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ERIK PENSER BANK

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Guard Therapeutics

Resurrection

Ph II data from AKITA study

On Tuesday, Guard presented data from its ph II study (AKITA) with RMC-035 in CS-AKI. Recruitment was halted earlier this year after a futility analysis showed a low probability of reaching the primary endpoint (occurrence of AKI within 72 hours). The primary endpoint was indeed not reached, which the company argues was because the higher dose of medicine in the study (1.30 mg/kg) triggered AKI in a subset of patients (>60% of the study population).

Good effect on key secondary endpoints

The results, however, did show that RMC-035 had a good effect on key (long-term) secondary endpoints in the study, including MAKE90, an outcome measure the regulatory authorities want to see in a pivotal phase III study in acute kidney injury. Most interesting to us was the strong delta between RMC-035 and placebo in kidney function (eGFR) after 90 days, particularly in the pre-specified subset of patients with worse kidney function.

Justified share price rise

During Tuesday's trading, the share price shot up some 220%, which we consider a justified reaction given the share's performance since March, trading at a negative enterprise value. We believe the equity market needs some time to process these results and that the share will be revalued over time. We once again include RMC-035 in CS-AKI in our valuation, with an LoA of 35%. Our fair value is SEK 1.9–2.0 per share. We currently model a (risk-adjusted) advance payment from a potential partner during 2024, which explains the large revenue increase that year. We also model a rights issue of SEK 100m during 2024. Should Guard undertake a ph III study in-house, we believe it will require additional capital.

Change in estimates

	23e	24e	25e
Total revenue	0,0%	0,0%	0,0%
EBITDA, adj.	0,0%	0,0%	0,0%
EPS, adj.	0,0%	0,0%	0,0%

Upcoming events

Q3 - report	10 November 2023
Q4 - report	21 February 2024

Company facts (SEK m)

Number of shares	503m
Market capitalization	374
Net debt	-128
EV	246
Free float	67%
Daily trading volume, average	10 834k
Bloomberg Ticker	GUARD SS EQUITY

Analyst

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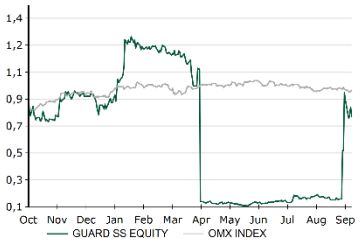
Forecast (SEK m)

	2022	2023e	2024e	2025e
Total revenue	0	0	505	21
Revenue growth	N.m.	N.m.	N.m.	-96%
EBITDA, adj.	-115	-114	416	-18
EBIT, adj.	-115	-114	416	-18
EPS, adj.	-0,2	-0,2	0,8	0,0
EPS growth, adj.	N.m.	N.m.	N.m.	N.m.
BV/share	0,4	0,1	1,2	1,1
Dividend per share	0,0	0,0	0,0	0,0
EBIT margin	Neg.	Neg.	82,5%	Neg.
ROE, adj.	Neg.	Neg.	>100%	Neg.
ROCE, adj.	Neg.	Neg.	>100%	Neg.
EV/Sales	-	-	0,7x	18,2x
EV/EBITDA	-	-	0,9x	-
EV/EBIT	-	-	0,9x	-
P/E, adj.	-	-	0,9x	-
P/BV	2,3x	5,9x	0,6x	0,7x
FCF yield	-	-	>100%	-
Net debt / EBITDA	1,7x	0,7x	-1,4x	31,9x

Value and risk

Fair value	SEK 1,9 - 2,0
Share price	SEK 0,7
Risk level	Hög

Price Performance 12 months



Conflicts of interest

	Yes	No
Liquidity provider		✓
Certified adviser		✓
Transactions 12m		✓

Investment case

Guard Therapeutics is a research company developing clinical drug candidate RMC-035 (ROSguard) as a protective treatment against acute kidney injury (AKI), with an initial focus on heart surgery patients. RMC-035 is very well-documented preclinically, with a well-executed and strategically planned ph I programme. There are no approved treatments for AKI as of today, and the competitive environment is limited.

AKI affects more than 13 million people every year. Mortality is high and survivors are at risk of developing chronic renal impairment, with all its implications of increased morbidity and reduced quality of life. The market solely for the selected high-risk group undergoing cardiac surgery is estimated at SEK 5–10bn in the US and Europe.

Diagnosis and treatment of AKI has been globally identified as a high-priority area owing to the large medical needs and high costs associated with hospitalisation, extended hospital stays, and resource-heavy intensive care.

The global market for AKI, which includes many different patient segments, is estimated at SEK 250–300bn and is expected to expand further in the future. Although the company is relatively small, its management team is highly experienced in scientific and drug development, having held senior global positions in larger pharmaceutical companies. It also holds clinical and R&D expertise, specifically in the field of kidney diseases. The company has a well-thought-out clinical development programme combined with a traditional business model.

Company profile

Guard Therapeutics is a research company that develops therapies for diseases with a large medical need for effective treatments. The company is developing clinical drug candidate RMC-035 as a protective treatment against AKI, with an initial focus on cardiac surgery patients. Treatment with RMC-035 has the potential to save lives and prevent the chronic and extremely serious consequences of impaired kidney function, such as life-sustaining dialysis treatment.

The company is undertaking a ph II study (AKITA) in open heart surgery, plus a ph Ib study in kidney transplants.

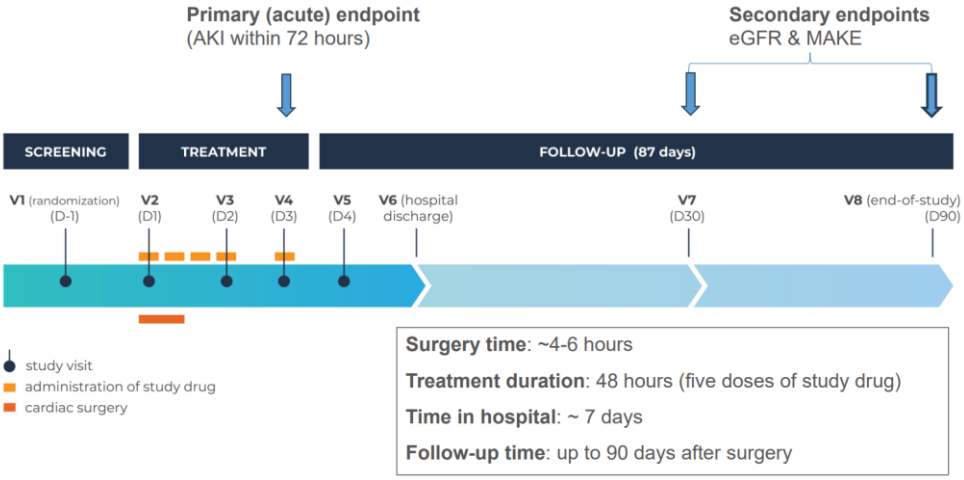
Valuation

We have chosen to value Guard Therapeutics using a probability adjusted DCF model. We arrive at a fair value of SEK 1.9–2.0 per share.

Study design

The purpose of the ph II AKITA study has been to investigate RMC-035's efficacy in preventing AKI during open heart surgery. The study was randomised, double-blind and placebo-controlled, with a total of 191 patients undergoing open heart surgery. It only recruited patients at high risk of developing AKI based on pre-defined biomarkers. Guard estimates that around 50% of this patient group would develop AKI, compared with up to ~30% in the broader population (Vives, 2019). The primary endpoint was evaluated after three days, although patients were monitored over 90 days to check safety and secondary endpoints. The primary endpoint in the study was a binary variable: "the number of patients who developed AKI within 72 hours of surgery".

AKITA study design



Source: Guard Therapeutics' investor call

Baseline patient characteristics

	RMC-035 (N=89)	Placebo (N=88)	
Age (years)	70.2 (8.5)	70.5 (8.1)	
Male	70 (78.7%)	69 (78.4%)	
Female	19 (21.3%)	19 (21.6%)	
Height (cm)	169.8 (8.9)	171.3 (9.0)	
Weight (kg)	83.3 (18.1)	86.3 (20.5)	
eGFR (mL/min/1.73m^2)	75.6 (18.1)	77.4 (18.2)	
Subgroup ≥ 60 mL/min/1.73m^2	55 (61.8 %)	57 (64.8 %)	Start dose: 1.30 mg/kg
Subgroup < 60 mL/min/1.73m^2	34 (38.2 %)	31 (35.2 %)	Start dose: 0.65 mg/kg

Source: Guard Therapeutics' investor call

Why was the primary endpoint not reached?

Generally, our view is that a study that fails to reach its primary endpoint has failed. This is because a study is designed and planned in advance for this specific outcome measure. This is more critical in a ph III study, based on which the company can seek market approval for the drug, since regulatory authorities set requirements for the endpoints to evaluate.

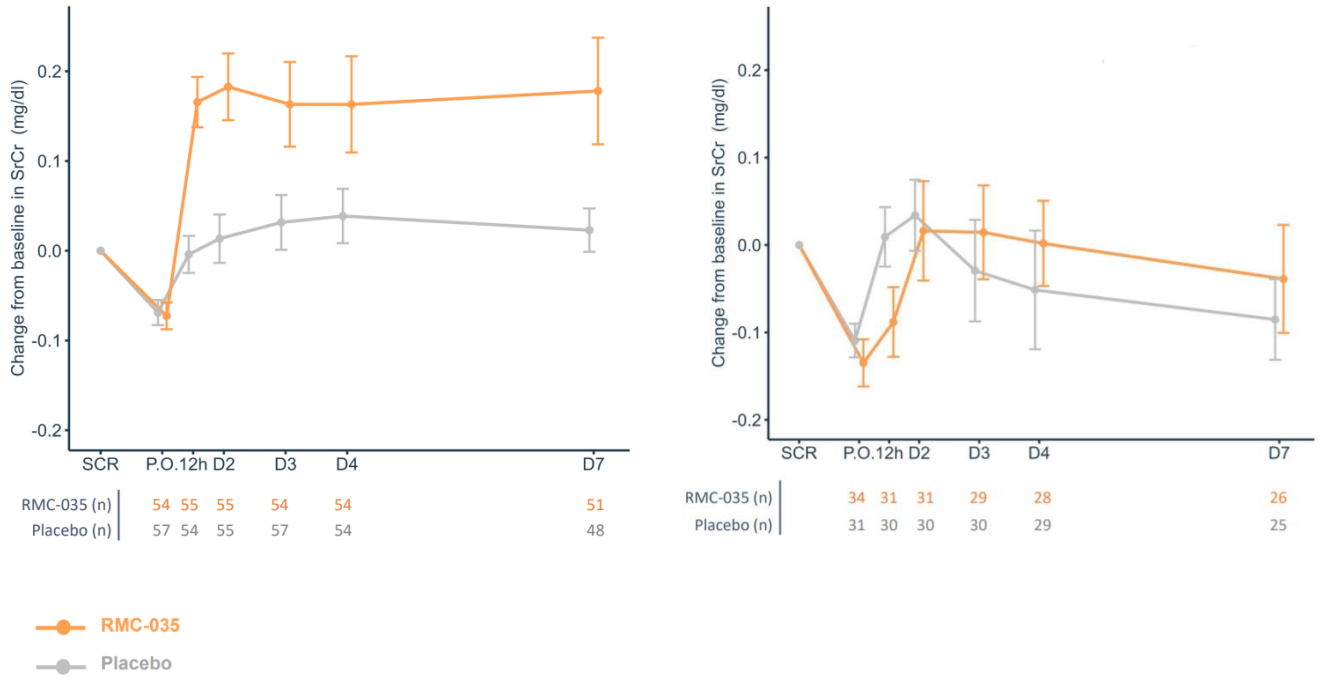
The primary endpoint in the AKITA study was "AKI occurrence within 72 hours", which is a surrogate marker for more long-term outcome measures, such as MAKE (major adverse kidney events). The reason for using a surrogate marker is typically to be able to evaluate the impact faster and detect an effect on a smaller patient population. It is thus common practice in early efficacy studies to investigate whether a drug works as intended without the need to include too many patients.

Guard's study showed that RMC-035 led to a higher incidence of AKI within 72 hours than placebo. This is, of course, not the result the company was hoping for when it designed the study and was also the reason for the recommendation to end patient recruitment.

The higher incidence of AKI in the RMC-035 arm stemmed from a subset of the study's patients with better kidney function (>60% of the study population), who also received a higher dose of the drug than the "sicker" subset. As shown in the chart below to the left, there was a sharp initial increase in creatinine in these patients, triggering AKI according to the study protocol's definition. The sharp increase in creatinine can be attributed, according to the company, to these patients having been given too high a drug dose.

Looking at the right-hand chart, patients who received a lower drug dose did not experience the same creatinine spike. This group performed better on both the primary endpoint and eGFR. The company's conclusion is that it will use this dose (or possibly even lower) in a ph III study.

Changes in creatinine levels until day seven: eGFR ≥60ml/min/1.73 m2 (left), eGFR <60ml/min/1.73 m2 (right)



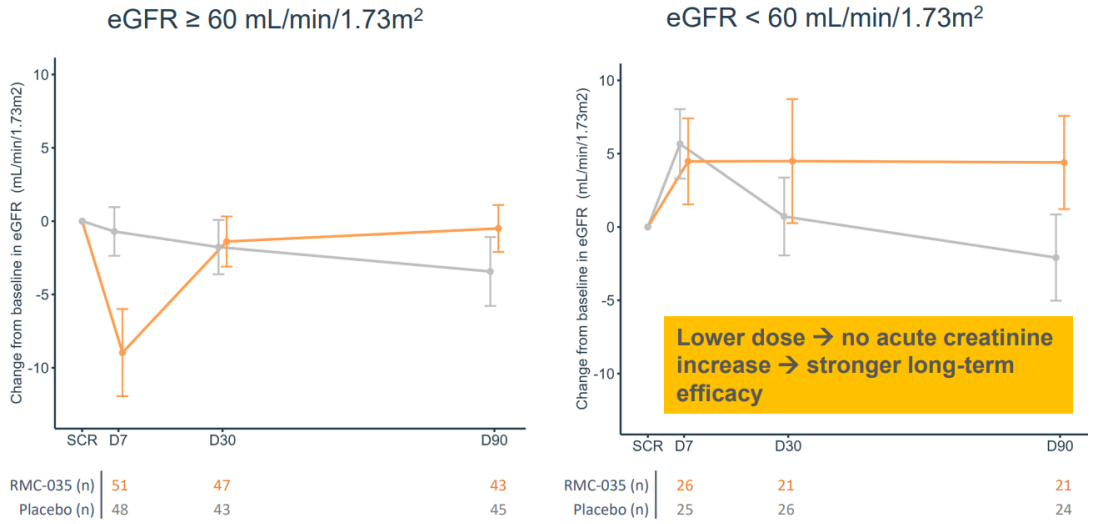
Source: Guard Therapeutics' investor call

Good effect on secondary endpoints

The study also included key secondary endpoints like eGFR at 90 days and MAKE (major adverse kidney events) at 90 days. Most interesting to us was the particularly strong numerical effect on eGFR, especially in the subset of patients with worse kidney function (eGFR <60ml/min/1.73 m2). The difference in eGFR between the study arms at 90 days was 4.3ml/min/1.73 m2 in the global study population (p=0.063), and 7.9 ml/min/1.73 m2 in patients with worse kidney function who received a lower dose (p=0.051).

To put these results into context, a 2018 workshop sponsored by National Kidney Foundation in association with the FDA and EMA indicated that a treatment effect on eGFR (improvement compared with placebo) of 0.5–1.0 ml/m per year over a three-year period would, with a high probability, lead to a clinically relevant improvement in patients' long-term kidney function and fewer incidences of terminal renal failure.

Effect on eGFR (kidney function) at 90 days, split by baseline kidney function (pre-specified)



Source: Guard Therapeutics' investor call

The effect on the MAKE90 endpoint was good. This is a binary composite measure that compares the number of cases of either death, need for dialysis, or ≥25% reduction in eGFR between treatment groups within 90 days. Here, 6.7% of patients in the RMC-035 group experienced MAKE, compared with 15.9% in the placebo group (relative risk: p=0.047). MAKE is the endpoint the regulatory authorities want to see in pivotal ph III studies in AKI.

Both eGFR at 90 days and MAKE90 were statistically significant at a 90% confidence level – the threshold level the company defined ahead of the study. We believe this was a fairly lenient threshold, and the company says it used this to keep the study size down. We believe lower p-values would have allowed for more confidence in the results, but we also understand a larger patient population is usually required to achieve an effect with high statistical significance using these longer-term endpoints, particularly the binary variable MAKE90. Should the delta between RMC-035 and placebo shown in the study be replicated in a larger ph III trial, we would have seen lower p-values.

The road ahead

Guard considers a ph III study to be the next development stage for RMC-035 in CS-AKI. We believe the data presented justifies this, but it might be necessary to undertake a study to evaluate the optimal dose for a ph III trial. Should it discover that a lower dose can deliver a better/equivalent effect to that used in the AKITA study, this new dose would likely be used instead.

DCF

Valuation output	
Sum of PV of FCF (explicit period)	859
PV of terminal value (perpetuity formula)	0
Enterprise value	**859**
Latest net debt	-128
Minority interests & other	0
Equity value	**987**
No. of shares outstanding (millions)	503.1
Equity value per share (SEK)	**1.96**

WACC assumptions	
Risk free nominal rate	2.5%
Market risk premium	5.5%
Small cap premium	6%
Extra risk premium	6%
WACC	20.0%

Sensitivity analysis - WACC					
WACC	18%	19%	**20%**	21%	22%
NPV	11301054		**987**	925	869
NPV/share	2.2	2.1	**2.0**	1.8	1.7

Implicit multipl.	2023e
EV/Sales	Nm.
EV/EBITDA	Nm.
EV/EBIT	Nm.
EV/NOPLAT	Nm.
P/E	Nm.
ROIC/WACC	Nm.
Current Share price	0.74

Terminal value assumptions	
Long term growth rate	Nm.
Long term EBIT margin	Nm.
Depreciation (% of sales)	Nm.
Capex (% of sales)	Nm.
Working cap. (% of sales)	Nm.
Tax rate	Nm.

Källa: EPB

Income statement

	2020	2021	2022	2023e	2024e	2025e
Net sales	**0**	**0**	**0**	**0**	**505**	**21**
Total revenus	**0**	**0**	**0**	**0**	**505**	**21**
Gross profit	**0**	**0**	**0**	**0**	**505**	**21**
R & D Expenses	-35	-75	-105	-106	-80	-30
Other Operating Expenses	-5	-7	-10	-8	-8	-8
EBITDA	**-40**	**-82**	**-115**	**-114**	**416**	**-18**
EBITDA, adjusted	**-40**	**-82**	**-115**	**-114**	**416**	**-18**
EBITA, adjusted	**-40**	**-82**	**-115**	**-114**	**416**	**-18**
EBIT	**-40**	**-82**	**-115**	**-114**	**416**	**-18**
EBIT, adjusted	**-40**	**-82**	**-115**	**-114**	**416**	**-18**
Net Financial Items	0	0	2	0	0	0
Profit before tax	**-40**	**-82**	**-113**	**-114**	**416**	**-18**
Profit before tax, adjusted	**-40**	**-82**	**-113**	**-114**	**416**	**-18**
Net income	**-40**	**-82**	**-113**	**-114**	**416**	**-18**
Net income, adjusted	**-40**	**-82**	**-113**	**-114**	**416**	**-18**
Sales Growth	-	*N.m.*	*N.m.*	*N.m.*	*N.m.*	*-96%*
Gross Margin	*Neg.*	*Neg.*	*Neg.*	*Neg.*	*100,0%*	*100,0%*
EBIT Margin, Adjusted	*Neg.*	*Neg.*	*Neg.*	*Neg.*	*82,5%*	*Neg.*
EPS, Adjusted	*-0,19*	*-0,24*	*-0,22*	*-0,23*	*0,83*	*-0,04*
EPS Growth, Adjusted	-	*N.m.*	*N.m.*	*N.m.*	*N.m.*	*N.m.*

Source: Guard Therapeutics International, EPB

Cash flow statement

	2020	2021	2022	2023e	2024e	2025e
EBIT	-40	-82	-115	-114	416	-18
Other Cash flow Items	0	1	1	0	0	0
Changes in working capital	2	4	12	-11	11	-20
Cash flow from operating activities	**-38**	**-78**	**-102**	**-126**	**428**	**-38**
Free cash flow	**-38**	**-78**	**-102**	**-126**	**428**	**-38**
New share issue / repurchase	74	176	113	0	100	0
Cash flow from financing	**74**	**176**	**113**	**0**	**100**	**0**
Cash flow	**36**	**99**	**10**	**-126**	**528**	**-38**
Net debt	**-90**	**-189**	**-201**	**-75**	**-603**	**-565**

Source: Guard Therapeutics International, EPB

Balance sheet

	2020	2021	2022	2023e	2024e	2025e
ASSETS						
Other current assets	1	2	2	1	5	0
Cash and cash equivalents	90	189	201	75	603	565
Total current assets	**91**	**190**	**203**	**76**	**608**	**565**
TOTAL ASSETS	**91**	**190**	**203**	**76**	**608**	**565**
EQUITY AND LIABILITIES						
Equity	80	176	177	63	579	562
Total equity	**80**	**176**	**177**	**63**	**579**	**562**
Other long-term liabilities	5	4	3	3	3	3
Total long-term liabilities	**5**	**4**	**3**	**3**	**3**	**3**
Accounts payable	3	6	11	7	15	0
Other current liabilities	4	5	11	4	11	1
Total current liabilities	**7**	**11**	**23**	**11**	**26**	**1**
TOTAL EQUITY AND LIABILITIES	**91**	**190**	**203**	**76**	**608**	**565**

Source: Guard Therapeutics International, EPB

Growth and margins

	2020	2021	2022	2023e	2024e	2025e
Revenue growth	-	N.m.	N.m.	N.m.	N.m.	-96%
EBITDA growth, adjusted	-	N.m.	N.m.	N.m.	N.m.	N.m.
EBIT growth, adjusted	-	N.m.	N.m.	N.m.	N.m.	N.m.
EPS growth, adjusted	-	N.m.	N.m.	N.m.	N.m.	N.m.
Gross margin	Neg.	Neg.	Neg.	Neg.	100,0%	100,0%
EBITDA margin	Neg.	Neg.	Neg.	Neg.	82,5%	Neg.
EBITDA margin, adjusted	Neg.	Neg.	Neg.	Neg.	82,5%	Neg.
EBIT margin	Neg.	Neg.	Neg.	Neg.	82,5%	Neg.
EBIT margin, adjusted	Neg.	Neg.	Neg.	Neg.	82,5%	Neg.
Profit margin, adjusted	Neg.	Neg.	Neg.	Neg.	82,5%	Neg.

Source: Guard Therapeutics International, EPB

Return

	2020	2021	2022	2023e	2024e	2025e
ROE, adjusted	Neg.	Neg.	Neg.	Neg.	>100%	Neg.
ROCE, adjusted	Neg.	Neg.	Neg.	Neg.	>100%	Neg.
ROIC, adjusted	Neg.	>100%	>100%	>100%	Neg.	>100%

Source: Guard Therapeutics International, EPB

Capital efficiency

	2020	2021	2022	2023e	2024e	2025e
Total short-term liabilities / total cost	16%	13%	20%	9%	29%	2%
Working capital / total revenue	-	-	-	-	-4%	-3%
Capital turnover rate	0,0x	0,0x	0,0x	0,0x	0,9x	0,0x

Source: Guard Therapeutics International, EPB

Financial position

	2020	2021	2022	2023e	2024e	2025e
Net debt	-90	-189	-201	-75	-603	-565
Equity ratio	87%	92%	88%	83%	95%	99%
Net debt / equity	-1,1x	-1,1x	-1,1x	-1,2x	-1,0x	-1,0x
Net debt / EBITDA	2,2x	2,3x	1,7x	0,7x	-1,4x	31,9x

Source: Guard Therapeutics International, EPB

Per share data

	2020	2021	2022	2023e	2024e	2025e
EPS	-0,19	-0,24	-0,22	-0,23	0,83	-0,04
EPS, adjusted	-0,19	-0,24	-0,22	-0,23	0,83	-0,04
FCF per share	-0,18	-0,23	-0,20	-0,25	0,85	-0,08
Dividend per share	0,00	0,00	0,00	0,00	0,00	0,00
Book value per share	0,37	0,51	0,35	0,13	1,15	1,12
Number of shares, m	213	343	503	503	503	503
Number of shares after dilution, average	213	343	503	503	503	503

Source: Guard Therapeutics International, EPB

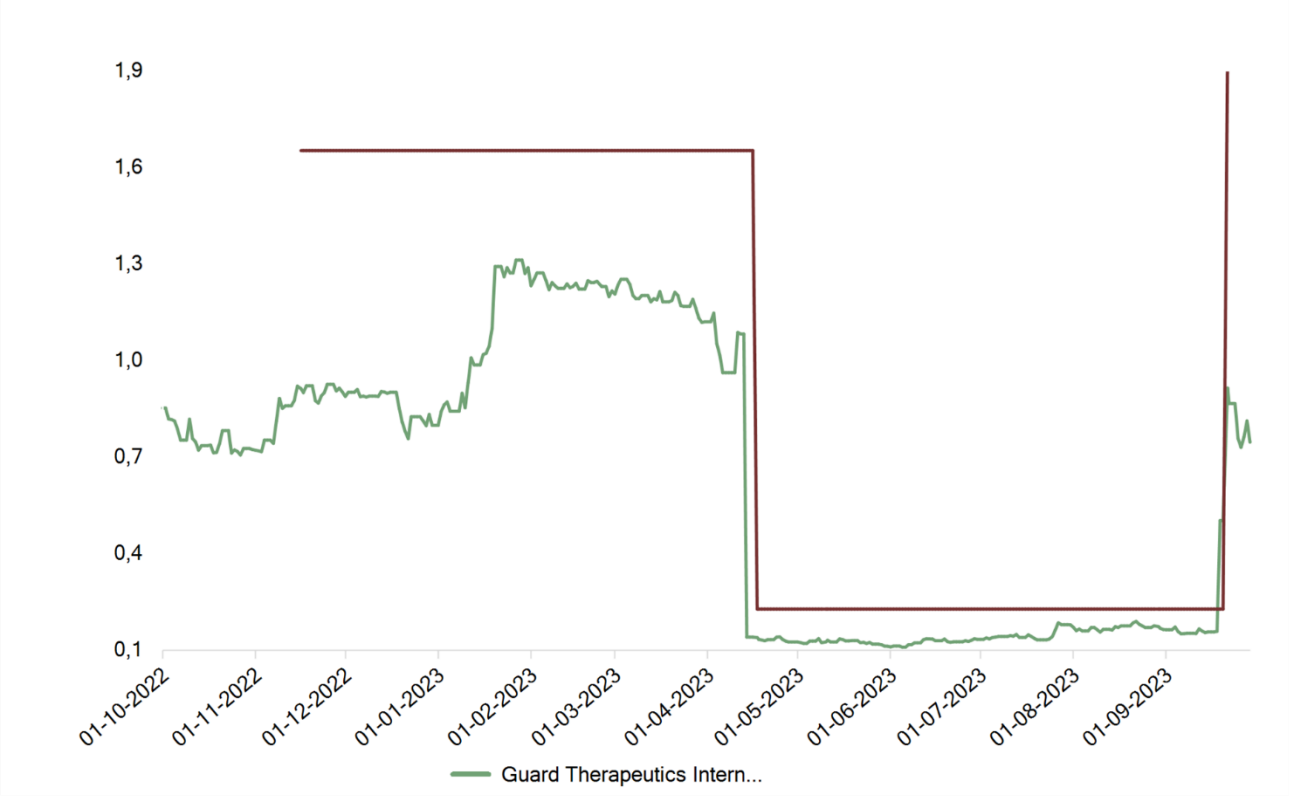
Valuation

	2020	2021	2022	2023e	2024e	2025e
P/E, adjusted	Neg.	Neg.	Neg.	Neg.	0,9x	Neg.
P/BV	3,5x	2,6x	2,3x	5,9x	0,6x	0,7x
P/FCF	Neg.	Neg.	Neg.	Neg.	0,9x	Neg.
FCF-yield	Neg.	Neg.	Neg.	Neg.	>100%	Neg.
Dividend yield	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%
Payout ratio, adjusted	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%
EV/Sales	Neg.	Neg.	Neg.	Neg.	0,7x	18,2x
EV/EBITDA, adjusted	Neg.	Neg.	Neg.	Neg.	0,9x	Neg.
EV/EBIT, adjusted	Neg.	Neg.	Neg.	Neg.	0,9x	Neg.
EV	187	264	199	374	374	374
Share price, year end	1,3	1,3	0,8	0,7	0,7	0,7

Source: Guard Therapeutics International, EPB

Share Price and Fair Value Chart

Guard Therapeutics International (GUARD SS EQUITY)



Source: EPB, IDC

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