



## QUARTERLY REPORT 3

September 2021 – May 2022

Diamyd Medical AB (publ), Fiscal year 2021/2022



## Developing Precision Medicine Therapies for Type 1 Diabetes

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>

## September 1, 2021 – May 31, 2022

- Net result: MSEK -63.4 (87.3), third quarter: MSEK -17.1 (-32.7). The previous year includes a one-off effect of corresponding MSEK 144.4 from divestment of shares in Companion Medical, Inc.
- Result per share: SEK -0.8 (1.3), third quarter: SEK -0.2 (-0.5)
- Cash flow from operating activities: MSEK -50.7 (-50.4), third quarter: MSEK -35.7 (-21.4)
- Cash and cash equivalents at May 31, 2022: MSEK 192.8 (194.2)

### Other events during the third quarter

- Analysis of prevention trial with Diamyd® published in Journal of Immunology Research
- First patient enrolled in the Phase III trial DIAGNODE-3
- Principal owner transferred half of his holdings in Diamyd Medical to his children
- New meta-analysis with Diamyd® published in Diabetes, Obesity and Metabolism
- Diabetes prevention project coordinated by Diamyd Medical presented at scientific conference
- Investigator-initiated clinical trial to evaluate booster injection with Diamyd® started

### Other events after the third quarter

- Analysis supporting treatment with Diamyd® published in The Journal of Clinical Endocrinology & Metabolism



“The scientific rational and evidence supporting our therapeutic diabetes vaccine Diamyd® was further strengthened the past quarter with three articles published in peer-reviewed scientific journals.”

Ulf Hannelius, CEO

# Comments by CEO Ulf Hannelius

In May we reported a significant milestone as the first patient was randomized in the precision medicine trial DIAGNODE-3 with Diamyd®. Approximately 20 clinics in Europe have so far been initiated and additional clinics and countries in Europe are underway.

In parallel, we are working diligently with the FDA with the aim to offer this important trial also to clinics and patients in the United States. As we aim to recruit the approximately 330 individuals with recent onset Type 1 Diabetes carrying the genetic HLA DR3-DQ2 haplotype for DIAGNODE-3 over the course of two years, there should be time to work with the FDA to resolve any outstanding questions, however we do have readiness to perform the trial solely in Europe if required to keep recruitment timelines.

A “Booster trial” with Diamyd®, DIAGNODE-B, has started where approximately six individuals who have previously been treated with intralymphatic Diamyd® and carry the responder haplotype HLA DR3-DQ2, will receive an additional booster injection. The Sponsor is Linköping University, and results will build on our existing insights into boosters and give knowledge about how effect of Diamyd® is possibly further improved and/or prolonged as is often the case with vaccines.

The scientific rational and evidence supporting our therapeutic diabetes vaccine Diamyd® was further strengthened the past quarter with three articles published in peer-reviewed scientific journals. These publications highlight three important findings:

- 1) As published in Diabetes, Obesity and Metabolism, a largescale meta-analysis showed how the therapeutic effect of Diamyd® on endogenous insulin production measured as C-peptide associates with improved blood glucose measured as HbA1c. This is to our knowledge the first time this association has been shown for a disease modifying therapy in Type 1 Diabetes and importantly supports the current regulatory requirements regarding clinical efficacy in pivotal trials.
- 2) As published in Journal of Clinical Endocrinology & Metabolism, results based on continuous glucose monitoring showed how treatment with Diamyd® increases time in optimal glucose range, decreases time in hyperglycemia and decreases glycemic variability. These are important patient centric measures highlighted in several talks during the 82<sup>nd</sup> Scientific Sessions organized held earlier this month in New Orleans and organized by the American Diabetes Association earlier this month.
- 3) As published in the Journal of Immunology Research, treatment with Diamyd® in healthy children at risk for Type 1 Diabetes leads to a decrease in T-lymphocyte counts compared to placebo. This is the first report of the immune response following Diamyd® treatment in this population and supports our efforts as part of the ASSET project ([www.asset.healthcare](http://www.asset.healthcare)) to predict and prevent Type 1 Diabetes.

ASSET, an innovation milieu focusing on risk prediction, prevention, and national screening of Type 1 Diabetes, coordinated by Diamyd Medical and supported by the Swedish Innovation Agency VINNOVA, was also presented at the Scandinavian Society for the Study of Diabetes meeting in Reykjavik last month. With ASSET financing we look forward to starting the first ever “prevention trial” in individuals carrying at least two beta cell autoantibodies and the HLA DR3-DQ2 haplotype, in order to save these individuals from becoming insulin requiring (Stage-3 Type-1 Diabetes). We expect to announce the 12-month results from the GADinLADA trial lead by Norwegian University of Science and Technology late summer/early autumn. Our collaborators in Norway will present results at the upcoming international EASD conference in Stockholm in September this year, highlighting the importance of intervention in LADA.

We are proud to be strong both regarding our cash position as well about our ongoing value creating activities including the pivotal Diamyd® program; the vaccine manufacturing facility in Umeå; our second diabetes clinical asset Remygen®, and our investments in artificial intelligence and stem cells.

All this gives us strength to advance our mission to fundamentally change the therapeutic landscape of Type 1 Diabetes.

Stockholm, June 22, 2022

Ulf Hannelius, *President and CEO*

## Other events during the third quarter

March 1, 2022 – May 31, 2022

### **Immunological analysis of prevention trial with Diamyd® was published in peer-reviewed scientific journal**

Results of an analysis of a previous prevention trial with Diamyd® (GAD-alum) treatment, which indicate a positive and sustained immunomodulating effect after treatment with Diamyd® in healthy children at risk for Type 1 Diabetes, have been published in Journal of Immunology Research.

### **The first patient was enrolled in Diamyd Medical's Phase III trial DIAGNODE-3**

The first patient received its first intralymphatic injection of Diamyd® in the precision medicine Phase III trial DIAGNODE-3. The trial will include approximately 330 patients aged 12 to 29 years newly diagnosed with Type 1 Diabetes who carry the genetically defined haplotype HLA DR3-DQ2.

### **Diamyd Medical's principal owner transferred half of his holdings in Diamyd Medical to his children**

Anders Essen-Möller notified the Swedish Financial Supervisory Authority of the sale of 4,500,000 Diamyd Medical shares in the form of gifts. Essen-Möller's five children each received 400,000 Class A shares and 500,000 Class B shares.

### **New meta-analysis with Diamyd® was published in peer-reviewed scientific journal**

An update of a large-scale meta-analysis supporting the efficacy of the therapeutic diabetes vaccine Diamyd® in individuals recently diagnosed with Type 1 Diabetes carrying the genetic HLA DR3-DQ2 haplotype was published in the peer-reviewed scientific journal Diabetes, Obesity and Metabolism. The analysis shows that treatment effect with Diamyd® on the preservation of endogenous insulin production measured as C-peptide is associated with a beneficial treatment effect on blood glucose measured as HbA1c.

### **Diabetes prevention project coordinated by Diamyd Medical was presented at a scientific conference**

The ASSET (AI for Sustainable Prevention of Autoimmunity in the Society) innovation milieu for the development of improved prevention strategies in Type 1 Diabetes, funded by the Swedish innovation agency VINNOVA was presented by CEO Ulf Hannelius at the Annual Meeting of the Scandinavian Society for the Study of Diabetes (SSSD), in Reykjavík in May.

### **New clinical trial will evaluate an additional injection (booster) with Diamyd®**

A new investigator-initiated clinical trial, DIAGNODE-B, started. The trial will evaluate the safety, impact on the immune system and the clinical efficacy of an additional injection with the antigen-specific immunotherapy Diamyd®. The trial has been approved by the Swedish Medical Products Agency and the Ethical Review Authority and will be offered to approximately 6 patients from the previous trials DIAGNODE-1 and DIAGNODE-2.

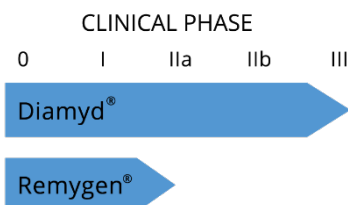
## Other events after the third quarter

### **Analysis supporting treatment with Diamyd® published in peer-reviewed scientific journal**

An article presenting analyses of Continuous Glucose Monitoring (CGM) data from the randomized, placebo-controlled Phase 2b trial DIAGNODE-2 that assessed three intralymphatic injections of the therapeutic diabetes vaccine Diamyd®, has been published in the peer-reviewed scientific journal The Journal of Clinical Endocrinology & Metabolism (JCEM).

## 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 demonstrated a significant treatment effect of Diamyd® in the predefined genetic patient group. A confirming Phase III trial, DIAGNODE-3, is on-going.

**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.





# 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, are evaluated in the Phase III trial DIAGNODE-3, in the Phase II trial GADinLADA and in the Phase I/II trial DIAGNODE-B.

Remygen®, which aims to stimulate the growth of beta cells in patients with diabetes, is evaluated in patients in the Phase I/II trial ReGenerate-1.

## Ongoing clinical trials

### Trials with Diamyd® in lymph node

- **DIAGNODE-3 - DIAMYD® IN LYMPH NODES WITH ORAL SUPPLEMENTATION OF VITAMIN D**

The placebo-controlled Phase III trial DIAGNODE-3 will include approximately 330 individuals aged 12 to 28 who have been recently diagnosed with type 1 diabetes and who carry the genetically defined haplotype HLA DR3-DQ2. The trial will be conducted at approximately 50 clinics, where almost half of all individuals with Type 1 Diabetes are estimated to carry the current haplotype. After an initial month in which all trial participants receive vitamin D, the individuals will be randomized 2:1, ie two out of three trial participants will receive three intralymphatic injections of Diamyd® and one in three will receive the corresponding placebo at one month intervals, with one primary reading 24 months after trial start. The design provides, based on efficacy data from previous studies on the HLA-restricted patient population, a high probability of reaching the primary endpoints; preservation of stimulated C-peptide and lower HbA1c. The Coordinating Investigator for the trial is Professor Johnny Ludvigsson at Linköping University. The Sponsor of the trial is Diamyd Medical.

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

The main aim of the trial is to evaluate the safety of intralymphatic treatment with Diamyd® in patients with LADA (Latent Autoimmune Diabetes in Adults). The patients have been recruited in Norway at the Norwegian University of Science and Technology (NTNU) in Trondheim, in collaboration with St. Olavs Hospital, University Hospital in Trondheim, and in Sweden at the Center for Diabetes, Akademiskt specialistcentrum, an academic specialist unit run in collaboration between Stockholm County's healthcare area, Karolinska Institutet and Karolinska University Hospital. The patients included in the trial are between 30 and 70 years old, have been diagnosed with LADA within the last 18 months and are not yet on insulin therapy. The Sponsor of the trial is the NTNU with Ingrid K Hals as Sponsor's representative. Diamyd Medical contributes with study drugs, expertise and some financial support for immunological analyzes and determination of HLA haplotypes. 12-month results are expected later in 2022.

- **DIAGNODE-B - ADDITIONAL INJECTION OF DIAMYD® IN LYMPH NODES**

The aim of the trial is to evaluate the safety of a booster (fourth/fifth) injection with Diamyd® and the effect on the immune system and the endogenous insulin production. DIAGNODE-B is an open-label investigator-initiated clinical trial enrolling Type 1 Diabetes patients who carry the genetically defined haplotype HLA DR3-DQ2 and are previously treated with intralymphatic injections of Diamyd®. The trial is planned to include approximately 6 patients who have either been treated with four injections in DIAGNODE-1, who will then receive a 5th intralymphatic injection of Diamyd®, or patients who participated in DIAGNODE-2, who will receive a 4th intralymphatic injection of Diamyd®, approximately 4 years after the last injection. The patients will be followed for 12 months after injection. The trial is conducted at the Clinical Research Unit at the University Hospital in Linköping. Sponsor of the trial is Linköping University with Professor Johnny Ludvigsson as Sponsor's representative.

### Trial with Remygen® (GABA)

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

An open-label, investigator initiated clinical trial with Remygen®. The trial includes 35 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. Results are expected in the first quarter of 2023.

## 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. Small-scale experimental production of GAD65 is now established at the manufacturing facility. Large-scale production is being set up primarily using Cytiva equipment. The property where the manufacturing is being established is owned by Diamyd Medical.



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

## Key figures

	3 months Mar-May 2021/22	3 months Mar-May 2020/21	9 months Sep-May 2021/22	9 months Sep-May 2020/21	12 months Sep-Aug 2020/21
Research and development costs, MSEK	-7.4	-24.1	-47.5	-36.2	-56.9
Liquid assets and short-term investments	192.8	194.2	192.8	194.2	139.4
Solidity, %	92	91	92	91	94
Result per share, before and after dilution, SEK	-0.2	-0.5	-0.8	1.3	0.9
Liquidity and short-term investment per share, SEK	2.5	2.7	2.5	2.7	1.9
Equity per share, SEK	3.5	3.0	3.5	3.0	2.6
Total Cash flow per share, SEK	-0.7	0.4	0.2	1.4	1.2
Share price per closing, SEK	18.9	31.7	18.9	31.7	39.6
Number of shares per closing	76 926 939	71 569 796	76 926 939	71 569 796	71 569 796
Average number of shares	76 926 939	69 169 796	76 127 807	69 169 796	69 794 454
Average number of employees	19	15	19	12	14

## Consolidated statement of comprehensive income

KSEK	Note	3 months Mar-May 2021/22	3 months Mar-May 2020/21	9 months Sep-May 2021/22	9 months Sep-May 2020/21	12 months Sep-Aug 2020/21
<b>OPERATING INCOME</b>						
Net income		374	137	338	202	253
Other operating income		647	20	1 073	75	191
<b>TOTAL OPERATING INCOME</b>		<b>1 020</b>	<b>157</b>	<b>1 411</b>	<b>277</b>	<b>444</b>
<b>OPERATING EXPENSES</b>						
External research and development costs		-7 446	-24 124	-47 532	-36 173	-56 860
External patent- and license costs		-1 386	-633	-3 672	-2 089	-2 501
Personnel costs		-5 454	-4 994	-14 628	-12 023	-16 174
Other external costs	2	-2 700	-2 641	-7 177	-6 663	-9 457
Other operating expenses		-611	-85	-874	-187	-551
Depreciation and impairment of material and immaterial assets		-991	-332	-2 265	-674	-782
<b>TOTAL OPERATING EXPENSES</b>		<b>-18 588</b>	<b>-32 809</b>	<b>-76 149</b>	<b>-57 810</b>	<b>-86 324</b>
<b>OPERATING RESULT</b>		<b>-17 568</b>	<b>-32 652</b>	<b>-74 738</b>	<b>-57 532</b>	<b>-85 880</b>
Net Financial income/expense	3	466	-21	11 326	144 825	145 925
<b>RESULT BEFORE TAXES</b>		<b>-17 102</b>	<b>-32 672</b>	<b>-63 411</b>	<b>87 293</b>	<b>60 046</b>
Taxes		-	-	-	-	-
<b>NET RESULT FOR THE PERIOD</b>		<b>-17 102</b>	<b>-32 672</b>	<b>-63 411</b>	<b>87 293</b>	<b>60 046</b>

*The Group was formed on October 31, 2021, in connection with Diamyd Medical AB's acquisition of Diamyd Properties AB. The first two months of the financial year therefore include only amounts relating to the parent company. The comparison periods refer to the parent company.*



# Consolidated balance sheet

KSEK	Note	31 May 2022	31 May 2021	31 Aug 2021
<b>ASSETS</b>				
NON-CURRENT ASSETS				
Intangible assets		-	100	65
Tangible assets	4	50 688	9 138	5 553
Financial assets	5	34 703	32 846	32 846
<b>TOTAL NON-CURRENT ASSETS</b>		<b>85 391</b>	<b>42 084</b>	<b>38 464</b>
CURRENT ASSETS				
Trade receivables		255	159	51
Other receivables		1 860	1 584	1 594
Prepaid expenses and accrued income		11 096	542	21 953
Short term investments		39 943	40 008	-
Liquid assets		152 866	154 186	139 376
<b>TOTAL CURRENT ASSETS</b>		<b>206 020</b>	<b>196 480</b>	<b>162 974</b>
<b>TOTAL ASSETS</b>		<b>291 411</b>	<b>238 564</b>	<b>201 438</b>
<b>EQUITY AND LIABILITIES</b>				
EQUITY				
<i>Restricted equity</i>				
Share capital		7 802	7 259	7 259
Statutory reserve		200	200	200
<i>Non-restricted equity</i>				
Share premium reserve non-restricted		390 507	248 998	248 895
Profit or loss brought forward		-67 100	-127 141	-127 141
Net result for the period		-63 411	87 293	60 046
<b>TOTAL EQUITY</b>		<b>268 003</b>	<b>216 608</b>	<b>189 258</b>
PROVISIONS				
Provisions		777	777	777
<b>TOTAL PROVISIONS</b>		<b>777</b>	<b>777</b>	<b>777</b>
CURRENT LIABILITIES				
Trade payables		9 981	2 680	5 572
Other payables		7 246	649	1 039
Prepaid income and accrued expenses		5 404	17 850	4 792
<b>TOTAL CURRENT LIABILITIES</b>		<b>22 630</b>	<b>21 179</b>	<b>11 402</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>291 411</b>	<b>238 564</b>	<b>201 438</b>

*The Group was formed on October 31, 2021, in connection with Dianyd Medical AB's acquisition of Dianyd Properties AB. The first two months of the financial year therefore include only amounts relating to the parent company. The comparison periods refer to the parent company.*

# Consolidated statement of cash flow

KSEK	Note	3 months Mar-May 2021/22	3 months Mar-May 2020/21	9 months Sep-May 2021/22	9 months Sep-May 2020/21	12 months Sep-Aug 2020/21
<b>OPERATING ACTIVITIES</b>						
Operating profit/loss		-17 568	-32 652	-74 738	-57 532	-85 880
Interest received		11	1	11	3	0
Interest paid		-59	-17	-238	-39	-71
<i>Non-cash flow items</i>						
Depreciation		991	332	2 785	674	782
Other non-cash flow items		417	64	634	112	362
<b>CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL</b>		<b>-16 208</b>	<b>-32 272</b>	<b>-71 546</b>	<b>-56 782</b>	<b>-84 806</b>
Increase (-) decrease (+) receivables		-4 950	-164	10 605	1 746	-19 566
Increase (+) decrease (-) debts		-14 539	10 999	10 277	4 681	-5 095
<b>NET CASH FLOW FROM OPERATING ACTIVITIES</b>		<b>-35 697</b>	<b>-21 437</b>	<b>-50 664</b>	<b>-50 355</b>	<b>-109 468</b>
<b>INVESTING ACTIVITIES</b>						
Investment in material assets		-397	-5 374	-46 595	-7 738	-4 225
Investment in financial assets		-	-1 200	-	-20 477	-20 477
Divestment of financial assets		-	-	-	2 827	2 827
Gain sold financial assets	3	-	-	6 653	144 414	144 414
Investment in short term investments		-19 935	-7	-39 943	-30 013	9 995
<b>NET CASH FLOW FROM INVESTING ACTIVITIES</b>		<b>-20 332</b>	<b>-6 581</b>	<b>-79 886</b>	<b>89 012</b>	<b>132 533</b>
<b>FINANCING ACTIVITIES</b>						
New issue		-	60 000	150 000	60 000	60 000
Issue expense		-	-3 173	-7 845	-3 173	-3 276
<b>NET CASH FLOW FROM FINANCING ACTIVITIES</b>		<b>-</b>	<b>56 827</b>	<b>142 155</b>	<b>56 827</b>	<b>56 724</b>
<b>TOTAL CASH FLOW FOR THE PERIOD</b>		<b>-56 029</b>	<b>28 809</b>	<b>11 605</b>	<b>95 484</b>	<b>79 789</b>
Cash and cash equivalents at beginning of period		208 397	125 446	139 376	58 367	58 367
Net foreign exchange difference		498	-68	1 885	336	1 221
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>		<b>152 866</b>	<b>154 186</b>	<b>152 866</b>	<b>154 186</b>	<b>139 376</b>

*The Group was formed on October 31, 2021, in connection with Diamyd Medical AB's acquisition of Diamyd Properties AB. The first two months of the financial year therefore include only amounts relating to the parent company. The comparison periods refer to the parent company.*

# Consolidated statement of changes in equity

KSEK	Share Capital	Statutory Reserve	Share premium reserve non restricted	Other non- restricted equity	Total Shareholders' equity
<b>OPENING BALANCE SEPTEMBER 1, 2020</b>	7 015	200	192 414	-127 140	72 489
New net result	-	-		60 046	60 046
New issue	243	-	59 757	-	60 000
Issue expenses	-	-	-3 276	-	-3 276
<b>CLOSING BALANCE AUGUST 31, 2021</b>	7 259	200	248 895	-67 095	189 258
<b>OPENING BALANCE SEPTEMBER 1, 2021</b>	<b>7 259</b>	<b>200</b>	<b>248 895</b>	<b>-67 095</b>	<b>189 258</b>
Net result	-	-	-	-63 411	-63 411
New issue	543	-	149 457	-	150 000
Issue expenses	-	-	-7 845	-	-7 845
<b>CLOSING BALANCE MAY 31, 2022</b>	<b>7 802</b>	<b>200</b>	<b>390 507</b>	<b>-130 506</b>	<b>268 003</b>

# Income statement for the parent company

KSEK	Note	3 months Mar-May 2021/22	3 months Mar-May 2020/21	9 months Sep-May 2021/22	9 months Sep-May 2020/21	12 months Sep-Aug 2020/21
<b>OPERATING INCOME</b>						
Net income		268	137	339	202	253
Other operating income		570	20	616	75	191
<b>TOTAL OPERATING INCOME</b>		<b>838</b>	<b>157</b>	<b>955</b>	<b>277</b>	<b>444</b>
<b>OPERATING EXPENSES</b>						
External research and development costs		-7 447	-24 124	-47 532	-36 173	-56 860
External patent- and license costs		-1 386	-633	-3 672	-2 089	-2 501
Personnel costs		-5 454	-4 994	-14 628	-12 023	-16 174
Other external costs		-2 729	-2 641	-7 382	-6 663	-9 457
Other operating expenses		-611	-85	-874	-187	-551
Depreciation and impairment of material and immaterial assets		-831	-332	-2 043	-674	-782
<b>TOTAL OPERATING EXPENSES</b>		<b>-18 457</b>	<b>-32 809</b>	<b>-76 131</b>	<b>-57 810</b>	<b>-86 324</b>
<b>OPERATING RESULT</b>		<b>-17 619</b>	<b>-32 652</b>	<b>-75 177</b>	<b>-57 532</b>	<b>-85 880</b>
Net Financial income/expense	3	560	-21	11 700	144 825	145 925
<b>RESULT BEFORE TAXES</b>		<b>-17 059</b>	<b>-32 672</b>	<b>-63 477</b>	<b>87 293</b>	<b>60 046</b>
Taxes		-	-	-	-	-
<b>NET RESULT FOR THE PERIOD</b>		<b>-17 059</b>	<b>-32 672</b>	<b>-63 477</b>	<b>87 293</b>	<b>60 046</b>

# Balance sheet for the parent company

KSEK	31 May 2022	31 May 2021	31 Aug 2021
<b>ASSETS</b>			
NON-CURRENT ASSETS			
Intangible assets	-	100	65
Tangible assets	25 946	9 138	5 553
Shares in subsidiaries	14 900	-	-
Other financial assets	42 170	32 846	32 846
<b>TOTAL NON-CURRENT ASSETS</b>	<b>83 017</b>	<b>42 084</b>	<b>38 464</b>
CURRENT ASSETS			
Trade receivables	255	159	51
Other receivables	1 430	1 584	1 594
Prepaid expenses and accrued income	11 234	542	21 953
Short term investments	59 940	40 008	-
Liquid assets	131 855	154 186	139 376
<b>TOTAL CURRENT ASSETS</b>	<b>204 714</b>	<b>196 480</b>	<b>162 974</b>
<b>TOTAL ASSETS</b>	<b>287 731</b>	<b>238 564</b>	<b>201 438</b>
<b>EQUITY AND LIABILITIES</b>			
EQUITY			
<i>Restricted equity</i>			
Share capital	7 802	7 259	7 259
Statutory reserve	200	200	200
<i>Non-restricted equity</i>			
Share premium reserve non-restricted	390 507	248 998	248 895
Profit or loss brought forward	-67 095	-127 141	-127 141
Net result for the period	-63 477	87 293	60 046
<b>TOTAL EQUITY</b>	<b>267 937</b>	<b>216 608</b>	<b>189 258</b>
PROVISIONS			
Provisions	777	777	777
<b>TOTAL PROVISIONS</b>	<b>777</b>	<b>777</b>	<b>777</b>
CURRENT LIABILITIES			
Trade payables	9 710	2 680	5 572
Other payables	69	649	1 039
Prepaid income and accrued expenses	9 237	17 850	4 792
<b>TOTAL CURRENT LIABILITIES</b>	<b>19 016</b>	<b>21 179</b>	<b>11 402</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>287 731</b>	<b>238 564</b>	<b>201 438</b>



# Notes

## Note 1 – General information and accounting principles

This interim report includes the parent company Diamyd Medical AB (publ), Corp. Reg. No. 556242-3797 and the subsidiary Diamyd Properties AB, Corp. Reg. No. 559041-0931. Unless otherwise stated, all amounts are in thousands of Swedish kronor (KSEK). Figures for comparative periods previous financial year refer to the parent company.

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 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 1 023 (677). As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 694 (799). Board member Karin Hehenberger was compensated KSEK 100 for consultancy services. Pricing has been set by the arm's length principle.

KSEK	Sep-May 2021/22	Sep-May 2020/21
Consultant fees and salaries to related parties	1 023	677
Consultant fees to Board members	794	799

## Note 3 – Net financial income/expense

The previous financial year includes a one-off effect from profit of corresponding 144.4 from the divestment of shares in Companion Medical, Inc. An additional MSEK 6.6 were received this financial year. Exchange rate effects on cash held in EUR and USD has affected the result by MSEK 4.6.

## Note 4 – Material assets

KSEK	31 May 2022	31 Aug 2021
Opening cost	5 553	5 553
Purchases Inventory	22 656	4 225
Purchases property	26 341	-
Closing accumulated cost	54 551	7 343
Depreciation, period	-2 137	-632
Closing accumulated depreciation	-3 862	-1 790
Closing carrying amount	50 688	5 553

## Note 5 – Financial assets

Diamyd Medical AB 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. As of May 31, 2022, 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 12.5 %. Diamyd Medical holds 20 % of the shares in the artificial intelligence company Mainly AI AB (corporate registration no 559258-7358). As of May 31, 2022, the carrying amount was MSEK 1.2.

## Note 6 – Acquisition of property

During the financial year, Diamyd Medical AB acquired the property where Diamyd Medical establishes production of GAD65 in Umeå. The property purchase was made through the purchase of all shares in Mark & Schakt Fastigheter i Umeå AB and disclosed as asset acquisition. The company (corporate registration no 559041-0931) is changed to Diamyd Properties AB. The property was acquired for MSEK 24.5, whereby MSEK 14.9 constituted purchases of the shares and MSEK 9.6 million redemption of loans.

# 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 2020/2021. 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, June 22, 2022

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

Karin Hehenberger  
Board member

Ulf Hannelius  
President & CEO

# Financial Calendar

Year-end Report	October 5, 2022
Annual Report	November 10, 2022
Annual General Meeting	December 1, 2022

# About Diamyd Medical

Diamyd Medical develops precision medicine 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 large genetically predefined patient group in a large-scale meta-analysis 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 recently diagnosed type 1 diabetes. DIAGNODE-3, a confirmatory Phase III trial is on-going. A vaccine manufacturing facility 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 individuals 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 as well as in the artificial intelligence company MainlyAI 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](mailto:info@fnca.se). Further information is available on <https://www.diamyd.com>.

**For more information, please contact:**

Ulf Hannelius, President and CEO, phone: +46 736 35 42 41

Diamyd Medical AB (publ), Box 7349, SE-103 90 Stockholm, Sweden

Phone: +46 8 661 00 26 Fax: +46 8 661 63 68 E-mail: [info@diamyd.com](mailto:info@diamyd.com) Reg. no: 556242-3797

The information was submitted for publication, through the agency of the contact person set out above, at 08.15 CET on June 22, 2022.