

Saniona

Sector: Biotech

Early Christmas gift from Mexico

Phase III trial completed, Medix to prepare for regulatory filings

Saniona announced yesterday that the tesofensine phase III trial met its primary and secondary endpoints. The results demonstrated statistically and clinically significant weight loss in obese patients (read our initial [comment](#) to this news).

Tesofensine not an isolated event

We argue that yesterday's news was encouraging, not only for tesofensine in the treatment of obesity in Mexico and Argentina but for the Tesomet programs in metabolic disease and rare eating disorders as well:

- Validate the rationale for PWS and HO (rare eating disorders)
- Increase partnership attractiveness for Tesomet within metabolic disorders (obesity RoW and T2D)
- The phase III data can potentially be used as a reference for other markets with high medical needs in obesity as well.

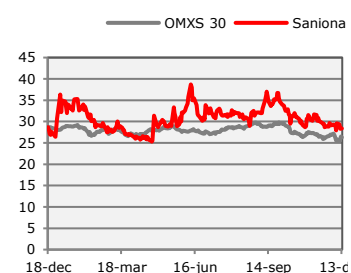
New valuation

Based on the positive outcome of the phase III trial, we have raised our Base Case to SEK 85 (77) per share. Our Bull and Bear Case is SEK 30 and 130 per share, respectively. Upcoming news flow includes data from Tesomet (phase I dose ratio optimization tesofensine/metoprolol), interim-analysis on NS2359 (phase II in cocaine addiction), and results from Tesomet in the rare eating disorder, PWS (phase II).

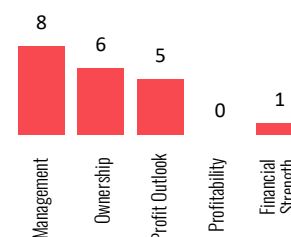
FAIR VALUE RANGE

BEAR	BASE	BULL
30,0	85,0	130,0

Sanion.st VERSUS OMXS30



REDEYE RATING



KEY STATS

Ticker	Sanion.st
Market	Small Cap
Share Price (SEK)	27,7
Market Cap (MSEK)	622
Net Debt 18E (MSEK)	-25
Free Float	73 %
Avg. daily volume (MSEK)	1,1

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KEY FINANCIALS (SEKm)	2016	2017	2018E	2019E	2020E	2021E
Net sales	75	21	56	28	54	88
EBITDA	5	-57	-33	-58	-38	36
EBIT	4	-57	-33	-58	-38	36
EPS (adj.)	0,0	-2,5	-1,5	-2,6	-1,7	1,6
EV/Sales	-0,7	-1,1	11,4	24,6	13,6	7,9
EV/EBITDA	-11,7	0,4	-19,6	-12,1	-19,4	19,3
EV/EBIT	-12,8	0,4	-19,3	-12,0	-19,1	19,5
P/E	0,0	0,0	-18,8	-10,7	-16,2	17,3

Investment Case

- A late-stage, broad pipeline with a target-driven research focus
- Run by an experienced management team that has been able to execute deals
- Orphan focus in eating disorders represent the largest value potential.
- A significant news flow for remaining 2018 and first half of 2019 (See also 'Catalysts' section)

Saniona is a late-stage, broad pipeline biotech company with a world-class research platform within ion channel drug development.

Saniona's management team has since the company's inception demonstrated their ability to enter into partnership deals and collaboration programs and thus running the company in a cost-efficient manner. The company has generated revenues every year since it was founded in 2011.

The investment case in Saniona is becoming increasingly oriented towards the Tesomet program and its orphan position within eating disorders. The Tesomet program has the potential to go-to-market with an own sales force in rare eating disorders, the potential reward vis á vis seeking licensing partners is incomparable. Furthermore, tesofensine (the active compound in Tesomet) recently reported robust efficacy results in a phase III trial in obesity patients. We argue that those data strengthen and validate the Tesomet programs in rare eating disorders as well.

The value drivers for the remaining 2018 and beginning of 2019 are substantial for the clinical pipeline. The most important events will be the read-outs from ongoing phase II and phase III trials with NS2359 (possible treatment for cocaine addiction), and Tesomet (Prader-Willis Syndrome). Other clinical read-outs include phase I results from Tesomet to assess dose ratio and phase I results from the Cadent Therapeutics program. Please see our 'Catalysts' section for a more comprehensive timeline on coming news flow. As previously mentioned, we also see the improved financial position and the current stock price levels to be taken into consideration when assessing the Saniona case.

Valuation

General assumptions:

- Swedish corporate tax of 22 percent
- WACC of 15 percent

Saniona: Sum-of-the-parts valuation									
Project	Indication	Current phase	Partner	Likelihood of Approval	Royalty rate*	Top Sales (\$m)	Launch year	Net Present Value (SEKm)**	Per share (SEK)
Clinical programs									
Tesofensine	Obesity	NDA	Medix (Mx, Arg)	90%	14%	115	2020	275	12
Tesomet	Obesity/T2D	Ph II	-	30%	18%	90	2023	42	2
Tesomet	PWS	Ph II	-	24%	80%	780	2022	1.269	56
NS2359	Cocaine Addiction	Ph II	University of Pennsylvania	12%	30%	500	2022	217	9
Cadent program	Ataxia	Ph I	Cadent Therapeutics	12%	5%	1.130	2024	76	3
Total value clinical pipeline								1.878	82
Preclinical pipeline - funded and/or CD selection									
BI program	Schizophrenia	Prec.	Boehringer Ingelheim	9%	7%	1.350	2025	152	7
SAN711	Neuropathic Pain	Prec.	-	5%	16%	1.250	2025	110	5
Total value CD preclinical pipeline								262	11
Technology value								2.140	
Net cash position (p. 2018-12-31)								25	
Shared costs								-276	
Ownership Cadent Therapeutics / Scandion Oncology								60	
Fair value								1.950	
Number of shares, full dilution (Mn)								22,8	
Per share value, SEK								85	

* Tesomet - PWS to be referred as margin

** totals may not sum due to roundings

Source: Redeye Research

Bear Case 30,0 SEK

Phase II study in adolescents (Tesomet - PWS) requires a longer dose-finding study to find the therapeutic window where it is both safe and have efficacy.

In the worst-case scenario, the PWS program is at jeopardy (~ - 50 SEK).

Interim-analysis of NS2359 does not support further clinical studies (- 9 SEK).

Base Case 85,0 SEK

In our Base-scenario, the positive contributors since our last update are related to our increased LoA for tesofensine.

We include projects in Saniona's pipeline where we see a clear preclinical/clinical path going forward, supported by long-term-funding in place, and what we believe the market is likely to consider in the investment case at the moment.

Please see our SOTP figure above as it represents our Base Case.

Bull Case 130,0 SEK

PWS phase II study in adolescents present top-line data. A phase II/III study is being conducted in 2020, following a dose-finding study. We raise our likelihood of approval accordingly (~ + 50 SEK).

Interim-analysis of the phase II trial for NS2359 against cocaine addiction reveal encouraging results, and the study continues to full read-out (+ 0 SEK is a yet possible scenario).

Catalysts

Study initiations

In the next months, initiation of new clinical trials could get started for:

- ph II in Hypothalamic Obesity (Tesomet)
- ph IIb in metabolic diseases (Tesomet)
- ph I in Neuropathic pain and itching disorders (SAN711)

Study results ph I (Tesomet)

Saniona is currently conducting a phase I study to optimize the dose ratio between tesofensine and metoprolol. Earlier preclinical toxicology studies with Tesomet as well as GMP production with the tablet has followed our timeline. We expect read-out being able to be presented in Q4'18.

Study results ph I (CAD-1883, Cadent Therapeutics)

We expect read-out from the ongoing phase I in healthy volunteers being able to be presented in Q4'18. A successful phase I study will pave the way for a clinical trial in Ataxia patients.

Study results ph II (Tesomet-PWS)

We expect read-out from the ongoing phase II in PWS patients (adolescents) being able to be presented in Q1'19.

Interim-results ph II (NS2359)

We expect interim read-out from the ongoing phase II in patients with cocaine addiction being able to be presented in Q4'18.

Summary Redeye Rating

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

Rating changes in the report: no changes.

Management: 8,0

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

Ownership: 6,0

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

Profit Outlook: 5,0

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

Profitability: 0,0

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

Financial Strength: 1,0

Saniona entered Q4'18 with a cash position of approximately SEK 37 million. The milestone payment of SEK 42 million, triggered by a candidate drug selection from Boehringer Ingelheim, was an important event from a financial strength perspective. However, we continue to have the financial strength rating unchanged until we have seen a substantial improvement.

INCOME STATEMENT	2016	2017	2018E	2019E	2020E
Net sales	75	21	56	28	54
Total operating costs	-70	-77	-89	-86	-92
EBITDA	5	-57	-33	-58	-38
Depreciation	0	-1	-1	-1	-1
Amortization	0	0	0	0	0
Impairment charges	0	0	0	0	0
EBIT	4	-57	-33	-58	-38
Share in profits	0	0	0	0	0
Net financial items	1	1	0	0	0
Exchange rate dif.	0	0	0	0	0
Pre-tax profit	5	-56	-33	-58	-38
Tax	-3	0	0	0	0
Net earnings	2	-56	-33	-58	-38

BALANCE SHEET	2016	2017	2018E	2019E	2020E
Assets					
<i>Current assets</i>					
Cash in banks	53	22	25	3	1
Receivables	15	11	17	16	15
Inventories	0	0	0	0	0
Other current assets	0	0	0	0	0
Current assets	68	33	42	19	16
<i>Fixed assets</i>					
Tangible assets	1	1	1	3	2
Associated comp.	0	0	0	0	0
Investments	2	6	6	6	6
Goodwill	0	0	0	0	0
Cap. exp. for dev.	0	0	0	0	0
0 intangible rights	0	0	0	0	0
0 non-current assets	0	0	0	0	0
Total fixed assets	3	8	8	9	9
Deferred tax assets	0	7	7	7	7
Total (assets)	71	48	57	35	32
Liabilities					
<i>Current liabilities</i>					
Short-term debt	0	0	18	9	27
Accounts payable	17	11	11	11	11
0 current liabilities	0	0	0	0	0
Current liabilities	17	11	29	20	38
Long-term debt	0	0	0	69	86
0 long-term liabilities	0	0	0	0	0
Convertibles	0	0	24	0	0
Total Liabilities	17	11	53	89	124
Deferred tax liab	0	0	0	0	0
Provisions	0	0	0	0	0
Shareholders' equity	54	38	5	-54	-92
Minority interest (BS)	0	0	0	0	0
Minority & equity	54	38	5	-54	-92
Total liab & SE	71	48	57	35	32

FREE CASH FLOW	2016	2017	2018E	2019E	2020E
Net sales	75	21	56	28	54
Total operating costs	-70	-77	-89	-86	-92
Depreciations total	0	-1	-1	-1	-1
EBIT	4	-57	-33	-58	-38
Taxes on EBIT	0	0	0	0	0
NOPLAT	4	-57	-33	-58	-38
Depreciation	0	1	1	1	1
Gross cash flow	5	-57	-33	-58	-38
Change in WC	5	-2	-6	1	1
Gross CAPEX	-1	-6	0	-2	0
Free cash flow	9	-64	-39	-59	-37

CAPITAL STRUCTURE	2016	2017	2018E	2019E	2020E
Equity ratio	77%	78%	8%	-152%	-290%
Debt/equity ratio	0%	0%	934%	-146%	-123%
Net debt	-53	-22	17	75	112
Capital employed	1	15	21	22	20
Capital turnover rate	1,1	0,4	1,0	0,8	1,7

GROWTH	2016	2017	2018E	2019E	2020E
Sales growth	450%	-72%	171%	-49%	91%
EPS growth (adj)	0%	0%	-41%	75%	-34%

DCF VALUATION		CASH FLOW, MSEK	
WACC (%)	15 %	NPV FCF (2018-2020)	-115
		NPV FCF (2021-2027)	940
		NPV FCF (2028-)	1040
		Non-operating assets	25
		Interest-bearing debt	0
		Fair value estimate MSEK	1890
Assumptions 2017-2023 (%)			
Average sales growth	40,5 %	Fair value e. per share, SEK	85
EBIT margin	-4,2 %	Share price, SEK	27,7

PROFITABILITY	2016	2017	2018E	2019E	2020E
ROE	4%	-123%	-157%	0%	0%
ROCE	8%	-124%	-79%	-164%	-169%
ROIC	70%	-5771%	-216%	-276%	-178%
EBITDA margin	6%	-274%	-58%	-203%	-70%
EBIT margin	6%	-276%	-59%	-205%	-71%
Net margin	3%	-272%	-59%	-205%	-71%

DATA PER SHARE	2016	2017	2018E	2019E	2020E
EPS	0,00	-2,51	-1,48	-2,59	-1,71
EPS adj	0,00	-2,51	-1,48	-2,59	-1,71
Dividend	0,00	0,00	0,00	0,00	0,00
Net debt	0,00	-0,99	0,74	3,35	5,00
Total shares	0,00	22,45	22,45	22,45	22,45

VALUATION	2016	2017	2018E	2019E	2020E
EV	-53,3	-22,3	638,3	696,9	734,0
P/E	0,0	0,0	-18,8	-10,7	-16,2
P/E diluted	0,0	0,0	-18,8	-10,7	-16,2
P/Sales	0,0	0,0	11,1	21,9	11,5
EV/Sales	-0,7	-1,1	11,4	24,6	13,6
EV/EBITDA	-11,7	0,4	-19,6	-12,1	-19,4
EV/EBIT	-12,8	0,4	-19,3	-12,0	-19,1
P/BV	0,0	0,0	138,3	-11,6	-6,8

SHARE PERFORMANCE		GROWTH/YEAR	16/18E
1 month	-7,7 %	Net sales	-13,6 %
3 month	-17,6 %	Operating profit adj	◆
12 month	-4,2 %	EPS, just	0,0 %
Since start of the year	-9,8 %	Equity	-71,2 %

SHAREHOLDER STRUCTURE %	CAPITAL	VOTES
Jørgen Drejer	10,8 %	10,8 %
Avanza Pension	5,6 %	5,6 %
Thomas Feldthus	5,4 %	5,4 %
Leif Andersson Consulting ApS	4,5 %	4,5 %
Palle Christophersen	3,7 %	3,7 %
Claus Brästrup	3,3 %	3,3 %
Nordnet Pensionsförsäkring	2,8 %	2,8 %
Nordea Liv & Pension	2,0 %	2,0 %
Christian Olofsson	1,9 %	1,9 %
ATS Finans AB	1,7 %	1,7 %

SHARE INFORMATION	
Reuters code	Sanion.st
List	Small Cap
Share price	27,7
Total shares, million	22,8
Market Cap, MSEK	621,8

MANAGEMENT & BOARD	
CEO	Jørgen Drejer
CFO	Thomas Feldthus
IR	
Chairman	J. Donald DeBethizy

FINANCIAL INFORMATION	
FY 2018 Results	February 21, 2019

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Redeye Rating and Background Definitions

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

Company Qualities

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

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

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

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

Management

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

Ownership

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

Profit Outlook

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

Profitability

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

Financial Strength

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

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Disclaimer

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Redeye Rating (2018-12-17)

Rating	Management	Ownership	Profit outlook	Profitability	Financial Strength
7,5p - 10,0p	47	47	20	11	21
3,5p - 7,0p	89	84	118	39	52
0,0p - 3,0p	14	19	12	100	77
Company N	150	150	150	150	150

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Anders Hedlund owns shares in Saniona: No

Klas Palin owns shares in Saniona: No

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