therapeutics	Small Molecule	IP agonist	Inhaled	2009	no*	483
Veletri	epoprostenol	Johnson & Johnson	Small Molecule	IP agonist	IV	2008	yes	not disclosed
Ventavis	iloprost	Johnson & Johnson	Small Molecule	IP agonist	Inhaled	2004	no	not disclosed
Remodulin	treprostinil sodium	United Therapeutics	Small Molecule	IP agonist	IV, SQ	2002	yes	517
Flolan	epoprostenol sodium	GlaxoSmithKline plc	Small Molecule	IP agonist	IV	1995	yes	not disclosed
Adcirca	tadalafil	United Therapeutics	Small Molecule	PDE5 inhibitor	oral	2009	yes	107
Revatio	sildenafil citrate	Pfizer Inc.	Small Molecule	PDE5 inhibitor	IV, oral	2005	yes	not disclosed
Adempas	rociguat	Bayer	Small Molecule	sGC stimulator	oral	2013	no	1,129
Opsumit	macitentan	Johnson & Johnson	Small Molecule	ER antagonist	oral	2013	no**	1,639
Letairis	ambrisentan	Gilead Sciences	Small Molecule	ER antagonist	oral	2007	yes	314
Tracleer	bosentan	Johnson & Johnson	Small Molecule	ER antagonist	oral	2001	yes	not disclosed

*Source: Biomedtracker, Datamonitor, lead company financial reports, Redeye Research; *generic available with a different formulation of API **generic approved, patent expiry Dec 2025*

PAH development pipeline

Our research revealed a diverse set of drug candidates for PH or PAH treatment. Candidates range from reformulations of APIs to novel molecular entities with various properties. United Therapeutics features five pipeline candidates among lead companies, while Johnson & Johnson is notably absent.

NDAs for two inhaled treprostinil formulations are currently under FDA review, with responses scheduled for H2 2021. In addition, several drug candidates currently undergo phase III clinical studies.

Sotatercept is a fusion protein binding activins and growth differentiation factors. Sotatercept thus rebalances growth signaling and prevents adverse vascular remodeling by binding up these pro-proliferative factors. Therefore, sotatercept would be the first biologic drug for PAH treatment and first-in-class. Sotatercept showed promising phase II results, lowering pulmonary vascular pressure significantly more than placebo and increasing exercise capacity (Humbert et al. 2021). Acceleron is currently running phase III trials (NCT04576988, NCT04896008, NCT04811092, NCT04796337), and Biomedtracker estimates a potential market launch in 2023.

Ralinepag is a potent IP agonist with a longer half-life (c. 24 hours) than approved IP agonists like treprostinil (c. 4.5 hours) and selexipag (c. 6.5-13 hours). A longer half-life enables more stable drug levels in patients and less frequent dosing relative to approved treatments. Phase II trials showed ralinepag treatment significantly lowering pulmonary vascular resistance and increasing exercise capacity (Torres et al. 2019). Having licensed ralinepag from Arena Pharmaceuticals in 2019, United Therapeutics conducts ongoing phase III trials (NCT03626688, NCT04084678). Biomedtracker projects a potential market launch for 2024.

INOpulse is a novel nitric oxide delivery system. It is in phase III trials for a subgroup of PH-ILD (a PH-CLD subgroup) and thus not immediately relevant for PAH therapy. However, label expansion to PAH could be possible in the future. Belleron Therapeutics is currently running a phase III trial (NCT03267108). Biomedtracker estimates a potential market approval in 2023.

Clinical development pipeline: Pulmonary hypertension and pulmonary arterial hypertension

Drug Name	API	Lead Company	Phase	LoA	Est. approval	Molecule	Target	Drug Classification	Administration
LIQ861	treprostinil	Liquidia Corp.	NDA	84%	H2 2021	Small Molecule	Prostacyclin Receptors	Non-NME	Inhaled
Tyvaso DPI	treprostinil	United Therapeutics	NDA	82%	H2 2021	Small Molecule	Prostacyclin Receptors	Non-NME	Inhaled
Sotatercept	sotatercept	Acceleron Pharma	III	51%	2023	Monoclonal Antibody	Activin A, TGF-beta and Superfamily	Biologic	IV, SQ
Ralinepag	ralinepag	United Therapeutics	III	49%	2024	Small Molecule	Prostacyclin Receptors	NME	Oral
INOpulse	nitric oxide	Bellerophon Therapeutics	III	48%	2023	Small Molecule	sGC, Nitric Oxide/ Nitrogen Monoxide	NME	Inhaled
MK-5475	MK-5475	Merck & Co.	II/III	11%		Not Specified	soluble guanylate cyclase	Unknown	N/A
Vasomera	pemziviptadil	PhaseBio Pharmaceuticals	IIb	10%		Peptide	VIP Receptor	NME	SQ, IV
Rodatristat Ethyl	rodatristat ethyl	Altavant Sciences	IIb	10%		Small Molecule	Tryptophan hydroxylase	NME	Oral
RT234	vardenafil	Respira Therapeutics	II	13%		Small Molecule	Unknown	Non-NME	Inhaled
Simdax	levosimendan	Tenax Therapeutics	II	11%		Small Molecule	PDE3, Potassium channels, Troponin-C	NME	Oral, IV
Aurora-GT		United Therapeutics	II	10%		Cell/gene therapy	NO Synthase, Stem Cells/Other Cell Therapies	Biologic	IV
BIA 5-1058	zamicastat	Bial Pharmaceuticals	II	10%		Small Molecule	DBH	NME	Oral
CXA-10	(9E)-10-nitrooctadec-9-enoic acid	Complexa	II	10%		Small Molecule	HSF-1, NF-Kappa B, NRF2	NME	Oral
GB002	seralutinib	Gossamer Bio	II	10%		Small Molecule	PDGF	NME	Inhaled
RP5063	brilaroxazine	Reviva Pharmaceuticals	II	10%		Small Molecule	D2R, D3R, D4R, Serotonin 5-HT1A receptor	NME	Oral
VentaProst	epoprostenol	Aerogen	II	10%		Small Molecule	Prostacyclin Receptors	Non-NME	Inhaled
VI-0106	tacrolimus	Vivus	II	10%		Small Molecule	Calcineurin phosphatase, FKBP12	Non-NME	Oral
INS-1009	treprostinil palmitil	Insmed Incorporated	I	6%		Small Molecule	Prostaglandin Receptors	Non-NME	Inhaled
Elafin	tiprelestat	Proteo	I	5%		Protein	hNE, Proteinase 3	NME	IV
Fyarro	sirolimus & albumin	AADi Bioscience LLC	I	5%		Small Molecule	mTOR/mTORC	Non-NME	IV
L-606	liposomal treprostinil	Pharmosa Biopharm	I	5%		Small Molecule	Prostaglandin Receptors	Non-NME	Inhaled
OreniPro	treprostinil sodium	United Therapeutics	I	5%		Small Molecule	Prostacyclin Receptors	Non-NME	Oral
PF-06842874	PF-06842874	Pfizer	I	5%		Small Molecule	CDK 4/6	NME	Oral
RemoPro	treprostinil sodium	United Therapeutics	I	5%		Small Molecule	Prostacyclin Receptors	Non-NME	SQ
SUD-004	sildenafil citrate	SUDA Pharmaceuticals	I	5%		Small Molecule	PDE5	Non-NME	Oral

Source: Biomedtracker, Redeye Research

Pulmonary arterial hypertension treatment algorithm

PAH treatment recommendations center on WHO functional classification (FC) (Datamonitor, Yaghi et al. 2020):

- FC I: Patient can carry out ordinary physical tasks without symptoms. Approximately 15% of PAH patients.
- FC II: Ordinary physical tasks cause shortness of breath, fatigue, chest pain, or lightheadedness/fainting. No symptoms at rest. Around 50% of PAH patients.
- FC III: Restricted ability to carry out ordinary tasks, symptoms upon light activity. Comfortable when resting. Some 30% of PAH patients.
- FC IV: All activity causes symptoms. Shortness of breath and fatigue even when resting. About 5% of PAH patients.

Low-risk patients may receive monotherapy, but most patients today receive combination therapy with two or even three agents. The American College of Chest Physicians updated its treatment recommendations in 2019, recommending treatment as summarized below:

- FC II: Patients are usually treatment naïve, initially receiving ER antagonists and PDE5 inhibitors. If treatment response is unsatisfactory, patients should switch to sGC stimulators.
- FC III: Similar recommendations as FC II if a patient is treatment naïve. Switch to IP agonists in patients with rapid disease progression.
- FC IV: IP agonist, often in combination with a PDE5 inhibitor and ER antagonist.

In general, rapid disease progression or suboptimal treatment response warrants combination therapy with multiple PAH drugs. Notably, all commonly used agents induce vasodilation in one way or another, i.e., treat PAH symptoms. Therefore, a potentially disease-modifying drug would be uniquely valuable.

Cereno's pipeline

Cereno currently has one drug candidate in phase II clinical development (CS1) and two drug candidates in preclinical development (CS585 and CS014).

CS1

Cereno's lead candidate, CS1, is an advanced controlled-release formulation of valproic acid (an epigenetic modulator). Valproic acid is a histone deacetylase inhibitor (HDACi) used to treat epilepsy, bipolar disorder, and migraine prevention. Recently, its epigenetic modulation properties spurred interest in using valproic acid to treat cancer, cardiovascular conditions, and metabolic disorders, among others (Ferreira et al. 2021).

Notably, evidence suggests a potential role for HDACs in PAH pathology. DNA in the cellular nucleus is wrapped around proteins called histones for condensation. HDACs remove acetyl groups from histones, leading to changed gene expression. Literature suggests increased HDAC levels in PAH, downregulating several genes involved in maintaining pulmonary vascular homeostasis. Interestingly, rodent models showed valproic acid counteracting PH (Thenappan et al. 2018). Thus, HDACi may have considerable potential in PAH treatment by counteracting adverse vascular remodeling. If Cereno successfully proves CS1's efficacy for PAH treatment, HDACis would constitute a new category among PAH drugs with substantial sales potential.

Cereno describes CS1's effects as antithrombotic, antifibrotic, anti-inflammatory, and pressure-relieving. These characteristics fit well with PAH's pathology. Cereno has been granted an ODD for CS1 in PAH treatment by the US FDA, securing market exclusivity in PAH seven years after launch, among other benefits. We believe that Cereno could obtain EU ODD for CS1 in PAH in the future. Additionally, Cereno has secured patent protection for CS1 until at least 2035 (WO2012120262, WO2016055797). Further, the company is working on continually strengthening IP protection around CS1 (WO2017175010, WO2017175013). Combining clinical use and formulation patent protection for CS1 with ODD gives Cereno strong IP protection for their drug candidate, we judge.

Cereno completed phase I trials with CS1 in healthy volunteers, showing the drug candidate's safety and tolerability. Further, CS1 lowered plasminogen activator inhibitor 1 (PAI-1) levels, indicating antithrombotic effects (Bergh et al. 2019). Moreover, animal studies have shown that valproic acid upregulates tissue plasminogen activator (t-PA), a protein involved in blood clot degradation (Svennerholm et al. 2014, Larsson et al. 2016). This further strengthens evidence around valproic acid's antithrombotic effect.

The company plans to initiate a phase II trial in H2 2021 at about six sites in the US to evaluate safety, tolerability, and exploratory efficacy in PAH patients. The non-placebo-controlled open-label trial will include 30 patients, with results scheduled for release in H2 2022. Cereno has partnered with Abbott to use their CardioMEMS™ HF System, enabling continual and remote pulmonary pressure measurements in study participants. We judge this will improve Cereno's ability to determine an optimal CS1 dose for future clinical trials and reliably detect changes in pulmonary pressure in study participants. Further, the company stated that using Abbott's CardioMEMS™ HF System enables it to include fewer patients in the phase II trial, saving both time and money.

Given CS1's broad efficacy profile, we see potential for label expansion into other CVD indications. Notably, while Cereno's planned phase II trial in VTE has been suspended due to the COVID-19 pandemic, thrombotic indications are still relevant for CS1. The company states that CS1 development in VTE is on hold until it completes phase II trials in PAH. We believe this is a smart strategy as PAH presents an opportunity to get CS1 to market with relatively small clinical studies. Once approved, Cereno can focus on label expansion into other rare or common CVD indications.

CS585

CS585 is an IP agonist. While competition from approved IP agonists is high, newer agents like Uptravi have demonstrated the commercial potential of this drug class. If CS585 proves more efficacious or safer/more convenient to administrate, it could generate substantial sales upon market approval.

CS014

Like CS1, CS014 is an HDACi. Cereno has acquired CS014 from Emeriti Bio AB in 2019. As described above, CS014 is currently in preclinical development at U-M. The company will decide how to proceed with the project and which CVD indications to target upon completion of preclinical development in H2 2023.

CS585 and CS014 (see below) currently undergo preclinical development as part of Cereno's collaboration with U-M for use in yet-to-be-determined CVD indications. The partnership extends until 2023, at which point both drug candidates should be ready for transition into phase I clinical trials. U-M has extensive in-house drug development expertise since acquiring Pfizer's preclinical drug development hub in Ann Arbor in 2009. Therefore, we are confident that CS585 and CS014 will undergo a robust preclinical development program conducted by experienced professionals.

Cereno Scientific: Pipeline

Pipeline									
Compound	MoA	Indication	Discovery	Preclinical	Phase I	Phase II	Phase III	NDA	Market
CS1	HDACi	PAH							
CS585	IP agonist	CVD							
CS014	HDACi	CVD							

Source: Cereno Scientific, Redeye Research

Sales model

Our current sales model considers projected PAH sales for CS1. There is uncertainty about timeline and nature of potential other CVD indications for CS1 upon possible label expansion. Therefore, we refrain from factoring further CVD indications into our model until active clinical development starts. This could happen as soon as clinical development for VTE is resumed or if clinical development for other CVD indications gets announced.

Currently, the company seems to focus on PAH, making us doubt whether VTE will be a focus following the upcoming phase II trial in PAH. We believe potential label expansions of CS1 are realistic in the long term; however, we judge it is currently unclear which indication(s) will be strategically smartest to pursue in addition to PAH.

We project Cereno to start a phase IIb/III PAH trial with CS1 in 2023 and complete it in 2025. We model an NDA submission for CS1 during 2026, followed by (conditional) FDA approval and market launch in 2027. Cereno may have to do a second phase III trial with CS1 in PAH. However, we think this would most likely occur after licensing, conditional approval, and market launch. Further, we judge the licensee would carry out this potential second phase III trial. We see the US as the commercial focus of PAH drugs and Cereno's development work. Therefore, we model a one-year delay in EU and Japan market application and approval/launch.

We use historical likelihood of phase success (LoS) and likelihood of approval (LoA) sourced from Datamonitor for our analysis. Following completed phase I studies, drug candidates for CVD treatment historically had 25% phase II LoS, 55% phase III LoS, and 84% NDA LoS (LoA 12%). Further, PAH/PH drug candidates had 39% phase II LoS, 93% phase III LoS, and 86% NDA LoS following successful phase I trials (LoA 31%). Notably, many drug candidates in PAH/PH seem to have been reformulated APIs already used in PAH/PH or had similar action mechanisms as already approved PAH/PH drugs. As CS1 has a novel mechanism of action and efficacy in PAH is uncertain, our estimates settle in between CVD and PAH/PH LoS. Therefore, we model 32% phase II LoS, 74% phase III LoS, and 85% NDA LoS (LoA 20%) for CS1.

Estimated LoS for CS1 in PAH

Phase	CVD Historical	PAH Historical	Redeye estimate CS1 in PAH
I	56%	69%	63%
II	25%	39%	32%
III	55%	93%	74%
NDA	84%	86%	85%

Source: Datamonitor, Redeye Research

CS585 and CS014 are still at very early stages and at least two years away from clinical studies. Therefore, we refrain from making sales projections for these agents. However, once one or both enter the clinic and concrete CVD indication(s) are targeted, we will factor them into our sales model and valuation.

PAH: CS1 addressable patient population and market share

We use Datamonitor disease prevalence estimates to model addressable patient population. Datamonitor provides diagnosed PAH prevalence and drug-treated PAH prevalence data (PAH-specific drugs) for the US, EU5, and Japan from 2017-2037. Based on patient population CAGR in this period, we extrapolated 2038-2040 prevalence ourselves. We use the number of drug-treated PAH patients in the geographies mentioned above as

addressable patient population, estimated at some 60% of diagnosed PAH patients. Further, we model a 10% peak market share in all geographies.

PAH: CS1 pricing

We estimate CS1 pricing based on how much other recently launched PAH drugs cost. In 2016, Actelion announced the annual per-patient price of Uptravi in the US around USD 160,000 to 170,000 before rebates. Dean et al. (2020) found median yearly pharmacy costs directly attributable to selexipag (Uptravi) at some USD 220,000 over 12 months (2017 price levels). The same study observed median yearly pharmacy costs directly attributable to oral treprostinil (Orenitram) of some USD 125,000. Burger et al. (2018) reported USD 91,098 PAH medication costs during the six months after patients started taking nonparenteral prostacyclins (inhaled or oral prostacyclin formulations). This cost can be compared to around USD 20,000 during the six months before prostacyclin treatment started. Annualizing the cost increase, nonparenteral prostacyclin treatment incurred c. USD 142,000 in drug costs (2015 price levels). Therefore, our Base Case assumes CS1 annualized per patient cost at USD 160,000 in the US and USD 80,000 in EU5 and Japan.

CS1: In-house development vs. partnership/licensing

We believe Cereno's coming two warrant exercises in September 2021 and September 2022 will bring in more than enough funds to finance its phase II study in PAH with CS1. The following phase IIb/III trial may require another capital raise, though funds from the coming warrant exercises should fund it at least partly. Further, we assume that phase IIb/III study design will enable an NDA submission and (conditional) marketing approval for CS1 in PAH. As Cereno has underlined, there is considerable potential for label expansions of CS1 into both other rare CVD diseases and more common CVD indications. Overall, we model that Cereno will license CS1 to a big pharmaceutical company following phase IIb/III in PAH. We project that successfully conducting a phase IIb/III study in-house will enable Cereno to negotiate a high royalty rate on future CS1 sales. We estimate Cereno will receive 20% of CS1 sales in royalties. Notably, we believe it is rational to license CS1 before label expansion. A larger organization will have the resources to conduct broader clinical development and execute full-scale CS1 commercialization in multiple indications. Given that United Therapeutics and Johnson & Johnson are the dominant players in the commercial PAH space, they are possible licensing partners in our view.

Notably, we believe CS1 licensing after phase IIb/III is the most likely future scenario. However, it would be possible for Cereno to license CS1 following phase II studies or carry out PAH commercialization in-house. We consider these two scenarios less likely but still possible.

Sales and milestone projections

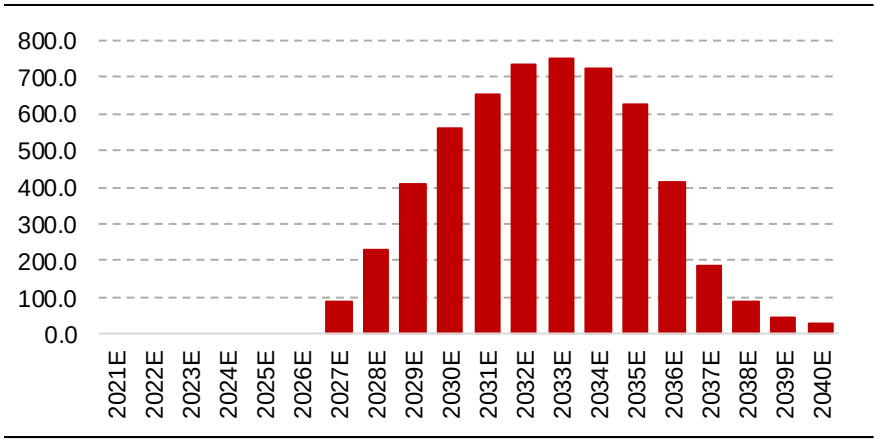
Looking at previous licensing deals in the PAH space, we project CS1 licensing following successful phase III PAH studies. Licensing will be worldwide, with Cereno receiving 20% royalties on CS1 sales. We model total deal value at USD 550m, with USD 50m being paid upfront. Further, we project milestone payments at USD 25m upon NDA submission, USD 75m upon marketing approval, and USD 400m sales-based milestone payments. Our model projects peak CS1 PAH sales in 2033 at some USD 750m.

Selected PAH reference deals

Year	Stage	Drug	Licensee	Licensor	Geography	Deal value (mUSD)	Upfront (mUSD)	Comment
2014	Market	Adempas, Verquvo	Merck & Co	Bayer	Worldwide ex. US	$2,100	$1,000	Cost/profit sharing
2018	III	ralinepag	United Therapeutics	Arena Pharmaceuticals	Worldwide	$1,200	$800	Double-digit royalty
2015	III	Trevyent	Cardiome	SteadyMed	EMEA, Canada	$15	$3	Double-digit royalty
2017	II	ralinepag, etrasimod	Everest Medicines	Arena Pharmaceuticals	Greater China, South Korea	$224	$12	Low double-digit royalty
2010	II	Uptravi	Nippon Shinyaku	Actelion	Japan	$50	$30	
2018	I	Tyvaso DPI	United Therapeutics	MannKind	Worldwide	$105	$60	Low double-digit royalty

Source: Biomedtracker, licensor/licensee press releases, Redeye Research

CS1 estimated PAH sales (USDm; not risk-adjusted)



Source: Redeye Research

PAH sales model CS1

PAH sales model		2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	2039E	2040E
Diagnosed PAH prevalence	**US**	**55,447**	**56,300**	**57,168**	**58,037**	**58,900**	**59,717**	**60,517**	**61,296**	**62,050**	**62,776**	**63,410**	**64,004**	**64,564**	**65,102**	**65,626**	**66,066**	**66,482**	**67,292**	**68,111**	**68,940**
	EU5	**18,950**	**19,073**	**19,200**	**19,336**	**19,483**	**19,630**	**19,784**	**19,943**	**20,106**	**20,270**	**20,422**	**20,571**	**20,716**	**20,853**	**20,984**	**21,087**	**21,178**	**21,325**	**21,473**	**21,623**
	JP	**3,146**	**3,136**	**3,125**	**3,114**	**3,102**	**3,090**	**3,077**	**3,064**	**3,050**	**3,036**	**3,021**	**3,006**	**2,991**	**2,975**	**2,960**	**2,944**	**2,927**	**2,915**	**2,903**	**2,891**
% treated with PAH-specific drugs	US	62%	62%	62%	62%	62%	62%	62%	62%	62%	62%	62%	62%	62%	62%	62%	62%	62%	62%	62%	62%
	EU5	56%	56%	56%	56%	56%	56%	56%	56%	56%	56%	56%	56%	56%	56%	56%	56%	56%	56%	56%	56%
	JP	61%	61%	61%	61%	61%	61%	61%	61%	61%	61%	61%	61%	61%	61%	61%	61%	61%	61%	61%	61%
Drug-treated PAH prevalence	US	34,503	35,034	35,574	36,114	36,651	37,160	37,658	38,142	38,612	39,063	39,458	39,827	40,176	40,511	40,837	41,111	41,370	41,873	42,383	42,899
	EU5	10,630	10,699	10,771	10,847	10,929	11,011	11,098	11,187	11,277	11,369	11,454	11,537	11,618	11,695	11,769	11,827	11,878	11,961	12,044	12,127
	JP	1,927	1,921	1,915	1,908	1,900	1,893	1,885	1,877	1,868	1,860	1,851	1,841	1,832	1,823	1,813	1,803	1,793	1,786	1,779	1,771
Launch curve	US							0.15	0.35	0.60	0.80	0.90	1.00	1.00	0.95	0.80	0.50	0.20	0.10	0.05	0.03
	EU5							0.00	0.15	0.35	0.60	0.80	0.90	1.00	1.00	0.95	0.80	0.50	0.20	0.10	0.05
	JP							0.00	0.15	0.35	0.60	0.80	0.90	1.00	1.00	0.95	0.80	0.50	0.20	0.10	0.05
Market share	US	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.5%	3.5%	6.0%	8.0%	9.0%	10.0%	10.0%	9.5%	8.0%	5.0%	2.0%	1.0%	0.5%	0.3%
	EU5	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.5%	3.5%	6.0%	8.0%	9.0%	10.0%	10.0%	9.5%	8.0%	5.0%	2.0%	1.0%	0.5%
	JP	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.5%	3.5%	6.0%	8.0%	9.0%	10.0%	10.0%	9.5%	8.0%	5.0%	2.0%	1.0%	0.5%
CS1-treated patients	US	0	0	0	0	0	0	565	1335	2317	3125	3551	3983	4018	3849	3267	2056	827	419	212	129
	EU5	0	0	0	0	0	0	0	168	395	682	916	1038	1162	1170	1118	946	594	239	120	61
	JP	0	0	0	0	0	0	0	28	65	112	148	166	183	182	172	144	90	36	18	9
Cost/year (USD)	US							160,000	160,000	160,000	160,000	160,000	160,000	160,000	160,000	160,000	160,000	160,000	160,000	160,000	160,000
	EU5							80,000	80,000	80,000	80,000	80,000	80,000	80,000	80,000	80,000	80,000	80,000	80,000	80,000	80,000
	JP							80,000	80,000	80,000	80,000	80,000	80,000	80,000	80,000	80,000	80,000	80,000	80,000	80,000	80,000
Product revenues (USDm)	**US**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**90.4**	**213.6**	**370.7**	**500.0**	**568.2**	**637.2**	**642.8**	**615.8**	**522.7**	**328.9**	**132.4**	**67.0**	**33.9**	**20.6**
	EU5	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**13.4**	**31.6**	**54.6**	**73.3**	**83.1**	**92.9**	**93.6**	**89.4**	**75.7**	**47.5**	**19.1**	**9.6**	**4.9**
	JP	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**2.3**	**5.2**	**8.9**	**11.8**	**13.3**	**14.7**	**14.6**	**13.8**	**11.5**	**7.2**	**2.9**	**1.4**	**0.7**
Total revenues (USDm)		**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**90.4**	**229.3**	**407.5**	**563.5**	**653.3**	**733.6**	**750.4**	**723.9**	**625.9**	**416.1**	**187.1**	**89.0**	**45.0**	**26.2**
Royalties (USDm)		0.0	0.0	0.0	0.0	0.0	0.0	18.1	45.9	81.5	112.7	130.7	146.7	150.1	144.8	125.2	83.2	37.4	17.8	9.0	5.2
Milestones (USDm)					0	50.0	25.0	75.0		200.0		200.0									
Phase		Phase II			Phase IIb/III			NDA	Market												
Probability		100%	100%	32%	32%	24%	24%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%

Cereno revenues and project costs	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E	2039E	2040E
Risk-adj. Revenue (USDm)	**0.0**	**0.0**	**0.0**	**0.0**	**11.8**	**5.9**	**18.7**	**9.2**	**56.5**	**22.6**	**66.3**	**29.4**	**30.1**	**29.0**	**25.1**	**16.7**	**7.5**	**3.6**	**1.8**	**1.0**
Risk-adj. Revenue (SEKm)	**0.0**	**0.0**	**0.0**	**0.0**	**101.4**	**50.7**	**160.6**	**79.1**	**485.6**	**194.4**	**570.4**	**253.1**	**258.9**	**249.7**	**215.9**	**143.6**	**64.5**	**30.7**	**15.5**	**9.0**
Development costs	3.8	3.8	10.0	5.0	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Probability	100%	100%	32%	32%	32%	24%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Risk-adj. dev. costs (USDm)	**3.8**	**3.8**	**3.2**	**1.6**	**1.6**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Risk-adj. dev. costs (SEKm)	**32.3**	**32.3**	**27.5**	**13.8**	**13.8**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Source: Datamonitor, Redeye Research

Valuation

We base our valuation on risk-adjusted discounted cash flow (DCF) analysis, reflecting Cereno's current financials, projected milestone payments, and estimated future cashflows from CS1 PAH sales in the US, EU5, and Japan. Our model uses a weighted average cost of capital (WACC) of 14%.

In September 2021, Cereno will raise up to SEK 98.4m in a warrant exercise (TO1). As a result, we understand that share count will increase by up to c. 34.5 million. Our valuation already considers the estimated increased cash (we model 10% issuing costs) on the balance sheet and increased share count (c. 32.5% dilution based on share count after warrant exercise). Thus, our target price represents our estimated fair value following the September 2021 warrant exercise. We estimate that the warrant exercise will be fully subscribed at the maximum price of SEK 2.85 per share. Our valuation does not yet account for the coming September 2022 warrant exercise (TO2), which could raise up to SEK 114.8m before costs while increasing share count by up to c. 34.5 million.

Base Case: SEK 6.0 per share

Our Base Case scenario assumes solid phase II data in PAH with CS1, potentially introducing a novel drug class (HDACi) in the PAH treatment algorithm:

- CS1 shows good safety and tolerability in phase II with exploratory efficacy suggesting a potential treatment effect in PAH
- Likelihood for phase II success 32% (LoA 20%)
- USD 50m upfront payment upon CS1 licensing in 2025 following phase III (Total deal value USD 550m)

Bull Case: SEK 11.0 per share

Our Bull Case assumes strong phase II data in PAH with CS1 and licensing during phase III:

- CS1 shows good safety and tolerability in phase II with exploratory efficacy suggesting a strong treatment effect in PAH, CS1 may be disease-modifying
- Likelihood of approval 38%
- USD 50m upfront payment upon CS1 licensing in 2024 during phase III (Total deal value USD 550m)

Bear Case: SEK 2.3 per share

Our Bear Case scenario assumes weak phase II data in PAH with CS1 and a lower deal value upon licensing:

- CS1 shows acceptable safety and tolerability in phase II, but clinical trials reveal no/negligible treatment effect in PAH
- Likelihood of approval 6%
- USD 25m upfront payment upon CS1 licensing in 2025 following phase III (Total deal value USD 525m)

Cereno scenario analysis

	BEAR	BASE	BULL
CS1 efficacy in PAH	Weak	Solid	Strong
LoA	6%	20%	38%
Upfront payment (USDm)	25	50	50
Deal value (USDm)	525	550	550
Licensing deal	2025	2025	2024
Fair value (SEK/share)	**2.3**	**6.0**	**11.0**
Upside/Downside	**-55%**	**18%**	**116%**

Source: Redeye Research

Sensitivity analysis

Required returns vary among investors. Further, CS1 being Cereno's only clinical drug candidate makes CS1's phase II LoS a critical variable. Therefore, we have conducted a sensitivity analysis, investigating how varying WACC and phase II LoS affect our Base Case price per share.

Sensitivity analysis

	WACC				
Phase II LoS	10%	12%	**14%**	16%	18%
12%	3.6	3.1	**2.7**	2.4	2.2
22%	5.9	5.1	**4.4**	3.8	3.4
32%	**8.3**	**7.1**	**6.0**	**5.2**	**4.5**
42%	10.7	9.0	**7.7**	6.6	5.7
52%	13.0	11.0	**9.3**	8.0	6.9
62%	15.4	13.0	**11.0**	9.4	8.1

Source: Redeye Research

Peer valuation

As Cereno is a pre-revenue company, multiple valuation is useless. However, comparing market cap and enterprise value to peers could be helpful. We compare Cereno's market cap to other Stockholm-listed pharmaceutical companies in the CVD or orphan space. Cereno's market cap and enterprise value seem to align with peers who have completed phase I trials, e.g., Abliva. Successful phase II studies with CS1, followed by phase III, could bring Cereno's valuation up to par with more mature peers, e.g., Vicore.

Cereno peer table

Company	Ticker	Market cap (SEKm)	EV (SEKm)
Cereno Scientific	CRNO	366	320
Annexin Pharmaceuticals	ANNX	150	139
Vicore	VICO	1,450	1,052
Saniona	SANION	1,029	595
Abliva	ABLI	267	191

Source: Redeye Research, at market close 20 August 2021

Expected news flow and catalysts

During H2 2021, we expect Cereno to start its phase II trial with CS1 in PAH and successfully carry out the coming TO1 warrant exercise. Subsequently, the phase II trial data and TO2 exercise will likely be the most important news items in 2022. Notably, phase II clinical trial commencement and phase II trial data are news items that we believe will generate interest in TO1 and TO2 exercises. We judge that solid phase II data with CS1 constitutes an important milestone for HDACi efficacy in PAH patients. We see phase II topline data as the major catalyst within the coming year.

Longer-term, we see phase IIb/III trial initiation with CS1 in 2023, followed by phase IIb/III trial data presentation in 2025 as significant catalysts. Successfully confirming efficacy in phase IIb/III would put Cereno in a strong negotiating position for CS1 licensing, we judge. Further, we believe it would serve as validation of HDACi efficacy in PAH.

Currently, we estimate CS1 FDA approval for PAH treatment in 2026, followed by EU and Japan approval in 2027. Further, we project CS014 and CS585 potentially entering phase I clinical trials in 2023-2024.

Cereno Scientific: Expected news flow and catalysts

Time	News/Catalyst	Importance
H2 2021	CS1 phase II trial in PAH starts	Low
H2 2021	TO1 subscription rights exercise	Medium
H2 2022	**CS1 phase II in PAH, topline data**	**High**
H2 2022	TO2 subscription rights exercise	Medium
2023	CS1 phase IIb/III study in PAH commences	Medium
2023/2024	Phase I studies with CS014 and/or CS585 start	Low
2025	**CS1 phase IIb/III results in PAH**	**High**
2025	CS1 licensing/partnership deal	Medium
2026	CS1 NDA submission US	Medium
2027	**CS1 market approval in US**	**High**
2027	CS1 marketing application submission in EU and JP	Low
2028	CS1 market approval EU and JP	Medium

Source: Cereno Scientific, Redeye Research

Short-term financial outlook

Cereno held some SEK 60m cash and equivalents on its balance sheet at the end of Q1 2021. Accounting for the coming warrant exercises in September 2021 and September 2022, we project that proceeds will enable Cereno to finance operations until c. 2024. This assumes that both TO1 and TO2 are fully subscribed and occur at maximum price (TO1: SEK 2.85 per share in Sep 2021; TO2: SEK 3.33 per share in Sep 2022; share count increases by c. 34.5 million). We estimate issuing costs at some 10%. At Redeye Growth Day 2021, Cereno's CEO, Sten R. Sörensen, confirmed that the company does not need further near-term funding following the warrant exercises. However, it may still opt for another financing round for strategic reasons. We believe this is a prudent strategy.

Appendix 1 – Management and board of directors

Cereno Scientific: Board and management

Management			A shares	B shares	Warrants
CEO	Sten Sörensen, BSc	CEO since joining in 2015. Collective 37 years of experience in the biotech and finance, incl. Senior positions at Monsanto, Astra Zeneca, and PWC. Chairman of the board at Saromics Biostructures AB and owner of Bridge Consulting AB.	0	785,407	250,000
CFO	Daniel Brodén, MSc MBA	CFO since 2019, before acting CFO since 2018. Previously CFO of GU Ventures' portfolio companies and auditor at Frejs Revisorer and PwC.	0	44,232	100,000
CMO	Björn Dahlöf, MD PhD	CMO since 2018. Board member since 2012. Associate professor of Cardiovascular Prevention at Shalgrenska Academy with 35+ years experience as practicing MD. Extensively experienced in drug development, clinical trials, and drug lifecycle management in the CVD field.	123,920	832,815	100,000
CSO	Niklas Bergh, MD	Co-founder of Cereno. CEO 2012-2015. CSO since 2015. Associate professor at Sahlgrenska Academy. Practicing cardiology specialist at Sahlgrenska University Hospital, focusing on the body's anti-thrombotic defense system. Extensive preclinical and clinical anti-thrombotic research experience.	230,128	964,995	50,000
Chief IP Officer	Jonas Faijerson Säljö, PhD	Chief IP officer since 2019. Board member in 2012. Licensed pharmacist and holds PhD in Neurobiology. Previously research experience in CVD. Expert in commercializing medical innovations. Senior IP Business consultant and CEO at Synergon AB.	135,440	736,174	50,000
Chief Clinical & Regulatory Officer	Tiina Seppä, PhD	Joined in 2021 following 14 years at Orion Corporation with senior roles in regulatory affairs. Other previous roles as inspector at Finnish Medicines Agency and researcher at University of Helsinki. Senior consultant at NDA Group AB.	0	0	0
Director Translational Research	Michael Holinstat, PhD	Joined Cereno in 2021. Associate professor at University of Michigan, leading translational drug development programs in hemostasis and thrombosis at the Pharmacology Department. Primarily employed by University of Michigan Medical School.	0	0	0
Senior Dev Director	Jan-Peter Idström, PhD	Employed since 2017. Previous experience at Gothenburg University and 20+ years in pharmaceutical industry, including roles at Astra Zeneca and Vitrolife. Expertise in drug development ranging from discovery to market. Owner and consultant at JPI Consulting AB.	0	0	100,000
Director Communications & IR	Tove Bergenholt, MSc	Joined in 2020. Extensive experience in international communications and investor relations working for AZ, Merck KGaA, Bayer, and in the Swedish biotech industry. COO, communications director, and consultant at MSC Nordics.	0	0	0
Project Director	Stine Birk Hansen, MSc	Joined Cereno in 2021. Wide-ranging strategy & finance experience from Novozymes, Deloitte, and KPMG. Senior Management Consultant at MSC Nordics.	0	0	0

Board of Directors			A shares	B shares	Warrants
Chair	Catharina Bäärnhielm, PhD	Chairman of the board since joining in 2015. Extensive experience from senior management and strategy roles in the pharmaceutical industry, most recently Astra Zeneca. Sits on GU Venture's board of directors.	0	195,300	0
Member	Björn Dahlöf, MD PhD	See management.	123,920	832,815	100,000
Member	Jonas Faijerson Säljö, PhD	See management.	135,440	736,174	50,000
Member	Sverker Jern, MD	Co-founder. Board member since 2012. His research laid the groundwork CS1 development. Published 150+ scientific articles. Authored medical textbooks and training programs based on his extensive experience in CVD and metabolic research. Chief of Clinical Physiology at Sahlgrenska University	232,760	988,567	0
Member	Anders Svensson, MD	On board since 2018. Physician with 20+ years academic experience in CVD research, followed by senior roles in international drug development at Astra Zeneca and Roche. Owner at C Anders Svensson Consulting, advising biotech companies.	0	100,550	30,000
Member	Klementina Österberg, MBA	Board member since 2014. Extensive investment experience, especially seed financing and managing startups. CEO of GU Ventures. Share ownership is GU Ventures.	0	1,556,497	0
Member	Rein Piir	Joined board in 2021. Wide-ranging experience from senior roles in capital markets, IR, business development, incl. Head of equity research at Carnegie Investment Bank and IR/CFO at Medivir. CEO of Piir & Partner and member of Irlab Therapeutics' board of directors.	0	0	0
Deputy member	Niklas Bergh, PhD	See management.	230,128	964,995	50,000
Deputy member	Jesper Dahlberg	Board member since 2021. Experienced lawyer and executive. In-house lawyer and business developer at GU Ventures.	0	0	0

Source: Cereno Scientific, Redeye Research

Income statement (SEKm, risk-adjusted)	2019	2020	2021E	2022E	2023E
Revenues	**-**	**-**	**-**	**-**	**-**
Cost of Revenues	-	-	-	-	-
Gross Profit	**-**	**-**	**-**	**-**	**-**
Selling Expenses	-	-	-	-	-
Administrative Expenses	1	1	10	13	5
R & D Expenses	-	-	32	32	28
Other Op. Expense / (Income)	12	14	-	-	-
EBITDA	**(13)**	**(16)**	**(42)**	**(45)**	**(33)**
Depreciation	-	0	-	-	-
Amortization	-	-	-	-	-
EBIT	**(13)**	**(16)**	**(42)**	**(45)**	**(33)**
Interest Income	-	-	-	-	-
Interest Expenses	2	0	-	-	-
Non-recurring Income / (Expenses)	-	-	-	-	-
EBT	**(15)**	**(16)**	**(42)**	**(45)**	**(33)**
Income Tax Expenses	-	(0)	-	-	-
Effective Tax Rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Non-Controlling Interests	-	-	-	-	-
Net Income	**(15)**	**(16)**	**(42)**	**(45)**	**(33)**

Source: Cereno Scientific, Redeye Research

Balance sheet (SEKm, risk-adjusted)	2019	2020	2021E	2022E	2023E
Current Assets					
Cash & Equivalents	26	66	101	159	126
Inventories	-	-	-	-	-
Accounts Receivable	1	1	-	-	-
Other Current Assets	-	1	-	-	-
Total Current Assets	**28**	**67**	**101**	**159**	**126**
Non-Current Assets					
Property, Plant & Equipment, Net	0	0	0	0	0
Goodwill	-	-	-	-	-
Intangible Assets	36	45	45	45	45
Right-of-Use Assets	-	-	-	-	-
Shares in Associates	0	0	0	0	0
Other Long-Term Assets	-	-	-	-	-
Total Non-Current Assets	**36**	**45**	**45**	**45**	**45**
Total Assets	**64**	**112**	**146**	**204**	**171**
Current Liabilities					
Short-Term Debt	-	9	-	-	-
Accounts Payable	2	1	-	-	-
Accrued Expenses	1	2	-	-	-
Other Current Liabilities	0	0	-	-	-
Total Current Liabilities	**4**	**12**	**-**	**-**	**-**
Non-Current Liabilities					
Long-Term Debt	-	-	-	-	-
Other Long-Term Liabilities	0	0	-	-	-
Total Non-current Liabilities	**0**	**0**	**-**	**-**	**-**
Shareholder's Equity	60	100	146	204	171
Basic Shares Outstanding, EOP	40.2	71.8	106.3	140.9	140.9
Book Value Per Share	1.5	1.4	1.4	1.4	1.2
Total Liabilities & Equity	**64**	**112**	**146**	**204**	**171**

Source: Cereno Scientific, Redeye Research

Cash flow statement (SEKm, risk-adjusted)	2019	2020	2021E	2022E	2023E
Operating Activities					
Net Income	(15)	(16)	(42)	(45)	(33)
Associated Income / (loss)	1	0	-	-	-
Depreciation	-	0	-	-	-
Amortization	-	-	-	-	-
Net Working Capital Change, Decrease / (Increase)	(9)	(1)	(1)	-	-
Other Long-Term Liabilities, Increase / (Decrease)	2	0	(0)	-	-
Operating Cash Flow	**(21)**	**(16)**	**(44)**	**(45)**	**(33)**
Investing Activities					
Capital Expenditures	(0)	(0)	-	-	-
Investment in Intangible Assets	(12)	(8)	-	-	-
Other Long Term Assets	-	-	-	-	-
Investing Cash Flow	**(12)**	**(8)**	**-**	**-**	**-**
Financing Activites					
Short-Term Debt, Issuance / (Repayment)	-	9	(9)	-	-
Long-Term Debt, Issuance / (Repayment)	-	-	-	-	-
Share Issuance / (Repurchase)	49	55	89	103	-
Dividends Paid to Shareholders	-	-	-	-	-
Dividends Paid to Non-Controlling Interest	-	-	-	-	-
Repayment of Lease Liabilities	-	-	-	-	-
Other Financing Activites	(1)	-	-	-	-
Financing Cash Flow	**48**	**64**	**79**	**103**	**-**
Net Cash Flow	**15**	**40**	**35**	**58**	**(33)**
Cash Balance	**26**	**66**	**101**	**159**	**126**

Source: Cereno Scientific, Redeye Research

Summary Redeye Rating

The rating consists of three valuation keys, each constituting an overall assessment of several factors that are rated on a scale of 0 to 1 points. The maximum score for a valuation key is 5 points.

Rating changes in the report

People: 3

Cereno has qualified, passionate, and focused management and employees. The company clearly communicates its goals to shareholders. Further, Cereno's team dynamically copes with difficult situations and seizes new opportunities. Employee compensation seems reasonable given the company's financial position and industry peer remuneration. Senior management owns significant equity in the company, aligning their interests with shareholders. Most board members are independent of the company.

Business: 3

Cereno has secured strong intellectual property protection through clinical use and formulation patents. Further, the company has secured orphan drug designation in the US. This gives Cereno a moat for its business, preventing competitors from copying their products and luring customers away in the short term. The company has a communicated business strategy. The potential for substantial value creation if drug candidates are effective means there is an already existing need to be satisfied with Cereno's products. Clinical trials failing is a significant operational risk, as invested capital will likely not be recovered and potential future revenues are eliminated.

Financials: 1

Cereno is a pre-revenue company with remaining clinical development for several years before cashflows from product sales may become positive. Even after a potential market launch, peak drug sales will be uncertain. Until operating cashflow can finance operations, Cereno will have to raise capital to fund the company and product development. Capital raises will likely dilute existing shareholders' ownership stake. However, if approved and marketed, Cereno's drug candidates could generate very large cashflows and substantial profitability.

Redeye Rating and Background Definitions

Company Quality

Company Quality is based on a set of quality checks across three categories; PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive long-term earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of people behind a business is a significant part of understanding the long-term drive of the company. It all comes down to doing business with people you trust, or at least avoiding dealing with people of questionable character.

The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

Business

If you don't understand the competitive environment and don't have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won't succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.

The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company's financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.

The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

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Disclaimer

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Redeye Rating (2021-08-22)

Rating	People	Business	Financials
5p	31	16	4
3p - 4p	127	111	42
0p - 2p	5	36	117
Company N	163	163	163

Duplication and distribution

CONFLICT OF INTERESTS

Christian Binder owns shares in the company : No
Filip Einarsson owns shares in the company : No

Redeye performs/have performed services for the company and receives/have received compensation from the company in connection with this.