
Performance VS OMXS30

Share Information

Share Price SEK	6.86
Number of shares (M)	112.5
Marketplace	NASDAQ Stockholm
CEO	Thomas Feldthus
Chairman	J. Donald DeBethizy

Key Stats

Market Cap	N/A
Entprs. Value (EV)	--
Net Debt (2024Q4)	-297.8 MSEK
30 Day Avg Vol	1183 K
Dividend Yield	N/A

Top Holders

Name	Ownership
Avanza Pension	9.04%
Nordnet Pensionsförsäkring	4.91%
Nordea Liv & Pension	2.99%
Jørgen Drejer	2.28%
Joakim Tedroff	2.24%
Dan Peters	2.09%
Handelsbanken Fonder	1.57%
Thomas Feldthus	1.24%
Thomas Kreutzfeldt	1.22%
Daniel Bölstad Jensen	1.2%

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Saniona Q4: Strengthened position

Redeye returns with an updated view of Saniona following the Q4 report and recent events in the company.

Strong report as expected

As expected, Saniona was profitable during the quarter following the USD28m upfront payment from Acadia for SAN711 - a very significant upfront in a Nordic historical context, with revenues of SEK313m. OPEX continued at a stable rate, also as Saniona's research is covered to some extent by its collaborations. However, we expect costs to increase a bit as Saniona can increase its ambitions with its internal pipeline following the Acadia deal. We furthermore expect an additional capital injection from the warrant program soon. Finally, Saniona is eligible to receive a milestone payment of USD10m in 2026 when Acadia plans to start a phase II study.

Progress in pipeline

Q4 was a transformational quarter for the company following the licensing agreement with Acadia. Furthermore, the company saw progress with its partners Medix's application for approval with Tesofensine in Mexico and funding of its joint venture Cephagenix.

Slightly raised valuation

We largely reiterate our valuation for now but have raised our assumptions for Tesofensine a bit following the regulatory update in Mexico, leading to a raised base case to SEK12 (11) per share. We think that Saniona has a very strong portfolio, and as we currently value the company, no single drug candidate is responsible for the majority of the value, which we see as a strength compared to many of its peers - especially as Saniona has the financial resources to take several of its drug candidates forward. We are a bit surprised by the recent negative development in the share price, but expect that it relates to the warrant program and perhaps high expectations related to the Tesofensine approval process in Mexico.

Key Financials

SEKm	2023	2024	2025e	2026e
Total Revenue	16.8	316.2	27.0	392.9
Revenue Growth	10.2%	1777%	-91.5%	1355%
EBIT	-81.1	220.6	-107.7	293.3
EBIT Margin	-481%	nm.	-399%	74.6%

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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.

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 and specifically the subunit $\alpha 3$. GABA is a target for several drugs, including benzodiazepines such as Valium, which can lead to for example pain relief. Today's treatments target GABA 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

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.

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.

💎 Valuation

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.

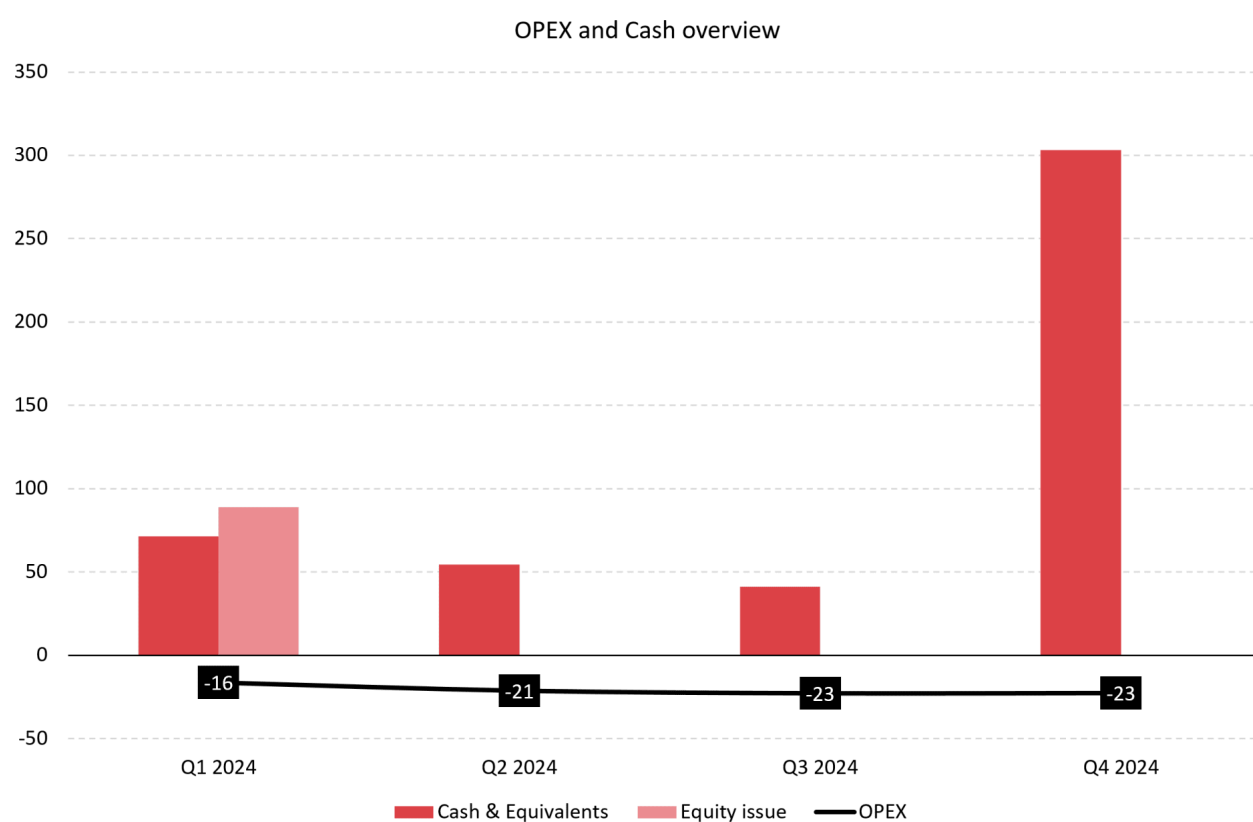
Product Candidate	Indication	Research	LOP/CS	Pre-clinical	Phase 1	Phase 2a	Phase 2b	Phase 3	Comment	
SAN2355	Epilepsy	[Progress bar]				[Arrow]				Positioned for focal/generalized epilepsy and paediatric epilepsy with additional opportunities in bipolar disorders, MDD and others
SAN2219	Epilepsy	[Progress bar]				[Arrow]				Positioned for epilepsy acute repetitive seizures with multiple expansion opportunities in rare and severe epilepsy
SAN2465	Depressive disorder	[Progress bar]				[Arrow]				Positioned for major depressive disorder (rapid onset and refractory MDD) with additional potential in a rare paediatric disease, Dub15q
GABA Program	Epilepsy	[Progress bar]				[Arrow]				Positioned for rare pediatric epilepsy syndrome with multiple expansion opportunities in rare and severe epilepsy
Tesofensine Medix	Obesity	[Progress bar]								Under regulatory review – partnership with Mexican market leader Medix, near-term revenue potential through double digit royalties
Tesomet	HO, PWS	[Progress bar]								Positioned for partnering following successful phase 2a data
SAN711 Acadia	Essential tremor	[Progress bar]								Partnership entitling Saniona to milestone payments of up to USD 582m plus royalties
SAN903	IBD, Fibrotic / inflammatory	[Progress bar]								Positioned for partnering following successful IND/CTA enabling studies
AstronauTx Program	Alzheimer's	[Progress bar]				[Arrow]				Partnership entitling Saniona to milestone payments of up to USD 177m plus royalties
Boehringer Program	Schizophrenia	[Progress bar]				[Arrow]				Partnership entitling Saniona to milestone payments of up to EUR 76.5m plus royalties
Cephagenix Program	Migraine	[Progress bar]				[Arrow]				Joint venture, Saniona owned 33% prior to seed financing in Dec 2024

Source: Saniona

Q4 review

- Revenues amounted to SEK313.4m (SEK5.4m)
- Operating expenses amounted to SEK-22.9m (SEK-25.2m)
- Operating profit amounted to -SEK290.4m (-SEK19.8m)
- Cash and cash equivalents at the end of the quarter amounted to SEK303.3 (SEK30.1m)

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



As expected, a strong report

As expected, Saniona was profitable during the quarter following the USD28m upfront payment from Acadia for SAN711 - a very significant upfront in a Nordic historical context, with revenues of SEK313m. OPEX continued at a stable rate, also as Saniona's research is covered to some extent by its collaborations. However, we expect costs to increase a bit as Saniona can increase its ambitions with its internal pipeline following the Acadia deal. We furthermore expect an additional capital injection from the warrant program soon. Finally, Saniona is eligible to receive a milestone payment of USD10m in 2026 when Acadia plans to start a phase II study. During the quarter, Saniona also repaid its remaining debt to Fenja, and Fenja converted convertibles of SEK2m.

Progress in the pipeline

Q4 was a transformational quarter for the company following the licensing agreement with Acadia, which, to us, is a credible partner with a relevant pipeline. During Acadia's Q4 call, it was mentioned regarding Essential Tremor in the US that:

[...] roughly 1 million of them currently receiving some kind of therapy. The only approved product for essential tremor came to the market in the US more than 50 years ago, and literature estimates suggest that as many of half of treated patients don't improve with treatment.

We look forward to initiating a Phase 2 study in 2026. Between now and then, we're collecting more data in Phase 1, our particular focus is an elderly cohort to ensure that our dosing and development plans take into account the needs of the full potential patient population."

We have initially assumed that SAN711 will target non-responders. We want to note that Essential Tremor is a relatively underresearched indication, likely because it seems to be under/misdiagnosed and that many patients are not fully aware of having the disease (also because of the variability in severity). Furthermore, as Acadia also mentions, there has been little to no innovation in a long time. There is an upside potential, we argue, if the diagnosis/treatment rate increases following the potential approval of SAN711, but we still estimate that SAN711 initially will target patients with more severe conditions (and will price it accordingly).

Tesofensine

In February, it was announced that Saniona's partner in Mexico, Medix, submitted a "final" application following interactions with COFEPRIS, a Mexican regulatory agency. According to Saniona's release, "Medix S.A. de S.V. (Medix) has worked closely with COFEPRIS on the approval pathway for tesofensine in Mexico. Following these discussions, Medix now sees a clear path to regulatory approval and is revising its application based on COFEPRIS's feedback". In relation to Medix resubmission, Saniona stated that "I congratulate the Medix team on this significant achievement. Following feedback from COFEPRIS, they have updated and resubmitted the complete tesofensine dossier - approximately 20,000 pages - addressing all regulatory questions and requests". The approval process in Mexico has been lengthy and difficult to assess, but we are reassured that Mexix and COFEPRIS appear to be aligned. We have raised our assumptions a bit following the resubmission, mainly increasing the likelihood of approval and assuming approval in 2025 (it could potentially be soon, but we don't fully know). As we have previously said, we will likely revisit our assumptions further once Tesofensine (hopefully) is approved. For example, Saniona has mentioned plans beyond Mexico, and mentions South America as a "first logical step".

SAN2355

Earlier this morning, it was announced that Saniona has initiated "GMP manufacturing, drug product development, and PK/GLP toxicology studies for SAN2355" with the aim of filing a clinical trial application by year-end. In relation to our last update, we put an initial valuation on SAN2355, Saniona's subtype-selective activator of Kv7.2/Kv7.3, with a focus on focal/generalized seizures, and assumed a licensing deal in 2026. We keep our assumptions for now. As we also have said, we expect to include the company's other prioritized pre-clinical assets (SAN2219 and SAN2465) as they move closer to the clinic (expected in 2026), likely in the relative near term.

Cephagenix

In January, it was announced that Saniona's joint venture Cephagenix, which was co-founded with Professor Jes Olesen and aims to develop anti-migraine treatments, has secured up to EUR9m in "tranche seed financing from AdBio Partners and Abbvie Ventures". According to the release, the proceeds will be used to advance the KATP program towards candidate selection. As we then wrote, we note that AdBio and Abbvie Ventures are reputable investors with strong networks – which, in our view, further validates Cephagenix and its development plan, and we also note that migraine is a significant indication with high unmet medical need. According to the 2023FY report, Saniona owned 33.3% of Cephagenix. We hope to learn more soon about the company's program.

Valuation

We largely reiterate our valuation for now but have raised our assumptions for Tesofensine a bit following the regulatory update in Mexico. We have also modified our assumption regarding the warrant program as the share price has fallen a bit since our last update and also adjusted the USD/SEK assumption a bit.

In total, we raise our base case to SEK12 (11) per share. We think that Saniona has a very strong portfolio, and as we currently value the company, no single drug candidate is responsible for the majority of the value, which we see as a strength compared to many of its peers - especially as Saniona has the financial resources to take several of its drug candidates forward. We are a bit surprised by the recent negative development in the share price, but expect that it relates to the warrant program and perhaps high expectations related to the Tesofensine approval process in Mexico. Saniona has a strong position, and we see further potential for positive surprises, including related to licensing deals.

Project	Indication	Phase	Estimated launch	LoA	Peak sales (USDm)	Deal size (USDm)	rNPV (SEKm)
SAN711 (Acadia)	Epilepsy	I	2033	15%	711	610	169
	Essential Tremor	I	2032	14%	1416		346
Tesomet	HO	IIb	2032	33%	565	120	290
Tesofensine (Medix)	Obesity	Regulatory	2025	85%	45	2	150
AstronauTx	Alzheimer's disease	Preclinical	2034	3%	1229	177	71
SAN2355	Epilepsy	Preclinical	2032	9%	1324	400	259
Boehringer Ingelheim	Schizophrenia	Preclinical	2034	6%	287	90	65
Technology value (SEKm)							1,351
Net cash (SEKm)							394
Shared costs (SEKm)							-203
Equity value (SEKm)							1,542
Shares outstanding (million)							113
Diluted shares outstanding (million)							134
Equity value per share (SEK)							12

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.

The upfront payment was previously part of the rNPV in Essential tremor but was moved to the cash position in relation to the Q4-report.

Top Holders		
Name	Ownership	Last File Date
Avanza Pension	9.04%	2025-01-29
Nordnet Pensionsförsäkring	4.91%	2025-01-29
Nordea Liv & Pension	2.99%	2025-01-29
Jørgen Drejer	2.28%	2025-01-29
Joakim Tedroff	2.24%	2025-01-29
Dan Peters	2.09%	2025-01-29
Handelsbanken Fonder	1.57%	2025-01-31
Thomas Feldthus	1.24%	2025-01-29
Thomas Kreutzfeldt	1.22%	2025-01-29
Daniel Bölstad Jensen	1.2%	2025-01-29

Redeye Quality Rating

Company Quality

Company Quality is based on a set of quality checks across three categories; PEOPLE, BUSINESS, FINANCE. These are the guiding locks 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

4 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:

1. Passion 2. Execution 3. Capital Allocation 4. Communication 5. Compensation 6. Ownership 7. Board

+ Positives

- Strong visionary leadership from CEO Thomas Feldthus, with clear long-term goals and adaptable strategies for drug development and partnerships.
- Lean, decentralized organization promoting accountability, with a research-driven culture and long-tenured management team.
- Consistent delivery on promises, including significant licensing agreements and a clear focus on capital allocation for long-term value creation.
- Transparent and candid investor communication, with a focus on long-term business value and consistent storytelling over time.

- Negatives

- Lack of long-term historic profitability and consistent returns on capital, making it difficult to assess long-term financial sustainability.
- Weak commitment to sustainability reporting, which may become increasingly important for stakeholders and investors.

Business

3 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. character.

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

1. Business Scalability 2. Market Structure 3. Value Proposition 4. Economic Moat 5. Operational Risks

+ Positives

- Strong potential for significant revenue growth if drug candidates reach the market, with meaningful reinvestment opportunities in drug development pipeline.
- Asset-light business model typical of biotech companies, allowing for efficient scaling without heavy capital expenditures.
- Benefits from secular trends such as aging populations and increasing prevalence of targeted diseases.
- Possesses a good patent portfolio and unique ion channel platform, providing a competitive advantage in drug development.
- Focused on indications with few approved treatments, potentially capturing significant market share in targeted areas.

- Negatives

- Currently, there is significant recurring income, relying on research-related compensation and potential future drug approvals. However, potential to soon get recurring revenues with Tesofensine.
- Operating in an industry (biotech) with historically lower returns on invested capital compared to the 15% benchmark.
- Highly dependent on regulatory approvals, with constant risk of delays or rejections impacting business success.
- Limited geographic diversification of potential revenue base, with likely high dependence on the U.S. market and national reimbursement agencies.

Redeye Quality Rating

Financials

1 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 Financials rating is based on quantitative scores in seven categories:

1. Earnings Power 2. Profit Margin 3. Growth Rate 4. Financial Health 5. Earnings Quality

+ Positives

- Strong short-term liquidity with current assets 1.5 times greater than current liabilities, indicating good working capital management.
- Cash and short-term investments cover expected cash burn for a long time, demonstrating financial stability and reducing immediate fundraising needs.

- Negatives

- Lack of long-term profitability across various metrics (Gross Profit Margin, Operating Margin, ROE, ROA), suggesting challenges in generating sustainable earnings.
- Absence of consistent revenue and earnings growth, potentially indicating difficulties in scaling the business or capturing market share.

Rating Distribution

Redeye Covered Companies			
Rating	People	Business	Financials
5	5	7	1
3-4	135	119	37
0-2	17	31	119
Companies	157	157	157

Disclaimer

Redeye does not issue any investment recommendations for fundamental research. However, Redeye has developed a proprietary research and rating model, Redeye Rating, in which each company is analyzed and evaluated. This research 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.

Financials

Income Statement			
SEKm	2023	2024	2025e
Net Sales	16.8	0.0	4.4
Other Income	0.0	2.8	1.4
Total Revenue	16.8	316.2	27.0
Cost of Sales	-5.1	-5.1	0.0
Gross Profit	11.8	311.1	27.0
Operating Expenses	-83.2	-82.8	-127.0
EBITDA	-71.4	228.2	-100.0
Depreciation and Amortization	-9.7	-7.7	-7.7
EBIT	-81.1	220.6	-107.7
Net Financial Items	-23.2	-34.9	0.0
EBT	-101.2	185.7	-107.7
Income Tax Expenses	8.5	-18.3	0.0
Net Income	-92.7	170.2	-107.7
Balance Sheet			
SEKm	2023	2024	2025e
Assets			
Non-current assets			
Property, Plant and Equipment (Net)	3.3	2.9	-4.8
Goodwill	0.0	0.0	0.0
Intangible Assets	4.9	4.8	4.8
Right-of-Use Assets	7.2	4.8	4.8
Other Non-Current Assets	3.5	3.1	3.1
Total Non-Current Assets	19.0	15.6	7.9
Current assets			
Inventories	0.0	0.0	0.0
Accounts Receivable	2.5	15.0	15.0
Other Current Assets	11.7	5.9	5.9
Cash Equivalents	31.0	303.3	299.3
Total Current Assets	45.2	324.2	320.2
Total Assets	64.1	339.7	328.1
Equity and Liabilities			
Non-current liabilities			
Long Term Debt	65.2	0.0	0.0
Long Term Lease Liabilities	0.69	0.0	0.0
Other Non-Current Lease Liabilities	2.5	2.6	2.6
Total Non-Current Liabilities	68.4	2.6	2.6
Current liabilities			
Short Term Debt	0.0	5.4	5.4
Short Term Lease Liabilities	5.5	5.1	5.1
Accounts Payable	8.2	17.5	17.5
Other Current Liabilities	4.0	77.3	77.3
Total Current Liabilities	17.7	105.3	105.3
Equity	-21.9	231.8	220.2
Total Liabilities and Equity	64.1	339.8	328.1

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