

Biotechnology | Sweden | 10 October 2024

Diamyd Medical

Q4 results

Full steam ahead in DIAGNODE 3

Diamyd Medical's Q4 report brought no surprises in terms of numbers, the CEO's comments provided various interesting data points. Within the framework of the DIAGNODE 3 study, all 60 clinics have now been activated, with 161 patients recruited so far. A look at clinicaltrials.gov shows that all but one of the clinics is currently recruiting patients, which raises expectations that the timetable can be maintained. We also learned that the work on the Umeå manufacturing facility is running according to plan and that the company has also strengthened the team to evaluate future business possibilities for external manufacturing there.

An eventful year

During the year, the company has made enormous progress in accelerating the potential market approval of Diamyd. The completed futility analysis got the go-ahead from an independent safety committee, recommending that the study continues according to its plan. Another crucial milestone has been successful discussions with the FDA in the US; the agency has now approved the use of the C peptide as a predictive marker for clinical use. This enables the use of earlier interim analysis from the ongoing ph III DIAGNODE 3 study, planned for March 2026. If all goes to plan, this opens the door for an approval application and potential accelerated approval in the US in late 2026 or early 2027.

Stable financial position

Change in estimates

The company finds itself in a robust financial position, with cash and cash equivalents of around SEK132m as of the end of August. Given the recently completed redemption of warrants (subscription rate of 95%), further milestone payments from the co-operation with Breakthrough T1D, and the sale of Companion Medical shares, the company has further strengthened its cash chest with an additional SEK65m-plus. The share trades a good deal below our fair value, but we believe it can take time before this value gap closes. We judge the most important catalysts for the share will be: 1) interim data from DIAGNODE 3, and 2) a potential partnership agreement.

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	25e	26e	27e
Total Revenues	0.0%	0.0%	0.0%
EBIT, adj.	-0.6%	7.6%	0.0%
EPS, adj.	7.4%	11.5%	0.0%
Upcoming eve	nts		
Q1 - report		29 Januai	y 2025
Company facts	, (SEK)	m)	
Company facts	o (OLIVI	11)	
Number of shares			104m
Market capitalisation	on		1,416
Net debt			-132
EV			1,283
Free float			90%
Daily trading volum	ne, avera	ge	175k
Bloomberg Ticker	DM'	YDB SS E	QUITY
Analyst			
Ludvig Svensson			

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Forecasts (SEk	(m)			
	23/24	24/25e	25/26e	26/27e
Total Revenues	4	3	3	38
Revenue growth	-	-	0%	N.m.
EBITDA, adj.	-136	-162	-182	-167
EBIT, adj.	-147	-167	-187	-171
EPS, adj.	-1.5	-1.5	-1.8	-1.6
EPS growth	N.m.	N.m.	N.m.	9%
BV/share	1.4	0.3	0.4	-
EBIT margin	Neg.	Neg.	Neg.	Neg.
ROE, adj.	Neg.	Neg.	Neg.	Neg.
ROCE, adj.	Neg.	Neg.	Neg.	Neg.
EV/Sales	9871.0x	1283.2x	1283.2x	35.3x
EV/EBITDA	Neg.	Neg.	Neg.	Neg.
EV/EBIT	Neg.	Neg.	Neg.	Neg.
P/E, adj.	Neg.	Neg.	Neg.	Neg.
P/BV	9.7x	43.6x	30.5x	Neg.
FCF yield	Neg.	Neg.	Neg.	Neg.
Net debt / EBITDA	N.m.	N.m.	N.m.	N.m.

Share price Risk level	S	SEK 13.6 High
Price Performance	12 montl	hs
22		
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Conflicts of interest		
	Vac	No

SEK 35.0 - 45.0

Value and risk Fair value

Liquidity provider 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 SEK35-45.

DCF

Valuation output		WACC assumptions		Sensitivity a	analysis				
Sum of PV of FCF (explicit period)	3768	Risk-free nominal rate	2.5%	WACC	16%	17%	18%	19%	2
PV of terminal value (perpetuity formula)	0	Market risk premium	5.5%	NPV	4591	4229	3900	3599	33
Enterprise value	3768	Small cap premium	4.0%	NPV/share	44	41	37	35	
Latest net debt	-132	Extra risk premium	6.0%						
Equity value	3900	WACC	18.0%						
No. of shares outstanding (millions)	104.1								
Equity value per share (SEK)	37								
Implicit multiple	2024e	Terminal value assumptions							
EV/Sales	N.m.	Long-term growth rate	N.m.						
EV/EBITDA	N.m.	Long-term EBIT margin	N.m.						
EV/EBIT	N.m.	Depreciation (% of sales)	N.m.						
EV/NOPLAT	N.m.	Capex (% of sales)	N.m.						
P/E	N.m.	Working capital (% of sales)	N.m.						
ROIC/WACC	N.m.	Tax rate	N.m.						
Current share price	14.2								

Source: Company, Penser Access by Carnegie

Income statement						
	20/21	21/22	22/23	23/24	24/25e	25/26e
Net sales	0	0	1	0	1	1
Other operating income	0	2	19	4	2	2
Total revenues	0	3	20	4	3	3
Other Operating Expenses	-86	-121	-120	-140	-165	-185
EBITDA	-85	-118	-100	-136	-162	-182
EBITDA, adjusted	-85	-118	-100	-136	-162	-182
Depreciation	-1	-4	-5	-11	-5	-5
EBITA, adjusted	-86	-123	-105	-147	-167	-187
EBIT	-86	-123	-105	-147	-167	-187
EBIT, adjusted	-86	-123	-105	-147	-167	-187
Net Financial Items	146	15	0	-5	8	1
Profit before tax	60	-108	-105	-152	-159	-186
Profit before tax, adjusted	60	-108	-105	-152	-159	-186
Net income	60	-108	-105	-152	-159	-186
Net income, adjusted	60	-108	-105	-152	-159	-186
Sales Growth	Neg.	482%	N.m.	Neg.	Neg.	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	-1.01	-1.46	-1.53	-1.79
EPS Growth, Adjusted	N.m.	N.m.	28%	N.m.	N.m.	N.m.

Source: Diamyd Medical, Penser by Carnegie

Cash flow statement						
	20/21	21/22	22/23	23/24	24/25e	25/26e
EBIT	-86	-123	-105	-147	-167	-187
Other Cash flow Items	1	4	6	15	12	6
Changes in working capital	-25	18	-1	8	0	0
Cash flow from operating activities	-110	-101	-100	-124	-155	-181
Investments in Fixed Assets	-4	-35	-11	-8	-5	0
Other Cash flow from investments	137	-42	40	-20	20	0
Cash flow from Investments	133	-77	28	-28	15	0
Free cash flow	23	-178	-72	-152	-139	-181
New share issue / repurchase	57	142	71	142	56	200
Cash flow from financing	57	142	71	142	56	200
Cash flow	80	-35	-1	-10	-83	19
Net debt	-139	-160	-128	-132	-29	-48

Source: Diamyd Medical, Penser by Carnegie

Balance sheet						
	20/21	21/22	22/23	23/24	24/25e	25/26e
ASSETS						
Tangible fixed assets	6	46	52	49	49	44
Financial assets	33	18	13	9	9	9
Total fixed assets	38	64	65	58	58	53
Other current assets	24	13	13	27	27	27
Cash and cash equivalents	139	160	128	132	29	48
Total current assets	163	173	141	159	56	75
TOTAL ASSETS	201	237	206	217	114	128
EQUITY AND LIABILITIES						
Equity	189	214	185	146	32	46
Total equity	189	214	185	146	32	46
Other long-term liabilities	1	1	1	31	41	41
Total long-term liabilities	1	1	1	31	41	41
Accounts payable	6	10	5	17	17	17
Other current liabilities	6	12	15	23	23	23
Total current liabilities	11	21	20	40	40	40
TOTAL EQUITY AND LIABILITIES	201	237	206	217	114	128

Source: Diamyd Medical, Penser by Carnegie

Growth and margins						
	20/21	21/22	22/23	23/24	24/25e	25/26e
Revenue growth	Neg.	482%	N.m.	Neg.	Neg.	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.	28%	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	23/24	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	23/24	24/25e	25/26e
Accounts receivable / total revenue	11%	10%	0%	1%	-	-
Total short-term liabilities / total cost	13%	18%	17%	29%	24%	22%
Working capital / total revenue	>100%	-310%	-33%	-304%	-433%	-433%
Capital turnover rate	0.0x	0.0x	0.1x	0.0x	0.1x	0.1x

Source: Diamyd Medical, Penser by Carnegie

Financial position						
	20/21	21/22	22/23	23/24	24/25e	25/26e
Net debt	-139	-160	-128	-132	-29	-48
Equity ratio	94%	91%	90%	67%	29%	36%
Net debt / equity	-0.7x	-0.7x	-0.7x	-0.9x	-0.9x	-1.0x
Net debt / EBITDA	N.m.	N.m.	N.m.	N.m.	N.m.	N.m.

Source: Diamyd Medical, Penser by Carnegie

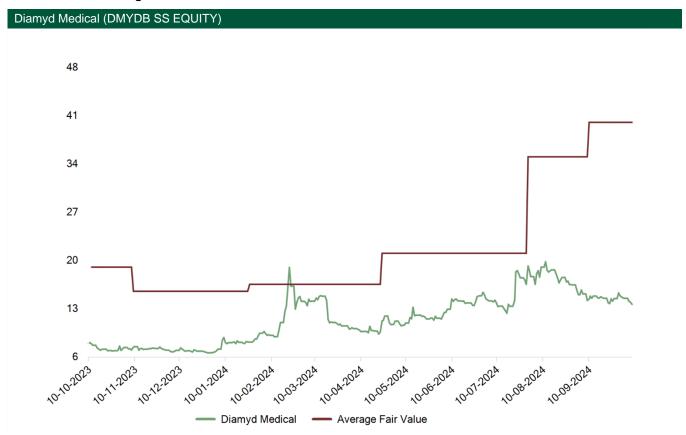
Per share data						
	20/21	21/22	22/23	23/24	24/25e	25/26e
EPS	0.84	-1.40	-1.01	-1.46	-1.53	-1.79
EPS, adjusted	0.84	-1.40	-1.01	-1.46	-1.53	-1.79
FCF per share	0.32	-2.31	-0.69	-1.46	-1.34	-1.74
Book value per share	2.64	2.79	1.78	1.40	0.31	0.45
Number of shares, m	71.6	76.9	104	104	104	104
Number of shares after dilution, average	71.6	76.9	104	104	104	104

Source: Diamyd Medical, Penser by Carnegie

Valuation						
	20/21	21/22	22/23	23/24	24/25e	25/26e
P/E, adjusted	17.6x	Neg.	Neg.	Neg.	Neg.	Neg.
P/BV	5.6x	4.8x	3.7x	9.7x	43.6x	30.5x
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	45.5x	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	892	1,283	1,283	1,283
Share price, year end	14.8	13.4	6.6	13.6	13.6	13.6

Source: Diamyd Medical, Penser by Carnegie

Share Price and Average Fair Value Chart



Source: Penser by Carnegie, IDC

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