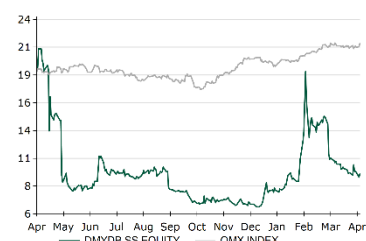


Biotechnology | Sweden | 24 April 2024

An exciting future on the cards

After adjusting for the cash injection, the new number of shares and the higher LoA for Diamyd at 50% (40%), our fair value ticks up to SEK20–22 per share (16–17). Diamyd now has an exciting future ahead, with interim analysis this summer as the key event and near-term catalyst for the share price.



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 SEK 20–22.

Fast track

In February, the company announced it had received fast track designation for its Diamyd immunotherapy. This is one of the programmes the FDA can use to potentially simplify or shorten the route to market approval for a drug that it believes has the potential to address a large medical need. Even more exciting for the company is that Diamyd is the first drug candidate in the diabetes field to achieve fast track status.

A fast track designation brings several regulatory advantages, including:

- A market application processing time of six months, rather than ten
- The possibility of accelerated approval based on bio-/surrogate markers
- Potential for closer and more frequent discussions with the FDA

We also understand that there is a possibility of accelerated approval based solely on the C peptide as the primary endpoint. Should the FDA opt for this, it would naturally shorten the time to market considerably. Such an approach would likely mean Diamyd sending in an application for accelerated approval based on the C peptide (which can read out sooner than HbA1c) and then finalises this with an application for full approval once the HbA1c data is available. We believe investors should consider this a bull-case scenario, and we still expect that data on both the C peptide and HbA1c will be required for market approval, which we forecast during 2028.

Recruitment update

Diamyd aims for full patient recruitment to the study to be completed before the end of 2024. We note that this implies a considerable increase in recruitment pace versus what we have seen so far. Patient recruitment began in 2022, and earlier in April, the company announced it had recruited 100 patients for the study. It also stated that more than 300 patients have been screened as part of the study.

We believe its target to have all patients recruited this year is challenging, but we bear in mind that the recruitment curve for clinical studies tends to rise exponentially as more clinics are included and begin admitting patients. Moreover, it has taken a while for US clinics to be included in the study and to start patient recruitment. In addition, the company has said that no patients have dropped out of the study. Given that Diamyd has been conservative in its assumptions regarding drop-outs from the study, we believe there is the possibility of its completing the study early while still achieving the targeted statistical strength, which would, of course, shorten the timeline.

DCF

Valuation output		WACC assumptions		Sensitivity analysis					
Sum of PV of FCF (explicit period)	2006	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	2600	2360	2143	1947	1770
Enterprise value	2006	Small cap premium	4.0%	NPV/share	26	24	21	20	18
Latest net debt, incl. est. issue	-137	Extra risk premium	6.0%						
Equity value	2143	WACC	18.0%						
No. of shares outstanding (millions)	99.7								
Equity value per share (SEK)	21								
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	9.8								

Source: Company, EPB

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%

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 / EBITDA	N.m.	N.m.	N.m.	N.m.	N.m.	N.m.

Source: Diamyd Medical, Penser by Carnegie

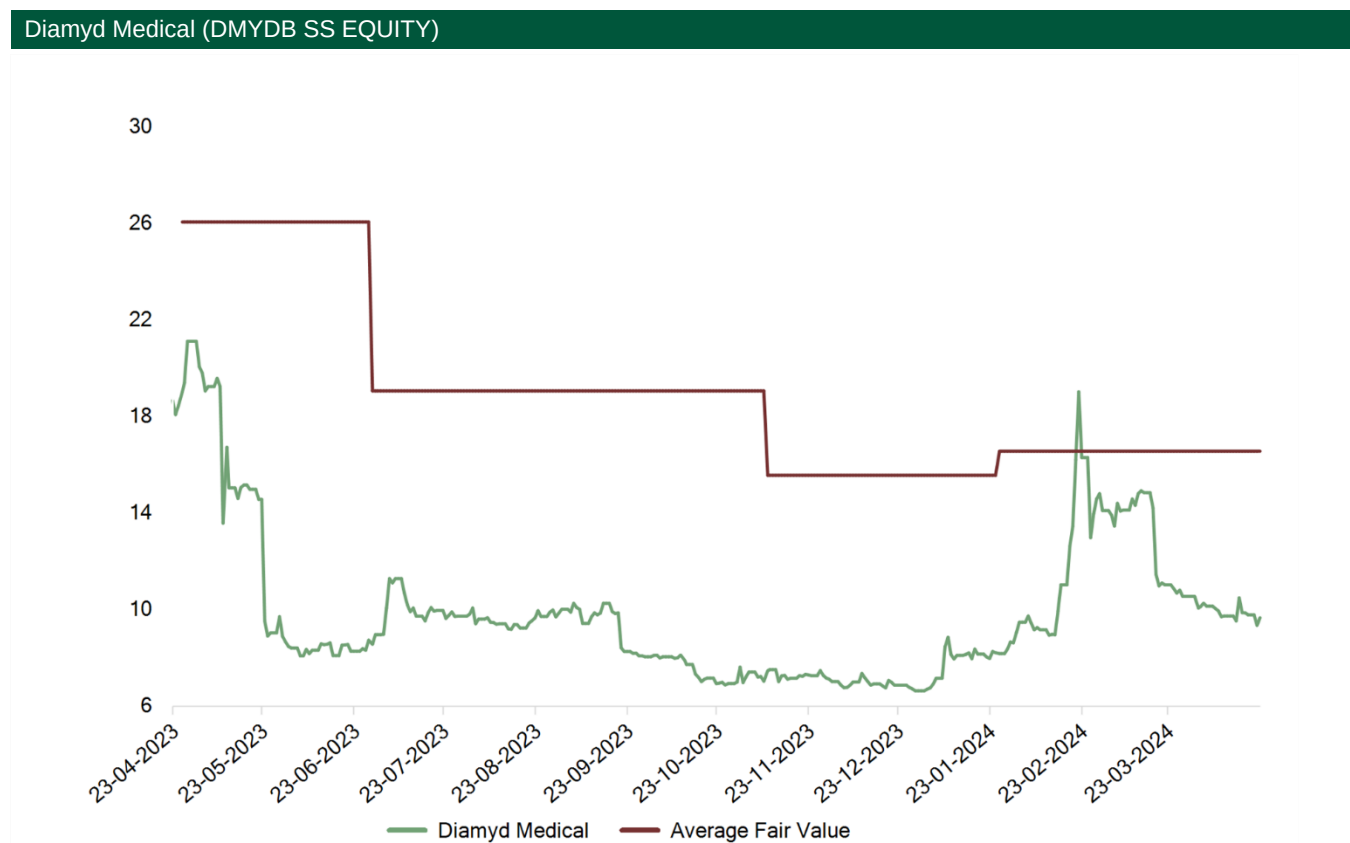
Per share data						
	20/21	21/22	22/23	23/24e	24/25e	25/26e
EPS	0.84	-1.40	-1.05	-1.33	-1.65	-2.02
EPS, adjusted	0.84	-1.40	-1.05	-1.33	-1.65	-2.02
FCF per share	0.32	-2.31	-0.72	-1.37	-1.60	-1.96
Book value per share	2.64	2.79	1.86	1.78	0.63	0.61
Number of shares, m	71.6	76.9	99.7	99.7	99.7	99.7
Number 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	5.4x	15.3x	15.6x
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	820	820	820
Share price, year end	14.8	13.4	6.6	9.6	9.6	9.6

Source: Diamyd Medical, Penser by Carnegie

Share price and average fair value chart



Source: Penser by Carnegie, IDC

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