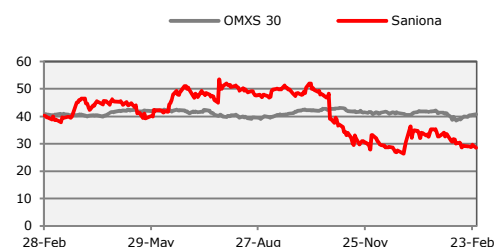
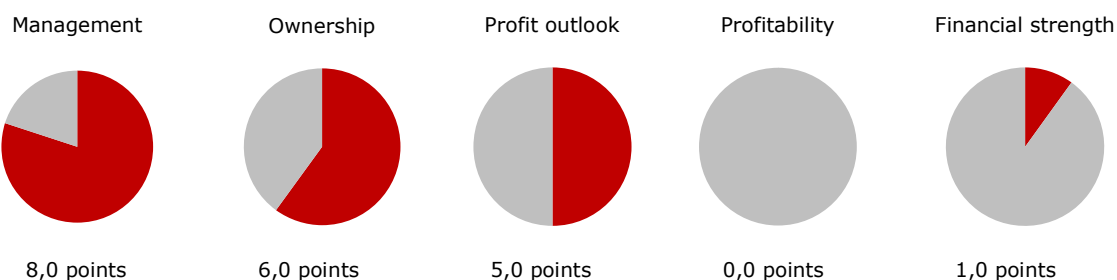


**Summary**
**Saniona (Sanion.st)**
**What to Expect in 2018**

- In this update, we will go through Saniona's opportunities and challenges for the next 12 months. We believe 2018 and beginning 2019 will be a period of value drivers as ever seen before.
- Following the transition of analyst at Redeye, we have done a thorough analysis of our valuation and financial forecasts and landed on a base case of SEK 70 (72). Nothing fundamentally has changed in our perception of the company and our conclusion stay firm: Saniona is undervalued.

List: Small Cap  
 Market Cap: 615 MSEK  
 Industry: Biotech  
 CEO: Jörgen Drejer  
 Chairman: J. Donald DeBethizy


**Redeye Rating (0 – 10 points)**

**Key Financials**

	2016	2017	2018E	2019E	2020E	Share information	
Revenue, MSEK	75	21	48	33	52	Share price (SEK)	28,3
Growth	450%	-72%	133%	-32%	58%	Number of shares (m)	21,8
EBITDA	5	-57	-32	-52	-18	Market Cap (MSEK)	615
EBITDA margin	6%	-274%	-66%	-159%	-34%	Net debt (MSEK)	16
EBIT	4	-57	-32	-53	-18	Free float (%)	73 %
EBIT margin	6%	-276%	-67%	-161%	-35%	Daily turnover ('000)	1 850
Pre-tax earnings	5	-56	-32	-53	-18	Analysts:	
Net earnings	2	-56	-32	-53	-18	Anders Hedlund	
Net margin	3%	-272%	-67%	-161%	-35%	anders.hedlund@redeye.se	
Dividend/Share	0,00	0,00	0,00	0,00	0,00		
EPS adj.	0,00	-2,59	-1,48	-2,43	-0,84		
P/E adj.	0,0	0,0	-19,1	-11,6	-33,6		
EV/S	-0,7	-1,1	13,1	18,7	11,9		
EV/EBITDA	-11,7	0,4	-19,9	-11,7	-34,7		

**Important information:** All information regarding limitation of liability and potential conflicts of interest can be found at the end of the report.

## Redeye Rating: Background and 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.

## **Tesofensine – Soon on the Mexican Obesity Market?**

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In early February, Saniona announced that the last patient of the total n=372 had been recruited to the phase III study with tesofensine. A successful result from that study followed by approval process will entail access to the markets in Mexico and Argentina. Before we proceed in our analysis of what that value could bring to Saniona, let us first do a recap of the tesofensine project and the ongoing clinical study in Mexico.

Saniona acquired the tesofensine project from NeuroSearch A/S in October 2014. tesofensine is a triple monoamine reuptake inhibitor, thereby inhibits the presynaptic reuptake of dopamine, noradrenaline, and serotonin. Through its mechanism of action, the hypothesis is that tesofensine reduces food craving, reduces appetite as well as increases fat burn.

A clinical phase IIb (named TIPO-1) took place between 2006-2007 and were published in the prestigious medical journal Lancet in 2008. TIPO-1 was a randomized, double-blind, placebo-controlled trial conducted at five Danish clinical sites, evaluating tesofensine for obesity. A patient population of n=203 were enrolled, n=161 completed the study. At baseline, patients were randomly assigned to four different arms; tesofensine 1.0 mg, tesofensine 0.5 mg, tesofensine 0.25 mg or placebo. Administration took place in the same manner for all arms, i.e. once a daily dose for 24 weeks. Primary endpoint was efficacy as measured by percentage change in body weight. After 24 weeks of treatment, the adjusted mean weight reduction to that of placebo was 4,5% for tesofensine 0.25 mg arm, 9,2% for tesofensine 0.5 mg arm, and 10,6% for tesofensine 1.0 mg arm, suggesting that tesofensine is effective in producing weight loss in obese patients over 6 months.

In an industrial context, Saxenda (Novo Nordisk) is expected to be the market leading drug for obesity in US, reaching estimated sales of almost USD 800 million by 2026 according to Datamonitor. Saxenda is a GLP-1 receptor agonist with thus a different mechanism of action than tesofensine. In Saxenda's pivotal clinical trial (n=3,731), it showed a mean weight loss of 8,0% in treatment arm 1 (3.0 mg once daily dose of Saxenda) while arm 2 (placebo) showed a mean weight loss of 2,6%. The treatment period was 68 weeks, i.e. more than half a year longer treatment period than TIPO-1.

*We argue that tesofensine could become a market leading product in Mexico*

Leading us back to present time, in tesofensine we see a potential best-in-class drug that could become a market leader in Mexico and Argentina. Obesity in Mexico is alarming, having one of the largest obese population ratios. Due to its best-in-class potential, we are estimating a market share of 30% by 2025. Assuming the market today for prescribed medicine is worth USD 250 million and growing annually by 5%, it would lead to top sales of roughly USD 115 million. Our adjustment from previous update is not reflecting any decrease in belief of potential, a market share of 30% is tough

yet realistic. On the other hand, we considered our royalty rate in the lower end of our estimate and have adjusted it to 14%.

*A current phase III study that share similarities with previous successful studies*

The ongoing phase III study is being carried out by Saniona's partner Medix and the study design shares many characteristics with the TIPO-1 study. Patients are being randomly assigned to two treatment arms (0.25 mg or 0.5 mg tesofensine) or to placebo arm. The administration of the tablet is once a daily dose for 24 weeks and where the primary endpoint is absolute and percentage change in body weight over the treatment period. Due to its similarities with TIPO-1, we have set a high likelihood of approval that will remain unchanged. Our likelihood of approval is 60% with a clinical trial phase III success of 67%. The results from that study is important not only from a Mexico perspective but for the Tesomet project as well. Can the results from the TIPO-1 be repeated in the phase III trial, we are likely to see an increased partner interest for the Tesomet program.

*Saniona could potentially have their first drug on the market in 2020*

We have also updated our timeline of tesofensine which is supported by the high pace in recruitment of patients. We think topline results could be presented by early 2019. After a more thorough analysis since our [research note](#) on the topic, we think the approval process will take approximately a year, given successful results. The approval process is handled by Medix which is one of the market leaders in the field. Consequently, we have adjusted first sales to occur in early 2020. There is a potential red flag in the approval process if the phase III study will show an elevated heart rate in the 0.5 mg arm as did in TIPO-1 which could put pressure on the timeline and potential approval. The large medical need for effective drugs against obesity and just the fact that market leader Medix is carrying out this phase III support our likelihood of approval.

## Tesomet in Metabolic Diseases – towards Phase IIb (but first let’s Complete that PK/PD study)

The main driver continues to be Tesomet in metabolic diseases, representing approximately half of our total value. Saniona’s phase IIa study met its primary endpoint with a statistically significant decrease in heart rates for patients treated with placebo. Secondary endpoints included systolic and diastolic blood pressures which were reduced by a numeric average of 3,1 and 2,2 mmHg for patients treated with Tesomet as compared to an average decrease of 0,7 and 0,2 mmHg in placebo. Furthermore, body weight and waist circumference showed efficacy. Patients treated with Tesomet resulted in a body weight reduction of 3,5% from baseline compared to 0,3% in placebo and with waist circumference of 2,29 cm in the Tesomet treatment group vis á vis 0,03 reduction in waist circumference for placebo. The glycemic secondary efficacy endpoint was not significantly reduced. Preliminary data suggested reduction in liver fat content. We think that the rather short treatment period of 12 weeks could explain that the glycemic endpoints were not met and that a phase IIb with a longer treatment period of 24 weeks in its study design could support that measure as well. Until then, we continue to value the Tesomet project from an obesity market potential. We would be likely to raise our top sales estimates significantly if we see a clear clinical evidence that support the development in the Type 2 Diabetes (T2D) indication.

The health economic costs for obesity are massive and were expected to cause the US society a total bill of USD 300 billion (Datamonitor) in 2014. Most of that vast number is related to productivity loss and medical costs. The obesity market for prescribed drugs are on the other hand largely underpenetrated. The reason is the preferable treatment options over prescribed drugs such as change in lifestyle and surgery. By 2016, the drug obesity market was estimated to a total of USD 544 million by 2016 with a compounded annual growth rate (CAGR) of 7,9%. We think a high CAGR is supported by the currently low penetration in the drug obesity market, a favor in trend by doctors to subscribe drugs that prove to be safe and have efficacy, the large health economic costs, and through strengthened reimbursements which is today poor in the US.

Sales Estimate of Currently Marketed Drugs (\$m)											
Drug Name	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
Belviq	42	43	42	40	37	33	28	24	21	18	18
Contrave	58	63	68	75	81	88	95	101	108	114	119
Qsymia	58	67	79	91	103	116	128	139	148	156	163
Saxenda	267	296	341	395	457	530	604	666	718	757	784
Xenical	119	121	114	105	97	92	85	81	79	78	79
<b>Total</b>	<b>544</b>	<b>589</b>	<b>644</b>	<b>705</b>	<b>775</b>	<b>859</b>	<b>940</b>	<b>1 011</b>	<b>1 074</b>	<b>1 123</b>	<b>1 163</b>

Source: Datamonitor

Actual revenues from Bloomberg tell us that Saxenda is running ahead of its estimate curve. Saxenda reached sales of USD 389 million in 2017 as compared to estimated USD 296 million. Datamonitor states that efficacy will be the most crucial factor when deciding between weight loss drugs. This

statement serves Tesomet well and is why we have almost solely relied on Saxenda’s estimate curve when estimating top sales for Tesomet. We estimate sales for Tesomet in the obesity market of USD 950 million (achieved in year 2029).

A pivotal clinical trial (phase III) in obesity is subject to a large patient population and a long study duration. Saniona will not be able to carry out such a study themselves. The phase IIb study will hence be crucial to attract a license partner. We believe a phase IIb study could get started by end of this year.

**Overview of Marketed Obesity Drugs Pivotal Trials**

Drug	Company	Mechanism of Action (MoA)	Patient Population	Study Duration
Belviq	Eisai	Selective 5-HT <sub>2C</sub> serotonin receptor agonist	7,200	Approximately 5.5 years from phase III initiation to approval.
Contrave	Orexigen	Sustained-release formulation of Bupropion (dopamine reuptake inhibitor) and Naltrexone (opioid antagonist). Exact MoA not known.	3,200	Approximately 7 years from phase III initiation to approval.
Qsymia	Vivus	Combination of phentermine (anorexigenic agent), and Topiramate (antiepileptic drug). Exact MoA not known.	3,800	Approximately 5 years from phase III initiation to approval.
Saxenda	Novo Nordisk / J&J	GLP-1 receptor agonist	3,700	Approximately 4 years from phase III initiation to approval.
Xenical	Roche	Lipase inhibitor	3,300	N/A

Source: *Clinicaltrials.gov, Datamonitor, Redeye Research*

## **Tesomet in Eating Disorders – We have faith!**

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We will start this section as well by doing a quick recap of Saniona’s project within eating disorders. In April 2017, Saniona initiated a small, exploratory phase IIa study with Prader-Willi syndrome (PWS) patients. PWS is a rare, genetic disorder caused by a defect on chromosome number 15. The disease is characterized by abnormal and constant hunger due to dysfunctional signaling in parts of the brain that control appetite. Consequently, many of the PWS patients develop morbidly obese. There is currently no cure for PWS and due to its rarity, Saniona intends to apply for orphan status.

When Saniona decided to perform an interim analysis and un-blind the phase IIa study ([research note](#)), the stock market reacted strongly negative and have not been able to re-bounce since. It is currently staying in the region of SEK 30. Our analysis by that time suggested that the potential problems in the study would be indication-related since PWS is a complex disease and conducting clinical studies in the field is a challenge. We have gone through other clinical programs through the years within PWS and can see that drop-outs and termination of PWS programs is not that uncommon. We also know that tesofensine has so far been administered in 1,300 patients and thus is well tolerated.

Results from the study were presented in January 2018. We were encouraged by the results in weight reduction and hyperphagia, albeit being a small, exploratory study. Hyperphagia is characterized by constant food craving and is the main reason why PWS cannot be left unattended. It decreased from 10.00 (n=6) at baseline to 1.00 (n=5) after eight weeks, and 0.00 after 13 weeks (n=2) with 0.00 being equivalent to no signs of hyperphagia as measured by the hyperphagia questionnaire. The hyperphagia questionnaire is a caregiver based questionnaire that offers a quantifiable outcome measure.

Interim-analysis concluded that in some patients, the plasma concentrations of tesofensine reached four times higher than the anticipated levels which could explain the adverse events. We know now that metabolism of tesofensine in PWS patients are slow and has not been seen in previous trials with the drug. We hypothesize that a likely path going forward would be to initiate a new clinical phase II trial in PWS with a reduced dose at possibly 0.25 mg of tesofensine with a slow and careful run-in-phase the first weeks. As has been seen in previous clinical studies, tesofensine has been shown to have efficacy in those dose spans.

*PWS results were encouraging and would support further clinical studies*

So where does that leave us today then in our valuation of PWS? We concluded in January that our model, again solely from a PWS valuation perspective, could either be subject to:

- Discontinuation of the program and excluded in the model
- A postpone in estimated market launch by 1-2 years which would affect our valuation by a negatively of SEK 1,5 – 4,5
- No adjustments to our previous valuation.

Since we are not fully clear of the path ahead, we see a delay of possible 1-2 years caused by an additional phase II study with a different study design before pivotal studies can get started. We will continue to include PWS in our valuation model. However, we choose not to change our risk-adjusted assumption of 20% and we remain with a top sales estimate of USD 240 million (based on an annual pricing of USD 30,000), both estimates probably being in the lower end on average. We also deem it still to be a possible outcome that Saniona find the PWS indication too difficult to proceed with. So here we say it again: Tesomet is interesting in other eating disorders as well. Saniona have strong data in animal and human models for tesofensine/Tesomet, a binge eating program could potentially start in a phase II setting. The potential within eating disorders for Tesomet is high with large unmet medical need, but we think it will require some careful navigation from the Saniona management team in these complex diseases. We cannot relate to the drama seen in the stock market that started in October 2017 when Saniona decided to start interim-analysis.



## **Interim-analysis from Cocaine Addiction Program Approaching**

In conjunction to the acquirement of tesofensine from NeuroSearch in 2014, Saniona also bought the NS2359 project for the treatment of cocaine addiction (CA). NS2359 is also a triple monoamine reuptake inhibitor that blocks the reuptake of dopamine, norepinephrine, and serotonin in a comparable manner as for cocaine. NS2359 has a long half-time which makes frequent dosing irrelevant. The pharmacological profile of NS2359 suggests that by stabilizing and normalizing dopamine levels, it both reduces the craving for cocaine, reduce the withdrawal from cocaine, and decrease the cocaine induced euphoria.

NS2359 were originally developed by NeuroSearch in collaboration with Glaxo Smith Kline (GSK) and evaluated for the treatment of Major Depressive Disorder (MDD) and ADHD in 2007. In the clinical trials for MDD and ADHD, it was revealed that NS2359 did not cause euphoria. Preclinical- and clinical studies have showed that NS2359 significantly attenuates cocaine self-administration and do not cause any negative interactions with cocaine. Since NS2359 has been tested in several indications, NS2359 has been extensively evaluated from a tolerability and safety perspective.

Saniona is currently conducting a proof-of-concept, phase II, double-blind trial. The trial is conducted in collaboration at Treatment Research Center (TRC) in University of Pennsylvania, and with funding from currently two philanthropic foundations. All future commercial rights are attributed to Saniona. The primary outcome measure will be urine drug screen for benzoylecgonine (BE), the main metabolite for cocaine. If a sample tests positive for BE during a week, that will be reported as a cocaine use week. If sample tests negative for BE during a week, that will be reported as an abstinent week. The hypothesis is that more NS2359 treated patients will have abstinent weeks at the end of the treatment period than the placebo treatment arm. The patient enrollment is expected to be 80 CA subjects. The study is designed with one-week baseline followed by eight weeks of treatment with either NS2359 or placebo where patients are randomly assigned to. We expect interim data from the study to be published in Q3'18 which will lead to one of three possible outcomes:

*Interim-analysis expected in Q3'18*

1. The interim-analysis reveal statistical significance that NS2359 patients have more abstinent weeks and a pivotal study can subsequently start
2. The interim-analysis support continuation of the phase II program
3. Interim-analysis conclude that NS2359 is not working.

If the first outcome will play out, Saniona will likely need to seek further external funding or perhaps a partner deal to take NS2359 in pivotal clinical studies. We have an updated estimate market launch of 2022 which will probably entail that phase III studies will have to start in 2019. Other than

that, we have not made any significant changes to our NS2359 valuation model.

*No drug treatments today  
for cocaine addiction*

As far as we are aware, there are currently no pharmacological treatment against cocaine addiction although there is a rising problem and several clinical studies are ongoing. The standard treatment is psychotherapy, group therapies, and self-help programs. According to results from the 2014 National Survey on Drug Use and Health, there were 1,5 million users of cocaine in USA. If we assume a rather lower pharmacological treatment rate for cocaine addiction of 50%, which are in line with other dependence related disorders, and an annual cost of approximately USD 2,000, the market potential would be some USD 1,5 billion in the US alone. A 30% market penetration would then reach top sales of USD 500 million which we have in our model (unchanged from last update). Our risk adjusted likelihood of approval remains as well at 12%.

## Summary of Catalysts in 2018

Value drivers 0-12 months	Project	Timing	Impact
Tesomet phase I study results	Tesomet	Q1'18	Moderate
CD selection which will entail a milestone payment of appr. USD 5 million	BI program	Q3'18	Moderate
TRC to perform interim-analysis in the cocaine addiction program	NS2359	Q3'18	Moderate
Start of a longer ph II study with Tesomet within Metabolic diseases	Tesomet	Q3'18	Major
Data from phase III to be presented.	Tesofensine	Q1'19	Major

Källa: Redeye Research

*A diversified pipeline with many catalysts in this year*

Naturally, the clinical programs deserve the most attention and causes the largest value drives during the coming 12 months. We expect in addition that we will see some positive news and further development in the preclinical programs and the other partnership programs. Saniona has currently three own preclinical programs: IK program, Nicotinic a6 program (funded by MJFF<sup>1</sup> until March 2018), and SAN711. Of those three we think SAN711 has the potential to reach clinical stage within 12 months, possibly in early 2019. SAN711 is a first-in-class compound, selective to GABAa  $\alpha 3$  subunit for the treatment of neuropathic pain and itching disorders.

In the partnership research and spin-out programs, we have forecasted a candidate drug (CD) selection by Boehringer Ingelheim (BI) to occur in Q3'18 (as can be seen in the table above). It is a slight postpone of timeline since we had it estimated already in 2017 and were a bit disappointed that it didn't happen last year. From what we have learned, the program is still running with enthusiasm from BI. A CD selection will entail a risk adjusted milestone of approximately SEK 32 million in our financials of Saniona. The Ataxia program, where Saniona holds a 7% stake in Cadent Therapeutics and will receive future royalties, is progressing into clinical stage in 2018 according to our timeline.

Of relevance is also potential license agreements for the clinical programs of Tesomet (metabolic diseases) and NS2359. To not cry wolf, we choose not to include license agreements in the table above, with the reservation that it is relevant for both the mentioned programs in 2018 and/or 2019.

<sup>1</sup> Michael J. Fox Foundation

**Risks 0 – 12 Months****Tesofensine / Tesomet program: Risks include delay and absence of top-line results in Mexico**

As stated above, we think top-line results from the phase III study could be presented in Q1'19. The absence of top-line results would force us to delete the tesofensine program in our valuation model and it would affect the valuation negatively in the Tesomet program as well. This is a general risk we are presenting: all clinical studies have an element of risk not providing significant change. In the case of tesofensine, we have a high likelihood of approval that we think is well backed.

There is still a possible outcome that Saniona find the PWS indication too difficult to continue with. We are currently valuing the project to SEK 8 which would be excluded if that would be the case. The top-line results presented in January were encouraging as we see it and will support further clinical studies.

If we go back again to the tesofensine program, there is a risk that the results could reveal elevated heart rates as in TIPO-1. That could provide further questions from the Mexican authority issues and delay market launch or even stop market launch. There are several counter-arguments to this risk, e.g. an alarming obesity situation in Mexico could make the authorities hard-prioritize efficacy.

Saniona is currently conducting a phase I study to investigate the pharmacokinetic (PK) profile of the fixed-dose combination of tesofensine and metoprolol. This will pave the way for future studies. If the PK give additional questions on how to optimize the release of this combination, it would likely cause delays in the Tesomet program.

**Cocaine Addiction interim-analysis don't meet its primary endpoint**

We would be forced to exclude the NS2359 project from our valuation model (SEK 8) if the interim-analysis conclude it is not working. There are no drugs available against cocaine addiction today as far as we know and addiction disorders are complex treatment groups which is why we have a rather low risk-adjusted likelihood of approval.

## Financials

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Saniona didn't reveal any major drama in their Q4'17 results. Revenue came in at SEK 4,6 million (5,4 M) with an operating profit of SEK -16,6 million (-15,0 M). Full year results included revenues at SEK 20,7 million (74,9 M) with an operating profit of SEK -57,2 million (4,2 M). The year over year changes were expected and related to upfront payments totaling SEK 60,4 million in 2016 from partners.

End of last year, Saniona entered a funding deal ([research note](#)) with Nice & Green (N&G) that could secure financing of SEK 144 million. Although we don't find it likely that the deal will be prolonged to all 24 tranches, we think it was the right funding choice to make under the current circumstances with a low trading share price and we will follow how the deal evolves closely. The deal could become important if Saniona can buy itself additional time and some financial rest for potentially 1-2 years. We will by then have a clearer picture on how the programs with tesofensine/Tesomet have proceeded. The deal also proves again that the management team are able to reach deals whether it is of finance or business nature. We would like to emphasize though that a convertible structure like the deal with N&G doesn't fully mitigate the risk for share dilution. It could also cause a short-term overhang of the share price since we don't see N&G as a long-term shareholder.

Saniona ended the year with approximately SEK 22 million cash on hand. We have seen some tendencies to the share price being hold back due to the cash position. However, the agreement with N&G is now in place and the first three tranches are mandatory in Q1'18. As of today (180227), two tranches have been drawn and where SEK 5,5 million of the first tranche has been converted to common stock at an average share price of SEK 28,10.

Overall, we see the financial situation as stable but as we stated above, we will follow how the deal with N&G proceeds before we make any changes to our Redeye Rating.

Below is our financial forecast for the next-coming three years. In 2018-2019, revenues will be linked to funding partner agreements and milestone payments from BI and Proximagen. Sales are estimated to be higher in 2020 vis á vis 2019 and 2018 as tesofensine start to generate royalties to Saniona. On the cost side, we have anticipated a small ramp-up in Saniona personnel over the coming years. Other external costs are primarily related to costs for preclinical and clinical development of the programs, especially Tesomet and a longer phase IIb study but also costs for the in-house programs IK, SAN711, and Nicotinic a6.

*First two tranches drawn from the N&G deal*

*CD selection could trigger milestone payment in 2018*

The income statement is risk-adjusted.

<b>Income Statement (SEKm)*</b>					
	<b>2016</b>	<b>2017</b>	<b>2018E</b>	<b>2019E</b>	<b>2020E</b>
Net Sales	74,921	20,693	48,242	32,846	51,845
Other Income	0,000	0,000	0,000	0,000	0,000
<b>Total Operating Income</b>	<b>74,921</b>	<b>20,693</b>	<b>48,242</b>	<b>32,846</b>	<b>51,845</b>
<b>Operating Expenses</b>					
Raw Materials and Consumables	-1,476	-3,262	-2,263	-2,363	-2,150
Other External Costs	-51,098	-51,387	-54,400	-58,050	-41,704
Personnel costs	-17,805	-22,672	-23,239	-24,784	-25,700
Depreciations and write-downs	-0,384	-0,560	-0,500	-0,500	-0,600
<b>Total Operating Expenses</b>	<b>-70,763</b>	<b>-77,881</b>	<b>-80,401</b>	<b>-85,697</b>	<b>-70,154</b>
<b>Operating Profit</b>	<b>4,158</b>	<b>-57,188</b>	<b>-32,160</b>	<b>-52,852</b>	<b>-18,309</b>
<b>Operating Profit %</b>	<b>5,5%</b>	<b>-276,4%</b>	<b>-66,7%</b>	<b>-160,9%</b>	<b>-35,3%</b>
Net Financials	0,757	0,913	0,000	0,000	0,000
<b>Profit/Loss after Financial Items</b>	<b>4,915</b>	<b>-56,275</b>	<b>-32,160</b>	<b>-52,852</b>	<b>-18,309</b>
Tax	-2,696	7,086	0,000	0,000	0,000
<b>Profit/Loss</b>	<b>2,217</b>	<b>-49,190</b>	<b>-32,160</b>	<b>-52,852</b>	<b>-18,309</b>

Source: Redeye Research

\* totals may not sum due to roundings

## Valuation

We value Saniona in a risk-adjusted cash flow model in which each individual project is valued in a Sum-of-the-Parts model. The net present value is calculated based on a WACC of 15,3% (changed from 15,4% in last update). This results in a SOTP value of SEK 70 (72) per share in our base scenario, representing a significant upside from current share price levels.

### Sum-of-the-Parts Valuation

#### Saniona

Project	Indication	Partner	Likelihood of Approval		Top Sales (\$m)	Launch year	Net Present Value (SEKm)*
			Approval	rate			
Tesofensine	Obesity	Medix (Mx, Arg)	60%	14%	115	2020	165
Tesomet	Obesity/T2D	-	30%	18%	950	2023	645
Tesomet	PWS	-	20%	38%	240	2022	178
NS2359	Cocaine Addiction	University of Pennsylvania	12%	30%	500	2022	190
BI program	Schizophrenia	Boehringer Ingelheim	9%	7%	1 350	2025	108
Cadent program	Ataxia	Cadent Therapeutics	9%	5%	1 000	2024	44
Proximagen	CNS	Proximagen	8%	6%	610	2027	30
Nicotinic a6 program	Parkinson's Disease	Michael J. Fox Foundation	4%	12%	910	2026	40
SAN711	Neuropathic Pain	-	5%	16%	1 250	2025	95
IK Program	IBD	-	5%	16%	1 800	2027	113
<b>Technology value</b>							<b>1 609</b>
Net cash position							22
Shared costs							-138
Ownership Cadent Therapeutics							30
<b>Fair value</b>							<b>1 523</b>
Number of shares, full dilution (Mn)							22
<b>Per share value, SEK</b>							<b>70</b>

Source: Redeye Research

\* totals may not sum due to roundings

## Case Scenarios

To create a dynamic view of our valuation of Saniona, we have also scheduled an optimistic Bull scenario as well as a pessimistic Bear scenario. The scenarios are based on outcome of events in 2018 and 2019.

### Bull Scenario

Our bull case scenario makes basically the same assumptions as last update where we see that:

- The PWS indication continues, causing merely a delay of one year from original plan. A phase IIb study starts and we update likelihood of approval accordingly
- The top-line results of the Medix Phase III study with tesofensine meet its primary endpoint. NDA process is initiated and our likelihood of approval is adjusted accordingly
- Following a successful phase I study, Saniona starts a phase IIb trial for Tesomet in the second half of 2018. Completion of study support further studies in obesity and T2D. Top sales estimates are raised to USD 1,500 million and likelihood of approval is adjusted accordingly
- Interim-analysis of phase II trial for NS2359 show promising results and the study continues
- The value of Cadent Therapeutics increases to USD 75 million

- The projects within BI an Proximagen progress according to plan. BI selects CD in 2018 followed by initiation of clinical studies in 2019. Proximagen selects CD in 2019.

Our fair value estimate in the bull case scenario amounts to **SEK 125**

#### **Bear Scenario**

Our pessimistic scenario considers the risk for:

- NS2359 interim analysis does not support further clinical studies
- Tesomet within eating disorders is being temporarily on hold. We exclude it from the valuation model accordingly
- Tesofensine results become subject of interpretation, both from a safety and efficacy perspective. Authorities require additional data and market launch is being delayed by at least two years. Likelihood of approval is being adjusted downwards
- Tesomet program is being further delayed and phase IIb study does not start in 2018 nor in 2019. The obesity market for prescribed drugs remain underpenetrated, we adjust our top sales estimates to USD 600 million
- Proximagen program is being discontinued
- BI milestone for CD selection does not happen in 2018 nor in 2019 and collaboration is hence being discontinued.

Our fair value estimate in the bear case scenario amounts to **SEK 28**



## Summary Redeye Rating

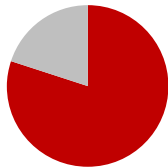
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The rating consists of five valuation keys, each constituting an overall assessment of several factors that are rated on a scale of 0 to 2 points. The maximum score for a valuation key is 10 points.

### Rating changes in the report

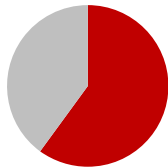
Management adjusted + 1,0 p. Profit outlook adjusted -0,5 p.

Management 8,0p



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 as well as research partner deals. Other advantages include substantial shareholding for management.

Ownership 6,0p



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 5,0p



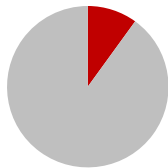
The largest potential for Saniona is in the metabolic field with tesofensine/Tesomet. The obesity market, albeit creating enormous health economic costs in high-income countries, are largely underpenetrated from a prescribed drug perspective. We think that over time, obesity drugs that proves to be safe and have efficacy can nevertheless reach top sales in the span USD 500 - 1,000 million. Furthermore, and according to our estimates, Saniona could start to obtain recurrent revenue from tesofensine in 2020.

Profitability 0,0p



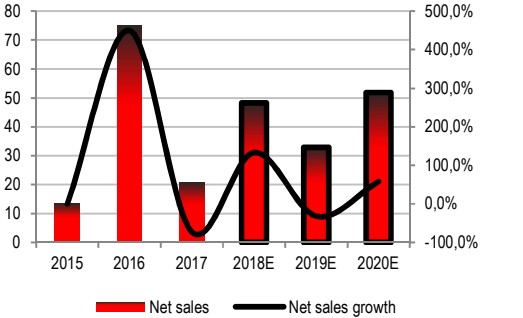
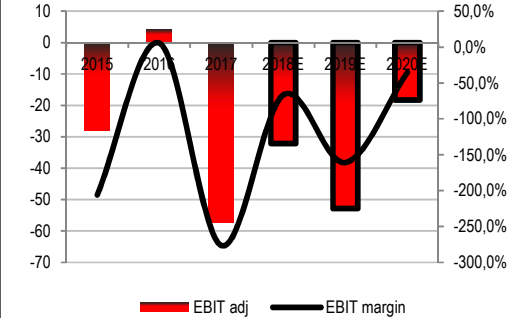
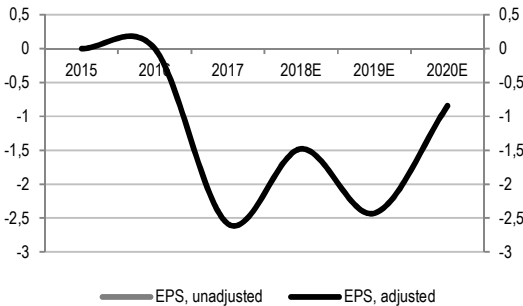
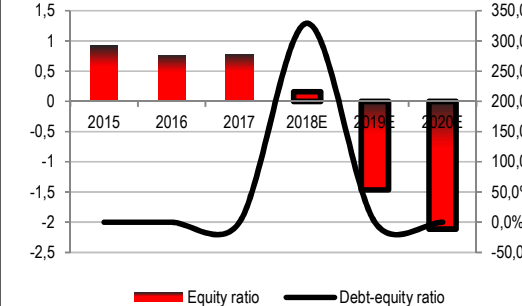
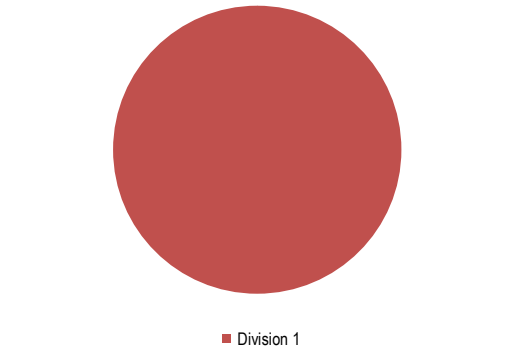
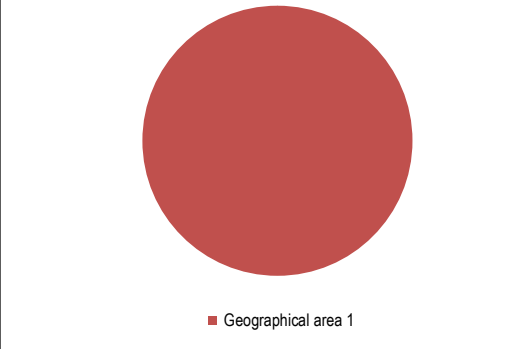
The company is several years from achieving sustainable profitability. Like most other companies in this development phase, there is no history of profitability, which drives up the rate of return required by investors.

Financial strength 1,0p



Saniona ended 2017 with SEK 22 million in cash. Capital strength rating remain intentionally unchanged since we want to see how the deal with Nice & Green evolves.

<b>Income statement</b>						<b>DCF valuation</b>		<b>Cash flow, MSEK</b>			
	2016	2017	2018E	2019E	2020E	WACC (%)	15,3 %	NPV FCF (2018-2020)	-22		
Net sales	75	21	48	33	52			NPV FCF (2021-2027)	754		
Total operating costs	-70	-77	-80	-85	-70			NPV FCF (2028-)	768		
<b>EBITDA</b>	<b>5</b>	<b>-57</b>	<b>-32</b>	<b>-52</b>	<b>-18</b>			Non-operating assets	22		
Depreciation	0	-1	-1	-1	-1			Interest-bearing debt	0		
Amortization	0	0	0	0	0			Fair value estimate MSEK	1523		
Impairment charges	0	0	0	0	0			Assumptions 2017-2023 (%)			
<b>EBIT</b>	<b>4</b>	<b>-57</b>	<b>-32</b>	<b>-53</b>	<b>-18</b>	Average sales growth	36,1 %	<b>Fair value e. per share, SEK</b>	<b>70,0</b>		
Share in profits	0	0	0	0	0	EBIT margin	6,7 %	Share price, SEK	28,3		
Net financial items	1	1	0	0	0						
Exchange rate dif.	0	0	0	0	0						
<b>Pre-tax profit</b>	<b>5</b>	<b>-56</b>	<b>-32</b>	<b>-53</b>	<b>-18</b>						
Tax	-3	0	0	0	0						
<b>Net earnings</b>	<b>2</b>	<b>-56</b>	<b>-32</b>	<b>-53</b>	<b>-18</b>						
<b>Balance</b>						<b>Profitability</b>					
	2016	2017	2018E	2019E	2020E	ROE	4%	-123%	-149%	0%	0%
<b>Assets</b>						ROCE	8%	-124%	-105%	442%	32%
<i>Current assets</i>						ROIC	70%	-5771%	-210%	-251%	39%
Cash in banks	53	22	2	0	0	EBITDA margin	6%	-274%	-66%	-159%	-34%
Receivables	15	11	17	16	15	EBIT margin	6%	-276%	-67%	-161%	-35%
Inventories	0	0	0	0	0	Net margin	3%	-272%	-67%	-161%	-35%
Other current assets	0	0	0	0	0						
<b>Current assets</b>	<b>68</b>	<b>33</b>	<b>19</b>	<b>16</b>	<b>15</b>						
<i>Fixed assets</i>											
Tangible assets	1	1	1	3	2						
Associated comp.	0	0	0	0	0						
Investments	2	6	6	6	6						
Goodwill	0	0	0	0	0						
Cap. exp. for dev.	0	0	0	0	0						
O intangible rights	0	0	0	0	0						
O non-current assets	0	0	0	0	0						
<b>Total fixed assets</b>	<b>3</b>	<b>8</b>	<b>8</b>	<b>9</b>	<b>9</b>						
Deferred tax assets	0	7	7	7	7						
<b>Total (assets)</b>	<b>71</b>	<b>48</b>	<b>34</b>	<b>32</b>	<b>31</b>						
<b>Liabilities</b>											
<i>Current liabilities</i>											
Short-term debt	0	0	0	0	0						
Accounts payable	17	11	11	80	97						
O current liabilities	0	0	0	0	0						
<b>Current liabilities</b>	<b>17</b>	<b>11</b>	<b>11</b>	<b>80</b>	<b>97</b>						
Long-term debt	0	0	0	0	0						
O long-term liabilities	0	0	0	0	0						
Convertibles	0	0	18	0	0						
<b>Total Liabilities</b>	<b>17</b>	<b>11</b>	<b>29</b>	<b>80</b>	<b>97</b>						
Deferred tax liab	0	0	0	0	0						
Provisions	0	0	0	0	0						
Shareholders' equity	54	38	5	-47	-66						
Minority interest (BS)	0	0	0	0	0						
<b>Minority &amp; equity</b>	<b>54</b>	<b>38</b>	<b>5</b>	<b>-47</b>	<b>-66</b>						
<b>Total liab &amp; SE</b>	<b>71</b>	<b>48</b>	<b>34</b>	<b>32</b>	<b>31</b>						
<b>Free cash flow</b>						<b>Share performance</b>					
	2016	2017	2018E	2019E	2020E	1 month	-13,7 %	Growth/year	Net sales	15/17e	
Net sales	75	21	48	33	52	3 month	-3,6 %	Operating profit adj		◆	
Total operating costs	-70	-77	-80	-85	-70	12 month	-29,9 %	EPS, just		0,0 %	
Depreciations total	0	-1	-1	-1	-1	Since start of the year	-8,0 %	Equity		-68,3 %	
<b>EBIT</b>	<b>4</b>	<b>-57</b>	<b>-32</b>	<b>-53</b>	<b>-18</b>						
Taxes on EBIT	0	0	0	0	0						
<b>NOPLAT</b>	<b>4</b>	<b>-57</b>	<b>-32</b>	<b>-53</b>	<b>-18</b>						
Depreciation	0	1	1	1	1						
<b>Gross cash flow</b>	<b>5</b>	<b>-57</b>	<b>-32</b>	<b>-52</b>	<b>-18</b>						
Change in WC	5	-2	-6	70	18						
Gross CAPEX	-1	-6	0	-2	0						
<b>Free cash flow</b>	<b>9</b>	<b>-64</b>	<b>-38</b>	<b>16</b>	<b>0</b>						
<b>Capital structure</b>						<b>Shareholder structure %</b>					
	2016	2017	2018E	2019E	2020E		Capital	Votes			
Equity ratio	77%	78%	16%	-146%	-212%	Jörgen Drejer	11,3 %	11,3 %			
Debt/equity ratio	0%	0%	329%	0%	0%	Thomas Feldthus	8,6 %	8,6 %			
Net debt	-53	-22	16	0	0	Avanza Pension	5,3 %	5,3 %			
Capital employed	1	15	21	-47	-66	Leif Andersson Consulting ApS	4,6 %	4,6 %			
Capital turnover rate	1,1	0,4	1,4	1,0	1,7	Palle Christophersen	3,8 %	3,8 %			
						Claus Brästrup	3,4 %	3,4 %			
						Nordnet Pensionsförsäkring	2,7 %	2,7 %			
						Janus Schreiber Larsen	1,8 %	1,8 %			
						Nordea Liv & Pension	1,5 %	1,5 %			
						Christian Olofsson	1,3 %	1,3 %			
<b>Growth</b>						<b>Share information</b>					
	2016	2017	2018E	2019E	2020E	Reuters code	Sanion.st				
Sales growth	450%	-72%	133%	-32%	58%	List	Small Cap				
EPS growth (adj)	0%	0%	-43%	64%	-65%	Share price	28,3				
						Total shares, million	21,8				
						Market Cap, MSEK	614,8				
						<b>Management &amp; board</b>					
						CEO	Jörgen Drejer				
						CFO	Thomas Feldthus				
						IR					
						Chairman	J. Donald DeBethizy				
<b>Financial information</b>						<b>Analysts</b>					
Q1 report						Redeye AB					
Q2 report						Anders Hedlund	Mäster Samuelsgatan 42, 10tr				
Q3 report						anders.hedlund@redeye.se	111 57 Stockholm				
FY 2018 Results							February 21, 2019				

Revenue & Growth (%)	EBIT (adjusted) & Margin (%)
 <p>Net sales (red bars) and Net sales growth (black line) from 2015 to 2020E. Net sales peaked in 2016 and 2020E, while growth peaked in 2016 and 2020E.</p>	 <p>EBIT adj (red bars) and EBIT margin (black line) from 2015 to 2020E. EBIT adj fluctuates significantly, with a major negative spike in 2017. EBIT margin follows a similar trend, peaking in 2016 and 2020E.</p>
Earnings per share	Equity & debt-equity ratio (%)
 <p>EPS, unadjusted (grey line) and EPS, adjusted (black line) from 2015 to 2020E. Adjusted EPS shows a significant decline from 2015 to 2017, followed by a recovery through 2020E.</p>	 <p>Equity ratio (red bars) and Debt-equity ratio (black line) from 2015 to 2020E. Equity ratio is positive from 2015 to 2017, then becomes negative. Debt-equity ratio peaks in 2018E and remains high through 2020E.</p>
Sales division	Geographical areas
 <p>100% Division 1</p>	 <p>100% Geographical area 1</p>
Conflict of interests	Company description
<p><b>Anders Hedlund owns shares in the company : No</b></p> <p>Redeye performs/have performed services for the Company and receives/have received compensation from the Company in connection with this.</p>	<p>Saniona is a drug research and development company based in Copenhagen. The company target diseases in the area of Central Nervous System (CNS), metabolic diseases, autoimmune diseases, and treatment of pain. The research platform is focused on ion channels which controls the passage of charged ions across cell membranes. The company was founded in 2011 and has 24 employees. Saniona has been listed since 2014, and is since 2017 listed on the main market of OMX Nasdaq Stockholm (List: Small Cap).</p>

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**Redeye Rating (2018-03-01)**

Rating	Management	Ownership	Profit outlook	Profitability	Financial Strength
7,5p - 10,0p	47	44	18	10	20
3,5p - 7,0p	73	67	103	35	46
0,0p - 3,0p	13	22	12	88	67
Company N	133	133	133	133	133

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