Saniona

Sector: Biotech

Q2 2023: One deal achieved

Redeye returns with an updated view of Saniona following the Q2 report. We reiterate our stance that 2023 will be an important year for the company – most notably to deliver on its goal of non-dilutive incomes. We are overall encouraged by recent events in the company and raise our valuation somewhat.

Report in line

We note that the report came in roughly as we expected, with a relatively stable OPEX at SEK-25.7million per quarter (we expected SEK22m), still indicating a new normal at "Scandinavian levels". The majority of the costs remains related to R&D/other external costs at SEK-13.8m followed by SEK-8.8m in personnel costs. Revenues landed at SEK3.9m and related to Saniona's collaborations.

One deal achieved

Although it seems that the market had high expectations for a first deal (the company has a goal to deliver two this year) with a significant upfront payment, we are still impressed by the licensing agreement with AstronauTx even though the revenue in the near future seems limited (mainly research funding expected at SEK15m the first year). It clearly shows that there is a lot of optionality in Saniona's Ionbase platform as we did not anticipate that Saniona would venture into Alzheimer's disease. We note however that this is very early stage and that there also is an option agreement baked into the collaboration structure. We therefore see this more as a testament to the platform's capabilities than a major contributor to our valuation.

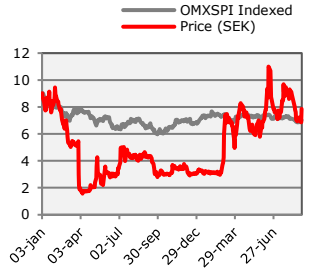
Nudge our base case to SEK 9.5 (8) per share

We largely reiterate our previous sum-of-the-parts valuation but make a few adjustments relating to Tesofensine (raise LoA to 85%), reduce the assumed rights issue to SEK50m and include an initial valuation of the AstronauTx research collaboration.

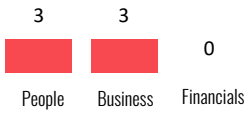
FAIR VALUE RANGE

BEAR	BASE	BULL
1	9.5	20

SANION VERSUS OMXS30



REDEYE RATING



KEY STATS

Ticker	SANION
Market	Small Cap
Share Price (SEK)	8
Market Cap (SEKm)	503
Free Float (%)	92

Key Financials (SEKm)	2021	2022	2023E	2024E
Revenues	11	15	48	53
Revenue growth	0	0	3	0
EBITDA	-403	-218	-34	-31
EBIT	-412	-226	-38	-33

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Investment Thesis

Case: Turn around case with plenty of value

2022 was a turbulent year for Saniona, which included a major restructuring of the management team, stopped clinical studies with Tesomet due to financial difficulties and a refocused strategy towards business development. We see high quality in Saniona's assets, including its mid-stage orphan drug candidate Tesomet, phase I asset SAN711 (targeting neurophatic pain), and in the long run: its many assets from its Ion Channel Platform. We have so far been impressed by the new leadership and its swift cost reductions. To further turn the case around, we argue that a licensing agreement by H2 2023 and further advancement with phase I candidate SAN711 will be key.

Evidence: Validated platform and history of collaborations

The Saniona case offers some unique factors: a validated, target-driven research platform focused on ion channels, including its lead candidate SAN711 that presented positive phase I data in 2022, combined with Tesomet, a mid-stage asset (phase IIb ready) targeting two rare eating disorders—PWS and HO. Saniona's research platform has been validated by several collaborations and spinouts over the years, providing non-dilutive funding from upfront payments and milestones – and the current (reinstated) CEO and management team have a proven track record at Saniona: Assuring given the turnaround situation the company is in.

Evidence:

In 2022, Saniona reported a positive outcome from its phase I trial (n=66) with SAN711, the most advanced drug candidate stemming from its ion channel platform. The purpose of the study was to evaluate safety and tolerability, and the secondary objective was to study binding to target receptors (measures by PET). The compound is designed as a potential first-in-class positive allosteric modulator of the neurotransmitter GABAA and specifically the subunit α3. GABAA is a target for several drugs, including benzodiazepines such as Valium, which can lead to for example pain relief. Today's treatments target GABAA more broadly (including subunits α1 and α5) which can lead to unwanted side effects such as sedation, risk of abuse and motoric instability). The company reports that the drug was safe and tolerable, and that most adverse events were mild with the exception of a few moderate events mainly unrelated to drug administration. The company further states that side effect profile is significantly different from non-selective GABA modulators (which is a core part of the value proposition, we argue). As further indicated by the PET results, the company also reports that a therapeutic level of receptor occupancy (50-72%) may be achieved at tolerated multiple dose levels (0.8mg twice daily). To us, the phase I results are also a needed validation of the company's ion channel platform and approach to drug development. Following the shift away from the US and in-house development of Tesomet, the company's early-stage candidates (most notably SAN711 and SAN 903) have become an increasingly important part of the investment case, as well as the drug discovery platform in itself.

Saniona's history of collaborations extend to company's such Boehringer Ingelheim, Medix and Cadent Therapeutics/Novartis – and the company has in total brought in roughly SEK 400 million as of today.

Challenge I: Regaining Investors' and Market Confidence

In retrospect, the company's pivot towards the US and in-house clinical development, including its high ambitions and expenses, was premature and damaged the reputation of Saniona. Furthermore, the company has lost a few cornerstone institutional investors. We think that the new management team has done the right things lately: Smaller organization, significantly reduced costs and a focus on business development. To further turn the company around, additional execution on its new strategy will be needed.

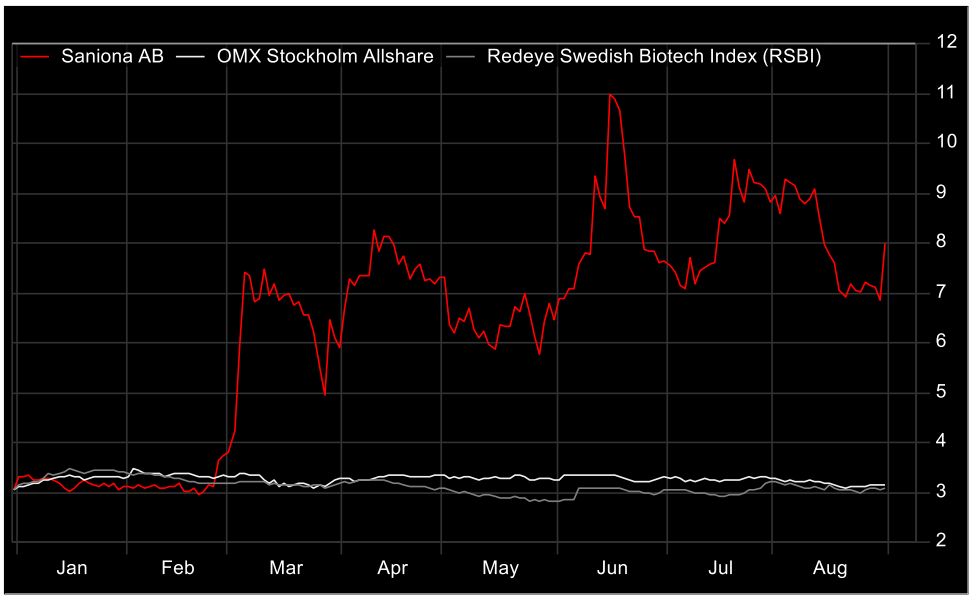
Challenge II – Funding Needs

Even though Saniona has reduced costs by some 75%, the company is still in need of additional funding for its operations and clinical programs, although the renegotiated loan with Formue Nord has extended the runway longer into 2024. The company has declared that it will focus on non-dilutive funding from partnering. The company has started to turn its reputation around, but strong execution – preferably a licensing deal with a significant upfront payment - would be a major relief. Also, a strong launch of Tesofensine could add further runway.

Strong value proposition

We largely reiterate our positive stance on Saniona's clinical drug candidates and research platform, but we see that uncertainty about funding could monopolize investors' attention as we go further into 2023. To turn the case around, we argue that a funding solution and/or licensing agreement by H2 2023 and further advancement with phase I candidate SAN711 will be key in pushing the share toward and beyond our Base Case of SEK 9.5 Per Share.

Share Price Development (YTD)



Source: Factset; Redeye Research

#	Holders	Saniona	Capital	Votes
1	Avanza Pension	4871896	7,81%	7,81%
2	Nordnet Pensionsförsäkring	2530980	4,06%	4,06%
3	Jørgen Drejer	2364711	3,79%	3,79%
4	Tredje AP-fonden	1886792	3,02%	3,02%
5	Formue Nord A/S	1741301	2,72%	2,72%
6	Dan Peters	1400000	2,24%	2,24%
7	Joakim Tedroff	1065862	1,71%	1,71%
8	Nordea Liv & Pension	1052182	1,69%	1,69%
9	Thomas Feldthus	965000	1,55%	1,55%
10	Leif Andersson Consulting ApS	793725	1,27%	1,27%

Source: Holdings/Modular Finance

In 2022, the outflows in Saniona accelerated following the refocused strategy and changed management team, including previous top share holder RA Capital and Fjärde AP-fonden (4th AP Fund). For now, the ownership appears more stable – an important contributor to the more stable price in Saniona. We note that major in/outflows have related to Formue Nord (so far we can only see inflow).

Q1 Review

We note that the report came in roughly as we expected, with a relatively stable OPEX at SEK-25.7million per quarter (we expected SEK22m), still indicating a new normal at "Scandinavian levels". The majority of the costs remains related to R&D/other external costs at SEK-13.8m followed by SEK-8.8m in personnel costs. Revenues landed at SEK3.9m and related to Saniona's collaborations.

Financing and OPEX Review

Source: Saniona (historical numbers) and Redeye Research (estimates)

At the end of Q1, the cash position was SEK69.4 million, and Saniona furthermore renegotiated its loan with Formue Nord. Part of the loan, amounting to SEK13m, has been repaid, primarily through the issuance of new shares priced at SEK8.5. This move takes advantage of the stock's previous rally, although it has led to a selling pressure recently. While SEK61m of the loan is still outstanding, the repayment deadline has been pushed to 31st of January 2025, granting an additional year. Although the loan is not cheap and a commitment fee of SEK4.8m (payable in shares) is tied to the amended agreement, this arrangement alleviates some of the short-to-medium-term capital need. We note that Saniona has a cash runway into the end of Q1 2024 if no further revenues come to the company from now on. We however see several opportunities for additional revenues such as another deal with an upfront payment, a milestone payment from Boehringer Ingelheim (In the report, Saniona again mentions that it has made significant progress in the collaboration with Boehringer Ingelheim that could trigger a milestone payment)[1] and revenues and a milestone payment from Medix.

[1] For example: In 2018, Saniona received SEK42m in relation to a candidate selection by BI. A milestone on this level would be a significant contributor we judge.

In the case of Medix, the annual report mentions that Saniona is eligible to receive SEK21m related to prespecified regulatory milestones. We assume that at least half will likely be paid in relation to an approval in Mexico but assume that revenues for Tesofensine will come mainly in 2024 and forward. We were further encouraged to see additional pre-clinical data (article here) that further validates Tesofensine's mechanism and effect as a weight loss drug.

In summary, Saniona is engaged in numerous activities that have the potential to bring in capital without dilution. The outcomes can vary widely based on timing and implementation. In the near term, we currently include one licensing agreement in Q4 with an upfront payment of USD5m relating to SAN711. However, we note that there are a lot of potential assets ready for a deal, such as SAN903 and the Kv7 epilepsy program, where Saniona is close to select a clinical candidate.

AstronauTx Research Collaboration

Although it seems that the market had high expectations for a first deal (the company has a goal to deliver two this year) with a significant upfront payment, we are still impressed by the licensing agreement with AstronauTx even though the revenue in the near future seems limited (mainly research funding expected at SEK15m the first year). The aim is to " identify new treatments for Alzheimer's disease and other neurodegenerative conditions by modulating a novel, undisclosed ion channel target". A core focus will be to utilize Saniona's proprietary IonBase platform. The deal value amounts to SEK 1.9bn (USD177m) plus royalties (if option is exercised which is during a limited time). USD102m are related to R&D and regulatory miletsones and USD75m to commercialization. Royalties are tiered to sales. It clearly shows that there is a lot of optionality in Saniona's Ionbase platform as we did not anticipate that Saniona would venture into Alzheimer's disease. We note however that this is very early stage and that there also is an option agreement baked into the collaboration structure. We therefore see this more as a testament to the platform's capabilities than a major contributor to our valuation.

Overall, we think that the company has continued to deliver and continued its turnaround, although we hope to see a more transformative licensing agreement with a more significant upfront payment in the second agreement Saniona aims to deliver this year. We would like to see pipeline advancements with Saniona's in-house clinical assets, mainly SAN711 and Tesomet. An agreement that continues the advancement of one or several of these assets would be a major breakthrough that could lead to a more significant re-evaluation of our valuation. This could also give Saniona the flexibility to continue with some of its clinical program's inhouse – as we now get the impression that most of the focus relates to business development and early stage research.

Valuation

We largely reiterate our previous sum-of-the-parts valuation but make a few adjustments, leading to a higher base case of SEK 9.5 (8) per share. We note that Saniona is a platform company with a lot of assets, including spinoffs and assets that Saniona has a stake in (Cephagenix, Initiator etc), but consider the projects below the "core" that we include in our valuation. Other projects are "free-of-charge" at the moment.

- We raise our likelihood of approval to 85% for Tesofensine in Mexico, which is a typical assumption for an NDA stage asset in the disease area. This as we have better insight into the process and that Medix has proceeded with the application
- We still assume a rights issue as Saniona still has repay the loan to Formue Nord in early 2025, but the amended agreement should buy Saniona some additional time. We pencil in a rights issue in Q2/Q3 2024 but note that it will depend on Saniona's success with business development and also potential revenues from Tesofensine
- We set an initial valuation of the AstronauTx agreement. We note that it is very early stage where we know little about the mechanism of action, relevant patient populations and so onn. Furthermore, AstronauTx has negotiated an option in the agreement. We discuss this project more in-depth once we know more about the progress.

Sum-of-the-parts: Saniona

Asset	Indication	LoA	Royalties	Peak sales (USDm)	Deal size (USDm)	rNPV (SEKm)
SAN711	Pain	12%	14%	1 101	200	**297**
Tesomet - HO	Hypothalmic Obesity	33%	10%	553	120	**475**
AstronauTx	Alzheimer's Disease	3%	7%	1 206	177	**91**
Boehringer Ingelheim	Schizofrenia	6%	7%	415	88	**107**
Tesofensine	Obesity	85%	14%	37	2	**151**
Project value (SEKm)						1 121
Estimated Net cash (2023)						52,0
Shared costs incl. tax (SEKm)						-488,53
Fair value (SEKm)						684,03
Shares outstanding (2023)						71,7
Value per share (SEK)						9,5

Source: Redeye Research.

Sensitivity analysis: Stock price/raised funds and our base case

Rights issue scenario table						
		Stock price				
		7,0	7,5	8,0	8,5	9,0
SEKm	10	9,8	9,8	9,8	9,8	9,8
	20	9,7	9,7	9,7	9,7	9,8
	30	9,5	9,6	9,6	9,7	9,7
	40	9,4	9,5	9,6	9,6	9,6
	50	9,3	9,4	9,5	9,5	9,6
	60	9,2	9,3	9,4	9,5	9,5
	70	9,2	9,2	9,3	9,4	9,5
	80	9,1	9,2	9,3	9,4	9,4
	90	9,0	9,1	9,2	9,3	9,4

Source: Redeye Research

Appendix:

We continue to be impressed by the many programs and drug candidates within Saniona's portfolio. In December, the company announced a new candidate, SAN2219, which is the first preclinical candidate from the GABA-A A2/A3 activation program, that has shown encouraging preclinical data in for example epilepsy. Furthermore, Saniona announced exciting progress in the joint venture Cephagenix, targeting mainly migraine. According to the report, Cephagenix has successful reached pre-clinical in vivo validation for treatment of migraine.

Saniona: Clinical Projects Under Development

	Project	Indication	Research	Pre-clinical	Phase I	Phase II	Phase III	NDA	Market
Eating Disorders	Tesomet	PWS HO							
	Tesofensine	Obesity							
Ion Channel Platform	SAN 711	Rare neuropathic disorders							
	SAN 903	Inflammatory Bowel Disease							
	SAN 2219	Epilepsy							

Completed development phase
External development
Ongoing phase

Ion Channel Platform

Saniona possesses a proprietary drug discovery engine that focuses on modulating ion channels - a well-established and validated target for several successful drugs on the market. The company's in-house team has unique competencies and methods, resulting in a library of over 20,000 proprietary molecules that target different types of ion channels. Last year, Saniona achieved a significant milestone when its first candidate from the platform, SAN711, entered clinical trials, which were completed last year. Another potential drug candidate, SAN903, with the ability to inhibit inflammation and fibrosis, has also progressed well and is ready for clinical development.

Ion channels are unique proteins that regulate the passage of charged ions across the lipid membrane that surrounds all cells. These membrane proteins are expressed in all types of cells, including the central and peripheral nervous systems. Despite being a high-potential target, ion channels are highly heterogeneous and, as a result, are often seen as difficult to explore. Saniona's value proposition lies in developing "highly selective, subtype-specific, state-dependent ion channel modulators and inhibitors," which utilize its "ionbase" database as the backbone of drug discovery. Saniona's in-house expertise allows it to develop modulators specific to a particular ion channel, enabling the desired effect without affecting other channels and potentially leading to adverse effects. Additionally, the company has a defined and sometimes unique set of methods, including imaging technology, assay design, and electrophysiological approaches. While ion channel drug discovery is complex, we believe investors should view the platform as an increasingly critical part of Saniona's equity story, ultimately providing the company with additional drug candidates over time.

Summary Redeye Rating

The rating consists of three valuation keys, each constituting an overall assessment of several factors that are rated on a scale of 0 to 1 points. The maximum score for a valuation key is 5 points.

Rating changes in the report

People: 3

No changes

Business: 3

No changes

Financials: 0

	2022	2023E	2024E
INCOME STATEMENT			
Revenues	15	48	53
Cost of Revenues	4	0	1
Gross Profit	11	48	53
Operating Expenses	229	82	84
EBITDA	-218	-34	-31
Depreciation & Amortization	0	4	2
EBIT	-226	-38	-33
Net Financial Items	-27	-10	-2
EBT	-252	-48	-35
Income Tax Expenses	-7	0	0
Non-Controlling Interest	0	0	0
Net Income	-245	-48	-35
BALANCE SHEET			
Assets			
Current assets			
Cash & Equivalents	112	73	78
Inventories	0	1	1
Accounts Receivable	5	3	3
Other Current Assets	11	7	4
Total Current Assets	127	84	86
Non-current assets			
Property, Plant & Equipment, Ne	6	1	0
Goodwill	0	0	0
Intangible Assets	7	7	7
Right-of-Use Assets	10	10	10
Shares in Associates	1	1	1
Other Long-Term Assets	3	3	3
Total Non-Current Assets	26	22	20
Total Assets	154	106	106
Liabilities			
Current liabilities			
Short-Term Debt	6	6	6
Short-Term Lease Liabilities	0	0	0
Accounts Payable	14	16	1
Other Current Liabilities	3	5	5
Total Current Liabilities	23	27	12
Non-current liabilities			
Long-Term Debt	76	63	63
Long-Term Lease Liabilities	0	0	0
Other Long-Term Liabilities	2	2	2
Total Non-current Liabilities	78	65	65
Non-Controlling Interest	0	0	0
Shareholder's Equity	53	14	29
Total Liabilities & Equity	154	106	106
CASH FLOW			
NOPAT	-220	-38	-33
Change in Working Capital	-23	9	-12
Operating Cash Flow	-15	-35	-45
Capital Expenditures	0	0	0
Investment in Intangible Assets	-1	0	0
Investing Cash Flow	-1	0	0
Financing Cash Flow	-21	-3	50
Free Cash Flow	-16	-35	-45
NOPAT	-2,5	-0,9	1,5
Change in Working Capital	1,9	-0,2	0,9
Operating Cash Flow	-0,2	0,4	5,0
Capital Expenditures	0,0	0,0	0,0
Investment in Intangible Assets	-2,1	-1,7	-2,7
Investing Cash Flow	-1,5	-3,4	-6,7
Financing Cash Flow	-1,3	-1,5	-1,5
Free Cash Flow	-2,3	-1,3	2,3

DCF Valuation Metrics	Sum FCF (SEKm)
Project value (SEKm)	938,4
Estimated Net cash (2023)	52,0
Shared costs incl. tax (SEKm)	-450,4
Fair value (SEKm)	539,9
Shares outstanding (2023)	71,7
Value per share (SEK)	7,5

Redeye Rating and Background Definitions

Company Quality

Company Quality is based on a set of quality checks across three categories; PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive long-term earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of people behind a business is a significant part of understanding the long-term drive of the company. It all comes down to doing business with people you trust, or at least avoiding dealing with people of questionable character.

The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

Business

If you don't understand the competitive environment and don't have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won't succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.

The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company's financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.

The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

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Redeye does not issue any investment recommendations for fundamental analysis. However, Redeye has developed a proprietary analysis and rating model, Redeye Rating, in which each company is analyzed and evaluated. This analysis aims to provide an independent assessment of the company in question, its opportunities, risks, etc. The purpose is to provide an objective and professional set of data for owners and investors to use in their decision-making.

Redeye Rating (2023-09-01)

Rating	People	Business	Financials
5	7	6	2
3-4	154	149	40
0-2	25	31	144

Duplication and distribution

CONFLICT OF INTERESTS
Fredrik Thor owns shares in the company : No
Kevin Sule owns shares in the company No
Redeye performs/have performed services for the Company and receives/have received compensation from the Company in connection with this.