



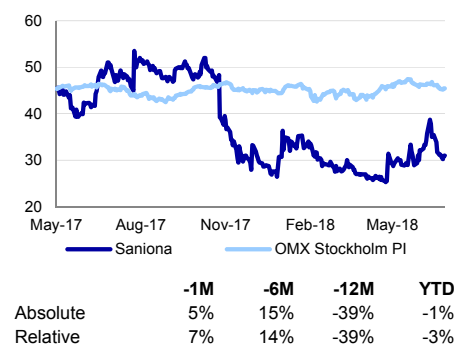
Saniona

Healthcare | Sweden

KEY DATA

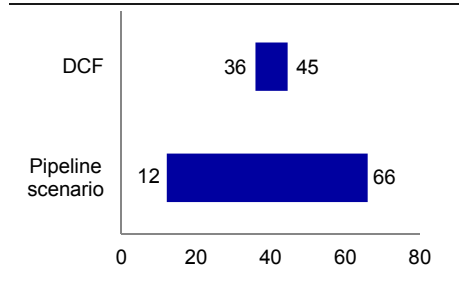
Country	Sweden
Bloomberg	SANION SS
Reuters	SANION.ST
Share price	30.45
Free float	73%
Market cap (m)	SEK 672
Website	www.saniona.com
Next report date	22 August 2018

PERFORMANCE



Source: FactSet and Bloomberg

VALUATION APPROACH



Source: Nordea estimates

A pipeline play on orphan obesity

The Saniona equity story in brief

The equity story in Saniona is mainly about Tesomet, the company's franchise molecule addressing obesity and orphan indications, which provides exposure to attractive market opportunities that could drive income and the share. The company also has other projects in the pipeline to crystallise value. We believe cash burn should be funded into late 2020, beyond potential key pipeline catalysts.

Tesomet – the biggest upside, the biggest risk

The lead product Tesomet is in ph II trials for obesity and the orphan indications of Prader-Willi syndrome (PWS) and hypothalamic obesity, manifested by insatiable hunger and morbid obesity. With compelling weight loss and hyperphagia data already reported in ph II trials and the regulatory focus on orphan diseases, we estimate USD 360m in peak sales for PWS alone. We risk-adjust sales by 15% and reach SEK 26 per share. If we include PWS fully, we see potential blue-sky upside of SEK 200 per share. We currently assign no value to hypothalamic obesity, type II diabetes, or other indications, thus these also constitute upside potential.

Tesomet and Tesofensine to address obesity epidemic in RoW

The commercial opportunity presented by obesity holds the potential to be much larger than PWS, with 600-700 million obese people worldwide, but the market is still in the development phase commercially. We ascribe SEK 31 per share to Tesofensine and Tesomet combined, assuming USD ~400m in combined peak sales in Mexico, Argentina and other RoW markets.

Funded beyond key pipeline catalysts

Net cash, partnerships, and a convertible notes funding agreement should fund cash burn into late 2020, in our view. By then, numerous catalysts should provide potential opportunities to crystallise value, including ph III top-line data on Tesofensine in obesity (Q1 2019) and ph II readouts for Tesomet in PWS (ph IIa in Q4 2018; ph IIb around Q1 2020), hypothalamic obesity (Q4 2019) and obesity (2020).

Valuation

We value Saniona using a DCF model. Based on our underlying valuation assumptions, estimates and pipeline scenarios, we value Saniona at SEK 36-45 per share. Risks include: 1) pipeline failures, delays or regulatory hurdles; 2) partners' and Saniona's ability to successfully commercialise Tesofensine and Tesomet; 3) executing future out-licensing deals; and 4) funding needs beyond 2020.

Nordea Markets – Analysts

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SUMMARY TABLE – KEY FIGURES

SEKm	2017	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Revenue	21	49	38	57	47	78	314	303	433
EBIT	-57	-37	-77	-123	-48	-17	169	177	306
Free cash flow	-58	-12	-60	-94	-38	-13	148	140	251
Net cash	22	82	95	0	-38	-50	98	237	488

Source: Company data and Nordea estimates

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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 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, starting in two to five years' time, to take over funding. Hence, 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 for investors, but also a potential great reward.

The Saniona equity story

Saniona is a Denmark-based small cap biotech company listed in Sweden. The company has a broad pipeline, with one product in ph III for obesity and two 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.

Given that investors are willing to take on the common biotech risk in a small-cap company only comprising pipeline projects and no marketed products – and thus having 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 looming in the pipeline.

Factors to consider when investing in Saniona

We view the following as key when considering an investment in the Saniona stock

- 1) Saniona's late-stage pipeline programmes address small, rare diseases, where the company could go all the way to the market on its own, but also larger indications, such as obesity, through a partnership approach with selected pharmaceutical companies.
- 2) The high unmet medical needs in rare diseases has 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.
- 3) Saniona's lead asset, Tesomet, has been shown to reduce both body weight and hyperphagia (insatiable appetite), thus providing patients with a novel treatment option that holds potential not only in obesity but also multiple rare obesity-associated disorders, such as Prader-Willi syndrome and hypothalamic obesity.
- 4) Tesofensine and Tesomet could be favourably positioned to address the high unmet medical needs in obesity treatment in Mexico, Argentina and other RoW markets.
- 5) Saniona's early-stage pipeline should provide investors with positive news flow, deals, sustainable growth prospects and valuation optionality over the long term.
- 6) Funding should be sufficient until late 2020 – beyond important key pipeline catalysts.

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. Although this may not seem appealing in a commercial perspective, 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 towards rare diseases. These include market exclusivity for seven to ten years, premium pricing, and the Priority Review Voucher Program, among others. So, 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

As we conclude in this report, 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 is also by far the largest risk should it fail in clinical trials or fail to gain approval by regulators.

We illustrate our Tesomet forecasts below, split according to indication. On a risk-adjusted basis, we forecast that the drug will generate up to SEK ~700m in revenue for Saniona. The main driver is its sales potential in orphan disorders.

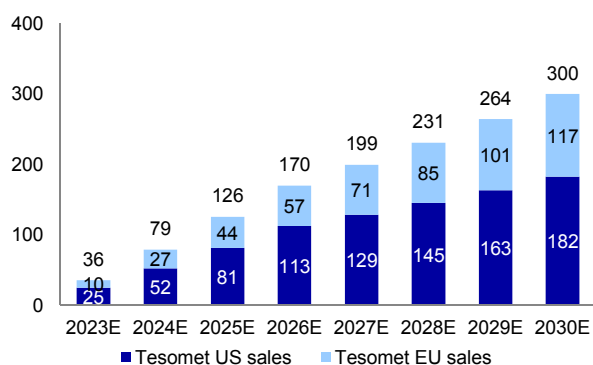
TESOMET FORECAST SUMMARY (RISK-ADJUSTED REVENUE)

SEKm	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E
Prader-Willi (15% risk-adj)	47	104	166	224	263	305	349	395	445	461	477	240	121	83	44
- 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	47	104	166	224	263	305	349	395	445	461	477	240	121	83	44
- Growth (y/y)	N.a.	122%	59%	35%	17%	16%	14%	13%	13%	4%	4%	-50%	-50%	-32%	-47%
Obesity (40% risk-adj)	24	50	79	110	145	182	191	200	210	220	231	157	80	73	66
- Growth (y/y)	N.a.	110%	57%	40%	31%	26%	5%	5%	5%	5%	5%	-32%	-49%	-8%	-9%
Total Tesomet	71	155	245	334	408	487	540	596	655	681	709	397	201	156	110
- Growth (y/y)	N.a.	118%	58%	37%	22%	19%	11%	10%	10%	4%	4%	-44%	-49%	-22%	-29%
Share of total sales	39%	51%	57%	68%	76%	84%	89%	90%	92%	93%	94%	91%	87%	87%	88%
Share of total sales growth	68%	70%	69%	149%	172%	168%	204%	112%	111%	132%	132%	98%	96%	86%	85%

Source: Nordea estimates

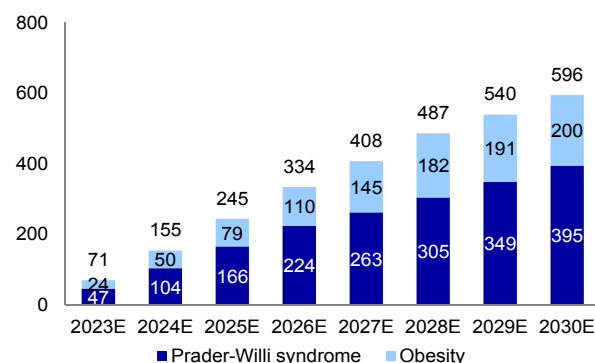
At present, we do not include explicit forecasts for hypothalamic obesity in our valuation; so, it remains potential upside to our valuation.

TESOMET SALES FORECASTS IN PWS (USDm)



Source: Nordea estimates

TESOMET RISK-ADJ. SALES FORECASTS (SEKm)



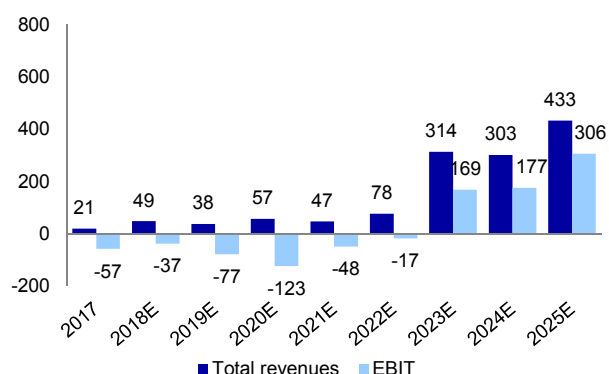
Source: Nordea estimates

Tesofensine and Tesomet to address the obesity epidemic in RoW

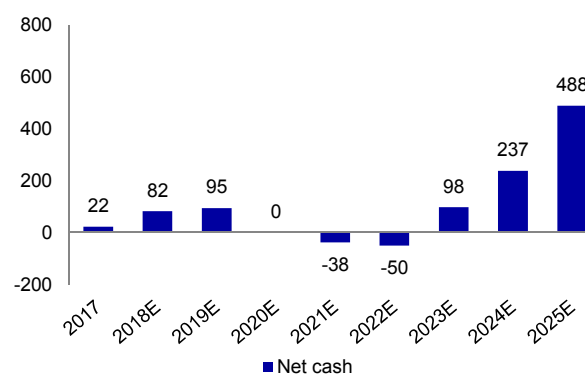
The commercial opportunity presented by obesity holds the potential to be much larger than Prader-Willi syndrome and hypothalamic obesity. Obesity afflicts around 600-700 million people worldwide and some 24 million adults in Mexico, but the

provide potential opportunities to crystallise value, including ph III top-line data on Tesofensine in obesity and ph II readouts for Tesomet in Prader-Willi syndrome, hypothalamic obesity and obesity.

SANIONA REVENUE AND EBIT FORECASTS (SEKm)



SANIONA NET CASH FORECASTS (SEKm)



Source: Company data and Nordea estimates

Source: Company data and Nordea estimates

Our model assumes that Saniona turns profit-making and cash flow positive in 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	49	38	57	47	78	314	303	433	493	536	583	609	659
Growth	N.a.	134%	-22%	52%	-17%	64%	303%	-4%	43%	14%	9%	9%	4%	8%
Product sales and royalties	0	0	0	20	47	78	182	303	433	493	536	583	609	659
Tesofensine, obesity	0	0	0	20	47	78	111	148	188	159	128	96	69	63
Tesomet, Prader-Willi syndr	0	0	0	0	0	0	47	104	166	224	263	305	349	395
Tesomet, Hypothalamic obesi	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Tesomet, obesity	0	0	0	0	0	0	24	50	79	110	145	182	191	200
NS2359, CNS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other (milestones/PRV)	21	49	38	38	0	0	132	0	0	0	0	0	0	0
Gross profit	21	49	38	57	47	78	314	302	431	491	533	580	605	655
Gross margin	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	99%	99%	99%
R&D to revenue	207%	103%	213%	244%	105%	64%	16%	17%	12%	10%	9%	9%	8%	8%
In SEK	-43	-50	-80	-140	-50	-50	-50	-50	-50	-50	-50	-50	-50	-50
S&D to revenue	0%	0%	0%	0%	0%	0%	16%	10%	7%	6%	6%	5%	5%	5%
In SEK	0	0	0	0	0	0	-50	-30	-30	-30	-30	-30	-30	-30
Admin & other costs to revenu	169%	72%	93%	70%	95%	58%	14%	15%	10%	9%	8%	8%	7%	7%
In SEK	-35	-35	-35	-40	-45	-45	-45	-45	-45	-45	-45	-45	-45	-45
EBIT	-57	-37	-77	-123	-48	-17	169	177	306	366	408	455	480	530
EBIT margin	-276%	-75%	-206%	-214%	-100%	-22%	54%	58%	71%	74%	76%	78%	79%	80%
PTP	-56	-36	-77	-123	-48	-17	169	177	306	366	408	455	480	530
Net profit	-49	-28	-60	-96	-37	-13	132	138	239	285	318	355	375	413
Free cash flow	-58	-12	-60	-94	-38	-13	148	140	251	293	325	362	377	418
Net cash	22	82	95	0	-38	-50	98	237	488	781	1,106	1,467	1,845	2,263

Source: Company data and Nordea estimates

Although it would need to establish sales and distribution channels to market Tesomet in orphan diseases on its own, the company intends to remain a highly focused R&D engine. We consequently assume that driving drugs through clinical development and towards the market will be prioritised over near-term profitability. We argue that this strategy seems prudent and note that success with the early-stage pipeline and subsequent advancement into ph II clinical studies will drive value for the company; as will pipeline progress with Tesomet in Prader-Willi syndrome, hypothalamic obesity and obesity.

Valuation summary

We value Saniona based on a discounted cash flow (DCF) approach – as we do with all other pharma and biotech companies in our coverage universe. Based on our underlying valuation assumptions, estimates and pipeline scenarios (detailed in the valuation section on pages 10-15), we value Saniona at SEK 36-45 per share, taking into account a WACC between 12.5% and 14.5%.

Looking at the value split in the SOTP valuation summary below, Tesomet stands out to us as the clear value driver in Saniona. We apply a 13.5% WACC to our DCF and SOTP in the SOTP valuation table illustrated below.

SANIONA SOTP VALUATION (SEK PER SHARE)

Project	Indication	Peak sales (USDm)	Potential launch	NPV (SEKm)	Prob.	Adj. NPV (SEKm)	Adj. NPV per share	Adj. NPV share (%)
Tesofensine	Obesity	204	2020	603	60%	362	16	41%
Tesomet	Obesity	350	2023	828	40%	331	15	38%
Tesomet	Prader-Willi syndrome	362	2023	3,542	15%	531	24	60%
Priority Review Voucher	Prader-Willi syndrome	N.a.	2023	341	15%	51	2	6%
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				5,314		1,276	58	145%
Group costs not allocated to individual projects				-416	100%	-416	-19	-47%
Net cash/(debt)				22	100%	22	1	3%
SOTP valuation				4,920		881	40	100%

Source: Company data and Nordea estimates

We ascribe SEK 31 per share to combined Tesofensine and Tesomet royalties on obesity sales on a risk-adjusted basis, while Tesomet's sales potential in orphan diseases accounts for SEK 26 per share in our valuation on heavily risk-adjusted sales (15% approval probability). We currently assign no value to Tesomet's use in other obesity-related indications, such as hypothalamic obesity, type II diabetes, NASH or binge eating, for which there may be additional upside; nor do we ascribe any value to the company's early-stage pipeline programmes.

Three key pipeline programmes are expected to read out over the coming 12 months: NS2359 ph IIa in cocaine addiction, Tesomet ph IIa in PWS in adolescents, and Tesofensine ph III in obesity.

SANIONA UPSIDE POTENTIAL AND DOWNSIDE RISK TO SOTP VALUATION

Event	Upside	SEK per share	Downside	SEK per share
Tesofensine ph III trial in obesity	Positive ph III topline data	9	Launch postponed three years	-4
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
Potential upside/downside to base case		26		-28
Potential valuation		66		12

Source: Company data and Nordea estimates

Share price trigger outlook

Company-related news flow for the coming 12 months suggests important triggers ahead, with a news flow heavy 2018, continuing into 2019 as well.

SANIONA UPCOMING NEWS FLOW

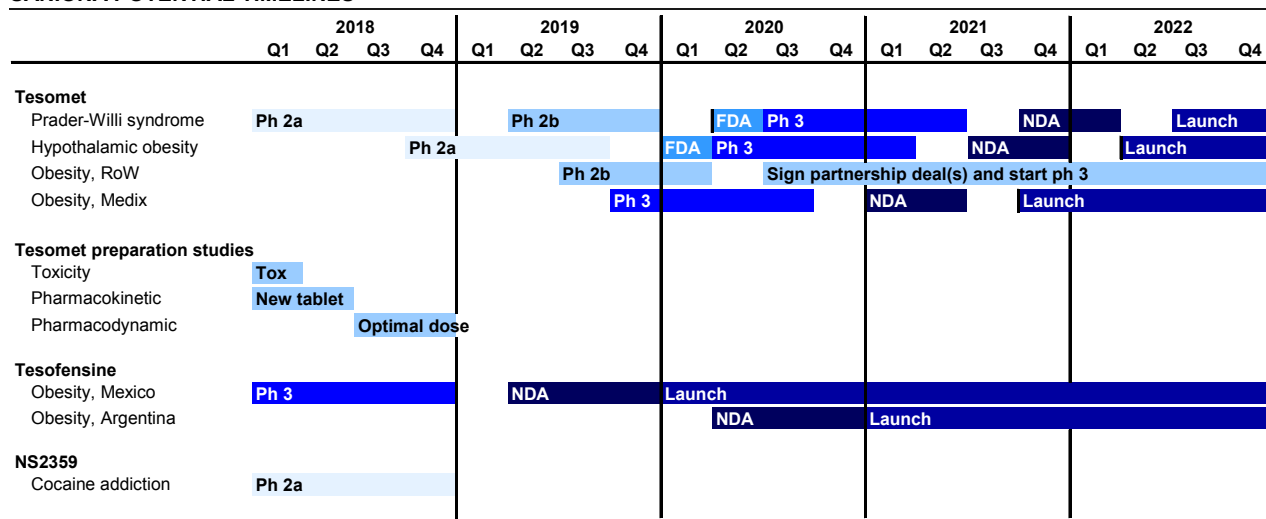
Timeline	Project	Event	Indication	Description
Q4 2018	NS2359	Ph 2a interim data	Cocaine addiction	Saniona expects to report ph 2a interim results in H2 2018
Q4 2018	Tesomet	Ph 2a results	Prader-Willi syndrome	Results from ph 2a study in adolescents (step 2)
Q4 2018	Tesomet	Ph 1 results	-	Results from ph 1 pharmacodynamic study
Q4 2018	Tesomet	Ph 2a study initiated	Hypothalamic obesity	Saniona plans to start a ph 2a study around Q4 2018
Q1 2019	Tesofensine	Ph 3 results	Obesity	Saniona and its partner Medix expect topline data by early 2019
H1 2019	Tesomet	Ph 2b study initiated	Prader-Willi syndrome	We expect Saniona to start a ph 2b dose-finding study in Prader-Willi
H2 2019	Tesomet	Ph 2b study initiated	Obesity	We expect Saniona to start a ph 2b study in obesity
2018/2019	Pre-clinical	Deal	-	Potential for partnership deals on pre-clinical programmes
2018/2019	Pre-clinical	Deal	-	Potential for spin-outs on pre-clinical programmes
2018/2019	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

Source: Company data and Nordea estimates

We highlight below what we consider the key triggers in Saniona in the coming 12 months:

- **Q4 2018:** Ph IIa interim results on NS2359 in cocaine addiction
- **Q4 2018:** Ph IIa results on Tesomet in Prader-Willi syndrome (adolescents)
- **Q1 2019:** Ph III top-line results in obesity for Tesofensine
- **2019-20:** Potential partnership deals announced on Tesomet in metabolic diseases, securing further development in pivotal ph III trials as well as commercialisation agreements across sales regions.

SANIONA POTENTIAL TIMELINES



Source: Company data and Nordea estimates

The timelines illustrated above are obviously subject to board decisions, financial planning, progress with clinical trials etc.

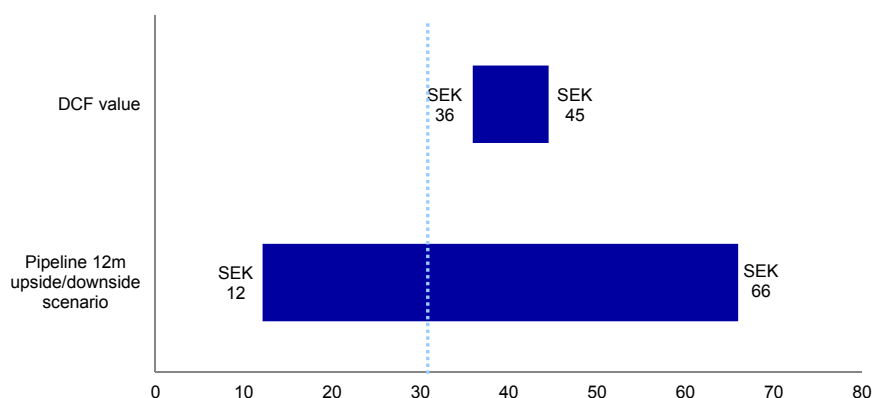
Valuation

We conduct a DCF valuation to fully capture the underlying fundamental equity value for Saniona. We favour a bottom-up NPV model comprising probability-adjusted NPVs for each key pipeline project, summarised in a SOTP valuation. Based on our underlying valuation assumptions, estimates and pipeline scenarios for key events occurring over the next 12 months, we value Saniona at SEK 36-45 per share.

We value Saniona at SEK 36-45 per share

We value Saniona based on a discounted cash flow (DCF) approach, as we do with all other pharma and biotech companies in our coverage universe. Based on our underlying valuation assumptions, estimates and pipeline scenarios – detailed in the following sections – we value Saniona at SEK 36-45 per share, taking into account a WACC between 12.5% and 14.5% as well as a downside and upside scenario based on events that could drive the share over the coming 12 months.

VALUE PER SHARE, SEK



Source: Nordea estimates

Clinical achievements could have a significant impact on valuation in both a positive and negative direction

SOTP valuation summary

Our valuation model comprises probability-adjusted net present values (NPVs) involving a DCF analysis to value each pipeline project individually. This means that revenue and cash flow for the product candidates are adjusted to reflect the probability we ascribe to each successfully reaching the commercial phase, implying that clinical achievements could have a significant impact on valuation in both a positive and negative direction, depending on the outcome. The model extends 20 years (2018E-37E) in order 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. The components are enumerated in the table below.

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	604	60%	362	16	41%
Tesomet	Obesity	350	2023	829	40%	332	15	38%
Tesomet	Prader-Willi syndrome	362	2023	3,545	15%	532	24	60%
Priority Review Voucher	Prader-Willi syndrome	N.a.	2023	341	15%	51	2	6%
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				5,320		1,277	58	145%
Group costs not allocated to individual projects				-418	100%	-418	-19	-47%
Net cash/(debt)				22	100%	22	1	3%
SOTP valuation				4,924		881	40	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. 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 rate Saniona's risk profile higher, given that the company has no marketed products to finance its operations at the current stage as opposed to Bavarian Nordic (stockpiling smallpox vaccines for the US government) and Zealand Pharma (products within type II diabetes), and that its pipeline is more early-stage compared with eg Zealand Pharma, making the company's cash flow more risky as well as more dependent on external financing.

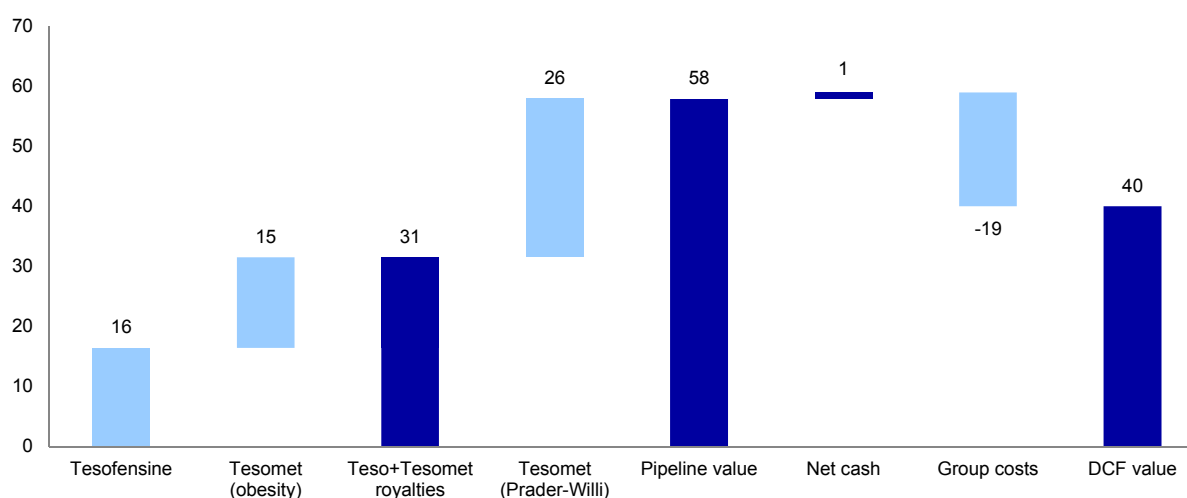
We provide a sensitivity table below, showing how a higher or lower WACC would impact our DCF value.

VALUE PER SHARE (SEK): WACC SENSITIVITY

	WACC				
	11.5%	12.5%	13.5%	14.5%	15.5%
Base case scenario	50	45	40	36	32
Upside scenario	81	73	66	60	55
Downside scenario	16	14	12	11	9

Source: Nordea estimates

The sensitivity analysis suggests that applying a WACC in line with the one we use for Zealand Pharma could take our DCF-based value up to SEK 50 per share. This highlights the potential value creating we envision in the stock when the pipeline advances through clinical trials, de-risking the company.

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 ~26 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 in the stock, with the potential to take Saniona's market cap to entirely new levels. On our estimates, Saniona's market cap would, all else being equal, be boosted to SEK ~5bn or SEK ~230 per share when fully including Tesomet in PWS in our model with 100% risk adjustment. This highlights the considerable upside to the share on positive news flow related to Tesomet's development in orphan diseases over the next few years.

We ascribe SEK ~31 per share to combined Tesofensine and Tesomet royalties on obesity sales on a risk-adjusted basis.

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 do not attach any value to Saniona's early-stage (ph I and pre-clinical) pipeline projects in our model, nor do we include projects for which we have yet to see ph II results (NS2359 for cocaine addiction) – in line with our general valuation approach across our pharma and biotech coverage universe. 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 a limited willingness to pay for preclinical 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 considerable potential 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.
- Hence, it will often create more noise than benefit to argue for a pre-clinical pipeline valuation.

To mitigate the fact that we do not add any value to these assets, we do not assume increasing R&D spend for these 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 start 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 in the next 12 months. Three key pipeline programmes are expected to read out over this period: NS2359 ph IIa in cocaine addiction, Tesomet ph IIa in PWS in adolescents, and Tesofensine ph III in obesity. These trials could have a significant impact on valuation in both a positive and negative direction, depending on the outcome, as highlighted below.

SANIONA UPSIDE POTENTIAL AND DOWNSIDE RISK TO SOTP VALUATION

Event	Upside	SEK	
		per share	Downside
Tesofensine ph III trial in obesity	Positive ph III topline data	9	Launch postponed three years
Tesomet ph IIa trial in PWS (adolescents)	Positive safety and efficacy	11	PWS is abandoned
NS2359 ph IIa	Positive safety and efficacy	6	Fails
Potential upside/downside to base case		26	-28
Potential valuation		66	12

Source: Company data and Nordea estimates

We list our assumptions for upside and downside scenarios below, as well as the implied share price in each scenario.

Upside scenario: SEK 66 per share

Our upside scenario incorporates positive results from trials with key pipeline programmes in the next 12 months and is based on the same valuation methodologies and an unchanged discount rate (13.5%).

- Positive safety and efficacy data in the ph III trial for Tesofensine in obesity, supporting a likely market approval. This alone could add SEK ~9 per share to our valuation.
- Positive safety and efficacy data in the ph IIa trial for Tesomet in Prader-Willi syndrome in adolescents could add around SEK 11 per share to our valuation, as it would de-risk the programme and boost confidence in Tesomet's opportunities in this difficult-to-treat population.
- Positive safety and efficacy data in the ph IIa trial for NS2359 in cocaine addiction (interim analysis), supporting continued progress for the programme. This could add around SEK 6 per share.
- Saniona's other pipeline projects do not contribute much value.
- Together, these catalysts could boost our valuation to SEK 66 per share.

SANIONA SOTP VALUATION – UPSIDE SCENARIO

Project	Indication	Peak sales (USDm)	Potential launch	NPV (SEKm)	Prob.	Adj. NPV (SEKm)	Adj. NPV per share	Adj. NPV share (%)
Tesofensine	Obesity	204	2020	604	90%	543	25	37%
Tesomet	Obesity	350	2023	829	40%	332	15	23%
Tesomet	Prader-Willi syndrome	362	2023	3,696	20%	739	34	51%
Priority Review Voucher	Prader-Willi syndrome	N.a.	2023	341	20%	68	3	5%
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.	864	15%	130	6	9%
Pre-clinical programs		N.a.	N.a.	0	0%	0	0	0%
Pipeline value				6,334		1,812	82	124%
Group costs not allocated to individual projects				-375	100%	-375	-17	-26%
Net cash/(debt)				22	100%	22	1	2%
SOTP valuation				5,981		1,459	66	100%

Source: Company data and Nordea estimates

Downside scenario: SEK 12 per share

Our downside scenario considers the valuation impact on our model, assuming that news flow on key pipeline programmes is negative in the next 12 months.

- Ph III top-line data for Tesofensine in obesity reads out with mixed results, in terms of safety or efficacy, and regulatory authorities require a new trial. Implementing a three-year delay in our model would, all else equal, take out SEK ~4 per share.
- Tesomet ph IIa trial in adolescents with Prader-Willi syndrome reads out with mixed results, showing promising weight loss and hyperphagia data, similar to the ph IIa results in adults, but mixed safety data. Saniona comes to the conclusion that it will be too complicated to continue development in PWS, and abandons the development to pursue other orphan diseases with Tesomet instead – namely hypothalamic obesity. We remove PWS from our model, negatively impacting our valuation by SEK ~24 per share.
- NS2359 ph IIa trial in cocaine addiction fails. This would be neutral for our valuation, as we do not include the project in the model, given its high-risk nature.
- Saniona's other pipeline projects do not contribute much value.
- Together, these setbacks could lower our valuation to SEK 12 per share.

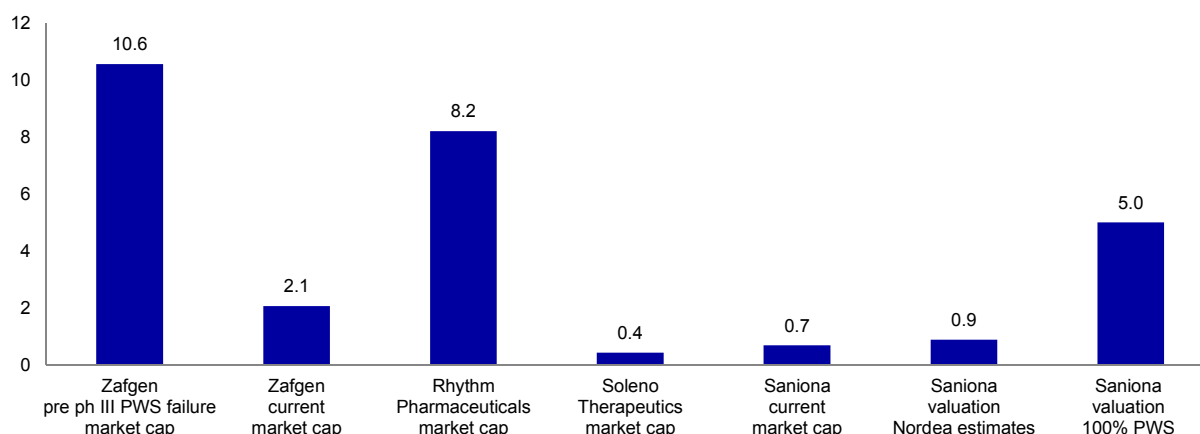
SANIONA SOTP VALUATION – DOWNSIDE SCENARIO

Project	Indication	Peak sales (USDm)	Potential launch	NPV (SEKm)	Prob.	Adj. NPV (SEKm)	Adj. NPV per share	Adj. NPV share (%)
Tesofensine	Obesity	216	2020	445	60%	267	12	100%
Tesomet	Obesity	350	2023	829	40%	332	15	124%
Tesomet	Prader-Willi syndrome	362	2023	N.a.	0%	0	0	0%
Priority Review Voucher	Prader-Willi syndrome	N.a.	2023	N.a.	0%	0	0	0%
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	921	N.a.	N.a.	0%	0	0	0%
Pre-clinical programs		N.a.	N.a.	0	0%	0	0	0%
Pipeline value				1,274		598	27	224%
Group costs not allocated to individual projects				-353	100%	-353	-16	-132%
Net cash/(debt)				22	100%	22	1	8%
SOTP valuation				943		268	12	100%

Source: Company data and Nordea estimates

Valuation benchmarking

In addition to our fundamental approach to valuing Saniona and its pipeline programmes, we provide valuation benchmarking below. We note that a company like Zafgen in the US traded at around USD 40-45 per share or USD ~1.2bn in market cap (equal to SEK ~10bn) until its lead candidate – beloranib – failed ph 3 development in PWS and was discontinued owing to two patient deaths in the treatment group receiving the drug.

SANIONA VALUATION COMPARISON, SEKbn

Source: Company data, Thomson Reuters and Nordea estimates

Looking at Zafgen's clinical pipeline at that time, beloranib was in ph III development in PWS but ran trials in hypothalamic obesity and obesity as well – similar to the indications for Saniona's Tesomet, although beloranib was more late-stage (ph III versus ph II with Tesomet). Screening the company's current pipeline, Zafgen has taken a new shot at the PWS indication with a programme in preclinical development as well as a programme in type II diabetes. Despite this early-stage pipeline, Zafgen's current market cap is around USD 230m (SEK ~2.1bn) – three times as large as Saniona's market cap (SEK ~0.7bn).

We believe another interesting valuation benchmark is the market cap for other companies pursuing Prader-Willi or other rare obesity-associated disorders. These include US-based Rhythm Pharmaceuticals and Soleno Therapeutics.

SANIONA PIPELINE VERSUS PEERS

Peer comparison	Zafgen pre failure	Zafgen now	Rhythm	Soleno	Saniona
Lead candidate(s)	Beloranib	ZGN-1061 & ZGN-1258	Setmelanotide	DCCR	Tesomet
Prader-Willi syndrome	Phase 3	Phase 1	Phase 2	Phase 3	Phase 2
Hypothalamic obesity	Phase 2	-	-	-	Phase 2
Obesity	Phase 2	-	Phase 2	Phase 2	Phase 2
Type 2 diabetes	-	Phase 2	-	-	-
Market cap, SEKbn	10.6	2.1	8.2	0.4	0.7

Source: Company data and Nordea estimates

Saniona may be eligible for a priority review voucher, which could carry a value of around SEK 1bn

Besides looking at peer valuations, we also note that Saniona may be eligible for a priority review voucher (PRV) for Tesomet in Prader-Willi if the product delivers positive results in the clinical trials and achieves regulatory approval in the US. We explain this concept in principle on pages 22-27. A PRV is transferable and could thus be sold in the market to other pharmaceutical companies. Historical transactions have recently been valued at around USD 120m or SEK ~1bn. This is a considerable amount bearing in mind that Saniona's entire market cap is currently only around SEK 700m.

We expect Saniona to deliver final ph III data for Tesomet in PWS by 2021-22. Hence, an approval could come in 2023 in the US. As soon as Tesomet is approved, the company may be awarded the PRV and can subsequently decide to sell it to a third party. Below, we illustrate recent transactions with PRVs.

RECENT TRANSACTIONS WITH PRIORITY REVIEW VOUCHERS

Year	Seller	Buyer	Price (USDm)
2014	BioMarin	Regeneron, Sanofi	68
2014	Knight Therapeutics	Gilead Sciences	125
2015	Retrophin	Sanofi	245
2015	United Therapeutics	AbbVie	350
2016	PaxVax Bermuda	Gilead Sciences	200
2017	Serepta Therapeutics	Gilead Sciences	125
2017	BioMarin	Not disclosed	125
2017	Ultragenyx	Novartis	130
2018	Spark Therapeutics	Jazz Pharmaceuticals	110
2018	Not disclosed	Novo Nordisk	120
Average			160
Average, 2017 and 2018			122

Source: Regulatory Affairs Professionals Society and Nordea

We include a PRV on Tesomet and assume that Saniona can sell it for USD 100m. On a risk-adjusted basis (15% – similar to our risk adjustment on Tesomet alone) and after tax, this adds SEK ~2 per share to our valuation. Fully including the PRV in our model (100%), it would add around SEK 15 per share or SEK 341m on an NPV basis.

Company overview

Saniona is a Denmark-based clinical stage biotech company listed in Sweden on Nasdaq Stockholm Small Cap. The company has a broad pipeline, with one product in ph III for obesity (Tesofensine) and two products in ph II (Tesomet for obesity and rare diseases related to obesity, and NS2359 for cocaine addiction). The company is focused on developing Tesomet. It finances most other lead and preclinical assets through partnerships or research grants; a key strategy for the company, securing a low cash burn rate. Saniona has secured its financial position until at least 2020.

Striving to become a commercial stage company

Saniona is a Danish clinical stage biotech company established in November 2011 by the current CEO, with the CFO, CSO and one board member as co-founders. It focuses on developing drugs for metabolic diseases, the central nervous system, autoimmune diseases and pain management.

Saniona's pipeline currently includes one product in ph III clinical development and two products in ph II. Tesofensine is currently being tested in a ph III trial in obesity, while Tesomet is running ph II trials in two areas: obesity and rare diseases related to obesity, such as Prader-Willi syndrome and hypothalamic obesity. NS2359 is in ph II for cocaine addiction.

SANIONA'S LATE-STAGE PIPELINE

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

Source: Company data and Nordea

Saniona also has pipeline projects in pre-clinical development in-house using its novel technology platform, on which the company has signed several partnerships. This has helped to secure long-term growth and value as projects develop to the clinical stage and it also acts as a funding source for internal R&D until the company's lead pipeline programmes (Tesofensine and Tesomet) potentially reach the market.

SANIONA'S EARLY-STAGE PIPELINE

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

Source: Company data and Nordea

Business model secures pipeline progression at a low cash burn rate

Strategically, Saniona intends to develop and commercialise treatments for rare diseases in orphan drug indications on its own, while its strategy in big global diseases, such as obesity and type II diabetes, is to engage in partnerships with larger pharmaceutical companies. The clinical studies in these indications are larger, more expensive and more time consuming, and the commercialisation efforts and financial strength required exceed Saniona's resources.

Among Saniona's nine pipeline projects, it is only financing four on its own: the Tesomet programme and three pre-clinical stage programmes (SAN711, IK and Kv7). All other pipeline programmes are either financed through research grants or partnerships, enabling Saniona to keep and advance a broad pipeline and still follow

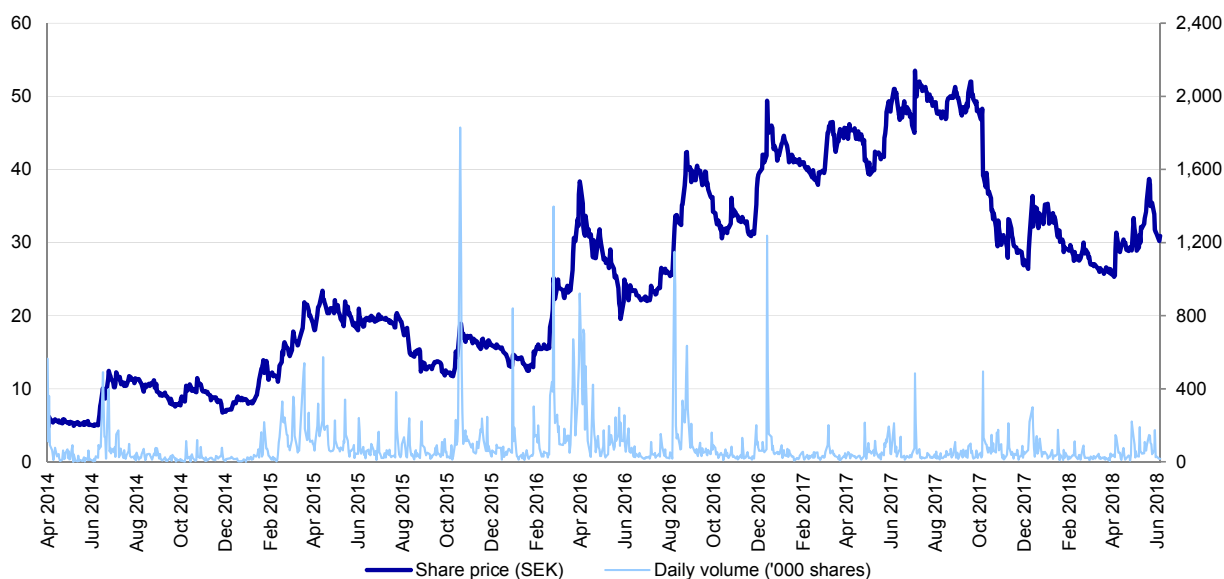
a focused financial policy on the cost side, helping to secure a low cash burn. Saniona currently has five short-term strategic priorities in its transition to becoming a commercial stage company and generating further value in its programmes and to its shareholders:

- 1) To develop and attain market approval for Tesomet in eating disorders in the US and Europe, with a focus on orphan drug indications, enabling it to move all the way to the market on its own.
- 2) To develop and attain market approval for Tesomet in metabolic diseases such as obesity and type II diabetes through partnerships with pharmaceutical companies in non-US and non-EU markets.
- 3) To attain market approval for Tesofensine in collaboration with its commercial partner, Medix.
- 4) To develop at least one drug candidate internally from its ion-channel research platform and transition it to ph II clinical trials prior to partnering. This looks set to be SAN711. Saniona plans to initiate a ph I trial in neuropathic pain and itching disorders in H1 2019.
- 5) To leverage its leading position within ion channel research by entering into partnerships with pharmaceutical companies.

Share price development and company milestones since IPO

Saniona's share price development since its IPO in April 2014 is illustrated below (data up to 28 June 2018).

SANIONA'S SHARE PRICE DEVELOPMENT SINCE IPO



Source: Thomson Reuters and Nordea

Saniona began operations fully in 2012 and has since built a pipeline and research platform by acquiring NeuroSearch's activities and commercial rights to pipeline programmes, including Tesofensine, NS2359, its technology platform as well as several pre-clinical projects during the period 2012-17.

Since then, Saniona has prioritised the acquired activities and added additional value into the programmes by entering spin-out deals and signing promising and value-adding partnerships on the pre-clinical pipeline as well as on Tesofensine in obesity. It has also developed Tesomet internally by combining Tesofensine with the beta-

blocker Metoprolol to create an even more attractive product. Tesomet has the ability to alleviate Tesofensine's dose-dependent increase in heart rate without it affecting Tesofensine's solid weight loss properties as a monotherapy.

We list and comment on selected company milestones below.

- **August 2012:** Saniona acquires NeuroSearch's technology platform including patents and data in relation to 15 preclinical and clinical programmes
- **April 2014:** Saniona is listed on AktieTorget in Sweden
- **October 2014:** Saniona acquires the rights to NeuroSearch's two clinical development compounds, Tesofensine and NS2359
- **February 2016:** Saniona enters into a drug development and commercialisation collaboration with Medix, covering Tesofensine and Tesomet in obesity in Mexico and Argentina
- **April 2016:** Saniona initiates ph IIa study for Tesomet in type II diabetes
- **May 2016:** Saniona moves to Nasdaq First North Premier
- **May 2016:** Saniona acquires the rights to NeuroSearch's remaining product portfolio comprising the clinical development compounds ACR325 and ACR343
- **June 2016:** The University of Pennsylvania initiates ph IIa study for NS2359 in cocaine addiction
- **August 2016:** Saniona and Boehringer Ingelheim sign collaboration agreement, with the objective to discover and develop novel compounds within schizophrenia
- **January 2017:** Saniona reports positive top line results from the Tesomet ph IIa study in type II diabetes
- **April 2017:** Saniona initiates ph IIa study for Tesomet in Prader-Willi syndrome
- **June 2017:** Saniona moves to Nasdaq Stockholm Small Cap
- **August 2017:** Saniona's partner Medix initiates ph III study for Tesofensine in obesity
- **October 2017:** Saniona announces that it decides to perform an interim analysis in its ph IIa study with Tesomet in Prader-Willi syndrome
- **January 2018:** Saniona reports top line results from the Tesomet ph IIa study in Prader-Willi syndrome
- **February 2018:** Saniona announces that its partner, Medix, has completed recruitment for ph III study for Tesofensine in obesity
- **March 2018:** Saniona announces that its collaboration partner, Cadent Therapeutics, has initiated ph I trial for CAD-1883 in ataxia and essential tremor, marking the first programme from its technology platform to enter clinical development
- **April 2018:** Saniona announces that it will progress to step 2 (adolescents) in the ph IIa study in Prader-Willi syndrome
- **June 2018:** Saniona announces that it plans to initiate a ph IIa study in hypothalamic obesity

The company's share price has risen around 700% since it was listed in April 2014. This is, in our view, justified by the positive news flow over the years as well as the progression with its pipeline and de-risked programmes as discussed above.

Financial position

Given that Saniona is a biotech company with no marketed products, it does not generate a recurrent income stream from product sales or royalty income to finance its operations at the current stage. Consequently, for a significant time to come (two years or more), Saniona will be dependent on major pharmaceutical companies' interest in investing in, developing and commercialising projects from Saniona's pipeline.

SANIONA'S FINANCIAL POSITION

INCOME STATEMENT							
SEKm	2012	2013	2014	2015	2016	2017	Sum
Net sales	8	13	22	14	75	21	153
Operating expenses	-10	-15	-30	-42	-71	-78	-246
EBIT	-2	-2	-8	-28	4	-57	-93
Financial items	0	0	1	-1	1	1	2
Pre tax profit	-2	-2	-8	-29	5	-56	-92
Tax	1	0	2	6	-3	7	13
Net income	-2	-1	-6	-23	2	-49	-79

BALANCE SHEET							
SEKm	2012	2013	2014	2015	2016	2017	
Non-current assets	0	2	2	2	3	8	
Current receivables	1	1	4	8	15	18	
Cash and cash equivalents	7	1	10	47	53	22	
Total assets	8	4	16	57	71	48	
Equity	-2	-3	9	53	54	38	
Total liabilities	10	7	7	5	17	11	
Total equity and liabilities	8	4	16	58	71	49	

CASH FLOW STATEMENT							
SEKm	2012	2013	2014	2015	2016	2017	Sum
Cash flow from operating activities	7	-4	-8	-29	8	-57	-83
Cash flow from investing activities	0	-2	-1	-1	-1	-6	-11
Cash flow from financing activities	0	0	18	67	0	33	118
Cash flow	7	-6	9	37	7	-30	24

Source: Company data and Nordea

Looking at the development in the income statement, Saniona has generated revenue every year since it was founded in 2012, largely from upfront payments on collaborations (such as the Boehringer Ingelheim deal) and grants. Over time it should transition into more recurrent income when Saniona's pipeline products potentially reach the market. We envision a trend over the coming two to five years in which the P&L quality clearly improves, based on the transition from lumpy one-off milestone payments to more predictable recurring income. This should be generated through royalty payments on product sales commercialised by partners (Tesofensine and Tesomet in obesity) as well as product sales on products that Saniona develops and commercialises on its own (primarily Tesomet in orphan diseases).

Low cash burn and funding secured until at least 2020E

It is worth noting that Saniona's cash burn is relatively limited thanks to its business model, in which partners act as the primary financing source of its pipeline programmes. Saniona's cash position was SEK 22.3m at year-end 2017 and accumulated cash burn has been less than SEK 100m since 2012, despite it having financed two ph II studies and three research programmes itself. Nevertheless, one should expect continued investments in clinical development (Tesomet in particular) and pre-clinical development, which will be a drag on the cash position until the first products are on the market. Average cash spending has been some SEK 20m a year.

Saniona has entered into a convertible notes funding agreement with private Swiss company Nice & Green S.A. Nice & Green has committed to subscribe up to SEK 72m in convertible notes in individual SEK 6m tranches over a 12-month period, which could be prolonged by Saniona. Saniona has the right to extend the agreement for an extra SEK 72m at the same terms (totalling SEK 144m), which would be sufficient to support its operations at least until 2020, excluding any potential milestone income from partners and potential new collaborations. To date (26 June 2018), Saniona has received five tranches (SEK 30m total), the most recent in May 2018.

The funding agreement is an interesting tool to finance the company in the medium term and bridge a potential funding gap in the short to medium term. It provides the company with additional financial flexibility at a time when pipeline progress with Tesomet in obesity and rare diseases (eg Prader-Willi syndrome and hypothalamic obesity) is in a critical phase.

Saniona's operations are secured until at least 2020E...

Management team with strong industry experience and execution skills

Saniona's management team has built a strong expertise thanks to previous experience in other pharmaceutical companies and since founding Saniona. Management has secured funding, made progress with key pipeline programmes and signed several partnership deals, including a key deal related to its Tesofensine and Tesomet programmes in obesity, thus financing the clinical development and securing future royalty income.

The convertible note agreement signed with Nice & Green also shows that Saniona's management team is able to execute and plan accordingly for the future by providing the company with financial flexibility to enable investments in its pipeline to seek long-term value. We consider this highly important, given the upcoming need to finance further development for key assets such as Tesomet.

Together, the three-member management team has strong industry knowledge, with more than 85 years combined experience in the healthcare industry, thanks to leading positions at Nordic healthcare companies as board members, VPs and in management.

EXECUTIVE MANAGEMENT TEAM



Jørgen Drejer
CEO



Thomas Feldthus
CFO



Palle Christophersen
CSO

Source: Company images and Nordea (also covers following management profiles)

CEO: JØRGEN DREJER

- **Nationality:** Danish
- **Born:** 1955
- **Saniona experience:** Since 2011; Founder
- **Education:** M.Sc. in Pharmaceutical Sciences (University of Copenhagen) and PhD in Neurobiology (University of Copenhagen)
- **Background:** EVP and CSO at Neurosearch as well as co-founder and board member at NsGene, SophionBiosciences, Antalium, Azign and Atonomics
- **Other current assignments:** Board member at 2cureX and Monta Biosciences
- **No. shares:** 2,344,711 privately owned (10.6%)

CFO: THOMAS FELDTTHUS

- **Nationality:** Danish
- **Born:** 1960
- **Saniona experience:** Since 2011; Co-founder
- **Education:** M.Sc. in Engineering (Technical University of Denmark) and M.Sc in Management (London Business School)
- **Background:** CFO and co-founder at Symphogen A/S
- **Other current assignments:** CEO at Fertilizer Invest ApS
- **No. shares:** 1,870,000 privately owned (8.5%)

CSO: PALLE CHRISTOPHERSEN

- **Nationality:** Danish
- **Born:** 1958
- **Saniona experience:** Since 2011; Co-founder
- **Education:** M.Sc. in Biology (University of Copenhagen) and PhD in Physiology (University of Copenhagen)
- **Background:** Has held various VP and research positions with NeuroSearch A/S, most recently in Vitro Pharmacology
- **No. shares:** 820,000 privately owned (3.7%)

SANIONA'S BOARD OF DIRECTORS

Position	Name	Independent	Joined	No. shares	Selective professional profile
Chairman	J. Donald deBethizy	Yes	2018	None	Former CEO, Santaris Pharma; Former CEO, Targacept
Board member and CEO	Jørgen Drejer	No	2012	2,344,711	Former EVP and CSO, Neurosearch A/S
Board member	Anna Ljung	Yes	2018	None	CFO, Moberg Pharma
Board member	Claus Bræstrup	Yes	2014	735,700	Former CEO, H Lundbeck A/S
Board member	Carl Johan Sundberg	Yes	2015	None	Several board member positions and Professor in Physiology

Source: Company data and Nordea

Drug development and orphan diseases

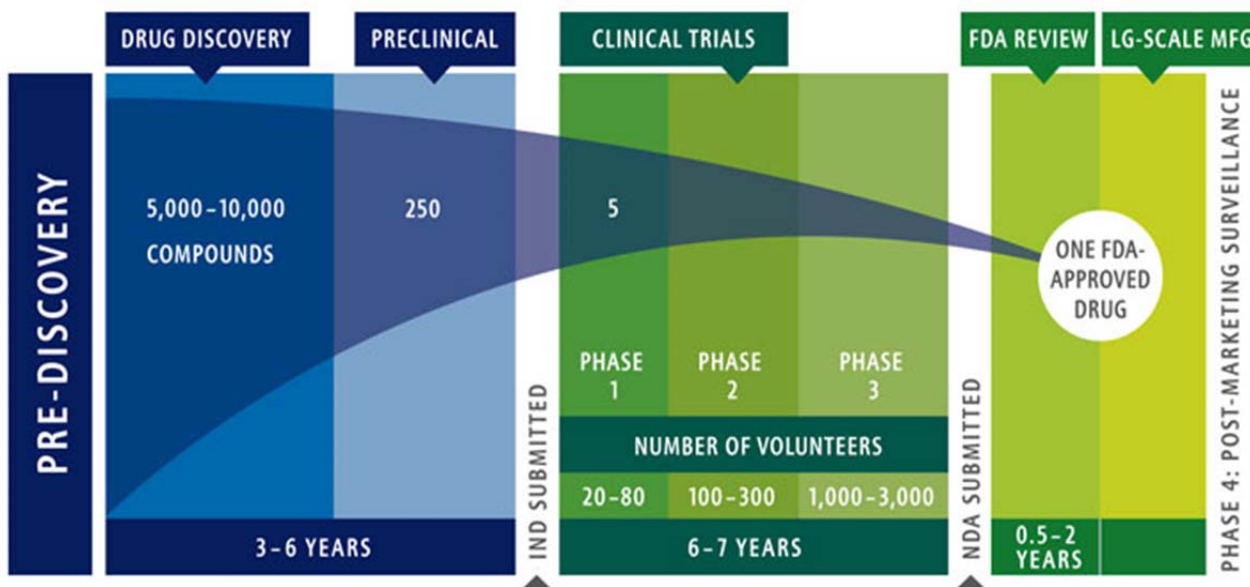
Orphan drugs are products aimed at rare diseases. The pharmaceutical industry has little incentive to develop treatments for these conditions due to the poor profitability outlook under usual marketing conditions. However, orphan diseases represent an interesting area for a company like Saniona, in our view, given that: 1) the company would be able to move a product all the way to the market on its own; 2) there is a high unmet medical need; 3) the price points and sales potential is attractive relative to the investments needed to pursue the area; 4) the company may be awarded a so-called Priority Review Voucher, which can be sold to a third party.

Drug development is a long, expensive and risky road

Developing a new drug can be a costly affair and take several years. Depending on the drug and disease area, the total cost can amount to more than USD 1bn – and that only includes the cost for successfully developing a drug. To that, a company has to add the costs for all other programs that were later discontinued.

The illustration below shows the stages a drug typically undergoes before it reaches the market. The drug development starts with pre-clinical discovery, research and development; then it moves into clinical trials (ph I, II, and III) for subsequent review with the regulatory authorities. The development cost and timelines may, however, differ depending on the disease area and indication in question.

DRUG DISCOVERY AND DEVELOPMENT: A LONG AND RISKY ROAD



Source: Regulatory Affairs Professionals Society

Historically, fewer than one in 10 drugs that enter phase I clinical trials are ultimately approved by the regulatory authority in the US, the Food and Drug Administration (FDA). For some indications, such as diseases within the central nervous system (Alzheimer's disease in particular) or cancer, success rates can be even lower (<5%).

For larger pharmaceutical companies, the risk profile may not be a big issue versus the potential return on investment and need to invest in the pipeline in order to maintain long-term growth. For smaller biotech companies, the expensive development and long timelines pose a risk that often prevents these companies from developing drugs for disease areas where the expected return on investment is simply not attractive.

INCENTIVE TO DEVELOP DRUGS ACROSS DISEASE AREAS

	Common diseases	Tropical diseases	Rare diseases
Patient population	Large	Large	Small
Willingness to pay	Yes	No	Yes
Attractive market	Yes	No	No

Source: Nordea

While the market for drugs treating common diseases such as type II diabetes is well-developed and attractive, this is not the case with certain tropical diseases or rare orphan diseases, despite a huge unmet medical need. This is either because developing countries lack the ability to pay enough to allow the drug developer to recoup its development costs (tropical diseases) or because the condition affects too few people (rare diseases), thus the market is too small to recoup development costs unless the drug developer charges exorbitant prices, which is not sustainable in the long term.

SELECTED DISEASES ACROSS DISEASE AREAS

Common diseases	Tropical diseases	Rare paediatric diseases
Diabetes	Malaria	Batten Disease
Obesity	Cholera	Duchenne muscular dystrophy
Asthma	Tuberculosis	Childhood Interstitial Lung Disease
Influenza	Leishmaniasis	Ehlers-Danlos syndromes
Acne	Leprosy	Ellis Van Creveld syndrome
Chronic kidney disease	Yaws	Gaucher disease
Depression	Ebola Virus	Neuroblastoma
Alzheimer's disease	Zika virus	Prader-Willi syndrome

Source: EvaluatePharma and Nordea

Orphan diseases

Orphan drug: a product aimed at rare diseases for which the industry is less incentivized to develop treatments due to the poor profitability outlook

An orphan drug is defined as a pharmaceutical product aimed at diseases or disorders so rare that the pharmaceutical industry has little interest in developing and marketing drugs for them. The prevalence required in order to be dubbed a "rare disease" varies across regions, with the US defining it as a condition that affects fewer than 200,000 people (ie, less than 0.06% of the population).

RARE DISEASE DEFINITIONS ACROSS GEOGRAPHIC REGIONS

	US	EU	Japan
Regional definition	<200,000	<5 in 10,000	<50,000
Equivalent to	<6 in 10,000	<250,000	<4 in 10,000

Source: EvaluatePharma and Nordea

Rare and neglected diseases are typically less researched and understood, another obstacle for companies hoping to develop treatments for these diseases. They would have to conduct more early-stage research and perform multiple laboratory trials before deciding on the right strategy forward.

Financial incentives to invest in orphan diseases

Given the limited commercial opportunity, progress in drug development within orphan diseases has been close to non-existent. Fewer than 10 drugs for orphan diseases reached the market in the US between 1973 and 1983, according to the FDA. We list three incentives below that pharmaceutical companies are presented with in order to encourage drug development to benefit neglected diseases.

Orphan Drug Act

The US Congress passed the Orphan Drug Act in 1983. Under the law, companies are provided with three primary incentives to invest in treatments for orphan diseases:

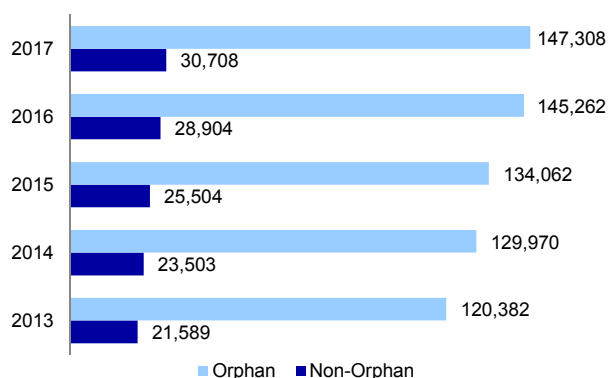
- **Funding:** The act supported companies with research grants and contracts to perform clinical trials.
- **Tax credits:** Companies were enabled to claim a 50% tax credit for qualified clinical testing expenses incurred when investigating orphan drugs.
- **Market exclusivity:** Companies are eligible for an additional seven-year market exclusivity in the US, during which time the FDA is not permitted to approve a generic, thus giving the sponsors extra time to recoup their initial investments in R&D and turn a profit. In the EU, a similar program gives market exclusivity for ten years.

To date, this program has proven popular and has successfully enabled more than 600 drugs to be developed for rare diseases in the US since 1983. Following a successful implementation in the US, similar policies have been adopted in other key markets, most notably in Japan in 1993 and the EU in 2000.

Higher pricing

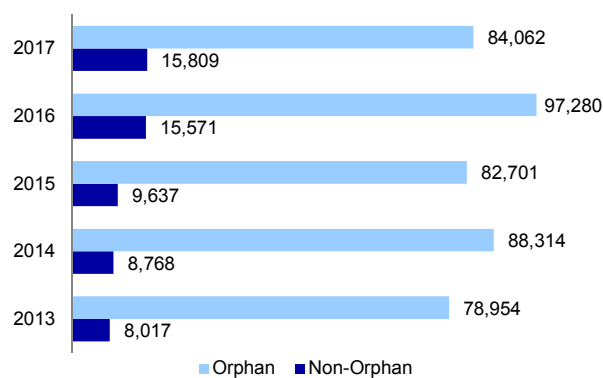
Drug companies developing drugs for orphan diseases can charge a substantially higher price for these than for non-orphan drugs, another source of return on investment. EvaluatePharma estimates that the mean annual cost per patient was USD 147,308 for an orphan drug in 2017 versus USD 30,708 for a non-orphan drug.

MEAN COST PER PATIENT PER YEAR



Source: EvaluatePharma and Nordea

MEDIAN COST PER PATIENT PER YEAR



Source: EvaluatePharma and Nordea

Faster review times – Priority Review

Prior to approval, each drug must go through a detailed review process in the US by the FDA. However, not all drugs are reviewed in the exact same way. FDA has implemented a two-tiered system distinguishing between review times – Standard Review and Priority Review. While most drugs are reviewed by the FDA under standard review times, a Priority Review designation allows the FDA to take action on an application within six months as opposed to ten months under standard review.

The process can be illustrated below. FDA ultimately decides on the review designation for every marketing application but an applicant may expressly request priority review. FDA then informs the applicant within 60 days whether the application meets the requirements for a Priority Review designation.

PRIORITY REVIEW DESIGNATION PROCESS



Source: FDA and Nordea

A Priority Review designation will direct overall attention and resources towards drugs that demonstrate the potential to be a significant improvement in safety or effectiveness when compared to standard applications or which are intended for use in serious conditions. For patients with serious diseases with a high unmet medical need, the expedited review enables them to have access to potentially life-changing treatments, while for companies, a priority review allows them to market their product more quickly, thus enabling them to improve their return on investments.

Priority Review Voucher programme

The priority review voucher system was made law in 2007 in the US, following a proposal in a 2006 paper "Developing Drugs for Developing Countries" published in the journal Health Affairs by researchers at Duke University in the US. In their paper, the authors proposed a novel incentive mechanism dubbed a Priority Review Voucher (PRV) to provide pharmaceutical companies with an incentive to conduct research and development for drugs specifically targeted at neglected tropical diseases, such as malaria, tuberculosis, leishmaniasis and dengue.

These companies win a prize – a voucher – that can be redeemed to receive an accelerated review (priority review) for another new drug application, thereby cutting the review time from ten months to six months. The Priority Review Voucher may be used as the companies wish, which also includes selling the voucher to other pharmaceutical companies.

THE PRIZE – A PRIORITY REVIEW VOUCHER

A Priority Review Voucher can be seen as a prize for developing a treatment for a neglected disease



Source: Regulatory Affairs Professionals Society

It is important to note that the voucher does not have to be used on another drug application targeted at a neglected tropical disease – it could be used on a potential blockbuster drug targeting a commercial disease, such as diabetes.

Rare paediatric diseases were added to the programme in 2012 through the Food and Drug Administration Safety and Innovation Act (FDASIA). This programme includes rare diseases that primarily affect individuals aged from birth to 18 years.

The redemption process is illustrated below:

PRIORITY REVIEW VOUCHER REDEMPTION PROCESS



Source: FDA and Nordea

Big pharma companies are generally keen on buying these PRVs to speed up their own drug reviews. The price is market driven, generally driven by three factors:

- 1) The value for a buyer in reaching the market earlier and time value of money
- 2) The value for a buyer in staying on the market for longer, ie, longer effective patent life due to an earlier entry
- 3) The value for a buyer in preventing key competitors from getting a head-start, ie competitive benefits

Transactions with PRVs in recent years have varied in value, with deals valued between USD 110m and USD 350m.

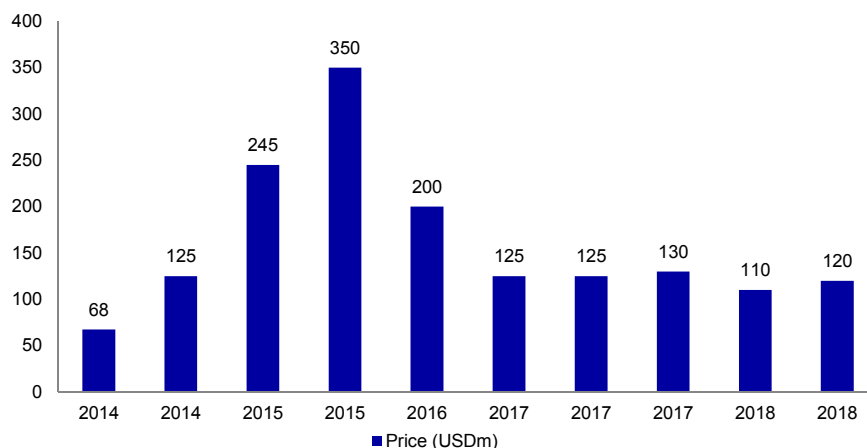
RECENT TRANSACTIONS WITH PRIORITY REVIEW VOUCHERS

Year	Seller	Buyer	Price (USDm)
2014	BioMarin	Regeneron, Sanofi	68
2014	Knight Therapeutics	Gilead Sciences	125
2015	Retrophin	Sanofi	245
2015	United Therapeutics	AbbVie	350
2016	PaxVax Bermuda	Gilead Sciences	200
2017	Serepta Therapeutics	Gilead Sciences	125
2017	BioMarin	Not disclosed	125
2017	Ultragenyx	Novartis	130
2018	Spark Therapeutics	Jazz Pharmaceuticals	110
2018	Not disclosed	Novo Nordisk	120

Source: Company data, Regulatory Affairs Professionals Society and Nordea

The deal value peaked at USD 350m in 2015 but has since slipped to around USD 200m in 2016 and USD 110-130m in 2017 and 2018, where it seems to have stabilised.

PRIORITY REVIEW VOUCHER PRICE DEVELOPMENT



Source: Company data, Regulatory Affairs Professionals Society and Nordea

The reasons behind the lower selling prices may be attributable to the following two factors, both related to supply and demand:

- 1) **The value depends on what the buyer needs.** Back when Sanofi and Regeneron purchased BioMarin's PRV in 2014, they applied it to their cholesterol-lowering drug Praluent in order to leapfrog Amgen's competing drug Repatha in the US. For Sanofi and Regeneron, the value in being first to the market was material, justifying the purchase price. Similarly, Sanofi acquired a PRV in 2015, allowing the company to bring its type II diabetes combo product Soliqua to the market. This follows the dictum "an asset is worth what someone is willing to pay".
- 2) **The value depends on the supply in the market.** While the seller may desire to get the highest price possible, it will be more difficult if the buyer is able to find more than one PRV on offer. With more and more PRVs being issued over time, the market becomes more competitive. Hence, while the value attached to the accelerated review time is important, the price may be more closely tied to the seller's willingness to transact. For example, a small biotech company may need cash to fund operations and R&D, which will drive the market price down.

CURRENT OUTSTANDING PRIORITY REVIEW VOUCHERS

Holder	Awardee	Voucher type
Alexion Pharmaceuticals	Alexion Pharmaceuticals	Rare Paediatric Disease
Ionis Pharmaceuticals	Ionis Pharmaceuticals	Rare Paediatric Disease
Marathon Pharmaceuticals	Marathon Pharmaceuticals	Rare Paediatric Disease
Chemo Research SL	Chemo Research SL	Tropical Disease
Novartis	Ultragenyx	Rare Paediatric Disease
AbbVie	United Therapeutics	Rare Paediatric Disease
AstraZeneca	Wellstat Therapeutics	Rare Paediatric Disease

Source: Regulatory Affairs Professionals Society and Nordea

Positive ph III data for Tesomet in PWS may enable an FDA PRV

We believe recent deals represent an interesting read-across to Saniona. The potential positive results with Tesomet in Prader-Willi syndrome in late-stage trials and regulatory approval may lead to a PRV award. In that case, we believe that Saniona would sell the PRV in the market. This offers a substantial cash opportunity, likely in the SEK 1bn area. This is a considerable when bearing in mind that Saniona's entire market cap is currently only around SEK 0.7bn.

Tesofensine

Tesofensine – Set to hit the obesity market by 2020

- **Peak sales forecast:** USD ~200m in obesity sales in Mexico and Argentina combined by 2025E
- **Valuation:** SEK 16 per share with 60% risk-adjustment
- **Next news flow:** Ph III obesity trial is expected to be completed in 2018, with top-line data expected by early 2019; regulatory approval in Mexico during late 2019 and potential launch in Mexico by 2020

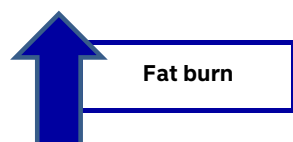


1. Tesofensine reduces food cravings by stimulating the pleasure reward centre:

It has been shown that humans feel pleasure when eating as the action stimulates dopamine. Dopamine functions as a neurotransmitter (a chemical released by neurons [nerve cells] to send signals to other nerve cells) in the brain and helps control the brain's reward or pleasure centres. Obese patients are often addicted to and crave food and sugar due to under-stimulated reward circuits in the brain. Tesofensine helps to reduce the cravings by slightly stimulating the reward centre in the brain through dopamine.



2. Tesofensine normalises appetite by stimulating the satiety centre: Humans achieve satiety (the state achieved when the need for food has been satisfied) by eating as it stimulates the satiety centre. Obese patients have continuous hunger due to under-stimulation. Tesofensine helps to normalise appetite and hunger by stimulating the satiety centre through serotonin. Numerous research studies suggest that serotonin plays an important role in satiety, explaining why it has been a viable target in weight control.



3. Tesofensine increases fat burn in the body: Humans respond to stress by mobilising energy from fat and increasing the heart rate; both functions are controlled by a hormone and neurotransmitter called noradrenaline (norepinephrine). Obese patients accumulate fat due to reduced fat burn, which Tesofensine then helps by increasing noradrenaline. Noradrenaline also induces an increased heart rate to enable the body to react fast and perform well in stressful situations.

Clinical trials with Tesofensine

Tesofensine has been through around ten clinical trials, and more than 1,200 patients have been exposed to treatment with Tesofensine on relevant dosing, including obesity patients and patients with central nervous system (CNS) disorders.

TESOFENSINE CLINICAL TRIAL EXPERIENCE

Product	Indication	Enrollment	Phase	Sponsor	Ct.gov identifier
Tesofensine	Obesity	32	I/II	Neurosearch	NCT00428415
Tesofensine	Obesity	140	II	Neurosearch	NCT00481104
Tesofensine	Obesity	203	II	Neurosearch	NCT00394667
Tesofensine	Parkinson Disease	50	II	NINDS	NCT00006077
Tesofensine	Parkinson Disease	254	II	Boehringer Ingelheim	NCT00148512
Tesofensine	Parkinson Disease	261	II	Boehringer Ingelheim	NCT00148486
Tesofensine	Alzheimer Disease	430	II	Boehringer Ingelheim	NCT00153010
Tesofensine	Obesity	372	III	Medix	N.a.

Source: Company data and clinicaltrials.org

Tesofensine was previously partnered with Boehringer Ingelheim (BI), which investigated the drug in two CNS disorders, Alzheimer's and Parkinson's. As it did not meet its primary efficacy endpoints in these indications, BI evaluated the partnership

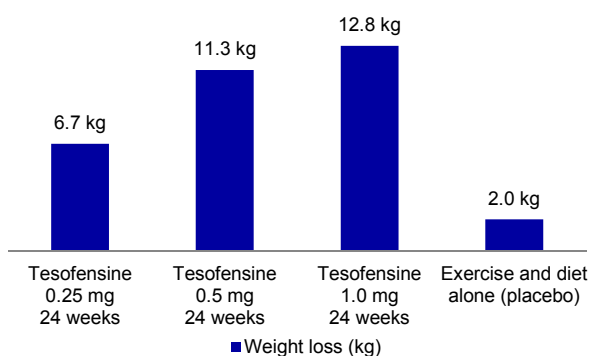
and terminated it. BI returned all regulatory rights for the compound to NeuroSearch, which later sold it to Saniona. While clinical data did not support Tesofensine's development in Alzheimer's and Parkinson's, the data reported in obesity demonstrated Tesofensine as an agent that provided robust weight loss while maintaining a desirable tolerability and safety profile. The main issue with the drug from a commercial perspective is an increase in heart rate, which we will discuss later in this section.

Ph IIb obesity study showed robust and superior weight loss data

Tesofensine's originator (NeuroSearch) reported positive results in a ph IIb study (TIPO-1 trial) in September 2007 with ~200 adult patients with obesity in five Danish obesity management centres. The impressive weight loss findings were subsequently published in the Lancet, one of the world's most esteemed medical journals. Patients were randomised into four arms, receiving either 0.25 mg Tesofensine, 0.5 mg Tesofensine, 1.00 mg Tesofensine or placebo tablets once daily for 24 weeks. The trial tested Tesofensine's efficacy and safety in conjunction with reduced caloric intake (300 kcal deficit per day) and increased physical activity (30-60 minutes). The primary endpoint was percentage change in body weight compared to baseline at week 24.

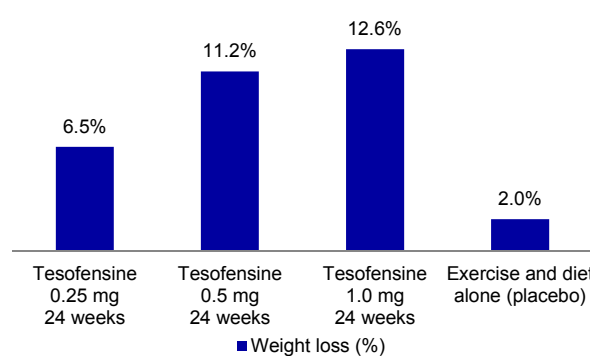
Results showed that patients on Tesofensine lost a solid 11.3 kg and 12.8 kg over 24 weeks on the two highest doses, corresponding to 11%-13% reduction in body weight. This compares to 2.0% achieved by patients exposed to diet, exercise and placebo alone. Placebo-adjusted weight loss was between 9.2% and 10.6%.

TESOFENSINE REDUCTION IN BODY WEIGHT (KG)



Source: Company data and Nordea

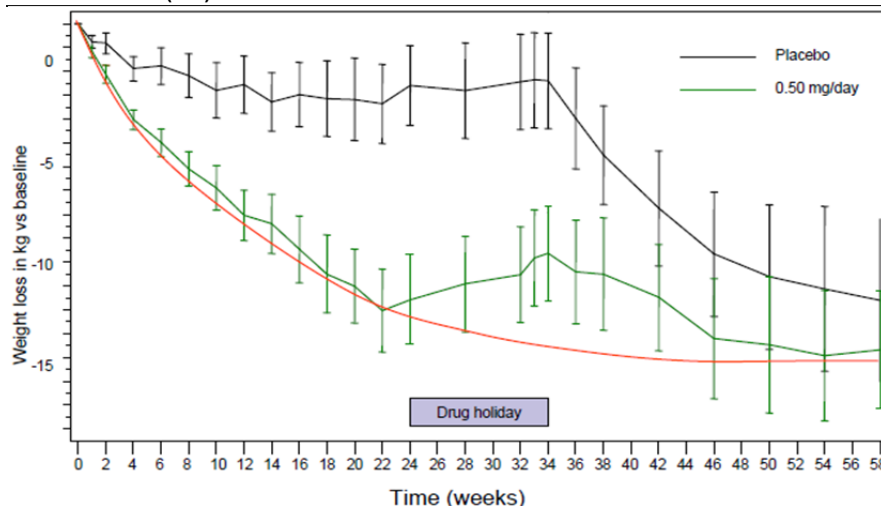
TESOFENSINE REDUCTION IN BODY WEIGHT (%)



Source: Company data and Nordea

Weight loss in the placebo group levelled out at week 16 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 TIPO-1 AND TIPO-4



Source: Company data

Interestingly, as the chart above illustrates, the study was extended by 24 weeks as an open label extension trial called TIPO-4, in which 140 patients who completed the 24-week ph IIb trial (TIPO-1) were re-enrolled after around a three-month drug holiday. All patients (both those in a Tesofensine group but also those previously included in placebo) were then treated with 0.5 mg Tesofensine, which the company considers the therapeutic dose. At 48 weeks, patients had lost 14-15% in bodyweight compared to baseline. The extension trial also confirmed the TIPO-1 results as the patients who were previously treated with the placebo lost an additional ~9 kg during the 24 weeks, suggesting that Tesofensine induces a solid weight loss in obese patients.

The table below compares the results for the relevant therapeutic dose (0.5 mg) in TIPO-1 and TIPO-4 (24 weeks and 48 weeks) with existing commercially available anti-obesity prescription drugs in the US as well as Novo Nordisk's semaglutide. We stress that it is non-scientific to compare data across trials owing to differences in trial size and the different patients. Direct head- to-head comparison trials with other anti-obesity drugs are needed before any firm conclusion about comparative efficacy can be made. Although comparisons with other obesity trials should be approached with caution, the Tesofensine ph IIb data appears to be highly competitive; however, larger ph III studies are needed to substantiate these findings.

TESOFENSINE WEIGHT LOSS DATA VERSUS OTHER ANTI-OBESITY DRUGS

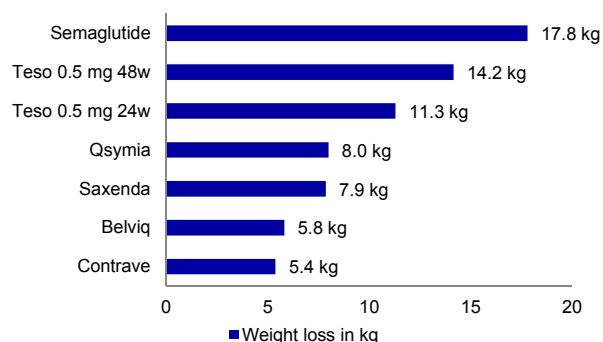
	Teso 0.5 mg	Teso 0.5 mg	Qsymia 7.5 mg	Saxenda 3 mg	Contrave 32 mg	Belviq 10 mg
N	50	N.m.	488	2487	538	3098
Trial duration (weeks)	24	48	56	56	56	52
Phase	2	2	3	3	3	3
Body weight (kg)						
Baseline (mean) in kg	101	101	103	106	100	100
Reduction in body weight, active treatment (kg)	11.3	14.2	8.0	7.9	5.4	5.8
Reduction in body weight, active treatment (%)	11.2%	14.0%	7.8%	7.4%	5.4%	5.8%
Reduction in body weight, placebo	2.0%	N.a.	1.2%	3.0%	1.3%	2.5%
Reduction in body weight, placebo adjusted	9.2%	N.a.	6.6%	4.5%	4.1%	3.3%
Patients losing ≥5% body weight	87%		62%	62%	42%	47%
Patients losing ≥10% body weight	53%		37%	34%	21%	22%

Teso: Tesofensine; Sema = Semaglutide

Source: Company data, FDA and Nordea

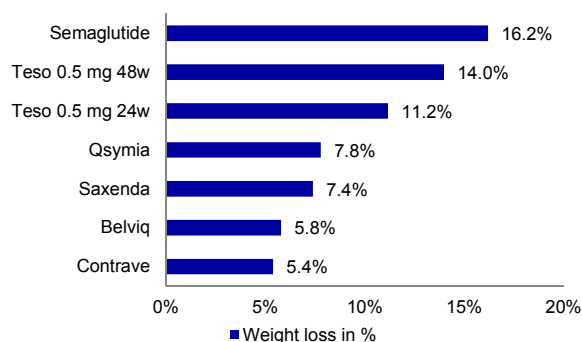
The maximum percentage change in weight loss achieved to date for existing commercially available anti-obesity prescription drugs in the US is some 7-8% at therapeutic relevant doses, depending on the comparator arm benchmarked against (dosing and patient population included in the trial). This suggests that Tesofensine has the potential to produce twice the weight loss as currently approved drugs, and it even shows a superior weight loss at only 24 weeks.

TESOFENSINE WEIGHT LOSS VS OTHER DRUGS



Source: Company data, FDA and Nordea

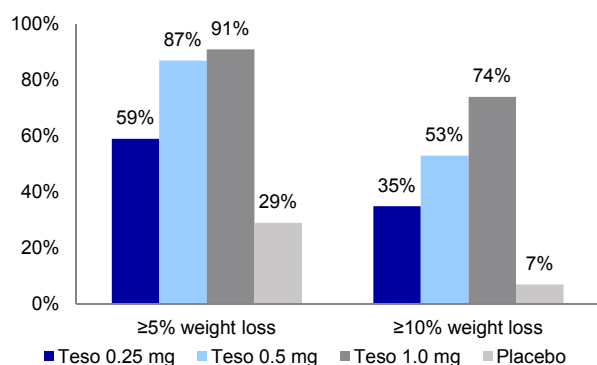
TESOFENSINE WEIGHT LOSS VS OTHER DRUGS



Source: Company data, FDA and Nordea

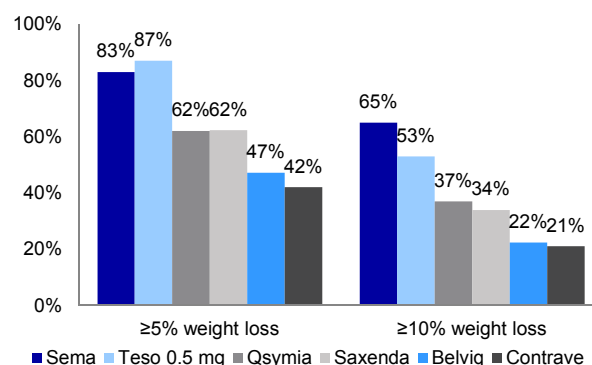
The only drug in the same weight loss league as Tesofensine is Novo Nordisk's Semaglutide; an injectable GLP-1 drug marketed in type II diabetes in the US under the brand name Ozempic, but that is currently also being investigated in obesity. Semaglutide reported positive ph II results in 2017 and current market expectations are for a launch in 2021. While Novo may seem like a big company to compete against in obesity, we note that it primarily targets other markets (US/EU) and that Semaglutide likely will be priced markedly higher than Tesofensine; hence, Saniona and Novo will likely not compete for the same patients. Comparing the two drugs does not, in our view, make much sense as Tesofensine's sales uptake will depend much more on Medix being able to switch patients currently treated with inferior products or drive uptake among new patient groups.

PATIENTS ACHIEVING ≥5% AND ≥10% WEIGHT LOSS



Source: Company data, FDA and Nordea

PATIENTS ACHIEVING ≥5% AND ≥10% WEIGHT LOSS



Source: Company data, FDA and Nordea

Looking at the weight loss distribution across Tesofensine doses, patients losing 10% body weight or more increased by a factor of eight to ten versus placebo in the two highest Tesofensine doses.

Well-tolerated, but increased heart rate signal a potential concern

Tesofensine appears to have an overall well-tolerated safety profile. The adverse events profile looks similar to placebo and is consistent with reuptake inhibitors targeting noradrenaline, serotonin and dopamine, with the most common adverse events being dry mouth, nausea, diarrhoea and insomnia. The main issue with the drug in a commercial perspective is its dose-related increase in heart rate observed in the Tesofensine group. Tesofensine leads to an additional eight beats per minute in the Tesofensine 0.5 mg dose (the therapeutic dose).

TESOFENSINE HEART RATE INCREASE AND ADVERSE EVENTS PROFILE VS OTHER ANTI-OBESITY DRUGS

	Teso 0.5 mg	Placebo	Qsymia 7.5 mg	Saxenda 3 mg	Contrave 32 mg	Belviq 10 mg
Adverse events and metabolic variables						
Increased heart rate (beats per minute)	7.8	0.4	>5	2-3	1-2	-1
Nausea	20%	10%	4%	39%	33%	8%
Vomiting	6%	2%	N.m.	16%	11%	4%
Diarrhea	8%	6%	6%	21%	7%	7%
Dry mouth	42%	12%	14%	2%	8%	5%
Insomnia	12%	2%	6%	2%	9%	4%

Teso: Tesofensine

Source: Company data, FDA and Nordea

We note that a drug-related increase in heart rate is probably not directly harmful to patients. Smaller increases in heart rate are a common phenomenon in anti-obesity agents, as evident in the table above showing that all existing commercial available anti-obesity drugs on the market but Belviq also lead to an increased heart rate.

Similar associated effects on heart rate have been observed in diabetes patients treated with drugs with weight loss properties, such as those in the GLP-1 class, albeit with much smaller heart rate increases (half for GLP-1s versus Tesofensine). The following table below lists the absolute heart rate increase and selected adverse events as reported in their respective US labels.

TESOFENSINE HEART RATE INCREASE VERSUS SELECTED DIABETES DRUGS

	Teso 0.5 mg	Placebo	Ozempic 1.0 mg	Victoza 1.2 mg	Trulicity 1.5 mg	Bydureon 2 mg
Adverse events and metabolic variables						
Increased heart rate (beats per minute)	7.8	0.4	2-3	2-3	2-4	2-4
Nausea	20%	10%	20%	18%	21%	11%
Vomiting	6%	2%	9%	6%	13%	11%
Diarrhea	8%	6%	9%	10%	13%	11%

Teso: Tesofensine

Source: Company data, FDA and Nordea

Tesofensine 0.5 mg had no effect on blood pressure, whereas the 1.0 mg dosage significantly increased systolic and diastolic blood pressure. We note that this may not pose a problem as such, as Saniona will only use the 0.5 mg dose or lower in future studies in obesity or other obesity-related indications. However, we believe it would be important to keep an eye on heart rate and blood pressure in the upcoming ph III data and flag that larger ph III studies (1,000-plus patients) are needed to substantiate these safety findings and assess the heart rate signal fully. This poses a potential risk in the upcoming ph III trial, together with the fact that the trial is performed in Mexico, which could disturb the efficacy signals due to less compliance in these sites.

Pivotal ph III study fully recruited – results due by early 2019

Saniona and Medix announced in early February 2018 that it has completed recruitment for its pivotal ph III clinical trial, enrolling 372 adult patients with obesity. Patients are randomised into three arms with 124 patients in each arm receiving either 0.25 mg Tesofensine, 0.5 mg Tesofensine or placebo once daily for 24 weeks, with the primary endpoint being absolute and percent change in body weight compared to baseline over the treatment period. This endpoint is similar to the ph II study, as we illustrate below.

TESOFENSINE PH II AND PH III TRIAL DESIGN COMPARISON

Trial comparison	Phase 2	Phase 3
N	203	372
Trial duration	24 weeks	24 weeks
Follow-up	24 weeks	12 weeks
Trial duration, including follow-up	48 weeks	36 weeks
Administration	Once daily	Once daily
Available doses in trial		
0.25 mg	Yes	Yes
0.5 mg	Yes	Yes
1.0 mg	Yes	No
Primary endpoint		
Percent change and absolute change in body weight	Yes	Yes
Secondary endpoints		
Patients losing $\geq 5\%$ and $\geq 10\%$ body weight	Yes	Yes
Safety and Tolerability	Yes	Yes
Metabolic including glycaemic endpoints	Yes	Yes
Data from questionnaires	Yes	Yes

Source: Company data and Nordea

The trial is expected to be completed in 2018 and headline results are expected in late 2018 or early 2019. We expect Tesofensine, pending positive ph III results, to be launched in 2020 in Mexico and in Argentina a year later.

TESOFENSINE: POTENTIAL TIMELINE FOR OBESITY

	2018				2019				2020				2021				2022			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Tesofensine																				
Obesity, Mexico	Ph 3				NDA				Launch											
Obesity, Argentina									NDA				Launch							

Source: Company data

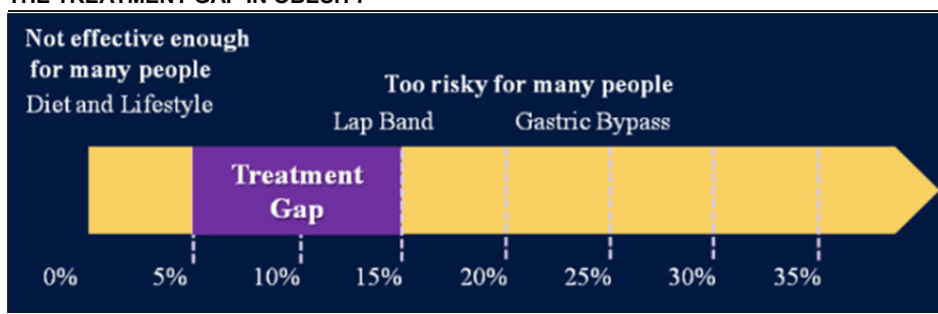
Tesofensine's weight loss suggests it could be competitive to gastric bypass

+10% weight loss in ph III would be promising for uptake

For years, major pharmaceutical companies have been struggling to develop drugs that could induce a +10 kg weight loss in obese patients. If Tesofensine proves to live up to its weight loss results in ph III studies, it could compete against bariatric surgery (gastric bypass). There is no doubt that a gastric bypass is the most effective procedure today to lose weight, as it usually results in 15-20% reduction in bodyweight. The flip side, however, is that the procedure is very invasive and expensive.

Treatment gap encompassing severely obese who do not want surgery, but need more than just diet, exercise and lifestyle changes

THE TREATMENT GAP IN OBESITY



Source: American Diabetes Associations

Diet, exercise and lifestyle changes unfortunately do not provide enough bang for the buck, and hence there is a treatment gap for severely obese patients who do not want to undergo surgery but still need more than diet and lifestyle changes. This is where we see Tesofensine – or Saniona's combination product Tesomet – potentially fitting in very well.

Tesofensine licence and intellectual property rights

The patent on Tesofensine expired in 2017, but the formulation patent and softer patents are filed and pending approval. The Mexican market provides companies with a five-year data package exclusivity from market approval, according to guidelines from the Mexican regulator, Cofepris. During this five-year period, competitors are not allowed to use clinical trials and other information provided by the producing company to prove the drug's safety and efficacy. Assuming a launch in 2020, potential competition could thus in theory be allowed to launch generic versions around 2025-26, depending on the speed at which generic companies are able to finish clinical trials and achieve market approval.

Tesofensine revenue modelling

As can be seen in our detailed bottom-up obesity model in the table 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)

Estimates on obesity prevalence across countries vary depending on the source. We have presented data on the development in obesity prevalence across countries as well as discussed on pages 60-68. Using these statistics, we assume that the addressable market for Tesofensine is some 24 million adults in Mexico and 7 million in Argentina (2015 numbers).

Existing commercially available anti-obesity drugs are generally priced at USD 10 per day in the US on a list price basis, while 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, a slight premium to the currently marketed drugs in Mexico but still attractive 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), this takes the price per patient to USD 365 per year. 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, as suggested in the TIPO-4 study discussed earlier.

We expect Tesofensine, pending positive results, to be launched in 2020 in Mexico and assume that Medix will launch the drug in Argentina a 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 to existing commercially available anti-obesity drugs in Mexico, which is dominated by old generic compounds with questionable efficacy and safety profiles. This will lead to Tesofensine replacing existing drugs but also help increase the market for prescription Rx products in Mexico in both volume and value, due to higher prices (USD 2 per day with Tesofensine versus some USD 1.5 for competitors) and longer treatment periods in patients (six months with Tesofensine versus up to five months for competitors). We also envision the drug driving uptake among new patient groups, as additional obese patients may seek treatment when efficacious and well-tolerated products (such as Tesofensine) are available, thus growing total prescription volumes in the market.

TESOFENSINE REVENUE MODEL FOR OBESITY – MEXICO SALES

	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Obesity - Mexico											
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	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
Risk-adj. sales, USDm	13	27	42	59	78	98	83	68	52	35	33
Risk-adj. sales, SEKm	112	236	372	522	685	864	734	599	458	312	286

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	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
Risk-adj. sales, USDm	0	4	8	13	18	24	20	15	10	9	9
Risk-adj. sales, SEKm	0	35	73	115	161	212	173	132	90	83	75

Source: Nordea estimates

Given that Tesofensine only has a five-year market exclusivity once launched, we expect revenues to fade in 2026 and beyond as we model in generic competition. There may be upside to this assumption, depending on the speed for which other companies launch generic versions and how fast their market penetration pans out.

TESOFENSINE COMBINED REVENUE AND ROYALTY FORECASTS

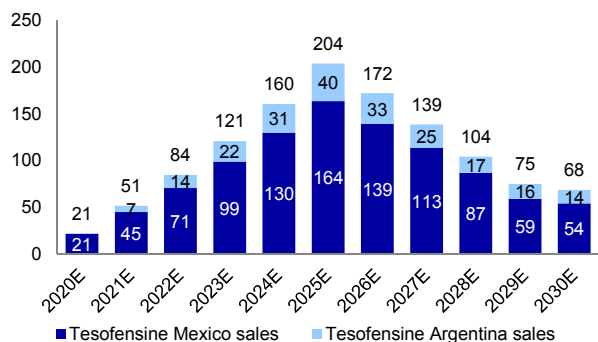
Obesity	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Tesofensine sales, USDm	21	51	84	121	160	204	172	139	104	75	68
Mexico	21	45	71	99	130	164	139	113	87	59	54
Argentina	0	7	14	22	31	40	33	25	17	16	14
Risk-adjustment	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
Risk-adj. sales, USDm	13	31	51	72	96	122	103	83	62	45	41
Risk-adj. sales, SEKm	112	271	446	637	847	1,076	907	732	548	394	361
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	20	47	78	111	148	188	159	128	96	69	63
Mexico	20	41	65	91	120	151	128	105	80	55	50
Argentina	0	6	13	20	28	37	30	23	16	14	13

Source: Nordea estimates

We model up to USD 204m in Tesofensine sales in Mexico and Argentina combined in 2025E. We risk-adjust sales by 60%, reflecting the drug being in ph III development, the solid efficacy reported in the ph II obesity trial and that Mexican healthcare authorities will not require any long-term pre-approval cardiovascular outcome trials. While we see the heart rate signal posing a potential concern, the drug appears to have an overall well-tolerated safety profile, which we believe supports our relatively high risk-adjustment.

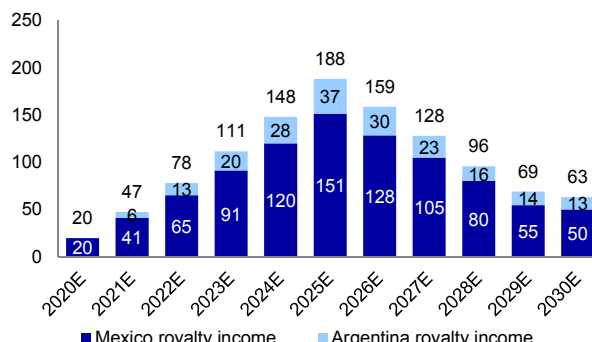
Saniona is entitled to regulatory milestone payments and double-digit royalties on product sales in Mexico and Argentina. We assume the latter to be between 15% and 20%, in line with many other deals seen in the healthcare space on drug collaborations signed prior to ph III. We model in the mid-point, ie 17.5%. This results in royalty income starting at SEK 20m in 2020E, increasing to SEK 188m in 2025E.

TESOFENSINE SALES FORECASTS (USDm)



Source: Nordea estimates

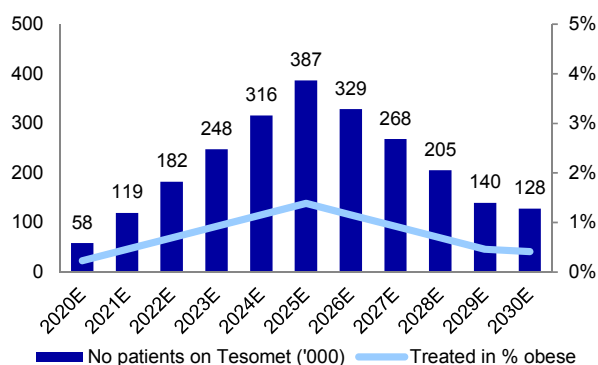
TESOFENSINE ROYALTY FORECASTS (SEKm)



Source: Nordea estimates

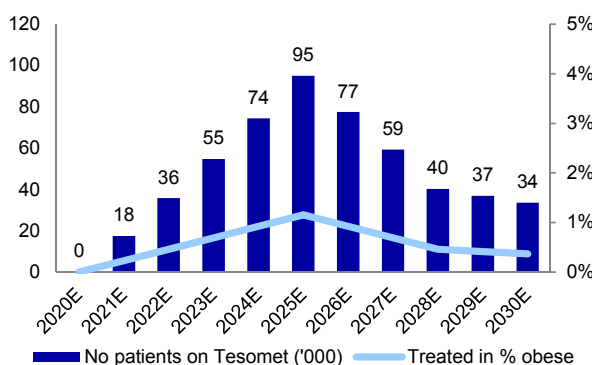
We base these estimates under the assumption that in Mexico, for example, approximately 387,000 patients will be on Tesofensine treatment at the peak. Market statistics suggest that only approximately 1.1 million patients (around 1 in 22) are treated with a prescription medicine annually in Mexico. However, the market is dominated by old generic compounds, with questionable efficacy and troublesome side-effect profiles. Hence, there should be opportunities for 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 and a more benign side-effect profile compared to Meridia's chequered cardiovascular profile.

Looking at a competing treatment, some 200,000 to 250,000 patients undergo bariatric surgeries in the US alone on an annual basis. For the patients losing the most weight on Tesofensine, the results may likely be close to the efficacy seen with bariatric surgery, but with many fewer side effects and a non-invasive and much cheaper alternative.

We have incorporated our Tesofensine revenue forecasts in obesity into our DCF model below. This valuation does not include any revenue from other indications or products in Saniona's pipeline. The company will not have any costs in relation to sales, as Medix will incur all costs. Hence, the only expense in our DCF is tax on operating income. We apply the same discount rate on Tesofensine as we apply to the overall company (13.5%), while conservatively setting the terminal value to zero in all years beyond our explicit forecast period (2018E-37E).

TESOFENSINE DCF ANALYSIS: OBESITY

SEKm	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E
Royalties	0	0	19	47	77	110	146	186	157	127	95	68	62	56	50	44	37	30	22	14
Tesofensine, Mexico	0	0	19	41	64	90	119	149	127	104	79	54	50	45	40	35	30	24	19	13
Tesofensine, Argentina	0	0	0	6	13	20	28	37	30	23	16	14	13	12	10	9	7	5	4	2
Other income	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total revenues	0	0	19	47	77	110	146	186	157	127	95	68	62	56	50	44	37	30	22	14
Operating expenses:																				
COGS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
R&D	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
S&D	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Admin	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Operating income	0	0	19	47	77	110	146	186	157	127	95	68	62	56	50	44	37	30	22	14
Tax	0	0	-4	-10	-17	-24	-32	-41	-35	-28	-21	-15	-14	-12	-11	-10	-8	-7	-5	-3
Tax rate	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%
Free cash flow (FCFF)	0	0	15	37	60	86	114	145	122	99	74	53	49	44	39	34	29	23	17	11
Years	0.54	1.54	2.54	3.54	4.54	5.54	6.54	7.54	8.54	9.54	10.54	11.54	12.54	13.54	14.54	15.54	16.54	17.54	18.54	19.54
Discount factor	0.93	0.82	0.73	0.64	0.56	0.50	0.44	0.39	0.34	0.30	0.26	0.23	0.20	0.18	0.16	0.14	0.12	0.11	0.10	0.08
Net Present Value FCFF	0	0	11	23	34	43	50	56	42	30	19	12	10	8	6	5	4	3	2	1

DCF calculation	
Sum NPV FCFF	357
Terminal value	0
DCF value	357
No shares (fully diluted)	22
Value per share	16

Source: Nordea estimates

The forecasts and DCF valuation are subject to assumptions on many parameters. We therefore provide sensitivity tables below, showing how changes in key assumptions would impact Tesofensine's NPV value in this indication.

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

		Price per day (USD)				
		1.0	1.5	2.0	2.5	3.0
Risk-adjusted sales	20%	3	4	5	7	8
	40%	5	8	11	14	16
	60%	8	12	16	21	25
	80%	11	16	22	27	33
	100%	14	21	27	34	41

Source: Nordea estimates

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

		Treatment duration (months)				
		2	4	6	8	10
Risk-adjusted sales	20%	2	4	5	7	9
	40%	4	7	11	15	18
	60%	5	11	16	22	27
	80%	7	15	22	29	37
	100%	9	18	27	37	46

Source: Nordea estimates

The sensitivity analysis suggests that changes in our underlying assumptions on pricing, treatment duration, royalty rate, discount rate and approval probability could take Tesofensine's value up to SEK 27-46 per share if the ph III top-line data is positive and the drug achieves market approval.

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

		Royalty rate				
		14.5%	16.0%	17.5%	19.0%	20.5%
Risk-adjusted sales	20%	5	5	5	6	6
	40%	9	10	11	12	13
	60%	14	15	16	18	19
	80%	18	20	22	24	26
	100%	23	25	27	30	32

Source: Nordea estimates

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

		Discount rate (WACC)				
		11.5%	12.5%	13.5%	14.5%	15.5%
Risk-adjusted sales	20%	6	6	5	5	5
	40%	13	12	11	10	10
	60%	19	18	16	15	14
	80%	25	23	22	20	19
	100%	31	29	27	26	24

Source: Nordea estimates

Tesomet

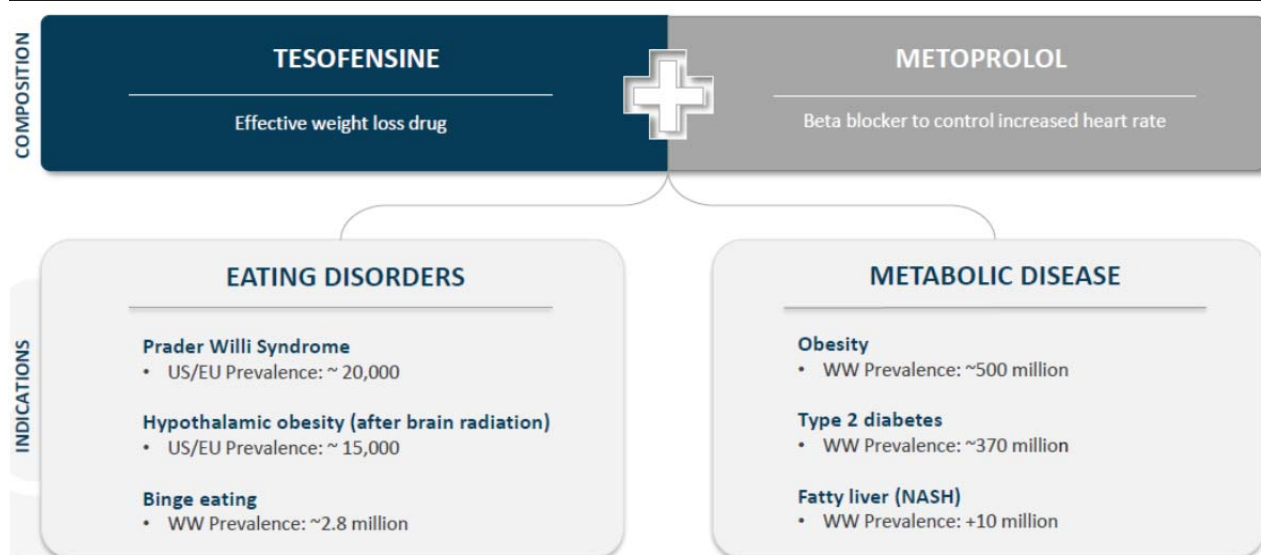
Tesomet – Saniona’s key value driver

- **Peak sales forecast:** USD ~360m within Prader-Willi syndrome in the US and EU combined; USD 350m in obesity sales in non-US and non-EU markets
- **Valuation:** SEK 26 per share in Prader-Willi syndrome with 15% risk-adjusted sales; SEK 15 per share in obesity with 40% risk-adjustment
- **Next news flow:** Results from ph IIa study in adolescents with Prader-Willi syndrome expected during Q4 2018; Initiate ph IIa study in hypothalamic during Q4 2018; Initiate ph IIb trial in obesity and ph IIb in Prader-Willi during H1 2019

Tesomet is a fixed-dose combination of Tesofensine and a beta blocker called Metoprolol

Tesomet is an oral fixed-dose combination between Tesofensine and a beta blocker called Metoprolol. It was developed by Saniona to create an even more attractive product than Tesofensine. Tesomet has the ability to alleviate Tesofensine's dose-dependent increase in heart rate without it affecting Tesofensine's robust weight-loss properties as a monotherapy.

TESOMET COMPOSITION AND INDICATION PROFILE



Source: Company data

Given that Tesomet is solely based on Tesofensine, Saniona could in theory target the same indications with both products. This includes obesity as well as various diseases caused by or associated with obesity, including:

- Type II diabetes
- Non-alcoholic fatty liver disease (NASH)
- Prader-Willi syndrome
- Hypothalamic obesity
- Binge eating

We see several advantages with Tesomet over Tesofensine

We see several advantages with Tesomet over Tesofensine, including regulatory approval, commercial uptake and the patent situation.

The fact that it alleviates the heart rate issue while addressing orphan drug markets with high unmet medical needs generally creates a better safety margin with regards to safety acceptance and thereby a higher likelihood that it will achieve regulatory approval, pending good efficacy data. Regulators generally accept more side effects in indications characterised by a high unmet medical need, but the fewer the side effects, the better the chances are.

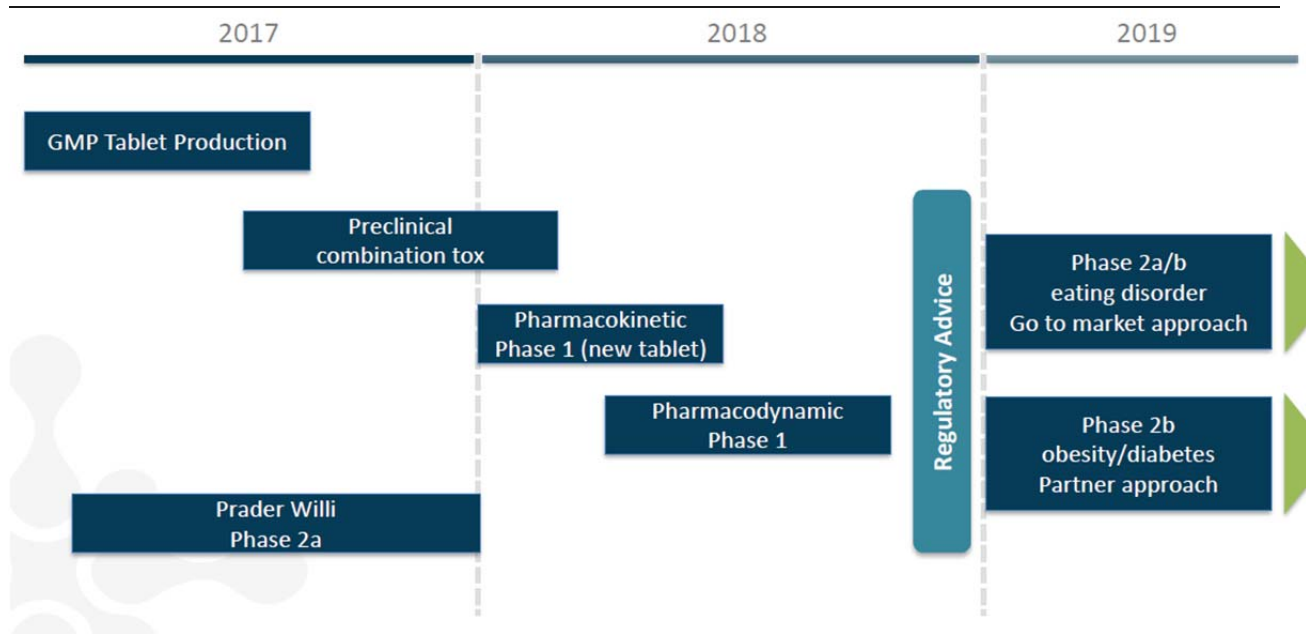
Tesomet is also favoured when assessing the commercial opportunities across markets, we believe, as although manageable, the increased heart rate would likely pose a barrier to commercial uptake in many markets.

Tesomet may have patent protection until 2036, another advantage over Tesofensine

Saniona has also – as we will discuss later – built a strong patent portfolio around Tesomet, which combined may provide patent protection until 2036. This is another advantage with Tesomet versus Tesofensine in a sales and net present value perspective, as Tesofensine's patent expired in 2017.

Looking at where the company is today with Tesomet (figure below), Saniona has started preparing for long-term ph II and ph III clinical studies (eg six months or longer) through a few steps.

TESOMET DEVELOPMENT AND PARTNERING STRATEGY



Source: Company data

- 1) Saniona has produced its GMP-validated (good manufacturing practices) Tesomet fixed-dose combination tablets for use in clinical trials.
- 2) Saniona has successfully completed the pre-clinical combination toxicity study allowing the company to run long-term studies in patients (the company has up to now not been allowed to perform trials for six months or longer).
- 3) Saniona has successfully completed a small pharmacokinetic ph I study with its novel patented fixed-dose combination tablet (containing both Tesofensine and Metoprolol), demonstrating that the tablet releases the compounds in the same way as co-administration of separate Tesofensine and Metoprolol tablets.
- 4) Saniona plans to do a pharmacodynamic trial starting shortly to find the optimal dose combination between Tesofensine and Metoprolol for all therapeutic relevant Tesofensine monotherapy doses (0.25 mg, 0.5 mg and 0.75 mg), which neutralises the increase in heart rate caused by Tesofensine.

The company expects to have everything in place later this year (only the pharmacodynamic trial needs to be completed, as listed above) after which it can prepare ph IIb studies in obesity and Prader-Willy syndrome. We anticipate these studies to start in 2019.

TESOMET: POTENTIAL TIMELINE FOR OBESITY AND RARE DISEASES

	2018				2019				2020				2021				2022			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Tesomet																				
Prader-Willi syndrome	Ph 2a				Ph 2b				FDA	Ph 3					NDA					Launch
Hypothalamic obesity			Ph 2a						FDA	Ph 3					NDA					Launch
Obesity, RoW					Ph 2b															
Obesity, Medix							Ph 3							NDA						Launch
Tesomet preparation studies																				
Toxicity	Tox																			
Pharmacokinetic	New tablet																			
Pharmacodynamic			Optimal dose																	

Source: Company data and Nordea estimates

The timelines illustrated above are obviously subject to board decisions and financial planning, and may change, dependent on clinical trial outcomes and how smooth the process goes with enrolment in clinical trials, discussions with regulators etc.

Set to pursue a go-to market strategy in orphan indications

Saniona's strategy with Tesomet is clear. It divides the development programme for Tesomet into two, depending on the indication area:

- 1) Develop and attain market approval for Tesomet in the US and EU internally in eating disorders and orphan drug indications (Prader-Willi syndrome and hypothalamic obesity), thus enabling the company to move all the way to the market on its own and retain the upside.
- 2) Develop and attain market approval for Tesomet in non-US and non-EU markets through partnerships with pharmaceutical companies for metabolic diseases, such as obesity and type II diabetes.

The orphan drug and eating disorder space represents a unique go-to market opportunity for a company like Saniona. The company should be able to take the programme to the market on its own, given that the investments needed to develop and commercialise a drug in this field are more manageable versus obesity or type II diabetes, as highlighted in the table below.

DIFFERENCE BETWEEN DEVELOPING TESOMET ACROSS INDICATIONS

	US+EU	Selected RoW countries
Obesity		
Trial duration (months)	>12	6
Required no. patients	>1000	3-400
Costly to run trials	Yes	Yes
Pre-approval CV outcome trial required	Yes	No
Market for anti-obesity drugs	Yes	Yes
Competitors	Yes	Yes
High unmet medical need	Yes	Yes
Rare diseases		
Trial duration (months)	6	6
Required no. patients	100	100
Costly to run trials	No	No
Market for rare diseases	Yes	No
Competitors	No	No
High unmet medical need	Yes	Yes

Source: Nordea

The orphan drug space allows Saniona to fast track through clinical ph II and ph III development to regulatory filings at a low investment

The orphan drug and eating disorder space allows Saniona to follow a relatively fast path through clinical ph II and ph III development to regulatory filings at a low investment, as it requires relatively short and small clinical trials – both ph II and ph III clinical studies can be done in some six months and would only require ~100 patients. Meanwhile, the commercial set-up to target 15,000-20,000 patients with Prader- Willi syndrome in the US and Europe combined through medical specialists is manageable as opposed to pursuing metabolic diseases on its own would – which would require a large investment in sales reps, longer and bigger trials etc.

Saniona to strike partnership deals with Tesomet in metabolic diseases

Saniona's strategy in obesity and other metabolic diseases caused by or associated with obesity (eg type II diabetes) is to enter into partnerships with larger pharmaceutical companies in non-US and non-EU markets. However, the company seeks to mature and build more value into the Tesomet programme in metabolic diseases by building the combined clinical data package through long-term ph IIb studies in obesity and diabetes prior to signing partnership agreements in those indications.

Partner already lined up in Mexico

The company already has a partner in Mexico (Medix) with exclusive rights to develop and commercialise both Tesofensine and Tesomet in the obesity market in Mexico and Argentina. Medix has already started a ph II study with Tesofensine and we expect it to explore Tesomet in obesity in late-stage trials as well, with a pivotal ph III trial to be planned and initiated in either 2019 or 2020.

This leaves all other markets open for partnership agreements on Tesomet. To our knowledge, Saniona has already been in talks with several pharmaceutical companies in this field across regions. The company generally senses a good interest across the board, but we speculate deals are not to occur until Saniona has reported ph III top-line data for Tesofensine (Q1 2019) and ph IIb data for Tesomet in obesity (Q1 2020) in order to assess the compound's weight loss potential and de-risk the development programme.

Saniona has demonstrated Tesomet's robust weight-loss properties while confirming its cardiovascular neutral profile

Clinical trials with Tesomet

Besides studies testing Tesofensine (the active ingredient in Tesomet) as a monotherapy, Saniona has completed four clinical trials in more than 100 subjects including obese volunteers, patients with type II diabetes and Prader-Willi syndrome patients. Through these trials, Saniona has demonstrated Tesomet's robust weight-loss properties while confirming its cardiovascular neutral profile (no increase in heart rate or blood pressure compared to placebo) and maintained desirable tolerability and safety profile.

TESOMET CLINICAL TRIAL EXPERIENCE

Product	Indication	Enrollment	Phase	Sponsor	Ct.gov identifier
Tesomet	Prader-Willi Syndrome	15	IIa	Saniona	NCT03149445
Tesomet	Type II diabetes	60	IIa	Saniona	NCT02737891
Tesomet	Healthy male subjects	60	I	Saniona	NCT03286829
Tesomet	Obese volunteers	60	I	Saniona	NCT03488719

Source: clinicaltrials.org

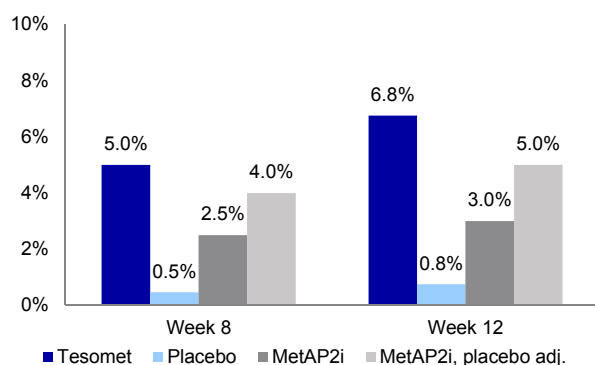
Ph IIa PWS study in adults showed highly promising efficacy data...

Saniona is running a ph IIa study investigating Tesomet in patients with Prader-Willi syndrome. The study is divided into two steps. Step 1 is testing Tesomet in adults with PWS, which then will be extended to adolescents (step 2).

The company reported top-line results from step 1 in January 2018, which included nine adult patients. Tesomet achieved a positive outcome on the primary endpoint (change from baseline on body weight) with a clinically meaningful reduction in body weight for the PWS patients treated with Tesomet compared to placebo. Patients on Tesomet lost 5% in body weight after eight weeks, increasing to 6.75% after 12 weeks.

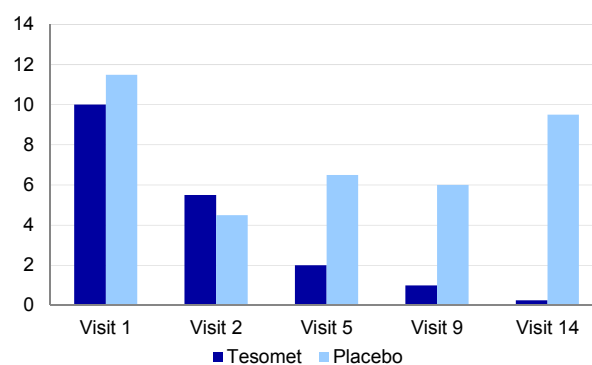
Tesomet also led to a dramatic decrease in hyperphagia (extreme and insatiable appetite in patients) measured by the validated hyperphagia questionnaire for clinical trials. It appears that patients almost completely lost their hyperphagia whereas patients receiving placebo exhibited somewhat the same level in all visits.

REDUCTION IN BODY WEIGHT VERSUS PLACEBO



Source: Company data and Nordea

HYPERPHAGIA SCORE IN PWS PATIENTS



Source: Company data and Nordea

PWS patients are usually not voluntarily stopping to eat, supporting the solid results for Tesomet in this indication

Although this was obviously a very small study (N=9), the efficacy results were still quite convincing, in our view. With regards to the observed weight loss and food craving among patients in the study, it is worth noting that patients diagnosed with PWS are usually not voluntarily stopping to eat, quite the contrary actually. Hence, the positive results on these efficacy parameters in the Tesomet group, though being a small study, look highly promising for its continued development in this indication, in our view. While comparisons with other trials should be approached with caution, we have included beloranib (MetAP2i) in the weight loss graph, supporting Tesomet's clinically meaningful results in this patient population.

While no serious adverse events were reported during the study, some patients reported worsening of existing behavioural problems

...but the drop-out rate highlights the difficulties in running PWS trials

While the results in adults showed promising efficacy results, the adverse events and drop-out rates were more problematic at the high dose level used in the study. No serious adverse events were reported during the study, but some patients experienced a worsening of existing behavioural problems. This prompted Saniona to decide to perform an interim analysis in which it un-blinded the study and analysed the data on an individual patient level in order to determine the relationship between drug exposure and observed efficacy and safety signals.

The company reported the conclusions and results from the interim analysis in a headline release in January 2018. The analysis showed that Tesofensine (the main molecule in Tesomet) has a much longer half-life in these PWS patients, meaning that it stays in the body for a longer time than normally, leading to higher plasma concentration levels. This may explain the high drop-out rates occurring in the trial. Interestingly, the deteriorated behavioural problems observed during the study in some patients receiving Tesomet reversed when they were offered a temporary reduction in dose during the study, suggesting that by reducing the dose, it may be possible to reduce the plasma concentration to a level where Tesomet is better tolerated in this highly sensitive patient group while at the same time remaining efficacious.

The study suggested that lower doses should be implemented in future PWS trials

The study clearly highlighted the challenges in running studies in adult PWS patients. Behavioural problems are not as developed and widespread in adolescents, indicating that it should be easier to treat teenagers and children, especially when implementing lower doses than what otherwise be considered therapeutic (0.5 mg Tesofensine).

Green light to expand study to include adolescents

Ph IIa PWS study will be progressed into adolescents

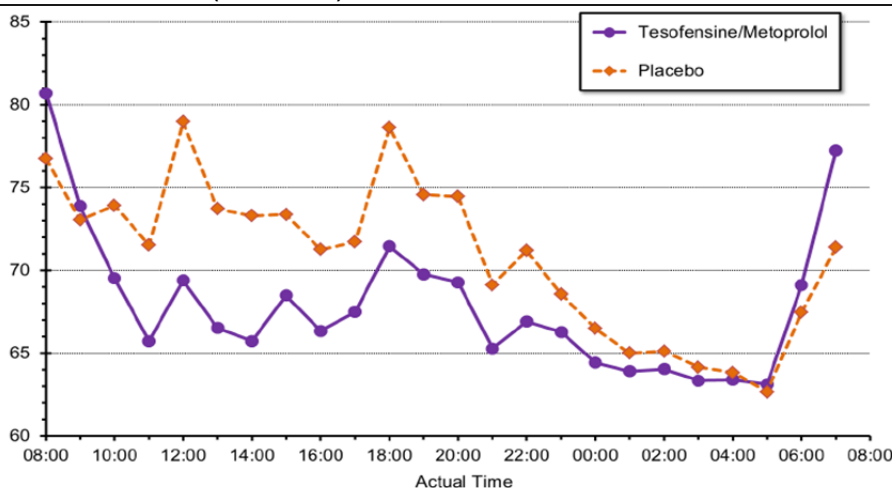
Saniona announced in April that it has obtained approval to initiate step 2 in the ph IIa study in Prader-Willi syndrome. This follows positive discussions with key opinion leaders in the field and the results reported in adults showing that Tesomet has the potential to significantly reduce both body weight but also, importantly, the extreme and insatiable appetite in patients (hyperphagia). Saniona expects to include up to ten adolescents with PWS, while treating the patients with a lower dose in order to secure that the drug is tolerated in this patient population.

Ph IIa study in type II diabetes supports Tesomet's neutral CV profile

Saniona has reported top-line results in January 2017 from its ph IIa study investigating Tesomet in a trial enrolling 60 patients with type II diabetes over three months. Tesomet achieved a positive outcome on the primary endpoint (change from baseline on mean 24-hour heart rate) with a statistically significant reduction in heart rate for patients treated with Tesomet compared to placebo. Tesomet reduced the mean 24-hour heart rate by ~4 beats per minute on average (p=0.0038). No new or unexpected safety issues were observed in the study.

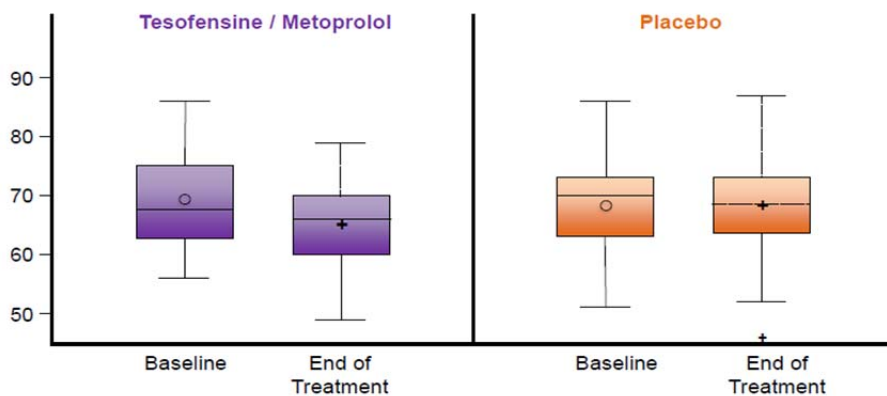
The charts below shows that the combination between Tesofensine and Metoprolol led to a significant reduction in mean 24-hour heart rate profile compared to placebo, while also leading to a significant reduction in the quiet hour heart rate compared to placebo.

MEAN HEART RATE (BEATS/MIN) BEFORE AND AFTER TREATMENT



Source: Roman V. Dvorak et al

QUIET HOUR HEART RATE (BEATS/MIN) BEFORE AND AFTER TREATMENT



Source: Roman V. Dvorak et al

Meanwhile, Tesomet showed a progressive and statistically significant reduction in body weight compared to placebo. Patients on Tesomet lost 3.5 kg (3.5%) on average versus 0.3 kg in the placebo group. This demonstrates that by adding Metoprolol to Tesofensine, Saniona is able to alleviate Tesofensine's dose-dependent increase in heart rate without it affecting Tesofensine's robust weight loss properties.

Tesomet IP and patent protection

Although the patent on Tesomet's two individual components has already expired (Tesofensine's patent expired in 2017 and Metoprolol is generic), Saniona has built a strong patent portfolio around Tesomet, based on issued patents and patent applications, which together may provide patent protection until 2036. This covers the components listed in the table below.

TESOMET IP AND PATENT PROTECTION IN THE US AND EU

	US	EU
The formulation patent covering the fixed dose tablet	2034	Pending
The combination between Tesofensine and Metoprolol	2034	Pending
The use of Tesofensine and Metoprolol in obesity, diabetes and other obesity-related diseases	2036	2036

Source: Company data and Nordea

Orphan exclusivities in the US and EU could provide market exclusivity for Tesomet for seven years (US) and ten years (EU) from approval

In addition to its patents, Tesomet is also expected to be protected by orphan exclusivities in the US and EU, which could provide market exclusivity for seven years (US) and ten years (EU), respectively, from approval. During this period, the regulatory bodies (FDA and EMA) are barred from approving the same product (generics) for the same orphan indication. We expect Saniona to seek orphan drug designation for Tesomet in Prader-Willi and hypothalamic obesity in both the US and EU. Assuming a launch in the US and EU in 2023, orphan drug exclusivities should provide protection in the US and the EU until 2030 and 2033, respectively.

Tesomet revenue modelling

We illustrate and explain the assumptions behind our bottom-up revenue models for Tesomet in orphan diseases (Prader-Willi syndrome and hypothalamic obesity) as well as obesity in the sections below. Saniona is also considering the potential for Tesomet in other indications, such as type II diabetes, fatty liver disease (NASH) and binge eating.

We illustrate our Tesomet forecasts below, split per indication. On a risk-adjusted basis, we forecast the drug to generate up to SEK ~700m 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)	47	104	166	224	263	305	349	395	445	461	477	240	121	83	44
- 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	47	104	166	224	263	305	349	395	445	461	477	240	121	83	44
- Growth (y/y)	N.a.	122%	59%	35%	17%	16%	14%	13%	13%	4%	4%	-50%	-50%	-32%	-47%
Obesity (40% risk-adj)	24	50	79	110	145	182	191	200	210	220	231	157	80	73	66
- Growth (y/y)	N.a.	110%	57%	40%	31%	26%	5%	5%	5%	5%	5%	-32%	-49%	-8%	-9%
Total Tesomet	71	155	245	334	408	487	540	596	655	681	709	397	201	156	110
- Growth (y/y)	N.a.	118%	58%	37%	22%	19%	11%	10%	10%	4%	4%	-44%	-49%	-22%	-29%
Share of total sales	39%	51%	57%	68%	76%	84%	89%	90%	92%	93%	94%	91%	87%	87%	88%
Share of total sales growth	68%	70%	69%	149%	172%	168%	204%	112%	111%	132%	132%	98%	96%	86%	85%

Source: Nordea estimates

We estimate USD ~360m in Tesomet sales in PWS

The market for PWS is characterised by a high unmet medical need. Symptoms such as the inability to control hunger and food intake (hyperphagia) remain difficult to

treat and no medications have proven effective in regulating appetite in patients with PWS to date. This leaves a big opportunity for companies that successfully develop treatments that decrease hyperphagia. Tesomet's ph IIa results in adult patients with Prader-Willi syndrome showed that the drug led to a dramatic decrease in hyperphagia, albeit we flag that larger studies (ph IIb and ph III) are needed to substantiate these results.

We use four sales drivers to model revenues for Tesomet in Prader-Willi syndrome:

- 1) Number of patients with Prader-Willi syndrome in the US and the EU
- 2) Number of patients with Prader-Willi syndrome identified, diagnosed and treated in the US and the EU
- 3) Daily treatment cost for Tesomet in the US and the EU
- 4) Tesomet penetration (market share)

We list our revenue assumptions in the tables below. Although prevalence estimates differ among studies, the birth incidence is around one in 15,000 to one in 25,000 in the US and Europe. We have assumed the prevalence to be one in 15,000 in both regions while assuming that 35% are correctly identified, diagnosed and receiving the needed treatment, in line with patient statistics provided by the Prader-Willi Syndrome Association (USA). This suggests that ~8,000 PWS patients in the US and ~12,000 in the EU are available for treatment with Tesomet, ie some 20,000 combined.

TESOMET PWS ASSUMPTION - US

Prevalence	1/15,000
Diagnosed and treated	35%
Peak penetration	30%
Costs (list)	85,000 USD
Gross-to-net discount	25%
Risk-adjustment	15%

Source: Nordea estimates

TESOMET PWS ASSUMPTION - EU

Prevalence	1/15,000
Diagnosed and treated	35%
Peak penetration	20%
Costs (list)	42,500 USD
Gross-to-net discount	0%
Risk-adjustment	15%

Source: Nordea estimates

We expect Saniona to achieve orphan drug designation on Tesomet in the US and the EU, thus securing premium pricing in the market. Orphan drug pricing varies depending on the drug and is subject to final clinical data, the perceived benefits for the patients and families, and negotiations in individual countries, based on incremental benefit assessment and prevalence/cost to society. EvaluatePharma (a leading healthcare-focused market intelligence company) estimates that the mean cost for an orphan drug in 2017 was USD ~147,000 per patient per year. Total care and medical costs are estimated to be around USD 100,000-300,000 per year for a PWS patient, putting potential treatment costs into perspective.

There are no approved drugs in PWS to benchmark against, but we would not be surprised to see an anti-PWS drug priced at a list price between USD 50,000-100,000 per patient per year in the US – we assume 85,000 – while we expect gross-to-net discounts to be around 20-25%, due to rebates paid to eg Medicaid. We expect the EU price to be around 50% lower than the US list price.

We may be too conservative with these estimates, as it is not unusual to see orphan drugs priced at more than USD 150,000 per year in indications with prevalence below one in 10,000 in the US. But this ultimately comes down to the incremental benefit that Tesomet provides patients, where we argue that ph IIb and ph III results are needed to substantiate the results generated with Tesomet. We also flag the big focus on pricing in the pharma space, including on orphan drugs, which is likely to continue and explains why we would rather be conservative than too optimistic. Tesomet will generate healthy sales and value to Saniona and shareholders no matter what; hence, a higher price remains upside to our estimates.

TESOMET REVENUE MODEL FOR PRADER-WILLI SYNDROME – US SALES

PWS - US	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
US population ('000)	339,297	341,672	344,064	346,472	348,898	351,340	353,799	356,276	358,770	361,281	363,810	366,357	368,921
Growth	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%
PWS prevalence	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%
No estimated cases	22,620	22,778	22,938	23,098	23,260	23,423	23,587	23,752	23,918	24,085	24,254	24,424	24,595
Treated	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%
Treated	7,917	7,972	8,028	8,084	8,141	8,198	8,255	8,313	8,371	8,430	8,489	8,548	8,608
Tesomet penetration	5%	10%	15%	20%	22%	24%	26%	28%	30%	30%	30%	15%	8%
No treated with Tesomet	396	797	1,204	1,617	1,791	1,968	2,146	2,328	2,511	2,529	2,547	1,282	646
Costs, USD (list)	85,000	87,550	90,177	92,882	95,668	98,538	101,494	104,539	107,675	110,906	114,233	114,233	114,233
Cost inflation	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	0%	0%
Gross-to-net discount	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%
Costs, USD (net)	63,750	65,663	67,632	69,661	71,751	73,904	76,121	78,404	80,757	83,179	85,675	85,675	85,675
Tesomet sales, USDm	25	52	81	113	129	145	163	182	203	210	218	110	55
Risk-adjustment	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
Risk-adj. sales, USDm	4	8	12	17	19	22	25	27	30	32	33	16	8
Risk-adj. sales, SEKm	33	69	108	149	170	192	216	241	268	278	288	145	73

Source: Nordea estimates

TESOMET REVENUE MODEL FOR PRADER-WILLI SYNDROME – EU SALES

PWS - EU	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EU population ('000)	522,362	523,929	525,501	527,077	528,658	530,244	531,835	533,431	535,031	536,636	538,246	539,861	541,480
Growth	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
PWS prevalence	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%
No estimated cases	34,824	34,929	35,033	35,138	35,244	35,350	35,456	35,562	35,669	35,776	35,883	35,991	36,099
Treated	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%
Treated	12,188	12,225	12,262	12,298	12,335	12,372	12,409	12,447	12,484	12,522	12,559	12,597	12,635
Tesomet penetration	2%	5%	8%	10%	12%	14%	16%	18%	20%	20%	20%	10%	5%
No treated with Tesomet	244	611	981	1,230	1,480	1,732	1,986	2,240	2,497	2,504	2,512	1,260	632
Costs, USD (list)	42,500	43,775	45,088	46,441	47,834	49,269	50,747	52,270	53,838	55,453	57,116	57,116	57,116
Cost inflation	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	0%	0%
Gross-to-net discount	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Costs, USD (net)	42,500	43,775	45,088	46,441	47,834	49,269	50,747	52,270	53,838	55,453	57,116	57,116	57,116
Tesomet sales, USDm	10	27	44	57	71	85	101	117	134	139	143	72	36
Risk-adjustment	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
Risk-adj. sales, USDm	2	4	7	9	11	13	15	18	20	21	22	11	5
Risk-adj. sales, SEKm	14	35	58	75	93	113	133	155	177	183	189	95	48

Source: Nordea estimates

We project that Tesomet will be launched in 2023 in the US and model a ramp starting with 5% penetration, gradually increasing to 30% in 2030 in the US. Meanwhile, in the EU we model a launch in 2023 and a ramp starting with 2% penetration, peaking at 20% in 2030. While we may be too conservative on penetration assumptions in the EU, we note that this region generally has lower payer willingness and that it could take time to secure reimbursement across European countries. The latter is a general structural issue in the EU, with cost watchdogs such as NICE in the UK implementing a strict cost/benefit assessment policy. Assuming orphan drug market exclusivity and patent protection until 2033, we model that sales will decline in the years beyond 2033 owing to generics penetrating the market.

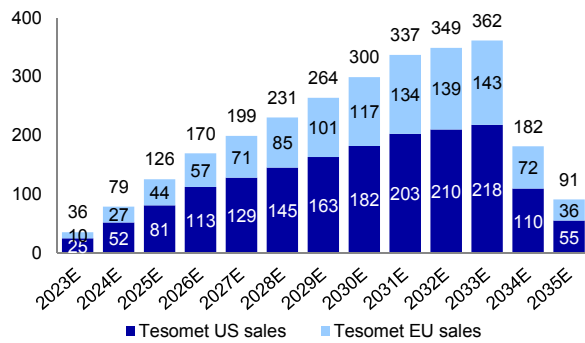
TESOMET COMBINED REVENUE FORECASTS IN PRADER-WILLI SYNDROME

PWS	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Tesomet sales, USDm	36	79	126	170	199	231	264	300	337	349	362	182	91
US	25	52	81	113	129	145	163	182	203	210	218	110	55
EU	10	27	44	57	71	85	101	117	134	139	143	72	36
Risk-adjustment	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
Risk-adj. sales, USDm	5	12	19	25	30	35	40	45	51	52	54	27	14
Risk-adj. sales, SEKm	47	104	166	224	263	305	349	395	445	461	477	240	121
US	33	69	108	149	170	192	216	241	268	278	288	145	73
EU	14	35	58	75	93	113	133	155	177	183	189	95	48

Source: Nordea estimates

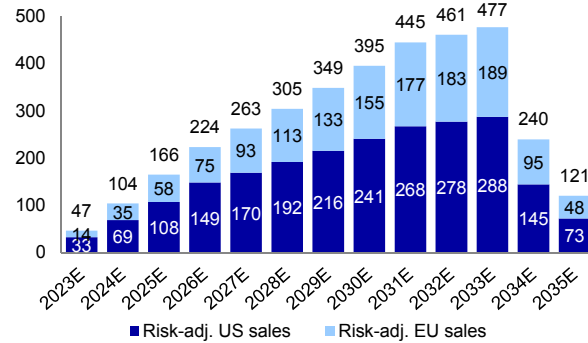
We estimate USD ~360m in non-risk-adjusted peak sales (2033E) with Tesomet in Prader-Willi syndrome in the US and the EU combined while applying a conservative 15% probability to reflect the risks in trials in this difficult-to-treat patient population as well as the fact that larger studies are needed to substantiate the results generated with Tesomet. Our forecasts translate into SEK 47m in risk-adjusted sales to Saniona in 2023E, increasing to SEK 477m by 2033E.

TESOMET FORECASTS IN PWS (USDm)



Source: Nordea estimates

TESOMET RISK-ADJ. FORECASTS IN PWS (SEKm)



Source: Nordea estimates

Our analysis suggests that Tesomet is worth SEK 26 per share in PWS alone

We have incorporated our Tesomet revenue forecasts in PWS into a discounted cash flow (DCF) model below. This valuation only includes revenue related to Tesomet in PWS. Besides product sales, we include a priority review voucher and assume that Saniona can sell it for USD 100m (SEK ~880m). On a risk-adjusted basis (15% – similar to our risk-adjustment on Tesomet alone), this adds SEK 132m in revenue in 2023E

We assume Tesomet will generate a high gross margin for Saniona (99%), while modelling in investments in a dedicated sales force as well as relevant support functions, etc, in order to ensure proper sales uptake by targeting doctors and treatment centres. We apply the same discount rate to Tesomet in PWS as we apply to the overall company (13.5%), while conservatively setting the terminal value to zero in all years beyond our explicit forecast period (2018E-37E).

Our analysis suggests that Tesomet is worth SEK 26 per share in PWS alone on our revenue and valuation assumptions.

TESOMET DCF ANALYSIS: PRADER-WILLI SYNDROME

SEKm	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E
Product sales	47	104	166	224	263	305	349	395	445	461	477	240	121	83	44
Other income	132	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total revenues	179	104	166	224	263	305	349	395	445	461	477	240	121	83	44
Operating expenses:															
COGS	0	-1	-2	-2	-3	-3	-3	-4	-4	-5	-5	-2	-1	-1	0
R&D	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
S&D	-50	-30	-30	-30	-30	-30	-30	-30	-30	-30	-30	-30	-30	-30	-30
Admin	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Operating income	129	73	134	192	230	272	315	362	411	426	443	208	89	52	14
Tax	-28	-16	-30	-42	-51	-60	-69	-80	-90	-94	-97	-46	-20	-11	-3
Tax rate	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%
Free cash flow (FCFF)	100	57	105	150	180	212	246	282	320	333	345	162	70	40	11
Years	5.52	6.52	7.52	8.52	9.52	10.52	11.52	12.52	13.52	14.52	15.52	16.52	17.52	18.52	19.52
Discount factor	0.50	0.44	0.39	0.34	0.30	0.26	0.23	0.21	0.18	0.16	0.14	0.12	0.11	0.10	0.08
Net Present Value FCFF	50	25	40	51	54	56	57	58	58	53	48	20	8	4	1

DCF calculation	
Sum NPV FCFF	583
Terminal value	0
DCF value	583
No shares (fully diluted)	22
Value per share	26

Source: Company data and Nordea estimates

The forecasts and DCF valuation are subject to assumptions on many parameters. We therefore provide sensitivity tables below, showing how changes in each assumption would affect our peak sales estimate and Tesomet's NPV value in this indication.

The sensitivity analysis suggests that changes in our underlying assumptions on pricing and peak penetration in our model could take Tesomet's peak sales to between USD ~300m and up to USD some 700m.

PEAK SALES (USDm): PRICING VS PENETRATION

		Annual treatment costs in the US				
		35,000	60,000	85,000	110,000	135,000
Peak penetration in the US	20%	99	170	241	312	383
	25%	124	213	301	390	479
	30%	149	255	362	468	574
	35%	174	298	422	546	670
	40%	199	340	482	624	766

Source: Nordea estimates

PEAK SALES (USDm): PRICING VS PRICE HIKES

		Annual treatment costs in the US				
		35,000	60,000	85,000	110,000	135,000
Annual price increase	0.0%	111	190	269	348	427
	1.5%	129	220	312	404	496
	3.0%	149	255	362	468	574
	4.5%	172	295	418	541	664
	6.0%	198	340	482	624	765

Source: Nordea estimates

The sensitivity tables below illustrate how changes in selected underlying assumptions would impact Tesomet's NPV value on a per-share basis.

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

		Annual treatment costs in the US				
		35,000	60,000	85,000	110,000	135,000
Risk-adjusted sales	5%	1	3	6	9	12
	10%	5	11	16	22	27
	15%	10	18	26	35	43
	20%	14	26	37	48	59
	100%	89	144	200	255	310

Source: Nordea estimates

VALUE PER SHARE (SEK): RISK-ADJ VS PRICE HIKES

		Annual treatment costs in the US				
		35,000	60,000	85,000	110,000	135,000
Annual price increase	0.0%	8	15	22	29	36
	1.5%	9	17	24	32	39
	3.0%	10	18	26	35	43
	4.5%	11	20	29	38	47
	6.0%	12	22	32	42	51

Source: Nordea estimates

VALUE PER SHARE (SEK): RISK-ADJ VS COSTS

		Annual S&D costs versus base case				
		-20	-10	0	20	100
Risk-adjusted sales	5%	9	7	6	4	-7
	10%	19	18	16	14	4
	15%	29	28	26	24	14
	20%	39	38	37	34	24
	100%	202	201	200	197	187

Source: Nordea estimates

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

		Discount rate (WACC)				
		11.5%	12.5%	13.5%	14.5%	15.5%
Risk-adjusted sales	5%	7	7	6	5	5
	10%	20	18	16	15	13
	15%	32	29	26	24	22
	20%	45	40	37	33	30
	100%	243	220	200	181	165

Source: Nordea estimates

Including Tesomet in PWS fully in our model with 100% approval probability would (all else equal) boost its standalone value to SEK ~200 per share. While the sensitivity analysis suggests that changes in underlying assumptions on pricing and peak sales in general have a high impact on the NPV value per share, changes in S&D cost assumptions are less impactful. Assuming S&D costs to be up to SEK 100m higher every year than the base case assumptions illustrated in the DCF would, all else equal, only reduce Tesomet's NPV value by around SEK 12 per share.

Hypothalamic obesity to provide additional sales potential

Saniona recently announced that it plans to initiate a ph IIa study in hypothalamic obesity (HO). This indication has several things in common with Prader-Willi syndrome, including clinical symptoms, clinical trial design and potential orphan drug designation. Both Prader-Willi syndrome and hypothalamic obesity are characterised by insatiable hunger (hyperphagia) and obesity, suggesting that patients should benefit from the same treatment as PWS patients.

Tesomet and Tesofensine have been shown to induce robust weight loss in patients while also leading to a dramatic decrease in hyperphagia in PWS patients. We also highlight that Abbott's sibutramine showed a significant decrease in BMI and body weight in patients with hypothalamic obesity. Sibutramine inhibits serotonin and noradrenaline – similar to Tesofensine and Tesomet. These observations add support to Tesomet's potential benefit in this indication, in our view.

At present, we do not include explicit forecasts for this indication in our valuation; hence, it remains potential upside. We nevertheless detail below how a hypothalamic obesity revenue model could look.

TESOMET REVENUE MODEL FOR HYPOTHALAMIC OBESITY – US SALES

Hypothalamic obesity - US	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
US population ('000)	339,297	341,672	344,064	346,472	348,898	351,340	353,799	356,276	358,770	361,281	363,810	366,357	368,921
Growth	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%
Craniopharyngioma prevalence	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%
No estimated cases	6,786	6,833	6,881	6,929	6,978	7,027	7,076	7,126	7,175	7,226	7,276	7,327	7,378
% developing HO	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
No estimated cases	3,393	3,417	3,441	3,465	3,489	3,513	3,538	3,563	3,588	3,613	3,638	3,664	3,689
Tesomet penetration	5%	10%	15%	20%	22%	24%	26%	28%	30%	30%	30%	15%	8%
No treated with Tesomet	170	342	516	693	768	843	920	998	1,076	1,084	1,091	550	277
Costs, USD (list)	85,000	87,550	90,177	92,882	95,668	98,538	101,494	104,539	107,675	110,906	114,233	114,233	114,233
Cost inflation	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	0%	0%
Gross-to-net discount	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%
Costs, USD (net)	63,750	65,663	67,632	69,661	71,751	73,904	76,121	78,404	80,757	83,179	85,675	85,675	85,675
Tesomet sales, USDm	11	22	35	48	55	62	70	78	87	90	94	47	24

Source: Nordea estimates

TESOMET REVENUE MODEL FOR HYPOTHALAMIC OBESITY – EU SALES

Hypothalamic obesity - EU	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EU population ('000)	522,362	523,929	525,501	527,077	528,658	530,244	531,835	533,431	535,031	536,636	538,246	539,861	541,480
Growth	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
Craniopharyngioma prevalence	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%	0.002%
No estimated cases	10,447	10,479	10,510	10,542	10,573	10,605	10,637	10,669	10,701	10,733	10,765	10,797	10,830
% developing HO	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
No estimated cases	5,224	5,239	5,255	5,271	5,287	5,302	5,318	5,334	5,350	5,366	5,382	5,399	5,415
Tesomet penetration	2%	5%	8%	10%	12%	14%	16%	18%	20%	20%	20%	10%	5%
No treated with Tesomet	104	262	420	527	634	742	851	960	1,070	1,073	1,076	540	271
Costs, USD (list)	42,500	43,775	45,088	46,441	47,834	49,269	50,747	52,270	53,838	55,453	57,116	58,830	60,595
Cost inflation	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%
Gross-to-net discount	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Costs, USD (net)	42,500	43,775	45,088	46,441	47,834	49,269	50,747	52,270	53,838	55,453	57,116	58,830	60,595
Tesomet sales, USDm	4	11	19	24	30	37	43	50	58	60	61	32	16

Source: Nordea estimates

We calculate USD ~240m in non-risk-adjusted peak sales (2033E) with Tesomet in hypothalamic obesity in the US and the EU combined.

TESOMET COMBINED REVENUE FORECASTS IN HYPOTHALAMIC OBESITY

Hypothalamic obesity	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Tesomet sales, USDm	15	34	54	73	85	99	113	128	145	150	155	79	40
US	11	22	35	48	55	62	70	78	87	90	94	47	24
EU	4	11	19	24	30	37	43	50	58	60	61	32	16
Risk-adjustment	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
Risk-adj. sales, USDm	2	5	8	11	13	15	17	19	22	22	23	12	6
Risk-adj. sales, SEKm	24	52	83	112	132	153	175	198	223	231	239	122	62

Source: Nordea estimates

Tesomet could be worth SEK 10 per share in hypothalamic obesity alone

Incorporating the revenue forecasts in hypothalamic obesity into a DCF yields the results shown below. We assume the same gross margin and investments in launch activities (sales force, relevant support functions, etc) as for Tesomet in PWS, while also applying the same approval probability (15%).

Our analysis suggests that Tesomet could be worth SEK 10 per share in hypothalamic obesity alone based on our revenue and valuation assumptions.

TESOMET DCF ANALYSIS: HYPOTHALAMIC OBESITY

SEKm	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E
Product sales	24	52	83	112	132	153	175	198	223	231	239	122	62	43	23
Tesomet, HO	24	52	83	112	132	153	175	198	223	231	239	122	62	43	23
Other income	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total revenues	24	52	83	112	132	153	175	198	223	231	239	122	62	43	23
Operating expenses:															
COGS	0	-1	-1	-1	-1	-2	-2	-2	-2	-2	-2	-1	-1	0	0
R&D	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
S&D	-50	-30	-30	-30	-30	-30	-30	-30	-30	-30	-30	-30	-30	-30	-30
Admin	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Operating income	-27	22	52	81	101	121	143	166	191	199	207	91	31	12	-7
Tax	6	-5	-12	-18	-22	-27	-31	-37	-42	-44	-46	-20	-7	-3	2
Tax rate	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%
Free cash flow (FCFF)	-21	17	41	63	79	95	112	130	149	155	162	71	24	10	-6
Years	5.52	6.52	7.52	8.52	9.52	10.52	11.52	12.52	13.52	14.52	15.52	16.52	17.52	18.52	19.52
Discount factor	0.50	0.44	0.39	0.34	0.30	0.26	0.23	0.21	0.18	0.16	0.14	0.12	0.11	0.10	0.08
Net Present Value FCFF	-10	7	16	22	24	25	26	27	27	25	23	9	3	1	0

DCF calculation	
Sum NPV FCFF	222
Terminal value	0
DCF value	222
No shares (fully diluted)	22
Value per share	10

Source: Company data and Nordea estimates

We provide sensitivity tables below, showing how changes in assumptions would impact Tesomet's potential peak sales and NPV value on a per-share basis in this indication.

PEAK SALES (USDm): PRICING VS PENETRATION

		Annual treatment costs in the US				
		35,000	60,000	85,000	110,000	135,000
Peak penetration in the US	20%	43	73	103	134	164
	25%	53	91	129	167	205
	30%	64	109	155	201	246
	35%	74	128	181	234	287
	40%	85	146	207	267	328

Source: Nordea estimates

PEAK SALES (USDm): PRICING VS PRICE HIKES

		Annual treatment costs in the US				
		35,000	60,000	85,000	110,000	135,000
Annual price increase	0.0%	47	81	115	149	183
	1.5%	55	94	134	173	213
	3.0%	64	109	155	201	246
	4.5%	74	126	179	232	284
	6.0%	85	146	207	267	328

Source: Nordea estimates

VALUE PER SHARE (SEK): RISK-ADJ. VS PRICING

		Annual treatment costs in the US				
		35,000	60,000	85,000	110,000	135,000
Risk-adjusted sales	5%	-2	-1	1	2	3
	10%	0	3	5	8	11
	15%	2	6	10	14	18
	20%	4	9	15	20	26
	100%	35	63	90	118	146

Source: Nordea estimates

VALUE PER SHARE (SEK): RISK-ADJ. VS WACC

		Discount rate (WACC)				
		11.5%	12.5%	13.5%	14.5%	15.5%
Risk-adjusted sales	5%	1	1	1	0	0
	10%	7	6	5	5	4
	15%	12	11	10	9	8
	20%	18	16	15	13	12
	100%	111	100	90	82	74

Source: Nordea estimates

Tesomet in obesity

While the geographical target market is clear in Prader-Willi syndrome (US and EU), potential Tesomet sales in obesity are more uncertain to model, as the company has not signed any deals with pharmaceutical partners on Tesomet besides the deal with Medix in Mexico and Argentina. Hence, modelling sales potential based on a bottom-up approach in each country/market is more uncertain at this point.

The revenue model below shows projected sales and royalties in Mexico and Argentina. We use the same assumptions as in our Tesofensine revenue model on pricing and treatment potential. Hence, the additional inputs in the model are assumptions on penetration, risk-adjustment and royalty rate.

TESOMET REVENUE MODEL FOR OBESITY – MEXICO AND ARGENTINA COMBINED SALES

Obesity - Medix	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Obese population ('000)	34,759	35,454	36,163	36,886	37,624	38,377	39,144	39,927	40,726	41,540	42,371	43,218	44,083
Growth		2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Obesity prevalence													
Treated	4.6%	4.6%	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)	1,604	1,636	1,668	1,702	1,736	1,771	1,806	1,842	1,879	1,917	1,955	1,994	2,034
Tesomet penetration	5%	10%	15%	20%	25%	30%	30%	30%	30%	30%	30%	20%	10%
No treated ('000)	80	164	250	340	434	531	542	553	564	575	586	399	203
Cost, USD, daily	2.2	2.3	2.3	2.4	2.5	2.5	2.6	2.7	2.8	2.9	2.9	2.9	2.9
Cost, USD, annually	399	411	423	436	449	462	476	491	505	520	536	536	536
Price increase	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	0%	0%
Tesomet sales, USDm	32	67	106	148	195	246	258	271	285	299	314	214	109
Risk-adjustment	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%
Risk-adj. sales, USDm	13	27	42	59	78	98	103	108	114	120	126	86	44
Risk-adj. sales, SEKm	111	234	369	516	678	855	898	943	991	1,041	1,094	744	379

Source: Nordea estimates

Regarding sales in markets outside Mexico and Argentina, we expect Saniona will out-licence Tesomet in obesity to a commercial partner prior to launch, in line with the company's strategy with Tesomet in the metabolic field. Potential sales regions mainly include other South American markets as well certain Asian markets, as Saniona focuses on positioning Tesomet in Prader-Willi syndrome and hypothalamic obesity in the US and the EU. Otherwise, there would be a commercial pricing issue, with a substantial pricing difference across indications (USD 365 per year in obesity versus USD ~85,000 in PWS).

TESOMET REVENUE MODEL FOR OBESITY – OTHER MARKETS

Obesity - Non-Medix	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Obese population ('000)	10,000	10,100	10,201	10,303	10,406	10,510	10,615	10,721	10,829	10,937	11,046	11,157	11,268
Growth		1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Obesity prevalence													
Treated	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.
Treatment potential ('000)	200	202	204	206	208	210	212	214	217	219	221	223	225
Tesomet penetration	5%	10%	15%	20%	25%	30%	30%	30%	30%	30%	30%	20%	10%
No treated ('000)	10	20	31	41	52	63	64	64	65	66	66	45	23
Cost, USD, daily	2.2	2.3	2.3	2.4	2.5	2.5	2.6	2.7	2.8	2.9	2.9	2.9	2.9
Cost, USD, annually	399	411	423	436	449	462	476	491	505	520	536	536	536
Price increase	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%	0%	0%
Tesomet sales, USDm	4	8	13	18	23	29	30	32	33	34	36	24	12
Risk-adjustment	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%
Risk-adj. sales, USDm	2	3	5	7	9	12	12	13	13	14	14	10	5
Risk-adj. sales, SEKm	14	29	45	63	81	101	106	110	114	119	124	83	42

Source: Nordea estimates

We estimate Tesomet will generate up to USD 350m in non-risk-adjusted peak sales in obesity. We set a 40% approval probability and assume the royalty rate in the Medix deal to be the same as with Tesofensine (17.5%), while we anticipate Saniona to retain 30% in other markets, as Saniona at that time has built an improved data

package for Tesofensine and Tesomet to strengthen the company's negotiation power with partners. Our forecasts translate into SEK ~230m in royalties in 2033E.

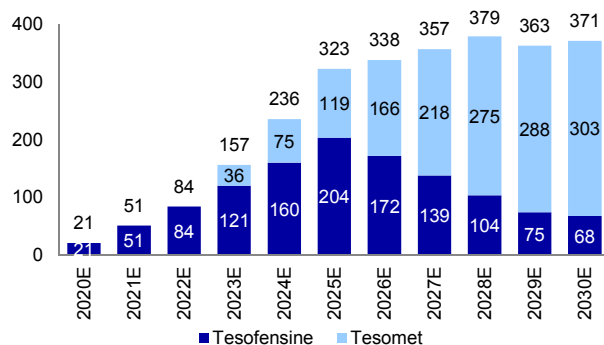
TESOMET COMBINED REVENUE AND ROYALTY FORECASTS IN OBESITY

Tesomet obesity	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Sales, USDm	36	75	119	166	218	275	288	303	318	333	350	238	121
Mexico and Argentina	32	67	106	148	195	246	258	271	285	299	314	214	109
Other markets	4	8	13	18	23	29	30	32	33	34	36	24	12
Risk-adjustment	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%
Risk-adj. sales, USDm	14	30	48	67	87	110	115	121	127	133	140	95	48
Risk-adj. sales, SEKm	127	266	418	585	768	967	1,015	1,065	1,118	1,173	1,232	837	426
Royalty rate, Medix	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%
Royalty rate, Other markets	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
Royalties, SEKm	24	50	79	110	145	182	191	200	210	220	231	157	80
Mexico and Argentina	20	41	65	91	120	151	159	167	175	184	194	132	67
Other markets	4	9	14	19	25	31	32	33	35	36	38	25	13

Source: Company data and Nordea estimates

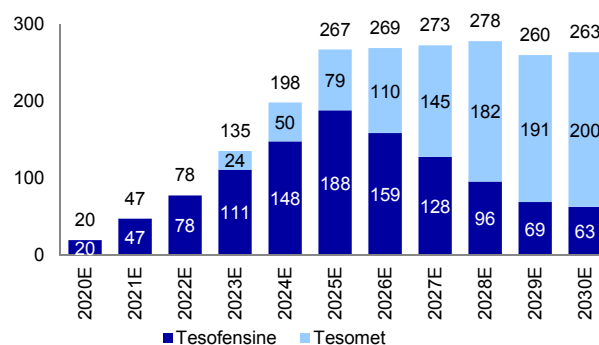
As indicated in the charts below, we forecast Saniona/Medix will drive patient switching from Tesofensine to Tesomet, offsetting the patent cliff for Tesofensine in 2025E-26E, and hence expect Saniona to maintain sales levels until Tesomet's patent expires.

SANIONA COMBINED OBESITY SALES (USDm)



Source: Nordea estimates

SANIONA COMBINED OBESITY ROYALTIES (SEKm)



Source: Nordea estimates

Tesomet sales in obesity are incorporated into a DCF model below.

TESOMET DCF ANALYSIS: OBESITY

SEKm	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E
Royalties	24	50	79	110	145	182	191	200	210	220	231	157	80	73	66
Tesomet, Mex+Arg	20	41	65	91	120	151	159	167	175	184	194	132	67	62	56
Tesomet, Other markets	4	9	14	19	25	31	32	33	35	36	38	25	13	12	10
Other income	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total revenues	24	50	79	110	145	182	191	200	210	220	231	157	80	73	66
Operating expenses:															
COGS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
R&D	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
S&D	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Admin	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Operating income	24	50	79	110	145	182	191	200	210	220	231	157	80	73	66
Tax	-5	-11	-17	-24	-32	-40	-42	-44	-46	-48	-51	-35	-18	-16	-15
Tax rate	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%
Free cash flow (FCFF)	19	39	62	86	113	142	149	156	164	172	180	122	62	57	52
Years	5.52	6.52	7.52	8.52	9.52	10.52	11.52	12.52	13.52	14.52	15.52	16.52	17.52	18.52	19.52
Discount factor	0.50	0.44	0.39	0.34	0.30	0.26	0.23	0.21	0.18	0.16	0.14	0.12	0.11	0.10	0.08
Net Present Value FCFF	9	17	24	29	34	38	35	32	30	27	25	15	7	5	4

DCF calculation	
Sum NPV FCFF	332
Terminal value	0
DCF value	332
No shares (fully diluted)	22
Value per share	15

Source: Nordea estimates

The forecasts and DCF valuation are subject to assumptions on many parameters. The sensitivity tables below shows how changes in underlying assumptions would impact Tesomet's NPV value in obesity.

VALUE PER SHARE (SEK): RISK-ADJ. VS PRICING

		Price per day (USD)				
		1.0	1.5	2.0	2.5	3.0
Risk-adjusted sales	20%	4	6	8	9	11
	30%	6	8	11	14	17
	40%	8	11	15	19	23
	60%	11	17	23	28	34
	100%	19	28	38	47	56

Source: Nordea estimates

VALUE PER SHARE (SEK): RISK-ADJ. VS WACC

		Discount rate (WACC)				
		11.5%	12.5%	13.5%	14.5%	15.5%
Risk-adjusted sales	10%	5	4	4	3	3
	20%	9	8	8	7	6
	40%	19	17	15	14	12
	60%	28	25	23	20	18
	100%	46	42	38	34	31

Source: Nordea estimates

Market overview: Eating disorders

Eating disorders are characterised by inadequate or excessive food intake and severe distress or concern about body weight or shape. This section describes the various obesity-related eating disorders that Saniona pursues or might pursue in the future. These include Prader-Willi syndrome, hypothalamic obesity and binge eating.

Eating disorders

Eating disorders is the common term for illnesses that are characterised by irregular eating habits and severe distress or concern about body weight or shape. While some are genetically explained, others can develop during childhood or in adults due to for example, brain damage or various psychological causes. Humans with eating disorders typically have an inadequate or excessive food intake, which, ultimately, can damage their well-being and be fatal. In this section, we focus on eating disorders related to excessive food intake (ie, obesity-related eating disorders), as patients with these conditions may benefit by treatment with Saniona's Tesomet. These include:

- Prader-Willi syndrome
- Hypothalamic obesity
- Binge eating

SELECTED OBESITY-RELATED EATING DISORDERS

	Prader-Willi syndrome	Hypothalamic obesity	Binge eating
Prevalence	1 in 15,000	1 in 50,000	2,800,000
High unmet medical need	Yes	Yes	Yes
Orphan disease	Yes	Yes	No
Rare paediatric disease	Yes	No	No
Potential for PRV	Yes	No	No

Source: Company data and Nordea

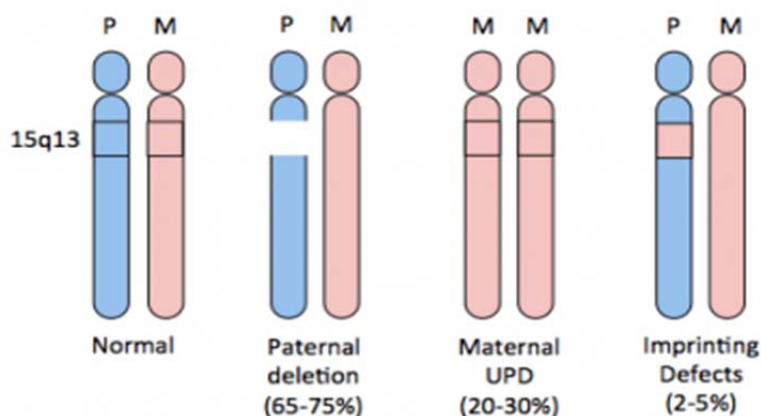
While both Prader-Willi syndrome and hypothalamic obesity are orphan diseases – thus with a potential to obtain orphan drug status, a rapid path to the market and premium pricing – binge eating is a more common disease seen among all age groups, and patients are not necessarily obese, though the binge eating episodes lead to weight gain. All the eating disorders are mental health disorders that affect a person's thinking, behaviour, and physical well-being, but to varying degrees.

Prader-Willi syndrome

Prader-Willy syndrome (PWS) is a complex genetic disorder affecting appetite, metabolism, cognitive function and behaviour. PWS is associated with changes in the inherited chromosome 15 from the father (paternal chromosome 15). The genetic defect causing this can occur in three ways:

- 1) PWS by deletion. Most often, the chromosome 15 that was inherited from the father is missing or deleted in this region.
- 2) PWS by maternal uniparental disomy (Maternal UPD). Another 20-30% of cases occur when the entire chromosome from the father is missing and there are two chromosome 15's from the mother present instead.
- 3) PWS by imprinting mutation. Finally, a small genetic mutation causes the paternal chromosome 15 genetic material to be inactive.

PRADER-WILLI SYNDROME: GENETIC MECHANISMS



Source: Prader-Willi Syndrome Association USA

The critical paternal genes lacking in patients with PWS play an important role in many bodily functions, including regulating hunger and satiety (ie the state achieved when the need for food has been satisfied). While the problem is not yet fully understood, patients with PWS never feel full; they suffer from a constant, uncontrollable extreme urge to eat (hyperphagia) that persists no matter how much they eat. To make things worse, they need less food than people without the syndrome because their bodies have less muscle and tend to burn fewer calories (~800 calories per day). As a result, patients with PWS typically become morbidly obese and suffer significant mortality..

Besides the eating problems, PWS is characterised by behavioural problems, including impaired speech and language, sudden mood changes, temper tantrums, stubbornness, aggression, and difficulties coping with changes in the daily routine. The behavioural problems are reported to worsen with age and are especially pronounced in adulthood. Patients also tend to have cognitive impairment, usually mild to moderate mental retardation.

PRADER-WILLI SYNDROME IN DEVELOPMENT: APPETITE AND WEIGHT GAIN

Phase	Median age	Characteristics
0	Utero	Decreased foetal movement and lower birth weight than normal foetuses
1a	0-9 months	Hypotonia and difficulty feeding with or without failure to thrive
1b	9-25 months	Improved growth and weight increases at a normal rate
2a	2.1-4.5 years	Weight increases without a change in appetite or caloric intake
2b	4.5-8 years	Weight gain is associated with an increased interest in food
3	8 years	Hyperphagia, food-seeking and rarely feeling full

Source: Nutritional Phases in Prader-Willi Syndrome, NCBI 2012, and Nordea

The symptoms change over time: the extreme hunger and food obsession most commonly begin to surface between ages three and eight years old, whereas the behavioural problems start in the teens.

Rare disease with high unmet medical need

Although prevalence estimates differ between studies, the birth incidence is around one in 15,000 to one in 25,000 in the US and Europe. To put it into perspective, one in 700 babies are born with Down syndrome – ie Down syndrome is about 20-30 times more likely to occur than PWS. PWS is not gender-specific and affects both sexes with approximately the same frequency across all races and ethnicities worldwide. Given its prevalence and onset at birth, PWS is both a rare paediatric disease and an orphan disease.

Currently, treatments available for PWS only manage to treat the symptoms as they arise; there is no cure and there are no effective pharmacological treatments for the underlying causes. PWS patients may benefit from human growth hormone (HGH) treatment, which helps by not only improving growth during childhood, adult height, and body composition but also by increasing muscle mass and possibly cognition, thus improving patients' lives as they feel better and stronger.

While HGH has many benefits in PWS patients, challenging symptoms associated with PWS remain difficult to treat – the inability to control hunger and food intake, in particular. No medication has proved effective in regulating appetite in patients with PWS. Hence, strict control, limited access to food (including padlocking food storage), diet and round-the-clock supervision by a caretaker or family member are the only ways to prevent life-threatening overeating and extreme obesity at present. PWS patients left unattended will continuously seek, steal and consume any obtainable food, including unprepared, raw meat, which thus has severe consequences that affect not only patients but also their families and carry a very high cost to payers and society.

Bariatric surgery, such as gastric banding or bypass, has generally proved to be a very effective treatment option in the general obese population. However, it has not been shown to reduce food obsession or achieve long-term weight reduction in PWS patients. The treatment is generally contraindicated in PWS patients, given that patients exhibit a low sensitivity to pain and a chronic and continuous urge to eat to the point whereby they can rupture their stomachs.

Anti-obesity drugs might benefit the PWS population owing to their weight loss properties and potential effect on satiety. Only a few clinical trials are ongoing in this disease at present, including two HGH agents in ph III.

ONGOING CLINICAL TRIALS IN PRADER-WILLI SYNDROME

Phase	Product	Generic name	Company	Therapy
3	Eutrophine	somatropin recombinant	LG Chem	HGH
3	CinnaTropin	somatropin recombinant	CinnaGen	HGH
3	DCCR	diazoxide choline	Soleno Therapeutics	KATP channel
2	GLWL-01	-	Eli Lilly	Unclassified
2	Setmelanotide	setmelanotide	Rhythm Pharmaceuticals	MC4R
2	Cannabidiol	cannabidiol	Insys Therapeutics	Cannabinoid
2	Livoltide	livoltide	Millendo Therapeutics	Ghrelin agonist
2	Tesomet	tesofensine; metoprolol	Saniona	Triple reuptake inhibitor

Source: Company data, clinicaltrials.gov, EvaluatePharma and Nordea

HGH = Human Growth Hormone; DCCR = Diazoxide Choline Controlled Release; KATP channel = ATP dependent potassium channel activator; MC4R = Melanocortin-4 receptor agonist

Besides HGH agents, Saniona is up against a US based company called Soleno Therapeutics with a product in ph III and other US based biotech companies, such as Rhythm Pharmaceuticals, Millendo Therapeutics and Insys Therapeutics.

Hypothalamic obesity

The hypothalamus is located in the brain and controls and regulates important biological functions, including body temperature and hunger. Hypothalamic obesity is a rare disease that can occur from damage to the hypothalamus, either from brain tumours in this region, surgery or radiation therapy. The most common damage to the hypothalamus is caused by craniopharyngioma, a rare (estimated to affect around one in 50,000 people in the US) slow-growing tumour in the brain found near the pituitary gland and the hypothalamus, most commonly occurring in children between five and ten years old.

HYPOTHALAMIC REGION



Source: Company data

While craniopharyngioma is a benign tumour (not cancerous) and does not spread beyond this area, its location in the brain can affect the immune and endocrine systems, leading to delayed development, impaired vision and headache, among other conditions; hence, it needs treatment. The current treatment for craniopharyngioma involves surgical intervention to remove the tumour followed by subsequent radiation therapy. The procedure can lead to complications, including damage to the hypothalamus, resulting in insatiable hunger and morbid obesity. This has been reported to occur in some 30-77% of patients following treatment.

Hypothalamic obesity has several things in common with Prader-Willi syndrome, including clinical symptoms, clinical trial design and potential orphan drug designation. Both Prader-Willi syndrome and hypothalamic obesity are characterised by insatiable hunger (hyperphagia) and obesity. Hypothalamic obesity is thus often referred to as "acquired PWS" and patients should benefit from the same treatment as PWS patients.

Binge eating

Whereas both PWS and hypothalamic obesity are orphan diseases, binge eating is a more common disease seen among all age groups, middle-aged women in particular. Binge eating disorder is the most common eating disorder in the US and is estimated to affect 2.8 million people in the US alone, although the exact prevalence is difficult to estimate, as patients with eating disorders often suffer in silence.

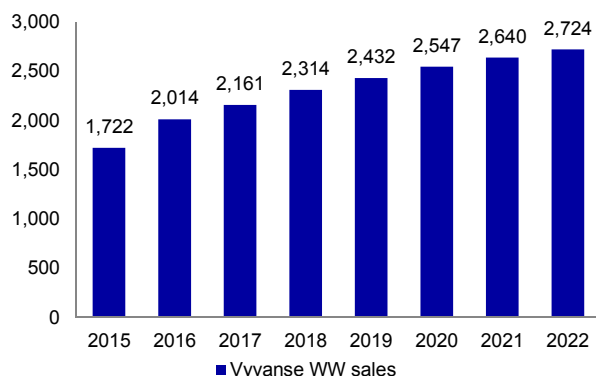
The disease is characterised by recurrent eating episodes in which people eat excessive amounts of food in a single setting at a rapid pace and lose control during the binge (eg a feeling that one cannot stop eating or control what or how much he/she is eating). These episodes occur at least once a week for three months or longer.

Unlike PWS and hypothalamus obesity, patients with binge eating are not necessarily obese and could appear to be of normal weight and hence successfully hide their illness. Similar to anorexia, binge eating disorder is a mental health disorder that affects a person's thinking, behaviour and physical well-being, with individuals feeling guilt, shame, distress, anxiety or even depression following a binge eating episode.

Current treatment options are aimed at reducing eating binges and, where necessary, weight loss. As it is a mental illness associated with negative emotions, such as guilt, shame and poor self-image, treatment may typically also address psychological issues through psychotherapy.

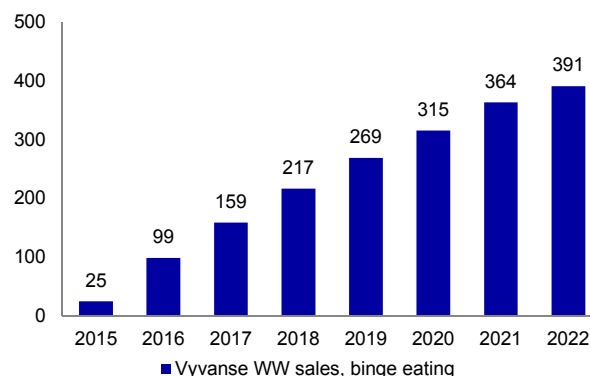
Shire's Vyvanse (an amphetamine and stimulant) is currently the only FDA-approved product to treat moderate to severe binge eating disorder. Initially launched in attention deficit hyperactivity disorder (ADHD) in 2007, it gained approval in binge eating in 2015, and sales are expected to hit around USD 400m in binge eating alone.

VYVANSE FORECASTS (USDm)



Source: Company data, EvaluatePharma and Nordea

VYVANSE FORECASTS IN BINGE EATING (USDm)



Source: Company data, EvaluatePharma and Nordea

Being an amphetamine, Vyvanse can, however, be habit-forming and abused, and serious adverse events and side effects can occur (black-box warning).

ONGOING CLINICAL TRIALS IN BINGE EATING

Phase	Product	Generic name	Company	Therapy
3	Saxenda	liraglutide	Novo Nordisk	GLP-1
3	Dasotraline	dasotraline hydrochloride	Sumitomo Dainippon Pharma	Triple reuptake inhibitor
3	HLD-900	amphetamine	Highland Therapeutics	Amphetamine
3	Narcan	naloxone hydrochloride	Opiant Pharmaceuticals	Opioid receptor
2	Trintellix	vortioxetine hydrobromide	Takeda	Antidepressant

Source: Company data, clinicaltrials.gov, EvaluatePharma and Nordea

Other drugs may help reduce symptoms, including antidepressants or anti-obesity drugs, in addition to cognitive behavioural therapy.

Market overview: Obesity

The market for anti-obesity drugs is still in the development phase. Nevertheless, the statistics are clear: obesity is a global burden that has reached epidemic proportions, with high prevalence rates across the US, Europe and RoW; the global healthcare costs related to obesity complications are massive; and the correlation with diseases such as type II diabetes and cardiovascular disease is evident. Expanding the obesity market and the patient base, educating physicians, improving the reimbursement situation across markets and changing the treatment paradigm remain crucial to commercial success for anti-obesity drugs.

Obesity is a global health epidemic

Overweight and obesity are conditions in which people have abnormal or excessive fat accumulation that may impair health. The body mass index (BMI) is a tool commonly used to classify overweight and obesity in adults. BMI is defined as a person's weight in kg divided by his/her height in metres squared (kg/m^2). Overweight is a BMI greater than or equal to 25 ($\text{BMI} \geq 25$), while obesity is a BMI greater than or equal to 30. This may, however, vary depending on geography, with some Asian countries applying lower thresholds.

As we describe in detail in this section, the obesity market is still in the development phase and patients and society face many problems, including the following:

- Patients with obesity lack treatment options, as physicians are not taught how to treat it;
- Funding and reimbursements are a hurdle for physicians and patients, despite obesity's correlation with, in particular, type II diabetes and cardiovascular disease;
- Patients with obesity engage in several serious weight loss attempts, but only a few are able to maintain the weight off;
- Most patients with obesity and the general public consider weight loss to be a person's own responsibility completely, which may prevent them from seeking help from a healthcare professional;
- Global healthcare costs related to obesity complications are expected to increase by 50% by 2025 to USD 1.2tn, primarily driven by obesity-related comorbidities such as type II diabetes and cardiovascular disease;
- Significantly more people are obese globally (~700 million) than have diabetes (~415 million).

OBESITY – THE REALITY



It is a significant cost burden for society



There is no specialty managing it



Physicians are not taught how to treat it



Patients are discriminated against for being obese



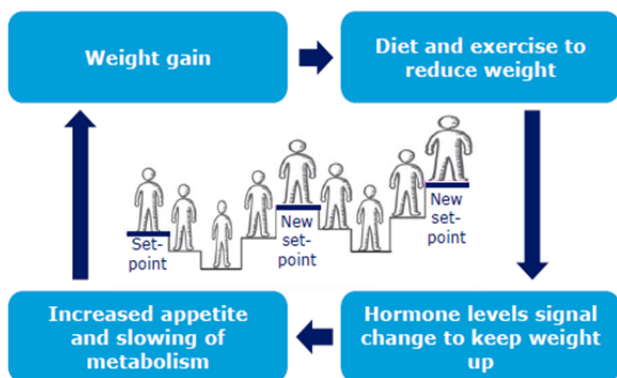
Patients lack treatment options

Source: Novo Nordisk

The problem with obesity from an individual's perspective is portrayed below. Several studies have shown that body weight is maintained at a stable range (set point), and as soon as the body weight deviates from this through diet and exercise, the body will do everything it can to get back to the original weight and fat level by regulating appetite and adjusting the basal metabolic rate.

OBESITY IS A CHRONIC DISEASE THAT REQUIRES TREATMENT

The set-point theory portrays how metabolic changes affect the ability to lose weight



The body fights weight loss for people with obesity

- The body "remembers" its highest body weight and defends this body weight as the "new normal weight"
- During weight loss, changes occur in appetite-regulating hormones, which increase hunger
- If people with obesity do not eat enough, the hormones trigger the body to conserve energy
- Changes in hormones persist for at least 5-10 years following weight loss

Source: Novo Nordisk

Looking at the development in obesity across countries, it has risen to epidemic proportions. The World Health Organization (WHO) estimates that more than 1.9 billion adults were overweight worldwide in 2014, including roughly 650 million obese adults and more than 100 million children. Estimates vary depending on the source, but the prevalence is in this ballpark.

The table below shows the development in obesity among adults, clearly highlighting that obesity has sky-rocketed since 1980.

DEVELOPMENT IN NO. OF ADULTS WITH OBESITY (MILLIONS)

Country	1980	1985	1990	1995	2000	2005	2010	2015
Argentina	3.4	3.5	3.6	4.1	4.8	5.2	5.9	6.8
Australia	1.7	1.7	1.8	2.1	2.8	3.6	4.7	5.3
Brazil	5.9	7.6	9.2	10.5	13.3	19.0	26.8	32.2
Canada	2.0	2.2	2.5	3.4	4.1	4.9	5.3	5.8
China	3.2	5.8	8.9	12.7	21.6	31.9	41.5	56.7
France	2.9	3.3	3.5	4.0	4.8	6.1	7.3	7.8
Germany	5.6	6.2	6.8	8.5	10.5	12.0	13.6	14.5
Japan	1.4	1.5	1.9	2.6	3.2	3.1	3.1	3.0
Mexico	5.4	7.1	9.0	11.4	13.7	16.2	19.8	22.9
United Kingdom	6.5	6.6	6.9	7.7	9.1	10.6	11.7	12.1
United States	20.4	22.4	28.1	38.0	51.7	65.9	77.1	80.7
Global	169.0	195.7	228.4	275.5	350.2	431.4	523.6	609.1

Source: The Global Burden of Disease Study 2015 and Nordea

Contrary to popular belief, obesity is not a health issue confined to the US. While the US tops obesity rankings, a high prevalence is also found in many countries in Europe, as well as in, for example, Mexico, Australia, Brazil and oil-rich countries in the Gulf, such as Kuwait, Saudi Arabia, Qatar, Bahrain and the UAE.

DEVELOPMENT IN OBESITY PREVALENCE AMONG ADULTS

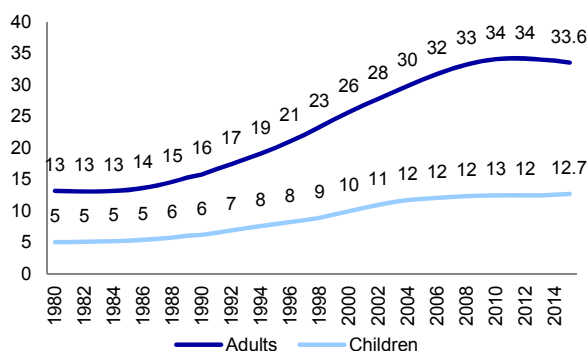
Country	1980	1985	1990	1995	2000	2005	2010	2015
Argentina	19.6%	19.0%	18.3%	19.2%	20.5%	20.5%	21.9%	23.2%
Australia	17.2%	15.6%	14.9%	16.1%	20.1%	23.9%	28.2%	28.8%
Brazil	9.6%	10.6%	11.2%	11.3%	12.6%	15.9%	20.4%	22.6%
Canada	12.3%	12.0%	12.6%	15.8%	18.0%	20.0%	20.1%	20.5%
China	0.6%	1.0%	1.3%	1.6%	2.5%	3.5%	4.1%	5.3%
France	7.8%	8.4%	8.6%	9.4%	10.8%	13.2%	15.4%	15.7%
Germany	9.8%	10.5%	10.9%	13.3%	16.2%	18.3%	20.5%	20.9%
Japan	1.8%	1.8%	2.1%	2.7%	3.2%	3.1%	3.0%	2.8%
Mexico	17.6%	20.0%	21.4%	22.9%	24.1%	25.5%	27.7%	28.6%
United Kingdom	16.3%	16.0%	16.2%	17.9%	20.7%	23.4%	24.7%	24.3%
United States	13.2%	13.4%	15.8%	20.0%	25.7%	30.9%	34.1%	33.6%
Global	7.0%	7.2%	7.5%	8.1%	9.4%	10.6%	11.7%	12.5%

Source: The Global Burden of Disease Study 2015 and Nordea

The obesity pandemic is not as high in Asian countries like China, India and Japan relative to their US and EU counterparts. Nevertheless, it is still a big problem socially and economically in those countries. Indeed, recent studies show that the obesity prevalence has doubled in more than 70 countries since 1980. These findings mirror similar global trends in type II diabetes.

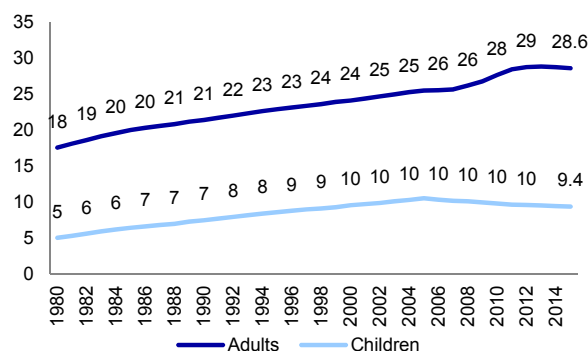
From 1980 to 2015, a significant increase in obesity occurred in both adults and children. The graphs below illustrate the development in obesity prevalence in the US and Mexico. The latter is the market in which Saniona is seeking approval for its anti-obesity drug Tesofensine.

DEVELOPMENT IN OBESITY IN THE US (%)



Source: The Global Burden of Disease Study 2015 and Nordea

DEVELOPMENT IN OBESITY MEXICO (%)



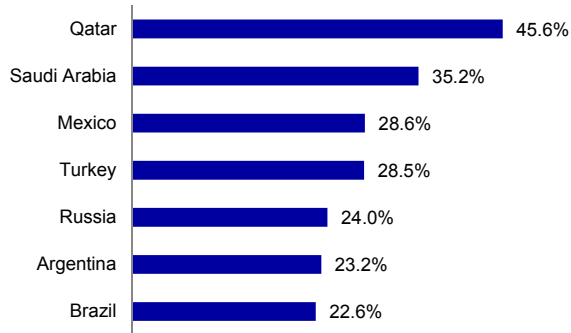
Source: The Global Burden of Disease Study 2015 and Nordea

Although the development in the US and Mexico has been flattish recently, it is still increasing in absolute terms, given the growing population.

Development in Asia and South America

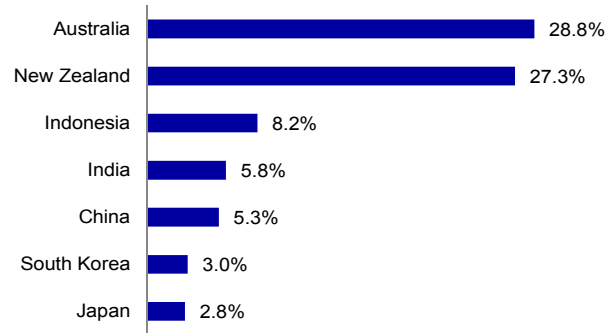
Looking at obesity rates outside the US and Europe, many RoW countries have obesity prevalence above 20%, suggesting that Saniona – in collaboration with pharmaceutical partners – could target several markets with its anti-obesity drugs Tesofensine and Tesomet.

OBSESITY PREVALENCE IN RoW



Source: The Global Burden of Disease Study 2015 and Nordea

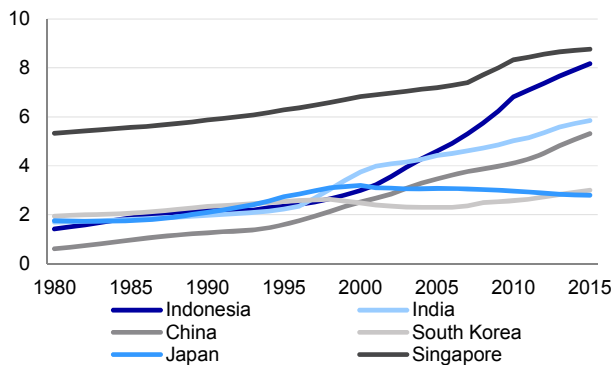
OBSESITY PREVALENCE IN ASIA-PACIFIC



Source: The Global Burden of Disease Study 2015 and Nordea

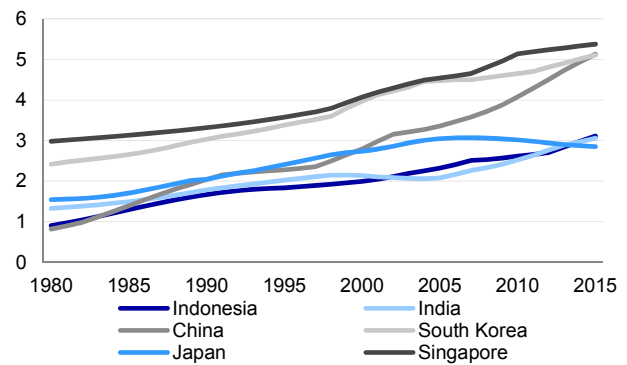
While countries in the Asia-Pacific region, ie countries like China, India and Japan, are currently showing lower obesity prevalence rates than more developed countries, this hides important disparities between urban and rural demography characteristics and masks an alarming increase in childhood obesity. In India and China, for example, the obesity rates in cities are three to four times higher than in rural areas, reflecting higher incomes in urban areas, higher food consumption, less active labour, more office jobs and more access to fast food. The developing, middle-income countries like India and Indonesia have seen obesity more than double among their youth populations, while China's has sextupled.

DEVELOPMENT IN ASIA, ADULTS (%)



Source: The Global Burden of Disease Study 2015 and Nordea

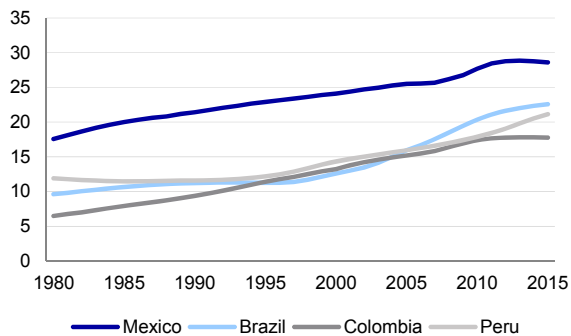
DEVELOPMENT IN ASIA, CHILDREN (%)



Source: The Global Burden of Disease Study 2015 and Nordea

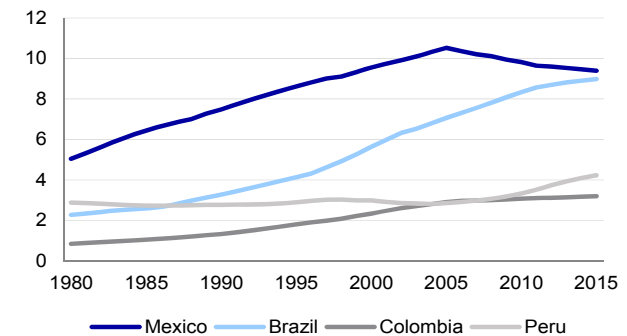
The population in several South American countries, such as Mexico, Argentina and Brazil are also experiencing an obesity epidemic, with a rising trend.

DEVELOPMENT IN LAT-AM, ADULTS (%)



Source: The Global Burden of Disease Study 2015 and Nordea

DEVELOPMENT IN LAT-AM, CHILDREN (%)

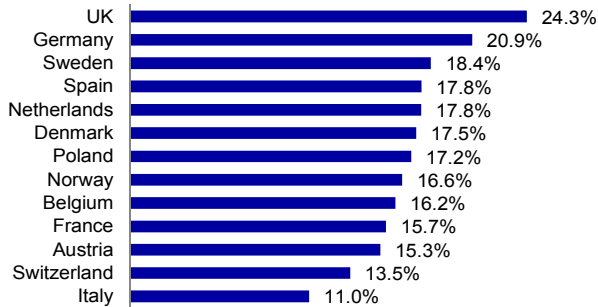


Source: The Global Burden of Disease Study 2015 and Nordea

Development in Europe

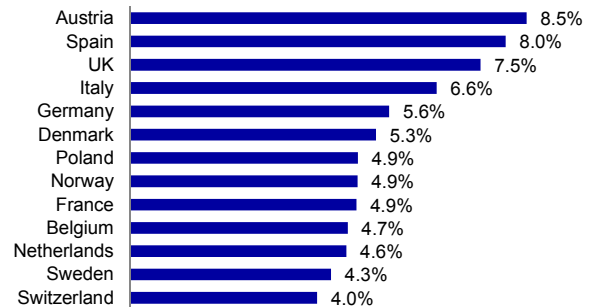
Approximately one in four adults are obese in the UK and one in five in Germany. Indeed, in the more obese European countries, prevalence is now on a par with similar data for the US only 15 years ago; ie it seems that the surge in prevalence is at a parallel rate to the US, indicating what can be expected for several European countries.

OBESITY PREVALENCE IN EUROPE, ADULTS



Source: The Global Burden of Disease Study 2015 and Nordea

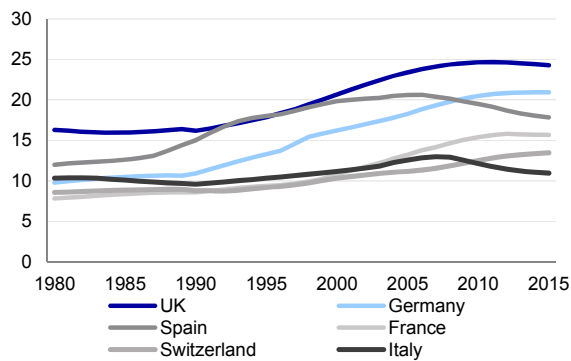
OBESITY PREVALENCE IN EUROPE, CHILDREN



Source: The Global Burden of Disease Study 2015 and Nordea

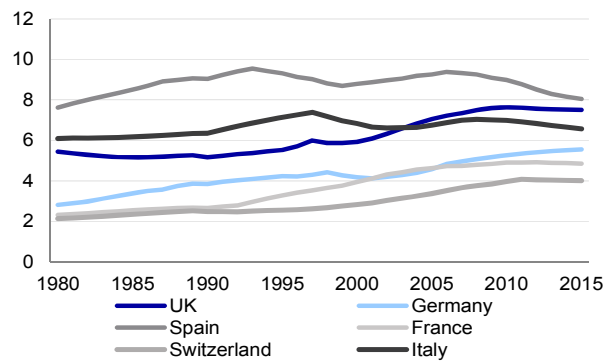
The trends in Europe since 1980 are also similar to those seen in the US, indicating that several European countries have experienced a rise in obesity prevalence, which is expected to increase further, according to OECD projections.

DEVELOPMENT IN EU PREVALENCE, ADULTS



Source: The Global Burden of Disease Study 2015 and Nordea

DEVELOPMENT IN EU PREVALENCE, CHILDREN

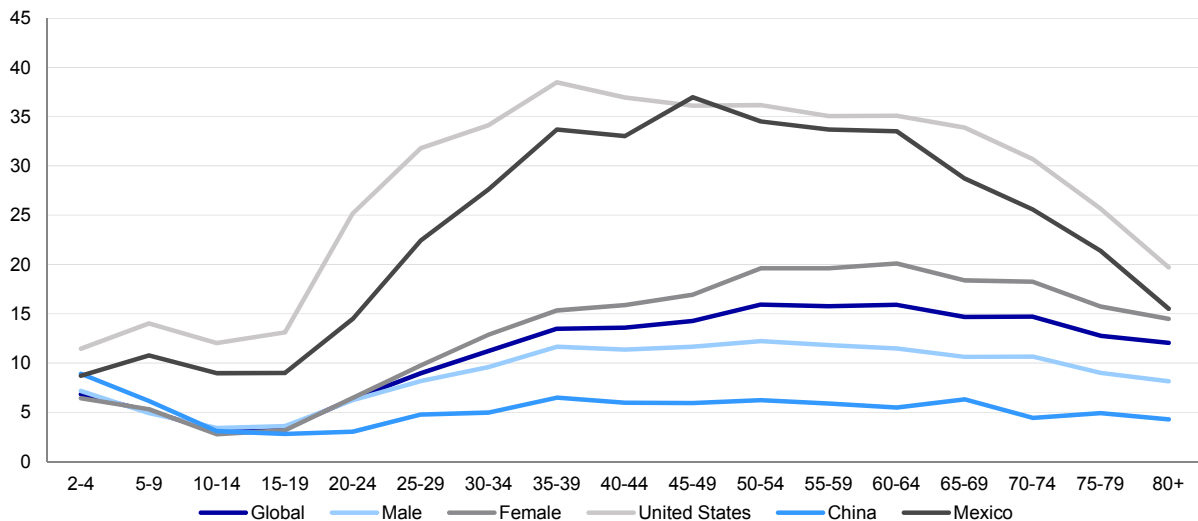


Source: The Global Burden of Disease Study 2015 and Nordea

Obesity prevalence across age group and income levels

Looking at the prevalence across age groups, obesity is more common among women than men in all age brackets. The prevalence seems to increase with age and peak in women when they are between 60 and 64 years and in men when they are between 50 and 54 years. On a country-specific basis, the obesity prevalence in the US has been seen to increase steeply with age and peak between 35 and 39.

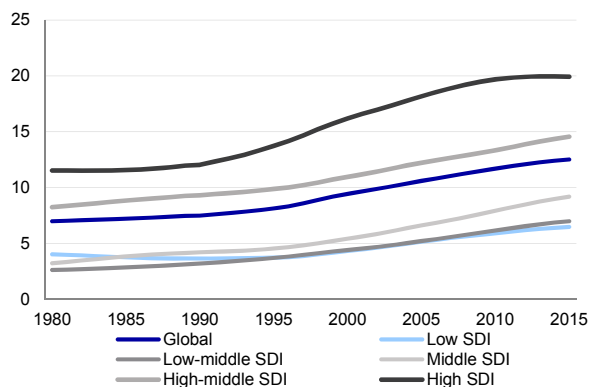
OBESITY PREVALENCE BY AGE GROUP (%)



Source: The Global Burden of Disease Study 2015, NEJM June 2017, and Nordea

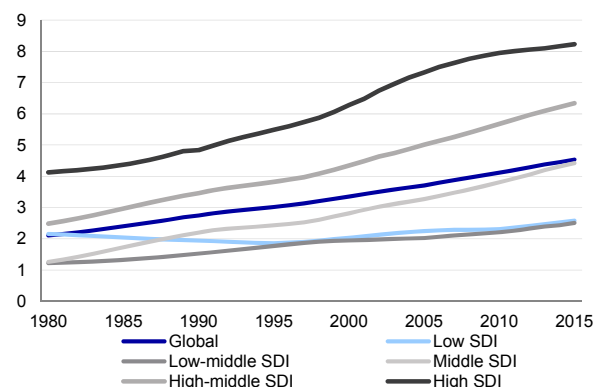
Obesity does appear to be correlated with a country's wealth (see graphs below, based on the SDI index). This is an interesting observation, as global wealth is generally increasing and hence looks set to drive a continued surge in obesity rates in less developed countries.

DEVELOPMENT BY SDI INDEX, ADULTS (%)



Source: The Global Burden of Disease Study 2015, NEJM June 2017, and Nordea

DEVELOPMENT BY SDI INDEX, CHILDREN (%)



Source: The Global Burden of Disease Study 2015, NEJM June 2017, and Nordea

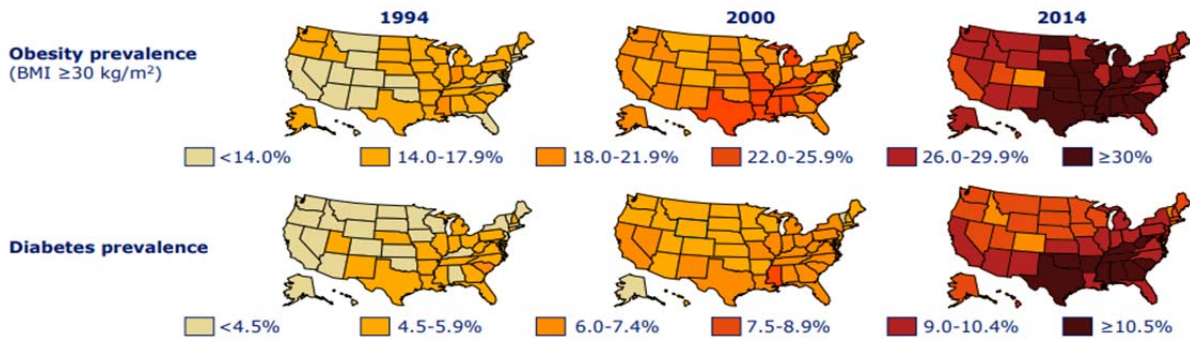
The sociodemographic index (SDI) used in the graphs measures a region's sociodemographic development based on average income per person, educational attainment and total fertility rate (TFR). These measures are ranked on a scale, where a low SDI represents the lowest income per capita, lowest educational attainment and highest TFR observed across all regions from 1980 to 2015, whereas a high SDI represents the highest income per capita, highest educational attainment and lowest TFR. The correlation between a high SDI and increasing obesity is very obvious.

Obesity and diabetes – a co-dependent relationship

The rise in obesity rates and increase in type II diabetes have been closely correlated. A sedentary lifestyle and a high-fat, carbohydrate-rich diet are associated with both type II diabetes and obesity, explaining the co-dependent relationship.

As illustrated below, the development in diabetes prevalence in the US is fuelled by growing obesity prevalence.

OBESITY AND DIABETES PREVALENCE AMONG ADULTS



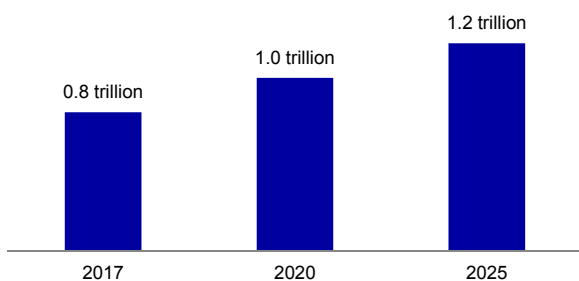
Source: Centre for Disease Control and Prevention

Besides diabetes, there is also a strong relationship between obesity and cardiovascular disease (eg heart attack and stroke), hypertension (high blood pressure), respiratory conditions – and even cancer.

The obesity-related economic and social burden

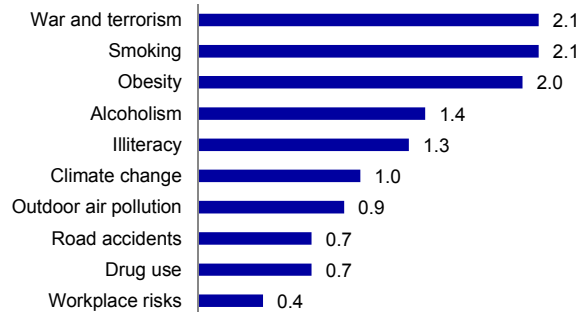
With swelling obesity numbers, the annual economic impact on global GDP and direct medical expenditure in healthcare systems is massive. Global healthcare costs related to obesity complications are expected to increase by 50% by 2025 to USD 1.2tn, primarily driven by obesity-related comorbidities such as type II diabetes and cardiovascular disease. Besides the direct costs for healthcare systems, there are also significant (but less measurable) indirect costs, including costs related to lost productivity.

GLOBAL COSTS RELATED TO OBESITY (USD)



Source: World Obesity Federation and Nordea

GLOBAL ECONOMIC IMPACT ON GDP (USDtn)



Source: McKinsey Global Institute and Nordea

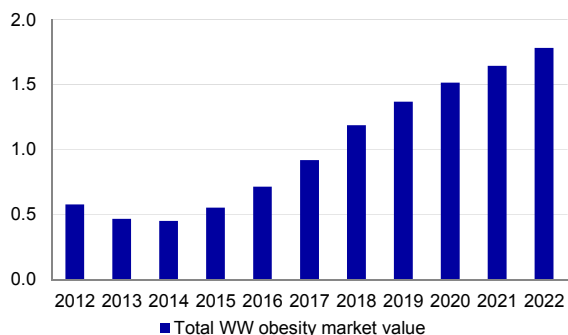
McKinsey Global Institute has estimated that the global economic impact associated with obesity is roughly USD 2tn annually. This places obesity among the leading social burdens, along with smoking and armed violence.

The obesity market is still in the development phase

While the obesity epidemic is a global burden, the global healthcare costs related to obesity complications are massive, and the correlation with diseases such as type II diabetes and cardiovascular disease is evident, the market for anti-obesity agents is still in the development phase.

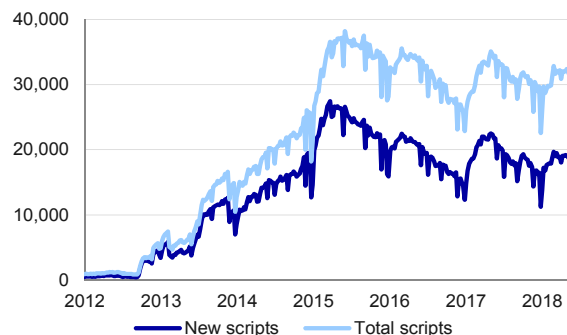
The global obesity market remains small in value terms and represents a clear commercial challenge, with some USD 0.9bn in total sales for existing commercially available anti-obesity prescription drugs.

TOTAL GLOBAL OBESITY MARKET VALUE (USDbn)



Source: Company data, Evaluate Pharma and Nordea

TOTAL MARKET IN US PRESCRIPTIONS PER WEEK



Source: Symphony Health Solutions and Nordea

Although the market has exhibited solid growth rates since the dip in 2014, boosted by new agents entering the market, absolute growth has been relatively muted compared to the growth in other pharmaceutical classes – despite the high obesity population globally (600-700 million people).

Competitive landscape – it is all about building the market

We believe that expanding the branded obesity market is crucial to success for Saniona's anti-obesity drugs (Tesofensine and Tesomet) and any other anti-obesity agents. Hence, the key question is not who can reach the highest market share; it is all about expanding the market, expanding the patient base, educating physicians, improving the reimbursement situation across markets, changing the treatment paradigm and changing the general perception that obesity is a problem that can be controlled solely by diet and exercise.

Zooming in on treatment statistics, less than 5% receive treatment with an anti-obesity medication (AOM). This highlights the high unmet medical need, as there are few effective anti-obesity drugs available and reimbursement for these medications is still limited on a global scale.

THE UNMET MEDICAL NEED IN OBESITY TREATMENT

Only 2% of the 650 million people with obesity are treated with prescription medication



Key barriers to effective obesity management

- Mindset**
 - Belief that obesity is self-inflicted
 - Focus on acute weight loss rather than chronic weight management
- Few prescribers engaged**
 - Physicians not equipped to engage in and treat obesity
- Limited patient access**
 - Funding and reimbursement a hurdle for physicians and patients

Source: Novo Nordisk and IQVIA (formerly IMS) MIDAS 2017

Larger pharmaceutical companies, such as Novo Nordisk, have entered the field. Novo Nordisk is investing heavily in building the market by continuing its global sales efforts, starting with its anti-obesity drug Saxenda (high-dose liraglutide) and over time potentially Semaglutide, and by continuing its efforts in having obesity acknowledged as a chronic disease, thereby expanding the prescriber base. Other larger pharmaceutical companies present in the metabolic and cardiovascular fields have also entered the fray, including Sanofi.

Screening clinical trials and pipelines among other pharmaceutical and biotech companies suggest that obesity is becoming an increasingly important field, with more and more products entering the market in recent years, and also investments in pre-clinical and clinical assets to strengthen their position in a market with more than 700 million obese patients worldwide (versus 415 million with diabetes, for example) and ~15 million with morbid obesity (BMI >40) in the US alone.

All in all, we see a potentially ballooning market for effective anti-obesity drugs: the patient population is big, obesity's correlation with deadly diseases is evident, and the related healthcare costs are substantial. This will not play out in the coming one to two years, however, but is more a long-term source of potential.

News flow in the coming 12-18 months

The coming 12-18 months is an important time for Saniona. It is likely to report ph III top-line results on Tesofensine in obesity and update the market on the next steps for Tesomet. We will also have more insight into NS2359's potential. The triggers start with ph IIa data on NS2359 in Q4 2018, followed by ph IIa data on Tesomet in adolescents with Prader-Willi syndrome. Going into 2019 and 2020, the important catalysts will be ph III topline results on Tesofensine in obesity by early 2019 and regulatory approval in Mexico by late 2019.

Several share price triggers throughout 2018 and 2019

Company-related news flow for the coming 12 months indicates that news flow will be heavy in 2018 and continue into 2019.

SANIONA 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 H2 2018
Q4 2018	Tesomet	Ph 2a results	Prader-Willi syndrome	Results from ph 2a study in adolescents (step 2)
Q4 2018	Tesomet	Ph 1 results	-	Results from ph 1 pharmacodynamic study
Q4 2018	Tesomet	Ph 2a study initiated	Hypothalamic obesity	Saniona plans to start a ph 2a study around Q4 2018
Q1 2019	Tesofensine	Ph 3 results	Obesity	Saniona and its partner Medix expect topline data by early 2019
H1 2019	Tesomet	Ph 2b study initiated	Prader-Willi syndrome	We expect Saniona to start a ph 2b dose-finding study in Prader-Willi
H2 2019	Tesomet	Ph 2b study initiated	Obesity	We expect Saniona to start a ph 2b study in obesity
2018/2019	Pre-clinical	Deal	-	Potential for partnership deals on pre-clinical programmes
2018/2019	Pre-clinical	Deal	-	Potential for spin-outs on pre-clinical programmes
2018/2019	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

Source: Company data and Nordea

We highlight below what we consider the key triggers in Saniona in the coming 12 months:

- **Q4 2018:** Ph IIa interim results on NS2359 in cocaine addiction
- **Q4 2018:** Ph IIa results on Tesomet in Prader-Willi syndrome (adolescents)
- **Q1 2019:** Ph III topline results in obesity for Tesofensine
- **2019-20:** Potential partnership deals announced on Tesomet in metabolic diseases, thereby securing further development in pivotal ph III trials as well as commercialisation agreements across sales regions

During the coming six months, we will know more about NS2359's potential in cocaine addiction and whether the efficacy signals in patients receiving the drug support continued development for the compound in this indication.

News flow on Tesomet is a big trigger during 2018 and 2019

A potentially big value-enhancing trigger would be promising news flow on Tesomet throughout 2018 and 2019; years that look set to bring several updates and answers on this pipeline program.

We are likely to see an update on the next steps for Tesomet in obesity as well as the highly interesting and important orphan drug space, including ph IIa data in Prader-Willi syndrome in adolescents by Q4 2018. We expect the company to initiate ph II trials in obesity (ph IIb), Prader-Willi syndrome (ph IIb) and hypothalamic obesity (ph IIa), for data in either late 2019 or early 2020.

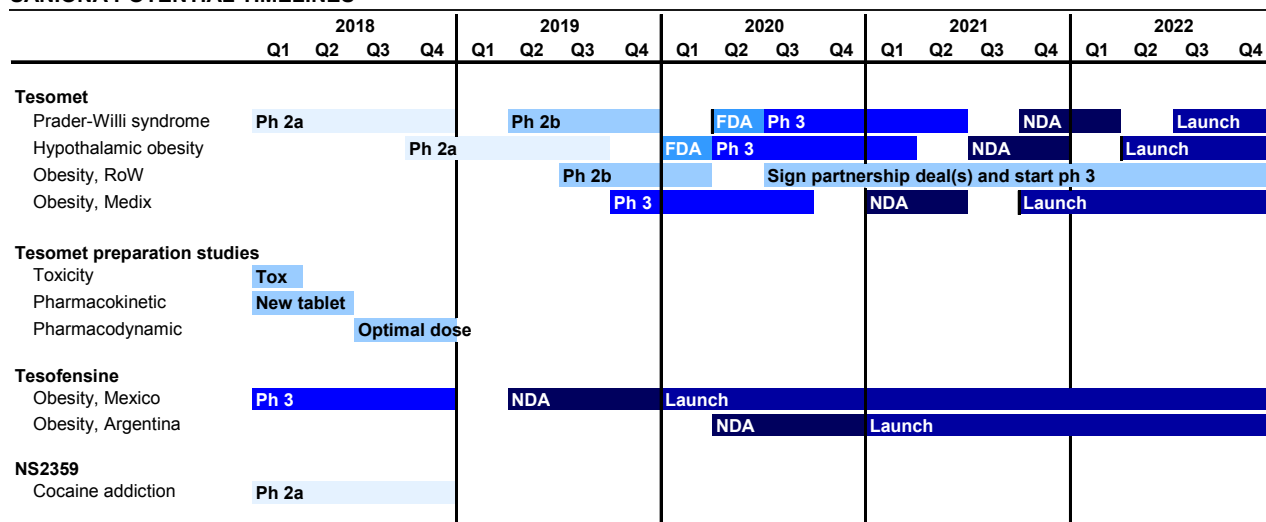
Tesofensine is a key near-term value driver, with ph III topline results expected by early 2019...

Going into 2019, we highly anticipate the upcoming ph III topline results for Tesofensine, which remains a big trigger in the Saniona case as it could be the first pipeline program to potentially reach the commercial stage. The company expects the study to be completed in 2018 for topline data by early 2019 and we believe the clinical data could arrive by early Q1 2019, given that Saniona's partner, Medix, completed recruitment to the trial in January 2018.

...which may provide a positive read-across to Tesomet as well

Being the first pipeline program in Saniona to potentially reach the commercial stage, we view Tesofensine as an important product and value driver for the company, both financially but also sentiment- and de-risking wise. Positive ph III results in this trial will in our view also provide a positive read-across to Tesomet (fixed-dose combination between Tesofensine and Metoprolol), validating the molecule and supporting its potential in obesity, while, at the same time, sharpening the partner interest in the Tesomet program from pharmaceutical companies.

SANIONA POTENTIAL TIMELINES



Source: Company data and Nordea

The timelines illustrated above are obviously subject to board decisions and financial planning, and may change, dependent on clinical trial outcomes and how smooth the process goes with enrolment in clinical trials, discussions with regulators etc.

Appendix 1: Saniona revenue and P&L overview

SANIONA REVENUE AND P&L OVERVIEW

SEKm	2017	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Total revenues	21	49	38	57	47	78	314	303	433	493	536	583	609	659
Growth	N.a.	134%	-22%	52%	-17%	64%	303%	-4%	43%	14%	9%	9%	4%	8%
Product sales and royalties	0	0	0	20	47	78	182	303	433	493	536	583	609	659
Tesofensine, obesity	0	0	0	20	47	78	111	148	188	159	128	96	69	63
Tesomet, Prader-Willi syndrome	0	0	0	0	0	0	47	104	166	224	263	305	349	395
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	24	50	79	110	145	182	191	200
NS2359, CNS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other (milestones/PRV)	21	49	38	38	0	0	132	0	0	0	0	0	0	0
Gross profit	21	49	38	57	47	78	314	302	431	491	533	580	605	655
Gross margin	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	99%	99%	99%
R&D to revenue	207%	103%	213%	244%	105%	64%	16%	17%	12%	10%	9%	9%	8%	8%
In SEK	-43	-50	-80	-140	-50	-50	-50	-50	-50	-50	-50	-50	-50	-50
S&D to revenue	0%	0%	0%	0%	0%	0%	16%	10%	7%	6%	6%	5%	5%	5%
In SEK	0	0	0	0	0	0	-50	-30	-30	-30	-30	-30	-30	-30
Admin & other costs to revenue	169%	72%	93%	70%	95%	58%	14%	15%	10%	9%	8%	8%	7%	7%
In SEK	-35	-35	-35	-40	-45	-45	-45	-45	-45	-45	-45	-45	-45	-45
EBIT	-57	-37	-77	-123	-48	-17	169	177	306	366	408	455	480	530
EBIT margin	-276%	-75%	-206%	-214%	-100%	-22%	54%	58%	71%	74%	76%	78%	79%	80%
PTP	-56	-36	-77	-123	-48	-17	169	177	306	366	408	455	480	530
Net profit	-49	-28	-60	-96	-37	-13	132	138	239	285	318	355	375	413
Free cash flow	-58	-12	-60	-94	-38	-13	148	140	251	293	325	362	377	418
Net cash	22	82	95	0	-38	-50	98	237	488	781	1,106	1,467	1,845	2,263

Source: Company data and Nordea estimates

Appendix 2: Current partnerships

Saniona commercialises its research and pipeline efforts either on its own or through partnerships with selected pharmaceutical companies to secure and boost long-term growth and value. We list its ongoing collaboration agreements below.

Productos Medix, S.A de S.V (Medix)

- **What:** Medix is a Mexican pharmaceutical company focused on obesity and is the market leader in Mexico in this area.
- **Relevant Saniona programmes:** Tesofensine and Tesomet in obesity in Mexico and Argentina.
- **When:** February 2016.
- **Terms agreed:** Medix has exclusive rights to develop and commercialise Tesofensine and Tesomet in the obesity market in Mexico and Argentina. The agreement entitles Saniona to regulatory milestone payments and double-digit royalties on product sales in Mexico and Argentina, while Medix finances the studies and is responsible for the clinical development and regulatory filings. Saniona retains all rights to Tesofensine and Tesomet in all other markets.

Boehringer Ingelheim

- **What:** Boehringer Ingelheim is a top 20 global pharmaceutical company based in Germany.
- **Relevant Saniona programmes:** Research collaboration with the objective of discovering and developing novel compounds within schizophrenia.
- **When:** August 2016.
- **Terms agreed:** Saniona will receive research funding during the joint research period and up to EUR 90m in milestone payments including an upfront payment of EUR 5m. Furthermore, Saniona is eligible to receive royalties on worldwide net sales relating to products discovered under the collaboration.

The Treatment Research Center (TRC), University of Pennsylvania

- **What:** TRC is a clinical outpatient treatment centre with a fully certified clinical laboratory and data management unit. TRC has an active recruitment process and network in place for cocaine addiction and screens about 250 cocaine-dependent patients per year.
- **Relevant Saniona programmes:** NS2359 for cocaine addiction.
- **When:** June 2015.
- **Terms agreed:** Saniona granted TRC rights to perform a ph II trial for NS2359. TRC applied for public funding and grants to finance the clinical development, including grants from the Dana Foundation and the Groff Foundation. Saniona retains all commercial rights to NS2359.

The Michael J. Fox Foundation for Parkinson's Research

- **What:** The Michael J. Fox Foundation (MJFF) is the world's largest non-profit funder of Parkinson's research and is dedicated to accelerating a cure for Parkinson's disease and improved therapies for those living with the condition today. MJFF has funded more than USD 750m in research to date.
- **Relevant Saniona programmes:** Nicotinic $\alpha 6$ programme.
- **When:** February 2016.
- **Terms agreed:** MJFF awarded Saniona a research grant of up to USD 590,700 to develop nicotinic $\alpha 6$ modulators in Parkinson's disease. Saniona retains all rights to any potential products developed and commercialised from the programme.

Cadent Therapeutics

- **What:** Cadent Therapeutics was established in March 2017 through a merger between Saniona's spin-out company, Ataxion, and Luc Therapeutics. Cadent Therapeutics is a precision neuroscience company focusing on creating molecules to treat movement and cognitive disorders. Saniona has 7% ownership in the company.
- **Relevant Saniona programmes:** SK programme, including CAD-1883, which is currently in ph I clinical development for ataxia and essential tremors.
- **When:** March 2017.
- **Terms agreed:** In addition to ownership in Cadent Therapeutics, Saniona is eligible to receive royalties on any potential products developed and commercialised from the SK programme, including CAD-1883.

Appendix 3: Current spin-out companies

Besides commercialising its research and pipeline efforts on its own or through partnerships, Saniona also enters into joint-venture or spin-out agreements in which its financial partner helps finance a specific programme in Saniona's pipeline in order to share the potential upside. Saniona already has three spin-out companies: Initiator Pharma, Cadent Therapeutics, and Scandion Oncology.

Initiator Pharma

- **What:** Initiator Pharma is a pharmaceutical company based in Aarhus, Denmark. It was formed in May 2016 through the acquisition of three programmes from Saniona that the latter did not intend to develop internally. The lead compound will be positioned for erectile dysfunction. Initiator Pharma has subsequently raised capital by being publicly listed in order to start preparing for clinical trials.
- **Relevant Saniona programmes:** Three pre-clinical pipeline programmes.
- **When:** May 2016.
- **Saniona's ownership:** 0%. All shares previously held by Saniona in Initiator Pharma A/S were distributed to Saniona's shareholders as an extraordinary dividend. The record date for the dividend payment was 21 October 2016.

Cadent Therapeutics

- **What:** Cadent Therapeutics was established in March 2017 through a merger between Saniona's spin-out company, Ataxion, and Luc Therapeutics. Cadent Therapeutics is a precision neuroscience company focusing on creating molecules to treat movement and cognitive disorders.
- **Relevant Saniona programmes:** SK programme, including CAD-1883, which is currently in ph I clinical development for ataxia and essential tremors.
- **When:** March 2017.
- **Saniona's ownership:** 7%.

Scandion Oncology

- **What:** Scandion Oncology was formed in May 2017 through the acquisition of a clinical candidate (termed SCO101) and related platform from Saniona. Through this spin-out, Saniona and the Scandion Oncology management and investors share the potential upside in assets that Saniona did not intend to develop internally. Scandion Oncology has raised DKK 2m in seed financing.
- **Relevant Saniona programmes:** SCO101 for cancer.
- **When:** May 2017.
- **Saniona's ownership:** 47.3% (as of 31 December 2017).

Reported numbers and forecasts

INCOME STATEMENT

SEKm	2012	2013	2014	2015	2016	2017	2018E	2019E	2020E	2021E	2022E
Net revenue	n.a.	13	22	14	75	21	49	38	57	47	78
Revenue growth	n.a.	n.a.	63.0%	-37.2%	449.7%	-72.4%	134.4%	-22.5%	52.4%	-17.2%	64.3%
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	-1	-7	-27	5	-57	-36	-77	-123	-48	-17
Depreciation and impairments PPE	0	0	-1	-1	0	-1	-1	0	0	0	0
EBITA	0	-2	-8	-28	4	-57	-37	-77	-123	-48	-17
Amortisation and impairments	0	0	0	0	0	0	0	0	0	0	0
EBIT	n.a.	-2	-8	-28	4	-57	-37	-77	-123	-48	-17
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	1	-1	1	1	1	1	1	1	1
Pre-tax profit	0	-2	-8	-29	5	-56	-36	-76	-122	-47	-16
Reported taxes	0	0	2	6	-3	7	8	17	27	10	4
Net profit from continued operations	0	-1	-6	-23	2	-49	-28	-59	-95	-36	-12
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	-1	-6	-23	2	-49	-28	-59	-95	-36	-12
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.	-9.1%	-34.5%	-200.4%	6.1%	-273.7%	-74.2%	-205.9%	-214.2%	-100.2%	-21.8%
EBITA	n.a.	-12.5%	-38.0%	-206.0%	5.5%	-276.4%	-75.3%	-205.9%	-214.2%	-100.2%	-21.8%
EBIT	n.a.	-12.5%	-38.0%	-206.0%	5.5%	-276.4%	-75.3%	-205.9%	-214.2%	-100.2%	-21.8%
Adjusted earnings											
EBITDA (adj)	0	-1	-7	-27	5	-57	-36	-77	-123	-48	-17
EBITA (adj)	0	-2	-8	-28	4	-57	-37	-77	-123	-48	-17
EBIT (adj)	0	-2	-8	-28	4	-57	-37	-77	-123	-48	-17
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.	-9.1%	-34.5%	-200.4%	6.1%	-273.7%	-74.2%	-205.9%	-214.2%	-100.2%	-21.8%
EBITA (adj)	n.a.	-12.5%	-38.0%	-206.0%	5.5%	-276.4%	-75.3%	-205.9%	-214.2%	-100.2%	-21.8%
EBIT (adj)	n.a.	-12.5%	-38.0%	-206.0%	5.5%	-276.4%	-75.3%	-205.9%	-214.2%	-100.2%	-21.8%
Performance metrics											
CAGR last 5 years											
Net revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	29.5%	11.6%	33.3%	-8.7%	30.4%
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.m.	n.m.	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.	-63.1%	-70.1%	-99.8%	-121.2%	-161.4%	-112.0%
Average EBITDA margin	n.a.	n.a.	n.a.	n.a.	n.a.	-61.1%	-68.5%	-98.7%	-120.6%	-160.9%	-111.9%
VALUATION RATIOS - ADJUSTED EARNINGS											
SEKm	2012	2013	2014	2015	2016	2017	2018E	2019E	2020E	2021E	2022E
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.m.	n.m.	n.m.	n.m.	n.m.
EV/EBITA (adj)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.m.	n.m.	n.m.	n.m.	n.m.
EV/EBIT (adj)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.m.	n.m.	n.m.	n.m.	n.m.
VALUATION RATIOS - REPORTED EARNINGS											
SEKm	2,012	2,013	2,014	2,015	2,016	2,017	2018E	2019E	2020E	2021E	2022E
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.	13.9	19.7	14.6	18.4	11.4
EV/EBITDA	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.m.	n.m.	n.m.	n.m.	n.m.
EV/EBITA	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.m.	n.m.	n.m.	n.m.	n.m.
EV/EBIT	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.m.	n.m.	n.m.	n.m.	n.m.
Dividend yield (ord.)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	0.0%	0.0%	0.0%	0.0%	0.0%
FCF yield	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	-1.6%	-7.1%	-11.3%	-4.5%	-1.5%
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	2012	2013	2014	2015	2016	2017	2018E	2019E	2020E	2021E	2022E
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	1	1	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	1	1	1	1	6	0	0	0	0	0
Total non-current assets	0	2	2	2	3	8	1	1	1	1	1
Inventory	0	0	0	0	0	0	0	0	0	0	0
Accounts receivable	0	1	3	8	14	18	12	9	14	12	19
Other current assets	0	0	1	0	1	1	1	1	1	0	1
Cash and bank	0	1	10	47	53	22	82	95	0	-38	-50
Total current assets	0	2	13	55	68	41	96	105	16	-25	-30
Assets held for sale	0	0	0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total assets	0	4	15	58	71	48	96	106	17	-24	-29
Shareholders equity	0	-3	9	53	54	38	82	95	0	-36	-49
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	-3	9	53	54	38	82	95	0	-36	-49
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	2	0	0	0	0	0	0
Accounts payable	0	2	2	3	6	5	5	4	6	5	8
Other current liabilities	0	5	4	2	9	6	10	8	11	7	12
Short term interest bearing debt	0	0	0	0	0	0	0	0	0	0	0
Total current liabilities	0	7	7	5	17	11	15	11	17	12	19
Liabilities for assets held for sale	0	0	0	0	0	0	0	0	0	0	0
Total liabilities and equity	0	4	15	58	71	48	96	106	17	-24	-29
Balance sheet and debt metrics											
Net debt	0	-1	-10	-47	-53	-22	-82	-95	0	38	50
Working capital	0	-6	-3	4	0	8	-1	-1	-1	0	1
Invested capital	0	-4	-1	6	3	15	0	0	-1	1	2
Capital employed	0	-3	9	53	54	38	82	95	0	-36	-49
ROE	n.m.	86.9%	-201.0%	-74.4%	4.1%	-107.1%	-46.3%	-67.3%	-200.6%	198.3%	29.0%
ROIC	n.m.	72.9%	288.8%	-870.7%	76.0%	-498.2%	-379.1%	n.m.	n.m.	n.m.	-888.9%
ROCE	n.a.	57.2%	-94.1%	-53.0%	7.7%	-152.0%	-44.5%	-81.8%	n.m.	131.2%	35.1%
Net debt/EBITDA	n.m.	0.8	1.3	1.7	-11.7	0.4	2.3	1.2	0.0	-0.8	-2.9
Interest coverage	n.a.	-118.5	-197.4	-23.8	22.0	-148.7	n.m.	n.m.	n.m.	n.m.	n.m.
Equity ratio	n.m.	-73.0%	56.8%	91.8%	76.7%	77.8%	84.9%	89.3%	-0.9%	148.7%	167.2%
Net gearing	n.m.	31.5%	-110.4%	-88.8%	-98.2%	-59.3%	-100.4%	-100.0%	231.2%	-103.7%	-103.4%

Source: Company data and Nordea estimates

CASH FLOW STATEMENT

SEKm	2012	2013	2014	2015	2016	2017	2018E	2019E	2020E	2021E	2022E
EBITDA (adj) for associates	0	-1	-7	-27	5	-57	-36	-77	-123	-48	-17
Paid taxes	0	0	0	0	0	0	8	17	27	10	4
Net financials	0	0	0	0	0	0	1	1	1	1	1
Change in provisions	0	0	0	0	2	-2	0	0	0	0	0
Change in other LT non-IB	0	-1	0	-1	0	-5	6	0	0	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	-5	0	1	-2	7	0	0	0	0	0
Funds from operations (FFO)	0	-7	-7	-27	5	-56	-21	-59	-95	-36	-12
Change in NWC	0	3	0	-2	3	-1	9	0	0	-2	0
Cash flow from operations (CFO)	0	-4	-8	-29	8	-57	-12	-60	-94	-38	-13
Capital expenditure	0	-2	-1	0	-1	-1	0	0	0	0	0
Free cash flow before A&D	0	-5	-9	-29	7	-58	-12	-60	-94	-38	-13
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	-5	-9	-29	7	-58	-12	-60	-94	-38	-13
Dividends paid	0	n.a.	n.a.	n.a.	0	0	0	0	0	0	0
Equity issues / buybacks	0	0	18	67	0	33	72	72	0	0	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	6	0	0	0	-6	0	0	0	0	0
Change in cash	0	1	9	37	6	-31	60	12	-94	-38	-13
Cash flow metrics											
Capex/D&A	n.m.	361.9%	105.9%	31.7%	212.5%	126.2%	0.0%	n.m.	n.m.	n.m.	n.m.
Capex/Sales	n.a.	-12.2%	-3.7%	-1.8%	-1.1%	-3.4%	0.0%	0.0%	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.	31	31	31	31	31
Market cap.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	758	836	836	836	836
Enterprise value	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	676	742	836	874	886
Diluted no. of shares, year-end (m)	0.0	0.0	0.0	0.0	0.0	21.5	24.4	27.0	27.0	27.0	27.0

Source: Company data and Nordea estimates

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