Saniona

Sector: Biotech

Q4 2023: Financing in place

Redeye returns with an updated view of Saniona following the Q4 report and recent rights issue and reiterate our valuation.

Report in line

The report was in line with expectations, also as preliminary numbers already had been released, with revenues of SEK5.4m and operating expenses at -25.2m. The revenues related to ongoing agreements with Boehringer Ingelheim and AstronauTx. Saniona recently finalized a rights issue with a subscription rate of 63% that brought in SEK89m before issue costs. After Saniona's payment to Formue Nord, we estimate that Saniona will keep around SEK60m in cash on top of Q4s cash position of SEK31m.

Continued activity

We like Saniona's precision approach to epilepsy and there has been a lot of activity in the company recently. In December, it was announced that Saniona had selected SAN2355 as the first clinical candidate from its KV7 epilepsy program, after announcing in November that it had initiated the candidate selection program. SAN2355 is a subtype-selective activator of Kv7.2/Kv7.3 channels. In January, it was announced that Saniona had selected an additional clinical candidate, the GABAA α5 negative allosteric modulator SAN2465, for preclinical development. SAN2465 will target major depressive disorder, which again shows the broad potential of Saniona's platform and the precision targeting of its drug candidates.

Reiterated base case of SEK6 per share

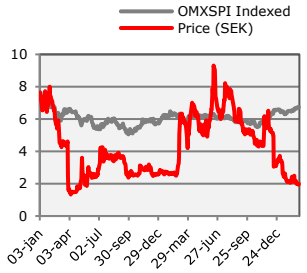
We just recently adjusted our valuation after the outcome of the rights issue and reiterate our base case of SEK6 per share. We see good prospects for value-enhancing activities in 2024, including further advancement with SAN711, a Tesofensine launch in Mexico and progress with the early-stage pipeline will be key, and also potentially also licensing agreement, which is a key priority for the company.

Key Financials (SEKm)	2021	2022	2023	2024E	2025E
Revenues	11	15	17	62	56
EBITDA	-403	-218	-71	-27	-32
EBIT	-412	-226	-81	-29	-38
Net Income	-373	-245	-104	-37	-43

FAIR VALUE RANGE

BEAR	BASE	BULL
0.7	6	15

SANION VERSUS OMXS30



REDEYE RATING

KEY STATS

Ticker	SANION
Market	Small Cap
Share Price (SEK)	2
Market Cap (SEKm)	222
Free Float (%)	92

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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

We think that the new management team has done the right things: 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 – preferably a licensing deal.

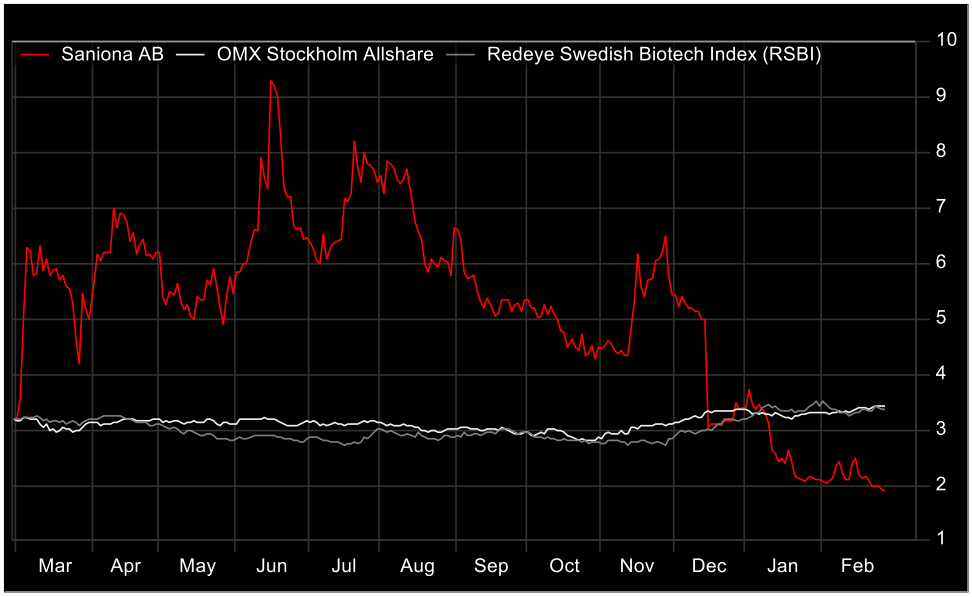
Challenge II – Long term funding

Saniona has recently finalized a rights issue and should have funding for the upcoming year, depending on priorities, but it may need additional funding, also to repay the remaining loan from Formue Nord. The company has declared that it will focus on non-dilutive funding from partnering but also on its epilepsy pipeline. Strong execution on this strategy– 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, and have accounted for the recent rights issue in our model. We see further advancement with SAN711 and Tesomet in Mexico, and potentially a licensing deal, as key drivers in pushing the share toward and beyond our Base Case of SEK 6 Per Share.

Share Price Development (1 Year)



Source: Factset; Redeye Research

Ownership

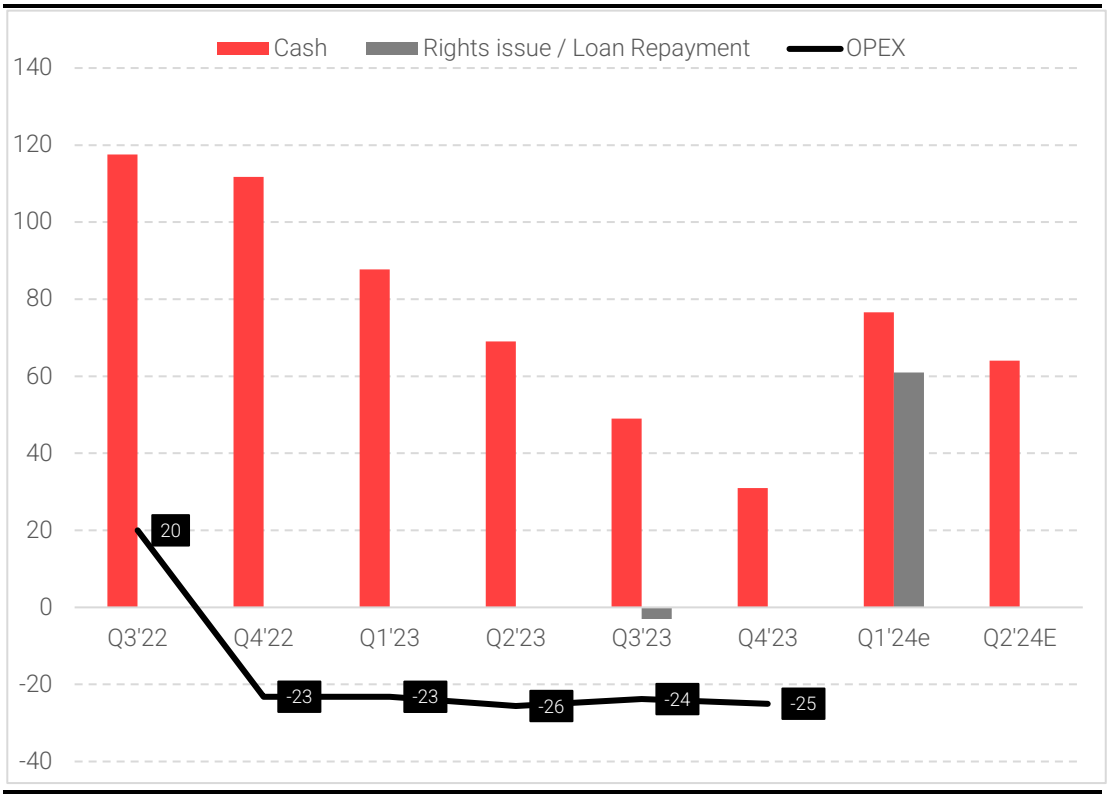
#	Holders	Saniona	Capital	Votes
1	Avanza Pension	4772682	7,44%	7,44%
2	Nordnet Pensionsförsäkring	5869038	5,28%	5,28%
3	Jørgen Drejer	2364711	3,69%	3,69%
4	Tredje AP-fonden	1886792	2,94%	2,94%
5	Dan Peters	1550000	2,42%	2,42%
6	Fredrik Lundgren	1984438	1,78%	1,78%
7	Wilhelm Risberg	1984438	1,78%	1,78%
8	Nordea Liv & Pension	1093671	1,71%	1,71%
9	Thomas Kreutzfeldt	1005569	1,57%	1,57%
10	Joakim Tedroff	986494	1,54%	1,54%

Source: Holdings/Modular Finance

Q4 Review

The report was in line with expectations, also as preliminary numbers already had been released, with revenues of SEK5.4m and operating expenses at -25.2m. The revenues related to ongoing agreements with Boehringer Ingelheim and AstronauTx. OPEX remains at a relatively stable level around SEK-25m quarterly.

Financing and OPEX Review



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

Saniona recently finalized a rights issue with a subscription rate of 63% that brought in SEK89m before issue costs, that were mentioned to land at around SEK16m if fully subscribed. Earlier this month, it was reported that parts of the guarantor payment will be paid in shares, equivalent to SEK8m (out of roughly SEK10m), increasing Saniona's net proceeds in cash somewhat (but increasing the dilution). Out of the remaining proceeds, Saniona will repay SEK20m to Formue Nord, and SEK41.2m remains from the loan. SEK10m out of the remaining loan have been converted to convertibles in the company. Overall, we estimate that Saniona will keep around SEK60m in cash on top of Q4s cash position of SEK31m.

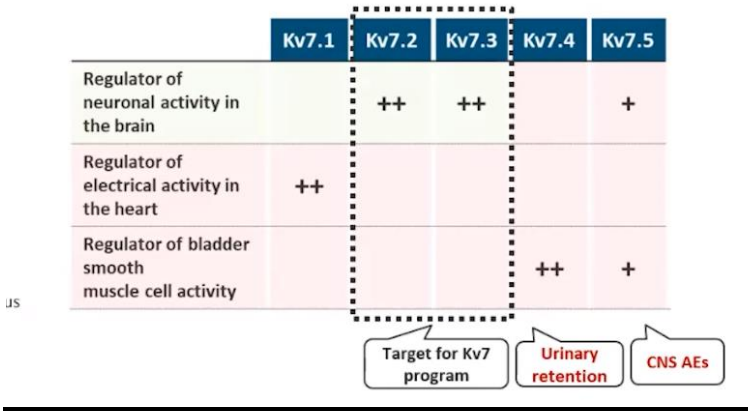
As we have previously stated, there are a lot of moving parts in Saniona, including a potential Tesofensine approval in Mexico, which could lead to a milestone payment of up to SEK20m (we assume half), milestone payment from Boehringer Ingelheim and income from several of its research collaborations. However, we note that exact timelines remain uncertain. In the report, it is stated that "*our research activities are now fully funded through three partnerships and cover a fair share of our operating overheads*", and Saniona further states that it expects to receive SEK27.3m in research funding on an annual basis. Most of the remaining proceeds will be used to advance its epilepsy assets such as SAN711 and SAN2355 and support business development efforts, and mr Feldthus mentions that "*this will enable us to initiate the proof-of-concept studies for SAN711 and progress other epilepsy assets into clinical*

development either in collaboration with partners or internally based on income from new partnerships, milestones under existing collaboration agreements, and potential royalties under the agreement with Medix." Depending on activities, cash should last into 2025, potentially through the warrant program in April if the company receives additional income beyond the research funding or if costs go down somewhat during the year, which we will evaluate in upcoming reports.

Research programs:

We like Saniona's precision approach to epilepsy and there has been a lot of activity in the company recently. In December, it was announced that Saniona had selected SAN2355 as the first clinical candidate from its KV7 epilepsy program, after announcing in November that it had initiated the candidate selection program. SAN2355 is a subtype-selective activator of Kv7.2/Kv7.3 channels. 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.

Target for KV7 program

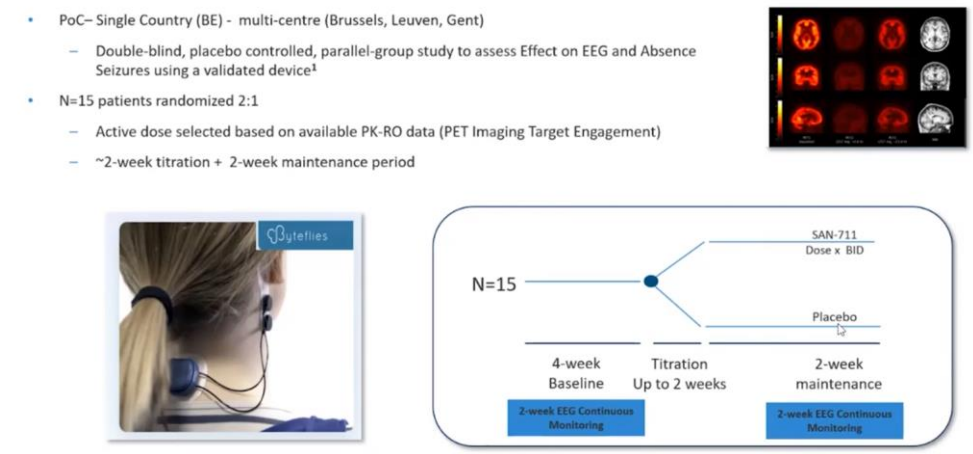


Source: Saniona

In January, it was announced that Saniona had selected an additional clinical candidate, the GABAA α5 negative allosteric modulator SAN2465, for preclinical development. SAN2465 will target major depressive disorder, which again shows the broad potential of Saniona's platform and the precision targeting of its drug candidates. Saniona indicates that the results will be discussed with potential partners, and we expect this program to be positioned for collaboration mainly. Readers can see an interview we conducted with CSO Karin Sander Nielsen here. Saniona has previously selected SAN2219, and 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.

The most advanced drug candidate is SAN711, which is a phase II ready candidate, and 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. Saniona has shared a potential trial design for "proof-of-concept", which could be conduced in relatively few patients (n=15) and thus potentially increase the value in the candidate further at a relatively low cost. We hope to learn more about the company's plans for SAN711 in upcoming months and will return with a more thorough review.

Proof-of-concept trial – potential design



Source: Saniona

Pipeline overview

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								**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
SAN2355	Epilepsy								**Positioned for focal/generalized epilepsy** and paediatric epilepsy
SAN2465	Depressive disorder								**Positioned for partnering** following candidate selection for rapid onset major depressive disorder
GABA program	Epilepsy								**Positioned for rare pediatric epilepsy syndrome** with multiple expansion opportunities in rare and severe epilepsy
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 reiterate our previous sum-of-the-parts valuation since the outcome of the rights issue, leading to a reiterated base case at SEK6 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 Other projects are "free-of-charge" at the moment.

- We pencil in the warrant program in 2025 and the subsequent dilution
- Assume a USD/exchange rate of 10.64, the average through Q4, per our guidlines
- Reiterated WACC at 14%

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	**304**
Tesomet - HO	Hypothalmic Obesity	33%	10%	553	119	**484**
AstronauTx	Alzheimer's Disease	3%	7%	1 206	177	**95**
Boehringer Ingelheim	Schizofrenia	6%	7%	415	88	**98**
Tesofensine	Obesity	85%	14%	37	2	**153**
Project value (SEKm)						1 135
Estimated Net cash (diluted)						79,5
Shared costs incl. tax (SEKm)						-444,61
Fair value (SEKm)						769,87
Shares outstanding est (2024)						131,2
Value per share (SEK)						6,0

Source: Redeye Research.

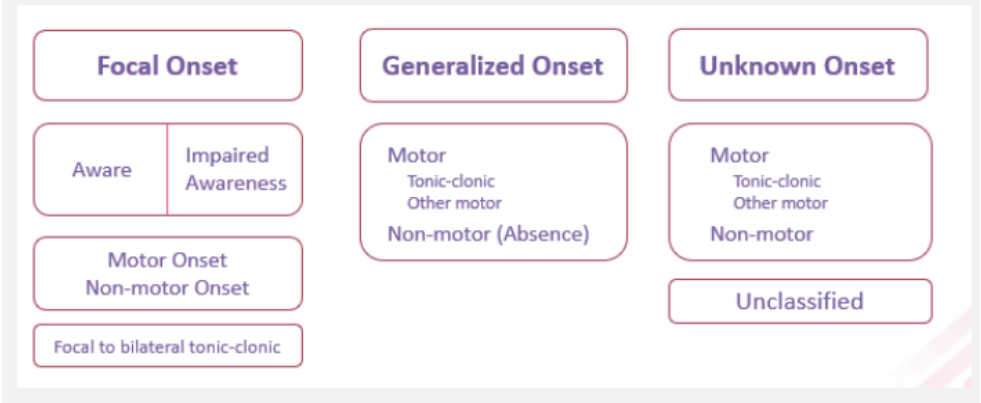
Appendix:

Overview of Epilepsy Market

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.

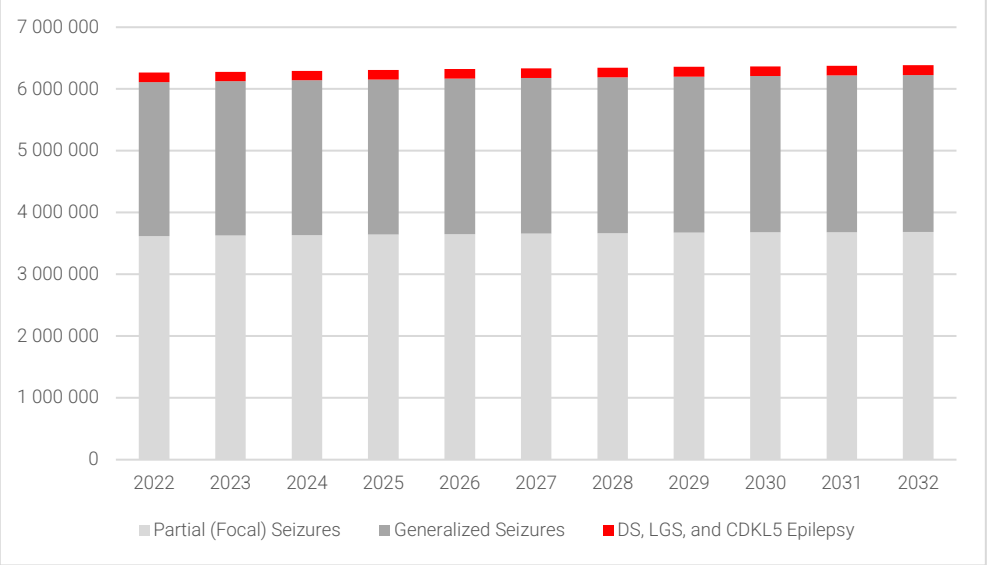
Classification of epileptic seizures (basic)



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.

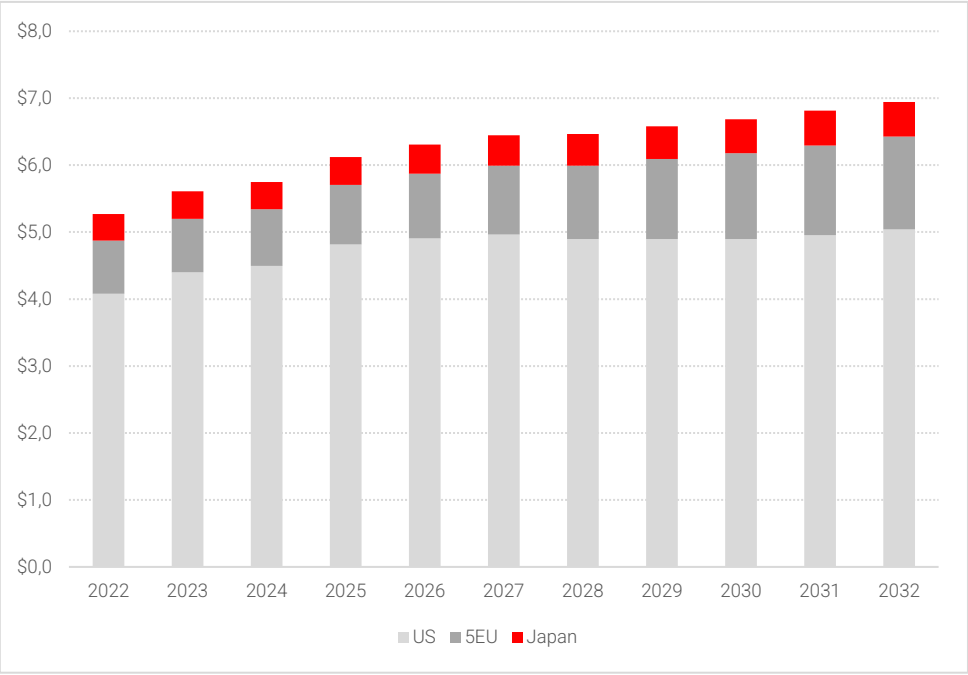
Patient population – Epilepsy (US, EU5 and JPN)



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

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. In 2021, Saniona achieved a significant milestone when its first candidate from the platform, SAN711, entered clinical trials, which were completed in 2022.

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	2023	2024E	2025E
INCOME STATEMENT				
Revenues	15	17	62	56
Cost of Revenues	4	5	1	1
Gross Profit	11	12	62	55
Operating Expenses	229	83	89	87
EBITDA	-218	-71	-27	-32
Depreciation & Amortization	0	10	2	6
EBIT	-226	-81	-29	-38
Net Financial Items	-27	-23	-8	-5
EBT	-252	-104	-37	-43
Income Tax Expenses	-7	-8	0	0
Non-Controlling Interest	0	0	0	0
Net Income	-245	-96	-37	-43
BALANCE SHEET				
Assets				
Current assets				
Cash & Equivalents	112	31	56	41
Inventories	0	0	1	1
Accounts Receivable	5	11	3	3
Other Current Assets	11	3	5	4
Total Current Assets	127	45	65	49
Non-current assets				
Property, Plant & Equipment, Ne	6	3	1	-4
Goodwill	0	0	0	0
Intangible Assets	7	5	5	5
Right-of-Use Assets	10	7	7	7
Shares in Associates	1	0	0	0
Other Long-Term Assets	3	3	3	3
Total Non-Current Assets	26	19	17	12
Total Assets	154	64	82	61
Liabilities				
Current liabilities				
Short-Term Debt	6	5	5	6
Short-Term Lease Liabilities	0	0	0	0
Accounts Payable	14	8	1	18
Other Current Liabilities	3	4	6	6
Total Current Liabilities	23	18	13	30
Non-current liabilities				
Long-Term Debt	76	66	46	0
Long-Term Lease Liabilities	0	0	0	0
Other Long-Term Liabilities	2	2	2	2
Total Non-current Liabilities	78	68	48	2
Non-Controlling Interest	0	0	0	0
Shareholder's Equity	53	-22	21	29
Total Liabilities & Equity	154	64	82	61
CASH FLOW				
NOPAT	-220	-74	-29	-38
Change in Working Capital	-23	-3	0	18
Operating Cash Flow	-15	-86	-35	-19
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	-18	60	4
Free Cash Flow	-16	-86	-35	-19

DCF Valuation Metrics	Sum FCF (SEKm)
Project value (SEKm)	1135,0
Estimated Net cash (diluted)	79,5
Shared costs incl. tax (SEKm)	-444,6
Fair value (SEKm)	769,9
Shares outstanding est (2024)	131,2
Value per share (SEK)	6

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 Rating (2024-03-01)

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.