



Penser Access by Carnegie

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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														
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

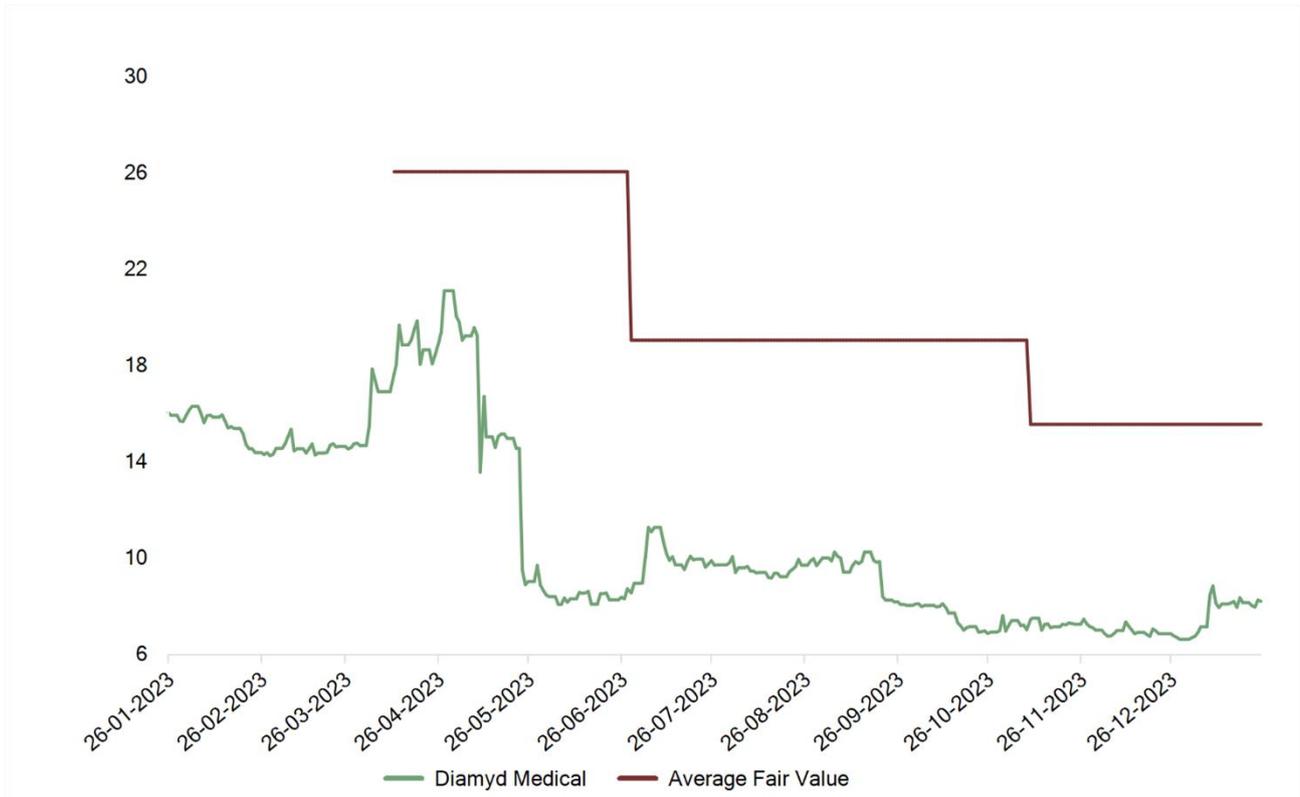
Valuation

	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 MedicalDMYDB SS EQUITY



Source: Carnegie, IDC

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