

Saniona Q2: Continued progress, exciting autumn ahead

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Redeye returns with an updated view of Saniona following the Q2 report and recent progress.



Fredrik Thor

No surprises in the report

As expected, the report contained no significant surprises. Revenues amounted to SEK8m and were also related this quarter to licensing/partnering agreements with Boehringer Ingelheim and AstronautX. OPEX landed at SEK-24m and was related to other external costs of SEK-12m (-13.8m) and personnel costs of SEK-8.8m (-SEK8.8m).

Several potential catalysts in H2

In the report, Saniona states that it has applied for approval to start a phase I MAD/biomarker study with SAN711 and expects to start patient recruitment in September, indicating that the timeline to present Q4 is still on track. The company also reports progress with SAN2355 and states that the preclinical work and regulatory filing for phase I should be ready in 9 months if funding allows. Furthermore, the company indicates progress in the ongoing approval process for Tesofensine in Mexico. Finally, the company reiterates its goal to land at least one partnership during the year.


Reiterated base case

We note that the share price has rallied significantly recently, likely due to anticipation around a Mexico approval and relief after guarantors have sold out their shares (at least, that is how we interpret the latest data from Holdings). For now, we reiterate our base case of SEK6 per share, but note that both key catalysts in H2 (Tesofensine approval, licensing agreement) could allow us to revisit our valuation. Furthermore, we believe that the company's current activities related to SAN711 also could constitute a catalyst if signs are promising.

Key financials

Key Financials

SEKm	2022	2023	2024e	2025e
Revenues	15.3	16.8	62.4	56.0
EBITDA	-217.9	-71.4	-15.1	-31.9
EBIT	-225.7	-81.1	-17.0	-37.5



REDEYE QUALITY RATING

3 3 0

People Business Financials

FAIR VALUE RANGE

Price 4.36

Bear 0.70 Bull 15.0

Base 6.00

TIMELINESS

4

KEY STATS

Market Cap	484.9 MSEK
Entprs. Value (EV)	468.7 MSEK
Net Debt (2024e)	-16.2 MSEK
30 Day Avg Vol	529 K
Shares Outstanding	111.2M
Price / Earnings	N/A
PEG	0.3x
Dividend Yield	N/A

Data from 2024-09-02 11:18

IMPORTANT INFORMATION

All information regarding limitation of liability and potential conflicts of interest can be found at the end of the report.

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Q2 review

- Revenues amounted to SEK8m (SEK3.8m)
- Operating expenses amounted to SEK-24m (SEK-25.7m)
- *Operating loss amounted to -SEK16m (-SEK21.8m)*
- *Cash and cash equivalents at the end of the quarter amounted to SEK54.4m (SEK69.4m)*

(The numbers in parenthesis refer to the corresponding quarter of last year)

Product Candidate	Indication	Research	LOP/CS	Pre-clinical	Phase 1	Phase 2a	Phase 2b	Phase 3	Comment
Tesofensine	Obesity	[Progress bar]							Under regulatory review with potential approval in 2024 – partnership with market leader Medix, representing near-term revenue potential through double digit royalty
Tesomet	HO, PWS	[Progress bar]							Positioned for partnering following successful phase 2a data (2019)
SAN711	Epilepsy	[Progress bar]							Positioned for absence seizures following positive phase 1 data (2022). Value-inflection points in 2024/25
SAN903	IBD, Fibrotic / inflammatory	[Progress bar]							Positioned for partnering following successful IND/CTA enabling studies
SAN2355	Epilepsy	[Progress bar]							Positioned for focal/generalized epilepsy and paediatric epilepsy
SAN2219	Epilepsy	[Progress bar]							Positioned for epilepsy acute repetitive seizures with multiple expansion opportunities in rare and severe epilepsy
SAN2465	Depressive disorder	[Progress bar]							Positioned for partnering following candidate selection for rapid onset major depressive disorder
GABA program	Epilepsy	[Progress bar]							Positioned for rare pediatric epilepsy syndrome with multiple expansion opportunities in rare and severe epilepsy
AstronautX	Alzheimer's	[Progress bar]							Partnership agreement entitling Saniona to milestone payments of up to USD 177m plus royalties
Boehringer Ingelheim	Schizophrenia	[Progress bar]							Partnership agreement entitling Saniona to milestone payments of up to EUR 76.5m plus royalties
Cephagenix	Migraine	[Progress bar]							Joint venture, Saniona owns 33%

Source: Saniona

No major surprises

As expected, the report contained no significant surprises. Revenues amounted to SEK8m and were also related to licensing/partnering agreements with Boehringer Ingelheim and AstronautX this quarter. OPEX landed at SEK-24m and was related to other external costs of SEK-12m (-13.8m) and personnel costs of SEK-8.8m (-SEK8.8m).



External Research & Development expenses (SEKm)	Q2 24	Q2 23
Tesomet	0.1	1.4
SAN711	4.3	2.5
SAN903	0.2	0.2
SAN2355	2.3	0.0
Other programs	1.9	2.3
Total	8.9	6.5

Progress in the pipeline

In the report, Saniona states that it has applied for approval to start a phase I MAD/biomarker study with SAN711 and expects to start patient recruitment in September, indicating that the timeline to present results in Q4 is still on track. The plan is then to start a proof-of-concept study in children with absence seizures in spring 2025. The company also reports progress with SAN2355 and states that the preclinical work and regulatory filing for phase I should be ready in 9 months if funding allows.

Regarding Tesofensine's ongoing application process in Mexico, the company now states: "Following a dialog with the regulatory agency in 2023/24, Medix submitted an updated application with additional information and documentation in May 2024. The regulatory agency has had no further comments or questions, and we are now awaiting the final decision for approval of tesofensine for obesity in Mexico.

To us, this sounds like progress, and we hope no further questions will arise in the final moments of the process. We reiterate our assumption that there will be a decision in H2 this year. As Saniona states, the company will receive a milestone payment and royalties, and an approval soon would be helpful also for Saniona's near-term financials. We reiterate our model assumptions for now but will return with a more thorough take on Tesofensine once it (hopefully) is approved, and we learn more about Medix's strategy. As we have previously stated, the potential is very high, and Medix has a strong standing in the Mexican market. There is also a good rationale for an effective drug that is easily administered and priced below the GLP1-analogues. Still, our insight into Medix (given that it's a private company) is limited, and we hope to learn more about its plans soon.

As in the previous quarter, Saniona reiterates its goal of entering at least one new collaboration this year, hoping to get a significant upfront payment. Beyond the Mexico approval, this remains one of the key catalysts for the company and, in our view, the most transformative one - as it would (again) prove Saniona's business model and finalize the turnaround.

Valuation

We note that the share price has rallied significantly recently, likely due to anticipation around a Mexico approval and relief after guarantors have sold out their shares (at least, that is how we interpret the last data from Holdings). For now, we reiterate our base case of SEK6 per share, but note that both key catalysts in H2 (Tesofensine approval, licensing agreement) could allow us to revisit our valuation. Furthermore, we believe that the company's current activities related to SAN711 also could constitute a catalyst if signs are promising.

Asset	Indication	LoA	Royalties	Peak sales (USDm)	Deal size (USDm)	rNPV (SEKm)
SAN711	Epilepsy/pain	12%	14%	1126	200	294
Tesomet - HO	Hypothalamic Obesity	33%	10%	553	119	518
AstronauTx	Alzheimer's Disease	3%	7%	1206	177	101
Boehringer Ingelheim	Schizophrenia	6%	7%	415	88	105
Tesofensine	Obesity	85%	14%	37	2	164
Project value (SEKm)						1,182
Estimated Net cash (diluted)						72
Shared costs incl. tax (SEKm)						-459
Fair value (SEKm)						795
Shares outstanding est						133
Value per share (SEK)						6

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.

Name	Ownership	Last File Date
Avanza Pension	8.46%	2024-07-29
Nordnet Pensionsförsäkring	5.16%	2024-07-29
Nordea Liv & Pension	3.02%	2024-07-29
Tredje AP-fonden	2.77%	2024-07-29
Jørgen Drejer	2.31%	2024-07-29
Joakim Tedroff	2.24%	2024-07-29
Dan Peters	2.11%	2024-07-29
Thomas Kreutzfeldt	1.82%	2024-07-29
Thomas Feldthus	1.26%	2024-07-29
Göran Erlandsson	1.05%	2024-07-29

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Investment thesis

Case

Turn Around Case with Plenty of Value

We see the 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.

Supportive Analysis

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 (measured by PET). The compound is designed as a potential first-in-class positive allosteric modulator of the neurotransmitter GABA_A and specifically the subunit $\alpha 3$. GABA_A is a target for several drugs, including benzodiazepines such as Valium, which can lead to for example pain relief. Today's treatments target GABA_A 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 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

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

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.

◆ Valuation

Strong value proposition in Saniona

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.

Quality Rating

People: 3

Business: 3

Financials: 0

Financials

Income statement

SEKm	2023	2024e	2025e
Revenues	16.8	62.4	56.0
Cost of Revenue	5.1	0.51	0.90
Operating Expenses	83.2	77.0	87.0
EBITDA	-71.4	-15.1	-31.9
Depreciation	0.00	1.9	5.6
Amortizations	0.00	0.00	0.00
EBIT	-81.1	-17.0	-37.5
Shares in Associates	0.39	0.39	0.39
Interest Expenses	26.3	11.0	5.0
Net Financial Items	-23.2	-8.0	-5.0
EBT	-104.3	-25.0	-42.5
Income Tax Expenses	-8.5	0.00	0.00
Net Income	-95.8	-25.0	-42.5

Rating 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 longterm 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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Fredrik Thor owns shares in the company : No.

Redeye performs/has performed services for Saniona and receives/has received compensation from these Companies in connection with this.