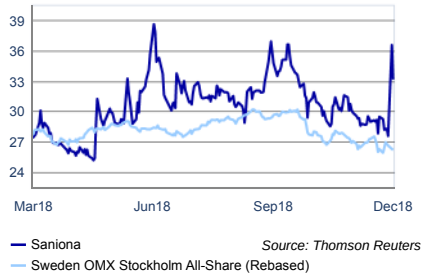
Saniona

Healthcare
Sweden

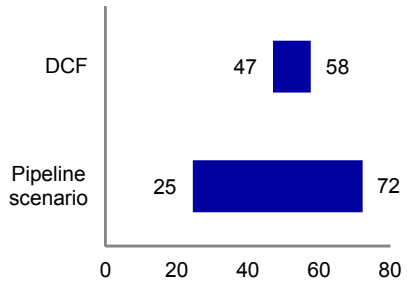
KEY DATA

Stock country	Sweden
Bloomberg	SANION SS
Reuters	SANION.ST
Share price (close)	SEK 33.25
Free Float	73%
Market cap. (bn)	EUR 0.07/SEK 0.75
Website	https://saniona.com/
Next report date	21 Feb 2019

PERFORMANCE



VALUATION APPROACH



Source: Nordea estimates

ESTIMATE CHANGES

Year	2018E	2019E	2020E
Sales	0%	0%	17%
EBIT (adj)	0%	0%	8%

Source: Nordea estimates

Nordea Markets - Analysts

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Tesofensine strikes back; solid ph III obesity data

We view Saniona's positive Tesofensine ph III headline results in obesity as an important de-risking event. In our view the results were solid, with a meaningful 10% average weight loss despite the short trial duration (24 weeks versus 52 weeks for other trials). We consequently increase our risk adjustment on Tesofensine to 90% (from 60%), boosting our DCF-derived valuation range to SEK 47-58 (38-47) per share.

Tesofensine: 10% weight loss in ph III

Saniona announced that Tesofensine met its primary and secondary endpoints in the ph III obesity registration trial, inducing an average of 10% weight loss in 24 weeks. While we have yet to see the full ph III data, we believe the positive trial de-risks Saniona's outlook and equity story.

Tesofensine will target the obesity epidemic in Latin America

The obesity market is still in the development phase, but holds the potential to be substantial – there are 600-700 million obese people worldwide. Tesofensine was previously developed by NeuroSearch for the US market, but these plans took a hit due to changed regulatory requirements from the FDA (pre-approval CVOT). Saniona and its partner Medix now seek to launch the drug in Mexico and Argentina. We ascribe SEK 26 per share to Tesofensine, assuming USD ~200m in peak sales.

Next steps with Tesofensine and upcoming triggers

During 2019, we expect regulatory filing and an approval decision for Tesofensine in Mexico. Tesomet ph IIa data in Prader-Willi syndrome will be another critical event; the trial is expected to conclude in early 2019 with headline results available in Q1 2019. We also expect ph IIa data from NS2359 in cocaine addiction during the coming months, but we consider this a risky readout with low expectations priced into the share price.

Updated valuation range: SEK 47-58 per share

We increase our risk adjustment on Tesofensine to 90% (from 60%), boosting our DCF-derived valuation range to SEK 47-58 per share (SEK 38-47). We base our valuation only on Tesofensine and Tesomet in PWS and obesity, assigning no value to Tesomet's potential in other indications, or to early-stage pipeline projects such as NS2359 or CAD-1883. Risks include pipeline failures, delays, regulatory hurdles, commercialisation hurdles for Tesofensine and Tesomet, and funding needs beyond 2020.

SUMMARY TABLE - KEY FIGURES

SEKm	2014	2015	2016	2017	2018E	2019E	2020E
Total revenue	22	14	75	21	59	38	68
EBITDA (adj)	-7	-27	5	-57	-49	-77	-112
EBIT (adj)	-8	-28	4	-57	-50	-77	-112
EBIT (adj) margin	-38.0%	-206.0%	5.5%	-276.4%	-83.5%	-205.9%	-164.8%
EPS (adj)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EPS (adj) growth	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
DPS (ord)	0.00	0.00	0.00	0.00	0.00	0.00	0.00
EV/Sales	n.a.	n.a.	n.a.	n.a.	12.1	20.6	12.7
EV/EBIT (adj)	n.a.	n.a.	n.a.	n.a.	n.m.	n.m.	n.m.
P/E (adj)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
P/BV	n.a.	n.a.	n.a.	n.a.	11.0	10.2	-422.2
Dividend yield (ord)	n.a.	n.a.	n.a.	n.a.	0.0%	0.0%	0.0%
FCF Yield bef acq & disp	n.a.	n.a.	n.a.	n.a.	-2.8%	-7.0%	-10.0%
Net debt	-10	-47	-53	-22	-72	-84	1
Net debt/EBITDA	1.3	1.7	-11.7	0.4	1.5	1.1	0.0
ROIC after tax	n.m.	n.m.	76.0%	n.m.	n.m.	n.m.	n.m.

Source: Company data and Nordea estimates

Tesofensine ph III data lowers risks

We view Saniona's positive Tesofensine ph III headline results in obesity as an important de-risking event. In our view, the results were solid, with a meaningful 10% average weight loss despite the short trial duration (24 weeks versus 52 weeks in competitor trials). We consequently increase our risk adjustment for Tesofensine to 90% (from 60%).

Tesofensine ph III obesity data de-risks the equity story

Tesofensine met its primary and secondary endpoints in its pivotal ph III obesity trial, de-risking the company's outlook and equity story, in our view

On 17 December, Saniona announced the important pivotal ph III headline data for Tesofensine in obesity. Tesofensine met its primary and secondary endpoints by showing statistically and clinically significant weight loss compared to placebo. We still need to see the full detailed ph III data published in a medical journal, but we make a few conclusions based on the initial top-line results:

1. The ph III data confirmed robust weight loss (10% after only 24 weeks) seen in the ph II trial, supporting our estimates on Tesofensine's sales potential.
2. Tesofensine's weight loss data was highly statistically and clinically significant ($p<0.001$).
3. Tesofensine appeared well-tolerated in the study, with no CV risks or new safety issues highlighted, and adverse events similar to placebo (according to Saniona's stock exchange release; no specific details have been published yet).
4. The ph III data provides a positive read-across to Tesomet, as it validates the molecule and its weight-loss properties. It does not change our view, however, that we still need to see additional data from patients with Prader-Willi syndrome to fully assess the drug's tolerability for this difficult-to-treat population – and to substantiate the findings related to hyperphagia, an uncontrollable extreme urge to eat that persists no matter how much the patients eat. Hyperphagia is arguably the toughest challenge and highest unmet medical need in PWS patients, hence we need more evidence before we revisit our risk adjustment for this pipeline project.

10% average weight loss – potentially more to come over time

Tesofensine led to an average of 10% weight loss – something we view as clinically meaningful data for patients and regulators, especially when benchmarking versus competing obesity drugs

Tesofensine led to an average 10% weight loss (non-placebo adjusted), and the p-value in the study was very significant ($p<0.001$). This mirrors the results from ph II, where Tesofensine on average led to 11.2% weight loss.

The table below compares Tesofensine's ph III weight loss results with its ph II data as well as current commercially available anti-obesity prescription drugs in the US. It also includes Novo Nordisk's semaglutide, which is currently in ph III development.

We stress that it is unscientific to compare data across trials, owing to differences in trial size and patient profiles. Direct head-to-head comparison trials with other anti-obesity drugs are needed before any firm conclusion about comparative efficacy can be made. Nevertheless, on the surface, the Tesofensine ph III data appears competitive, in our view.

TESOFENSINE WEIGHT LOSS DATA COMPARISON

	Teso	Teso 0.25 mg	Teso 0.50 mg	Sema 0.4 mg	Qsymia 7.5 mg	Saxenda 3 mg	Contrave 32 mg	Belviq 10 mg
N	372	52	50	957	488	2487	538	3098
Trial duration (weeks)	24	24	24	52	56	56	56	52
Phase	3	2	2	2	3	3	3	3
Company	Saniona	Saniona	Saniona	Novo	Vivus	Novo	Nalpropion	Eisai
Efficacy								
Baseline (mean) in kg	-	103	101	111	103	106	100	100
Reduction in body weight, active treatment (%)	10%	6.5%	11.2%	13.8%	7.8%	7.4%	5.4%	5.8%
Reduction in body weight, placebo	-	2.0%	2.0%	2.3%	1.2%	3.0%	1.3%	2.5%
Reduction in body weight, placebo adjusted	-	4.5%	9.2%	11.5%	6.6%	4.5%	4.1%	3.3%
Patients losing ≥5% body weight	-	59%	87%	83%	62%	62%	42%	47%
Patients losing ≥10% body weight	>50%	35%	53%	65%	37%	34%	21%	22%

Source: Company data, FDA and Nordea

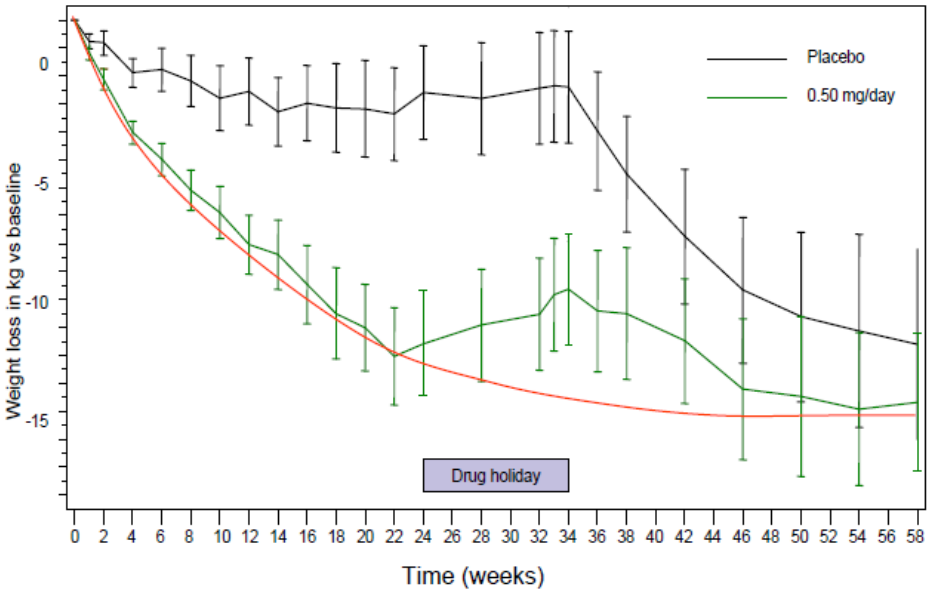
We highlight that the 10% weight loss was achieved after only 24 weeks – other trials ran for 52-56 weeks

The maximum percentage change in weight loss achieved to date is 7-8% with therapeutically relevant doses, depending on the comparator arm benchmarked (dosing and patient population included in the trial). In these ph III trials, patients were treated for twice as long (52-56 weeks). This suggests that Tesofensine showed superior weight loss versus other agents – despite only being a 24-week trial.

We also note that the 24-week ph III trial might underestimate the weight loss. While we have not seen the full dataset (only headline results), we note that weight loss in the placebo group levelled out at week 16 in the ph II trial but continued in the Tesofensine groups, suggesting there could be more to come with longer treatment duration beyond the already impressive weight reduction seen in the trial.

WEIGHT LOSS (KG) DURING PH II TIPO-1 AND TIPO-4 TRIALS

The 24-week ph III trial might underestimate the weight loss, according to data from the ph II trial showing that weight loss continued in the Tesofensine group over time; this could be important not only for patients but also for potential Tesofensine uptake and peak sales



Source: Company data

Tesofensine appeared well-tolerated – no CV risks highlighted

While we obviously have not seen the full dataset yet, Saniona commented that Tesofensine was well-tolerated, with adverse events similar to placebo. We have previously noted that a potential risk could be elevated cardiovascular signals.

Tesofensine induced a low but statistically significant increase in heart rate – but this is not new

According to the release, Tesofensine induced a low but statistically significant increase in heart rate. This is not new and will likely be considered manageable by the Mexican regulators, we believe, given that the ph III design and endpoints were agreed upon and the ph II data was discussed prior to initiating the pivotal ph III trial.

Smaller increases in heart rate are a common phenomenon in anti-obesity agents. All existing commercially available anti-obesity drugs on the market but Belviq induce increased heart rate.

No significant effect on blood pressure – positive

Importantly, we also stress that no significant effect on blood pressure was observed during the ph III trial. This was a potential risk mentioned in the Lancet paper discussing the Tesofensine ph II trial. We consider it positive that no signal was seen on blood pressure in the ph III trial.

Estimate changes

We raise our risk adjustment on Tesofensine from 60% up to 90%, which leads to higher top-line and earnings estimates

Following the positive ph III headline results, we increase our risk adjustment on the Tesofensine obesity project to 90% (from 60%). As we still model a launch in Mexico during 2020 and in Argentina during 2021, our 2018 and 2019 estimates remain unchanged. Our risk-adjusted sales estimates for Tesofensine (in SEKm), however, are consequently raised by 50% for 2020 and beyond, which therefore also raises our total group revenue and EBIT estimates, as highlighted below.

ESTIMATE CHANGES

	New estimates						Estimate changes					
SEKm	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**
Total revenues	**59**	**38**	**68**	**73**	**120**	**353**	**0%**	**0%**	**17%**	**50%**	**50%**	**19%**
Product sales and royalties	0	0	30	73	120	245	n.a.	n.a.	50%	50%	50%	31%
Tesofensine, obesity	0	0	30	73	120	172	n.a.	n.a.	50%	50%	50%	50%
Tesomet, Prader-Willi syndrome	0	0	0	0	0	48	n.a.	n.a.	n.a.	n.a.	n.a.	0%
Tesomet, Hypothalamic obesity	0	0	0	0	0	0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Tesomet, obesity	0	0	0	0	0	25	n.a.	n.a.	n.a.	n.a.	n.a.	0%
NS2359, CNS	0	0	0	0	0	0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Other (milestones/PRV)	59	38	38	0	0	109	0%	0%	0%	n.a.	n.a.	0%
Gross profit	**59**	**38**	**68**	**73**	**120**	**353**	**0%**	**0%**	**17%**	**50%**	**50%**	**19%**
R&D costs	-74	-80	-140	-50	-50	-50	0%	0%	0%	0%	0%	0%
S&D costs	0	0	0	0	0	-50	n.a.	n.a.	n.a.	n.a.	n.a.	0%
Admin costs	-35	-35	-40	-45	-45	-45	0%	0%	0%	0%	0%	0%
EBIT	**-50**	**-77**	**-112**	**-22**	**25**	**208**	**0%**	**0%**	**-8%**	**-53%**	**-271%**	**38%**
PTP	-49	-77	-112	-22	25	208	0%	0%	-8%	-53%	-271%	38%
Net profit	-38	-60	-87	-17	20	162	0%	0%	-8%	-53%	-271%	38%
Free cash flow	-22	-60	-86	-18	20	180	0%	0%	-9%	-50%	-287%	36%
Net cash	72	84	-1	-20	1	181	0%	0%	-86%	-58%	-101%	140%

Source: Company data and Nordea estimates

Modelling Tesofensine sales

In our initiation report (dated 29 June 2018), we reviewed the obesity market, the Tesofensine project and its sales potential. In this section, we recap our model assumptions and present our updated sales estimates. We estimate USD ~200m in peak sales for Tesofensine in Mexico and Argentina combined, which we risk-adjust by 90%, given the regulatory risk still present.

Tesofensine – set to hit the obesity market by 2020

- **Our peak sales forecast**: USD ~200m in obesity sales in Mexico and Argentina combined by 2025
- **Valuation**: SEK 26 per share with 90% risk-adjustment
- **Next news flow**: Regulatory filing and subsequent marketing approval in Mexico during 2019; potential launch in Mexico by 2020; regulatory filing and subsequent marketing approval in Argentina for potential launch in 2021

Tesofensine revenue modelling

As shown in our detailed bottom-up obesity model in the tables below, we use four sales drivers to model revenues for Tesofensine:

- Number of patients with obesity per country
- Number of patients treated with an anti-obesity drug per country
- Daily treatment cost for Tesofensine
- Tesofensine penetration (market share)

We base our patient forecasts on obesity data provided by The Global Burden of Disease Study 2015, which compiled data on obesity and overweight prevalence rates and numbers on a per country level from 1980 to 2015. Consequently, we model that around 24 million adults in Mexico were obese in 2015, while we assume the figure to be 7 million in Argentina, growing in line with general population growth in both countries.

We assume Tesofensine will be priced at USD 2 per day and that patients stay on treatment for six months – similar to the ph II and ph III trial...

Existing commercially available anti-obesity drugs are generally priced at USD 10 per day in the US on a list price basis, whereas Novo's Saxenda is priced at USD 40 per day. In Mexico, existing anti-obesity drugs sell at around USD 50 per month (USD ~1.5 per day). We assume Tesofensine will be priced at USD 2 per day; this is a slight premium to the currently marketed drugs in Mexico, but we argue that this would still be an attractive price to drive volume uptake in the market. Provided that patients stay on treatment for six months (similar to the treatment duration in the ph II and ph III trial – ie 24/26 weeks), this corresponds to a price per patient of USD 365 per year.

...but there may be upside to this, given that the weight loss curve in the ph II trial continued to decline over time, indicating that a longer treatment period could result in further weight loss

There may, however, be upside to these estimates, given that clinical data generated with Tesofensine indicates that patients may stay on treatment for longer than six months, given that the weight loss curve in the ph II trial continued to decline over time, indicating that a longer treatment period with Tesofensine (52 weeks, for instance) could result in further weight loss. We expect Tesofensine, pending marketing approval, to be launched in 2020 in Mexico and assume that Medix will launch the drug in Argentina one year later (2021).

We model a ramp-up starting with 5% market penetration in 2020, gradually increasing to 30% in 2025. We believe this will be driven by Tesofensine being a superior weight-loss drug on efficacy and safety compared with existing commercially available anti-obesity drugs in Mexico, which are dominated by old generic compounds with questionable efficacy and safety profiles. In our view, this should subsequently drive sales via:

- Tesofensine cannibalising (replacing) existing drugs;
- Tesofensine increasing the market for prescription products in Mexico, due to higher prices (USD 2 per day with Tesofensine vs around USD 1.5 for competitors) and longer treatment time on the drug (six months with Tesofensine vs up to five

months for competitors); and,

- Tesofensine driving uptake among new patient groups, as additional obese patients may seek treatment when efficacious and well-tolerated products (such as Tesofensine) are available, thereby growing total prescription volumes in the market.

TESOFENSINE: REVENUE MODEL FOR OBESITY – MEXICO SALES

Obesity - Mexico	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Obese population ('000)	25,301	25,807	26,323	26,849	27,386	27,934	28,493	29,063	29,644	30,237	30,841
Growth	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Obesity prevalence	28.6%	28.6%	28.6%	28.6%	28.6%	28.6%	28.6%	28.6%	28.6%	28.6%	28.6%
Treated	4.6%	4.6%	4.6%	4.6%	4.6%	4.6%	4.6%	4.6%	4.6%	4.6%	4.6%
Treatment potential ('000)	1,167	1,191	1,214	1,239	1,264	1,289	1,315	1,341	1,368	1,395	1,423
Tesofensine penetration	5%	10%	15%	20%	25%	30%	25%	20%	15%	10%	9%
No treated with Tesofensine ('000)	**58**	**119**	**182**	**248**	**316**	**387**	**329**	**268**	**205**	**140**	**128**
Cost, USD, daily	2.0	2.1	2.1	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3
Treatment duration (months)	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0
Cost, USD, annually	365	376	387	399	411	423	423	423	423	423	423
Cost inflation		3%	3%	3%	3%	3%	0%	0%	0%	0%	0%
Tesofensine sales, USDm	**21**	**45**	**71**	**99**	**130**	**164**	**139**	**113**	**87**	**59**	**54**
Risk-adjustment	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%
Risk-adj. sales, USDm	**19**	**40**	**63**	**89**	**117**	**147**	**125**	**102**	**78**	**53**	**49**
Risk-adj. sales, SEKm	**174**	**365**	**575**	**805**	**1,057**	**1,333**	**1,133**	**924**	**707**	**481**	**441**
Royalty rate to Saniona	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%
Risk-adj. royalties, USDm	3	7	11	16	20	26	22	18	14	9	9
Risk-adj. royalties, SEKm	30	64	101	141	185	233	198	162	124	84	77

Source: Nordea estimates

TESOFENSINE: REVENUE MODEL FOR OBESITY – ARGENTINA SALES

Obesity - Argentina	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Obese population ('000)	7,453	7,602	7,754	7,910	8,068	8,229	8,394	8,562	8,733	8,907	9,086
Growth	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Obesity prevalence	23.2%	23.2%	23.2%	23.2%	23.2%	23.2%	23.2%	23.2%	23.2%	23.2%	23.2%
Treated	4.6%	4.6%	4.6%	4.6%	4.6%	4.6%	4.6%	4.6%	4.6%	4.6%	4.6%
Treatment potential ('000)	344	351	358	365	372	380	387	395	403	411	419
Tesofensine penetration	0%	5%	10%	15%	20%	25%	20%	15%	10%	9%	8%
No treated with Tesofensine ('000)	**0**	**18**	**36**	**55**	**74**	**95**	**77**	**59**	**40**	**37**	**34**
Cost, USD, daily	2.0	2.1	2.1	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3
Treatment duration (months)	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0
Cost, USD, annually	365	376	387	399	411	423	423	423	423	423	423
Cost inflation		3%	3%	3%	3%	3%	0%	0%	0%	0%	0%
Tesofensine sales, USDm	**0**	**7**	**14**	**22**	**31**	**40**	**33**	**25**	**17**	**16**	**14**
Risk-adjustment	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%
Risk-adj. sales, USDm	**0**	**6**	**12**	**20**	**28**	**36**	**29**	**23**	**15**	**14**	**13**
Risk-adj. sales, SEKm	**0**	**54**	**113**	**178**	**249**	**327**	**267**	**204**	**139**	**127**	**116**
Royalty rate to Saniona	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%
Risk-adj. royalties, USDm	0	1	2	3	5	6	5	4	3	2	2
Risk-adj. royalties, SEKm	0	9	20	31	44	57	47	36	24	22	20

Source: Nordea estimates

Given that Tesofensine only has five-year market exclusivity once launched, we expect revenues to fade in 2026 and beyond, as we anticipate generic competition. There may be upside to this assumption, depending on the speed at which other companies launch generic versions and how fast their market penetration materialises. Nevertheless, we are not that concerned about this, as we expect Saniona to develop Tesomet in obesity as well. We view Tesomet as the bridge over the Tesofensine patent expiry and expect this to protect the long-term value.

TESOFENSINE: COMBINED REVENUE AND ROYALTY FORECASTS

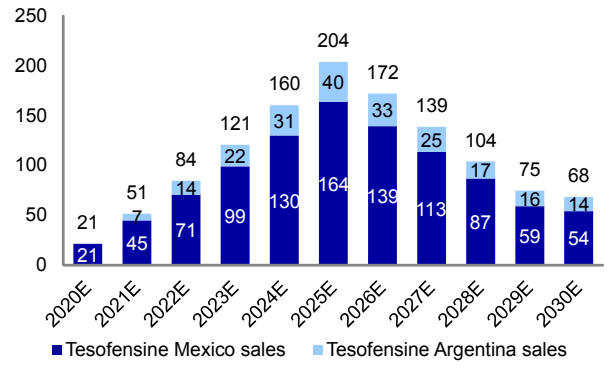
Obesity	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Tesofensine sales, USDm	**21**	**51**	**84**	**121**	**160**	**204**	**172**	**139**	**104**	**75**	**68**
Mexico	21	45	71	99	130	164	139	113	87	59	54
Argentina	0	7	14	22	31	40	33	25	17	16	14
Risk-adjustment	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%
Risk-adj. sales, USDm	**19**	**46**	**76**	**109**	**144**	**183**	**155**	**125**	**93**	**67**	**62**
Risk-adj. sales, SEKm	**174**	**418**	**687**	**983**	**1,306**	**1,660**	**1,400**	**1,128**	**846**	**608**	**557**
Royalty rate to Saniona	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%
Risk-adj. royalties, SEKm	**30**	**73**	**120**	**172**	**229**	**290**	**245**	**197**	**148**	**106**	**97**
Mexico	30	64	101	141	185	233	198	162	124	84	77
Argentina	0	9	20	31	44	57	47	36	24	22	20

Source: Nordea estimates

We model up to USD 204m in Tesofensine sales in Mexico and Argentina combined in 2025E. We risk-adjust sales by 90%, reflecting the drug having reported positive ph III results and that Mexican healthcare authorities should not require any long-term pre-approval cardiovascular outcome trials. However, as is the case with other marketing applications, there is still a regulatory risk.

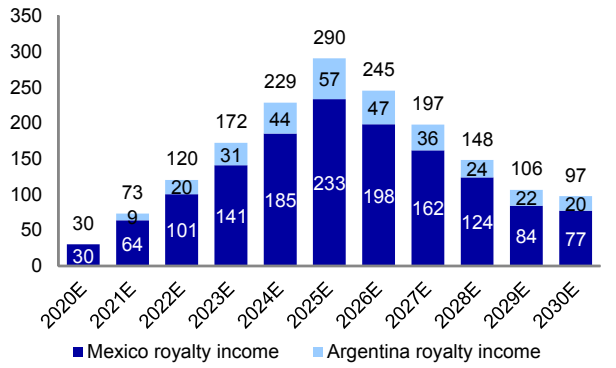
Saniona is entitled to regulatory milestone payments and double-digit royalties on product sales in Mexico and Argentina. We assume the latter to be between 15% and 20%, in line with many other deals seen in the healthcare space on drug collaborations signed prior to ph III. We pencil in the midpoint, ie 17.5%. This results in royalty income starting at SEK 30m in 2020E and increasing to SEK 290m in 2025E.

TESOFENSINE: SALES FORECASTS, USDm



Source: Nordea estimates

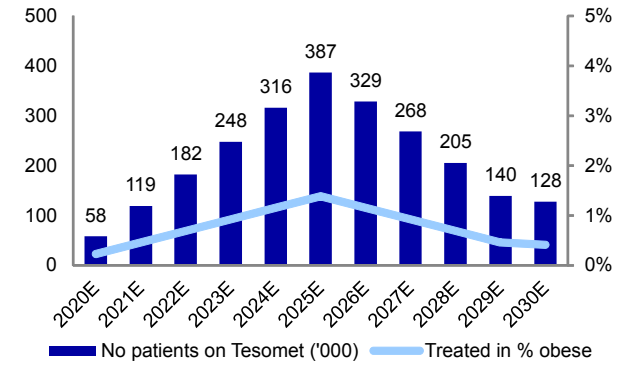
TESOFENSINE: ROYALTY FORECASTS, SEKm



Source: Nordea estimates

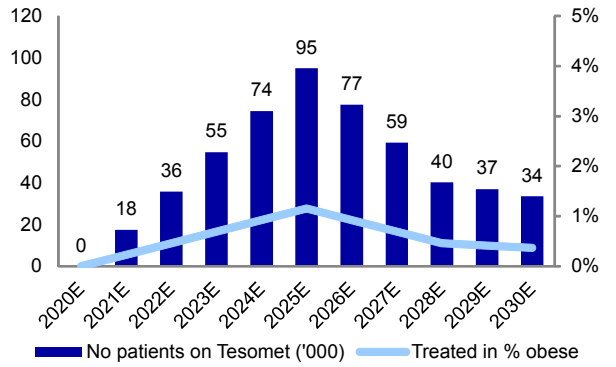
We base these estimates on the assumption that in Mexico, for example, approximately 387,000 patients would be on Tesofensine treatment at peak. Market statistics suggest that only ~1.1 million patients (around 1 in 22) are treated with a prescription medicine for obesity annually in Mexico. However, the market is dominated by old generic compounds, with questionable efficacy and troublesome side-effect profiles. Hence, we believe there should be opportunities for a decent market share uptake and new patients seeking treatment when efficacious and well-tolerated products (such as Tesofensine) are made available on the market.

NUMBER OF PATIENTS ON TESOMET IN MEXICO



Source: Nordea estimates

NUMBER OF PATIENTS ON TESOMET IN ARGENTINA



Source: Nordea estimates

We also note that Abbott's Meridia (sibutramine) reached approximately 100,000 patients before its US regulatory approval was withdrawn in 2010, despite limited efficacy and a problematic risk profile. Tesofensine is likely to provide a superior weight loss benefit, we believe, and a more benign side-effect profile compared with Meridia's chequered cardiovascular profile.

Sensitivity analysis on net present value (valuation)

Assuming market approval in Mexico and that our assumptions prove too conservative, Tesofensine could be worth up to SEK 40-50 per share

The forecasts presented above and the value we assign to the project are subject to assumptions on many parameters. We therefore provide sensitivity tables below, showing how changes in key assumptions would impact Tesofensine's net present value in this indication.

The sensitivity analysis suggests that changes to our underlying assumptions for pricing, treatment duration, royalty rate, discount rate and approval probability could lift Tesofensine's value per share up towards the SEK 40-50 level, provided that the drug achieves market approval in Mexico and Argentina, while either lowering the pricing assumptions to USD 1.0 per day or treatment duration to four months could take the value down to the SEK 15-20 level.

At present, we stick to our estimates until there is a more tangible data point on patient compliance and drug uptake. We will revisit our assumptions when more data points become available and when the drug starts to generate sales.

VALUE PER SHARE (SEK): RISK-ADJUSTMENT VS PRICING

		Price per day (USD)				
		1.0	1.5	2.0	2.5	3.0
Risk-adjusted sales	70%	10	15	21	26	31
	80%	12	18	23	29	35
	90%	13	20	**26**	33	40
	100%	15	22	29	37	44

Source: Nordea estimates

VALUE PER SHARE (SEK): RISK-ADJUSTMENT VS DURATION

		Treatment duration (months)				
		2	4	6	8	10
Risk-adjusted sales	70%	7	14	21	27	34
	80%	8	16	23	31	39
	90%	9	18	**26**	35	44
	100%	10	20	29	39	49

Source: Nordea estimates

VALUE PER SHARE (SEK): RISK-ADJUSTMENT VS ROYALTY

		Royalty rate				
		14.5%	16.0%	17.5%	19.0%	20.5%
Risk-adjusted sales	70%	17	19	21	22	24
	80%	19	21	23	25	28
	90%	22	24	**26**	29	31
	100%	24	27	29	32	34

Source: Nordea estimates

VALUE PER SHARE (SEK): RISK-ADJUSTMENT VS WACC

		Discount rate (WACC)				
		11.5%	12.5%	13.5%	14.5%	15.5%
Risk-adjusted sales	70%	23	22	21	19	18
	80%	27	25	23	22	21
	90%	30	28	**26**	25	23
	100%	33	31	29	28	26

Source: Nordea estimates

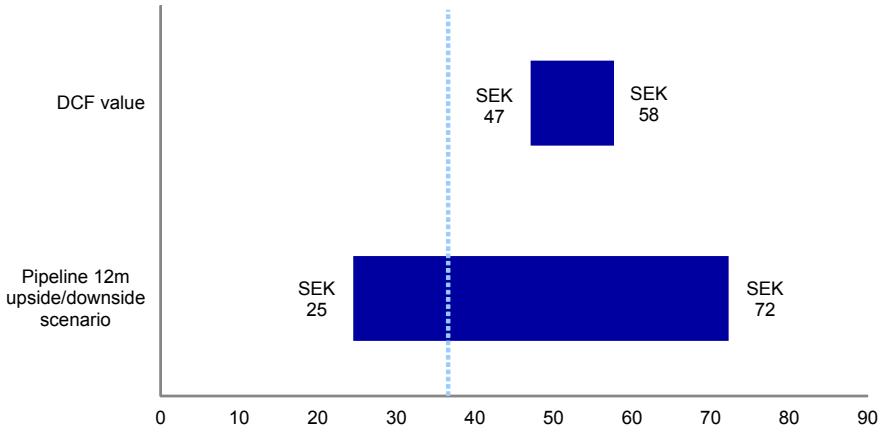
Valuation

We conduct a DCF valuation to fully capture the underlying fundamental equity value for Saniona. We favour a bottom-up net present value (NPV) model comprising probability-adjusted NPVs for each key pipeline project. Based on our underlying valuation assumptions, estimates and pipeline scenarios for key events occurring over the next 12 months, we value Saniona at SEK 47-58 per share (previously SEK 38-47 per share, with the increase owing to positive ph III pivotal data for Tesofensine in obesity).

We value Saniona at SEK 47-58 per share

We value Saniona based on a discounted cash flow (DCF) approach, as we do with all other pharma and biotech companies. Based on our underlying valuation assumptions, estimates and pipeline scenarios – detailed in the following sections – we value Saniona at SEK 47-58 per share, taking into account a WACC between 12.5% and 14.5% and downside and upside scenarios based on events that could drive the share over the coming 12 months.

VALUE PER SHARE, SEK



Source: Nordea estimates

We increase our valuation to SEK 47-58 per share (previously SEK 38-47 per share) owing to the positive ph III pivotal data for Tesofensine in obesity reported on 17 December 2018. Consequently, we increase our risk approval on the Tesofensine obesity project to 90% (from 60%).

SOTP valuation summary

Clinical achievements could have a significant impact on valuation in either direction

Our valuation model comprises probability-adjusted NPVs involving a DCF analysis to value each pipeline project individually. We adjust revenue and cash flow for the product candidates to reflect the probability we ascribe to each successfully reaching the commercial phase. This implies that clinical achievements could have a significant impact on valuation in either a positive or a negative direction, depending on the outcome. The model extends for 20 years (2018E-37E) to properly capture the full NPV value for pipeline projects, while also giving the company full credit for patents, which may extend well into the 2030s for some projects.

SANIONA SOTP VALUATION – BASE CASE

Project	Indication	Peak sales (USDm)	Potential launch	NPV (SEKm)	Prob.	Adj. NPV (SEKm)	Adj. NPV per share	Adj. NPV share (%)
Tesofensine	Obesity	204	2020	660	90%	594	26	51%
Tesomet	Obesity	350	2023	906	40%	362	16	31%
Tesomet	Prader-Willi syndrome	362	2023	3,892	15%	584	26	50%
Priority Review Voucher	Prader-Willi syndrome	N.a.	2023	298	15%	45	2	4%
Tesomet	Hypothalamic obesity	155	N.a.	0	0%	0	0	0%
Tesomet	Type 2 diabetes	N.a.	N.a.	0	0%	0	0	0%
NS2359	Cocaine addiction	486	N.a.	0	0%	0	0	0%
Pre-clinical programs		N.a.	N.a.	0	0%	0	0	0%
Pipeline value				**5,757**		**1,585**	**70**	**135%**
Group costs not allocated to individual projects				-436	100%	-436	-19	-37%
Net cash/(debt)				22	100%	22	1	2%
SOTP valuation				**5,343**		**1,172**	**52**	**100%**

Source: Company data and Nordea estimates

With no marketed products, Saniona's cash flow is risky and the company is dependent on external financing

We apply a 13.5% discount rate (WACC) to our DCF in the table above. To benchmark this level versus other biotech companies, it is ~2 pp higher than the WACC we use for Zealand Pharma (11.5%) and ~2.8 pp higher than the WACC we use for Bavarian Nordic (10.7%). We believe this seems fair, as we deem Saniona's risk profile to be higher, given that it has no marketed products with which to finance its operations at the current stage, unlike Bavarian Nordic (stockpiling smallpox vaccines for the US government). Zealand Pharma recently sold its GLP-1 royalty stream to Royalty Pharma, providing the company with approximately DKK 1.15bn in net cash by year-end 2018 while having two products in ph III; combined this makes Saniona's cash flow riskier and more dependent on external financing than these two other biotech companies.

The sensitivity table below shows how a higher or lower WACC would impact our DCF value.

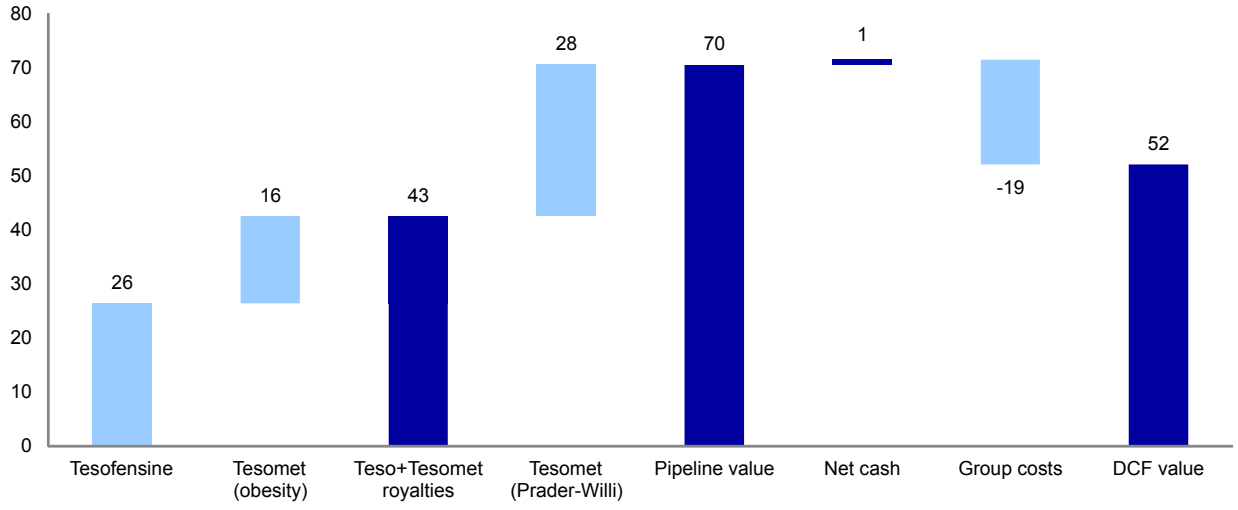
VALUE PER SHARE (SEK): WACC SENSITIVITY

	WACC				
	11.5%	12.5%	13.5%	14.5%	15.5%
Base case scenario	64	58	**52**	47	43

Source: Nordea estimates

Our sensitivity analysis suggests that applying a WACC in line with the one we use for Zealand Pharma (11.5%) could take our DCF-based value up to SEK 64 per share. This highlights the potential value creation we envisage for Saniona when its pipeline advances through clinical trials, derisking the company (in addition to the higher approval probabilities on pipeline projects).

SANIONA: SOTP VALUATION, SEK PER SHARE



Source: Company data and Nordea estimates

Tesomet's potential in PWS and other orphan diseases is the biggest potential value driver, in our view...

Looking at the value split, Tesomet stands out as the key value driver in Saniona. Our analysis suggests that Tesomet in Prader-Willi syndrome (PWS) alone is worth SEK ~28 per share on a risk-adjusted basis (15% approval probability). We view Tesomet's potential in PWS and other orphan diseases as the biggest catalyst for the stock, with the potential to take Saniona's market cap to entirely new levels.

...which in a blue-sky scenario, assuming positive ph III data and marketing approval, could boost our valuation towards SEK 250 per share based on our estimates

On our estimates, Saniona's market cap would, all else being equal, be boosted to SEK ~5.6bn or SEK ~250 per share if we were to fully include Tesomet in PWS in our model at 100% risk adjustment. This highlights the considerable upside to the share from positive news flow related to Tesomet in orphan diseases over the next few years. Note that we assign no value to Tesomet's potential use in hypothalamic obesity, type II diabetes, fatty liver disease (NASH) or binge eating, which remain free options in our model that could drive additional upside.

We ascribe SEK ~43 per share to combined Tesofensine and Tesomet royalties on obesity sales on a risk-adjusted basis.

We currently assign no value to early-stage pipeline projects, such as NS2359 or CAD-1883, for which we have yet to see efficacy data; thus, these constitute upside potential

We do not attach any value to Saniona's early-stage (ph I and pre-clinical) pipeline projects in our model or include projects for which we have yet to see ph II results (eg, NS2359 for cocaine addiction) – in line with our general valuation approach we apply to pharma and biotech companies. We argue that a pre-clinical pipeline is favoured among investors and should drive positive news flow, which is important in a biotech stock. Nevertheless, it attracts very little value. We believe this is reasonable, as:

- Investors will generally have limited willingness to pay for pre-clinical early-stage pipeline projects, given the extremely high attrition rates at this stage.
- It is inherently difficult to put a fair value on projects for which no safety and efficacy data has been reported in humans yet.
- Even with potential considerable future revenue and value, the pipeline projects would have to be risk-adjusted so heavily that the NPV effect would end up being only marginally accretive.
- Overall, it often creates more noise than benefits to argue for a pre-clinical pipeline valuation.

However, we note that we do not assume increasing R&D spending for the early-stage projects in our model either. Normally, a significant rise in spend would be modelled once drugs move into the clinical phase and revenue and income starts rising, but we do not assume this in our cost modelling.

Upside and downside scenarios

When addressing upside and downside to our base-case valuation, we look at events that could drive the share price over the next 12 months. Three key pipeline programmes are expected to either read out or have regulatory feedback over this period: 1) Tesofensine approval in obesity; 2) NS2359 ph IIa data in cocaine addiction; and, 3) Tesomet ph IIa data in Prader-Willi syndrome in adolescents. These events could have a significant impact on valuation in either direction, depending on their outcome, as highlighted below.

UPSIDE POTENTIAL AND DOWNSIDE RISK TO SOTP VALUATION

Event	Upside	SEK per share	Downside	SEK per share
Tesomet ph IIa trial in PWS (adolescents)	Positive safety and efficacy	11	PWS is abandoned	-24
NS2359 ph IIa	Positive safety and efficacy	6	Fails	0
Tesofensine in obesity	Marketing approval in Mexico	3	Launch postponed three years	-4
Potential upside/downside to base case		**20**		**-28**
Potential valuation		**72**		**25**

Source: Company data and Nordea estimates

Saniona: Revenue and P&L overview

REVENUE AND P&L OVERVIEW

SEKm	2017	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Total revenues	**21**	**59**	**38**	**68**	**73**	**120**	**353**	**388**	**542**	**589**	**617**	**649**	**661**	**710**
Growth	N.a.	187%	-37%	81%	8%	64%	194%	10%	40%	9%	5%	5%	2%	7%
Product sales and royalties	**0**	**0**	**0**	**30**	**73**	**120**	**245**	**388**	**542**	**589**	**617**	**649**	**661**	**710**
Tesofensine, obesity	0	0	0	30	73	120	172	229	290	245	197	148	106	97
Tesomet, Prader-Willi syndrome	0	0	0	0	0	0	48	107	171	230	271	313	359	407
Tesomet, Hypothalamic obesity	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Tesomet, obesity	0	0	0	0	0	0	25	52	81	113	149	187	196	206
NS2359, CNS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other (milestones/PRV)	21	59	38	38	0	0	109	0	0	0	0	0	0	0
Gross profit	21	59	38	68	73	120	353	386	540	587	614	645	658	706
Gross margin	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	99%	99%
R&D to revenue	207%	125%	213%	206%	68%	42%	14%	13%	9%	8%	8%	8%	8%	7%
In SEK	-43	-74	-80	-140	-50	-50	-50	-50	-50	-50	-50	-50	-50	-50
S&D to revenue	0%	0%	0%	0%	0%	0%	14%	8%	6%	5%	5%	5%	5%	4%
In SEK	0	0	0	0	0	0	-50	-30	-30	-30	-30	-30	-30	-30
Admin & other costs to revenue	169%	59%	93%	59%	61%	37%	13%	12%	8%	8%	7%	7%	7%	6%
In SEK	-35	-35	-35	-40	-45	-45	-45	-45	-45	-45	-45	-45	-45	-45
EBIT	**-57**	**-50**	**-77**	**-112**	**-22**	**25**	**208**	**261**	**415**	**462**	**489**	**520**	**533**	**581**
EBIT margin	-276%	-84%	-206%	-165%	-30%	21%	59%	67%	77%	78%	79%	80%	81%	82%
PTP	-56	-49	-77	-112	-22	25	208	261	415	462	489	520	533	581
Net profit	-49	-38	-60	-87	-17	20	162	204	324	360	382	406	416	453
Free cash flow	**-58**	**-22**	**-60**	**-86**	**-18**	**20**	**180**	**208**	**338**	**367**	**387**	**412**	**418**	**458**
Net cash	22	72	84	-1	-20	1	181	389	728	1,094	1,482	1,894	2,312	2,770

Source: Company data and Nordea estimates

News flow in the next 12 to 24 months

Key triggers in 2019 and 2020 primarily relate to updates on the Tesomet development programme, including ph IIa data in Prader-Willi syndrome – a readout that we expect to be important for the share price performance in the near term. The company expects the trial to be completed in early 2019 with top-line results available in Q1 2019. We will also have more insight into NS2359's potential soon, but we see this ph IIa project as a risky readout and have not included NS2359 in our model yet.

Tesomet ph IIa PWS results are expected in Q1 and are important for the case and the share price in the near term

Triggers in the coming 12-24 months

While Saniona has now reported the important pivotal Tesofensine ph III top-line results, 2019 will be another important year. Key to the share price in the near term will be Tesomet ph IIa data in Prader-Willi syndrome. The company expects the trial to be completed in early 2019 with top-line results available in Q1 2019. NS2359 will also deliver ph IIa data in cocaine addiction in Q4 2018 or potentially in Q1 2019, but we consider this project as a risky read-out and something that is seen as an option rather than one with high expectations in the market, given that it will be the first time NS2359 delivers efficacy data in this indication in a clinical trial. We have not included NS2359 in our model yet.

SANIONA'S UPCOMING NEWS FLOW

Timeline	Project	Event	Indication	Description
Q4 2018	NS2359	Ph 2a interim data	Cocaine addiction	Saniona expects to report ph 2a interim results in Q4 2018
Q4 2018	Tesomet	Ph 1 results	-	Results from ph 1 pharmacodynamic study
Q1 2018	Tesomet	Ph 2a results	Prader-Willi syndrome	Results from ph 2a study in adolescents (step 2)
Q1 2019	Tesomet	Ph 2a study initated	Hypothalamic obesity	Saniona plans to start a ph 2a study "within the coming months"
H1 2019	Tesomet	Ph 2b study initated	Prader-Willi syndrome	We expect Saniona to start a ph 2b dose-finding study in Prader-Willi
H2 2019	Tesomet	Ph 2b study initated	Obesity	We expect Saniona to start a ph 2b study in obesity
H2 2019	Tesofensine	Approval decision	Obesity	We expect a regulatory approval decision in Mexico by late-2019
2019/2020	Pre-clinical	Deal	-	Potential for partnership deals on pre-clinical programmes
2019/2020	Pre-clinical	Deal	-	Potential for spin-outs on pre-clinical programmes
2019/2020	Pre-clinical	Milestones	-	Progress and potential milestones under existing collaborations
2019/2020	Tesomet	Deal	Metabolic diseases	Potential for partnership deals on Tesomet in metabolic diseases
Competitors				
H1 2019	Tesomet	Ph 3 data	Prader-Willi syndrome	Ph 3 topline data for DCCR by Soleno Therapeutics

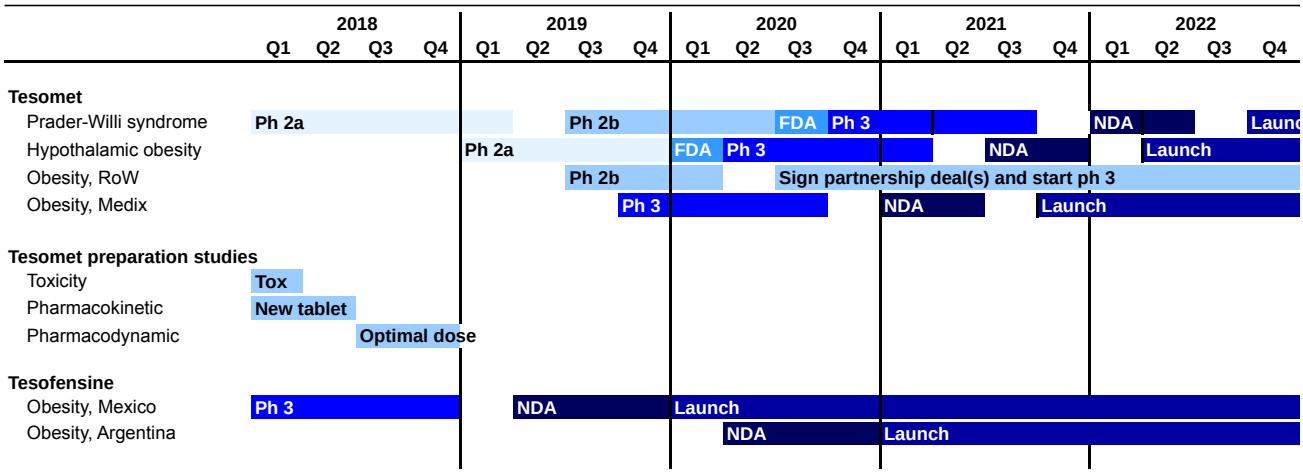
Source: Company data and Nordea estimates

The Tesomet study in PWS is divided into two steps. Step 1 tested Tesomet in adults with PWS, which will then be extended to adolescents (step 2). The company reported top-line results from step 1 in January 2018. Tesomet achieved a positive outcome on the primary endpoint (change in body weight from baseline) with a clinically meaningful reduction in body weight for the PWS patients treated with Tesomet compared to placebo. Tesomet also led to a dramatic decrease in hyperphagia (extreme and insatiable appetite in patients). No serious adverse events were reported during the study, but some patients experienced that their existing behavioural problems worsened. However, this reversed when patients were offered a temporary reduction in dose during the study, suggesting that by reducing the dose, Tesomet may be better tolerated in this highly sensitive patient group, while at the same time remaining efficacious.

Based on the findings in the study and discussions and feedback from key opinion leaders, Saniona will continue to give lower doses in the adolescent patient population in order to ensure that the drug is tolerated in this patient population.

We illustrate potential timelines for Tesomet and Tesofensine below. These timelines are obviously subject to board decisions and financial planning, and may change, depending on trial outcomes and how smoothly enrolment evolves in clinical trials, discussions with regulators, etc.

SANIONA'S TIMELINES FOR TESOMET AND TESOFENSINE



Source: Company data and Nordea

Factors to consider when investing in Saniona

The equity story in Saniona is mainly about Tesomet, the company's franchise molecule addressing high unmet medical needs in obesity and rare obesity-associated diseases. The company also has other high-potential projects in the pipeline to secure long-term growth, value and news flow, funded by partnerships and a funding agreement at the current stage until late 2020 – beyond important key pipeline catalysts. Potential product sales and royalties on product sales will tick in during the next two to five years, taking over funding. Saniona's share price performance will be highly dependent on clinical pipeline updates on its ongoing trials (mainly Tesomet and Tesofensine), posing a high risk to investors but also potentially great rewards.

The Saniona equity story

Saniona is a Denmark-based small cap biotech company listed in Sweden. It has a broad pipeline, with one product recently having reported positive ph III top-line results in obesity (Tesofensine) and three products in ph II, including Tesomet, the company's franchise molecule and key value driver, which may be used across several rare diseases related to obesity. For investors willing to take on the common biotech risk in a small cap company comprising just pipeline projects and no marketed products – and thus exposure to a company and a stock heavily dependent on clinical development, regulatory risk and volatile trading volumes – an investment in Saniona could provide exposure to attractive market opportunities in the orphan drug space and several catalysts in the pipeline.

Factors to consider when investing in Saniona

We view the following to be key when considering an investment in Saniona

- Saniona's late-stage pipeline programmes address small, rare diseases, where the company could go all the way to the market on its own, as well as larger indications, such as obesity, through a partnership approach with selected pharmaceutical companies.
- The high unmet medical needs in rare diseases have resulted in increased regulatory focus, with regulators in the US and EU (FDA and EMA) having implemented several financial incentives to invest in drug development in this area, creating attractive market opportunities.
- Saniona's lead asset, Tesomet, has been shown in trials to reduce both body weight and hyperphagia (insatiable appetite), providing patients with a novel treatment option with potential not only in obesity but also in multiple, rare obesity-associated disorders.
- Tesofensine and Tesomet could be favourably positioned to address the high unmet medical needs in obesity treatment in Mexico, Argentina and other RoW markets.
- Saniona's early-stage pipeline should provide investors with positive news flow, deals, sustainable growth prospects and valuation optionality over the long term.
- Funding should be sufficient until late 2020 – beyond important key pipeline catalysts.

We see the main risks in Saniona being:
1) pipeline failures, especially relating to Tesomet, delays or regulatory hurdles;
2) partners' and Saniona's ability to commercialise Tesofensine and Tesomet successfully; and,
3) funding needs beyond 2020

Key risk factors and potential investor concerns in the case

- Clinical trials are risky, and despite promising results in earlier clinical studies, key projects (Tesofensine and Tesomet) may fail later-stage studies, be delayed in development or fail to gain approval from regulatory authorities.
- Medix and Saniona's ability to commercialise Tesofensine and Tesomet successfully, pending successful clinical development and regulatory approvals.
- Executing future out-licensing deals with Tesomet in metabolic diseases and with the early-stage pipeline.
- Funding should be sufficient until late 2020, but depending on clinical results and partnership agreements, the company may need additional liquidity to continue advancing its pipeline products and fund operations beyond 2020.

Tesomet – a franchise molecule treating obesity-associated disorders

Saniona's lead asset, Tesomet, is an oral fixed-dose combination product between Tesofensine and a beta blocker called Metoprolol. Tesomet is in ph II clinical development for Prader-Willi syndrome (PWS). The company also intends to initiate ph II studies in hypothalamic obesity as well as metabolic diseases during 2019.

Patients with PWS and hypothalamic obesity suffer from a constant, uncontrollable, extreme urge to eat (hyperphagia), which persists no matter how much they eat, leading to morbid obesity.

SANIONA'S LATE-STAGE PIPELINE

Project	Indication	Phase 1	Phase 2a	Phase 2b	Phase 3	Next steps	Timing
Tesofensine	Obesity					Filing and approval	2019
Tesomet	Obesity					Ph 2b initiation	Q3 2019
Tesomet	Prader-Willi Syndrome					Ph 2a results	Q1 2019
Tesomet	Hypothalamic obesity					Ph 2a initiation	Q1 2019
NS2359	Cocaine Addiction					Ph 2a results	Q4 2018

Source: Company data and Nordea

The drug is set to report ph IIa data in adolescents with Prader-Willi syndrome in Q1 2019. Saniona will also initiate a ph IIa study in hypothalamic obesity, with initial data possibly reading out in late 2019/early 2020 (depending on enrolment status and trial start), as well as a ph IIb trial in obesity.

Tesomet addresses high unmet medical needs in orphan indications

We view Tesomet as addressing markets with high unmet medical needs in obesity and rare diseases associated with obesity

Tesomet could address two high unmet medical need areas: obesity and rare diseases associated with obesity. Tesomet and Tesofensine (the active ingredient in Tesomet), have generated compelling ph III data (December 2018) and ph IIb data in obesity as well as ph IIa data in adult patients with PWS across clinically relevant endpoints, showing that Tesomet has the potential to significantly reduce both body weight and – importantly – extreme and insatiable appetite in patients (hyperphagia).

Tesomet would present a novel drug launched in a market where no medication has proved effective in regulating hyperphagia in patients with PWS and hypothalamic obesity. There remains a high unmet medical need, as this is arguably the toughest challenge in treating patients with PWS and hypothalamic obesity.

Although prevalence estimates differ among studies, it is estimated that PWS afflicts 15,000-20,000 patients in the US and EU combined, while there are about 7,500-10,000 patients with hypothalamic obesity. This may not seem appealing from a commercial perspective, but the high unmet medical needs in rare diseases have increased regulatory focus worldwide, with both the FDA and EMA having implemented several financial incentives to invest in drug development for rare diseases. These include market exclusivity for seven to ten years, premium pricing, and the priority review voucher programme, among others.

The orphan drug space allows Saniona to fast-track through clinical studies to regulatory filings at a low investment, with potential for orphan drug designation, ensuring premium pricing and market exclusivity.

Tesomet: The biggest upside, the biggest risk

We view Tesomet as a major growth, earnings and valuation driver for Saniona in the coming years

We view Tesomet as a major growth, earnings and valuation driver for Saniona in the coming years. While Tesomet represents the largest upside to the case, it also represents by far the largest risk should it fail in clinical trials or fail to gain approval from regulators.

We provide our Tesomet forecasts below, split by indication. On a risk-adjusted basis, we forecast that the drug will generate up to SEK ~730m in revenue for Saniona. The main driver is its sales potential in orphan disorders.

TESOMET: FORECAST SUMMARY (RISK-ADJUSTED REVENUE)

SEKm	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E
Prader-Willi (15% risk-adj)	48	107	171	230	271	313	359	407	458	474	491	247	124	85	45
- Growth (y/y)	N.a.	122%	59%	35%	17%	16%	14%	13%	13%	4%	4%	-50%	-50%	-32%	-47%
Hypothalamic obesity	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
- Growth (y/y)	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.	N.a.
Total orphan disorders	48	107	171	230	271	313	359	407	458	474	491	247	124	85	45
- Growth (y/y)	N.a.	122%	59%	35%	17%	16%	14%	13%	13%	4%	4%	-50%	-50%	-32%	-47%
Obesity (40% risk-adj)	25	52	81	113	149	187	196	206	216	227	238	161	82	75	68
- Growth (y/y)	N.a.	110%	57%	40%	31%	26%	5%	5%	5%	5%	5%	-32%	-49%	-8%	-9%
Total Tesomet	**73**	**159**	**252**	**344**	**419**	**500**	**555**	**613**	**674**	**701**	**729**	**408**	**206**	**160**	**114**
- Growth (y/y)	N.a.	118%	58%	37%	22%	19%	11%	10%	10%	4%	4%	-44%	-49%	-22%	-29%
Share of total sales	30%	41%	46%	58%	68%	77%	84%	86%	88%	90%	91%	88%	82%	82%	83%
Share of total sales growth	59%	60%	60%	198%	270%	256%	422%	118%	118%	157%	158%	97%	95%	80%	79%

Source: Nordea estimates

At present, we do not include explicit forecasts for hypothalamic obesity in our valuation; this remains as potential upside to our valuation.

Early pipeline to generate positive news flow, deals and upside

Saniona's early-stage (ph I and pre-clinical) pipeline projects are developed in-house using its technology platform. The company is focused on developing Tesomet in orphan diseases, while it finances most other lead and pre-clinical assets through partnerships or research grants – a key strategy that ensures a low cash burn rate.

SANIONA'S EARLY-STAGE PIPELINE

Project	Indication	Pre-clinical Research	Pre-clinical Development	Phase 1	Phase 2a	Rights	Next steps
CAD-1883	Essential tremors					Cadent Therapeutics	Finish ph 2a
CAD-1883	Ataxia					Cadent Therapeutics	Finish ph 1
SAN711	Neuropathic pain and itching					Saniona	Move into ph 1
BI program	Schizophrenia					Boehringer Ingelheim	Move into ph 1
IK program	Inflammatory bowel disease					Saniona	Candidate selection
Kv7	Pain, epilepsy and UI					Saniona	Lead optimation
Nicotinic a6	Parkinson's disease					Saniona	Lead optimation

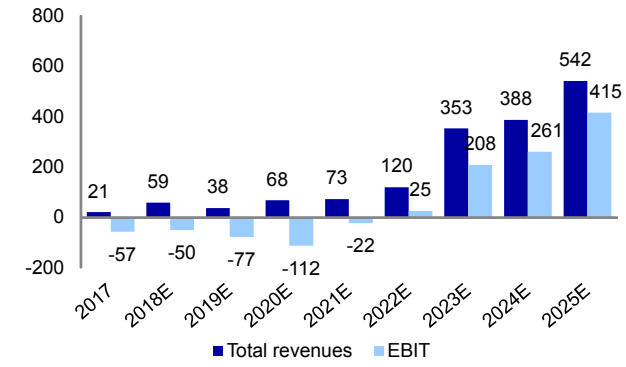
Source: Company data and Nordea

We do not attach any value to Saniona's early-stage pipeline in our valuation, but it offers valuation optionality and crystallises value as projects develop to the clinical stage or when entering potential partnerships deals, thus securing long-term growth and positive news flow.

Funded until late 2020 – beyond important key pipeline catalysts

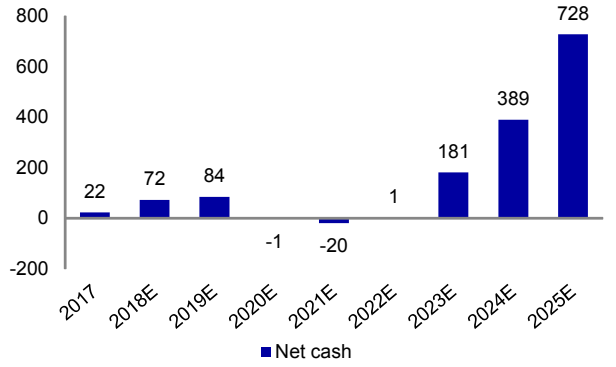
We expect funding to be sufficient to fund operations and cash burn until late 2020, thanks to net cash, partnership agreements and a convertible notes funding agreement. By that time, numerous late-stage clinical catalysts should provide potential opportunities to crystallise value, including Tesofensine marketing approval in Mexico and ph II readouts for Tesomet in PWS and hypothalamic obesity.

SANIONA: REVENUE AND EBIT FORECASTS, SEKm



Source: Company data and Nordea estimates

SANIONA: NET CASH FORECASTS, SEKm



Source: Company data and Nordea estimates

Our model assumes that Saniona turns profitable and cash flow positive in 2022/2023 thanks to Tesomet sales starting to kick in.

SANIONA: REVENUE AND P&L OVERVIEW

SEKm	2017	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Total revenues	**21**	**59**	**38**	**68**	**73**	**120**	**353**	**388**	**542**	**589**	**617**	**649**	**661**	**710**
Growth	N.a.	187%	-37%	81%	8%	64%	194%	10%	40%	9%	5%	5%	2%	7%
Product sales and royalties	**0**	**0**	**0**	**30**	**73**	**120**	**245**	**388**	**542**	**589**	**617**	**649**	**661**	**710**
Tesofensine, obesity	0	0	0	30	73	120	172	229	290	245	197	148	106	97
Tesomet, Prader-Willi syndrome	0	0	0	0	0	0	48	107	171	230	271	313	359	407
Tesomet, Hypothalamic obesity	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Tesomet, obesity	0	0	0	0	0	0	25	52	81	113	149	187	196	206
NS2359, CNS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other (milestones/PRV)	21	59	38	38	0	0	109	0	0	0	0	0	0	0
Gross profit	21	59	38	68	73	120	353	386	540	587	614	645	658	706
Gross margin	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	99%	99%
R&D to revenue	207%	125%	213%	206%	68%	42%	14%	13%	9%	8%	8%	8%	8%	7%
In SEK	-43	-74	-80	-140	-50	-50	-50	-50	-50	-50	-50	-50	-50	-50
S&D to revenue	0%	0%	0%	0%	0%	0%	14%	8%	6%	5%	5%	5%	5%	4%
In SEK	0	0	0	0	0	0	-50	-30	-30	-30	-30	-30	-30	-30
Admin & other costs to revenue	169%	59%	93%	59%	61%	37%	13%	12%	8%	8%	7%	7%	7%	6%
In SEK	-35	-35	-35	-40	-45	-45	-45	-45	-45	-45	-45	-45	-45	-45
EBIT	**-57**	**-50**	**-77**	**-112**	**-22**	**25**	**208**	**261**	**415**	**462**	**489**	**520**	**533**	**581**
EBIT margin	-276%	-84%	-206%	-165%	-30%	21%	59%	67%	77%	78%	79%	80%	81%	82%
PTP	-56	-49	-77	-112	-22	25	208	261	415	462	489	520	533	581
Net profit	-49	-38	-60	-87	-17	20	162	204	324	360	382	406	416	453
Free cash flow	**-58**	**-22**	**-60**	**-86**	**-18**	**20**	**180**	**208**	**338**	**367**	**387**	**412**	**418**	**458**
Net cash	22	72	84	-1	-20	1	181	389	728	1,094	1,482	1,894	2,312	2,770

Source: Company data and Nordea estimates

We assume that the company will prioritise driving drugs through clinical development and towards the market over near-term profitability. In our view, this strategy seems prudent, as success with early-stage pipeline projects and subsequent advancement into ph II clinical studies will drive value for the company, as will pipeline progress with Tesomet in PWS, hypothalamic obesity and obesity.

Reported numbers and forecasts

INCOME STATEMENT

SEKm	2010	2011	2012	2013	2014	2015	2016	2017	2018E	2019E	2020E
Net revenue	**n.a.**	**n.a.**	**n.a.**	**13**	**22**	**14**	**75**	**21**	**59**	**38**	**68**
Revenue growth	n.a.	n.a.	n.a.	n.a.	63.0%	-37.2%	449.7%	-72.4%	187.1%	-36.7%	80.8%
of which organic	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
of which FX	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBITDA	0	0	0	-1	-7	-27	5	-57	-49	-77	-112
Depreciation and impairments PPE	0	0	0	0	-1	-1	0	-1	-1	0	0
EBITA	0	0	0	-2	-8	-28	4	-57	-50	-77	-112
Amortisation and impairments	0	0	0	0	0	0	0	0	0	0	0
EBIT	n.a.	n.a.	n.a.	-2	-8	-28	4	-57	-50	-77	-112
of which associates	0	0	0	0	0	0	0	0	0	0	0
Associates excluded from EBIT	0	0	0	0	0	0	0	0	0	0	0
Net financials	0	0	0	0	1	-1	1	1	1	1	1
Changes in value, net	0	0	0	0	0	0	0	0	0	0	0
Pre-tax profit	**0**	**0**	**0**	**-2**	**-8**	**-29**	**5**	**-56**	**-49**	**-76**	**-111**
Reported taxes	0	0	0	0	2	6	-3	7	11	17	25
Net profit from continued operations	0	0	0	-1	-6	-23	2	-49	-38	-59	-86
Discontinued operations	0	0	0	0	0	0	0	0	0	0	0
Minority interests	0	0	0	0	0	0	0	0	0	0	0
Net profit to equity	0	0	0	-1	-6	-23	2	-49	-38	-59	-86
EPS	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**
DPS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
of which ordinary	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
of which extraordinary	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Profit margin in percent											
EBITDA	n.a.	n.a.	n.a.	-9.1%	-34.5%	-200.4%	6.1%	-273.7%	-82.7%	-205.9%	-164.8%
EBITA	n.a.	n.a.	n.a.	-12.5%	-38.0%	-206.0%	5.5%	-276.4%	-83.5%	-205.9%	-164.8%
EBIT	**n.a.**	**n.a.**	**n.a.**	**-12.5%**	**-38.0%**	**-206.0%**	**5.5%**	**-276.4%**	**-83.5%**	**-205.9%**	**-164.8%**
Adjusted earnings											
EBITDA (adj)	0	0	0	-1	-7	-27	5	-57	-49	-77	-112
EBITA (adj)	0	0	0	-2	-8	-28	4	-57	-50	-77	-112
EBIT (adj)	0	0	0	-2	-8	-28	4	-57	-50	-77	-112
EPS (adj)	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**	**n.a.**
Adjusted profit margins in percent											
EBITDA (adj)	n.a.	n.a.	n.a.	-9.1%	-34.5%	-200.4%	6.1%	-273.7%	-82.7%	-205.9%	-164.8%
EBITA (adj)	n.a.	n.a.	n.a.	-12.5%	-38.0%	-206.0%	5.5%	-276.4%	-83.5%	-205.9%	-164.8%
EBIT (adj)	n.a.	n.a.	n.a.	-12.5%	-38.0%	-206.0%	5.5%	-276.4%	-83.5%	-205.9%	-164.8%
Performance metrics											
CAGR last 5 years											
Net revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	34.8%	11.6%	37.9%
EBITDA	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EBIT	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.m.	n.m.	n.m.
EPS	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
DPS	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Average last 5 years											
Average EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	-63.1%	-73.0%	n.m.	n.m.
Average EBITDA margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	-61.1%	-71.4%	-99.8%	n.m.

VALUATION RATIOS - ADJUSTED EARNINGS

SEKm	2010	2011	2012	2013	2014	2015	2016	2017	2018E	2019E	2020E
P/E (adj)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EV/EBITDA (adj)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.m.	n.m.	n.m.
EV/EBITA (adj)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.m.	n.m.	n.m.
EV/EBIT (adj)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.m.	n.m.	n.m.

VALUATION RATIOS - REPORTED EARNINGS

SEKm	2010	2011	2012	2013	2014	2015	2016	2017	2018E	2019E	2020E
P/E	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EV/Sales	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	12.08	20.65	12.68
EV/EBITDA	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.m.	n.m.	n.m.
EV/EBITA	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.m.	n.m.	n.m.
EV/EBIT	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.m.	n.m.	n.m.
Dividend yield (ord.)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	0.0%	0.0%	0.0%
FCF yield	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	-2.8%	-7.0%	-10.0%
Payout ratio	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

Source: Company data and Nordea estimates

BALANCE SHEET

SEKm	2010	2011	2012	2013	2014	2015	2016	2017	2018E	2019E	2020E
Intangible assets	0	0	0	0	0	0	0	0	0	0	0
of which R&D	0	0	0	0	0	0	0	0	0	0	0
of which other intangibles	0	0	0	0	0	0	0	0	0	0	0
of which goodwill	0	0	0	0	0	0	0	0	0	0	0
Tangible assets	0	0	0	1	1	1	1	1	1	1	1
Shares associates	0	0	0	0	0	0	0	0	0	0	0
Interest bearing assets	0	0	0	0	0	0	0	0	0	0	0
Deferred tax assets	0	0	0	0	0	0	0	0	0	0	0
Other non-IB non-current assets	0	0	0	0	0	0	0	0	0	0	0
Other non-current assets	0	0	0	1	1	1	1	6	0	0	0
Total non-current assets	0	0	0	2	2	2	3	8	1	1	1
Inventory	0	0	0	0	0	0	0	0	0	0	0
Accounts receivable	0	0	0	1	3	8	14	18	15	9	17
Other current assets	0	0	0	0	1	0	1	1	2	1	2
Cash and bank	0	0	0	1	10	47	53	22	72	84	-1
Total current assets	0	0	0	2	13	55	68	41	89	95	17
Assets held for sale	0	0	0	0	0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total assets	**0**	**0**	**0**	**4**	**15**	**58**	**71**	**48**	**90**	**96**	**18**
Shareholders equity	0	0	0	-3	9	53	54	38	72	84	-2
Of which preferred stocks	0	0	0	0	0	0	0	0	0	0	0
Of which equity part of hybrid debt	0	0	0	0	0	0	0	0	0	0	0
Minority interest	0	0	0	0	0	0	0	0	0	0	0
Total Equity	0	0	0	-3	9	53	54	38	72	84	-2
Deferred tax	0	0	0	0	0	0	0	0	0	0	0
Long term interest bearing debt	0	0	0	0	0	0	0	0	0	0	0
Pension provisions	0	0	0	0	0	0	0	0	0	0	0
Other long-term provisions	0	0	0	0	0	0	0	0	0	0	0
Other long-term liabilities	0	0	0	0	0	0	0	0	0	0	0
Convertible debt	0	0	0	0	0	0	0	0	0	0	0
Shareholder debt	0	0	0	0	0	0	0	0	0	0	0
Hybrid debt	0	0	0	0	0	0	0	0	0	0	0
Total non-current liabilities	0	0	0	0	0	0	0	0	0	0	0
Short-term provisions	0	0	0	0	0	0	2	0	0	0	0
Accounts payable	0	0	0	2	2	3	6	5	6	4	7
Other current liabilities	0	0	0	5	4	2	9	6	12	8	14
Short term interest bearing debt	0	0	0	0	0	0	0	0	0	0	0
Total current liabilities	0	0	0	7	7	5	17	11	18	11	20
Liabilities for assets held for sale	0	0	0	0	0	0	0	0	0	0	0
Total liabilities and equity	**0**	**0**	**0**	**4**	**15**	**58**	**71**	**48**	**90**	**96**	**18**
Balance sheet and debt metrics											
Net debt	0	0	0	-1	-10	-47	-53	-22	-72	-84	1
Working capital	0	0	0	-6	-3	4	0	8	-1	-1	-2
Invested capital	0	0	0	-4	-1	6	3	15	-1	0	-1
Capital employed	0	0	0	-3	9	53	54	38	72	84	-2
ROE	n.m.	n.m.	n.m.	86.9%	n.m.	-74.4%	4.1%	n.m.	-69.3%	-76.1%	n.m.
ROIC	n.m.	n.m.	n.m.	72.9%	n.m.	n.m.	76.0%	n.m.	n.m.	n.m.	n.m.
ROCE	n.a.	n.a.	n.a.	57.2%	-94.1%	-53.0%	7.7%	n.m.	-69.2%	-91.8%	n.m.
Net debt/EBITDA	n.m.	n.m.	n.m.	0.8	1.3	1.7	-11.7	0.4	1.5	1.1	0.0
Interest coverage	n.a.	n.a.	n.a.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Equity ratio	n.m.	n.m.	n.m.	-73.0%	56.8%	91.8%	76.7%	77.8%	80.1%	88.2%	-11.1%
Net gearing	n.m.	n.m.	n.m.	31.5%	-110.4%	-88.8%	-98.2%	-59.3%	-100.8%	-100.0%	-62.8%

Source: Company data and Nordea estimates

CASH FLOW STATEMENT

SEKm	2010	2011	2012	2013	2014	2015	2016	2017	2018E	2019E	2020E
EBITDA (adj) for associates	**0**	**0**	**0**	**-1**	**-7**	**-27**	**5**	**-57**	**-49**	**-77**	**-112**
Paid taxes	0	0	0	0	0	0	0	0	11	17	25
Net financials	0	0	0	0	0	0	0	0	1	1	1
Change in provisions	0	0	0	0	0	0	2	-2	0	0	0
Change in other LT non-IB	0	0	0	-1	0	-1	0	-5	6	0	0
Cash flow to/from associates	0	0	0	0	0	0	0	0	0	0	0
Dividends paid to minorities	0	0	0	0	0	0	0	0	0	0	0
Other adj to reconcile to cash flow	0	0	0	-5	0	1	-2	7	0	0	0
Funds from operations (FFO)	**0**	**0**	**0**	**-7**	**-7**	**-27**	**5**	**-56**	**-31**	**-59**	**-86**
Change in NWC	0	0	0	3	0	-2	3	-1	9	-1	1
Cash flow from operations (CFO)	**0**	**0**	**0**	**-4**	**-8**	**-29**	**8**	**-57**	**-22**	**-60**	**-86**
Capital expenditure	0	0	0	-2	-1	0	-1	-1	0	0	0
Free cash flow before A&D	**0**	**0**	**0**	**-5**	**-9**	**-29**	**7**	**-58**	**-22**	**-60**	**-86**
Proceeds from sale of assets	0	0	0	0	0	0	0	0	0	0	0
Acquisitions	0	0	0	0	0	0	0	0	0	0	0
Free cash flow	0	0	0	-5	-9	-29	7	-58	-22	-60	-86
Dividends paid	0	0	0	n.a.	n.a.	n.a.	0	0	0	0	0
Equity issues / buybacks	0	0	0	0	18	67	0	33	72	72	0
Net change in debt	0	0	0	0	0	0	0	0	0	0	0
Other financing adjustments	0	0	0	0	0	0	0	0	0	0	0
Other non-cash adjustments	0	0	0	6	0	0	0	-6	0	0	0
Change in cash	0	0	0	1	9	37	6	-31	50	12	-86
Cash flow metrics											
Capex/D&A	n.m.	n.m.	n.m.	n.m.	n.m.	31.7%	n.m.	n.m.	0.0%	n.m.	n.m.
Capex/Sales	n.a.	n.a.	n.a.	-12.2%	-3.7%	-1.8%	-1.1%	-3.4%	0.0%	0.0%	0.0%
Key information											
Share price year end (/current)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	33	33	33
Market cap.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	790	861	861
Enterprise value	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	718	776	862
Diluted no. of shares, year-end (m)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	21.5	23.8	25.9	25.9

Source: Company data and Nordea estimates

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