



## Penser Access by Carnegie

Biotechnology | Sweden | 26 January 2024

# Diamyd Medical

## All eyes on DIAGNODE-3

### Comments on the report

Diamyd's report for 1Q of the fiscal year ending in August 2024 was in line with our expectations. The operating result came in at SEK -32m (-33), while cash flow reach SEK 51m (10) following the completed rights issue. Diamyd's cash position at the end of November was around SEK 177m. According to our estimates, this is sufficient to finance operations a little way into 2025.

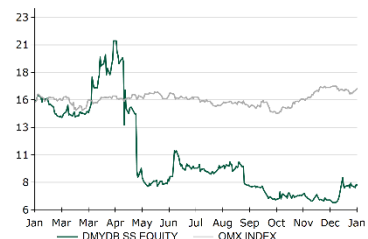
### Interim data expected in July

Interim data from the DIAGNODE-3 study should be released in July. This is an especially important data point as it will reveal whether the study has a clear likelihood of achieving its objectives based on the assumptions Diamyd made at the design stage. Interim analysis will be based on 70–80 patients and will evaluate the effect of Diamyd with regards to the C-peptide. We consider the bar for achieving the criteria to continue the study to be relatively low. Previous studies with Diamyd have shown a clear differentiation in the C-peptide between the treatment and the placebo group after six months. Meta analysis published in The Lancet in 2023 (Taylor et al.) to evaluate the relationship between the C-peptide and HbA1 showed that a clear separation in the C-peptide curves occurs particularly early after treatment initiation.

### Aiming to recruit the last patient in 2024

We believe Diamyd has already recruited somewhere around 80–100 patients for the DIAGNODE-3 study. Of the targeted 60+ recruited clinics, approximately 50 are secured. Diamyd aims to recruit a total of 280–330 patients by the end of 2024. We consider this a bold but achievable target. Our estimated timeline is still built on what management has communicated, but we reiterate the risk we see of a slight delay.

After making small adjustments to our estimates, we arrive at fair value of SEK 16–17 (15-16) per share.

| Change in estimates           |                 |      |      | Forecast (mSEK)   |       |        |        |        | Value and risk  |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
|-------------------------------|-----------------|------|------|-------------------|-------|--------|--------|--------|---|----------------|--|-----|----|--------------------|--|---|-------------------|--|---|------------------|--|---|
|                               | 24e             | 25e  | 26e  |                   | 22/23 | 23/24e | 24/25e | 25/26e | Fair value  | SEK16.0 - 17.0 |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| Total Revenues                | 0.0%            | 0.0% | 0.0% | Total Revenues    | 20    | 3      | 3      | 3      | Share price   | SEK8.2         |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| EBIT, adj.                    | 0.0%            | 0.0% | 0.0% | Revenue growth    | >100% | N.m.   | 0%     | 0%     | Risk level  | Hogh           |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| EPS, adj.                     | 0.0%            | 0.0% | 0.0% | EBITDA, adj.      | -100  | -147   | -197   | -207   | <div>Price performance 12 months</div>   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| Upcoming events               |                 |      |      | EBIT, adj.        | -105  | -152   | -202   | -212   |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| Q2 - report                   | 27 March 2024   |      |      | EPS, adj.         | -1.1  | -1.6   | -2.1   | -2.2   |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| Company facts (SEKm)SEKm      |                 |      |      | EPS growth        | 21%   | N.m.   | N.m.   | N.m.   |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| Number of shares              | 95m             |      |      | BV/share          | 2.0   | 1.1    | 1.1    | 1.5    |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| Market capitalisation         | 774             |      |      | EBIT margin       | Neg.  | Neg.   | Neg.   | Neg.   | <div>Conflicts of interest</div> <table><tr><th></th><th>Yes</th><th>No</th></tr><tr><td>Liquidity provider</td><td></td><td>✓</td></tr><tr><td>Certified adviser</td><td></td><td>✓</td></tr><tr><td>Transactions 12m</td><td></td><td>✓</td></tr></table> |                |  | Yes | No | Liquidity provider |  | ✓ | Certified adviser |  | ✓ | Transactions 12m |  | ✓ |
|                               | Yes             | No   |      |                   |       |        |        |        |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| Liquidity provider            |                 | ✓    |      |                   |       |        |        |        |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| Certified adviser             |                 | ✓    |      |                   |       |        |        |        |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| Transactions 12m              |                 | ✓    |      |                   |       |        |        |        |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| Net debt                      | -177            |      |      | ROE, adj.         | Neg.  | Neg.   | Neg.   | Neg.   |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| EV                            | 597             |      |      | ROCE, adj.        | Neg.  | Neg.   | Neg.   | Neg.   |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| Free float                    | 90%             |      |      | EV/Sales          | 40.9x | 199.0x | 199.0x | 199.0x |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| Daily trading volume, average | 117k            |      |      | EV/EBITDA         | Neg.  | -4.1x  | -3.0x  | -2.9x  |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| Bloomberg Ticker              | DMYDB SS EQUITY |      |      | EV/EBIT           | Neg.  | -3.9x  | -2.9x  | -2.8x  |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| Analyst                       |                 |      |      | P/E, adj.         | -5.9x | -5.1x  | -3.8x  | -3.6x  |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| Ludvig Svensson               |                 |      |      | P/BV              | 3.4x  | 7.3x   | 7.5x   | 5.5x   |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
| ludvig.svensson@carnegie.se   |                 |      |      | FCF yield         | -12%  | -20%   | -26%   | -27%   |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |
|                               |                 |      |      | Net debt / EBITDA | 1.3x  | 0.3x   | 0.2x   | 0.4x   |   |                |  |     |    |                    |  |   |                   |  |   |                  |  |   |

## 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 of 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 16–17.

## Reasoning behind potential price level for Diamyd

In early January, the company announced it had analysed the target market for Diamyd in the US. Interviews with payers, among other sources, revealed that a drug with Diamyd's profile in the proposed patient population should be priced in the range of USD 194,000–240,000 a year. This price range is considerably higher than what we currently use in our model, but is in line with the list price of TZIELD (USD ~194,000).

While this represents potentially large upside in our estimates, we have assumed, based on our lower price forecast, significant market penetration for Diamyd of 50% of the proposed target group with the HLA DR3-DQ2 gene type in the US. We believe a high price would hinder uptake and result in a lower penetration among the target population. A price of USD 200,000 per year and penetration of 50% should, according to our model, provide peak sales for Diamyd of USD 3,500m in the US alone, which we consider particularly aggressive. As a reference, analyst consensus is that TZIELD should achieve sales of USD 550m during 2028 (Evaluate Pharma).

The price for Diamyd will ultimately be a function of how long the drug can maintain patients' endogenous insulin production. It is possible that our current peak sales estimate for Diamyd (USD 940m worldwide) is too conservative given the indicated price level, but we would like more data on the clinical effect before we adjust our assumptions.

## DCF

| Valuation output                          |             | WACC assumptions       |       | Sensitivity analysis |      |      |             |      |      |
|---|-------------|------------------------|-------|----------------------|------|------|-------------|------|------|
| Sum of PV of FCF (explicit period)        | 1466        | Risk free nominal rate | 2.5%  | WACC                 | 16%  | 17%  | <b>18%</b>  | 19%  | 20%  |
| PV of terminal value (perpetuity formula) | 0           | Market risk premium    | 5.5%  | NPV                  | 2000 | 1812 | <b>1642</b> | 1490 | 1353 |
| <b>Enterprise value</b>                   | <b>1466</b> | Small cap premium      | 4.0%  | NPV/share            | 21   | 19   | <b>17</b>   | 16   | 14   |
| Latest net debt, inc est. issue           | -177        | Extra risk premium     | 6.0%  |                      |      |      |             |      |      |
| <b>Equity value</b>                       | <b>1642</b> | WACC                   | 18.0% |                      |      |      |             |      |      |
| No. of shares outstanding (millions)      | 95.0        |                        |       |                      |      |      |             |      |      |
| <b>Equity value per share (SEK)</b>       | <b>17</b>   |                        |       |                      |      |      |             |      |      |

| Implicit multipl.   | 2023e | 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 | 8.2   |                            |     |

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| Income statement                   |            |             |             |             |             |
|------------------------------------|------------|-------------|-------------|-------------|-------------|
|                                    | 20/21      | 21/22       | 22/23       | 23/24e      | 24/25e      |
| <b>Net sales</b>                   | <b>0</b>   | <b>0</b>    | <b>1</b>    | <b>1</b>    | <b>1</b>    |
| Other operating income             | 0          | 2           | 19          | 2           | 2           |
| <b>Total revenues</b>              | <b>0</b>   | <b>3</b>    | <b>20</b>   | <b>3</b>    | <b>3</b>    |
| Other Operating Expenses           | -86        | -121        | -120        | -150        | -200        |
| <b>EBITDA</b>                      | <b>-85</b> | <b>-118</b> | <b>-100</b> | <b>-147</b> | <b>-197</b> |
| <b>EBITDA, adjusted</b>            | <b>-85</b> | <b>-118</b> | <b>-100</b> | <b>-147</b> | <b>-197</b> |
| Depreciation                       | -1         | -4          | -5          | -5          | -5          |
| <b>EBITA, adjusted</b>             | <b>-85</b> | <b>-118</b> | <b>-100</b> | <b>-147</b> | <b>-197</b> |
| <b>EBIT</b>                        | <b>-86</b> | <b>-123</b> | <b>-105</b> | <b>-152</b> | <b>-202</b> |
| <b>EBIT, adjusted</b>              | <b>-86</b> | <b>-123</b> | <b>-105</b> | <b>-152</b> | <b>-202</b> |
| Net Financial Items                | 146        | 15          | 0           | 0           | 0           |
| <b>Profit before tax</b>           | <b>60</b>  | <b>-108</b> | <b>-105</b> | <b>-152</b> | <b>-202</b> |
| <b>Profit before tax, adjusted</b> | <b>60</b>  | <b>-108</b> | <b>-105</b> | <b>-152</b> | <b>-202</b> |
| <b>Net income</b>                  | <b>60</b>  | <b>-108</b> | <b>-105</b> | <b>-152</b> | <b>-202</b> |
| <b>Net income, adjusted</b>        | <b>60</b>  | <b>-108</b> | <b>-105</b> | <b>-152</b> | <b>-202</b> |
| Sales Growth                       | -          | >100%       | >100%       | N.m.        | 0%          |
| Gross Margin                       | N.m.       | >100%       | >100%       | >100%       | >100%       |
| EBIT Margin, Adjusted              | Neg.       | Neg.        | Neg.        | Neg.        | Neg.        |
| EPS, Adjusted                      | 0.84       | -1.40       | -1.11       | -1.60       | -2.13       |
| EPS Growth, Adjusted               | -          | N.m.        | 21%         | N.m.        | N.m.        |

Source: Diamyd Medical, Carnegie

| Cash flow statement                        |             |             |             |             |             |
|--|-------------|-------------|-------------|-------------|-------------|
|  | 20/21       | 21/22       | 22/23       | 23/24e      | 24/25e      |
| EBIT                                       | -86         | -123        | -105        | -152        | -202        |
| Other Cash flow Items                      | 1           | 4           | 6           | 6           | 6           |
| Changes in working capital                 | -25         | 18          | -1          | 1           | 1           |
| <b>Cash flow from operating activities</b> | <b>-110</b> | <b>-101</b> | <b>-100</b> | <b>-144</b> | <b>-195</b> |
| Investments in Fixed Assets                | -4          | -35         | -11         | -7          | -5          |
| Other Cash flow from investments           | 137         | -42         | 40          | 0           | 0           |
| <b>Cash flow from Investments</b>          | <b>133</b>  | <b>-77</b>  | <b>28</b>   | <b>-7</b>   | <b>-5</b>   |
| <b>Free cash flow</b>                      | <b>23</b>   | <b>-178</b> | <b>-72</b>  | <b>-152</b> | <b>-200</b> |
| New share issue / repurchase               | 57          | 142         | 71          | 73          | 200         |
| <b>Cash flow from financing</b>            | <b>57</b>   | <b>142</b>  | <b>71</b>   | <b>73</b>   | <b>200</b>  |
| <b>Cash flow</b>                           | <b>80</b>   | <b>-35</b>  | <b>-1</b>   | <b>-79</b>  | <b>0</b>    |
| <b>Net debt</b>                            | <b>-139</b> | <b>-160</b> | <b>-128</b> | <b>-49</b>  | <b>-49</b>  |

Source: Diamyd Medical, Carnegie

| Balance sheet                       |            |            |            |            |            |
|-------------------------------------|------------|------------|------------|------------|------------|
|                                     | 20/21      | 21/22      | 22/23      | 23/24e     | 24/25e     |
| <b>ASSETS</b>                       |            |            |            |            |            |
| Tangible fixed assets               | 6          | 46         | 52         | 54         | 54         |
| Financial assets                    | 33         | 18         | 13         | 13         | 13         |
| <b>Total fixed assets</b>           | <b>38</b>  | <b>64</b>  | <b>65</b>  | <b>67</b>  | <b>67</b>  |
| Other current assets                | 24         | 13         | 13         | 18         | 18         |
| Cash and cash equivalents           | 139        | 160        | 128        | 49         | 49         |
| <b>Total current assets</b>         | <b>163</b> | <b>173</b> | <b>141</b> | <b>67</b>  | <b>67</b>  |
| <b>TOTAL ASSETS</b>                 | <b>201</b> | <b>237</b> | <b>206</b> | <b>134</b> | <b>134</b> |
| <b>EQUITY AND LIABILITIES</b>       |            |            |            |            |            |
| Equity                              | 189        | 214        | 185        | 106        | 104        |
| <b>Total equity</b>                 | <b>189</b> | <b>214</b> | <b>185</b> | <b>106</b> | <b>104</b> |
| Other long-term liabilities         | 1          | 1          | 1          | 2          | 3          |
| <b>Total long-term liabilities</b>  | <b>1</b>   | <b>1</b>   | <b>1</b>   | <b>2</b>   | <b>3</b>   |
| Accounts payable                    | 6          | 10         | 5          | 10         | 10         |
| Other current liabilities           | 6          | 12         | 15         | 16         | 17         |
| <b>Total current liabilities</b>    | <b>11</b>  | <b>21</b>  | <b>20</b>  | <b>26</b>  | <b>27</b>  |
| <b>TOTAL EQUITY AND LIABILITIES</b> | <b>201</b> | <b>237</b> | <b>206</b> | <b>134</b> | <b>134</b> |

Source: Diamyd Medical, Carnegie

| Growth and margins      |       |       |       |        |        |
|-------------------------|-------|-------|-------|--------|--------|
|                         | 20/21 | 21/22 | 22/23 | 23/24e | 24/25e |
| Revenue growth          | -     | >100% | >100% | N.m.   | 0%     |
| EBITDA growth, adjusted | -     | N.m.  | 15%   | N.m.   | N.m.   |
| EBIT growth, adjusted   | -     | N.m.  | 14%   | N.m.   | N.m.   |
| EPS growth, adjusted    | -     | N.m.  | 21%   | 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, Carnegie

| Return         |       |       |       |        |        |
|----------------|-------|-------|-------|--------|--------|
|                | 20/21 | 21/22 | 22/23 | 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, Carnegie

| Capital efficiency                        |       |       |       |        |        |
|---|-------|-------|-------|--------|--------|
|   | 20/21 | 21/22 | 22/23 | 23/24e | 24/25e |
| Accounts receivable / total revenue       | 11%   | 10%   | 0%    | -      | -      |
| Total short-term liabilities / total cost | 13%   | 18%   | 17%   | 17%    | 14%    |
| Working capital / total revenue           | >100% | -310% | -33%  | -267%  | -300%  |

Source: Diamyd Medical, Carnegie

| Financial position |       |       |       |        |        |
|--------------------|-------|-------|-------|--------|--------|
|                    | 20/21 | 21/22 | 22/23 | 23/24e | 24/25e |
| Net debt           | -139  | -160  | -128  | -49    | -49    |
| Equity ratio       | 94%   | 91%   | 90%   | 79%    | 78%    |
| Net debt / EBITDA  | 1.6x  | 1.4x  | 1.3x  | 0.3x   | 0.2x   |

Source: Diamyd Medical, Carnegie

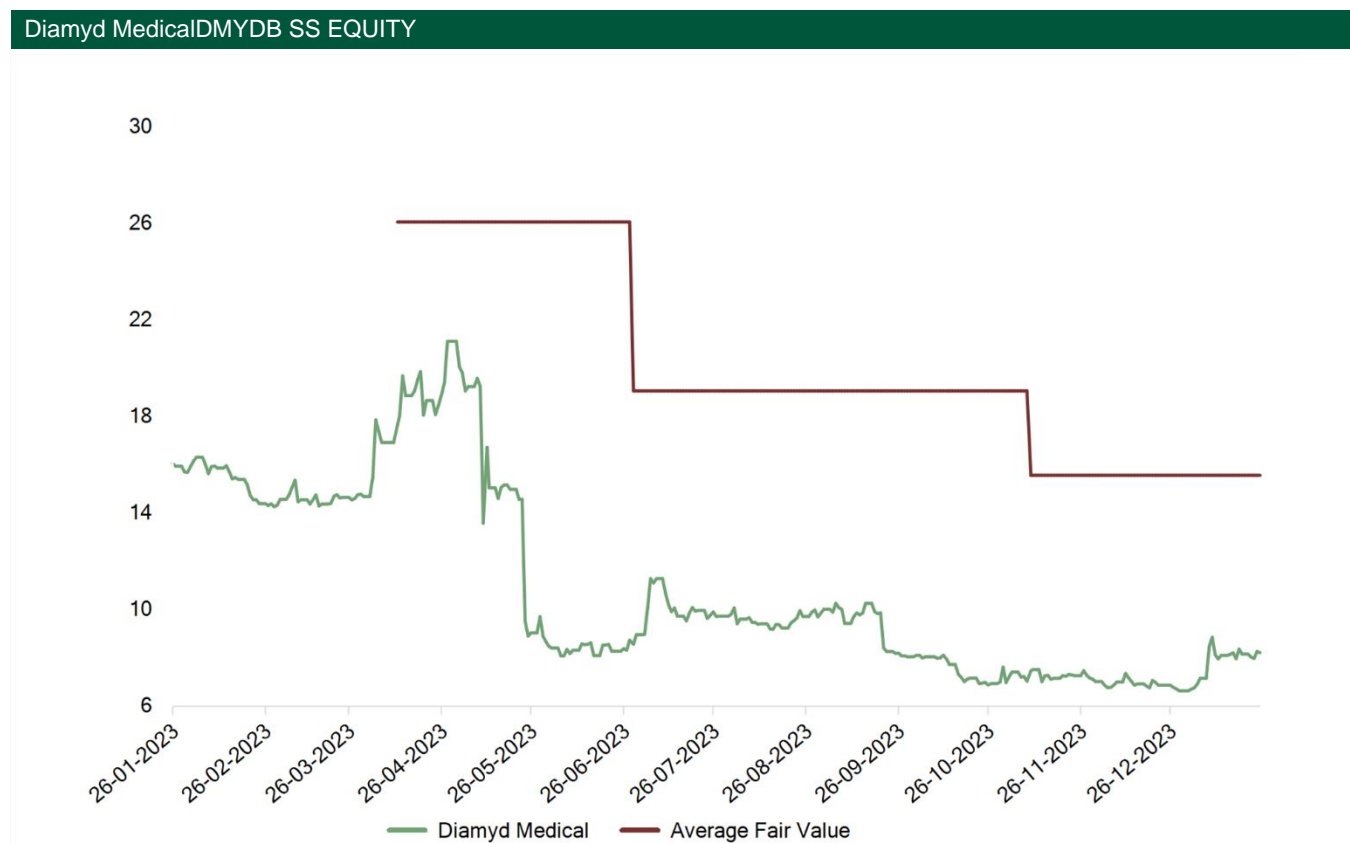
| Per share data                           |       |       |       |        |        |
|--|-------|-------|-------|--------|--------|
|  | 20/21 | 21/22 | 22/23 | 23/24e | 24/25e |
| EPS                                      | 0.84  | -1.40 | -1.11 | -1.60  | -2.13  |
| EPS, adjusted                            | 0.84  | -1.40 | -1.11 | -1.60  | -2.13  |
| FCF per share                            | 0.32  | -2.31 | -0.76 | -1.60  | -2.11  |
| Book value per share                     | 2.64  | 2.79  | 1.95  | 1.12   | 1.09   |
| Number of shares, m                      | 71.6  | 76.9  | 95.0  | 95.0   | 95.0   |
| Number of shares after dilution, average | 71.6  | 76.9  | 95.0  | 95.0   | 95.0   |

Source: Diamyd Medical, Carnegie

| Valuation              |          |        |       |        |        |
|------------------------|----------|--------|-------|--------|--------|
|                        | 20/21    | 21/22  | 22/23 | 23/24e | 24/25e |
| P/E, adjusted          | 17.6x    | Neg.   | Neg.  | Neg.   | Neg.   |
| P/BV                   | 5.6x     | 4.8x   | 3.4x  | 7.3x   | 7.5x   |
| P/FCF                  | 46.5x    | Neg.   | Neg.  | Neg.   | Neg.   |
| FCF-yield              | 2%       | 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 | 40.9x | 199.0x | 199.0x |
| EV/EBITDA, adjusted    | Neg.     | Neg.   | Neg.  | -4.1x  | -3.0x  |
| EV/EBIT, adjusted      | Neg.     | Neg.   | Neg.  | -3.9x  | -2.9x  |
| EV                     | 2,273    | 962    | 802   | 597    | 597    |
| Share price, year end  | 33.7     | 14.6   | 9.8   | 8.2    | 8.2    |

Source: Diamyd Medical, Carnegie

## Share Price and Average Fair Value Chart



Source: Carnegie, IDC



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