Saniona

Sector: Biotech

Q3 2023: A lot of activities going forward

Redeye returns with an updated view of Saniona following the Q3 report and recent milestones in the company. We largely reiterate our previous valuation and also take a look into the epilepsy field.

Report in line

The report came in largely as expected, with revenues of SEK5.5m and operating expenses at -23.8m. The revenues related to ongoing agreements with Boehringer Ingelheim, AstronauTx and Cephagenix and the increase, the company states, relates mainly to the new agreement with AstronauTx. OPEX remains at a relatively stable level around SEK-25m quarterly and we expect it to continue going forward.

Increased focus on epilepsy

As we have noted the last few quarters, Saniona is increasingly positioning itself as an epilepsy company, having both its Kv7-program, its SAN2219 candidate but also phase II ready SAN711, where the company recently has described the potential in a pre-clinical setting. We give a short description of the market but will return later with a more thorough review of Saniona's pipeline.

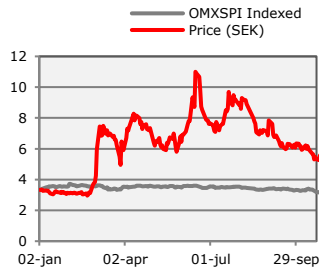
Adjust our base case to SEK 9 (9.5) per share

We largely reiterate our previous sum-of-the-parts valuation but make a few adjustments related to FX, WACC and share price assumptions, leading to a new base case at SEK 9 (9.5) per share. In the short term, we note that Saniona has a funding need and argue that a funding solution and/or licensing agreement/milestone payments by Q4/Q1 will be key for the share price going forward.

FAIR VALUE RANGE

BEAR	BASE	BULL
1	9	20

SANION VERSUS OMXS30



REDEYE RATING

KEY STATS

Ticker	SANION
Market	Small Cap
Share Price (SEK)	6.1
Market Cap (SEKm)	391
Free Float (%)	92

Key Financials (SEKm)	2021	2022	2023E	2024E
Revenues	11	15	17	81
EBITDA	-403	-218	-65	-3
EBIT	-412	-226	-66	-6

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Investment Thesis

Case: Turn around case with plenty of value

We see high quality in Saniona's assets, including its mid-stage orphan drug candidate Tesomet, soon commercial stage obesity drug Tesofensine, phase II ready asset SAN711, and in the long run: its many assets from its Ion Channel Platform, including the increasing pipeline within epilepsy. 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 in the near term and further advancement with SAN711, a Tesofensine launch in Mexico and Saniona's early stage pipeline 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.

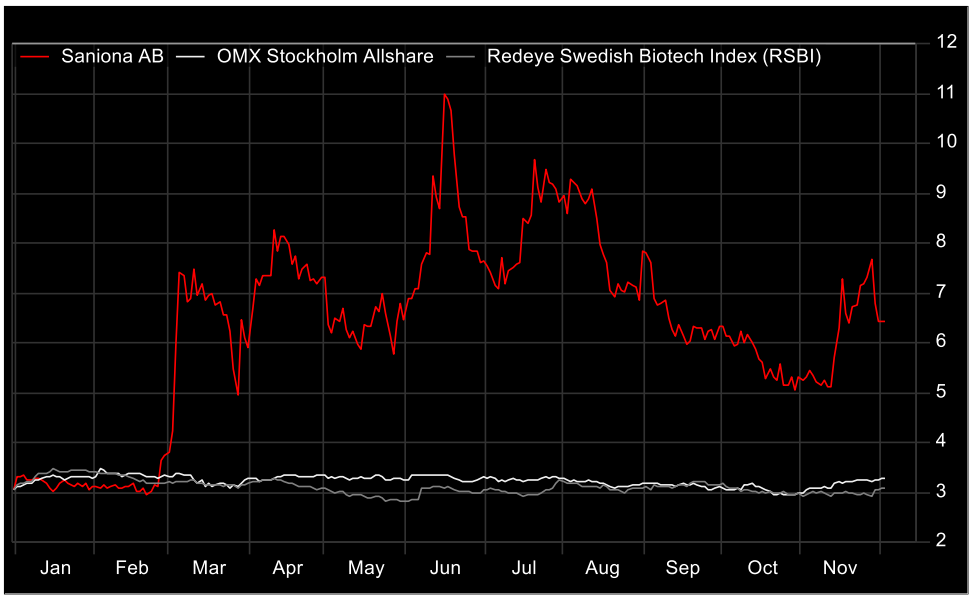
Challenge II – Funding Needs

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, with a lot of promising potential. In the short term, we note that Saniona has a funding need and argue that a funding solution and/or licensing agreement by Q4/Q1 and further advancement with SAN711 and Tesomet in Mexico will be key in pushing the share toward and beyond our Base Case of SEK 9 Per Share.

Share Price Development (YTD)



Source: Factset; Redeye Research

#	Holders	Saniona	Capital	Votes
1	Avanza Pension	5110991	7,97%	7,97%
2	Nordnet Pensionsförsäkring	2787437	4,35%	4,35%
3	Jørgen Drejer	2364711	3,69%	3,69%
4	Tredje AP-fonden	1886792	2,94%	2,94%
5	Dan Peters	1500000	2,34%	2,34%
6	Joakim Tedroff	1086494	1,69%	1,69%
7	Nordea Liv & Pension	1067635	1,66%	1,66%
8	Formue Nord A/S	1043500	1,63%	1,63%
9	Thomas Feldthus	965000	1,50%	1,50%
10	Thomas Kreutzfeldt	835800	1,30%	1,30%

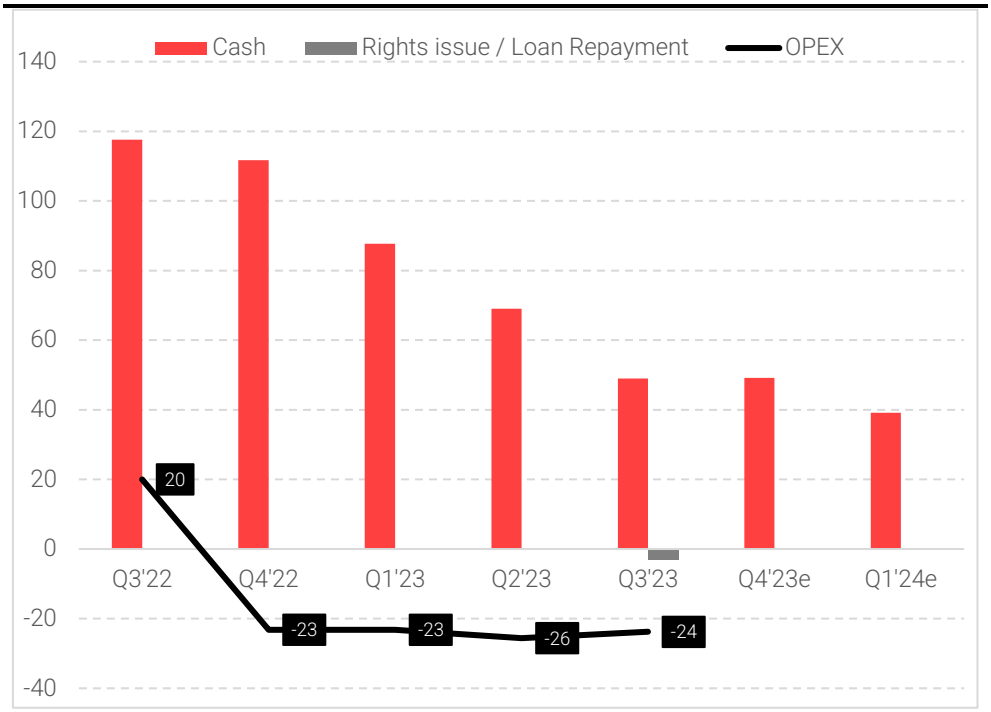
Source: Holdings/Modular Finance

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). According to the latest data from holdings/Modular Finance (2013-10-27), Formue Nord had sold roghly 40% of its position. Given the high liquidity in November, we assume that Formue Nord has continued to sell the last couple of weeks.

Q3 Review

The report came in largely as expected, with revenues of SEK5.5m and operating expenses at -23.8m. The revenues related to ongoing agreements with Boehringer Ingelheim, AstronauTx and Cephagenix and the increase, the company states, relates mainly to the new agreement with AstronauTx. OPEX remains at a relatively stable level around SEK-25m quarterly and we expect it to continue going forward.

Financing and OPEX Review



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

We reiterate our stance that Saniona has a cash runway into the end of Q1/start of Q2 2024 if no further revenues come to the company from now on, which is also in line with what the company is writing in its report. There are several potential income sources, including another deal with an upfront payment, a milestone payment from Boehringer Ingelheim (the company is making progress towards lead optimization which would trigger a milestone payment)[1] and revenues and a milestone payment from Medix.

As a reminder, in the annual report it is mentioned that Saniona is eligible to receive SEK21m related to prespecified regulatory milestones from Medix regarding Tesofensine. 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 note that an approval could come in December but also in Q1.

In summary, we reiterate our stance that 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/Q1 with an upfront payment of USD5m relating to SAN711 (in our model, we now book it in Q1). However, we note that there are a lot of potential assets ready for a deal, such as

[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.

SAN903 and the Kv7 epilepsy program. Still, Saniona needs to deliver at least SEK40m in income during the upcoming few months to avoid a rights issue in H1 2024 we judge.

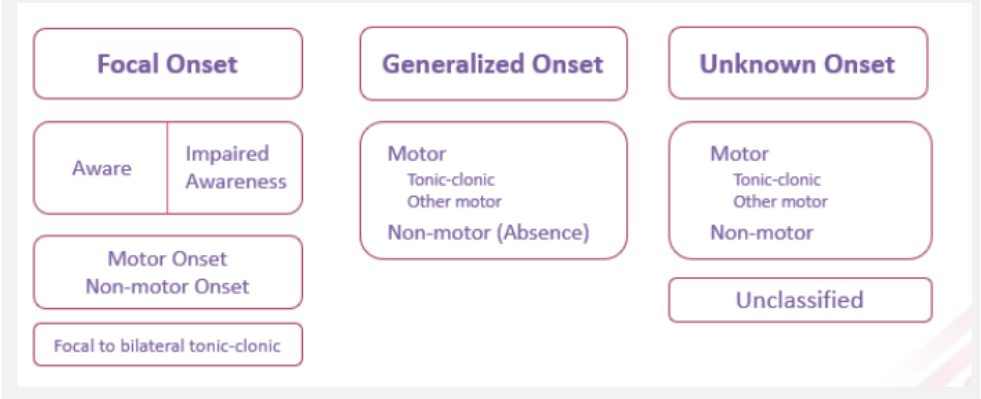
Overview of Epilepsy Market

As we have noted the last few quarters, Saniona is increasingly positioning itself as an epilepsy company, having its Kv7-program, its SAN2219 candidate but also phase II ready SAN711, where the company recently has described the potential in a pre-clinical setting.

Looking at the whole market, the prevalence of epilepsy according to Datamonitor is 56 million cases, which is expected to increase to 59 million by 2027. Epilepsy is thus one of the most common neurological disorders and also one of the most disabling, as it is the third leading contributor to the global burden of disease for neurological disorders according to Nature Reviews/GBD2015.

When it comes to categorization, seizures that typically start in one hemisphere of the brain and cause involuntary movements in a specific body area are known as focal-onset seizures (or partial-onset seizures) and generalized-onset seizures, on the other hand, begin at a specific point but quickly involve both brain hemispheres, leading to seizures that can affect the whole body. When the origin of a seizure cannot be determined, it is referred to as an unknown seizure type. There are also several subcategories that are used to further classify the disease by specialists, including further features related to the motor and non-motor categories. Furthermore, patients are typically further defined by the epilepsy type and epilepsy syndromes.

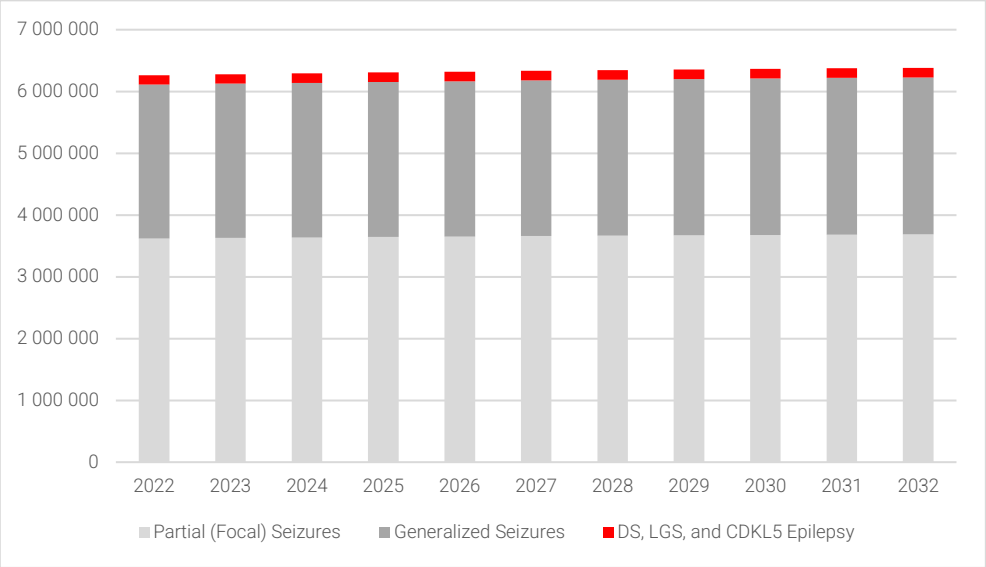
Classification of epileptic seizures (basic)



Source: Datamonitor; ILAE 2017

As seen below, partial (focal) seizures are the most common type followed by generalized seizures. There are also several rare forms of epilepsy that typically are genetic, including severe pediatric syndromes.

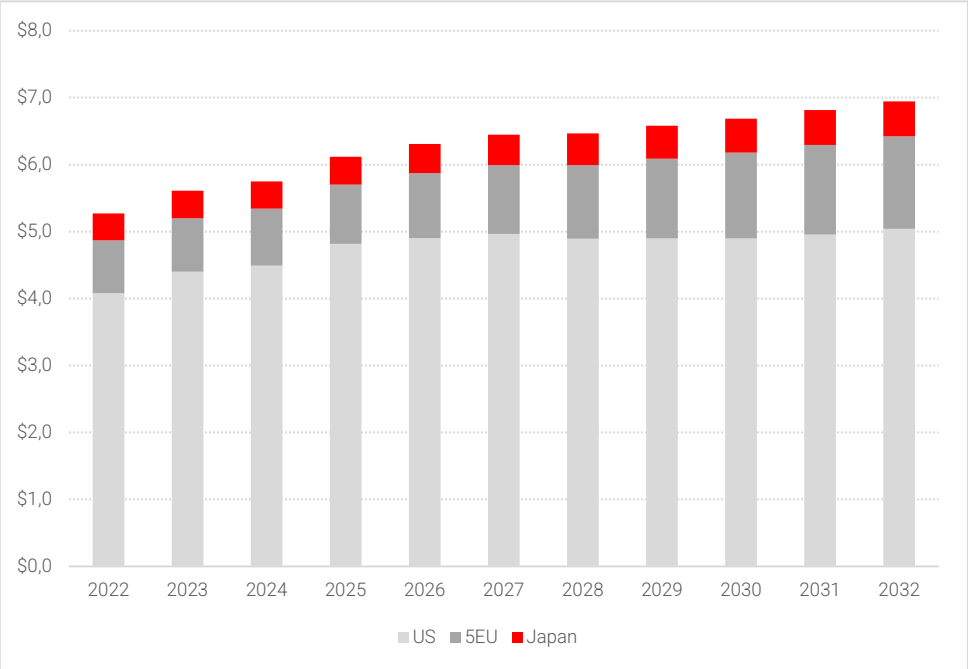
Patient population – Epilepsy (US, EU5 and JPN)



Source: Datamonitor

The market size is according to Datamonitor around USD5.5bn and expected to reach USD7bn by 2032. There is a high degree of generic drugs when it comes to traditional symptomatic epilepsy drugs (ASDs), with over 20 approved anti-seizure medications, and the market for drugs targeting partial-onset seizure, while the largest segment, is relatively saturated when it comes to first-line treatments. In this population, there is however a remaining unmet clinical need in non-responders/drug resistant patients, which amounts to over 30%. Key drugs in the POS segment are Keppra/Keppra XR, Lamictal/Lamictal XR, and Vimpat.

Market Size – Epilepsy (bnUSD)



Source: Datamonitor

Saniona's epilepsy programs

Saniona is positioning its several programs as precision treatments of epilepsy, targeting specific subsets of the patient population. SAN711, which is a phase II ready candidate, is currently positioned as a precision treatment for absence seizures, typically manifested in childhood or adolescence, with the goal to target spike-wave discharges specifically through GABAa a3.

For SAN2219, in the pre-clinical stage, the target is acute repetitive seizures, according to Saniona with a prevalence of around 300k in the US. Here, the goal is to differentiate the drug from approved benzodiazepines, where the clinical effect is known but where side effects are limiting their use, which Saniona hopes to achieve as SAN2219 lacks GABAa a1 activation.

For the Kv7 program, the focus is the larger indication of refractory focal onset seizures, ie the patients that do not respond to ordinary ASDs. Compared to previous non-selective Kv7 activators, Saniona's program targets Kv7.2 and Kv7.3 which is believed to avoid the tolerability issues of the previous generation while retaining anti-seizure activity. In November, Saniona announced that it had initiated the candidate selection phase for "a proprietary subtype selective frontrunner molecule from the Kv7 lead optimization program", indicating a swift process for the program.

Overall, we think that Saniona's epilepsy pipeline is very exciting, and Saniona's recent efforts have made it clear that the company's in-house development likely will focus on these activities going forward. Still, we note that the company's clinical plans are relatively early-stage still and we will return once we know more, including the next step for SAN711.

Pipeline

Product Candidate	Indication	Research	LOP/CS	Pre-clinical	Phase 1	Phase 2a	Phase 2b	Phase 3	Comment
Tesofensine	*Obesity*								**Potential market launch 2024** – partnership with market leader **Medix**, representing near-term revenue potential through mid-teens royalties and milestone
Tesomet	*HO, PWS*								**Positioned for partnering** following successful phase 2a data (2019)
SAN711	*Epilepsy*								**Positioned for absence seizures** following positive phase 1 data (2022). Value-inflection points in 2024/25
SAN903	*Fibrotic and inflammatory disorders*								**Positioned for partnering** following successful IND/CTA enabling studies
SAN2219	*Epilepsy*								**Positioned for acute repetitive seizures** with multiple expansion opportunities in rare and severe epilepsy
GABA program	*Epilepsy*								**Positioned for rare pediatric epilepsy syndrome** with multiple expansion opportunities in rare and severe epilepsy
Kv7 program	*Epilepsy*								Focal/Generalized Epilepsy Lead optimization
AstronauTx	*Alzheimer's*								Partnership agreement entitling Saniona to **milestone payments of up to USD 177m plus royalties**
Boehringer Ingelheim	*Schizophrenia*								Partnership agreement entitling Saniona to **milestone payments of up to EUR 76.5m plus royalties**
Cephagenix	Migraine								Joint venture, Saniona owns 33%

Source: Saniona

Valuation

We largely reiterate our previous sum-of-the-parts valuation but make a few adjustments, leading to a new base case at SEK 9 (9.5) 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. We include pre-clinical assets that are partnered. We will return with a more thorough review of Saniona's epilepsy assets once we know more about the clinical plans and funding. For example, longer in-house development of SAN711 could be feasible in a smaller indication such as absence seizures but it would require additional funding. Other projects are "free-of-charge" at the moment.

- 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. Since Q2, we have update our share price assumptions.
- Increase the WACC to to 14% (increase risk-free rate to 3% (2.5%)), per Redeye Policy

Sum-of-the-parts: Saniona

Asset	Indication	LoA	Royalties	Peak sales (USDm)	Deal size (USDm)	rNPV (SEKm)
SAN711	Epilepsy/pain	12%	14%	1 101	200	**273**
Tesomet - HO	Hypothalmic Obesity	33%	10%	553	119	**469**
AstronauTx	Alzheimer's Disease	3%	7%	1 206	177	**91**
Boehringer Ingelheim	Schizofrenia	6%	7%	415	88	**109**
Tesofensine	Obesity	85%	14%	37	2	**153**
Project value (SEKm)						1 095
Estimated Net cash (diluted)						54,5
Shared costs incl. tax (SEKm)						-483,65
Fair value (SEKm)						665,79
Shares outstanding (2023)						73,6
Value per share (SEK)						9,0

Source: Redeye Research.

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

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

Source: Redeye Research

Appendix:

We continue to be impressed by the many programs and drug candidates within Saniona's portfolio. In December last year, 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. The company has also made strong progress with its KV7 epilepsy program. 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.

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	2025E
INCOME STATEMENT				
Revenues	15	17	81	37
Cost of Revenues	4	0	1	1
Gross Profit	11	17	81	36
Operating Expenses	229	82	84	87
EBITDA	-218	-65	-3	-51
Depreciation & Amortization	0	2	2	4
EBIT	-226	-67	-6	-55
Net Financial Items	-27	-10	-2	-5
EBT	-252	-77	-8	-60
Income Tax Expenses	-7	0	0	0
Non-Controlling Interest	0	0	0	0
Net Income	-245	-77	-8	-60
BALANCE SHEET				
Assets				
Current assets				
Cash & Equivalents	112	36	74	18
Inventories	0	0	1	1
Accounts Receivable	5	1	4	2
Other Current Assets	11	3	6	3
Total Current Assets	127	39	86	23
Non-current assets				
Property, Plant & Equipment, Ne	6	4	2	-2
Goodwill	0	0	0	0
Intangible Assets	7	7	7	7
Right-of-Use Assets	10	10	10	10
Shares in Associates	1	1	1	1
Other Long-Term Assets	3	3	3	3
Total Non-Current Assets	26	25	22	19
Total Assets	154	64	108	42
Liabilities				
Current liabilities				
Short-Term Debt	6	6	6	6
Short-Term Lease Liabilities	0	0	0	0
Accounts Payable	14	6	1	12
Other Current Liabilities	3	2	8	4
Total Current Liabilities	23	13	15	21
Non-current liabilities				
Long-Term Debt	76	63	63	0
Long-Term Lease Liabilities	0	0	0	0
Other Long-Term Liabilities	2	2	2	2
Total Non-current Liabilities	78	65	65	2
Non-Controlling Interest	0	0	0	0
Shareholder's Equity	53	-14	28	18
Total Liabilities & Equity	154	64	108	42
CASH FLOW				
NOPAT	-220	-67	-6	-55
Change in Working Capital	-23	2	-6	13
Operating Cash Flow	-15	-73	-12	-43
Capital Expenditures	0	0	0	0
Investment in Intangible Assets	-1	0	0	0
Investing Cash Flow	-1	0	0	0
Financing Cash Flow	-21	-3	50	-13
Free Cash Flow	-16	-73	-12	-43

DCF Valuation Metrics	Sum FCF (SEKm)
Project value (SEKm)	1103,4
Estimated Net cash (diluted)	54,5
Shared costs incl. tax (SEKm)	-485,0
Fair value (SEKm)	672,9
Shares outstanding (2023)	73,6
Value per share (SEK)	9

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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Disclaimer

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Redeye Rating (2023-12-04)

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.