



ERIK PENSER BANK

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Diamyd Medical

Diabetes deal

Large deal within diabetes field

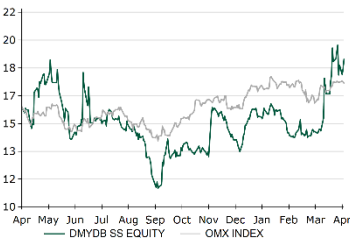
In this report, we highlight a recent diabetes deal: Sanofi's acquisition of Provention Bio for USD 2.9bn – equivalent to just over SEK 30bn. Provention's TZIELD drug is the first approved disease-modifying treatment for type 1 diabetes. There are both similarities and differences between TZIELD and Diamyd, but in this update we consider what a potential deal with Diamyd could be worth.

Possible acquisition value for Diamyd

We have applied the required rate of return (16%) and risk assessment (40%) we use in our DCF valuation of the company to our calculations. After discounting and risk adjustment, we have arrived at a possible acquisition value of SEK 5.2bn at present, corresponding to a share price of SEK 68 with the current shareholdings. It is important, however, for investors to recognise that acquisitions of Swedish research companies have historically been quite rare, and we thus do not believe this should be seen as a base case, but instead as an option.

Data from Remygen – next clear trigger

In this report, we reiterate our fair value of SEK 25–27 per share. We await the first data from the Remygen study – expected to be published in the first half of May.

Estimate changes				Forecasts (SEK m)					Valuation and risk													
	23e	24e	25e		21/22	22/23e	23/24e	24/25e	Fair value	SEK 25 - 27												
Total revenues	0,0%	0,0%	0,0%	Total revenues	3	3	3	3	Share price	SEK 19,0												
EBIT, adjusted	0,0%	0,0%	0,0%	Revenue growth	>100%	16%	0%	0%	Risk level	High												
EPS, adjusted	0,0%	0,0%	0,0%	EBITDA, adjusted	-118	-162	-182	-207	<div>12-mth share price development</div> 													
				EBIT, adjusted	-123	-167	-187	-212														
				EPS, adjusted	-1,4	-2,2	-2,4	-2,8														
				EPS growth	N.m.	N.m.	N.m.	N.m.														
				BV/share	2,8	3,9	1,5	2,1														
Coming events				Dividend per share	0,0	0,0	0,0	0,0	<div>Conflicts of interest</div> <table><tr><th></th><th>Yes</th><th>No</th></tr><tr><td>Market maker</td><td></td><td>✓</td></tr><tr><td>Certified adviser</td><td></td><td>✓</td></tr><tr><td>Transactions, 12 mth</td><td></td><td>✓</td></tr></table>			Yes	No	Market maker		✓	Certified adviser		✓	Transactions, 12 mth		✓
	Yes	No																				
Market maker		✓																				
Certified adviser		✓																				
Transactions, 12 mth		✓																				
Q3 - report	28 June 2023			EBIT margin	Neg.	Neg.	Neg.	Neg.														
Q4 - report	11 October 2023			ROE, adjusted	Neg.	Neg.	Neg.	Neg.														
Company details (SEKm)				ROCE, adjusted	Neg.	Neg.	Neg.	Neg.														
Number of shares	77m			EV/Sales	372,1x	391,0x	451,6x	437,7x														
Market capitalisation	1 415			P/book value	5,2x	4,7x	12,1x	8,9x														
Net debt	-102			Net debt/EBITDA	1,4x	1,5x	0,3x	0,5x														
EV	1 313																					
Free float	90%																					
Daily trading volume, average	134k																					
Bloomberg Ticker	DMYDB SS EQUITY																					
Analyst																						
Ludvig Svensson																						
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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 apply a risk-adjusted sum-of-the-parts model to our valuation of Diamyd. In this sum-of-the-parts model, we calculate each individual indication separately to arrive at a reasonable valuation of the company. Our fair value for Diamyd Medical is SEK 25–27 per share.

Major deal in the diabetes field

During March, we learned that Provention Bio, the company that developed the first approved disease-modifying treatment for type 1 diabetes (TZIELD), had received a takeover bid from Sanofi of USD 25.00 per share in cash, implying a value of some USD 2.9bn. The deal was made at a premium of 273% to the closing share price on the previous day. Deals in the type 1 diabetes field are naturally positive for Diamyd, and the acquisition gives an indication of the immense value the industry sees in advanced assets in this area. TZIELD was approved at the end of 2022, and US list price was set by Provention Bio at USD 194,000 for a two-week treatment course. This is a far higher price than analysts had expected (USD 70,000–80,000).

The market approval of TZIELD was based on results from ProTECT, a randomised, placebo-controlled ph II study with 76 patients with type 1 diabetes (stage 2). The results showed that treatment with TZIELD delayed patients' progression to stage 3 type 1 diabetes by around 25 months, compared with placebo. Stage 3 is typically when patients become reliant on insulin and experience many of the complications associated with the disease.

There are both similarities and differences between TZIELD and Diamyd. Both are potentially disease-modifying therapies, meaning they have the potential to impact the underlying disease and its course. This differs from insulin, for example, which only replaces the body's own insulin production, without influencing the course of the disease.

Overall, we expect Diamyd to have a better safety profile than TZIELD (which we have also seen in previous patient studies). Put simply, TZIELD works by inhibiting the function of specific parts of the immune system to maintain the functionality of beta-producing cells, while Diamyd focuses on teaching the immune system not to attack the beta-producing cells. Should Diamyd show that its approach can have an equivalent, or even a better, effect than TZIELD, we believe it would represent a more positive risk/benefit alternative for patients.

The difference in efficacy between the two drugs is much more difficult to predict. Both have been studied in a large number of patients, but comparing studies is always challenging, while the measures of effectiveness in the studies have not been the same. To simplify our calculations on Diamyd, we have chosen to assume that both constitute an equally appealing treatment.

Comparison: Diamyd vs TZIELD

	Diamyd	TZIELD
Class	Biologic	Biologic
Mechanism of action	Immunotherapy	Immunosuppression
Administration	Intralymphatic injection	Intravenous infusion
Treatment time	3x over 60 days	Daily for 14 days
Patient population	Type 1 diabetes with HLA DR3-DQ2 genotypes	Type 1 diabetes
Number of patients in pivotal study	330	76
List price per year	N/A	USD 194,000

Source: EPB

Possible acquisition value of Diamyd

Below, we picture a scenario in which Diamyd is acquired for the same purchase price as Provention Bio (USD 2.9bn) after a potential approval of the drug (2028). It is currently, without ph III from Diamyd, hard to know how the two drugs differ in terms of safety and efficacy. Better safety/efficacy could, of course, mean a higher purchase price, but also vice versa. We have applied the required rate of return (16%) and risk assessment (40%) we use in our DCF valuation of the company to our calculations. After discounting and risk adjustment, we have arrived at a possible acquisition value of SEK 5.2bn at present, corresponding to a share price of SEK 68 with the current shareholdings.

Our sensitivity analysis shows that the value depends to a great extent on the required rate of return and the probability of reaching the market. We believe this at least provides some indications that the equity market's expectations of Diamyd reaching the market are low at these levels (around 10–15% depending on WACC).

It is important, however, for investors to recognise that acquisitions of Swedish research companies have historically been quite rare, and we thus do not believe this should be seen as a base case, but instead as an option.

Calculations based on the deal

Sales value (USDbn)	2.9
Sales value (SEKbn)	30.45
Risk assessment	40%
Risk-adjusted value (SEKbn)	12.2
Required rate of return (WACC)	16%
Risk-adjusted discounted value (SEKbn)	5.2
Risk-adjusted discounted value per share	68

Source: EPB

Sensitivity analysis

		WACC				
		22%	19%	16%	13%	10%
Probability of reaching the market	10%	13	15	17	20	23
	25%	32	37	43	49	58
	40%	51	59	68	79	92
	70%	89	103	119	138	161
	100%	128	147	170	197	230

Source: EPB

DCF

Valuation output		WACC assumptions		Sensitivity analysis					
Sum of PV of FCF (explicit period)	1934	Risk-free nominal rate	2.5%	WACC	14%	15%	16%	17%	18%
PV of terminal value (perpetuity formula)	0	Market risk premium	5.5%	NPV	2484	2247	2036	1848	1680
Enterprise value	1934	Small cap premium	4.0%	NPV/share	32	29	26	24	22
Latest net debt	-102	Extra risk premium	4.0%						
Equity value	2036	WACC	16.0%						
No. of shares outstanding (millions)	76.9								
Equity value per share (SEK)	26								
Implicit multiple		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	16.9								

Source: Company, EPB

Income statement					
	20/21	21/22	22/23e	23/24e	24/25e
Net sales	0	0	1	1	1
Other operating income	0	2	2	2	2
Total revenues	0	3	3	3	3
Gross profits	0	3	3	3	3
Other operating expenses	-86	-121	-165	-185	-210
EBITDA	-85	-118	-162	-182	-207
EBITDA, adjusted	-85	-118	-162	-182	-207
EBITA, adjusted	-85	-118	-162	-182	-207
EBIT	-86	-123	-167	-187	-212
EBIT, adjusted	-86	-123	-167	-187	-212
Net financial items	146	15	0	0	0
Profit/loss before tax	60	-108	-167	-187	-212
Profit/loss before tax, adjusted	60	-108	-167	-187	-212
Net income	60	-108	-167	-187	-212
Net income, adjusted	60	-108	-167	-187	-212
Sales growth	-	>100%	16%	0%	0%
Gross margin	>100%	>100%	>100%	>100%	>100%
EBIT margin, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.
EPS, adjusted	0,84	-1,40	-2,17	-2,43	-2,75
EPS growth, adjusted	-	N.m.	N.m.	N.m.	N.m.

Source: Diamyd Medical, EPB

Cash flow statement					
	20/21	21/22	22/23e	23/24e	24/25e
EBIT	-86	-123	-167	-187	-212
Other cash flow items	1	4	4	5	5
Changes in working capital	-25	18	-1	1	1
Cash flows from operating activities	-110	-101	-163	-181	-206
Investments in fixed assets	-4	-35	-7	-4	-5
Other cash flows from investments	137	-42	40	0	0
Cash flows from investments	133	-77	33	-4	-5
Free cash flows	23	-178	-130	-185	-211
Rights issues / buybacks	57	142	250	0	250
Cash flows from financing	57	142	250	0	250
Cash flows	80	-35	120	-185	39
Net debt	-139	-160	-242	-61	-102

Source: Diamyd Medical, EPB

Balance sheet					
	20/21	21/22	22/23e	23/24e	24/25e
ASSETS					
Tangible fixed assets	6	46	48	47	48
Financial assets	33	18	18	18	18
Total fixed assets	38	64	66	65	66
Other current assets	24	13	18	18	18
Cash and cash equivalents	139	160	242	61	102
Total current assets	163	173	260	79	120
TOTAL ASSETS	201	237	327	144	186
EQUITY AND LIABILITIES					
Equity	189	214	301	117	158
Total equity	189	214	301	117	158
Other long-term liabilities	1	1	1	1	1
Total long-term liabilities	1	1	1	1	1
Accounts payable	6	10	10	10	10
Other current liabilities	6	12	15	16	17
Total current liabilities	11	21	25	26	27
TOTAL EQUITY AND LIABILITIES	201	237	327	144	186

Source: Diamyd Medical, EPB

Growth and margins					
	20/21	21/22	22/23e	23/24e	24/25e
Revenue growth	-	>100%	16%	0%	0%
EBITDA growth, adjusted	-	N.m.	N.m.	N.m.	N.m.
EBIT growth, adjusted	-	N.m.	N.m.	N.m.	N.m.
EPS growth, adjusted	-	N.m.	N.m.	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, EPB

Profitability					
	20/21	21/22	22/23e	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, EPB

Capital efficiency

	20/21	21/22	22/23e	23/24e	24/25e
Accounts receivable / total revenues	11%	10%	-	-	-
Total short-term liabilities / total costs	13%	18%	15%	14%	13%
Working capital / total revenues	>100%	-310%	-233%	-267%	-300%

Source: Diamyd Medical, EPB

Financial position

	20/21	21/22	22/23e	23/24e	24/25e
Net debt	-139	-160	-242	-61	-102
Equity ratio	94%	91%	92%	81%	85%
Net debt/equity	-0,7x	-0,7x	-0,8x	-0,5x	-0,6x
Net debt/EBITDA	1,6x	1,4x	1,5x	0,3x	0,5x

Source: Diamyd Medical, EPB

Share data

	20/21	21/22	22/23e	23/24e	24/25e
EPS	0,84	-1,40	-2,17	-2,43	-2,75
EPS, adjusted	0,84	-1,40	-2,17	-2,43	-2,75
FCF per share	0,32	-2,31	-1,69	-2,40	-2,75
Dividend per share	0,00	0,00	0,00	0,00	0,00
Book value per share	2,64	2,79	3,91	1,52	2,06
Number of shares, m	71,6	76,9	76,9	76,9	76,9
Number of shares after dilution, average	71,6	76,9	76,9	76,9	76,9

Source: Diamyd Medical, EPB

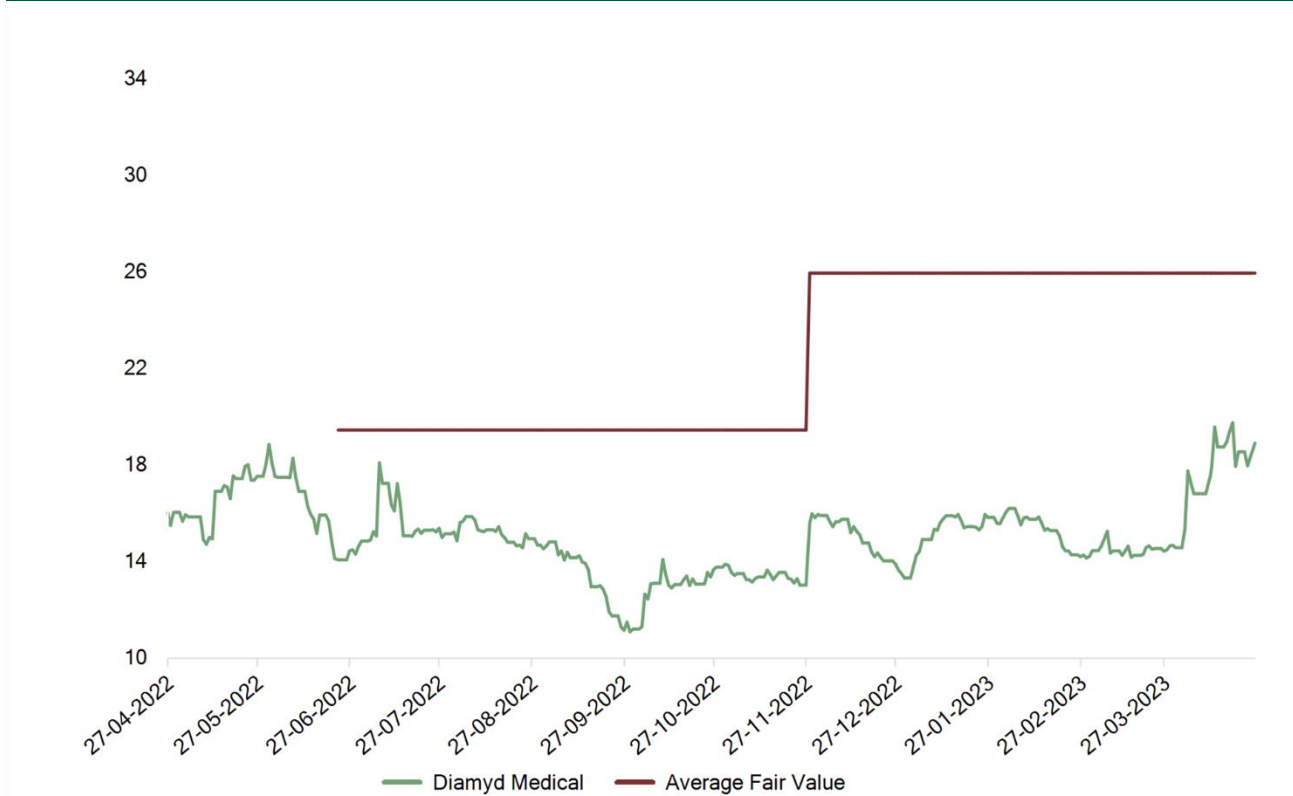
Valuation

	20/21	21/22	22/23e	23/24e	24/25e
P/E, adjusted	40,2x	Neg.	Neg.	Neg.	Neg.
P/book value	12,7x	5,2x	4,7x	12,1x	8,9x
P/FCF	105,9x	Neg.	Neg.	Neg.	Neg.
FCF yield	1%	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	391,0x	451,6x	437,7x
EV/EBITDA, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.
EV/EBIT, adjusted	Neg.	Neg.	Neg.	Neg.	Neg.
EV	2 273	962	1 173	1 355	1 313
Share price, year-end	33,7	14,6	18,4	18,4	18,4

Source: Diamyd Medical, EPB

Share price and average fair value

Diamyd Medical (DMYDB SS EQUITY)



Source: EPB, IDC

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