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Diamyd Medical

Successful interim data

What has happened?

On Tuesday evening, Diamyd Medical announced positive interim data from its ongoing phase III study, DIAGNODE-3, investigating drug candidate Diamyd in type 1 diabetes patients. The interim data evaluates six-month data from a total of 74 patients. This news means Diamyd has passed the futility assessment: an independent safety committee has judged that the study has the potential to reach one of its primary endpoints – C peptide – for the entire study population without requiring any changes to the design of the study.

What does this mean?

A positive readout of the interim data was critical for the case and comes as much appreciated news. The study will now continue to recruit patients according to the plan, with the aim of including around 330 patients. It is important to note that the data forming the basis for the interim analysis is still blinded for the company and so it cannot provide more concrete information to the market. What we can say with certainty is that the observed effect is sufficiently large to justify the study continuing to recruit patients.

What happens next?

Following the news of the positive interim data, we raise the likelihood of market approval to 70% (50%). Our new fair value is SEK30–40 (19–23) per share. There is upside potential in our estimated timeline should Diamyd receive accelerated approval based on C peptide, as this would mean it reaching the market earlier than we anticipate (2028). Coming share price catalysts include: updates on communication with the FDA regarding accelerated approval, potential partnerships, and updates on additional indications.

Change in estimates				Forecasts (SEKm)				Value and risk		
	24e	25e	26e	22/23	23/24e	24/25e	25/26e	Fair value	SEK 30.0 - 40.0	
Total revenues	0.0%	0.0%	0.0%	20	3	3	3	Share price	SEK 16.5	
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.		
Number of shares	100m			BV/share	1.9	1.8	0.6	0.6		
Market capitalisation	1,645			EBIT margin	Neg.	Neg.	Neg.	Neg.		
Net debt	-162			ROE, adj.	Neg.	Neg.	Neg.	Neg.		
EV	1,483			ROCE, adj.	Neg.	Neg.	Neg.	Neg.		
Free float	90%			EV/Sales	903.3x	1483.4x	1483.4x	1483.4x		
Daily trading volume, average	352k			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.	Conflicts of interest	
Ludvig Svensson				P/BV	3.5x	9.3x	26.3x	26.9x	Yes	No
ludvig.svensson@carnegie.se				FCF yield	Neg.	Neg.	Neg.	Neg.	Liquidity provider	✓
				Net debt / EBITDA	N.m.	N.m.	N.m.	N.m.	Certified adviser	✓
									Transactions 12m	✓

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 SEK30–40.

DCF

Valuation output		WACC assumptions		Sensitivity analysis					
Sum of PV of FCF (explicit period)	3055	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	3866	3525	3217	2938	2685
Enterprise value	3055	Small cap premium	4.0%	NPV/share	39	35	32	29	27
Latest net debt, inc est. issue	-162	Extra risk premium	6.0%						
Equity value	3217	WACC	18.0%						
No. No. of shares outstanding (millions)	99.7								
Equity value per share (SEK)	32								
Implicit multiple		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 capital (% of sales)	nm.						
ROIC/WACC	nm.	Tax rate	nm.						
Current share price	16.5								

Source: Company, 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

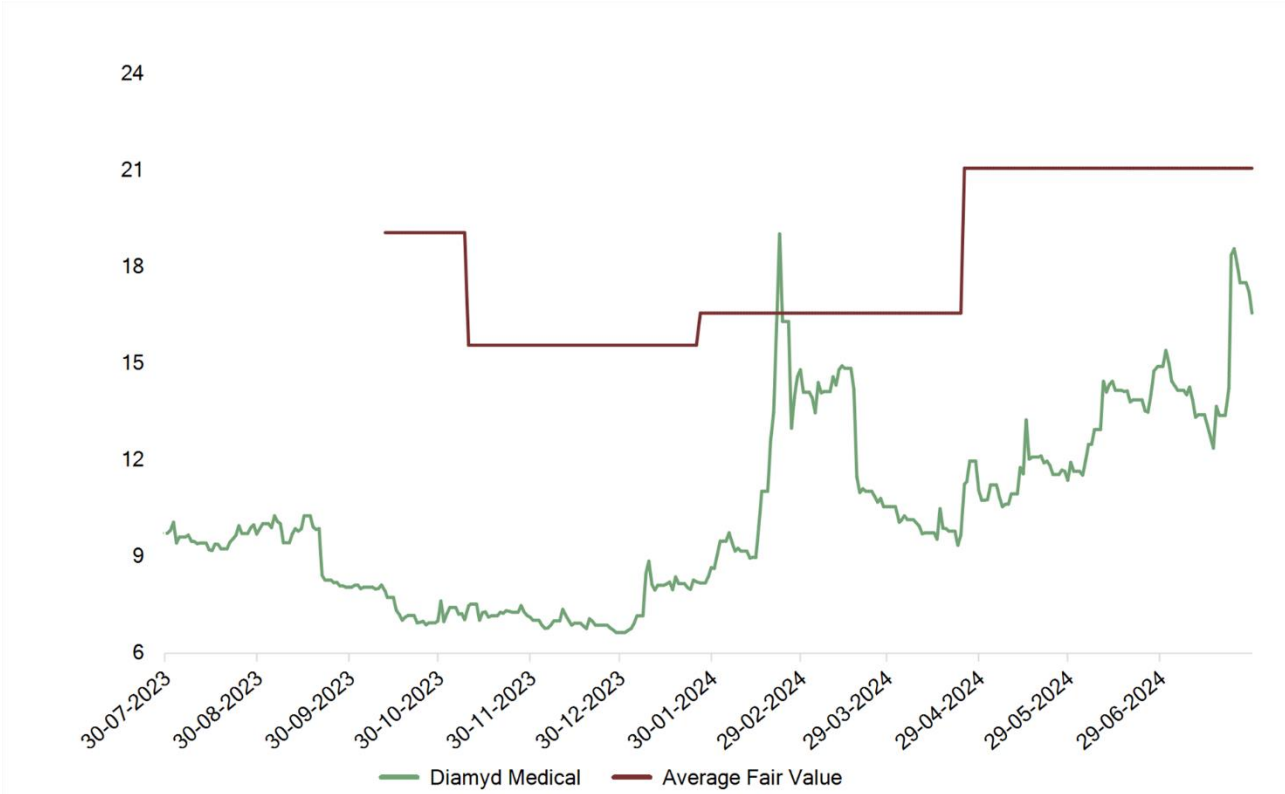
Valuation

	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	9.3x	26.3x	26.9x
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	1,483	1,483	1,483
Share price, year end	14.8	13.4	6.6	16.5	16.5	16.5

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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