

Saniona

Sector: Biotech

Transformational deal warrants an upgrade

Redeye returns with an updated view of Saniona following the Q3 report and the transformative licensing deal with Acadia. We raise our base case effective immediately and include the new indication (essential tremor) for SAN711 and an initial valuation of SAN2355, the preclinical epilepsy candidate that is soon ready to enter the clinic.

Q3 Report in line

The report in itself was rather undramatic, with revenues of SEK7.2m and operating expenses at -26m. As before, the revenues related to ongoing agreements with Boehringer Ingelheim and AstronauTx, and OPEX continues at a relatively stable level around SEK-25m quarterly. However, as the company now can increase its ambitions following the licensing agreement with Acadia – we expect costs to increase in 2025, but don't foresee a capital need for the company for a long time with its current strategy.

Licensing deal with Acadia

In late November, it was announced that Saniona had out-licensed its clinical stage drug candidate SAN711 (a first-in-class, highly selective GABAA-α3 PAM) to Acadia Pharmaceuticals, a US-based biotechnology company with a market cap of USD3bn, to target neurological diseases. In total, the deal is worth USD610m, including USD28m in an upfront, which was significantly higher than our expectation (USD200m in deal value). We are impressed by the licensing agreement and see it as a significant validation of the company's early-stage pipeline/platform and the continued turnaround since CEO Thomas Feldthus took over.

Raise our base case to SEK11 (6) and fair value range 3-25 (0.7-15)

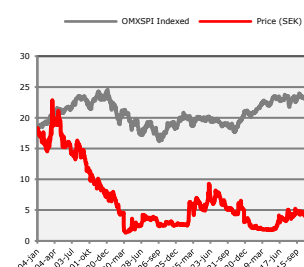
We see the licensing agreement as a substantial derisking of the case and argue that the company, following the significant capital injection from the upfront payment, holds a relatively unique position among Swedish pre-commercial biotech companies in being able to advance several drug candidates from pre-clinical stage through phase I without any need for additional capital. We include the new SAN711 indication (essential tremor) and include an initial valuation SAN2355, one of the company's prioritized projects following the capital injection and closest to the clinic. We also make some other adjustments, leading to a new base case of SEK11 (6) per share. Additionally, we raise our bear-and bull cases to reflect the significant reduction in financial risk and increased optionality.

| Key Financials (SEKm) | 2022 | 2023 | 2024e | 2025e | 2026e |
|-----------------------|------|------|-------|-------|-------|
| Revenues | 15 | 17 | 341 | 12 | 366 |
| EBITDA | -218 | -71 | 258 | -115 | 274 |
| EBIT | -226 | -81 | 251 | -121 | 267 |
| Net Income | -211 | -93 | 236 | -121 | 238 |

FAIR VALUE RANGE

| BEAR | BASE | BULL |
|---------|--------|---------|
| 3 (0.7) | 11 (6) | 25 (15) |

SANION VERSUS OMXS30



REDEYE RATING



KEY STATS

| | |
|-------------------|-----------|
| Ticker | SANION |
| Market | Small Cap |
| Share Price (SEK) | 6.7 |
| Market Cap (SEKm) | 750 |
| Free Float (%) | 94 |

ANALYSTS

Fredrik Thor
 Fredrik.thor@redeye.se
 Filip Lindkvist
 Filip.lindkvist@redeye.se

Investment Thesis

Case: Well-financed platform case with plenty of optionality

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 think that the current management has conducted a great turn-around – most recently with the transformational licensing agreement with Acadia - and the company now has a strong cash position that should sustain the company for several years, allowing it to advance its (mainly early-stage) in-house pipeline.

Evidence: Validated platform and history of collaborations

The Saniona case offers some unique factors: a validated, target-driven research platform focused on ion channels that has generated several drug candidates to date and a validated business model by several collaborations and spinouts over the years, providing non-dilutive funding from upfront payments and milestones – and the current CEO and management team have a proven track record of dealmaking specifically at Saniona: most notably the recent deal with Acadia.

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 $\alpha 3$. 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 $\alpha 1$ and $\alpha 5$) 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) 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 most recently Acadia Pharmaceuticals.

Challenge I: High risk in most assets

Saniona stands out from most peers due to its well-diversified portfolio, comprising a robust platform and multiple drug candidates in development. However, apart from Tesofensine (and Tesomet that is positioned for partnering), the majority of its internally developed candidates remain in the early stages of development, inherently carrying a high level of development risk. Progress with either Tesofensine or Tesomet could lead to a more balanced portfolio from a development risk perspective.

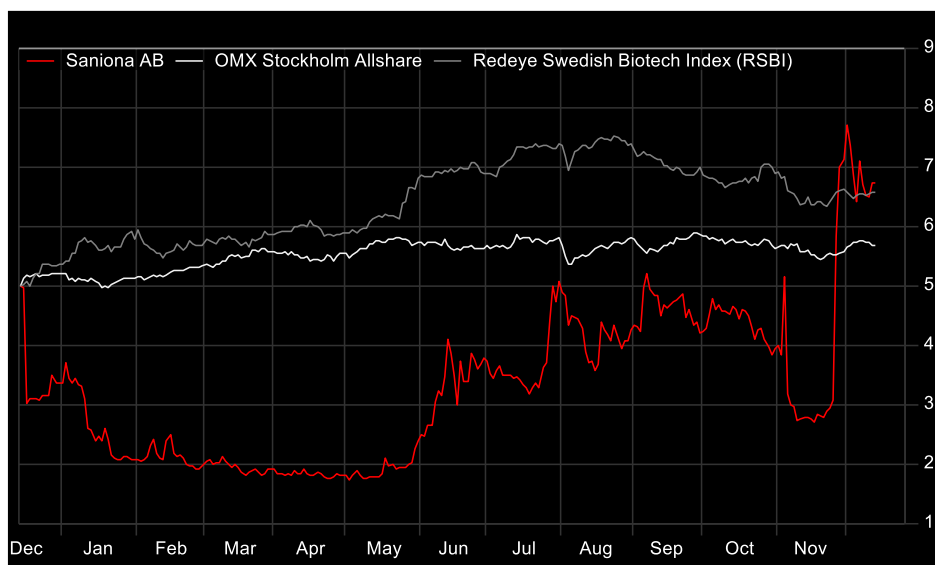
Challenge II – Keeping up momentum

Now when the financial risk has reduced significantly and Saniona can increase its ambitions, it will be important from a share price perspective for the company to continue to communicate its strategy as well as to continue to deliver on its plans to take several of its candidates into the clinic in order to keep the momentum, as it in combination with a potential Tesofensine approval are the main catalysts in the relative near term. In the long run, further licensing deals will be needed to take the company's drug candidates to the market.

Strong value proposition with reduced financial risk

We value Saniona through a 2024-2042 risk-adjusted DCF with a WACC of 14%, where each project is valued separately. We have a positive stance on Saniona's clinical drug candidates and research platform, with a lot of promising potential, and the increased optionality and financial strength following the recent deal with Acadia.

Share Price Development (1 Year)



Source: Factset; Redeye Research

Saniona's share price has experienced significant volatility over the past year. Following the announcement of a rights issue roughly a year ago, the stock initially faced downward pressure. Midway through 2024, speculation surrounding the potential approval of Tesofensine in Mexico drove a notable rally in the share price. However, in November, the announcement that the approval process had been delayed, with Tesofensine described as "not yet approved," triggered a negative market reaction. Later in the same month, Saniona announced a licensing deal with Acadia, which resulted in a significant share price increase of over 100% - well deserved in our view.

Ownership

| | No. of shares | Capital (%) | Votes (%) |
|----------------------------|---------------|-------------|-----------|
| Avanza Pension | 10447151 | 9% | 9% |
| Nordnet Pensionsförsäkring | 5218467 | 5% | 5% |
| Nordea Liv & Pension | 3368186 | 3% | 3% |
| Jørgen Drejer | 2564711 | 2% | 2% |
| Joakim Tedroff | 2524529 | 2% | 2% |
| Dan Peters | 2350000 | 2% | 2% |
| Wilhelm Risberg | 1984438 | 2% | 2% |
| Thomas Kreutzfeldt | 1876666 | 2% | 2% |
| Thomas Feldthus | 1400000 | 1% | 1% |
| Tredje AP-fonden | 1377761 | 1% | 1% |

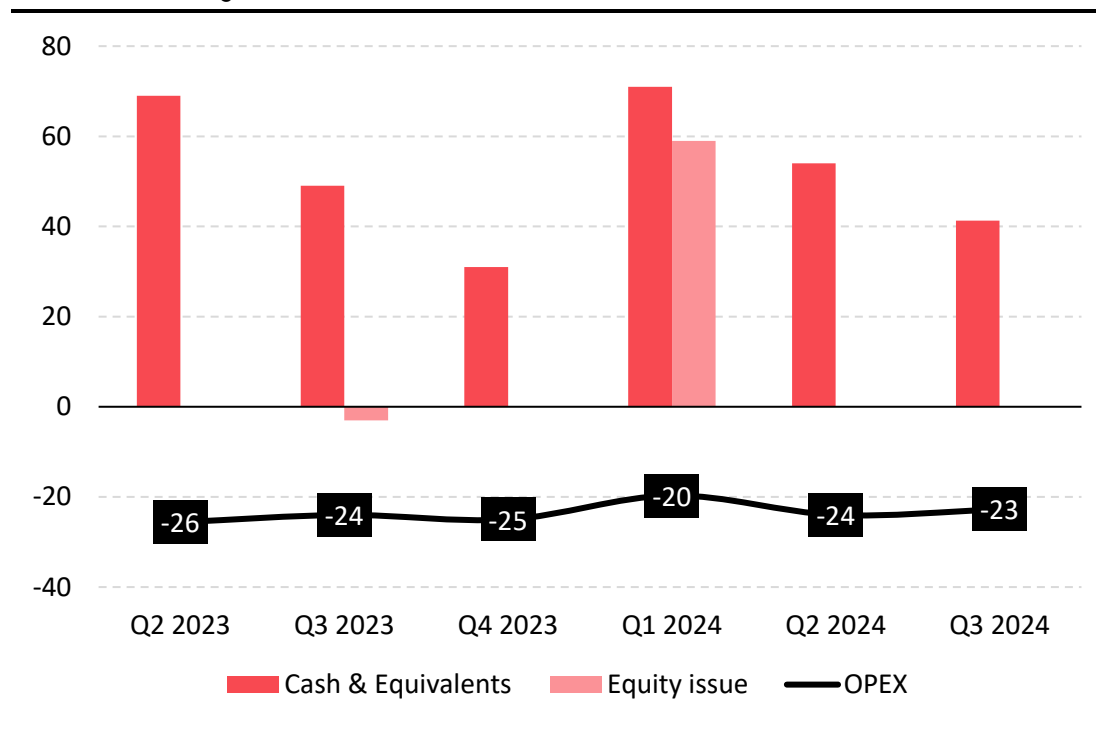
Source: Holdings/Modular Finance

We note that Tredje AP-fonden, according to Holdings, has significantly decreased its holdings in Saniona in November, potentially taking advantage of the strong momentum and volume in the share following the Acadia deal.

Q3 Review

The report in itself contained no major surprises, with revenues of SEK7.2m and operating expenses at -26m. As before, the revenues related to ongoing agreements with Boehringer Ingelheim and AstronauTx, and OPEX continues at a relatively stable level around SEK-25m quarterly. However, as the company now can increase its ambitions following the licensing agreement with Acadia, we expect costs to increase in 2025 - as the company will accelerate its pre-clinical programs and potentially take SAN2355 into the clinic during the year. However, given that Acadia will take over the costs for SAN711 – most of the R&D costs ahead will relate to the company's platform and early-stage assets. As Saniona mentioned in its press release, Acadia hopes to start a phase II trial by 2026, and Saniona will be compensated for the work related to SAN711 prior to that (for example, toxicology studies). With Saniona's outlined strategy (see more in the next section), we don't expect the company to need additional capital for the foreseeable future – although we expect the company to receive proceeds from the warrant program in H1 2025.

Financing and OPEX Review



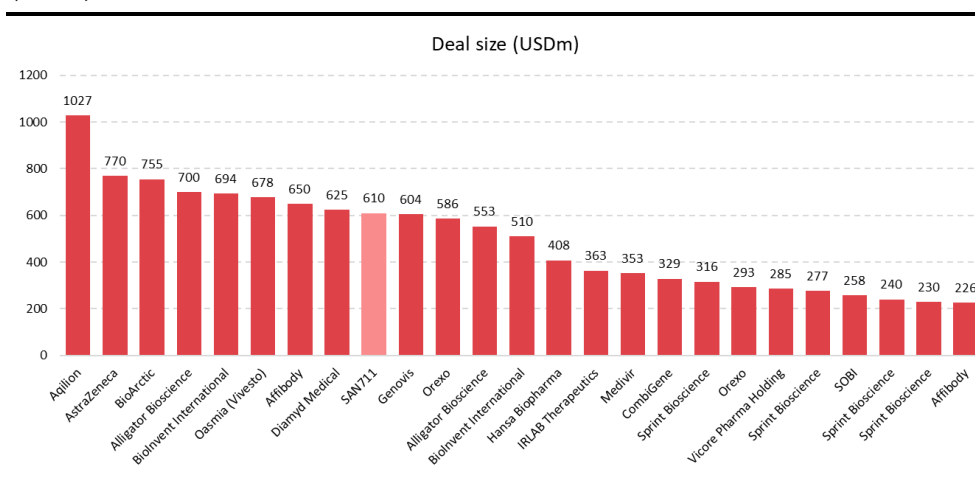
Source: Saniona (historical numbers) and Redeye Research (estimates)

Licensing deal with Acadia

In late November, it was announced that Saniona had out-licensed its clinical stage drug candidate SAN711 (a first-in-class, highly selective GABAA- α 3 PAM) to Acadia Pharmaceuticals, a US-based biotechnology company with a market cap of USD3bn, to target neurological diseases. In total, the deal is worth USD610m, including USD28m in an upfront payment and USD582m in “development, regulatory and commercial milestone payments, along with tiered royalties from mid single digits to low double digits on global net sales of SAN711”. The first indication that will be targeted is essential tremor, and Acadia intends to initiate a phase II trial in 2026. In relation to the start of the study, Saniona will receive USD10m in a milestone payment. The release further states that “The potential milestone payments to Saniona consist of up to US \$147 million subject to achievement of development and regulatory/commercialization milestones related to potential first and second indications, and up to US \$435 million subject to achievement of thresholds of annual net sales of SAN711 worldwide.” Acadia will also support Saniona’s ongoing phase I study and preparations for the phase II study.

As we then wrote, we are impressed by the licensing agreement which exceeded our expectations. One reason is the broad potential use of SAN711—as stated in the release, the first indication is essential tremor—but the milestone payments appear to be structured based on several indications. It is also a significant validation of the company’s early-stage pipeline/platform and the continued turnaround since CEO Thomas Feldthus took over.

SAN711 deal compared to selection of largest historic Swedish listed biotech deals (USDm)




Source: Global Data (data); Redeye Research (compiling)

The upfront payment (close to Saniona’s market cap before the announcement) is transformative for the company, in our view. Saniona can (and will) repay the remaining remaining debt to Fenja (around SEK30m + cSEK7m in convertibles at SEK3.1 per share that we expect will be drawn) while significantly expanding its pipeline ambitions—both by broadening and advancing them. Beyond that, Saniona could receive a significant sum from the TO4 program (we assume c95m) in April and, as previously mentioned, receive a new milestone already in 2026 from Acadia (USD10m). During Saniona’s presentation at Redeye’s Tech and Life Science Day, Saniona outlined that it will prioritize advancing its pre-clinical programs (SAN2355, SAN2219, SAN2465) through phase I (GABA program through pre-clinical), which we think is a sound strategy – especially given that the company has a lot of exciting early stage drug candidates (generated through its ion channel platform) and now a more proven business model with licensing at an early stage.

Pipeline and priorities

| Product Candidate | Indication | Research | LOP/CS | Pre-clinical | Phase 1 | Phase 2a | Phase 2b | Phase 3 | Comment |
|--------------------|------------------------------|-----------------|--------|--------------|----------------|----------|----------|---------|--|
| SAN2355 | Epilepsy | [Yellow bar] | | | [Yellow arrow] | | | | Positioned for focal/generalized epilepsy and paediatric epilepsy |
| SAN2219 | Epilepsy | [Yellow bar] | | | [Yellow arrow] | | | | Positioned for epilepsy acute repetitive seizures with multiple expansion opportunities in rare and severe epilepsy |
| SAN2465 | Depressive disorder | [Yellow bar] | | | [Yellow arrow] | | | | Positioned for rapid onset major depressive disorder and rare diseases |
| GABA Program | Epilepsy | [Yellow bar] | | | [Yellow arrow] | | | | Positioned for rare pediatric epilepsy syndrome with multiple expansion opportunities in rare and severe epilepsy |
| Tesofensine Medix | Obesity | [Dark blue bar] | | | | | | | Under regulatory review – partnership with Mexican market leader Medix, near-term revenue potential through double digit royalties |
| Tesomet | HO, PWS | [Blue bar] | | | | | | | Positioned for partnering following successful phase 2a data (2019) |
| SAN711 Acadia | Essential tremor | [Dark blue bar] | | | | | | | Partnership entitling Saniona to milestone payments of up to USD 582m plus royalties |
| SAN903 | IBD, Fibrotic / inflammatory | [Blue bar] | | | | | | | Positioned for partnering following successful IND/CTA enabling studies |
| AstronauTx Program | Alzheimer's | [Dark blue bar] | | | | | | | Partnership entitling Saniona to milestone payments of up to USD 177m plus royalties |
| Boehringer Program | Schizophrenia | [Dark blue bar] | | | | | | | Partnership entitling Saniona to milestone payments of up to EUR 76.5m plus royalties |
| Cephagenix Program | Migraine | [Dark blue bar] | | | | | | | Joint venture, Saniona owns 33% |

■ - Ongoing partnership
 ■ - Project positioned for partnership
 ■ - In-house development

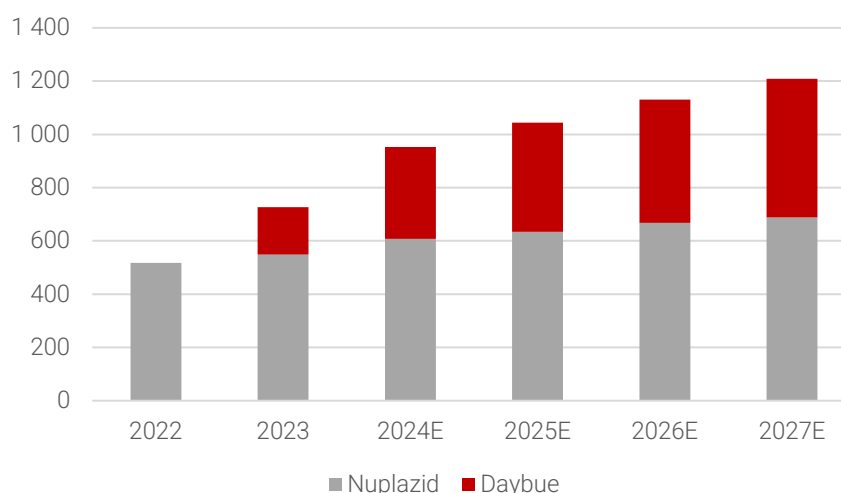


Source: Saniona presentation

Acadia Pharmaceuticals – background

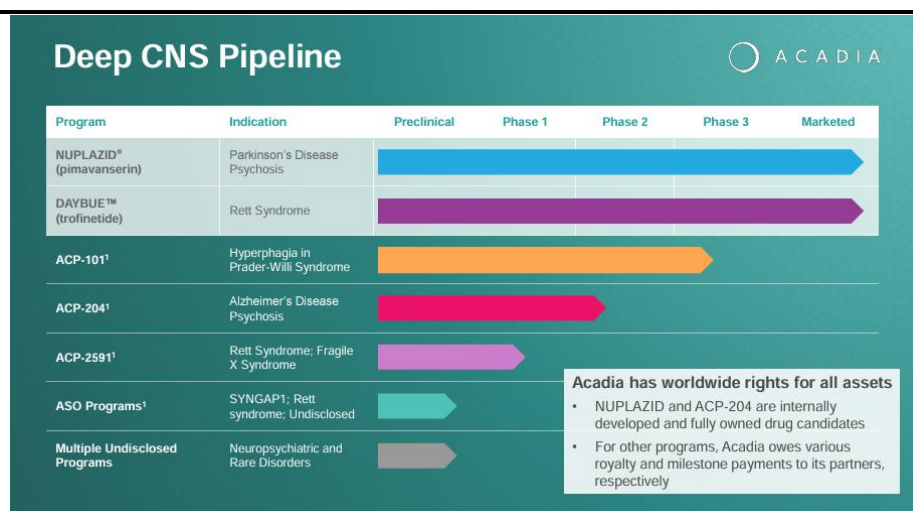
Acadia appears to be a suitable partner for Saniona, offering a good strategic fit with its focus on neurology/movement disorders and the opportunity to leverage the organization around its Parkinson’s drug, Nuplazid, which targets Parkinson’s psychosis. With a market cap of USD3bn, Acadia is a relatively modest-sized licensee, currently forecasted to generate sales of approximately USD1bn in 2024e. After years of losses, the company is cash flow positive and also expected to turn profitable in FY2024, delivering a net income of around USD100m according to Factset consensus. Most growth is expected to come from its second drug, Daybue, which targets Rett’s syndrome. Acadia just recently sold a priority review voucher for USD150m, which it received after the approval of Daybue. According to Fierce Pharma, Acadia has tried to expand the label of Nuplazid, including schizophrenia, but has quit its efforts and will likely focus on its other projects for growth, including SAN711. Beyond SAN711 and its commercial stage candidates, it has two late-stage drug candidates targeting Alzheimer’s disease psychosis and Prader Willis Syndrome.

Acadia – historic sales and estimates (USDm)



Source: Factset (data); Redeye Research (compiling)

Acadia Pharmaceuticals pipeline

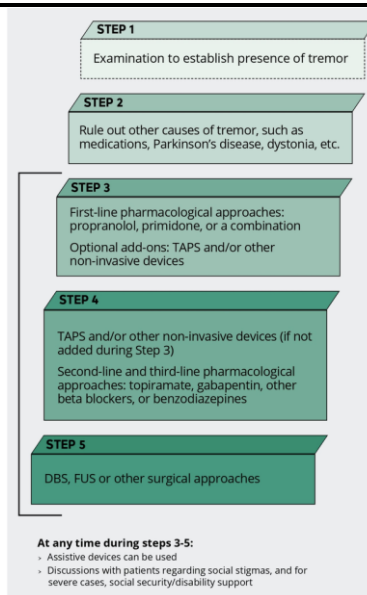


Source: Acadia

Essential Tremor

Essential tremor is progressive neurological disorder and one of the most common movement disorders – characterized by the patients’ hands, but also head, trunk and legs shake rhythmically – typically in relation to a voluntary movement. Age and family history are two key risk factors and about 5% of people above 60 years of age are affected. According to global data, there were around 2.3 million diagnosed prevalent cases of essential tremor in 2023 in the US, EU4+UK and Japan. Essential tremor is relatively commonly misdiagnosed with Parkinson’s disease or dystonia. Today’s treatments are mainly generics of betablockers, and anticonvulsants, but benzodiazepines (which targets GABA) are also used in later stages. About 30-60% of patients are helped by medications and we have seen numbers of a reduction of 30-50% in these patients. As pictured below, devices are also part of the treatment algorithm, including non-invasive devices such as Cala Trio (Transcutaneous Afferent Patterned Stimulation) and invasive devices such as DBS (“Deep Brain Stimulation”).

Treatment Algorithm – Essential Tremor



Source: International Essential Tremor Foundation

When it comes to new drugs, the pipeline is scarce and the deal activity before Saniona's deal with Acadia has been relatively modest. In recent years, both Sage Therapeutics and Jazz Pharmaceuticals have failed in phase II, leading the remaining drug candidate to mainly be Praxis Precision Medicines Ulixacaltamide in mid/late stage (it's in phase III). According to Praxis Q3 presentation, interim data from one of its trials is expected to be presented in Q1 2025. The phase II data was also in our view mixed, with a missed primary endpoint but met secondary endpoints.

In other words, we conclude that innovation in the indication has been low in recent years and that there is a clear rationale for addressing the unmet medical need in essential tremor.

SAN711 is designed as a potential first-in-class positive allosteric modulator of the neurotransmitter GABAA and specifically the subunit $\alpha 3$. GABAA is a target for several drugs, including benzodiazepines. Today's treatments target GABAA more broadly (including subunits $\alpha 1$ and $\alpha 5$) which can lead to unwanted side effects such as sedation, risk of abuse and motoric instability). In a pre-clinical paper from 2020 (Amrutkar et al), the authors from Saniona concluded that *"Benzodiazepines, which nonselectively enhances the effect of GABA at the GABAA $\alpha 1/2/3/5$ receptors, have been shown to be effective in treating ET. Their use, however, is limited due to sedation, ataxia, tolerance development and memory impairment. Sedation and ataxia are attributed to the activity at the $\alpha 1$ subunit while cognitive impairment is ascribed to the action on the $\alpha 5$ subunit of the GABAA receptors"* In the paper, the authors show that subunits $\alpha 2/\alpha 3$ have an anti-tremor effect without the targeting of $\alpha 1/\alpha 5$ subunits.

Saniona has in a phase I trial shown 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 the side effect profile is significantly different from non-selective GABA modulators (which is a core part of the value proposition, we argue). Looking forward, we expect more tox/safety studies to be conducted to confirm this in a more long-term setting.

Given that essential tremor is a new indication for Saniona and that we have limited insights into Acadia's reasoning, it is difficult to estimate exactly the drug will be positioned. Our initial thoughts are that as the first-line generic drugs are cheap and somewhat effective, making us to mainly assume that SAN711 will be used (at least initially) in non-responders. As mentioned above, Deep Brain Stimulation is also used as a last line of treatment and appears to be relatively rare according to our research. Still, DBS is an expensive treatment (surgery costs alone can exceed USD50 000, indicating willingness-to-pay for more severe patients. Another drug that one can look at is Nuplazid, Acadia's drug targeting Parkinson's Psychosis (relatively similar in size to Essential tremor non-responders) – where the list price amount to around USD50 000 annually. Given that essential tremor is a less severe condition, we expect that the pricing likely is lower than that of Nuplazid, although it will depend on clinical effect and positioning of the drug.

For SAN711 in essential tremor, we assume:

- Phase II initiated in 2026, approval in 2032
- SAN711 is used as a long-term treatment for patients that do not respond to first-line treatment of generic drugs (around 50%) and that are applicable for repetitive treatment 65%. We don't yet know the expected dosing schedule and how long patients will be treated with the drug.
- 70% compliance rate
- Peak penetration of 17.5% in the US; 10% in the EU4+UK and Japan
- Average net price USD20 000 annually in the US, 50% of that in the EU4+UK and Japan
- Likelihood of approval of 14%, which we base on the historic likelihood of approval in movement disorders from Global Data. We set a 90% likelihood of phase II starting.
- Average royalty of 8.5%
- We have distributed most milestones, including commercial, related to essential tremor (around USD400m) and the rest on SAN711 in absence seizures

We land at a peak sale of around USD1.4bn. We will return to these assumptions once we know more about Acadia's plans for the indication.

Sales model – Essential tremor

| SAN711 | | 2032e | 2033e | 2034e | 2035e | 2036e | 2037e | 2038e | 2039e | 2040e |
|---------------------------------------|--------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
| Development stage | | Market | Market | Market | Market | Market | Market | Market | Market | Market |
| Probability | | 14% | 14% | 14% | 14% | 14% | 14% | 14% | 14% | 14% |
| Disease prevalence | US | 1 149 165 | 1 166 402 | 1 183 899 | 1 201 657 | 1 219 682 | 1 237 977 | 1 256 547 | 1 275 395 | 1 294 526 |
| | EU4+UK | 1 162 933 | 1 180 377 | 1 198 082 | 1 216 054 | 1 234 294 | 1 252 809 | 1 271 601 | 1 290 675 | 1 310 035 |
| | JP | 304 297 | 308 861 | 313 494 | 318 197 | 322 970 | 327 814 | 332 732 | 337 722 | 342 788 |
| Addressable patients (TAM) | US | 344 750 | 349 921 | 355 169 | 360 497 | 365 905 | 371 393 | 376 964 | 382 618 | 388 358 |
| | EU4+UK | 348 880 | 354 113 | 359 425 | 364 816 | 370 288 | 375 842 | 381 481 | 387 203 | 393 011 |
| | JP | 91 289 | 92 659 | 94 048 | 95 459 | 96 891 | 98 344 | 99 820 | 101 317 | 102 836 |
| Penetration | US | 1,6% | 4,4% | 8,1% | 11,6% | 14,0% | 15,8% | 17,5% | 17,5% | 17,5% |
| | EU4+UK | 0,9% | 2,5% | 4,6% | 6,6% | 8,0% | 9,0% | 10,0% | 10,0% | 10,0% |
| | JP | 0,9% | 2,5% | 4,6% | 6,6% | 8,0% | 9,0% | 10,0% | 10,0% | 10,0% |
| Adherent treated patients | US | 3 801 | 10 716 | 20 014 | 29 146 | 35 859 | 40 946 | 46 178 | 46 871 | 47 574 |
| | EU4+UK | 2 198 | 6 197 | 11 574 | 16 855 | 20 736 | 23 678 | 26 704 | 27 104 | 27 511 |
| | JP | 575 | 1 621 | 3 028 | 4 410 | 5 426 | 6 196 | 6 987 | 7 092 | 7 199 |
| Net price | US | 20 732 | 20 815 | 20 898 | 20 981 | 21 065 | 21 150 | 21 234 | 21 319 | 21 404 |
| | EU4+UK | 10 366 | 10 407 | 10 449 | 10 491 | 10 533 | 10 575 | 10 617 | 10 660 | 10 702 |
| | JP | 10 366 | 10 407 | 10 449 | 10 491 | 10 533 | 10 575 | 10 617 | 10 660 | 10 702 |
| Product Sales (USDm) | US | 79 | 223 | 418 | 612 | 755 | 866 | 981 | 999 | 1 018 |
| | EU4+UK | 23 | 64 | 121 | 177 | 218 | 250 | 284 | 289 | 294 |
| | JP | 6 | 17 | 32 | 46 | 57 | 66 | 74 | 76 | 77 |
| Worldwide product sales (USDm) | | 108 | 304 | 571 | 835 | 1 031 | 1 182 | 1 338 | 1 364 | 1 390 |

Source: Redeye research

Valuation

As previously noted, we view the licensing agreement as a substantial derisking of the case and a confirmation of the turnaround led by Thomas Feldthus and the management team. With an upfront payment of USD28m, the opportunity to secure significant funds through the warrant program this spring (we estimate c95m), and an additional milestone payment of USD10m anticipated in 2026 when Acadia plans to commence the phase II trial for SAN711, the company holds a relatively unique position among Swedish pre-commercial biotech companies. This is further underscored by its robust pipeline of pre-clinical drug candidates and its ion channel platform's potential to generate additional assets in the future. As a result of the deal, we include, as mentioned previously essential tremor in our model. We also keep epilepsy (absence seizures) in our valuation of SAN711, to illustrate the optionality with the licensing agreement that could extend beyond essential tremor. However, we now assume that Acadia will initiate a phase II trial in absence seizures in 2028 (following completion of the phase II trial in ET) and also reduce our expectations somewhat until we know more about Acadia's plans. We speculate that the company may target absence seizures more broadly (for example childhood + juvenile) to get more similarly sized indications for pricing purposes, but it is difficult to know at this stage.

Furthermore, we include an initial valuation of SAN2355, Saniona's epilepsy program targeting the subtype-selective activator of Kv7.2/Kv7.3, with a focus on focal/generalized seizures, as this is the pre-clinical program that is closest to the clinic. We speculate that the drug candidate could be outlicensed in 2026 following a phase I trial, with an upfront payment of USD28m and total deal value of USD400m. We base our assumptions on that SAN2355 will target refractory focal onset seizures and use historic likelihood of approval figures (phase I-approval) for epilepsy, and also risk-adjust the pre-clinical development (likelihood of reaching phase I with 60%), leading to an initial judgement of likelihood of approval at 9%. We will return with a more extensive review of this candidate soon but want to highlight that Kv7 is a validated target and both clinically and from a deal perspective. Furthermore, we will likely include the company's other prioritized pre-clinical assets (SAN2219 and SAN2465) soon, potentially already in early 2025 if the company's plans are kept and the candidates. In Saniona's Q3 report, it expects SAN2355 to reach the clinic in late 2025 and SAN2219 & SAN2465 in 2026.

General assumptions:

- Following the raised share price, we also raise our assumed proceeds from the warrant program in 2025 (cSEK95m)
- Assume a USD/exchange rate of 11
- Reiterated WACC at 14%
- Following the uncertainties with Tesofensine's application in Mexico, we reduce the likelihood of approval to 60% and push the launch to late 2025/early 2026
- We have also made some adjustments to timeline for mainly Tesomet
- Following the deal, we have distributed most milestones from Acadia related to essential tremor indication

In total, we land at a new base case of SEK11 (6) 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). We include pre-clinical assets that are partnered and projects that are financed and expected to start clinical studies within around a year. Other projects are seen as optionalities for the moment.

Sum-of-the-parts: Saniona

| Project | Indication | Phase | Est. Launch | LoA | Peak sales (USDm) | Deal size (USDm) | rNPV (SEKm) |
|---|---------------------|-------------|-------------|-----|-------------------|------------------|-------------|
| SAN711 (Acadia) | Epilepsy | I | 2033 | 15% | 711 | 610 | 177 |
| | Essential Tremor | I | 2032 | 14% | 1416 | | 653 |
| Tesomet | HO | Iib | 2032 | 33% | 565 | 120 | 301 |
| Tesofensine (Medix) | Obesity | NDA | 2026 | 60% | 35 | 5 | 73 |
| AstronauTx | Alzheimer's disease | Preclinical | 2034 | 3% | 1229 | 177 | 72 |
| SAN2355 | Epilepsy | Preclinical | 2032 | 9% | 1324 | 400 | 254 |
| Boehringer Ingelheim | Schizophrenia | Preclinical | 2034 | 6% | 287 | 90 | 69 |
| Technology value (SEKm) | | | | | | | 1 599 |
| Est. diluted net cash (SEKm) | | | | | | | 93 |
| Shared costs and discount adjustment for YTD (SEKm) | | | | | | | -230 |
| Equity value (SEKm) | | | | | | | 1 462 |
| Shares outstanding (million) | | | | | | | 112 |
| Diluted shares outstanding (million) | | | | | | | 133 |
| Equity value per share (SEK) | | | | | | | 11 |

Source: Redeye Research

We have made some changes to our model, including how we present tax (previously included in row shared costs), now instead deducted per project. The upfront payment is currently part of the rNPV in Essential tremor but will be moved to the cash position once the Q4-results are presented.

Bear case: SEK3 (0.7) per share

We base our pessimistic scenario on the possibility that the company's collaboration with Acadia is ended due to negative phase II results, leading Saniona to cancel further development of SAN711. We also remove Tesomet and Tesofensine from our valuation, leading us to only focus on the company's pre-clinical assets in our valuation today (AstronauTx collaboration, SAN2355 and the Boehringer Ingelheim program).

Bull case: SEK25 (15) per share

We base our optimistic scenario on the assumption that the company successfully advances SAN2355 through phase I (LoA 15%) and outlicenses it with an upfront payment of USD28m and total deal value of USD500m. We also assume that Acadia succeeds in phase II with SAN711 (LoA 39%) and that Tesofensine is approved in Mexico. Finally, we include progress with SAN2219 and SAN2465 into clinic.

Appendix:

Recap of Research programs:

We like Saniona's precision approach to epilepsy and there has been a lot of activity in the company recently. About a year ago, 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

| | Kv7.1 | Kv7.2 | Kv7.3 | Kv7.4 | Kv7.5 |
|--|-------|-------|-------|-------|-------|
| Regulator of neuronal activity in the brain | | ++ | ++ | | + |
| Regulator of electrical activity in the heart | ++ | | | | |
| Regulator of bladder smooth muscle cell activity | | | | ++ | + |

Target for Kv7 program
 Urinary retention
 CNS AEs

Source: Saniona

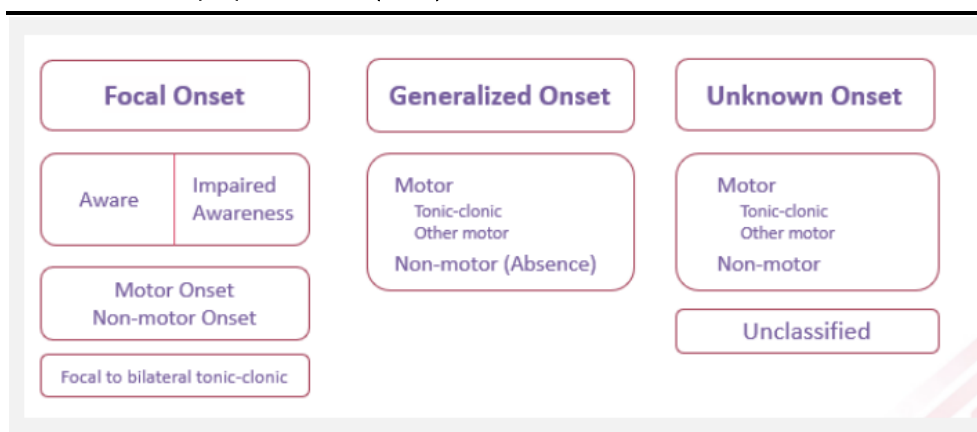
In January, it was announced that Saniona had selected an additional clinical candidate, the GABAA α 5 negative allosteric modulator SAN2465, for preclinical development. SAN2465 will target major depressive disorder, which again shows the broad potential of Saniona's platform and the precision targeting of its drug candidates. Saniona 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 GABA α 1 activation.

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)



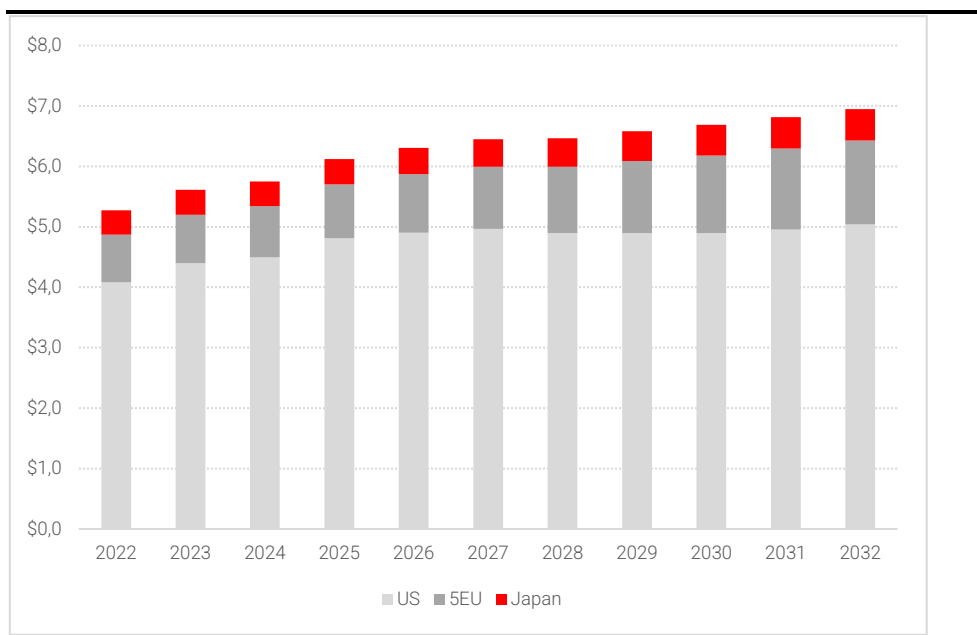
Source: Datamonitor; ILAE 2017

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)

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 (USDbn)



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

Rating changes in the report

People: 3

Business: 3

Financials: 0

| | 2023 | 2024e | 2025e | 2026e |
|---|------|-------|-------|-------|
| INCOME STATEMENT | | | | |
| Revenues | 17 | 341 | 12 | 366 |
| Cost of Revenues | -5 | -5 | 0 | 0 |
| Gross Profit | 12 | 336 | 12 | 366 |
| Operating Expenses | -83 | -78 | -127 | -92 |
| EBITDA | -71 | 258 | -115 | 274 |
| D&A | -10 | -7 | -7 | -7 |
| EBIT | -81 | 251 | -121 | 267 |
| Net Financial Items | -23 | 0 | 0 | 0 |
| EBT | -101 | 251 | -121 | 267 |
| Income Tax Expenses | 8 | -15 | 0 | -29 |
| Non-Controlling Interest | 0 | 0 | 0 | 0 |
| Net Income | -93 | 236 | -121 | 238 |
| BALANCE SHEET | | | | |
| Assets | | | | |
| Current assets | | | | |
| Cash & cash equivalents | 31 | 281 | 253 | 489 |
| Inventories | 0 | 0 | 0 | 0 |
| Accounts Receivable | 3 | 3 | 3 | 3 |
| Other Current Assets | 12 | 12 | 12 | 12 |
| Total Current Assets | 45 | 295 | 267 | 504 |
| Non-current assets | | | | |
| Property, Plant & Equipment, N | 3 | 3 | 3 | 3 |
| Goodwill | 0 | 0 | 0 | 0 |
| Intangible Assets | 5 | 6 | 7 | 8 |
| Right-of-Use Assets | 7 | 7 | 7 | 7 |
| Shares in Associates | 0 | 0 | 0 | 0 |
| Other Long-Term Assets | 3 | 3 | 3 | 3 |
| Total Non-Current Assets | 19 | 19 | 21 | 22 |
| Total Assets | 64 | 314 | 288 | 526 |
| Liabilities | | | | |
| Current liabilities | | | | |
| Short-Term Debt | 0 | 0 | 0 | 0 |
| Short-Term Lease Liabilities | 5 | 5 | 5 | 5 |
| Accounts Payable | 8 | 8 | 8 | 8 |
| Other Current Liabilities | 4 | 4 | 4 | 4 |
| Total Current Liabilities | 18 | 18 | 18 | 18 |
| Non-current liabilities | | | | |
| Long-Term Debt | 65 | 0 | 0 | 0 |
| Long-Term Lease Liabilities | 1 | 1 | 1 | 1 |
| Other Long-Term Liabilities | 2 | 2 | 2 | 2 |
| Total Non-current Liabilities | 68 | 3 | 3 | 3 |
| Non-Controlling Interest | 0 | 0 | 0 | 0 |
| Shareholder's Equity | -22 | 293 | 267 | 505 |
| Total Liabilities & Equity | 64 | 314 | 288 | 526 |
| CASH FLOW | | | | |
| EBT | -101 | 251 | -121 | 267 |
| Cash Flow from changes in Working Capital | 7 | 0 | 0 | 0 |
| Operating Cash Flow | -86 | 243 | -115 | 245 |
| Capital Expenditures | 0 | -6 | -7 | -7 |
| Investment in Intangible Asset | 0 | -1 | -1 | -1 |
| Investing Cash Flow | 0 | -7 | -8 | -8 |
| Financing Cash Flow | -8 | 14 | 95 | 0 |
| Free Cash Flow | -86 | 236 | -123 | 236 |

| DCF Valuation Metrics | Sum FCF (SEKm) |
|--------------------------------------|----------------|
| Technology value (SEKm) | 1 598 |
| Net cash (SEKm) | 93 |
| Shared costs (SEKm) | -230 |
| Equity value (SEKm) | 1 461 |
| Shares outstanding (million) | 111,9 |
| Diluted shares outstanding (million) | 133,1 |
| Fair Value per Share | 11 |

| | 2023 | 2024e | 2025e | 2026e |
|--------------------------|------|-------|-------|-------|
| CAPITAL STRUCTURE | | | | |
| Equity Ratio | -0,3 | 0,9 | 0,9 | 1,0 |
| Debt to equity | -3,0 | 0,0 | 0,0 | 0,0 |
| Net Debt | 34 | -281 | -253 | -489 |
| Capital Employ | 46 | 296 | 270 | 508 |
| Working Capita | 8,4 | 14,2 | 0,0 | 1,3 |

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.

Redeye Equity Research team

Management

Björn Fahlén
bjorn.fahlen@redeye.se

Tomas Otterbeck
tomas.otterbeck@redeye.se

Technology Team

Hjalmar Ahlberg
hjalmar.ahlberg@redeye.se

Henrik Alveskog
henrik.alveskog@redeye.se

Mattias Ehrenborg
mattias.ehrenborg@redeye.se

Jessica Grunewald
jessica.grunewald@redeye.se

Martin Wahlström
martin.wahlstrom@redeye.se

Anton Hoof
anton.hoof@redeye.se

Rasmus Jacobsson
rasmus.jacobsson@redeye.se

Viktor Lindström
viktor.lindstrom@redeye.se

Fredrik Nilsson
fredrik.nilsson@redeye.se

Fredrik Reuterhäll
fredrik.reuterhall@redeye.se

Niklas Sävås
niklas.savas@redeye.se

Oskar Vilhelmsson
Oskar.vilhelmsson@redeye.se

Editorial

Joel Karlsson
joel.karlsson@redeye.se

Life Science Team

Oscar Bergman
oscar.bergman@redeye.se

Christian Binder
christian.binder@redeye.se

Filip Einarsson
filip.einarsson@redeye.se

Mats Hyttinge
mats.hyttinge@redeye.se

Gustaf Meyer
gustaf.meyer@redeye.se

Richard Ramanius
richard.ramanius@redeye.se

Kevin Sule
kevin.sule@redeye.se

Fredrik Thor
fredrik.thor@redeye.se

Johan Unnerus
johan.unnerus@redeye.se

John Westborg
john.westborg@redeye.se

Filip Lindkvist
Filip.lindkvist@redeye.se

Disclaimer

Important information

Redeye AB ("Redeye" or "the Company") is a specialist financial advisory boutique that focuses on small and mid-cap growth companies in the Nordic region. We focus on the technology and life science sectors. We provide services within Corporate Broking, Corporate Finance, equity research and investor relations. Our strengths are our award-winning research department, experienced advisers, a unique investor network, and the powerful distribution channel redeye.se. Redeye was founded in 1999 and since 2007 has been subject to the supervision of the Swedish Financial Supervisory Authority.

Redeye is licensed to: receive and transmit orders in financial instruments, provide investment advice to clients regarding financial instruments, prepare and disseminate financial analyses/recommendations for trading in financial instruments, execute orders in financial instruments on behalf of clients, place financial instruments without position taking, provide corporate advice and services within mergers and acquisition, provide services in conjunction with the provision of guarantees regarding financial instruments and to operate as a Certified Advisory business (ancillary authorization).

Limitation of liability

This document was prepared for information purposes for general distribution and is not intended to be advisory. The information contained in this analysis is based on sources deemed reliable by Redeye. However, Redeye cannot guarantee the accuracy of the information. The forward-looking information in the analysis is based on subjective assessments about the future, which constitutes a factor of uncertainty. Redeye cannot guarantee that forecasts and forward-looking statements will materialize. Investors shall conduct all investment decisions independently. This analysis is intended to be one of a number of tools that can be used in making an investment decision. All investors are therefore encouraged to supplement this information with additional relevant data and to consult a financial advisor prior to an investment decision. Accordingly, Redeye accepts no liability for any loss or damage resulting from the use of this analysis.

Potential conflict of interest

Redeye's research department is regulated by operational and administrative rules established to avoid conflicts of interest and to ensure the objectivity and independence of its analysts. The following applies:

- For companies that are the subject of Redeye's research analysis, the applicable rules include those established by the Swedish Financial Supervisory Authority pertaining to investment recommendations and the handling of conflicts of interest. Furthermore, Redeye employees are not allowed to trade in financial instruments of the company in question, from the date Redeye publishes its analysis plus one trading day after this date.
- An analyst may not engage in corporate finance transactions without the express approval of management and may not receive any remuneration directly linked to such transactions.
- Redeye may carry out an analysis upon commission or in exchange for payment from the company that is the subject of the analysis, or from an underwriting institution in conjunction with a merger and acquisition (M&A) deal, new share issue or a public listing. Readers of these reports should assume that Redeye may have received or will receive remuneration from the company/companies cited in the report for the performance of financial advisory services. Such remuneration is of a predetermined amount and is not dependent on the content of the analysis.

Redeye's research coverage

Redeye's research analyses consist of case-based analyses, which imply that the frequency of the analytical reports may vary over time. Unless otherwise expressly stated in the report, the analysis is updated when considered necessary by the research department, for example in the event of significant changes in market conditions or events related to the issuer/the financial instrument.

Recommendation structure

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 (2024-12-13)

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

Duplication and distribution

This document may not be duplicated, reproduced or copied for purposes other than personal use. The document may not be distributed to physical or legal entities that are citizens of or domiciled in any country in which such distribution is prohibited according to applicable laws or other regulations.

Copyright Redeye AB.

CONFLICT OF INTERESTS

Fredrik Thor owns shares in the company : No

Filip Lindkvist 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.