

Saniona

Sector: Biotech

What to expect in 2019 (including the stock price)

What the Investment Case is about

In this report, we are going through what we expect in terms of opportunities and challenges during 2019. NDA filing with tesofensine in Mexico remains important. However, we continue to attribute the majority of the pipeline value to Tesomet in rare eating disorders. Hence, this report will focus on the current status of Tesomet in the PWS and HO indication.

Valuation update

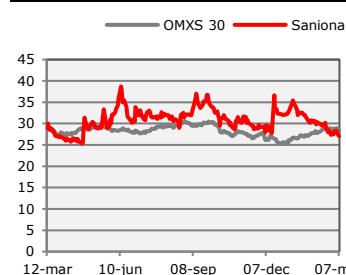
Following the inclusion of Tesomet – HO to our valuation, we have raised our Base Case to SEK 105 per share (85). Our Bull- and Bear Case is at SEK 170 (130) and SEK 30 (30) per share, respectively.

Our update in valuation leads accordingly to an increasing gap to current stock price levels. Therefore, we have dedicated a discussion of why the stock price is stuck around SEK 30 per share, despite an eventful last six months.

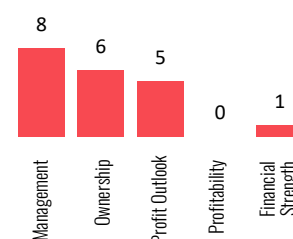
FAIR VALUE RANGE

BEAR	BASE	BULL
30	105	170

Sanion.st VERSUS OMXS30



REDEYE RATING



KEY STATS

Ticker	Sanion.st
Market	Small Cap
Share Price (SEK)	27.0
Market Cap (MSEK)	633
Net Debt 19E (MSEK)	102
Free Float	73 %
Avg. daily volume (MSEK)	2

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KEY FINANCIALS (SEKm)	2017	2018	2019E	2020E	2021E	2022E
Net sales	21	55	8	83	119	150
EBITDA	-57	-52	-94	-29	3	103
EBIT	-57	-54	-94	-30	3	103
EPS (adj.)	-2.4	-2.3	-4.0	-1.3	0.1	4.4
EV/Sales	N/A	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	N/A	N/A	N/A	N/A	N/A	N/A
EV/EBIT	N/A	N/A	N/A	N/A	N/A	N/A
P/E	N/A	N/A	N/A	N/A	N/A	N/A

PWS – Open-label will provide additional data

A very brief recap of the ongoing phase IIa study:

- The first part in Prader-Willi syndrome (PWS) patients (n = 9 adults) achieved a remarkable reduction in weight and hyperphagia at a daily dose of 0.5 mg Tesomet. However, we also learned that these patients metabolize tesofensine at a slow pace which may explain some of the observed side effects and dropout rates
- The second part in PWS patients (n = 9 adolescents) evaluated Tesomet at a daily dose of 0.125 mg. Tesomet was well tolerated, and eight of the nine patients are in an ongoing open-label extension study. However, the evaluated dose did not provide any meaningful differences in weight and hyperphagia over placebo. Reduction in hyperphagia and an increase in weight were seen in both treatment groups

The phase IIa study has now moved into an open-label extension study in PWS adolescents, of which eight out of nine patients have agreed to take part in. Saniona seeks to increase the daily dose to 0.25 mg in the open-label and has received approval in the Czech Republic; approval in Hungary is pending.

It is arguable if the second part in PWS adolescents should be seen as something negative, neutral or even a positive data reporting. We have broken it down according to below:

Positive aspects:

- We arguably believe, given the outcome of the first two parts of the phase IIa study, that there is a dose-regimen where Tesomet can provide efficacy and be safe and well tolerated. We also believe that this can be handled not only with fixed dose-regimens but also through adaptive study designs

Neutral aspects:

- We believe the open-label extension phase will be important and give additional data. Specifically, it will be interesting and important to see if 0.25 mg daily Tesomet could reach the therapeutically relevant plasma levels previously observed in obese trials with tesofensine
- The results from the second part were pretty much in line with our expectations. Lowering the dose to a quarter is quite a lot. Any signs of significant efficacy would have been a bonus in our view
- In general, the purpose of a phase II study is to provide relevant answers on how to design pivotal trials in terms of dose-regimens, dose-response etc. This was a phase IIa study; statistical meaningful efficacy parameters should be answered in future pivotal trials

Negative aspects:

- We are currently building the Saniona 'investment story' around Tesomet in eating disorders, and the major of our valuation is attributed to the PWS indication. There are a significant drop height risks from these levels if the development in this indication would be terminated.

In summary, we believe there is a clear rationale to continue in the PWS indication into larger clinical studies. We are eager to learn about additional data from the open-label part, which we believe could get presented in Q2'19.

Furthermore, we would find it interesting to see if a dose-adaptive study design could more efficiently capture the therapeutic window for Tesomet. At present, we are not changing our estimates in Tesomet - PWS.

Introducing Hypothalamic Obesity

Saniona have initiated a phase II study with Tesomet in patients suffering from Hypothalamic injury-induced Obesity (HIO or HO). The study will consist of 25 diagnosed HO patients where overweight is related to the disease. The first patients have already been recruited. It is a double-blind, single-center study carried out in Denmark. Treatment arms include randomization to placebo or treatment with 0.5 mg tesofensine/50 mg metoprolol for 24 weeks. The double-blind part will be followed by an open-label extension part for another 24 weeks. Primary objectives are safety measures; the secondary objective is an efficacy parameter, measured as a change in satiety and appetite. We expect data from the double-blinded part in Q4'19, following Saniona's own communication. We hope to learn that Tesomet is safe, well-tolerated and enable a rapid progression into pivotal trials.

HO is an ultra-rare eating disorder. A significant risk factor for developing HO is craniopharyngioma. It is a benign tumor in the hypothalamic region, often with onset in childhood. Upon surgery of the tumor, or from the growth of the tumor itself, it can cause injury in the hypothalamus region. Hypothalamus is a critical center in the brain to align the central nervous system to the endocrine system. It controls important functions, such as hunger and body weight. The injury can, therefore, cause uncontrolled signaling that manifests as insatiable hunger and craving for food. The symptoms are much related to what PWS patients experience. A distinction between the two patient-groups is that HO patients are often cognitively normal and are motivated to get treatment.

Estimates in HO

Available data in HO is rather limited. Our estimate of eligible prevalence bases on an incidence of craniopharyngioma of one in every 50.000 inhabitants (1/50.000), applied to the populations of the US and the main markets in Europe. We assume a conservative 35 percent of craniopharyngioma patients develop hypothalamic injuries, with complications such as insatiable hunger and food craving. Further, we assume a market penetration and annual treatment cost similar to Tesomet - PWS.

Saniona: Peak sales US within HO	
Prevalence (m)	0.002
Diagnosed and treated	90%
Diagnosed and treated (m)	0.002
Market penetration	35%
Saniona patients (m)	0.001
Annual treatment cost	140,000 USD
Top sales estimate (\$m)	100

Source: Redeye Reseach

Saniona: Peak sales Europe within HO	
Prevalence (m)	0.003
Diagnosed and treated	90%
Diagnosed and treated (m)	0.003
Market penetration	35%
Saniona patients (m)	0.001
Annual treatment cost	100,000 USD
Top sales estimate (\$m)	100

Source: Redeye Reseach

Other, key assumptions correspond to our assumptions in Tesomet – PWS:

- Risk-adjustment (LoA) at 24 percent
- Gross margin of 80 percent (highly conservative)
- Market launch in 2022, peak sales reached 2031

We have estimated a total cost for the phase II program of SEK 18 million; the majority falls under the income statement in 2019. Phase III costs and NDA filing are risk-adjusted based on success for the phase II program.

Year	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
(USDm)	Phase II	Phase III	NDA										
Sales	0	0	0	10	15	25	44	70	100	126	150	176	200
Margin %	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
Margin	0	0	0	8	12	20	35	56	80	101	120	141	160
Probability	24%	24%	24%	24%	24%	24%	24%	24%	24%	24%	24%	24%	24%
Risk adj. gross profit	0.0	0.0	0.0	1.9	2.9	4.8	8.4	13.3	19.0	24.0	28.5	33.5	38.1
In SEK	0.0	0.0	0.0	16.2	24.4	40.6	71.5	113.7	162.4	204.7	243.7	285.9	324.9
Risk adj. R&D Expenditure	-2.1	-3.2	-3.2	-0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
In SEK	-18	-27	-27	-1	0	0	0	0	0	0	0	0	0
Risk adj. Value	-2.1	-3.2	-3.2	1.7	2.9	4.8	8.4	13.3	19.0	24.0	28.5	33.5	38.1
Discount Factor	0.9	0.8	0.7	0.6	0.5	0.4	0.4	0.3	0.3	0.3	0.2	0.2	0.2
Risk adj net present value (rNPV)	-1.9	-2.5	-2.2	1.0	1.5	2.1	3.2	4.5	5.5	6.1	6.3	6.4	6.3
rNPV, post-tax	-1.5	-2.0	-1.7	0.8	1.2	1.7	2.6	3.5	4.4	4.8	5.0	5.1	5.0

Source: Redeye Research

Stock price discussion

Our new Base Case increases the gap to current stock price levels. It is relevant to discuss why the stock price won't move after an eventful six months. The discussion should rightfully be held from the three, most significant items we believe are holding back the stock price at the moment:

- An uncertainty on the path forward in Tesomet, eating disorders
- The convertible tranche agreement
- Additional funding needed

An uncertainty on the path forward in Tesomet, eating disorders

Our notion is that investors are not confident in the path going forward in eating disorders and would likely require additional data in PWS (and HO). We argue, as we discussed in the first section, that there is a clear rationale for Tesomet in PWS. Next data point from the open-label part will be important to see if the required plasma levels to demonstrate efficacy is reached when given 0.25 mg daily dose. In this regard, it is important to emphasize that Saniona addresses two rare eating disorders. It provides the company with strategic opportunities, as well as being risk-mitigated. Furthermore, our estimates in HO if treated as the only addressed indication is conservative at this point to mitigate cannibalizing effects on price for Tesomet.

The convertible tranche agreement

As of today, Saniona has drawn ten tranches á SEK 6 million each. Most of it has been converted to shares, and we also assume most of it has been sold on the market. It has created a selling pressure on the stock. Furthermore, given the increasingly bad reputation of convertible tranches, more often being referred to as 'death-spiraling' funding, we would consider other funding options as more feasible for Saniona at present. It leads us to the next item; additional funding needed.

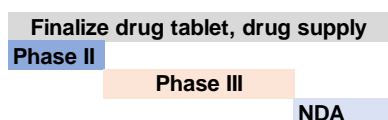
Additional funding needed

In the last interim-reports, Saniona has reported cash balances between SEK 18 – 55 million. We find it to occasionally be at all too low levels. The convertible tranche agreement has covered the operating expenses without strengthening the financials of Saniona. We want to see a substantial improvement in the financials during the year, which also leads to a strengthened ownership base.

The core of Saniona's 'Investment Case' is to target rare eating disorders with an own go-2-market strategy. It will drive costs in the next few years. Below is our, high-level development cost estimates for Saniona to make it to the market in the two rare eating disorders.

Saniona: Investment estimates in Tesomet

	2019	2020	2021	2022	Total
Tesomet	2	2	1		5
Tesomet - HO	18	72		5	95
Tesomet - PWS*	5	110		5	120
Total investment (SEKm)					220



* Ph II ongoing in PWS, est costs for remaining part
Source: Redeye Research

The investment opportunity is attractive, both from a cost and market potential. We argue that it was the right strategy to prioritize Tesomet in rare eating disorders. The upside potential in targeting indications that Saniona could take to market on its own, vis á vis a partner-dependent strategy is incomparable.

On the income side over the next few years, Saniona could start to be entitled to recurrent royalty income in the next year. Tesofensine in Mexico is currently risk-adjusted at high 90 percent. Below is how we anticipate the royalty income stream:

Tesofensine: Anticipated revenue streams

	2020	2021	2022	2023	2024	2025
Sales (USDm)	23	46	75	92	109	115
Royalty Rate	14%	14%	14%	14%	14%	14%
Royalty	3	6	10	13	15	16
Probability	90%	90%	90%	90%	90%	90%
Risk adj. Royalty	3	6	9	12	14	14
Risk adj royalty (SEKm)	25	49	80	99	118	124
Non-risk adj royalty (SEKm)	27	55	89	110	131	137
Medix milestone (USDm)		4				
Non-risk adj royalty (SEKm)		34				
Total, non-risk adj revenue (SEKm)	62	55	89	110	131	137

Source: Redeye Research

In the research collaboration with Boehringer Ingelheim (BI), we have estimated that a phase I initiation will trigger a milestone of approximately EUR 6 million (deal value in EUR). A phase I initiation will most likely happen in 2020.

Summary - Funding needed 2019-2021

Programs	Investment type	SEKm
Tesomet - PWS	Make it to the market	-115
Tesomet - HO	Make it to the market	-90
Tesomet	Tablet and drug supply	-5
Tesomet total		-210
Fixed overhead costs, 2019-2021		-135
Other pipeline costs		-35
Non risk-adjusted Income opportunities	Income type	
Tesofensine	Royalty income	117
BI program	Milestones	60
Current cash position		55
Est. tranches drawn in 2019		24
		-124

Source: Redeye Research

If we would treat the remaining pipeline as status quo, include fixed overhead costs and other clinical development outside of Tesomet, our somewhat simplified task suggests that additional funding of > SEK 120 million is needed over the next few years. We have included the year-end cash position and made the assumption that the first twelve tranches will be drawn (SEK 6 mn á 12 tranches, eight tranches drawn in 2018, four tranches drawn in 2019). However, we emphasize that we do not know how Saniona plans to treat future tranches; it bases solely on our assumption for this specific task.

Given that Saniona could have products on the market and be in phase III in eating disorders during the next few years, the investments and corresponding additional funding are rather modest. Furthermore, as always in the case of Saniona, several non-dilutive cash opportunities could play out during the period and strengthen the funding situation (new partnership deals, divestment of holdings, etc.). As the current strategy is highly focused on Tesomet in eating disorders, we see a rationale for Saniona to enter deals with their preclinical assets in the near- and mid-term in order to provide the company with non-dilutive cash. At the moment, we argue that the funding gap is a significant factor why the true value of Saniona's pipeline is not reflected in the stock price.

Investment Case

- Orphan focus in eating disorders represents the largest value potential
- Royalty from tesofensine sales in obesity (Mexico) could start to generate recurrent income to Saniona in 2020
- A late-stage, broad pipeline with a target-driven research focus

The investment case in Saniona is becoming increasingly oriented towards the Tesomet program, targeting the rare eating disorders: Prader-Willi syndrome and Hypothalamic injury-induced obesity (HIO/HO). Those disorders have symptoms of hyperphagia; a potentially life-threatening, insatiable craving for food. Available treatments are not able to treat the hyperphagia part of the disorders. Furthermore, PWS and HO represent an opportunity where Saniona has the potential to go-2-market with its own sales force in those indications. We estimate a peak-sales potential of USD 980 million for Tesomet in PWS and HO combined.

At the end of 2018, Medix (Saniona's partner in Mexico) reported positive phase III results with tesofensine in obese patients. It was a double-blinded, pivotal trial where patients were randomized to three treatment arms (placebo, 0.25 mg tesofensine once-daily, 0.5 mg tesofensine once-daily). The trial enrolled a total of 372 obese patients. The total treatment period was 24-weeks. Tesofensine demonstrated a statistically and clinically meaningful weight loss and once again proved its robustness in achieving weight reduction. Medix is now preparing for regulatory filings; we have estimated risk-adjusted (LoA currently at 90 percent) recurrent income from 2020 (see this report for anticipated revenue streams).

We are encouraged that the target-driven research approach on ion channels has progressed in recent years. CAD-1883 (Cadent Therapeutics) stem from the ion channel research platform and has gone into clinical development. Furthermore, we believe SAN-711 could enter clinical stage later this year.

The target-driven and interdisciplinary research platform entail Saniona to run a broad pipeline, in various indications with high medical needs. Their research platform has been validated by several research collaborations, 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.

News flow / Catalysts

Results from the open-label extension part (Tesomet – PWS)

The open-label part in the phase IIa study will provide additional and important data, where the dose is increased to 0.25 mg daily (approved in the Czech Republic, pending in Hungary).

Strength: Major

Time-frame: 0-6 months

Phase I study initiation (SAN711)

We expect the initiation of a phase I study on healthy volunteers in late H1'19 or early H2'19.

Strength: Minor

Time-frame: 0-6 months

Top-line results from the double-blinded part (Tesomet – HO)

We expect top-line results from the phase IIa study, the double-blinded part in Q4'19.

Strength: Moderate

Time-frame: 7-18 months

NDA approval and subsequent market launch (tesofensine – Obesity Mx)

We believe an NDA approval could happen in 2019, with a subsequent market launch in early 2020. Our likelihood of approval is currently at 90 percent.

Strength: Major

Time-frame: 7-18 months

Full data read-out (NS2359 – Cocaine addiction)

We believe a full data read-out from the ongoing phase II study at the end of 2019. So far 50 out of the planned 80 patients have been recruited. However, the recruitment pace has been slower than we expected so there is a risk the read-out will happen in 2020 instead.

Strength: Moderate

Time-frame: 7-18 months

Valuation

Saniona: Sum-of-the-parts valuation									
Project	Indication	Current phase	Partner	Likelihood of Approval	Royalty rate*	Top Sales (\$m)	Launch year	Net Present Value (SEKm)**	Per share (SEK)
Clinical programs - Rare eating disorders									
Tesomet	PWS	Ph II	-	24%	80%	780	2022	1,329	57
Tesomet	HO	Ph II	-	24%	80%	200	2022	307	13
Total - Rare eating disorders								980	70
Clinical programs - Partner									
Tesofensine	Obesity	NDA	Medix (Mx, Arg)	90%	14%	115	2020	290	12
NS2359	Cocaine Addiction	Ph II	University of Pennsylv	15%	30%	500	2024	218	9
Cadent program	Ataxia	Ph I	Cadent Therapeutics	12%	5%	1,130	2024	80	3
Total - clinical partner pipeline								588	25
Preclinical pipeline - funded and/or CD selection									
BI program	Schizophrenia	Precl.	Boehringer Ingelheim	9%	7%	1,350	2025	120	5
SAN711	Neuropathic Pain	Precl.	-	9%	16%	1,250	2025	218	9
Total value CD preclinical pipeline								339	15
Technology value								2,562	110
Net cash position (p. 2018-12-31)								55	
Shared costs								-250	
Ownership Cadent Therapeutics / Scandion Oncology								60	
Fair value								2,430	
Number of shares, full dilution (Mn)								23.3	
Per share value, SEK								105	
Partner available									
Tesomet	Obesity/T2D	Ph II							
Early preclinical pipeline									
Kv7 program	Pain, epilepsy, and	Precl.							
Nicotinic a6 program	Parkinson's Disease	Precl.							
IK Program	IBD	Precl.							

* Tesomet - PWS and HO to be referred as margin

** totals may not sum due to roundings

Source: Redeye Research

Bear Case 30.0 SEK

- In our pessimistic scenario, we factor in a continuous bear sentiment in the stock price. It is driven by the items in the previous section: uncertainty in the path forward in eating disorders, selling pressure, and uncertainty in the funding going forward

Base Case 105.0 SEK

- Our Base Case represents our SOTP figure above. The major positive contributor since the last update (SEK 85 per share) is the inclusion of the HO indication.
- We include projects in our valuation where we see a clear development path going forward, supported by funding in place, and what we believe the market is likely to consider in the investment case at the moment.

Bull Case 170.0 SEK

- Based on 1-2 year outcome scenario, we schedule that Tesomet in eating disorder advances, we update Likelihood of Approval accordingly
- We also factor in that tesofensine gets approved in Mexico and Saniona starts to receive recurrent royalty income within the coming 1-2 year's

Saniona: scenarioanalysis

	Bear	Base	Bull
SEK per share	30	105	170
Potential / Risk*	11%	289%	530%

* Based on close price 2019-03-11

Source: Redeye Research

Summary Redeye Rating

The rating consists of five valuation keys, each constituting an overall assessment of several factors that are rated on a scale of 0 to 2 points. The maximum score for a valuation key is 10 points.

Rating changes in the report: no changes

Management: 8.0

The company has a knowledgeable and experienced management team, which rises above the average in the industry. CEO and CFO have settled important deals for Saniona; license deals, research partner deals, as well as spin-outs. Other advantages include substantial shareholding for management.

Ownership: 6.0

Saniona's management and board of directors have significant ownership in the company, which distinguishes the company positively in relation to many others in the industry. The absence of strong institutional owners can be identified as a challenge for management and the board.

Profit Outlook: 5.0

Following Saniona's priority to take Tesomet within eating disorders to the markets in the EU and the US, the largest potential is now within eating disorders. In PWS and HO, it represents an opportunity where Saniona could develop a go-to-market strategy with its own sales force at the same time as high peak-sales can be achieved.

Profitability: 0.0

The company is still several years from achieving sustainable profitability. Like most other companies in this development phase, there is no consistent history of profitability, which drives up the rate of return required by investors.

Financial Strength: 1.0

Saniona entered 2019 with a cash position of approximately SEK 55 million. We estimate that Saniona's cost burn will increase over 2019 and 2020, driven by the clinical development in rare eating disorders (ph II and ph III). Additional funding is hence needed, see this report (section "Additional funding needed") for a more thorough analysis.

Redeye Rating and Background Definitions

The aim of a Redeye Rating is to help investors identify high-quality companies with attractive valuation.

Company Qualities

The aim of Company Qualities is to provide a well-structured and clear profile of a company's qualities (or operating risk) – its chances of surviving and its potential for achieving long-term stable profit growth.

We categorize a company's qualities on a ten-point scale based on five valuation keys; 1 – Management, 2 – Ownership, 3 – Profit Outlook, 4 – Profitability and 5 – Financial Strength.

Each valuation key is assessed based a number of quantitative and qualitative key factors that are weighted differently according to how important they are deemed to be. Each key factor is allocated a number of points based on its rating. The assessment of each valuation key is based on the total number of points for these individual factors. The rating scale ranges from 0 to +10 points.

The overall rating for each valuation key is indicated by the size of the bar shown in the chart. The relative size of the bars therefore reflects the rating distribution between the different valuation keys.

Management

Our Management rating represents an assessment of the ability of the board of directors and management to manage the company in the best interests of the shareholders. A good board and management can make a mediocre business concept profitable, while a poor board and management can even lead a strong company into crisis. The factors used to assess a company's management are: 1 – Execution, 2 – Capital allocation, 3 – Communication, 4 – Experience, 5 – Leadership and 6 – Integrity.

Ownership

Our Ownership rating represents an assessment of the ownership exercised for longer-term value creation. Owner commitment and expertise are key to a company's stability and the board's ability to take action. Companies with a dispersed ownership structure without a clear controlling shareholder have historically performed worse than the market index over time. The factors used to assess Ownership are: 1 – Ownership structure, 2 – Owner commitment, 3 – Institutional ownership, 4 – Abuse of power, 5 – Reputation, and 6 – Financial sustainability.

Profit Outlook

Our Profit Outlook rating represents an assessment of a company's potential to achieve long-term stable profit growth. Over the long-term, the share price roughly mirrors the company's earnings trend. A company that does not grow may be a good short-term investment, but is usually unwise in the long term. The factors used to assess Profit Outlook are: 1 – Business model, 2 – Sale potential, 3 – Market growth, 4 – Market position, and 5 – Competitiveness.

Profitability

Our Profitability rating represents an assessment of how effective a company has historically utilised its capital to generate profit. Companies cannot survive if they are not profitable. The assessment of how profitable a company has been is based on a number of key ratios and criteria over a period of up to the past five years: 1 – Return on total assets (ROA), 2 – Return on equity (ROE), 3 – Net profit margin, 4 – Free cash flow, and 5 – Operating profit margin or EBIT.

Financial Strength

Our Financial Strength rating represents an assessment of a company's ability to pay in the short and long term. The core of a company's financial strength is its balance sheet and cash flow. Even the greatest potential is of no benefit unless the balance sheet can cope with funding growth. The assessment of a company's financial strength is based on a number of key ratios and criteria: 1 – Times-interest-coverage ratio, 2 – Debt-to-equity ratio, 3 – Quick ratio, 4 – Current ratio, 5 – Sales turnover, 6 – Capital needs, 7 – Cyclicity, and 8 – Forthcoming binary events.

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Redeye Rating (2019-03-11)

Rating	Management	Ownership	Profit outlook	Profitability	Financial Strength
7,5p - 10,0p	49	47	19	11	20
3,5p - 7,0p	90	87	120	42	55
0,0p - 3,0p	13	18	13	99	77
Company N	152	152	152	152	152

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CONFLICT OF INTERESTS

Anders Hedlund owns shares in the company Saniona: No

Klas Palin owns shares in the company Saniona: No

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