



Penser Access by Carnegie

Biotechnology | Sweden | 26 January 2024

Diamyd Medical

All eyes on DIAGNODE-3

Comments on the report

Diamyd's report for 1Q of the fiscal year ending in August 2024 was in line with our expectations. The operating result came in at SEK -32m (-33), while cash flow reach SEK 51m (10) following the completed rights issue. Diamyd's cash position at the end of November was around SEK 177m. According to our estimates, this is sufficient to finance operations a little way into 2025.

Interim data expected in July

Interim data from the DIAGNODE-3 study should be released in July. This is an especially important data point as it will reveal whether the study has a clear likelihood of achieving its objectives based on the assumptions Diamyd made at the design stage. Interim analysis will be based on 70–80 patients and will evaluate the effect of Diamyd with regards to the C-peptide. We consider the bar for achieving the criteria to continue the study to be relatively low. Previous studies with Diamyd have shown a clear differentiation in the C-peptide between the treatment and the placebo group after six months. Meta analysis published in The Lancet in 2023 (Taylor et al.) to evaluate the relationship between the C-peptide and HbA1 showed that a clear separation in the C-peptide curves occurs particularly early after treatment initiation.

Aiming to recruit the last patient in 2024

We believe Diamyd has already recruited somewhere around 80–100 patients for the DIAGNODE-3 study. Of the targeted 60+ recruited clinics, approximately 50 are secured. Diamyd aims to recruit a total of 280–330 patients by the end of 2024. We consider this a bold but achievable target. Our estimated timeline is still built on what management has communicated, but we reiterate the risk we see of a slight delay.

After making small adjustments to our estimates, we arrive at fair value of SEK 16–17 (15-16) per share.

Change in estimates				Forecast (mSEK)				Value and risk														
	24e	25e	26e		22/23	23/24e	24/25e	25/26e	Fair value	SEK16.0 - 17.0												
Total Revenues	0.0%	0.0%	0.0%	Total Revenues	20	3	3	3	Share price	SEK8.2												
EBIT, adj.	0.0%	0.0%	0.0%	Revenue growth	>100%	N.m.	0%	0%	Risk level	Hogh												
EPS, adj.	0.0%	0.0%	0.0%	EBITDA, adj.	-100	-147	-197	-207	Price performance 12 months													
Upcoming events				EBIT, adj.	-105	-152	-202	-212														
Q2 - report	27 March 2024			EPS, adj.	-1.1	-1.6	-2.1	-2.2														
Company facts (SEKm)SEKm				EPS growth	21%	N.m.	N.m.	N.m.	Conflicts of interest													
Number of shares	95m			BV/share	2.0	1.1	1.1	1.5														
Market capitalisation	774			EBIT margin	Neg.	Neg.	Neg.	Neg.	<table border="1"> <thead> <tr> <th></th> <th>Yes</th> <th>No</th> </tr> </thead> <tbody> <tr> <td>Liquidity provider</td> <td></td> <td>✓</td> </tr> <tr> <td>Certified adviser</td> <td></td> <td>✓</td> </tr> <tr> <td>Transactions 12m</td> <td></td> <td>✓</td> </tr> </tbody> </table>			Yes	No	Liquidity provider		✓	Certified adviser		✓	Transactions 12m		✓
	Yes	No																				
Liquidity provider		✓																				
Certified adviser		✓																				
Transactions 12m		✓																				
Net debt	-177			ROE, adj.	Neg.	Neg.	Neg.	Neg.														
EV	597			ROCE, adj.	Neg.	Neg.	Neg.	Neg.														
Free float	90%			EV/Sales	40.9x	199.0x	199.0x	199.0x														
Daily trading volume, average	117k			EV/EBITDA	Neg.	-4.1x	-3.0x	-2.9x														
Bloomberg Ticker	DMYDB SS EQUITY			EV/EBIT	Neg.	-3.9x	-2.9x	-2.8x														
Analyst				P/E, adj.	-5.9x	-5.1x	-3.8x	-3.6x	<table border="1"> <thead> <tr> <th></th> <th>Yes</th> <th>No</th> </tr> </thead> <tbody> <tr> <td>Liquidity provider</td> <td></td> <td>✓</td> </tr> <tr> <td>Certified adviser</td> <td></td> <td>✓</td> </tr> <tr> <td>Transactions 12m</td> <td></td> <td>✓</td> </tr> </tbody> </table>			Yes	No	Liquidity provider		✓	Certified adviser		✓	Transactions 12m		✓
	Yes	No																				
Liquidity provider		✓																				
Certified adviser		✓																				
Transactions 12m		✓																				
Ludvig Svensson				P/BV	3.4x	7.3x	7.5x	5.5x														
ludvig.svensson@carnegie.se				FCF yield	-12%	-20%	-26%	-27%														
				Net debt / EBITDA	1.3x	0.3x	0.2x	0.4x														

Investment case

Diamyd is a late-stage biotech company. Its leading project, diabetes vaccine Diamyd, is currently undergoing a ph III study in type 1 diabetes. In a larger meta-study (patient base of 600+), Diamyd has shown a statistically significant and clinically relevant therapeutic effect (preservation of beta cell function) in a specific sub-group of newly diagnosed type 1 diabetes patients – those with the DR3-DQ2 gene. This gene is particularly common and constitutes 40–50% of all type 1 diabetes cases. It is this niche patient population that is included in the ph III study and given potential market approval, this will be the commercial target group for the Diamyd vaccine.

While we see high risk in the project, we believe the Diamyd vaccine is a unique drug candidate that could, if launched, prove a blockbuster with annual sales of USD 1bn globally.

Company profile

Diamyd Medical works with drug development, diabetes being its main focus area. Currently, Diamyd has two drug projects in clinical development: 1) diabetes vaccine Diamyd, which aims to interrupt the body's attack on its own insulin production, and 2) Remygen, a GABA-based oral medicine intended to restore the body's own insulin production.

Valuation

We use a risk-adjusted sum-of-the-parts (SOTP) valuation for Diamyd. Our fair value is SEK 16–17.

Reasoning behind potential price level for Diamyd

In early January, the company announced it had analysed the target market for Diamyd in the US. Interviews with payers, among other sources, revealed that a drug with Diamyd's profile in the proposed patient population should be priced in the range of USD 194,000–240,000 a year. This price range is considerably higher than what we currently use in our model, but is in line with the list price of TZIELD (USD ~194,000).

While this represents potentially large upside in our estimates, we have assumed, based on our lower price forecast, significant market penetration for Diamyd of 50% of the proposed target group with the HLA DR3-DQ2 gene type in the US. We believe a high price would hinder uptake and result in a lower penetration among the target population. A price of USD 200,000 per year and penetration of 50% should, according to our model, provide peak sales for Diamyd of USD 3,500m in the US alone, which we consider particularly aggressive. As a reference, analyst consensus is that TZIELD should achieve sales of USD 550m during 2028 (Evaluate Pharma).

The price for Diamyd will ultimately be a function of how long the drug can maintain patients' endogenous insulin production. It is possible that our current peak sales estimate for Diamyd (USD 940m worldwide) is too conservative given the indicated price level, but we would like more data on the clinical effect before we adjust our assumptions.

DCF

Valuation output		WACC assumptions		Sensitivity analysis					
Sum of PV of FCF (explicit period)	1466	Risk free nominal rate	2.5%	WACC	16%	17%	18%	19%	20%
PV of terminal value (perpetuity formula)	0	Market risk premium	5.5%	NPV	2000	1812	1642	1490	1353
Enterprise value	1466	Small cap premium	4.0%	NPV/share	21	19	17	16	14
Latest net debt, inc est. issue	-177	Extra risk premium	6.0%						
Equity value	1642	WACC	18.0%						
No. of shares outstanding (millions)	95.0								
Equity value per share (SEK)	17								
Implicit multipl. 2023e		Terminal value assumptions							
EV/Sales	nm.	Long term growth rate	nm.						
EV/EBITDA	nm.	Long term EBIT margin	nm.						
EV/EBIT	nm.	Depreciation (% of sales)	nm.						
EV/NOPLAT	nm.	Capex (% of sales)	nm.						
P/E	nm.	Working cap. (% of sales)	nm.						
ROIC/WACC	nm.	Tax rate	nm.						
Current Share price	8.2								

Källa: Bolaget, Penser Access By Carnegie

Income statement					
	20/21	21/22	22/23	23/24e	24/25e
Net sales	0	0	1	1	1
Other operating income	0	2	19	2	2
Total revenues	0	3	20	3	3
Other Operating Expenses	-86	-121	-120	-150	-200
EBITDA	-85	-118	-100	-147	-197
EBITDA, adjusted	-85	-118	-100	-147	-197
Depreciation	-1	-4	-5	-5	-5
EBITA, adjusted	-85	-118	-100	-147	-197
EBIT	-86	-123	-105	-152	-202
EBIT, adjusted	-86	-123	-105	-152	-202
Net Financial Items	146	15	0	0	0
Profit before tax	60	-108	-105	-152	-202
Profit before tax, adjusted	60	-108	-105	-152	-202
Net income	60	-108	-105	-152	-202
Net income, adjusted	60	-108	-105	-152	-202
Sales Growth	-	>100%	>100%	N.m.	0%
Gross Margin	N.m.	>100%	>100%	>100%	>100%
EBIT Margin, Adjusted	Neg.	Neg.	Neg.	Neg.	Neg.
EPS, Adjusted	0.84	-1.40	-1.11	-1.60	-2.13
EPS Growth, Adjusted	-	N.m.	21%	N.m.	N.m.

Source: Diamyd Medical, Carnegie

Cash flow statement					
	20/21	21/22	22/23	23/24e	24/25e
EBIT	-86	-123	-105	-152	-202
Other Cash flow Items	1	4	6	6	6
Changes in working capital	-25	18	-1	1	1
Cash flow from operating activities	-110	-101	-100	-144	-195
Investments in Fixed Assets	-4	-35	-11	-7	-5
Other Cash flow from investments	137	-42	40	0	0
Cash flow from Investments	133	-77	28	-7	-5
Free cash flow	23	-178	-72	-152	-200
New share issue / repurchase	57	142	71	73	200
Cash flow from financing	57	142	71	73	200
Cash flow	80	-35	-1	-79	0
Net debt	-139	-160	-128	-49	-49

Source: Diamyd Medical, Carnegie

Balance sheet

	20/21	21/22	22/23	23/24e	24/25e
ASSETS					
Tangible fixed assets	6	46	52	54	54
Financial assets	33	18	13	13	13
Total fixed assets	38	64	65	67	67
Other current assets	24	13	13	18	18
Cash and cash equivalents	139	160	128	49	49
Total current assets	163	173	141	67	67
TOTAL ASSETS	201	237	206	134	134
EQUITY AND LIABILITIES					
Equity	189	214	185	106	104
Total equity	189	214	185	106	104
Other long-term liabilities	1	1	1	2	3
Total long-term liabilities	1	1	1	2	3
Accounts payable	6	10	5	10	10
Other current liabilities	6	12	15	16	17
Total current liabilities	11	21	20	26	27
TOTAL EQUITY AND LIABILITIES	201	237	206	134	134

Source: Diamyd Medical, Carnegie

Growth and margins

	20/21	21/22	22/23	23/24e	24/25e
Revenue growth	-	>100%	>100%	N.m.	0%
EBITDA growth, adjusted	-	N.m.	15%	N.m.	N.m.
EBIT growth, adjusted	-	N.m.	14%	N.m.	N.m.
EPS growth, adjusted	-	N.m.	21%	N.m.	N.m.
Gross margin	>100%	>100%	>100%	>100%	>100%
EBITDA margin	Neg.	Neg.	Neg.	Neg.	Neg.
EBITDA margin, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.
EBIT margin	Neg.	Neg.	Neg.	Neg.	Neg.
EBIT margin, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.
Profit margin, adjusted	>100%	Neg.	Neg.	Neg.	Neg.

Source: Diamyd Medical, Carnegie

Return

	20/21	21/22	22/23	23/24e	24/25e
ROE, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.
ROCE, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.
ROIC, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.

Source: Diamyd Medical, Carnegie

Capital efficiency

	20/21	21/22	22/23	23/24e	24/25e
Accounts receivable / total revenue	11%	10%	0%	-	-
Total short-term liabilities / total cost	13%	18%	17%	17%	14%
Working capital / total revenue	>100%	-310%	-33%	-267%	-300%

Source: Diamyd Medical, Carnegie

Financial position

	20/21	21/22	22/23	23/24e	24/25e
Net debt	-139	-160	-128	-49	-49
Equity ratio	94%	91%	90%	79%	78%
Net debt / EBITDA	1.6x	1.4x	1.3x	0.3x	0.2x

Source: Diamyd Medical, Carnegie

Per share data

	20/21	21/22	22/23	23/24e	24/25e
EPS	0.84	-1.40	-1.11	-1.60	-2.13
EPS, adjusted	0.84	-1.40	-1.11	-1.60	-2.13
FCF per share	0.32	-2.31	-0.76	-1.60	-2.11
Book value per share	2.64	2.79	1.95	1.12	1.09
Number of shares, m	71.6	76.9	95.0	95.0	95.0
Number of shares after dilution, average	71.6	76.9	95.0	95.0	95.0

Source: Diamyd Medical, Carnegie

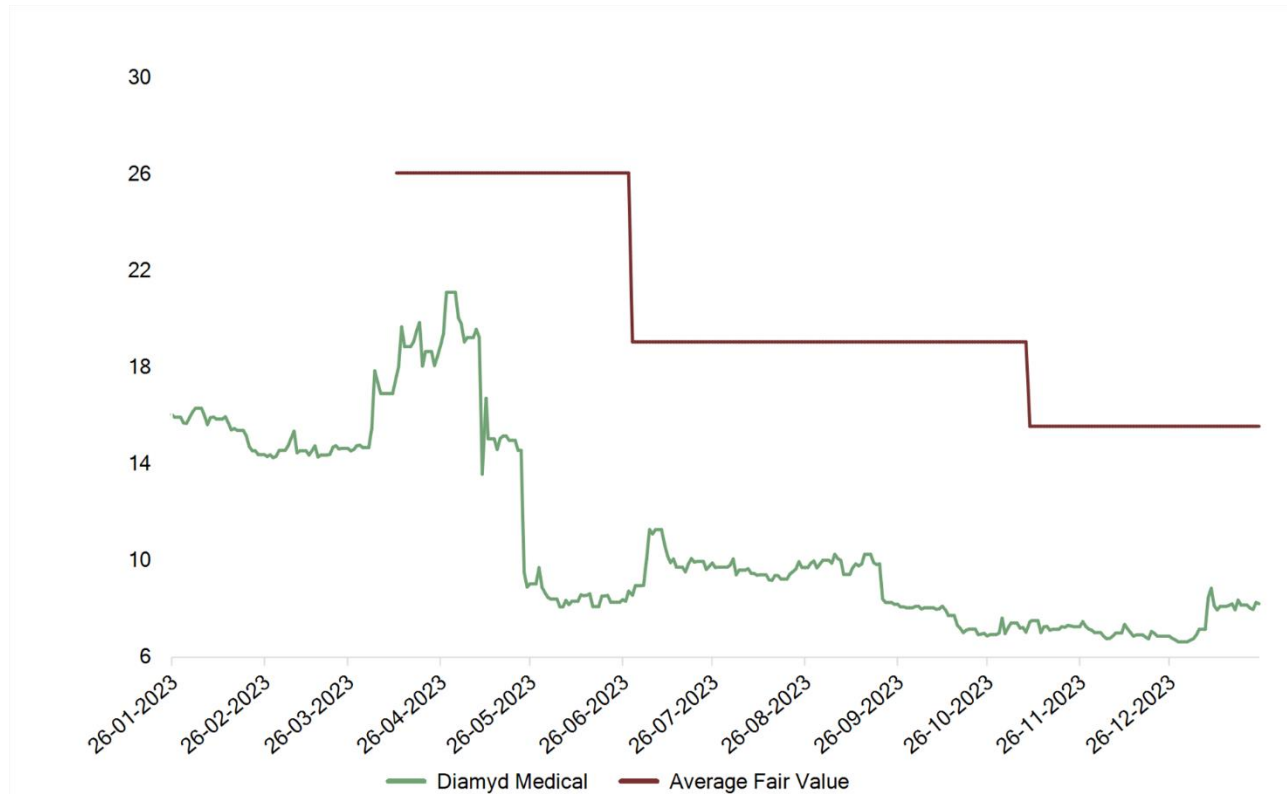
Valuation

	20/21	21/22	22/23	23/24e	24/25e
P/E, adjusted	17.6x	Neg.	Neg.	Neg.	Neg.
P/BV	5.6x	4.8x	3.4x	7.3x	7.5x
P/FCF	46.5x	Neg.	Neg.	Neg.	Neg.
FCF-yield	2%	Neg.	Neg.	Neg.	Neg.
Dividend yield	0.0%	0.0%	0.0%	0.0%	0.0%
Payout ratio, adjusted	0.0%	0.0%	0.0%	0.0%	0.0%
EV/Sales	5,118.3x	372.1x	40.9x	199.0x	199.0x
EV/EBITDA, adjusted	Neg.	Neg.	Neg.	-4.1x	-3.0x
EV/EBIT, adjusted	Neg.	Neg.	Neg.	-3.9x	-2.9x
EV	2,273	962	802	597	597
Share price, year end	33.7	14.6	9.8	8.2	8.2

Source: Diamyd Medical, Carnegie

Share Price and Average Fair Value Chart

Diamyd Medical IDMYDB SS EQUITY



Source: Carnegie, IDC

Disclosures and disclaimers

Carnegie Investment Bank AB

Carnegie Investment Bank AB (publ.) is a leading investment bank with a Nordic focus. The Carnegie group of companies, together "Carnegie", generates added value for institutions, companies and private clients in the areas of trade in securities, investment banking and private banking. Carnegie has approximately 600 employees, located in offices in six countries.

Penser by Carnegie

In November 2023, Carnegie acquired the commissioned research business from Erik Penser Bank AB. This included the business under which Erik Penser Bank AB e.g. has published its Penser Access and Penser Future research services. This business continues to be operated by Carnegie under the trademark Penser by Carnegie.

Valuation, methodology, and assumptions

Commissioned research reports include the analyst's assessment of a fair value range on the date the research was published based on various fundamental valuation methods. A commonly used method is DCF valuation, where future cash flows are discounted to today. Analysts may also use different valuation multiples, e.g. P/E ratio and EV/EBIT multiples, relative to industry peers to obtain a target price. For companies where it is appropriate, a fair value range can also be based on the analyst's assessment of a fair ratio relative to the net asset value of the company. Fair value ranges represent the assessment of the analyst(s) at the time of writing. For more information on valuation models, click [here](#)

Frequency of update

Penser by Carnegie's research analysis consists of case-based analyses, which implies that the frequency of the analytical report may vary over time. Unless otherwise expressly stated in the report, the analysis will be updated quarterly or when considered necessary by the research department, for example in the event of significant changes in market conditions or events related to the issuer/the financial instrument.

Analyst certification

The research analyst or analysts responsible for the content of this commissioned research report certify that, notwithstanding the existence of any potential conflicts of interests referred to herein, the views expressed in this commissioned research report accurately reflect the research analyst's personal views about the companies and securities covered. It is further certified that the research analyst has not been, nor is or will be, receiving direct or indirect compensation related to the specific ratings or views contained in this commissioned research report.

Potential conflicts of interest

Carnegie, or its subsidiaries, may from time to time perform investment banking or other services for, or solicit investment banking or other business from, any company mentioned in this report. Any such publicly announced business activity, during the past 12 months, will be referred to in this commissioned research report. A set of rules handling conflicts of interest is implemented in the Carnegie Group. Investment Banking and other business departments in Carnegie are surrounded by information barriers to restrict the flows of sensitive information. Persons outside such barriers may gain access to sensitive information only after having observed applicable procedures. The remuneration of persons involved in preparing this commissioned research report is not tied to investment banking transactions performed by Carnegie or a legal person within the same group.

Confidential and non-public information regarding Carnegie and its clients, business activities and other circumstances that could affect the market value of a security ("sensitive information") is kept strictly confidential and may never be used in an undue manner.

Internal guidelines are implemented in order to ensure the integrity and independence of research analysts. In accordance with the guidelines the research department is separated from the Investment Banking department and there are no reporting lines between the research department and Investment Banking. The guidelines also include rules regarding, but not limited to, the following issues; contacts with covered companies, prohibition against offering favourable recommendations, personal involvement in covered companies, participation in investment banking activities, supervision and review of research reports, analyst reporting lines and analyst remuneration.

Other material conflicts of interest

This report was commissioned and sponsored by the issuer (issuer-paid research).

Distribution restrictions

This commissioned research report does not have regard to the specific investment objectives, financial situation or particular needs of any specific person who may receive it. Investors should seek financial advice regarding the appropriateness of investing in any securities discussed in this commissioned research report and should understand that statements regarding future prospects may not be realized. Past performance is not necessarily a guide to future performance. Carnegie and its subsidiaries accept no liability whatsoever for any direct or consequential loss, including, without limitation, any loss of profits arising from the use of this commissioned research report or its contents. This commissioned research report may not be reproduced, distributed or published by any recipient for any purpose. The document may not be distributed to persons that are citizens of or domiciled in any country in which such distribution is prohibited according to applicable laws or other regulations.

This commissioned research report is distributed in Sweden by Carnegie Investment Bank AB. Carnegie Investment Bank AB is a bank incorporated in Sweden with limited liability which is authorised and regulated by the Swedish Financial Supervisory Authority (Finansinspektionen). In Finland this commissioned research report is issued by Carnegie Investment Bank AB, Finland Branch. The Finland branch is authorised by the Swedish Financial Supervisory Authority and subject to limited regulation by the Finnish Financial Supervisory Authority (Finanssivalvonta). In Norway this commissioned research report is issued by Carnegie AS, a wholly-owned subsidiary of Carnegie Investment Bank AB. Carnegie AS is regulated by the Financial Supervisory Authority of Norway (Finanstilsynet). In Denmark this commissioned research report is issued by Carnegie Investment Bank AB, Denmark Branch. The Denmark branch is authorised by the Swedish Financial Supervisory Authority and subject to limited regulation by the Danish Financial Supervisory Authority (Finanstilsynet).

This commissioned research report is distributed in the US by Carnegie, Inc., a US-registered broker-dealer and a member of FINRA and SIPC. Carnegie's research analysts located outside of the US are employed by non-US affiliates of Carnegie Inc. ("non-US affiliates") that are not subject to FINRA regulations. Generally, Carnegie research analysts are not registered with or qualified as research analysts with FINRA, and therefore are not subject to FINRA rule 2241 restrictions intended to prevent conflicts of interest by, among other things, prohibiting certain compensation practices, restricting trading by analysts and restricting communications with the companies that are the subject of the research report. Research reports distributed in the U.S. are intended solely for major US institutional investors and US institutional investors as defined under Rule 15a-6 of the Securities Exchange Act of 1934. This commissioned research report is provided for informational purposes only and under no circumstances is it to be used or considered as an offer to sell, or a solicitation of any offer to buy any securities. Reports regarding equity products are prepared by non-US affiliates of and distributed in the United States by Carnegie Inc. under Rule 15a-6(a)(3). When distributed by Carnegie Inc, Carnegie Inc. takes responsibility for the commissioned research report. Any US person who wishes to effect transactions based on this commissioned research report should contact Carnegie Inc. Investors in the US should be aware that investing in non-US securities entails certain risks. The securities of non-US issuers may not be registered with, or be subject to, the current information reporting and audit standards of the US Securities and Exchange Commission.

This commissioned research report has been issued in the UK by Carnegie UK which is the UK Branch of Carnegie Investment Bank AB. Carnegie UK is authorised and regulated by the Financial Conduct Authority (FCA).

Research Disclaimer

This commissioned research report is provided solely for information. It does not constitute or form part of, and shall under no circumstances be considered as an offer to sell or a solicitation of an offer to purchase or sell any relevant financial instrument.

This commissioned research report has been requested and paid for by the issuer and should therefore be considered a marketing communication (i.e not investment research). Payment for the report has been agreed in advance on a non-recourse basis. As commissioned research, this material can be considered an acceptable minor non-monetary benefit under MiFID II. It has not been prepared in accordance with the legal requirements designed to promote the independence of investment research. However, it is still subject to a prohibition on dealing ahead of the dissemination of the report.

Carnegie Investment Bank AB is responsible for the preparation of this commissioned research report in Sweden, Finland, Denmark, and the UK. Carnegie AS is responsible for the preparation of this commissioned research report in Norway. Carnegie Inc. is responsible for this research report in the US.

The information in this commissioned research report was obtained from various sources. While all reasonable care has been taken to ensure that the information is true and not misleading, Carnegie gives no representation or warranty, express or implied, about its accuracy or completeness. Carnegie, its subsidiaries and any of their officers or directors may have a position, or otherwise be interested in, transactions in securities that are directly or indirectly the subject of this commissioned research report. Any significant financial interests held by the analyst, Carnegie or a legal person in the same group in relation to the issuer will be referred to in the Company-specific disclosures below, and the Conflicts of interest on the front page of this report.

Company specific disclosures

Parts of this commissioned research report may have been submitted to the issuer prior to its publication.

Copyright © 2024 Carnegie

Carnegie Investment Bank AB
Regeringsgatan 56
SE-103 38 Stockholm
Tel: +46 8 676 88 00 Fax +46 8 676 88 95