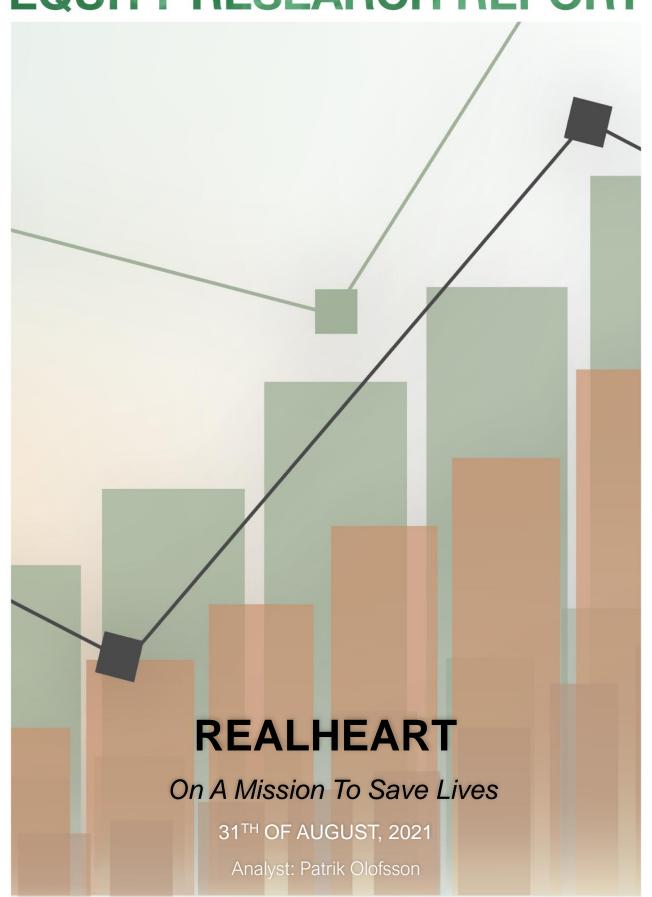


# **EQUITY RESEARCH REPORT**



# REAL HEART (HEART)

### ON A MISSION TO SAVE LIVES



More than 64 million people suffer from heart failure and only 7,000 heart transplants are performed each year. The problem is extensive and today there are no real sustainable solution for an artificial heart. Scandinavian Realheart AB (publ) ("Realheart" or the "Company") holds the world's first unique and patented four chamber Total Artificial Heart ("TAH"), which mimics the human heart's blood flow. Realheart intends to initiate their market launch during 2025, which is estimated to be followed by a rapid sales growth, with revenues reaching SEK108 M in 2027. Based on an applied P/S multiple and a discount rate, this yield a present value per share of SEK 13 in a Base scenario. Before market launch, we see several key value-driving activities, where steps in right direction should reduce the current valuation discount.

#### Blue Ocean Market

Millions of people globally suffer from heart problems and an alternative to save lives is a so-called total artificial heart (TAH). Today, however, only one (1) TAH is available on the market; SynCardia TAH. SynCardia's sales are estimated to grow by a CAGR of 15% until 2029, reaching approx. USD65M (~SEK565 M). Given SynCardia's expected sales development, and the fact that there are no other alternatives, it can be argued that Realheart operates within a Blue Ocean market, with a solid growth outlook.

#### Expected Market Launch In 2025

The potential market for Europe and the US is expected to consists of nearly 130,000 patients/year. If Realheart gradually increases their market share to reach only 0.5% of the target group by 2030, this would translate to ~650 patients/year. With the same pricing per transplant as SynCardia TAH of approx. SEK1.2 M, this would correspond to SEK780 M in revenues for Realheart.

#### Value Drivers Ahead

Carmat SA offers a bioprosthetic artificial heart that has obtained market approval, where the company during 2021 have sold their first commercialized artificial heart. Carmat are valued at about EUR420 M, thus more than 20x higher compared to Realheart. From an investor perspective, it can be argued that the valuation of Realheart may gradually increase the closer the Company gets to the launch year 2025, hence enabling return to investors even before any sales exist.

### **Strengthened Cash Position**

Realheart must finetune their product, obtain various approvals and efficiently balance available working capital until positive cash flows can be achieved. During August/September, Realheart raises SEK~68 M via an 91% secured rights issue. This will mainly be used to finance further product development and pre-clinical trials.

### SHARE PRICE SEK 5.9

VALUATION RANGE, PRESENT VALUTE 2027Y FORECAST

BEAR **SEK 4.0**  BASE **SEK 13.0**  BULL **SEK 19.0** 

The valuation is derived as a present value of sales forcasted in the year 2027. The potential valuation increase is expected to be gradual, given that assumed

Revenues         12         42         108         276         480         780           Gross Profit         5         19         53         141         254         429           Gross margin         40%         45%         49%         51%         53%         55%           Total operating costs         -41         -46         -60         -91         -132         -156           EBIT         -36         -27         -7         50         122         273           EBIT margin         neg.         neg.         neg.         18%         25%         35%           P/S         16,7         4,8         1,9         0,7         0,4         0,3           EV/S         11,2         3,2         1,2         0,5         0,3         0,2           EV/EBIT         neg.         neg.         neg.         2,7         1,1         0,5	SCANDINAVIAN REALHEART	r AB											
Market Cap (MSEK)         201.0¹           Net Cash (-)/Debt(+) (MSEK)         -66.6¹           Enterprise Value (MSEK)         134.4¹           W.52 Price Interval (SEK)         5.52 − 14.00           Stock Exchange         Spotlight Stock Market           SHARE PRICE DEVELOPMENT           1 Month         -15.3 %           3 Months         -8.3 %           1 Year         -8.0 %           YTD         -2.6 %           TOP SHAREHOLDERS (AS OF 2021-06-30)           Najar Medical & Invention AB         14.3 %           Eskilstuna Hem Fastighets AB         4.9 %           Försäkrings AB Avanza         3.9 %           Ålandsbanken i ägares ställe         2.2 %           Bilend Najar         1.7 %           CEO         Ina Laura           Chairman of the Board         Göran Hellers           FORECAST (BASE), SEKM         2025E         2026E         2027E         2028E         20201-11-18           FORECAST (BASE), SEKM         2025E         2026E         2027E         2028E         2020E         2030E           Revenues         12         42         108         276         480         780 <t< td=""><td colspan="12">Share Price (2021-08-30) (SEK) 5.9</td></t<>	Share Price (2021-08-30) (SEK) 5.9												
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Gross margin         40%         45%         49%         51%         53%         55%           Total operating costs         -41         -46         -60         -91         -132         -156           EBIT         -36         -27         -7         50         122         273           EBIT margin         neg.         neg.         neg.         18%         25%         35%           P/S         16,7         4,8         1,9         0,7         0,4         0,3           EV/S         11,2         3,2         1,2         0,5         0,3         0,2           EV/EBIT         neg.         neg.         neg.         2,7         1,1         0,5													
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<sup>1</sup> Based on the assumption that the current rights issue of SEK67.7 M is fully				_									



### INVESTMENT THESIS

#### Addressing A Rapid Growing Blue Ocean Market

Each year, only 7,000 heart failure patients globally are saved through heart transplants, which corresponds to only 3% of patients in need. In the US, more than 300,000 people die of heart failure each year, and forecasts show that heart failure diagnoses will increase too about 8 million by 2030. Treatments for heart failure can be done either through medication, or heart transplantation. The waiting times is often long and the current "transplantation rate" is forecasted to cover less than 10% of the actual need, as the mortality rate of advanced heart failure is up to 90% within a year. An alternative for replacing the failing heart is to provide a so-called Total Artificial Heart (TAH), which is done by surgery in the same way as in a heart transplantation. Besides from Carmat getting closer to market, there is today only one commercialised TAH available on the market, namely SynCardia (US). SynCardia Systems LLC's sales amounted to approx. USD16 M year 2019 and are forecasted to increase to approx. USD65 M in 2029, which is equivalent to a Compounded Annual Growth Rate (CAGR) of ~15%. For Realheart, this is interesting in several aspects; firstly, it means that an established market player has "paved the way", which favour Realheart's growth journey, secondly, that the number of market players are still so small that the TAH market can almost be compared with a Blue Ocean. Given a successful product and clinical development, Realheart is estimated to obtain market approval in 2025 and are thus able to initiate the commercial phase.

~15 % ANNUAL MARKET GROWTH 2019-2029E

#### **Value Drivers Within The Next 12-36 Months**

Realheart's lab tests results on blood look very promising and short term pre-clinical animal trials have been successful. Long term trials have been initiated during H1-21 and so far, there is nothing to suggest that Realheart TAH will not be significantly better than what is on the market today. To initiate clinical trials, two main types of data must be submitted to the FDA for review: animal trial data from a certified laboratory conducted according to Good Laboratory Practice (GLP) for six animals supported for 60 days, and reliability study data conducted on a set of eight pumps under the worst pumping conditions for six months. From this point, the first in-human study, consisting of high-risk individuals, are to be initiated. In parallel, Realheart continue the work with identifying suitable partners with the right experience and knowledge for high-quality medtech products. All of these events compose important steps until market lunch, and also constitutes as value drivers within the next 12-36 months, which can result in an increase in the share price. An interesting comparison can be made with the French company Carmat, which has some technical differences compared to Realheart's TAH, but with a similar purpose. Carmat have a Market Cap of approx. EUR420 M, which can bee compared to Realhearts EUR20 M, i.e., a more than 20x lower valuation. From an investor perspective, it can be argued, based on Carmat's present valuation, that the valuation of Realheart may increase gradually as the Company gets closer to market launch.

### Forecast And Valuation: A Summary

SEK ~780 M REVENUES 2030E In a Base scenario, Realheart is estimated to reach sales of approx. SEK108 M during 2027, and from that point grow at an average rate of 97% per year until 2030, reaching sales of approx. SEK780 M, corresponding to 0.5% of the addressable market. Some steps still remains before the potential market launch, which is a risk that must be considered in the financial scenarios that are presented in this analysis. With a target multiple of P/S 8.5x on estimated sales during the year 2027, and a conservative discount rate of 18%, which accounts for the time specific risk of events that are far away and have not yet occurred, this yields, in a Base scenario, a fundamental net present value per share of SEK 13.

#### A Long Road To Walk Until Market Launch

The road to market launch is challenging and Realheart must continue to fine-tune the product, go through different clinical phases, obtain necessary approvals and in an efficient way balance their working capital. Via the rights issue during August/September 2021, the cash position will be strengthened, where Realheart will receive a net amount of approx. SEK55 M, assuming a subscription rate of 100%. This will be sufficient to finance the business for a plus 12-month period going forward. From beyond that point, Realheart will need to obtain further external capital in order to finance various investments before a market launch is possible, where we assume that fundings could be obtained via a combination of additional shareholder capital and so-called "soft money", e.g., via grants and other R&D re-imbursement schemes.



# FINANCIAL FORECAST

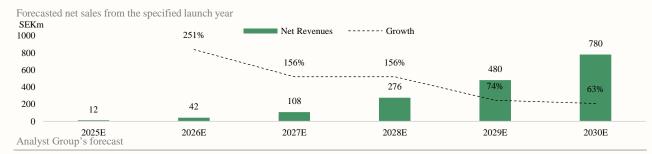
#### Revenue Forecast 2025-2030

Analyst Group's financial estimates of Realheart's revenues are based on 2025 being the year for the market launch of the TAH for normal-sized individuals, where the forecast period extends to 2030. Realhearts Go-To-Market strategy is to provide the product directly through a in-house sales organization by regional salesmen, alternatively via partners and / or distributors, primarily to hospitals within Europe and the US. In other geographic regions, the product may be sold primarily through partners and distributors. Business contracts are assumed to be initiated by for example a cardiologist or a cardiothoracic surgeon, where the hospitals then pays for the purchase of Realheart's TAH and receives compensation from the government or insurance companies, depending on the geographical market. The patient group that Realheart TAH primarily addresses are individuals that suffers from either chronic heart failure, and/or acute heart failure, a group consisting of millions of people within Europe and the US. However, not all patients within these diagnostic groups are suitable for a TAH treatment, e.g. the patient should not be too old due to the extent of the surgery, and the patient's chest needs to be large enough for the mechanical heart to fit. The potential market for Europe and the US is estimated to consist of a total of approx. 129,000 patient/year, equivalent to approx. USD16 billion in annual sales. Per patient, this corresponds to a product price of about SEK1.2 M, which is in line with the price for the SynCardia TAH. Over the past 35 years, SynCardia TAH has been implanted in almost 2,000 patients, corresponding to an average of 60 patients/year and thus only ~0.05% of the annual market size of 129,000 patients. The low market penetration is the result of low user-friendliness and 35-year-old technology which causes several side effects.

EVEN AT A SMALLER MARKET SHARE, SALES CAN INCREASE RAPIDLY

Given that Realheart can initiate a market launch during 2025, there should be room for the Company to take a large market share. With a conservative assumption that Realheart gradually increases their market share to 0.5% of the target group by 2030, this would translate to about 650 patients and total sales of SEK780 M. The level of revenues may be perceived as sensational or even striking, but it can be compared with SynCardia TAH's sales, which in 2019 amounted to approx. SEK140 M, and are expected to rise to SEK~565 M year 2029.

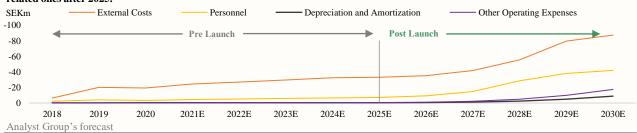
#### Our forecasts are primarily based on Realheart TAH, which is estimated to be launched in 2025 in Europe and the US.



#### **Operating Costs Pre/Post Expected Market Launch**

Until the assumed market launch in 2025, Realheart needs to conduct some OPEX investments, e.g., fine tuning of the product, clinical studies, regulatory work, etc. After market lunch, operating costs are estimated to increase, where the primary drivers are assumed to be derived partly from the production of the product itself, and partly from a more comprehensive sales organization for processing hospitals in markets such as the US, Canada and Europe.

# Operating expenses before 2025 are assumed to be related mainly to development and clinical trials, which will then shift to more sales-related ones after 2025.



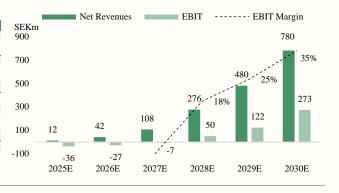


### VALUATION

#### The following is a summary of Analyst Group's financial forecast for Realheart after the expected market launch in 2025.

Financial forecast from estimated launch in 2025, Base scenario

Base scenario (SEKm)	2025E	2026E	2027E	2028E	2029E	2030E
Net Revenues	12	42	108	276	480	780
Other Operating Income	0	0	0	0	0	0
<b>Total Revenues</b>	12	42	108	276	480	780
COGS	-7	-23	-55	-135	-226	-351
Gross Profit	5	19	53	141	254	429
Gross Margin	40%	45%	49%	51%	53%	55%
Total Operating Costs	-41	-46	-60	-91	-132	-156
EBIT	-36	-27	-7	50	122	273
EBIT Margin	neg.	neg.	neg.	18%	25%	35%
Analyst Group's forecas	st					



**Valuation: Base Scenario** 

Since the financial forecast for Realheart assumes that the Company can perform high doubledigit growth after the expected market launch in 2025, the valuation is based on sales. P/S multiples for medtech companies in an early phase are generally high, due to initially low, or zero, sales. Over time, as sales increases, multiples tend to normalize in line with the company reaching a larger market share and a higher degree of maturity. Given a target multiple of P/S 8.5x on annual revenues of SEK108 M in 2027, this corresponds to a Market Cap of approx. SEK920 M. If Realheart reaches the market in 2025, this should, rather early, result in rapidly increasing sales, which would thus be considered a proof that the Company has both an attractive product and also the ability to reach a significant market share. For Realheart, some steps still remains before a market launch can be realized, where the Company must pass several clinical steps, evaluations and regulatory approvals. This constitutes a risk and, depending on the applied discount rate, which reflects the time risk from events that are several years away, and which have not yet occurred, different valuation levels are obtained. Analyst Group assumes a conservative discount rate of 18% for Realheart, which based on a company value of SEK920 million in 2027, results in a fundamental net present value per share today of SEK 13 in a Base scenario.

SEK 13 PER SHARE IN A BASE SCENARIO

#### **Bull Scenario**

The following is a selection of potential value drivers in a Bull scenario:

- Realheart delivers on their set agenda and results from both product development and clinical trials are positive, which contributes to a smooth process for regulatory approval and registration.
- Even before a launch is possible, Realheart has succeeded in establishing a broader network of contacts, which contributes to a faster market expansion after launch.
- Through the current rights issue, the cash position is strengthened, but additional capital will be necessary before positive cash flows can be achieved. Given a good business development, it should be possible to raise funds at a higher valuation, which reduces the dilution effect and enables a good return for investors.

Given a discount rate of 18% and a target multiple of P/S 9x on estimated sales of SEK153 M in 2027 in a Bull scenario, this yields a present value per share of SEK 19.1

#### **Bear Scenario**

The following is a selection of potential factors in a Bear scenario:

- Today's prerequisites speaks for Realheart, but a lot can happen that could result in a postponed market launch, which in a Bear scenario is assumed to take place in 2027.
- The delay results in an extended period of negative cash flows, which means that the Company's need for external capital increases.
- In the event of a "worse-than-expected" development, it is conceivable that capital raises will need to be conducted with a higher valuation discount, and thus may put a downward pressure on the share price.

In a Bear scenario, a lower valuation of the share is justified, mainly motivated by the fact that the Company's work towards the planned market launch does not develop as expected. Based on the financial estimates of such scenario, a target multiple of P/S 6x and a discount rate of 18%, this yields a present value per share of SEK 4 in a Bear scenario. <sup>1</sup>

SEK 19 PER SHARE IN A BASE SCENARIO

SEK 4 PER SHARE IN A BASE SCENARIO

<sup>1</sup>See Appendix page 6 for forecasts made in the Bull and Bear scenarios, respectively.





# <u>APPENDIX</u>

							Estimated Commercial Phase					
Base scenario (SEKm)	2019	2020	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net Revenues	0	0	0	0	0	0	12	42	108	276	480	780
Other Operating Income <sup>1</sup>	17	14	19	15	10	5	0	0	0	0	0	0
Total Revenues	17	14	19	15	10	5	12	42	108	276	480	780
COGS	0	0	0	0	0	0	-7	-23	-55	-135	-226	-351
Gross Profit	17	14	19	15	10	5	5	19	53	141	254	429
Gross Margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	40%	45%	49%	51%	53%	55%
External Costs	-20	-19	-24	-27	-29	-32	-33	-35	-42	-55	-79	-87
Personnel	-4	-3	-5	-5	-6	-7	-7	-9	-15	-28	-38	-42
Depreciation and Amortization	0	0	0	0	0	0	0	-1	-1	-2	-5	-9
Other Operating Expenses	0	0	0	0	0	-1	-1	-1	-2	-5	-10	-18
EBIT	-7	-9	-10	-18	-26	-35	-36	-27	-7	50	122	273
EBIT Margin	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	18%	25%	35%
D/G							165	4.0	1.0	0.7	0.4	0.2
P/S	n.a	n.a	n.a	n.a n	.a n.a	n.a	16,7	4,8	1,9	0,7	0,4	0,3
EV/S	n.a	n.a	n.a	n.a n	.a n.a	n.a	11,2	3,2	1,2	0,5	0,3	0,2
EV/EBIT	n.a	n.a	n.a	n.a n	.a n.a	n.a	neg.	neg.	neg.	2,7	1,1	0,5

							Estimated Commercial Phase					
Bull scenario (SEKm)	2019	2020	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net Revenues	0	0	0	0	0	0	19	75	153	310	507	1 018
Other Operating Income <sup>1</sup>	17	14	19	15	10	5	0	0	0	0	0	0
Total Revenues	17	14	19	15	10	5	19	75	153	310	507	1 018
COGS	0	0	0	0	0	0	-11	-40	-76	-146	-216	-407
Gross Profit	17	14	19	15	10	5	8	35	76	164	292	611
Gross Margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	40%	47%	50%	53%	58%	60%
External Costs	-20	-19	-23	-26	-28	-31	-32	-39	-49	-64	-89	-100
Personnel	-4	-3	-4	-5	-6	-9	-11	-19	-26	-33	-48	-58
Depreciation and Amortization	0	0	0	0	0	0	0	-1	-2	-3	-6	-11
Other Operating Expenses	0	0	0	0	0	-1	-1	-1	-3	-6	-11	-21
EBIT	-7	-9	-9	-16	-25	-36	-37	-25	-3	59	138	421
EBIT Margin	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	19%	27%	41%
P/S	n.a	n.a	n.a	n.a n	.a n.a	n.a	10,5	2,7	1,3	0,6	0,4	0,2
EV/S	n.a	n.a	n.a	n.a n	.a n.a	n.a	7,0	1,8	0,9	0,4	0,3	0,1
EV/EBIT	n.a	n.a	n.a	n.a n	.a n.a	n.a	neg.	neg.	neg.	2,3	1,0	0,3

										Estimated Commercial Phase			ase
Bear scenario (SEKm)	2019	2020	202	21E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net Revenues	0	0	(	)	0	0	0	0	0	9	31	72	159
Other Operating Income <sup>1</sup>	17	14	1	9	15	10	8	7	5	0	0	0	0
<b>Total Revenues</b>	17	14	1	9	15	10	8	7	5	9	31	72	159
COGS	0	0	(	)	0	0	0	0	0	-6	-17	-37	-78
Gross Profit	17	14	1	9	15	10	8	7	5	4	14	35	81
Gross Margin	n.a.	n.a.	n.	a.	n.a.	n.a.	n.a.	n.a.	n.a.	40%	45%	49%	51%
External Costs	-20	-19	-2	24	-26	-28	-31	-34	-36	-36	-38	-39	-41
Personnel	-4	-3	-	5	-7	-7	-9	-10	-11	-11	-13	-17	-20
Depreciation and Amortization	0	0	(	)	0	0	0	0	0	0	-1	-1	-2
Other Operating Expenses	0	0	(	)	0	0	-1	-1	-1	-1	-1	-2	-3
EBIT	-7	-9	-1	1	-18	-26	-33	-37	-42	-45	-38	-23	15
EBIT Margin	neg.	neg.	ne	g.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	10%
P/S	n.a	n.a	n.a	n.a	ı n.	a n.a	n.a	n.a	n.a	21,2	6,5	2,8	1,3
EV/S	n.a	n.a	n.a	n.a	n.	a n.a	n.a	n.a	n.a	14,2	4,3	1,9	0,8
EV/EBIT	n.a	n.a	n.a	n.a	n n.	a n.a	n.a	n.a	n.a	neg.	neg.	neg.	8,8

 $<sup>^{</sup>I}Constitutes \ mainly \ of \ capitalized \ development \ cost.$ 



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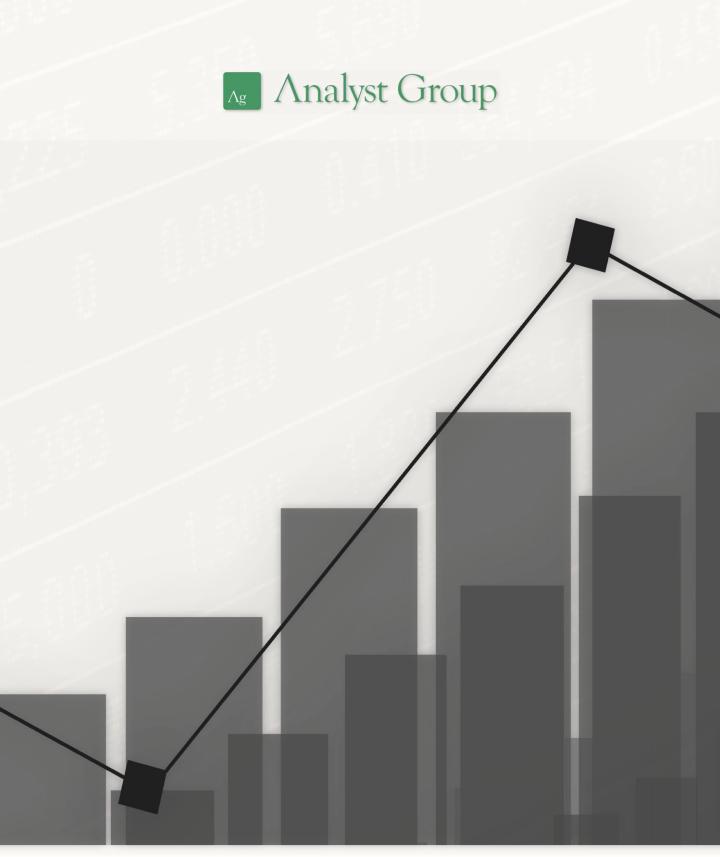
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