

Saniona

Sector: Biotech

Q1 2023: On the right path

Redeye returns with an updated view of Saniona following the Q1 report and recent events in the company. We reiterate our stance that 2023 will be an important year for the company – most notably to deliver on its goal of non-dilutive incomes.

Uneventful report

We note that the report came in roughly as we expected, with a relatively stable OPEX at SEK-23 million per quarter, indicating that Saniona has taken down its costs more permanently to a more sustainable level. The majority of the costs are related to R&D/other external costs at SEK-12m followed by SEK-8.5m in personnel costs. Revenues landed at SEK2m and related to Saniona's collaborations.

Focus on non-dilutive incomes

At the end of Q1, the cash position was SEK88 million, and Saniona currently has a loan from Formue Nord currently worth roughly SEK75m, due in the end of January 2024. With today's cash burn, Saniona has a runway until the due date for the loan but note that Saniona needs a capital injection for both the loan repayment and its operations thereafter, and it currently has a goal to deliver two deals by 2023. To us, the key will be to secure a sizable upfront payment. Saniona has a strong history of licensing- and R&D agreements, but we note that Saniona would need more than SEK100m (USD9m) in upfront payments, unless the loan is renegotiated again, to avoid a rights issue.

Slightly lower our base case

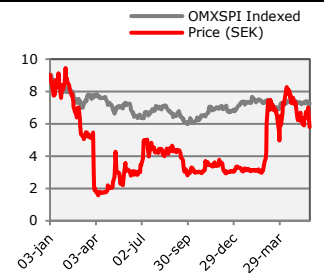
We largely reiterate our previous sum-of-the-parts valuation but make a few adjustments, leading to a slightly lowered base case of SEK8 (8.5) per share, mainly as we expect a slightly higher expected dilution in our base case, as well as updated assumptions regarding FX rates.

Key Financials (SEKm)	2021	2022	2023E	2024E	2025E
Revenues	11	15	61	59	15
Revenue growth	0	0	3	0	-1
EBITDA	-403	-218	-22	-25	-73
EBIT	-412	-226	-27	-27	-74

FAIR VALUE RANGE

BEAR	BASE	BULL
1	8	20

SANION VERSUS OMXS30



REDEYE RATING



KEY STATS

Ticker	SANION
Market	Small Cap
Share Price (SEK)	5,8
Market Cap (SEKm)	384
Free Float (%)	92

ANALYSTS

Fredrik Thor
 Fredrik.thor@redeye.se
 Kevin Sule
 Kevin.sule@redeye.se

Investment Thesis

Case: Turn around case with plenty of value

2022 was a turbulent year for Saniona, which included a major restructuring of the management team, stopped clinical studies with Tesomet due to financial difficulties and a refocused strategy towards business development. We see high quality in Saniona's assets, including its mid-stage orphan drug candidate Tesomet, phase I asset SAN711 (targeting neurophatic pain), and in the long run: its many assets from its Ion Channel Platform. 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 funding solution and/or licensing agreement by H2 2023 and further advancement with phase I candidate SAN711 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 $\alpha 3$. 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 and SAN 903) have become an increasingly important part of the investment case, as well as the drug discovery platform in itself.

Saniona's history of collaborations extend to company's such Boehringer Ingelheim, Medix and Cadent Therapeutics/Novartis – and the company has in total brought in roughly SEK 400 million as of today.

Challenge I: Regaining Investors' and Market Confidence

In retrospect, the company's pivot towards the US and in-house clinical development, including its high ambitions and expenses, was premature and damaged the reputation of Saniona. Furthermore, the company has lost a few cornerstone institutional investors. We think that the new management team has done the right things lately: Smaller organization, significantly reduced costs and a focus on business development. To further turn the company around, additional execution on its new strategy will be needed.

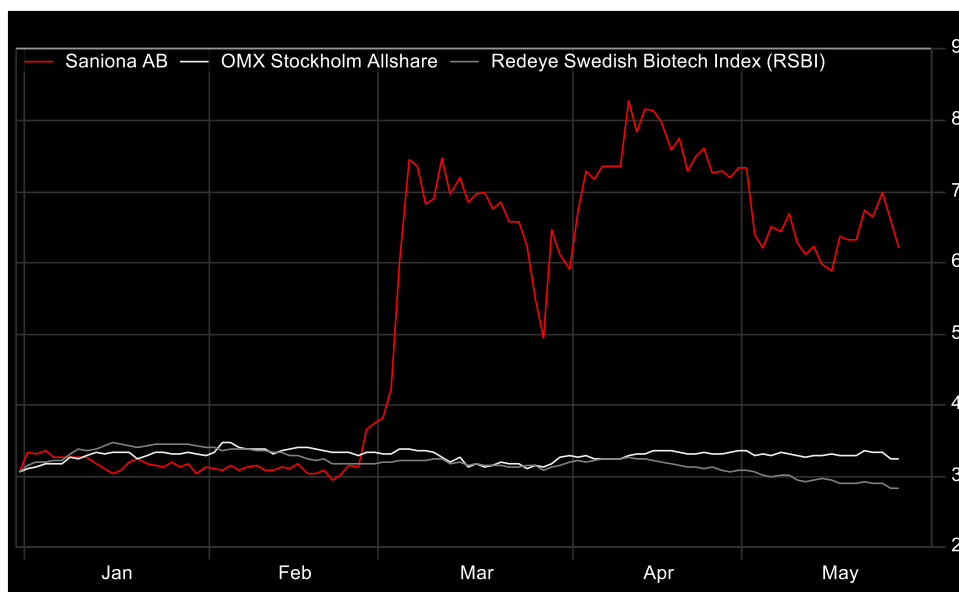
Challenge II – Funding Needs

Even though Saniona has reduced costs by some 75%, the company is still in need of additional funding for its operations and clinical programs. We estimate that the company has a cash runway into 2024– and the company has declared that it will focus on non-dilutive funding from partnering. The company has started to turn its reputation around, but strong execution – preferably a licensing deal with a significant upfront payment - would be a major relief. Also, a strong launch of Tesofensine could add further runway.

Strong value proposition and undemanding valuation

We largely reiterate our positive stance on Saniona's clinical drug candidates and research platform, but we see that uncertainty about funding could monopolize investors' attention as we go further into 2023. To turn the case around, we argue that a funding solution and/or licensing agreement by H2 2023 and further advancement with phase I candidate SAN711 will be key in pushing the share toward and beyond our Base Case of SEK 8 Per Share.

Share Price Development (YTD)



Source: Factset; Redeye Research

#	Holders	Nexstim	Capital	Votes
1	Avanza Pension	4600820	7,37%	7,37%
2	Nordnet Pensionsförsäkring	2614451	4,19%	4,19%
3	Jørgen Drejer	2364711	3,79%	3,79%
4	Tredje AP-fonden	1886792	3,02%	3,02%
5	Dan Peters	1400000	2,24%	2,24%
6	Joakim Tedroff	1088762	1,75%	1,75%
7	Hans Christian Thorn	1000000	1,60%	1,60%
8	Nordea Liv & Pension	972930	1,56%	1,56%
9	Thomas Feldthus	965000	1,55%	1,55%
10	Leif Andersson Consulting ApS	793725	1,27%	1,27%

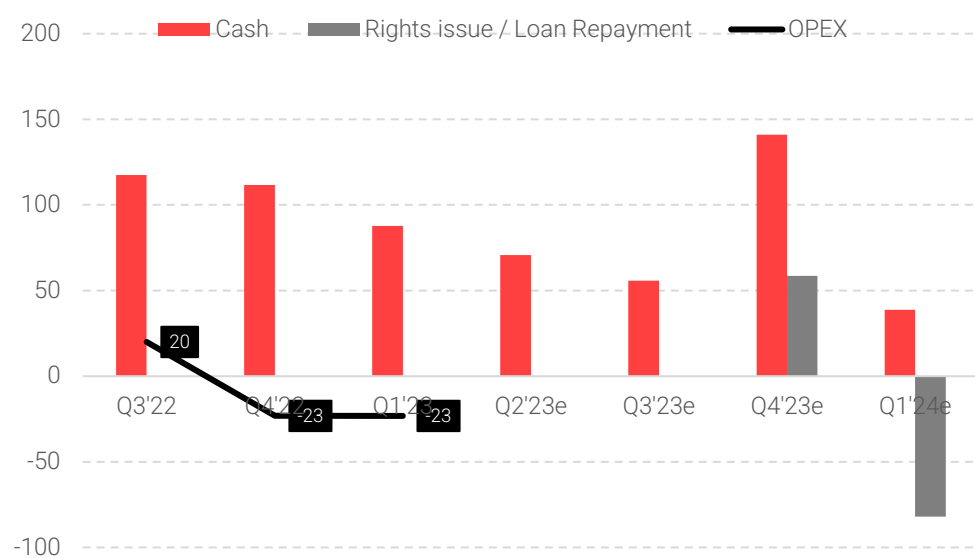
Source: Holdings/Modular Finance

In 2022, the outflows in Saniona accelerated following the refocused strategy and changed management team, including previous top share holder RA Capital and Fjärde AP-fonden (4th AP Fund). For now, the ownership appears more stable – an important contributor to the more stable price in Saniona. Following the positive opinion on Tesofensine in February, a lot of the flows appear to be driven by retail/private investors.

Q1 Review

We note that the report came in roughly as we expected, with a relatively stable OPEX at SEK-23 million per quarter, indicating that Saniona has taken down its costs more permanently to a more sustainable level. The majority of the costs are related to R&D/other external costs at SEK-12m followed by SEK-8.5m in personnel costs. Revenues landed at SEK2m and related to Saniona's collaborations. During the quarter, the Cephagenix joint venture program announced successful pre-clinical in vivo validation for treatment of migraine. Furthermore, as previously discussed by us, Saniona's partner Medix received a favorable opinion for Tesofesine for the treatment of obesity in Mexico.

Financing and OPEX Review



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

At the end of Q1, the cash position was SEK88 million, and Saniona currently has a loan from Formue Nord currently worth roughly SEK75m, due in the end of January 2024¹. With today's cash burn, Saniona has a runway until the due date for the loan but note that Saniona needs a capital injection for both the loan repayment and its operations thereafter. Saniona currently has a goal to deliver two partnerships by 2023 and we note that the language is less precise regarding the timing in the Q1 report, but on the other hand mentions that it has "negotiations". This could indicate more advanced processes. To us, the key will be to secure a sizable upfront payment. Saniona has a strong history of licensing- and R&D agreements, but we note that Saniona would need more than SEK100m (USD9m) in upfront payments, unless the loan is renegotiated again, to avoid a rights issue. Deals on this level (SEK50m+ in upfronts) are relatively rare in a Swedish/Nordic context, but note that for example the first R&D collaboration with Boehringer Ingelheim (later terminated) had an upfront payment of SEK47m. At this stage, we think that it would be preferable to prioritize upfront payments.

We note that the new management team has done the right things, and showed the market and potential partners that it has control over its costs, and we also note that the company's pipeline has been developed well: Saniona has several assets, including for example SAN711, SAN903 and Tesomet, that we believe could attract significant interest from potential licensing partners. We will be impressed if Saniona can deliver two significant licensing deals in 2023 but would like to see execution on one deal before including it in our base case (we

¹ 1% monthly interest rate until end of 2023, then 1.5%

include one today). In the report, Saniona also mentions that it has made significant progress in the collaboration with Boehringer Ingelheim that could trigger a milestone payment in 2023. We assume that this will be a relatively small sum but one that could contribute to close the capital need as well². Furthermore, Saniona's partner Medix has an ongoing regulatory process in Mexico with Tesofensine. In the annual report, it is mentioned that Saniona is eligible to receive SEK21m related to prespecified regulatory milestones. We assume that at least half will likely be paid in relation to an approval in Mexico, but assume that revenues for Tesofensine will come mainly in 2024 and forward. Overall, we note that Saniona has a lot of ongoing activities that could lead to non-dilutive capital injections, and we see a lot of potential scenarios depending on timing and execution.

Valuation

We largely reiterate our previous sum-of-the-parts valuation but make a few adjustments, leading to a slightly lowered base case:

- We update the SEK/USD exchange rate to 10.56 (a running average for Q1) according to Redeye policy
- Raise our estimates for a capital injection to SEK65m (55m) at 30% discount in H2. We expect that parts of the proceeds from the rights issue will be used to repay the loan to Formue Nord
- We assume an upfront payment of USD5m in H2 from a deal relating to SAN711

Sum-of-the-parts: Saniona

Asset	Indication	LoA	Royalties	Peak sales (USDm)	Deal size (USDm)	rNPV (SEKm)
SAN711	Pain	12%	14%	1 101	200	291
Tesomet - HO	Hypothalamic Obesity	33%	10%	553	120	476
Boehringer Ingelheim	Schizophrenia	6%	7%	415	88	105
Tesofensine	Obesity	80%	14%	32	0	107
Project value (SEKm)						979
Estimated Net cash (2023)						68,5
Shared costs incl. tax (SEKm)						-447,50
Fair value (SEKm)						599,87
Shares outstanding (2023)						76,8
Value per share (SEK)						8,0

Source: Redeye Research.

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

Rights issue scenario table						
		Stock price				
		5,0	5,5	6,0	6,5	7,0
SEKm	25	8,4	8,4	8,5	8,6	8,6
	35	8,2	8,3	8,4	8,4	8,5
	45	8,0	8,1	8,2	8,3	8,4
	55	7,9	8,0	8,1	8,2	8,3
	65	7,7	7,9	8,0	8,1	8,2
	75	7,6	7,8	7,9	8,0	8,1
	85	7,5	7,6	7,8	7,9	8,1
	95	7,3	7,5	7,7	7,9	8,0
	105	7,2	7,4	7,6	7,8	7,9

Source: Redeye Research

² For example: In 2018, Saniona received SEK42m in relation to a candidate selection by BI. A milestone on this level would be a significant contributor we judge.

Appendix:

We continue to be impressed by the many programs and drug candidates within Saniona’s portfolio. In December, the company announced a new candidate, SAN2219, which is the first preclinical candidate from the GABA-A A2/A3 activation program, that has shown encouraging preclinical data in for example epilepsy. Furthermore, Saniona announced exciting progress in the joint venture Cephagenix, targeting mainly migraine. According to the report, Cephagenix has successfully reached pre-clinical in vivo validation for treatment of migraine.

Saniona: Clinical Projects Under Development

	Project	Indication	Research	Pre-clinical	Phase I	Phase II	Phase III	NDA	Market
Eating Disorders	Tesomet	PWS HO	[Ongoing phase]			[Ongoing phase]			
	Tesofensine	Obesity	[Ongoing phase]						[External development]
Ion Channel Platform	SAN 711	Rare neuropathic disorders	[Ongoing phase]		[Ongoing phase]				
	SAN 903	Inflammatory Bowel Disease	[Ongoing phase]						
	SAN 2219	Epilepsy	[Ongoing phase]	[Ongoing phase]					
			[Completed development phase]						
			[External development]						
			[Ongoing phase]						

Ion Channel Platform

Saniona possesses a proprietary drug discovery engine that focuses on modulating ion channels - a well-established and validated target for several successful drugs on the market. The company’s in-house team has unique competencies and methods, resulting in a library of over 20,000 proprietary molecules that target different types of ion channels. Last year, Saniona achieved a significant milestone when its first candidate from the platform, SAN711, entered clinical trials, which were completed last year. Another potential drug candidate, SAN903, with the ability to inhibit inflammation and fibrosis, has also progressed well and is ready for clinical development.

Ion channels are unique proteins that regulate the passage of charged ions across the lipid membrane that surrounds all cells. These membrane proteins are expressed in all types of cells, including the central and peripheral nervous systems. Despite being a high-potential target, ion channels are highly heterogeneous and, as a result, are often seen as difficult to explore. Saniona’s value proposition lies in developing "highly selective, subtype-specific, state-dependent ion channel modulators and inhibitors," which utilize its "ionbase" database as the backbone of drug discovery. Saniona’s in-house expertise allows it to develop modulators specific to a particular ion channel, enabling the desired effect without affecting other channels and potentially leading to adverse effects. Additionally, the company has a defined and sometimes unique set of methods, including imaging technology, assay design, and electrophysiological approaches. While ion channel drug discovery is complex, we believe investors should view the platform as an increasingly critical part of Saniona’s equity story, ultimately providing the company with additional drug candidates over time.

Summary Redeye Rating

The rating consists of three valuation keys, each constituting an overall assessment of several factors that are rated on a scale of 0 to 1 points. The maximum score for a valuation key is 5 points.

Rating changes in the report

People: 3

No changes

Business: 3

No changes

Financials: 0

	2022	2023E	2024E	2025E		Sum FCF (SEKm)	
INCOME STATEMENT					DCF Valuation Metrics		
Revenues	15	61	59	15	Project value (SEKm)	979	
Cost of Revenues	4	0	0	1	Estimated Net cash (2023)	69	
Gross Profit	11	60	59	14	Shared costs incl. tax (SEKm)	-448	
Operating Expenses	229	82	84	87	Fair value (SEKm)	600	
EBITDA	-218	-22	-25	-73	Shares outstanding (2023)	77	
Depreciation & Amortization	0	5	2	1	Value per share (SEK)	8	
EBIT	-226	-27	-27	-75	SHAREHOLDER STRUCTURE	CAPITAL %	
Net Financial Items	-27	-6	-2	-5	1 Avanza Pension	4600820	7%
EBT	-252	-33	-29	-80	2 Nordnet Pensionsförsäl	2614451	4%
Income Tax Expenses	-7	0	0	0	3 Jørgen Drejer	2364711	4%
Non-Controlling Interest	0	0	0	0	4 Tredje AP-fonden	1886792	3%
Net Income	-245	-33	-29	-80	5 Dan Peters	1400000	2%
BALANCE SHEET					6 Joakim Tedroff	1088762	2%
Assets					7 Hans Christian Thorn	1000000	2%
Current assets					8 Nordea Liv & Pension	972930	2%
Cash & Equivalents	112	154	36	14	9 Thomas Feldthus	965000	2%
Inventories	0	1	1	0	10 Leif Andersson Consulti	793725	1%
Accounts Receivable	5	3	3	1			
Other Current Assets	11	9	5	1			
Total Current Assets	127	167	45	17			
Non-current assets							
Property, Plant & Equipment, Net	6	0	-2	-3			
Goodwill	0	0	0	0			
Intangible Assets	7	7	7	7			
Right-of-Use Assets	10	10	10	10			
Shares in Associates	1	1	1	1			
Other Long-Term Assets	3	3	3	3			
Total Non-Current Assets	26	21	19	18			
Total Assets	154	188	64	34			
Liabilities							
Current liabilities							
Short-Term Debt	6	6	6	6			
Short-Term Lease Liabilities	0	0	0	0			
Accounts Payable	14	20	1	5			
Other Current Liabilities	3	6	6	1			
Total Current Liabilities	23	32	13	12			
Non-current liabilities							
Long-Term Debt	76	76	0	0			
Long-Term Lease Liabilities	0	0	0	0			
Other Long-Term Liabilities	2	2	2	2			
Total Non-current Liabilities	78	78	2	2			
Non-Controlling Interest	0	0	0	0			
Shareholder's Equity	53	78	49	20			
Total Liabilities & Equity	154	188	64	34			
CASH FLOW							
NOPAT	-220	-27	-27	-75			
Change in Working Capital	-23	11	-15	6			
Operating Cash Flow	-15	-16	-42	-72			
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	59	-76	50			
Free Cash Flow	-16	-16	-42	-72			
NOPAT	-2,5	-0,9	1,5	3,1			
Change in Working Capital	1,9	-0,2	0,9	-0,6			
Operating Cash Flow	-0,2	0,4	5,0	6,2			
Capital Expenditures	0,0	0,0	0,0	0,0			
Investment in Intangible Assets	-2,1	-1,7	-2,7	-3,4			
Investing Cash Flow	-1,5	-3,4	-6,7	-7,4			
Financing Cash Flow	-1,3	-1,5	-1,5	0,8			
Free Cash Flow	-2,3	-1,3	2,3	2,8			

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

Alexander Flening

alexander.flening@redeye.se

Douglas Forsling

douglas.forsling@redeye.se

Forbes Goldman

forbes.goldman@redeye.se

Jessica Grünwald

jessica.grunwald@redeye.se

Jesper Henriksson

jesper.henriksson@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

Mark Siöstedt

mark.siostedt@redeye.se

Jacob Svensson

jacob.svensson@redeye.se

Niklas Sävås

niklas.savas@redeye.se

Danesh Zare

danesh.zare@redeye.se

Fredrik Reuterhäll

fredrik.reuterhall@redeye.se

Life Science Team

Sebastian Andersson

Sebastian.andersson@redeye.se

Oscar Bergman

oscar.bergman@redeye.se

Christian Binder

christian.binder@redeye.se

Filip Einarsson

filip.einarsson@redeye.se

Mats Hyttinge

mats.hyttinge@redeye.se

Ethel Luvall

ethel.luvall@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

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Redeye Rating (2023-05-29)

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

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Kevin Sule owns shares in the company No

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