



## QUARTERLY REPORT 2

September 2020 – February 2021

Diamyd Medical AB (publ), Fiscal year 2020/2021



Diamyd Medical's B-share is traded on Nasdaq First North Growth Market under the ticker DMYD B. Further information is available on <https://www.diamyd.com>

Figures in parentheses relate to the corresponding period previous financial year.

## September 1, 2020 – February 28, 2021

- Net result: MSEK 120.0 (30.3), second quarter 15.1 (37.1). The increase compared to previous year is a one-off effect of corresponding MSEK 144.4 due to profit from divestment of shares in Companion Medical, Inc.
- Result per share: SEK 1.7 (0.4), second quarter SEK 0.2 (0.5)
- Cash flow from operating activities: MSEK -28.9 (31.1), second quarter: MSEK -14.8 (37.2)
- Cash and cash equivalents at February 28, 2021: MSEK 165.5 (88.3)

### Significant events second quarter, December 1, 2020–February 28, 2021

- Diamyd Medical announced investment in MainlyAI
- Positive safety evaluation of Remygen® in high dose and in combination with Alprazolam gave the go-ahead for the continuation of the ReGenerate-1 trial
- Meta-analysis updated with DIAGNODE-2 results provided further support for a precision medicine approach using Diamyd®
- Immunological analysis of Phase IIb trial with Diamyd® showed differences between genetically defined patient groups
- Diamyd Medical and Critical Path Institute announced data sharing collaboration to develop advanced drug development tools in type 1 diabetes
- Diamyd Medical with MainlyAI and KTH were awarded VINNOVA funding for AI driven sustainable production
- An additional USD 3.2 million related to the divestment of Companion Medical were received

### Significant events after the reporting period

- Diamyd Medical selected Cytiva's FlexFactory platform to make precision medicine type 1 diabetes vaccine
- Diamyd Medical updated on the design of a Phase III Precision Medicine trial with Diamyd®



“The Phase 3 trial is based on the notion of precision medicine, where only individuals that we know beforehand to have a high likelihood of benefitting from the treatment will be enrolled.”

Ulf Hannelius, CEO

## Comments by CEO Ulf Hannelius

After advice from the European Medicinal Authority EMA and the US FDA, we are now in the process of initiating a pivotal Phase 3 trial with our therapeutic vaccine Diamyd® for type 1 diabetes. The trial is based on the notion of Precision Medicine, where only individuals that we know beforehand to have a high likelihood of benefitting from the treatment will be enrolled.

Approximately 330 individuals from the US and Europe with recent onset type 1 diabetes carrying the HLA DR3-DQ2 haplotype, a set of associated genetic variants present in up to half of all type 1 diabetes patients, will be enrolled in the trial which is designed to confirm the efficacy and safety of three injections of Diamyd® directly into a lymph node. Intralymphatic administration of Diamyd®, for which we have been granted patent protection in Europe, Japan, Australia, Russia, and Israel, with additional countries including the US pending, has shown to further increase the efficacy of the treatment compared to subcutaneous injections.

The trial is designed around the co-primary endpoints Change in endogenous insulin production measured as stimulated C-peptide and Change in long-term average blood glucose measured as HbA1c evaluated at 24 months from baseline. These two endpoints, supported by the EMA and FDA, incorporate both the biological and clinical effect measures to support the approval of the therapy. Importantly, the trial design provides, based on the comprehensive clinical effect data in the HLA-restricted patient population, a high statistical power that the trial will reach its co-primary endpoints.

On the data analytics side we are excited to have acquired a 20% ownership of MainlyAI AB. Both on the manufacturing side and on areas such as drug development and Precision Medicine applications, MainlyAI's expertise in artificial intelligence may become of substantial value to its future customers. Besides our recent investment in MainlyAI, we have also employed our first data scientist to further strengthen our capabilities in this area. Precision Medicine is sure to advance in the coming years.

In parallel with Phase 3, we continue to work with the establishment of our manufacturing facility in Umeå. Using the FlexFactory platform from Cytiva, a global provider of technologies and services for acceleration of development and manufacture of therapeutics, we will obtain the required flexibility and scalability to serve our needs in manufacturing, for GAD, the active ingredient in Diamyd®, but also for potential new internal and external assets. In these times, pharmaceutical manufacturing has become a top priority, and there may be important and exciting opportunities that our facility in Umeå will be able to serve.

*Stockholm, March 25, 2021*

Ulf Hannelius, *President and CEO*

# Significant events during the second quarter

December 1, 2020 – February 28, 2021

## **Investment in MainlyAI**

Diamyd Medical's investment will give a 20% ownership and a board seat in MainlyAI. The investment of SEK 1.2 million will facilitate MainlyAI's strategic focus on applying artificial intelligence, where the first project is sustainable production within the pharmaceutical sector.

## **Positive safety evaluation of Remygen® in high dose and in combination with Alprazolam gave the go-ahead for the continuation of the trial**

Following evaluation of safety data, an independent safety committee (DSMB) recommended the continuation of the investigator-initiated clinical trial ReGenerate-1, where Diamyd Medical's GABA-based study drug Remygen® is administered in combination with the GABA receptor modulator Alprazolam.

## **Meta-analysis updated with DIAGNODE-2 results provided further support for a precision medicine approach using Diamyd®**

The large-scale meta-analysis, previously published in August 2020, based on data from Phase III and Phase II trials in Europe and in the United States with the type 1 diabetes vaccine Diamyd® (GAD/alum), was updated with data from the European Phase IIb trial DIAGNODE-2. The meta-analysis comprises data from 627 individual patients and provided further support for a positive and statistically significant dose-dependent treatment response on the preservation of endogenous insulin production in individuals with type 1 diabetes that carry the HLA DR3-DQ2 haplotype.

## **Immunological analysis of Phase IIb trial with Diamyd® showed differences between genetically defined patient groups**

The first immunological results from DIAGNODE-2 showed that the immune response differed significantly between genetically defined patient groups for several immunological parameters following treatment with the diabetes vaccine Diamyd® (GAD-alum). The results were in line with the earlier observed difference in clinical response (announced in September 2020) between individuals positive or negative for HLA type DR3-DQ2.

## **Diamyd Medical and Critical Path Institute announced data sharing collaboration to develop advanced drug development tools in type 1 diabetes**

Diamyd Medical and the Critical Path Institute (C-Path) announced their collaboration to significantly improve the scientific community's insight into type 1 diabetes (T1D) through Diamyd Medical's contribution of fully anonymized data from a European Phase III trial to the Trial Outcome Measures Initiative (TOMI) T1D integrated database.

## **Diamyd Medical with MainlyAI and KTH were awarded VINNOVA funding for AI driven sustainable production**

The project will design, test and build a sustainability framework powered by artificial intelligence (AI) for Diamyd Medical's production facility in Umeå, Sweden.

## **Diamyd Medical received additional USD 3.2 million in connection with divestment of Companion Medical**

A milestone was achieved in connection with the acquisition of Companion Medical, Inc. by Medtronic plc. As previous shareholder in Companion Medical, Diamyd Medical received a part of the milestone payment, approximately USD 3.2 million, corresponding to approximately SEK 28 million.

# Significant events after the reporting period

## **Diamyd Medical selected Cytiva's FlexFactory platform to make precision medicine type 1 diabetes vaccine**

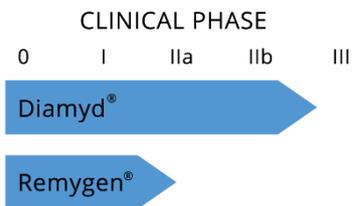
Diamyd Medical will install a new Cytiva FlexFactory platform in Umeå, Sweden. Once up and running, the clinical stage biopharmaceutical company will begin manufacturing its precision medicine vaccine. The first of its kind, the type 1 diabetes vaccine works to reprogram immune cells to prevent the destruction of pancreatic insulin producing beta cells.

### Phase III Precision Medicine trial with the Diabetes Vaccine Diamyd®

The upcoming Phase III trial with Diamyd® in new-onset type 1 diabetes will be based on the first precision medicine approach in the field. The trial is designed to confirm the effect and safety of Diamyd® in individuals recently diagnosed with type 1 diabetes who carry the genetic HLA DR3-DQ2 haplotype.

## Two drugs in clinical development

*Diamyd® and Remygen® are drugs in clinical development that focus on the underlying disease mechanisms of diabetes; the dysfunction and loss of insulin-producing beta cells in the pancreas.*



**Diamyd®** is an antigen-specific immunomodulating precision medicine diabetes vaccine for the treatment and prevention of autoimmune diabetes (type 1 diabetes and LADA, Latent Autoimmune Diabetes in Adults).

Clinical data indicate the potential of the diabetes vaccine Diamyd® to halt or stop the autoimmune destruction of insulin-producing beta cells in individuals that carry the HLA DR3-DQ2 haplotype. The effect is achieved by antigen-specific reprogramming of immune cells by administration of low doses of Diamyd® in superficial lymph nodes. By maintaining the endogenous insulin production, Diamyd® has the potential to make a significant difference in the daily life of patients as well significantly reduce the complications of type 1 diabetes. Topline results from the Phase IIb trial DIAGNODE-2 has demonstrated a significant treatment effect of Diamyd® in the predefined genetic patient group.

**Remygen®** is an oral regenerative and immunomodulatory drug candidate for the treatment of autoimmune- and type 2 diabetes. By stimulating the growth of insulin-producing cells, Remygen® has the potential to reverse the disease progression in autoimmune- and type 2 diabetes. Based on clinical data, Remygen® has also the potential to protect against hypoglycemia by improving the hormonal response. Remygen® is now being investigated in a clinical Phase I/II trial (ReGenerate-1), where clinical efficacy is evaluated with the aim of optimizing the treatment regimen ahead of registration-based trials.



## Ongoing clinical trials

Type 1 diabetes is a devastating disease which requires daily treatment with insulin to sustain life. The importance of finding a drug that improves the prospects for patients with diabetes is of utmost importance. The effect of intralymphatic administration of Diamyd®, an antigen-specific precision medicine immunotherapy aimed at stopping the immune system's attack on insulin-producing beta cells in autoimmune diabetes, is evaluated in the Phase IIb trial DIAGNODE-2 and in the Phase II trial GADinLADA.

Remygen®, which aims to stimulate the growth of beta cells in patients with diabetes, is evaluated in patients in a Phase I/II trial.

### Trials with Diamyd® in lymph node

- **DIAGNODE -2 - DIAMYD® IN LYMPH NODES WITH ORAL SUPPLEMENTATION OF VITAMIN D**

A follow-up double-blind randomized clinical trial where Diamyd® is administered directly into a lymph node with oral supplements of vitamin D. The trial encompasses 109 patients from Sweden, the Czech Republic, Spain and the Netherlands, aged 12-24 years who have recently been diagnosed with type 1 diabetes. The 15-month results were presented on September 14, 2020, demonstrating a significant treatment effect of Diamyd® in a predefined patient group. As of autumn 2019, patients who had not yet completed their last visit at 15 months were offered to participate in an extension of the trial for another 9 months. 53 patients agreed to participate in the extension trial and 15 of these patients have already been followed for 24 months. Results of this extended trial should be available in Q3 2021. Coordinating Investigator is Professor Johnny Ludvigsson at Linköping University, Sweden. Diamyd Medical is the Sponsor of the trial.

- **GADinLADA - DIAMYD® IN LYMPH NODES WITH ORAL SUPPLEMENTATION OF VITAMIN D**

An open-label, investigator initiated clinical trial where Diamyd® is administered directly into a lymph node with oral supplements of vitamin D. The trial, conducted in Norway and in Sweden, encompasses 15 patients aged 30-70 years diagnosed with LADA (Latent Autoimmune Diabetes in Adults) and not yet on insulin treatment. The aim with the trial is to evaluate the safety of intralymphatic treatment with Diamyd® in LADA patients and to continuously evaluate the immunological and clinical response during a one-year period. Sponsor of the trial is the Norwegian University of Science and Technology with Ingrid K Hals as sponsor representative.

### Trial with Remygen® (GABA)

- **REGENERATE-1 - REMYGEN®/ALPRAZOLAM**

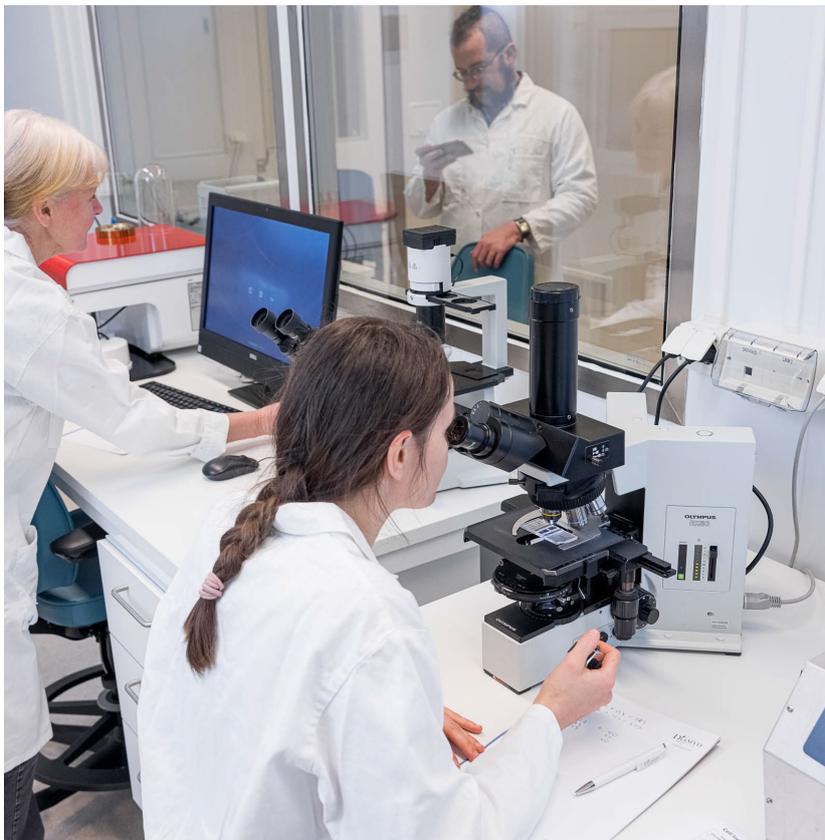
An open-label, investigator initiated clinical trial with Remygen®. The trial includes approximately 36 patients aged 18-50 who have had type 1 diabetes for more than five years with low to non-existing insulin production. Safety and initial efficacy results from the dose escalation section of the trial have paved the way to initiate the main trial and have also demonstrated a potential effect of Remygen® to improve the hormonal response to hypoglycemia. The main trial evaluates whether the insulin-producing cells can be regenerated and if the hormonal response to hypoglycaemia can be improved using Remygen® and the combination of Remygen® and Alprazolam. The trial is led by Professor Per-Ola Carlsson at Uppsala University, Sponsor of the trial.

# Manufacturing of GAD65 in Umeå

A new facility for vaccine manufacturing is being set up in Umeå, the Capital of Västerbotten County in Sweden, for the manufacture of recombinant GAD65, the active pharmaceutical ingredient in the therapeutic diabetes vaccine Diamyd® currently in late-stage clinical development. The 10 000 square feet site, comprising of clean rooms, laboratory facilities and office space, will facilitate full control, predictability and scalability of the manufacturing technology of the active ingredient. Diamyd Medical has chosen Cytiva's configurable single-use bioprocess manufacturing platform FlexFactory for the process.



*Site Manager Maja Johansson giving a guided tour to parts of the Company Board and Management at the production facility .*



*The site employs highly qualified specialists. Production scientists in action.*

## Key figures

|  | 3 months<br>Dec-Feb<br>2020/21 | 3 months<br>Dec-Feb<br>2019/20 | 6 months<br>Sep- Feb<br>2020/21 | 6 months<br>Sep-Feb<br>2019/20 | 12 months<br>Sep-Aug<br>2019/20 |
|--|--------------------------------|--------------------------------|---------------------------------|--------------------------------|---------------------------------|
| Research and development costs, MSEK               | -5.1                           | -3.0                           | -12.0                           | -5.7                           | -13.8                           |
| Solidity, %  | 95                             | 91                             | 95                              | 91                             | 81                              |
| Result per share, SEK                              | 0.2                            | 0.5                            | 1.7                             | 0.4                            | 0.1                             |
| Liquidity and short-term investment per share, SEK | 2.4                            | 1.3                            | 2.4                             | 1.3                            | 1.0                             |
| Equity per share, SEK                              | 2.8                            | 1.3                            | 2.8                             | 1.3                            | 1.0                             |
| Cash flow per share, SEK                           | -0.2                           | 0.5                            | 1.0                             | 0.7                            | 0.3                             |
| Share price per closing, SEK                       | 28.0                           | 14.6                           | 28.0                            | 14.6                           | 39.6                            |
| Number of shares per closing                       | 69 169 796                     | 69 169 796                     | 69 169 796                      | 69 169 796                     | 69 169 796                      |
| Average number of shares                           | 69 169 796                     | 69 169 796                     | 69 169 796                      | 69 169 796                     | 69 169 796                      |
| Average number of employees                        | 12                             | 7                              | 11                              | 7                              | 7                               |

## Income statement

| KSEK  | Note | 3 months<br>Dec-Feb<br>2020/21 | 3 months<br>Dec-Feb<br>2019/20 | 6 months<br>Sep-Feb<br>2020/21 | 6 months<br>Sep-Feb<br>2019/20 | 12 months<br>Sep-Aug<br>2019/20 |
|---|------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|
| <b>OPERATING INCOME</b>                                       |      |                                |                                |                                |                                |                                 |
| Net income  |      | 1                              | 48                             | 66                             | 166                            | 341                             |
| Other operating income  |      | 31                             | 749                            | 55                             | 762                            | 784                             |
| Other compensation and income                                 | 1    | 0                              | 43 174                         | -                              | 43 174                         | 43 174                          |
| <b>TOTAL OPERATING INCOME</b>                                 |      | <b>31</b>                      | <b>43 970</b>                  | <b>120</b>                     | <b>44 102</b>                  | <b>44 298</b>                   |
| <b>OPERATING EXPENSES</b>                                     |      |                                |                                |                                |                                |                                 |
| External research and development costs                       | 1    | -5 137                         | -2 991                         | -12 033                        | -5 725                         | -13 810                         |
| External patent- and license costs                            |      | -936                           | -552                           | -1 455                         | -995                           | -4 488                          |
| Personnel costs   | 2    | -3 654                         | -2 201                         | -7 029                         | -4 337                         | -9 195                          |
| Other external costs  | 2    | -2 043                         | -1 537                         | -4 025                         | -3 052                         | -6 858                          |
| Other operating expenses                                      |      | -74                            | -11                            | -102                           | -23                            | -59                             |
| Depreciation and impairment of material and immaterial assets |      | -184                           | -35                            | -342                           | -70                            | -149                            |
| <b>TOTAL OPERATING EXPENSES</b>                               |      | <b>-12 029</b>                 | <b>-7 326</b>                  | <b>-24 988</b>                 | <b>-14 202</b>                 | <b>-34 559</b>                  |
| <b>OPERATING RESULT</b>                                       |      | <b>-11 997</b>                 | <b>36 644</b>                  | <b>-24 867</b>                 | <b>29 900</b>                  | <b>9 739</b>                    |
| Net Financial income/expense                                  | 3    | 27 059                         | 484                            | 144 845                        | 445                            | -30                             |
| <b>RESULT BEFORE TAXES</b>                                    |      | <b>15 062</b>                  | <b>37 128</b>                  | <b>119 978</b>                 | <b>30 345</b>                  | <b>9 709</b>                    |
| Taxes   |      | -                              | -                              | -                              | -                              | -                               |
| <b>NET RESULT FOR THE PERIOD</b>                              |      | <b>15 062</b>                  | <b>37 128</b>                  | <b>119 978</b>                 | <b>30 345</b>                  | <b>9 709</b>                    |

# Balance sheet

| KSEK                                 | Note | 28 Feb<br>2021 | 29 Feb<br>2020 | 31 Aug<br>2020 |
|--------------------------------------|------|----------------|----------------|----------------|
| <b>ASSETS</b>                        |      |                |                |                |
| NON-CURRENT ASSETS                   |      |                |                |                |
| Intangible assets                    |      | 135            | 275            | 205            |
| Tangible assets                      |      | 4 061          | -              | 1 970          |
| Financial assets                     | 4    | 31 646         | 11 979         | 15 196         |
| <b>TOTAL NON-CURRENT ASSETS</b>      |      | <b>35 842</b>  | <b>12 253</b>  | <b>17 370</b>  |
| CURRENT ASSETS                       |      |                |                |                |
| Trade receivables                    |      | 91             | 55             | 79             |
| Other receivables                    |      | 1 352          | 1 443          | 3 594          |
| Prepaid expenses and accrued income  |      | 678            | 469            | 358            |
| Short term investments               |      | 40 001         | -              | 9 995          |
| Liquid assets                        |      | 125 446        | 88 273         | 58 367         |
| <b>TOTAL CURRENT ASSETS</b>          |      | <b>167 569</b> | <b>90 239</b>  | <b>72 394</b>  |
| <b>TOTAL ASSETS</b>                  |      | <b>203 411</b> | <b>102 493</b> | <b>89 764</b>  |
| <b>EQUITY AND LIABILITIES</b>        |      |                |                |                |
| EQUITY                               |      |                |                |                |
| <i>Restricted equity</i>             |      |                |                |                |
| Share capital                        |      | 7 015          | 7 015          | 7 015          |
| Statutory reserve                    |      | 200            | 200            | 200            |
| <i>Non-restricted equity</i>         |      |                |                |                |
| Share premium reserve non-restricted |      | 192 414        | 192 414        | 192 414        |
| Profit or loss brought forward       |      | -127 141       | -136 850       | -136 850       |
| Net result for the period            | 1    | 119 978        | 30 345         | 9 709          |
| <b>TOTAL EQUITY</b>                  |      | <b>192 467</b> | <b>93 125</b>  | <b>72 489</b>  |
| PROVISIONS                           |      |                |                |                |
| Pensions and other obligations       |      | 777            | 777            | 777            |
| Other provisions                     |      | -              | -              | -              |
| <b>TOTAL PROVISIONS</b>              |      | <b>777</b>     | <b>777</b>     | <b>777</b>     |
| CURRENT LIABILITIES                  |      |                |                |                |
| Trade payables                       |      | 3 854          | 1 363          | 7 254          |
| Other payables                       |      | 969            | 271            | 699            |
| Prepaid income and accrued expenses  |      | 5 343          | 6 956          | 8 544          |
| <b>TOTAL CURRENT LIABILITIES</b>     |      | <b>10 166</b>  | <b>8 590</b>   | <b>16 497</b>  |
| <b>TOTAL EQUITY AND LIABILITIES</b>  |      | <b>203 411</b> | <b>102 493</b> | <b>89 764</b>  |

# Statement of cash flow

| KSEK   | Note | 3 months<br>Dec-Feb<br>2020/21 | 3 months<br>Dec-Feb<br>2019/20 | 6 months<br>Sep-Feb<br>2020/21 | 6 months<br>Sep-Feb<br>2019/20 | 12 months<br>Sep-Aug<br>2019/20 |
|--|------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|
| <b>OPERATING ACTIVITIES</b>  |      |                                |                                |                                |                                |                                 |
| Operating profit/loss  | 1    | -11 997                        | 36 644                         | -24 867                        | 29 900                         | 9 739                           |
| Interest received  |      | 1                              | 2                              | 2                              | 2                              | 31                              |
| Interest paid  |      | -13                            | -8                             | -22                            | -26                            | -26                             |
| <i>Non-cash flow items</i>   |      |                                |                                |                                |                                |                                 |
| Depreciation   |      | 184                            | 35                             | 342                            | 70                             | 149                             |
| Other non-cash flow items  |      | 44                             | 0                              | 47                             | 0                              | -                               |
| <b>CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL</b> |      | <b>-11 782</b>                 | <b>36 673</b>                  | <b>-24 497</b>                 | <b>29 946</b>                  | <b>9 893</b>                    |
| Increase (-) decrease (+) receivables  |      | -446                           | 1 444                          | 1 910                          | 3 199                          | 1 134                           |
| Increase (+) decrease (-) debts  |      | -2 629                         | -918                           | -6 331                         | -2 054                         | 5 853                           |
| <b>NET CASH FLOW FROM OPERATING ACTIVITIES</b>                               |      | <b>-14 857</b>                 | <b>37 199</b>                  | <b>-28 918</b>                 | <b>31 090</b>                  | <b>16 880</b>                   |
| <b>INVESTING ACTIVITIES</b>  |      |                                |                                |                                |                                |                                 |
| Investment in material and immaterial assets                                 |      | -508                           | -                              | -2 364                         | -                              | -1 979                          |
| Investment in financial assets   | 4    | -19 277                        | -                              | -19 277                        | -                              | -3 217                          |
| Divestment of financial assets   | 3    | -                              | -                              | 2 827                          | -                              | -                               |
| Gain sold financial asset  |      | 27 454                         | -                              | 144 414                        | -                              | 40 001                          |
| Investment in short term investments   |      | -9 997                         | -                              | -30 006                        | 20 012                         | -29 984                         |
| <b>NET CASH FLOW FROM INVESTING ACTIVITIES</b>                               |      | <b>-2 329</b>                  | <b>-</b>                       | <b>95 593</b>                  | <b>20 012</b>                  | <b>4 821</b>                    |
| <b>TOTAL CASH FLOW FOR THE PERIOD</b>  |      | <b>-17 186</b>                 | <b>37 199</b>                  | <b>66 675</b>                  | <b>51 102</b>                  | <b>21 701</b>                   |
| Cash and cash equivalents at beginning of period                             |      | 143 058                        | 50 584                         | 58 367                         | 36 702                         | 36 702                          |
| Net foreign exchange difference  |      | -426                           | 490                            | 404                            | 469                            | -35                             |
| <b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>                            |      | <b>125 446</b>                 | <b>88 273</b>                  | <b>125 446</b>                 | <b>88 273</b>                  | <b>58 367</b>                   |

# Statement of changes in equity

| KSEK                              | Share Capital | Statutory Reserve | Share premium reserve non restricted | Other non-restricted equity | Total Shareholders' equity |
|-----------------------------------|---------------|-------------------|--------------------------------------|-----------------------------|----------------------------|
| OPENING BALANCE SEPTEMBER 1, 2019 | 7 015         | 200               | 192 414                              | -136 851                    | 62 780                     |
| Net result                        | -             | -                 | -                                    | 9 709                       | 9 709                      |
| CLOSING BALANCE AUGUST 31, 2020   | 7 015         | 200               | 192 414                              | -127 140                    | 72 489                     |
| OPENING BALANCE SEPTEMBER 1, 2020 | 7 015         | 200               | 192 414                              | -127 140                    | 72 489                     |
| Net result                        | -             | -                 | -                                    | 119 978                     | 119 978                    |
| CLOSING BALANCE FEBRUARY 28, 2021 | 7 015         | 200               | 192 414                              | -7 162                      | 192 467                    |

## Notes

### Accounting principles

Interim and annual reports are prepared with the application of the Annual Accounts Act and the Swedish Accounting Standards Board BFNAR 2012: 1 Annual Report and Consolidated accounts (K3).

### Note 1 – Other compensation and income, research and development costs

During the previous financial year, MUSD 4.5 was received from Protein Sciences Corporation as support for transition of the manufacturing process, which affected operating income by corresponding MSEK 43.2.

### Note 2 – Related-party transactions

During the period companies represented by immediate family members of the main owner and Board member Anders Essen-Möller were contracted as consultants. Total compensation for consultancy services and salaries to immediate family members amounted to KSEK 389 (381). As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 463 (463). Board member Mark Atkinson has been compensated for consultancy services by KSEK 105 (-). Pricing has been set by the arm's length principle.

| KSEK  | Sep-Feb<br>2020/21 | Sep-Feb<br>2019/20 |
|---|--------------------|--------------------|
| Consultant fees and salaries to related parties | 389                | 381                |
| Consultant fees to Board members                | 568                | 463                |

### Note 3 – Net financial income/expense/ divestment of financial assets

The increase compared to previous year is a one-off effect due to profit, including exchange rate effect, of corresponding 144.4 SEK from the divestment of shares in Companion Medical, Inc.

### Note 4 – Financial assets

Diamyd Medical owns shares in NextCell Pharma AB (corporate registration no 556965-8361) who develops stem cell therapies and operates a stem cell bank for private family saving of stem cells. The registered office is in Huddinge, Stockholm County. During the period, Diamyd Medical invested its pro rata share, MSEK 19.3, in a rights issue in NextCell Pharma. As of February 28, 2021, the carrying amount was approximately MSEK 31.0. Diamyd Medical's share of the equity as well as share of the votes was as of the same date approximately 12.8 %.

## Risks

Diamyd Medical's operations are associated with risks related to inter alia, drug development, commercialization, financing, intellectual property, collaborations with partners, authority decisions, agreements, and key personnel. For a description of the Company's risks, please see the Annual Report for the fiscal year 2019/2020. No significant changes in the Company's risk assessment have occurred since the Annual Report was issued.

## Statement

The Board of Directors and the CEO certify that the interim report gives a fair overview of the business, position and profit or loss of the Company and describes the principal risks and uncertainties that face the Company.

This report has not been reviewed by the Company's auditors.

Stockholm, March 25, 2021

Erik Nerpin  
Chairman of the Board

Anders Essen-Möller  
Board member

Maria-Teresa Essen-Möller  
Board member

Torbjörn Bäckström  
Board Member

Mark A. Atkinson  
Board member

Ulf Hannelius  
President & CEO

## Financial Calendar

Quarterly Report 3

June 23, 2021

Year-end Report

October 6, 2021

The reports will be available from these above dates at [www.diamyd.com](http://www.diamyd.com)

# About Diamyd Medical

Diamyd Medical develops therapies for type 1 diabetes. The diabetes vaccine Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. Significant results have been shown in a genetically predefined patient group in a large-scale metastudy as well as in the Company's European Phase IIb trial DIAGNODE-2, where the diabetes vaccine was administered directly into a lymph node in children and young adults with newly diagnosed type 1 diabetes. A new facility for vaccine manufacturing is being set up in Umeå for the manufacture of recombinant GAD65, the active ingredient in the therapeutic diabetes vaccine Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® as a therapy for regeneration of endogenous insulin production and to improve hormonal response to hypoglycaemia. An investigator-initiated Remygen® trial in patients living with type 1 diabetes for more than five years is ongoing at Uppsala University Hospital. Diamyd Medical is one of the major shareholders in the stem cell company NextCell Pharma AB.

Diamyd Medical's B-share is traded on Nasdaq First North Growth Market under the ticker DMYD B. FNCA Sweden AB is the Company's Certified Adviser; phone: +46 8-528 00 399, e-mail: info@fnca.se. Further information is available on <https://www.diamyd.com>.

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