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Diamyd Medical

Accelerated approval route confirmed

FDA accepts accelerated approval pathway

Diamyd Medical announced on Monday that it will submit its market approval application for lead candidate Diamyd via an accelerated approval pathway. This means the company will submit its approval application based on the results from interim 15-month analysis of the C peptide on a sample of some 170 patients, rather than waiting for the HbA1C data from the completed study programme (n=330). Diamyd Medical expects the interim readout results in March 2026. It will then compile the data and submit a Biologics License Application (BLA) to the FDA. This fast track designation is likely to reduce the FDA's processing time. We believe the drug candidate has the potential to receive market approval late in 2026 or early in 2027.

Both C peptide and HbA1C will be needed for full approval

We emphasise that the study will continue after the interim readout and that positive data on the HbA1C primary endpoint will very likely be needed for the drug candidate to receive full approval. The company's press release also stated that 148 patients have so far been randomised as part of the study, meaning that a further some 20 patients are required for the data on which the interim readout will be based.

Shortened route to market – fair value raised

Following this news, we bring forward our expectations for a launch of Diamyd, thus pushing up our fair value to SEK35–45 per share (30–40). We believe the company's current stable finances, plus the clear regulatory pathway to market for Diamyd, increase the likelihood of the company successfully finding an attractive partner to commercialise the drug candidate.

Change in estimates				Forecasts (SEKm)				Value and risk		
	24e	25e	26e		22/23	23/24e	24/25e	25/26e	Fair value	SEK 35.0 - 45.0
Total Revenues	0.0%	0.0%	0.0%	Total Revenues	20	3	3	3	Share price	SEK 14.2
EBIT, adj.	0.0%	0.0%	0.0%	Revenue growth	N.m.	-	0%	0%	Risk level	High
EPS, adj.	0.0%	0.0%	0.0%	EBITDA, adj.	-100	-132	-162	-197	Price Performance 12 months	
Upcoming events				EBIT, adj.	-105	-134	-166	-202		
Q4 - report	09 October 2024			EPS, adj.	-1.1	-1.3	-1.7	-2.0		
Company facts (SEKm)				EPS growth	25%	N.m.	N.m.	N.m.	Conflicts of interest	
Number of shares	100m			BV/share	1.9	1.8	0.6	0.6		
Market capitalisation	1,412			EBIT margin	Neg.	Neg.	Neg.	Neg.	Yes	No
Net debt	-162			ROE, adj.	Neg.	Neg.	Neg.	Neg.	Liquidity provider	✓
EV	1,250			ROCE, adj.	Neg.	Neg.	Neg.	Neg.	Certified adviser	✓
Free float	90%			EV/Sales	903.3x	1250.1x	1250.1x	1250.1x	Transactions 12m	✓
Daily trading volume, average	242k			EV/EBITDA	Neg.	Neg.	Neg.	Neg.		
Bloomberg Ticker	DMYDB SS EQUITY			EV/EBIT	Neg.	Neg.	Neg.	Neg.		
Analyst				P/E, adj.	Neg.	Neg.	Neg.	Neg.		
Ludvig Svensson				P/BV	3.5x	8.0x	22.6x	23.1x		
ludvig.svensson@carnegie.se				FCF yield	Neg.	Neg.	Neg.	Neg.		
				Net debt / EBITDA	N.m.	N.m.	N.m.	N.m.		

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 exceeding 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 SEK35–45.

DCF

Valuation output		WACC assumptions		Sensitivity analysis					
Sum of PV of FCF (explicit period)	3692	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	4540	4181	3854	3556	3284
Enterprise value	3692	Small cap premium	4.0%	NPV/share	46	42	39	36	33
Latest net debt, inc est. issue	-162	Extra risk premium	6.0%						
Equity value	3854	WACC	18.0%						
No. of shares outstanding (millions)	99.7								
Equity value per share (SEK)	39								

Implicit multipl.	2024e	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	14.2		

Källa: Bolaget, Penser Access by Carnegie

Income statement						
	20/21	21/22	22/23	23/24e	24/25e	25/26e
Net sales	0	0	1	1	1	1
Other operating income	0	2	19	2	2	2
Total revenues	0	3	20	3	3	3
Other Operating Expenses	-86	-121	-120	-135	-165	-200
EBITDA	-85	-118	-100	-132	-162	-197
EBITDA, adjusted	-85	-118	-100	-132	-162	-197
Depreciation	-1	-4	-5	-2	-4	-5
EBITA, adjusted	-86	-123	-105	-134	-166	-202
EBIT	-86	-123	-105	-134	-166	-202
EBIT, adjusted	-86	-123	-105	-134	-166	-202
Net Financial Items	146	15	0	1	1	1
Profit before tax	60	-108	-105	-133	-165	-201
Profit before tax, adjusted	60	-108	-105	-133	-165	-201
Net income	60	-108	-105	-133	-165	-201
Net income, adjusted	60	-108	-105	-133	-165	-201
Sales Growth	Neg.	482%	N.m.	Neg.	0%	0%
Gross Margin	N.m.	N.m.	N.m.	N.m.	N.m.	N.m.
EBIT Margin, Adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
EPS, Adjusted	0.84	-1.40	-1.05	-1.33	-1.65	-2.02
EPS Growth, Adjusted	N.m.	N.m.	25%	N.m.	N.m.	N.m.

Source: Diamyd Medical, Penser by Carnegie

Cash flow statement						
	20/21	21/22	22/23	23/24e	24/25e	25/26e
EBIT	-86	-123	-105	-134	-166	-202
Other Cash flow Items	1	4	6	3	5	6
Changes in working capital	-25	18	-1	1	1	0
Cash flow from operating activities	-110	-101	-100	-129	-160	-196
Investments in Fixed Assets	-4	-35	-11	-7	0	0
Other Cash flow from investments	137	-42	40	0	0	0
Cash flow from Investments	133	-77	28	-7	0	0
Free cash flow	23	-178	-72	-137	-160	-196
New share issue / repurchase	57	142	71	149	50	200
Cash flow from financing	57	142	71	149	50	200
Cash flow	80	-35	-1	12	-110	4
Net debt	-139	-160	-128	-139	-30	-34

Source: Diamyd Medical, Penser by Carnegie

Balance sheet						
	20/21	21/22	22/23	23/24e	24/25e	25/26e
ASSETS						
Tangible fixed assets	6	46	52	57	53	48
Financial assets	33	18	13	13	13	13
Total fixed assets	38	64	65	70	66	61
Other current assets	24	13	13	18	18	18
Cash and cash equivalents	139	160	128	139	30	34
Total current assets	163	173	141	157	48	52
TOTAL ASSETS	201	237	206	227	113	112
EQUITY AND LIABILITIES						
Equity	189	214	185	178	63	61
Total equity	189	214	185	178	63	61
Other long-term liabilities	1	1	1	24	24	24
Total long-term liabilities	1	1	1	24	24	24
Accounts payable	6	10	5	10	10	10
Other current liabilities	6	12	15	16	17	17
Total current liabilities	11	21	20	26	27	27
TOTAL EQUITY AND LIABILITIES	201	237	206	227	113	112

Source: Diamyd Medical, Penser by Carnegie

Growth and margins						
	20/21	21/22	22/23	23/24e	24/25e	25/26e
Revenue growth	Neg.	482%	N.m.	Neg.	0%	0%
EBITDA growth, adjusted	Neg.	Neg.	15%	Neg.	Neg.	Neg.
EBIT growth, adjusted	Neg.	Neg.	14%	Neg.	Neg.	Neg.
EPS growth, adjusted	N.m.	N.m.	25%	N.m.	N.m.	N.m.
Gross margin	N.m.	N.m.	N.m.	N.m.	N.m.	N.m.
EBITDA margin	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
EBITDA margin, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
EBIT margin	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
EBIT margin, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
Profit margin, adjusted	N.m.	Neg.	Neg.	Neg.	Neg.	Neg.

Source: Diamyd Medical, Penser by Carnegie

Return						
	20/21	21/22	22/23	23/24e	24/25e	25/26e
ROE, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
ROCE, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
ROIC, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.

Source: Diamyd Medical, Penser by Carnegie

Capital efficiency

	20/21	21/22	22/23	23/24e	24/25e	25/26e
Accounts receivable / total revenue	11%	10%	0%	-	-	-
Total short-term liabilities / total cost	13%	18%	17%	19%	16%	14%
Working capital / total revenue	>100%	-310%	-33%	-267%	-300%	-300%
Capital turnover rate	0.0x	0.0x	0.1x	0.0x	0.0x	0.0x

Source: Diamyd Medical, Penser by Carnegie

Financial position

	20/21	21/22	22/23	23/24e	24/25e	25/26e
Net debt	-139	-160	-128	-139	-30	-34
Equity ratio	94%	91%	90%	78%	55%	55%
Net debt / equity	-0.7x	-0.7x	-0.7x	-0.8x	-0.5x	-0.5x
Net debt / EBITDA	N.m.	N.m.	N.m.	N.m.	N.m.	N.m.

Source: Diamyd Medical, Penser by Carnegie

Per share data

	20/21	21/22	22/23	23/24e	24/25e	25/26e
EPS	0.84	-1.40	-1.05	-1.33	-1.65	-2.02
EPS, adjusted	0.84	-1.40	-1.05	-1.33	-1.65	-2.02
FCF per share	0.32	-2.31	-0.72	-1.37	-1.60	-1.96
Book value per share	2.64	2.79	1.86	1.78	0.63	0.61
Number of shares, m	71.6	76.9	99.7	99.7	99.7	99.7
Number of shares after dilution, average	71.6	76.9	99.7	99.7	99.7	99.7

Source: Diamyd Medical, Penser by Carnegie

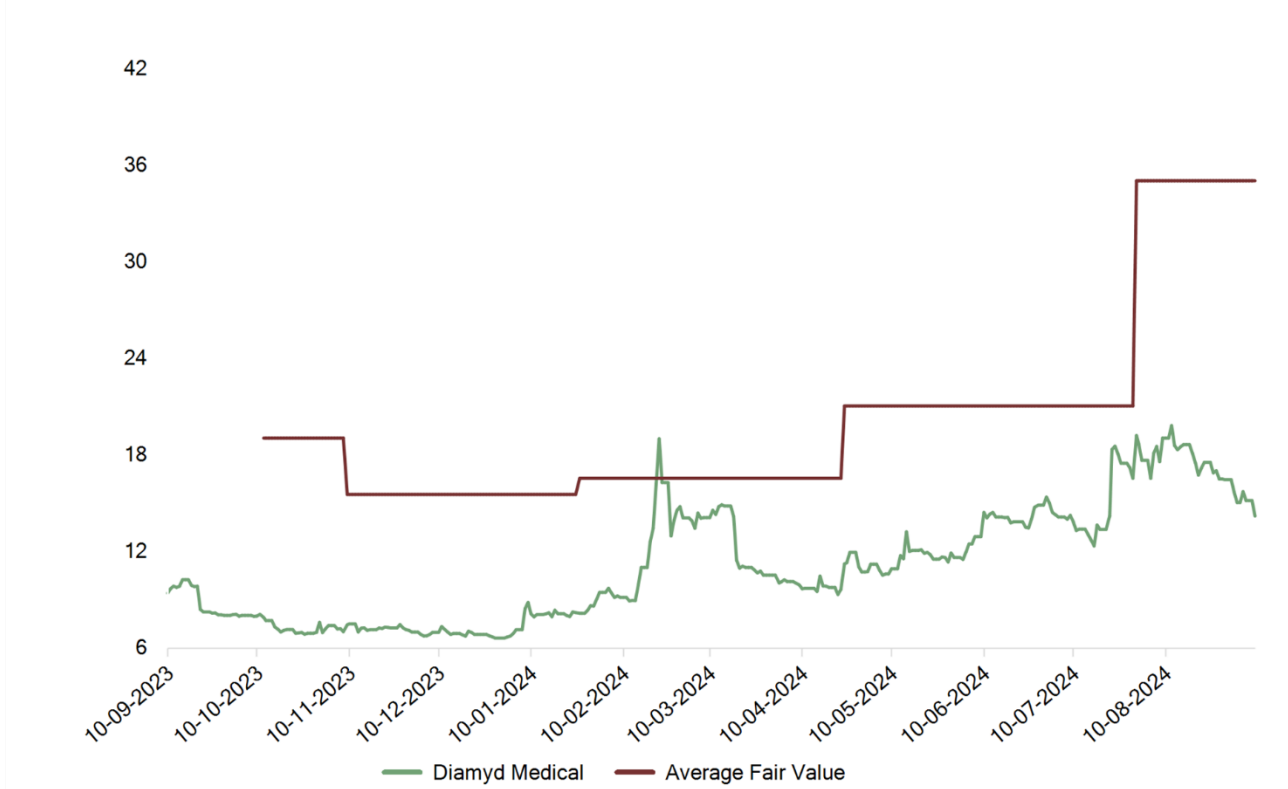
Valuation

	20/21	21/22	22/23	23/24e	24/25e	25/26e
P/E, adjusted	17.6x	Neg.	Neg.	Neg.	Neg.	Neg.
P/BV	5.6x	4.8x	3.5x	8.0x	22.6x	23.1x
P/FCF	46.5x	Neg.	Neg.	Neg.	Neg.	Neg.
FCF-yield	2%	Neg.	Neg.	Neg.	Neg.	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	100x	100x	43.3x	100x	100x	100x
EV/EBITDA, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
EV/EBIT, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.
EV	2,273	962	849	1,250	1,250	1,250
Share price, year end	14.8	13.4	6.6	14.2	14.2	14.2

Source: Diamyd Medical, Penser by Carnegie

Share Price and Average Fair Value Chart

Diamyd Medical (DMYDB SS EQUITY)



Source: Penser by Carnegie, IDC

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