

# Saniona

Sweden | Biotech | MCAP SEK 852m

Buy

Target Price  
Current Price  
Up/downside

SEK 55.1  
SEK 30,0  
84%

## Saniona: Closing in on the orphan drug market

Saniona has a broad pipeline of different drugs where Tesomet is currently the most promising one. Tesomet addresses rare metabolic disorders with a potential market value of 2,8bn USD annually. If Tesomet reaches the market Saniona could become a world-leading company in treating metabolic diseases. The probability of Tesomet passing further clinical studies is enhanced due to the main substance, Tesofensine, passing a phase 3 clinical trial. This increases the probability of Tesomet reaching the market by 7-12 %. A risk-adjusted DCF with a cost of equity of 9,56 % gives a fair value of 55,1 SEK, equal to an upside of 84 %.

Comparable data from phase 3 study in Tesofensine increase the probability of success by 7-12 % for Tesomet.

Tesomet is the main value driver for Saniona as well as the biggest risk and it will be used to treat the rare eating disorders Prader-Willi syndrome (PWS) and hypothalamic obesity (HO). These diseases are characterized by an extreme craving of food, also called hyperphagia. The craving is so bad that the most common cause of death for adolescent patients is eating until they suffocate. Because of the supporting data from the phase 3 study of Tesofensine the probability of reaching the market is estimated to be 7-12 % higher than the market average.

Sanionas late-stage pipeline		Phase 1	Phase 2a	Phase 2b	Phase 3	Registration
Substance	Indication					
Tesomet	Prader-Willi Syndrome	Completed	Completed	Completed	✓ Q1 2021	✓ Q1 2022 ✓ Q1 2023
Tesomet	Hypothalamic obesity	Completed	✓ Q2 2020	N/A	✓ Q1 2022	✓ Q1 2023
Tesofensine	Obesity (Mexico)	Completed	Completed	Completed	Completed	✓ Q3 2020
Tesofensine	Obesity (Argentina)	Completed	Completed	Completed	Completed	✓ Q1 2021

■ Completed    ■ Ongoing

With 26 % market penetration in 2030, Tesomet will hit peak sales of 8,9bn SEK which when applied to a DCF model gives an upside of 84%.

The price per patient for PWS/HO is high due to government subsidizing and since there is no treatment available today Tesomet sales are expected to be high with 1,2bn SEK first year and peak sales of 8,9bn SEK during 2030. While the number of patients with PWS/HO is just 29 000, due to government subsidizing the annual revenue per patient is 85-150k USD, resulting in potential market size of 2,8bn USD. These patients are currently untreated which should make it easy for Tesomet to take 4 % of the market when launched in 2023, increasing to 26 % by 2030. 1,2bn SEK in Tesomet sales during 2023 and peak sales of 8,9bn SEK in 2030 gives when applied to a risk-adjusted DCF model with a WACC of 9,56 %, an upside of 84%.

Jacob Helmersson  
Equity Research Analyst

### Market Data

	Stockholm
Listing Venue	Stockholm
Price (SEK)	30,0
No. of outstanding shares	28 412 519
Market Cap (m)	852,4
Cash & Cash Equivalents (m)	40,2
Debt (m)	0,0
Net Debt (m)	-40,2
Enterprise Value (m)	812,2

### Key Financials (SEK)

	18A	19A	20E	21E
Sales (m)	54,9	2,7	56	43,0
OPEX (m)	109,0	107,0	139,0	304,0
Operating profit (m)	-43,0	-81,0	-64,0	-204,0
EBIT (m)	-55,0	-103,9	-83,0	-261,0
EBIT - Margin (%)	-99,9%	-3846,7%	-146,4%	-600,2%

### Key Ratios (SEK)

	18A	19A	20E	21E
WACC	9,6%	9,6%	9,6%	9,6%
EV/Sales	14,8	301,3	14,5	18,9



### Major shareholders

Jørgen Drejer (CSO)	8,3%
Thomas Feldthus (CFO)	6,6%
Avanza Pension	6,1%
Leif Andersson consulting APS	3,3%
Nordnet pensionsförsäkring AB	3,0%
Total insider	14,9%
Total institutional	0%
<b>Total</b>	<b>27,3%</b>

## Investment thesis

Tesomet has a 7-12 % increased probability of reaching the market due to the active substance, Tesofensine, proving in a phase 3 trial that is highly effective at treating the symptoms Tesomet aims to treat in PWS and HO patients.

Tesomet has a 7-12 % higher than the average probability of success compared to other drugs in the same clinical phase due to the success of its main substance, Tesofensine. The result of the phase 3 study for Tesofensine showed an average weight loss of 10,4 % over 24 weeks in the patients by reducing their craving of food and increasing metabolic fat burn. Since Tesomet aims to treat extreme cravings for food and its main substance has showed that it is very effective in doing so, the probability of success for Tesomet increases by 7 % in both indications. The phase 2a data for Tesomet in PWS showed a dose-related efficiency which increases the probability of reaching the market by an additional 5 % for Tesomet in PWS. The average probability of success for drugs in the same clinical stage as Tesomet in PWS is 28 % and 19 % for Tesomet in HO<sup>1</sup>. The probability of reaching the market is 40 % for Tesomet in PWS and 26 % for Tesomet in HO compared to a market average of 28% respectively 19 %.

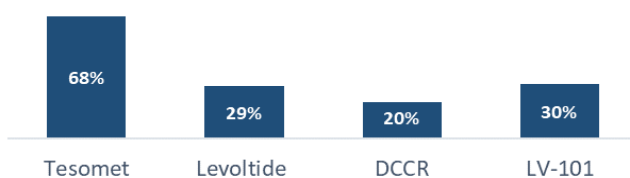
**If Tesomet passes clinical trials it will address 2bn USD market for PWS and 800M USD market for HO and is expected to take 26 % of both in 2030.**

PWS and HO are rare diseases which qualify Tesomet for premium pricing through orphan drug designation, resulting in a potential market size of 2,8bn USD. Saniona is expected to take 4 % of the total PWS and HO market in 2023, increasing to 26 % by 2030. Orphan drug designation is a status that can be assigned to drugs developed for rare diseases and result in premium pricing through government subsidizing. With orphan drug designation the price for one patient with PWS or HO is estimated to be 85-150k USD annually. There is 21 000 people with PWS and 8 000 with HO resulting in an estimated market potential of 2bn USD for PWS and 800M USD for HO and Saniona is estimated to take 26 % of these markets by 2030.

**Tesomet is 126-240 % more effective at reducing hyperphagia than other drugs in development negating the competitors advantage of potentially reaching the market a year before Tesomet.**

Tesomet showed in a phase 2a study that it is 126-240 % more effective at reducing hyperphagia than other drugs in development for PWS. The main competitors for the PWS market are Soleno Therapeutics with DCCR, Millendo Therapeutics with Levoltide and Levo Therapeutics with LV-101. While the competitors are slightly ahead in development and could reach the market one year before Saniona, it should not be a substantial issue since Tesomet is 126-240 % more effective. The hyperphagia was measured by a questioner answered by the patients parents. In the phase 2a study with Tesomet the hyperphagia was reduced by 68 % while competitors reduced hyperphagia by 20-30 %, as can be seen in the table below.

### Decrease in hyperphagia compared to competitors



<sup>1</sup> C.H. Wong, K.W. Siah and A.W. Lo, 'Estimation of clinical trial success rates and related parameters', *Biostatistics*, Volume 20, Issue 2, April 2019, p. 273–286

## Valuation

### Good risk/reward gives an upside of 84 %

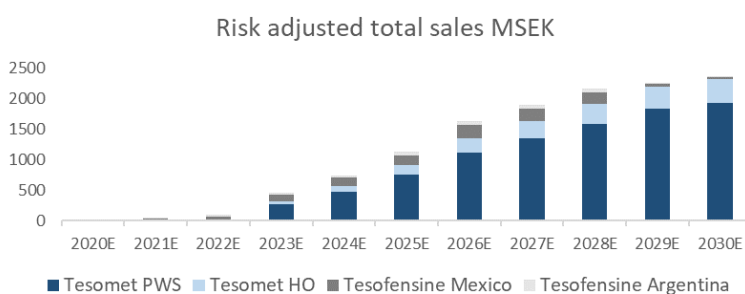
Based on a risk-adjusted DCF model, Saniona presents a good risk/reward scenario, with a fair value of 55,1 SEK per share, indicating an upside of 84 % from today. Since it is unsure if Tesomet or Tesofensine will reach the market the estimates have been risk-adjusted based on the probability of each drug reaching the market. Tesomet in PWS/HO has not yet received orphan drug status thus the probability of reaching the market decrease from 40 % to 30 % in Tesomet for PWS and from 26 % to 16 % in Tesomet for HO. The WACC is based on the average for the biotech industry within Sweden, which is 9,56 %. When constructing the DCF model EBIT was used instead of FCFF, however, this should have a negligible impact on NPV due to Saniona having no need for any large capital investments. Saniona will need to raise capital for future clinical studies therefore one right issue is expected. The DCF model has been adjusted for the dilution of 12,6 million additional shares based on an estimated capital need of 303 MSEK with an average discount of 20 % per share. The DCF model gives an upside of 84 % due to the above-average probability of reaching the market for Tesomet and Tesofensine.

### If Tesomet manages to reach the market it could contribute to net sales of 1,2bn SEK during the first year on the market in 2023.

Tesomet sales for PWS/HO are expected to be 1,2bn SEK during 2023 but have to be risk-adjusted based on the probability of Tesomet in PWS/HO reaching the market. The market penetration is expected to be 4 % for both drugs during 2023, growing to 26 % by 2030 based on the market penetration other orphan drugs had. Net sales of Tesomet in PWS during 2023 is expected to be 884 MSEK which after being risk-adjusted by 30 % is equivalent to net sales of 265 MSEK. Net sales of Tesomet in HO during 2023 is expected to be 343 MSEK which after being risk-adjusted by 16 % is equal to net sales of 55 MSEK. Net sales of Tesomet in 2023 is expected to be 1,2bn SEK and if risk-adjusted based on the probability of Tesomet in PWS/HO reaching the market, net sales would be 320 MSEK.

### The worlds most effective weight loss drug, Tesofensine, is expected to reach the Mexican market in 2020 contributing with an EBIT of 16 MSEK.

Sales of Tesofensine is expected to start in Mexico under 2020, and in Argentina 2021, utilizing their partner Medix with estimated royalties of 15 % from the sales of Tesofensine. Medix assumes that the market for treating obesity is currently worth 2,5bn SEK in Mexico and 800 MSEK in Argentina. Tesofensine is roughly twice as effective as current weight loss drugs so it is expected to quickly claim a large part of the obesity market in Mexico with 4 % market penetration in 2020 increasing to 35 % by 2026. With a royalty rate of 15 %, it is expected that Saniona will receive 17 MSEK in royalties in 2020, which adjusted for a 95,3 % probability of market approval will contribute with an EBIT of 16 MSEK.



Saniona	2016	2017	2018	2019	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E		
MSEK																						
Adj. Net Sales (MSEK)	76	21	55	3	56	43	91	457	737	1129	1626	1896	2164	2253	2360	2111	1858	1681	1422	1347	1074	
Adj. Revenue	76	21	55	3	56	43	91	457	737	1129	1626	1896	2164	2253	2360	2111	1858	1681	1422	1347	1074	
Adj. COGS	0	0	0	0	0	0	0	91	147	226	325	379	433	451	472	422	372	336	284	269	215	
R&T Gross profit	76	21	55	3	56	43	91	366	590	904	1301	1516	1731	1802	1888	1689	1486	1345	1137	1077	859	
OPEX (MSEK)																						
Depreciation and write-downs	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Raw materials and consumables	1	3	4	4	5	9	5	21	57	82	109	126	140	140	140	140	140	140	140	140	140	
Personnel costs	18	23	24	26	29	26	63	67	82	82	82	82	82	82	82	82	82	82	82	82	82	
Other external costs	51	51	80	75	105	270	109	140	162	162	162	162	162	162	162	162	162	162	162	162	162	
Total Operating Expenses	71	78	109	107	139	304	168	229	301	590	692	1021	1011	1002	1069	1131	1205	1341	1254	1353	1356	
Adj. EBITDA	5	-57	-54	-104	-83	-261	-77	137	289	339	488	569	649	676	708	633	557	504	427	404	322	
Depreciation	0	1	1																			
Adj. EBITA	5	-58	-55	-104	-83	-261	-77	137	289	339	488	569	649	676	708	633	557	504	427	404	322	
Amortization	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Adj. EBIT	5	-58	-55	-104	-83	-261	-77	137	289	339	488	569	649	676	708	633	557	504	427	404	322	
Interest Income	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Interest Expenses	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Adj. EBT	6	-57	-55	-104	-83	-261	-77	137	289	339	488	569	649	676	708	633	557	504	427	404	322	
Adj. Tax Expense	1	-13	-12	-23	-18	-57	-17	30	64	75	107	125	143	149	156	139	123	111	94	89	71	
Adj. Net Income	4	-44	-43	-81	-64	-203	-60	107	225	264	381	444	506	527	552	494	435	393	333	315	251	
Tesomet PWS																						
Estimated market value	N/A	N/A	20016	20416	20825	21241	21666	22099	22541	22992	23337	23687	24042	24403	24769	25141	25518	25900	26289	26683	27084	
Estimated market growth	N/A	N/A	2,00%	2,00%	2,00%	2,00%	2,00%	2,00%	2,00%	1,50%	1,50%	1,50%	1,50%	1,50%	1,50%	1,50%	1,50%	1,50%	1,50%	1,50%	1,50%	
Estimated market share	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	7,00%	11,00%	16,00%	19,00%	22,00%	25,00%	26,00%	23,00%	20,00%	18,00%	15,00%	14,00%	11,00%	
Estimated sales (MSEK)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	884	1578	2529	3734	4501	5289	6101	6440	5782	5104	4662	3943	3736	2979	
Tesomet HO																						
Estimated market value	N/A	N/A	8000	8110	8221	8333	8447	8563	8681	8799	8920	9042	9166	9292	9419	9548	9679	9811	9946	10082	10220	
Estimated market growth	N/A	N/A	1,37%	1,37%	1,37%	1,37%	1,37%	1,37%	1,37%	1,37%	1,37%	1,37%	1,37%	1,37%	1,37%	1,37%	1,37%	1,37%	1,37%	1,37%	1,37%	
Estimated market share	N/A	N/A	N/A	N/A	N/A	N/A	N/A	4%	7,00%	11,00%	16,00%	19,00%	22,00%	25,00%	26,00%	23,00%	20,00%	18,00%	15,00%	14,00%	11,00%	
Estimated sales (MSEK)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	343	608	968	1427	1718	2017	2323	2449	2196	1936	1766	1492	1411	1124	
Tesofinsine Mexico																						
Estimated market value	N/A	N/A	2500	2675	2862	3063	3277	3506	3752	4014	4295	4510	4736	4973	5221	5482	5756	6044	6346	6664	6997	
Estimated market growth	N/A	N/A	7,00%	7,00%	7,00%	7,00%	7,00%	7,00%	7,00%	7,00%	7,00%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	
Estimated royalties	N/A	N/A	N/A	N/A	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	
Estimated market share	N/A	N/A	N/A	N/A	4%	8%	15%	21%	24%	28,00%	35,00%	33,00%	28,00%	15,00%	10,00%	7,00%	5,00%	0,00%	0,00%	0,00%	0,00%	
Estimated sales (MSEK)	N/A	N/A	N/A	N/A	17	37	74	110	135	169	226	223	199	37	26	19	14	0	0	0	0	
Tesofinsine Argentina																						
Estimated market value	N/A	N/A	800	856	916	980	1049	1122	1201	1285	1375	1443	1515	1591	1671	1754	1842	1934	2031	2132	2239	
Estimated market growth	N/A	N/A	7,00%	7,00%	7,00%	7,00%	7,00%	7,00%	7,00%	7,00%	7,00%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	
Estimated royalties	N/A	N/A	N/A	N/A	N/A	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	
Estimated market share	N/A	N/A	N/A	N/A	N/A	6%	14%	20%	22%	30,00%	32,00%	28,00%	30,00%	20,00%	14,00%	8,00%	4,00%	0,00%	0,00%	0,00%	0,00%	
Estimated sales (MSEK)	N/A	N/A	N/A	N/A	N/A	9	22	34	40	58	66	61	68	16	12	7	4	0	0	0	0	
Entire portfolio																						
Tesomet PWS sales	N/A	N/A	N/A	N/A	N/A	N/A	N/A	884	1578	2529	3734	4501	5289	6101	6440	5782	5104	4662	3943	3736	2979	
Tesomet HO sales	N/A	N/A	N/A	N/A	N/A	N/A	N/A	343	608	968	1427	1718	2017	2323	2449	2196	1936	1766	1492	1411	1124	
Tesofinsine Mexico sales	N/A	N/A	N/A	N/A	17	37	74	110	135	169	226	223	199	37	26	19	14	0	0	0	0	
Tesofinsine Argentina sales	N/A	N/A	N/A	N/A	9	22	34	40	58	66	61	68	16	12	7	4	0	0	0	0	0	
Estimated total sales (MSEK)					17	46	96	1371	2360	3723	5453	6502	7573	8477	8927	8005	7057	6428	5435	5147	4103	
R&T sales estimation																						
Tesomet PWS	N/A	N/A	N/A	N/A	0	0	0	265	473	759	1120	1350	1587	1830	1932	1735	1531	1399	1183	1121	894	
Tesomet HO	N/A	N/A	N/A	N/A	0	0	0	55	97	155	228	275	323	372	392	351	310	283	239	226	180	
Tesofinsine Mexico	N/A	N/A	N/A	N/A	16	35	70	105	129	161	215	213	190	36	25	18	14	0	0	0	0	
Tesofinsine Argentina	N/A	N/A	N/A	N/A	0	8	21	32	38	55	63	58	65	15	11	7	4	0	0	0	0	
R&T adjusted total sales (MSEK)					16	43	91	457	737	1129	1626	1896	2164	2253	2360	2111	1858	1681	1422	1347	1074	

DCF																				Value	
WACC	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%	9,56%
Discount period	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Adj. EBIT	-83	-261	-77	137	289	339	488	569	649	676	708	633	557	504	427	404	322	289	264	381	444
DCF	-75	-217	-59	95	183	196	257	274	285	271	259	212	170	140	108	94	68				2263

Amount of shares	41 052 468
DCF (MSEK)	2263,42
Fair Value	55,13

Sources

<sup>1</sup> C.H. Wong, K.W. Siah and A.W. Lo, 'Estimation of clinical trial success rates and related parameters', *Biostatistics*, Volume 20, Issue 2, April 2019, p. 273–286

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