

# Saniona

Sector: Biotech

## Saniona: It's a New Case (But Currently in Two Minds)

Redeye gives an update to our notes after the transformational August for Saniona. While the financial risk is heavily mitigated after the incredible directed issue, we are a troublesome by the short-term selling pressure in the stock.

### Transformative for the Company

With the massive capital raise of USD 65 million to well-respected investors, this is a totally new equity story now. The top-tiered specialist investors truly validate the case. In addition, the cash position provides runway throughout 2023, we judge. Hence, the company is now ready to fully explore the true potential of its pipeline.

The combination of a validated research platform and mid-stage assets in rare indications distinguishes the Saniona-equity story. It makes it possible to both run a broad proprietary pipeline and maintain most of the asset value internally.

### Financials and Stock Performance Review

In this update, we also review the financials with a focus on the current year, present with new assumption to our valuation, as well as stock performance. The stock has been hurt with a selling pressure in the weeks following the directed issue, which we dig deeper into.

### Valuation with Significant Upside

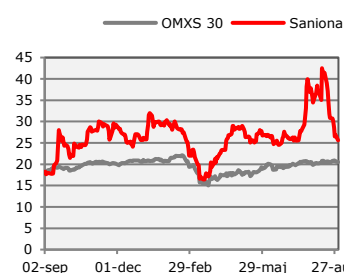
Our Base Case is SEK 75 per share. It is a small change to our indicatively Base Case after the directed issue but should be seen as pure cosmetics. We believe it is also interesting for investor to eye our Bear- and Bull Case of SEK 40 and 150 per share respectively. All in all, the current share levels of between SEK 25-30 per share offers an attractive risk/reward, and we argue that only moderate catalysts can start to decrease the gap.

KEY FINANCIALS (SEKm)	2018	2019	2020E	2021E	2022E	2023E
Net sales	0	3	68	43	137	163
EBITDA	0	-104	-65	-230	-76	-70
EBIT	0	-104	-66	-230	-77	-71

### FAIR VALUE RANGE

BEAR	BASE	BULL
40.0	75.0	150.0

### Sanion.st VERSUS OMXS30



### REDEYE RATING



### KEY STATS

Ticker	Sanion.st
Market	Small Cap
Share Price (SEK)	25.0
Market Cap (MSEK)	1526
Net Debt 20E (MSEK)	-588
Free Float	88 %
Avg. daily volume ('000)	0

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## Investment Case

For many years, Saniona has been undercapitalized, the most important explanation why Saniona has traded with a significant discount to its Scandinavian, orphan peers.

In August 2020, Saniona completed a directed issue of SEK 567 million to a phenomenal participant list. It includes RA Capital Management, New Leaf Venture Partners, and Pontifax Capital, as well as three of the Swedish pension funds; AP2, AP3, and AP4. RA Capital Management was the lead investor and is a top-tier healthcare specialist fund (worldwide).

With the funding now in place, which provides cash runway throughout 2023, we judge, Saniona now has the resources to explore the potential in its pipeline fully. If the outcome with tesomet plays out well in the next 2-3 years, Saniona could be worth an estimated USD 1-2 billion, supported by our peer-table in the Valuation section.

Saniona has unique aspects in the case; a validated, target-driven research platform focused on ion channels, combined with a mid-stage asset in tesomet targeting two rare eating disorders; Prader-Willi Syndrome (PWS) and Hypothalamic Obesity (HO). PWS and HO both have symptoms of morbid obesity and hyperphagia (an insatiable craving for food), the latter being a potentially life-threatening symptom, and for which there lack effective therapies. Tesomet is in a highly attractive pipeline position, and with the funding in place, Saniona is now ready to fully explore the potential of tesomet in rare disorders, as well as building its commercial organization in the US.

Saniona's ion channel research platform fuels its pipeline with new, first-in-class drug candidates in rare indications. With the funding in place, we see a reason to eye SAN711 and SAN903, two potential first-in-class candidates that stem from the ion channel research platform, in greater detail.

Saniona's research platform has been validated by several collaborations over the years, thus providing the company with non-dilutive funding from upfront payments and milestones. Saniona has generated revenues every year since it was founded in 2011; it is unique for a biotech company.

With the funding in place, Saniona has now also the resources to broaden its proprietary pipeline in rare indications. This is important, the vast majority of our pipeline value is attributed to tesomet in PWS and HO. We are excited to eventually learn more about the strategic efforts to broaden its proprietary pipeline in rare indications. This could mainly come from two sources, in our view:

- The ion channel research platform fuels the proprietary pipeline with first-in-class candidates
- Indication expansion with tesomet

## Key Risks

- Still a Way to Go in PWS and HO
  - We are currently risk-adjusting anticipated revenues at 40% (HO) and 35% (PWS), respectively. The development risks are, thus, still significant
  - There are also specific development risks when targeting rare diseases; the data is often complex, and the regulatory pathway is often new territory
- The transformation to a commercial biopharma company entails several risks. For instance, it requires the in-house experience of professionals that have undergone this journey before.
- Saniona faces many of the general risks associated with drug development. These include clinical development risk (binary case, borderline outcome, etc.), IP/patent risks, need for additional capital, regulatory risks, and sentiment volatility. Investors should be aware of these when considering the biotech sector.

## Financials & Valuation

### Short on Financials

We expect an increase in operating expenses H2'20 vis á vis H1'20 as CEO Levin now starts to build the US organization (three new hires to the executive leadership team announced in August), and with costs starting to kick in for a pivotal program in PWS and HO. Our guidance for the current year are:

- Operating expenses > SEK 135 mn
- Revenues of around SEK 70 mn in the form of royalties (tesofensine sales) and milestones (BI and Medix). Revenues for the current year are deemed as uncertain, and where we have a low insight
- A cash position of around SEK 600 mn at yearend 2020

### Valuation Summary – (Base Case)

Some key parameters to come with our Base Case of SEK 75 per share include:

- A tax rate of some 21%
- USD/SEK 9.5

We base our per share valuation on some 61 mn outstanding shares. The TO2 could increase the number of shares by another 1.5 mn shares. Regardless of the outcome from TO2, it will not have any material impact on our valuation.

Our new WACC of 13% (15%) should be seen in the light of a lowered financial risk following the directed issue, and also reflects the well-respected investors that validate the Saniona case.

Note again that SAN711 and SAN903 are early assets that are currently not included in our valuation. In the current half of 2020, we will start to dig deeper into SAN711, which should be Phase I ready.

A program that we raise some question mark to is NS2359, which is under the partner pipeline but currently lacks a commercial partner. NS2359 is in an ongoing phase IIa study in patients with cocaine addiction. However, there haven't been any updates since early 2019, when an interim-result of 40 patients in the ongoing phase II study supported further development.

Saniona: Sum-of-the-parts valuation									
Project	Indication	Current Phase	Partner	Likelihood of Approval	Royalty rate	Peak Sales (\$m)	Launch year	Net Present Value (SEKm)**	Per share (SEK)
<b>Clinical Programs - Rare Eating Disorders</b>									
Tesomet	PWS	Ph II	-	35%	-	540	2023	2,197	36
Tesomet	HO	Ph II	-	40%	-	310	2024	1,166	19
<b>Total - Rare eating disorders</b>						<b>850</b>		<b>3,363</b>	<b>55</b>
<b>Partner Programs</b>									
Tesofensine	Obesity	NDA	Medix (Mx, Arg)	90%	14%	116	2020	348	6
NS2359	Cocaine Addiction	Ph II	University of Pennsylvania	15%	30%	485	2025	320	5
Cadent program	ET/SCA	Ph II	Cadent Therapeutics	18%-20%	5%	1,016	2025	126	2
BI programs	Schizophrenia	Precl.	Boehringer Ingelheim	5%-7%	7%	941	2027/2030	151	2
<b>Total - clinical partner pipeline</b>								<b>945</b>	<b>15</b>
<b>Proprietary assets - On our Watchlist</b>									
SAN711	Neuropathic itching disorders (Rare)	Precl.	-						
SAN903	Inflammatory disorders (Rare)	Precl.	-						
<b>Technology value</b>								<b>4,308</b>	<b>71</b>
Net cash position (p. 2020-06-30) incl. Directed)								594	
Shared costs								-400	
Ownership Cadent Therapeutics / Scandion Oncology								100	
<b>Fair value</b>								<b>4,602</b>	
Number of shares, full dilution (Mn)								61.0	
<b>Per share value, SEK</b>								<b>75</b>	

\*\* totals may not sum due to roundings

Source: Redeye Research

## Scenario Analysis

After going through our estimates, we come up with fair values of SEK 40-75-150 per share (Bear-Base-Bull). Our somewhat lowered Base Case is pure cosmetics.

Our scenario analysis is based on outcomes in the proprietary pipeline a few years from now. In the short-term, the share will be driven by sentiment and potential noise from the directed issue. As we have seen in the last weeks, there's been a selling pressure in the stock, which we discuss further below.

### Bear Case 40.0 SEK

- Our Bear Case factor in a negative pivotal outcome in the PWS indication (2022)

### Base Case 75.0 SEK

- See our SOTP-model above

### Bull Case 150.0 SEK

- Our Bull Case factor in solid and robust phase III results in HO (2022)
- We raise the probability to 85% in HO, upping the probability in PWS as well to 50%.

#### Saniona: Summary of scenarioanalysis

	Bear	Base	Bull
SEK per share	40	75	150
Potential / Risk*	60%	200%	500%

\* Based on closing price 1 Sep 2020: SEK 25

Source: Redeye Research

## Supportive Peer Valuation

We find a Peer-discussion to be highly relevant in Saniona's case and supportive of our scenario valuation. As Saniona now has a cash position worth its name, and with the stronger focus on the US, we find it relevant to also peer against some US orphan companies. A highly relevant peer we have identified is Rhythm Pharmaceuticals (NASDAQ; RYTM). The company focuses on rare genetic disorders of obesity. Its lead candidate, setmelanotide, is in pivotal- and phase III phase in four rare indications related to obesity, none of them being PWS or HO.

### Peer Valuation: Scandinavian Orphan Companies

Company	Market cap (SEKm)**	Net cash (SEKm)***	EV (\$m)	Stage
<b>Scandinavian Orphan</b>				
Hansa Biopharma	8,624	1,390	7,234	Pivotal
Oncopeptides	8,539	938	7,601	Pivotal
Orphazyme*	3,348	855	2,493	Pivotal
Calliditas Therapeutics	5,103	1,460	3,643	Phase 3
<b>US Orphan****</b>				
Rhythm Pharmaceuticals	11,377	1,976	9,401	Pivotal
Zogenix Inc	11,420	3,373	8,047	Market
Mean (Scandinavia)	6,403	1,161	5,243	
Median (Scandinavia)	6,821	1,164	5,439	
<b>Saniona</b>	<b>1,526</b>	<b>550</b>	<b>976</b>	<b>Ph 2b</b>

\*DKK/SEK 1.4, \*\*\*\* USD/SEK 8.64

\*\* On Sep 2 \*\*\* Based on latest interim or latest estimates, adj. for adjacent issues

Source: Company reports, Bloomberg, Redeye Research

The cash position was an important piece of the puzzle that justify peering against other prominent orphan companies. We assess that the top-valued companies in our cohort (Hansa and Oncopeptides) are 2-3 years ahead of tesomet in development. There are some weaknesses in peer valuation. One is that it only provides a snapshot of the current valuation. Nonetheless, our peer analysis suggests that Saniona could be worth USD 1 billion within 2-3 years if tesomet in HO and PWS plays out well. We find this rather appealing.

## Stock Price Discussion

We still don't know the split between the investors participating in the directed issue. It makes it uncertain for us to have a clear view of the stock in the short-term. The ownership list looks as below, according to Holdings, but should be seen as incomplete as only RA Capital Management and Pontifax Venture Capital are included.

### Saniona: Top 10 Ownership

Owner	# of Shares	Value SEKm	Of Capital
RA Capital Management LP	11,792,452	298	19%
Pontifax Venture Capital	4,716,981	119	8%
Jørgen Drejer	2,344,711	59	8%
Avanza Pension	1,922,775	49	6%
Christian Olofsson	935,256	24	3%
Nordnet Pensionsförsäkring	884,592	22	3%
Leif Andersson Consulting ApS	873,179	22	3%
Thomas Feldthus	1,726,271	44	3%
Palle Christophersen	807,968	20	3%

Source: Holdings

Regarding the selling pressure in the last couple of weeks, the Broker Stats from the last couple of weeks is according to below. Obviously, it is quite a net outflow from MSE and GSI. Although we can't say when the selling pressure stops, the stock trading at some SEK 25 per share reflects highly depressed levels, in our view. We believe it shouldn't take that much from a news flow perspective to rebound from current share levels.

**Saniona: Broker Statistics**

Broker code	Broker name	Net volume	Net value	Buy volume	Buy VWAP	Buy value	Sell volume	Sell VWAP	Sell value
<b>Top-5 Net Buyers</b>									
AVA	Avanza Bank AB	937,132	30,376,413	2,445,974	32.9	80,498,579	1,508,842	33.2	50,122,166
NON	Nordnet Bank AB	570,393	17,468,841	1,552,826	33.2	51,604,013	982,433	34.7	34,135,171
DDB	Danske Bank A/S	151,085	5,142,953	231,913	33.4	7,755,709	80,828	32.3	2,612,756
SWB	Swedbank AB	145,847	4,687,905	214,030	32.3	6,913,275	68,183	32.6	2,225,370
ENS	Skandinaviska Enskilda Banken AB	141,669	4,209,585	278,083	30.9	8,605,702	136,414	32.2	4,396,117
<b>Top-5 Net Sellers</b>									
JPAG	JP Morgan AG	-97,213	-2,855,111	30,193	36.2	1,092,902	127,406	31.0	3,948,014
DBL	Deutsche Bank AG	-107,724	-2,946,586	46,000	39.7	1,827,208	153,724	31.1	4,773,793
UBS	UBS Europe SE	-190,515	-5,886,765	52,677	32.1	1,689,440	243,192	31.2	7,576,205
MSE	Morgan Stanley Europe	-763,308	-25,423,458	184,120	31.1	5,728,442	947,428	32.9	31,151,900
GSI	Goldman Sachs International	-806,576	-26,093,284	49,643	38.4	1,905,203	856,219	32.7	27,998,488

Source: Bloomberg, period between Aug 12 2020 to Aug 31 2020 (10 AM)

## Pipeline Catalysts

### **Phase I study initiation (SAN711)**

With the funding in place, Saniona stands ready to broaden its proprietary pipeline in rare disease, first out being SAN711

**Strength:** Minor

**Time-Horizon:** 0-6 months

### **Tesomet in HO**

For tesomet in HO, the next step is an end-of-phase 2-meeting with the FDA, expected in Q4'20. We believe a phase III study could get started in the next year.

**Strength:** Moderate

**Time-Horizon:** 0-6 months

### **Tesomet in PWS**

For tesomet in PWS, the next step is to initiate a pivotal phase IIb study, expected in Q4'20.

**Strength:** Moderate

**Time-Horizon:** 0-6 months

### **Indication expansion with tesomet in rare eating disorders**

After a brief scan from our side, we know that there are other rare disorders associated with morbid obesity and hyperphagia where tesomet could potentially prove efficacious.

**Strength:** Moderate

**Time-Horizon:** 0-6 months

### **Tesofensine approval and launch in Mexico**

We expect a market launch in Q4'20, which would entitle recurring revenues to Saniona in the form of royalties. Our likelihood of approval is currently at 90 percent

**Strength:** Moderate

**Time-Horizon:** 0-6 months

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## 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: Financials (+1)

#### **People: 4**

We believe the rare disease veteran, the Boston-based CEO Rami Levin possesses the right experience and attributes to execute on the new strategy. As Saniona continues its strategic transformation, it will be crucial to hire experienced personnel that can harvest on the commercial potential. The directed issue was certainly a bold and controversial move by Saniona. It's hard not to like the confidence and execution skills that CEO Levin has brought in to the company. The ownership structure has been strengthened substantially, following the good list of participants in the directed issue.

#### **Business: 3**

Saniona has a uniquely strong business model for a biotech company: Potential to go on its own to market in rare eating disorders A robust discovery platform that fuels new pipeline candidates, in the rare CNS space or out-licensing opportunities in larger indications Recurring revenues possibly kicking in from 2020 in the form of royalties

#### **Financials: 2**

Following the directed issue of SEK 567 mn, the financial risk has been mitigated in the coming years.

INCOME STATEMENT	2018	2019	2020E	2021E	2022E
Net sales	0	3	68	43	137
Total operating costs	0	-107	-133	-272	-213
EBITDA	0	-104	-65	-230	-76
Depreciation	0	0	-1	0	0
Amortization	0	0	0	0	0
Impairment charges	0	0	0	0	0
EBIT	0	-104	-66	-230	-77
Share in profits	0	20	100	0	0
Net financial items	0	0	0	0	0
Exchange rate dif.	0	0	0	0	0
Pre-tax profit	0	-84	34	-230	-77
Tax	0	0	0	0	0
Net earnings	0	-84	34	-230	-77

BALANCE SHEET	2018	2019	2020E	2021E	2022E
<b>Assets</b>					
<i>Current assets</i>					
Cash in banks	55	40	588	358	280
Receivables	8	6	5	5	2
Inventories	0	0	0	0	0
Other current assets	0	0	0	0	0
Current assets	63	46	593	363	282
<i>Fixed assets</i>					
Tangible assets	2	3	3	3	3
Associated comp.	11	39	81	81	81
Investments	0	0	0	0	0
Goodwill	0	0	0	0	0
Cap. exp. for dev.	0	0	0	0	0
0 intangible rights	0	0	0	0	0
0 non-current assets	0	0	0	0	0
Total fixed assets	12	42	84	84	84
Deferred tax assets	8	8	8	8	8
Total (assets)	83	96	685	455	373
<b>Liabilities</b>					
<i>Current liabilities</i>					
Short-term debt	0	0	0	0	0
Accounts payable	38	35	10	10	5
0 current liabilities	0	0	0	0	0
Current liabilities	38	35	10	10	5
Long-term debt	0	0	0	0	0
0 long-term liabilities	0	2	2	2	2
Convertibles	6	0	0	0	0
Total Liabilities	44	38	12	12	7
Deferred tax liab	0	0	0	0	0
Provisions	0	0	0	0	0
Shareholders' equity	39	58	673	443	366
Minority interest (BS)	0	0	0	0	0
Minority & equity	39	58	673	443	366
Total liab & SE	83	96	685	455	373

FREE CASH FLOW	2018	2019	2020E	2021E	2022E
Net sales	0	3	68	43	137
Total operating costs	0	-107	-133	-272	-213
Depreciations total	0	0	-1	0	0
EBIT	0	-104	-66	-230	-77
Taxes on EBIT	0	0	0	0	0
NOPLAT	0	-104	-66	-230	-77
Depreciation	0	0	1	0	0
Gross cash flow	0	-104	-65	-230	-76
Change in WC	29	0	-24	0	-2
Gross CAPEX	0	-2	0	0	0
Free cash flow	29	-105	-90	-230	-79

CAPITAL STRUCTURE	2018	2019	2020E	2021E	2022E
Equity ratio	47%	61%	98%	97%	98%
Debt/equity ratio	15%	0%	0%	0%	0%
Net debt	-49	-40	-588	-358	-280
Capital employed	-20	-21	3	4	6
Capital turnover rate	0.0	0.0	0.1	0.1	0.4

GROWTH	2018	2019	2020E	2021E	2022E
Sales growth	0%	66.350	2,451%	-37%	222%
EPS growth (adj)	0%	0%	-141%	-776%	-67%

DCF VALUATION	CASH FLOW, MSEK	
WACC (%)	13.0 %	
Assumptions 2020-2026 (%)		
Average sales growth	66.3 %	
EBIT margin	-82.7 %	Share price, SEK 25.0

PROFITABILITY	2018	2019	2020E	2021E	2022E
ROE	0%	-171%	9%	-41%	-19%
ROCE	0%	-161%	9%	-41%	-19%
ROIC	0%	527%	322%	-6620%	-2170%
EBITDA margin	0%	-3909%	-96%	-540%	-56%
EBIT margin	0%	-3909%	-97%	-541%	-56%
Net margin	0%	-3149%	50%	-541%	-56%

DATA PER SHARE	2018	2019	2020E	2021E	2022E
EPS	0.00	-1.37	0.56	-3.77	-1.25
EPS adj	0.00	-1.37	0.56	-3.77	-1.25
Dividend	0.00	0.00	0.00	0.00	0.00
Net debt	0.00	-0.66	-9.64	-5.87	-4.58
Total shares	0.00	61.04	61.04	61.04	61.04

VALUATION	2018	2019	2020E	2021E	2022E
EV	-48.7	-62.1	915.8	1,145.9	1,224.5

SHARE PERFORMANCE	GROWTH/YEAR		18/20E
1 month	-27.4 %	Net sales	12,920.1 %
3 month	-6.4 %	Operating profit adj	0.0 %
12 month	36.9 %	EPS, just	0.0 %
Since start of the year	-2.7 %	Equity	313.0 %

SHARE INFORMATION	
Reuters code	Sanion.st
List	Small Cap
Share price	25.0
Total shares, million	61.0
Market Cap, MSEK	1526.1

MANAGEMENT & BOARD	
CEO	Rami Levin
CFO	Anita Milland
IR	
Chairman	J. Donald DeBethizy

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## 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

### Important information

Redeye AB ("Redeye" or "the Company") is a specialist financial advisory boutique that focuses on small and mid-cap growth companies in the Nordic region. We focus on the technology and life science sectors. We provide services within Corporate Broking, Corporate Finance, equity research and investor relations. Our strengths are our award-winning research department, experienced advisers, a unique investor network, and the powerful distribution channel redeye.se. Redeye was founded in 1999 and since 2007 has been subject to the supervision of the Swedish Financial Supervisory Authority.

Redeye is licensed to; receive and transmit orders in financial instruments, provide investment advice to clients regarding financial instruments, prepare and disseminate financial analyses/recommendations for trading in financial instruments, execute orders in financial instruments on behalf of clients, place financial instruments without position taking, provide corporate advice and services within mergers and acquisition, provide services in conjunction with the provision of guarantees regarding financial instruments and to operate as a Certified Advisory business (ancillary authorization).

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### Recommendation structure

Redeye does not issue any investment recommendations for fundamental analysis. However, Redeye has developed a proprietary analysis and rating model, Redeye Rating, in which each company is analyzed and evaluated. This analysis aims to provide an independent assessment of the company in question, its opportunities, risks, etc. The purpose is to provide an objective and professional set of data for owners and investors to use in their decision-making.

### Redeye Rating (2020-09-02)

Rating	People	Business	Financials
5p	16	12	3
3p - 4p	109	86	35
0p - 2p	4	31	91
Company N	129	129	129

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### CONFLICT OF INTERESTS

Anders Hedlund owns shares in the company : No

Ludvig Svensson 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.