



# QUARTERLY REPORT 1

September 2021 – November 2021

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>

*Figures in parentheses relate to the corresponding period (parent company) previous financial year.*

## September 1, 2021 – November 30, 2021

- Net result: MSEK -37.8 (104.9). The previous year contains a one-off effect of corresponding MSEK 117.5 from divestment of shares in Companion Medical, Inc.
- Result per share: SEK -0.5 (1.5)
- Cash flow from operating activities: MSEK 0 (-14.0)
- Cash and cash equivalents at November 30, 2021: MSEK 240.7 (173.0)

## Significant events during the first quarter, September 1, 2021–November 30, 2021

- Diamyd Medical paused start of Phase III trial pending additional evaluations of manufacturing process
- Diamyd Medical announced to initiate its type 1 diabetes Phase III trial in Europe as discussions continue with FDA regarding partial clinical hold in the US
- Diamyd Medical and partners were awarded SEK 40 million in VINNOVA funding
- First regulatory approval to start the Phase III trial was received
- Start of the Phase III trial in the US was paused pending clarification of FDA questions
- Property with manufacturing facility in Umeå was acquired
- SEK 150 million was raised via a directed share issue

## Other events during the first quarter

- Clinical results with Diamyd Medical's study drug Remygen® were published in a scientific journal
- A new analysis supporting the effect of Diamyd® was elected to be presented at the ISPAD scientific conference

## Significant events after the first quarter

- Interim report indicated similar immunological response in LADA-patients treated with intralymphatic Diamyd® as in type 1 diabetes patients

## Other events after the first quarter

- Diamyd Medical patent for intralymphatic Diamyd® to be granted in China
- Australia granted Diamyd Medical a broadening of patent for intralymphatic injection of antigens in autoimmune diabetes



“With all activities ongoing that further strengthen the foundation of Diamyd Medical, we are fortunate to have a strong financial position; more than SEK 200 million in cash as of today will carry us well into 2023.”

Ulf Hannelius, CEO

## Comments by CEO Ulf Hannelius

We are very much looking forward to the upcoming Phase III precision medicine trial DIAGNODE-3, approved so far by Competent Authorities and Ethical Review Boards in the Czech Republic, the Netherlands, Spain and Poland. To get started with the trial soon - and since we do not compromise on safety anywhere - we have been working hard to rule out that a potential contamination early in the process could in any way affect the drug product. Indeed, we have a safe and robust process that encompasses several purification steps designed to remove contaminants of this nature and additional analyses are ongoing with the goal of being able to initiate DIAGNODE-3 and other trials in the development pipeline soonest possible.

Our investment in the Umeå manufacturing facility is central to securing long-term access and control over our Diamyd® flagship asset. The experimental small-scale manufacturing process is in place and the large-scale process equipment have been installed. Next, the plan is to have the process in Umeå tested, validated and GMP certified later this year and to get the facility approved and production ready in the second calendar quarter of 2023.

It was rewarding to see the interim results in December from GADinLADA, the pilot trial in LADA evaluating intralymphatic injections of Diamyd®. No safety issues were observed, and the immune response appears similar to what has been observed in type 1 diabetes patients treated with Diamyd®. This is the first time this administration mode of Diamyd® is evaluated in individuals diagnosed with LADA, providing important additional support for the safety and convenience of the therapy in a new indication as well as data that support the use of intralymphatic administration in individuals that are up to 70 years of age. A more thorough analysis of the clinical course, immune response and next steps including a potential pivotal trial in LADA will be possible once we have the 12 months results from GADinLADA trial later during 2022.

The quarter has seen advances in our patent portfolio where the Chinese patent office recently informed that they will approve patent claims that protect the intralymphatic administration mode of Diamyd®. These key patent claims have already been approved among other countries, in Europe and Japan and provide protection until 2035. The Australian patent office also informed that they approve, as the first region, intralymphatic administration of other beta cell antigens beyond GAD, most importantly insulin. These broadened patent claims provide incentives to develop antigen specific therapies that complement GAD, which given the importance of precision medicine in type 1 diabetes, is of high interest. Insulin-based immunotherapies should likely be targeted to individuals that carry the HLA DR4-DQ8 haplotype while GAD-based therapies like Diamyd® will be targeted to individuals that carry the HLA DR3-DQ2 haplotype.

With all activities ongoing that further strengthen the foundation of Diamyd Medical, we are fortunate to have a strong financial position; more than SEK 200 million in cash as of today will carry us well into 2023. I would like to thank the team and collaborators for your hard work and enthusiasm and our shareholders for helping us breaking new ground.

Stockholm, January 26, 2022

Ulf Hannelius, *President and CEO*

# Significant events during the first quarter

## September 1 – November 30, 2021

### **Diamyd Medical paused start of Phase III trial pending additional evaluations of current manufacturing process**

Diamyd Medical decided to pause the start of the precision medicine Phase III trial DIAGNODE-3 with the diabetes vaccine Diamyd® (GAD/alum) in recent onset type 1 diabetes, as well as the initiation of other clinical trials with Diamyd® pending additional evaluations of the current manufacturing process. A new analysis has shown the potential presence of a contamination early in the manufacturing process of the drug substance (GAD65) used in the existing study drug. Diamyd Medical will evaluate its specific removal before additional clinical work is conducted. The potential contamination is not connected to the new manufacturing facility being established in Umeå.

### **Diamyd Medical announced to initiate its type 1 diabetes Phase III trial in Europe as discussions continue with FDA regarding partial clinical hold in the US**

The FDA requested additional data to support Diamyd Medical's IND application for DIAGNODE-3. Outstanding questions largely pertained to manufacturing of the study drug and needed to be addressed before FDA's partial clinical hold for the Phase III trial in the US can be lifted. Given the delay this may entail, Diamyd Medical announced commence its initiation of the Phase III trial in Europe, while interactions with the FDA continue.

### **Diamyd Medical and partners were awarded SEK 40 million from VINNOVA for the prevention of autoimmune diseases**

The Swedish governmental innovation agency VINNOVA awarded SEK 40 million in financing for an innovation milieu in sustainable precision health that will be led by Diamyd Medical. The project aims to develop and evaluate new algorithms based on artificial intelligence (AI) for preventive precision medical treatments for type 1 diabetes and other autoimmune diseases. The innovation milieu also includes Mainly AI AB, Lund University, Sahlgrenska University Hospital, the National Diabetes Register and the Leading Healthcare Foundation. Diamyd Medical's part of the five-year grant amounts to approximately SEK 18 million.

### **First regulatory approval received to start the DIAGNODE-3**

The Swedish Medical Products Agency gave approval for the start of DIAGNODE-3. The trial is designed to confirm the efficacy and safety of Diamyd® in individuals recently diagnosed with type 1 diabetes, who carry the genetically defined haplotype HLA DR3-DQ2.

### **FDA paused the start of DIAGNODE-3 in the US**

The start of DIAGNODE-3 in the United States was paused by the US Food and Drug Administration (FDA) to clarify certain outstanding questions regarding the study drug.

### **Acquisition of property with manufacturing facility in Umeå**

Diamyd Medical announced the acquisition of the property in Umeå, Sweden, where production of the recombinant protein GAD65, the active component in the therapeutic diabetes vaccine Diamyd® is being established. The property is acquired for a purchase price of SEK 24.5 million and comprises approximately 20 000 square feet including the 10 000 square feet Diamyd Medical AB rents, as well as 90 000 square feet of land area.

### **Proceeds of SEK 150 million were raised via a directed share issue**

A directed share issue of 5 357 143 B-shares at a price of SEK 28 per share was completed. Through the directed share issue, the Company received gross proceeds of SEK 150 million. The directed share issue was subscribed by qualified investors.

## Other events during the first quarter

### **Clinical results with Diamyd Medical's study drug Remygen® were published in a scientific journal**

The clinical results from the dose-escalation part of the investigator-initiated clinical Phase I/II trial ReGenerate-1 evaluating Remygen® (GABA) in individuals with long-standing type 1 diabetes, have been published in the scientific journal BMJ Open Diabetes & Care. The patent-pending findings showed, as previously announced, that Remygen® established a counter-regulatory response to severely reduced blood sugar levels (hypoglycemia), indicating its potential use as a hypoglycemia-preventing treatment.

**Analysis that supports the effect of the diabetes vaccine Diamyd® was presented at the ISPAD conference**

An analysis showing the effect of the diabetes vaccine Diamyd® (GAD-alum) in reducing the time a patient has high blood glucose, was presented at the ISPAD conference (The International Society of Pediatric and Adolescent Diabetes), by Professor Johnny Ludvigsson, Principal Investigator of the clinical trial DIAGNODE-2.

## Significant events after the first quarter

**Interim report indicated similar immunological response in LADA-patients treated with intralymphatic Diamyd® as in type 1 diabetes patients**

An initial interim report from the open-label investigator-initiated clinical trial GADinLADA, in which the diabetes vaccine Diamyd® is administered directly into the lymph node in 14 patients aged 30 to 70 years with the autoimmune form of diabetes called LADA (Latent Autoimmune Diabetes in Adults), showed that treatment after five months is safe and tolerable. Preliminary analyses indicated that the immunological response to the treatment is similar to what has been observed in individuals with type 1 diabetes treated with Diamyd®.

## Other events after the first quarter

**Patent for intralymphatic injection of GAD in autoimmune diabetes to be granted in China**

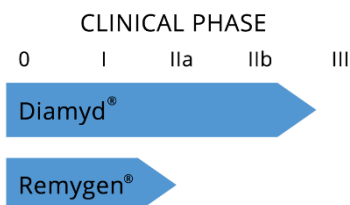
The patent that will be granted by the Chinese Patent Office is valid until 2035. The patent primarily protects the administration method of Diamyd® (GAD/alum) which has shown positive results in the Phase I/II and Phase IIb trials DIAGNODE-1 and DIAGNODE-2 and will be evaluated in the Phase III trial DIAGNODE-3.

**Australia granted as first region Diamyd Medical a broadening of a patent for intralymphatic injection of antigens in autoimmune diabetes**

The patent covers intralymphatic injection of beta cell antigens including insulin for the treatment and prevention of autoimmune diabetes. The approval is a division of the patent application previously approved in Australia on intralymphatic injection of GAD, the active component in the diabetes vaccine Diamyd® that Diamyd Medical is developing for type 1 diabetes and Latent Autoimmune Diabetes in Adults (LADA).

## 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.

**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, will be evaluated in the Phase III trial DIAGNODE-3 and is evaluated 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.

## Upcoming clinical trial

### Trial 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.

## Ongoing clinical trials

### Trial with Diamyd® in lymph node

- **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 Norwegian University of Science and Technology 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.

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



## Key figures

	3 months Sep-Nov 2021	3 months Sep-Nov 2020	12 months Sep-Aug 2020/21
Research and development costs, MSEK	-31.3	-6.9	-56.9
Liquid assets and short-term investments	240.7	173.0	139.4
Solidity, %	79	88	94
Result per share, before and after dilution, SEK	-0.5	1.5	0.9
Liquidity and short-term investment per share, SEK	3.4	2.5	1.9
Equity per share, SEK	4.1	2.6	2.6
Total Cash flow per share, SEK	1.1	1.2	1.2
Share price per closing, SEK	11.6	32.2	33.7
Number of shares per closing	76 926 939	69 169 796	71 569 796
Average number of shares	72 105 510	69 169 796	69 794 454
Average number of employees	19	10	14

## Consolidated statement of comprehensive income

KSEK	Note	3 months Sep-Nov 2021	3 months Sep-Nov 2020	12 months Sep-Aug 2020/21
OPERATING INCOME				
Net income		31	81	253
Other operating income		103	0	191
Other compensation and income		-	24	0
<b>TOTAL OPERATING INCOME</b>		<b>134</b>	<b>106</b>	<b>444</b>
OPERATING EXPENSES				
External research and development costs		-31 265	-6 897	-56 860
External patent- and license costs		-724	-519	-2 501
Personnel costs		-4 373	-3 375	-16 174
Other external costs		-2 363	-1 999	-9 457
Other operating expenses		-170	-27	-551
Depreciation and impairment of material and immaterial assets		-450	-158	-782
<b>TOTAL OPERATING EXPENSES</b>		<b>-39 345</b>	<b>-12 976</b>	<b>-86 324</b>
<b>OPERATING RESULT</b>		<b>-39 211</b>	<b>-12 870</b>	<b>-85 880</b>
Net Financial income/expense	3	1 444	117 786	145 925
<b>RESULT BEFORE TAXES</b>		<b>-37 768</b>	<b>104 916</b>	<b>60 046</b>
Taxes		-	-	-
<b>NET RESULT FOR THE PERIOD</b>		<b>-37 768</b>	<b>104 916</b>	<b>60 046</b>

# Consolidated balance sheet

KSEK	Note	30 Nov 2021	30 Nov 2020	31 Aug 2021
<b>ASSETS</b>				
NON-CURRENT ASSETS				
Intangible assets		30	170	65
Tangible assets		48 105	3 702	5 553
Financial assets	4	34 703	12 368	32 846
<b>TOTAL NON-CURRENT ASSETS</b>		<b>82 838</b>	<b>16 241</b>	<b>38 464</b>
CURRENT ASSETS				
Trade receivables		24	93	51
Other receivables		4 187	1 219	1 594
Prepaid expenses and accrued income		4 459	363	21 953
Short term investments		20 004	30 004	-
Liquid assets		220 654	143 058	139 376
<b>TOTAL CURRENT ASSETS</b>		<b>249 328</b>	<b>174 737</b>	<b>162 974</b>
<b>TOTAL ASSETS</b>		<b>332 166</b>	<b>190 977</b>	<b>201 438</b>
<b>EQUITY AND LIABILITIES</b>				
EQUITY				
<i>Restricted equity</i>				
Share capital		7 802	7 015	7 259
Statutory reserve		200	200	200
<i>Non-restricted equity</i>				
Share premium reserve non-restricted		390 507	192 414	248 895
Profit or loss brought forward		-67 095	-127 141	-127 141
Net result for the period		-37 767	104 916	60 046
<b>TOTAL EQUITY</b>		<b>293 646</b>	<b>177 405</b>	<b>189 258</b>
PROVISIONS				
Pensions and other obligations		2 514	777	777
<b>TOTAL PROVISIONS</b>		<b>2 514</b>	<b>777</b>	<b>777</b>
CURRENT LIABILITIES				
Trade payables		14 660	3 213	5 572
Other payables		3 144	836	1 039
Prepaid income and accrued expenses		18 202	8 746	4 792
<b>TOTAL CURRENT LIABILITIES</b>		<b>36 006</b>	<b>12 795</b>	<b>11 402</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>332 166</b>	<b>190 977</b>	<b>201 438</b>

# Consolidated statement of cash flow

KSEK	Note	3 months Sep-Nov 2021	3 months Sep-Nov 2020	12 months Sep-Aug 2020/21
<b>OPERATING ACTIVITIES</b>				
Operating profit/loss		-39 232	-12 870	-85 880
Interest received		25	1	0
Interest paid		-71	-8	-71
<i>Non-cash flow items</i>				
Depreciation		450	158	782
Other non-cash flow items		-137	3	362
<b>CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL</b>		<b>-38 966</b>	<b>-12 715</b>	<b>-84 806</b>
Increase (-) decrease (+) receivables		16 694	2 357	-19 566
Increase (+) decrease (-) debts		22 293	-3 702	-5 095
<b>NET CASH FLOW FROM OPERATING ACTIVITIES</b>		<b>21</b>	<b>-14 061</b>	<b>-109 468</b>
<b>INVESTING ACTIVITIES</b>				
Investment in material assets		-42 546	-1 856	-4 225
Investment in financial assets		-	-	-20 477
Divestment of financial assets		-	2 827	2 827
Gain sold financial assets		-	117 533	144 414
Investment in short term investments		-20 004	-20 009	9 995
<b>NET CASH FLOW FROM INVESTING ACTIVITIES</b>		<b>-62 550</b>	<b>98 495</b>	<b>132 533</b>
<b>FINANCING ACTIVITIES</b>				
New issue		150 000	-	60 000
Issue expenses		-7 845	-	-3 276
<b>NET CASH FLOW FROM FINANCING ACTIVITIES</b>		<b>142 155</b>	<b>-</b>	<b>56 724</b>
<b>TOTAL CASH FLOW FOR THE PERIOD</b>		<b>79 626</b>	<b>84 434</b>	<b>79 789</b>
Cash and cash equivalents at beginning of period		139 376	58 367	58 367
Net foreign exchange difference		1 653	256	1 221
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>		<b>220 654</b>	<b>143 058</b>	<b>139 376</b>

## 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				-37 767	-37 767
New issue	543	-	149 457	-	150 000
Issue expenses	-	-	-7 845	-	-7 845
<b>CLOSING BALANCE NOVEMBER 30, 2021</b>	<b>7 802</b>	<b>200</b>	<b>390 507</b>	<b>-104 862</b>	<b>293 646</b>

# Income statement for the parent company

KSEK	Note	3 months Sep-Nov 2021	3 months Sep-Nov 2020	12 months Sep-Aug 2020/21
<b>OPERATING INCOME</b>				
Net income		23	81	253
Other operating income		33	0	191
Other compensation and income		-	24	0
<b>TOTAL OPERATING INCOME</b>		<b>56</b>	<b>106</b>	<b>444</b>
<b>OPERATING EXPENSES</b>				
External research and development costs		-31 265	-6 897	-56 860
External patent- and license costs		-724	-519	-2 501
Personnel costs		-4 373	-3 375	-16 174
Other external costs		-2 305	-1 999	-9 457
Other operating expenses		-170	-27	-551
Depreciation and impairment of material and immaterial assets		-450	-158	-782
<b>TOTAL OPERATING EXPENSES</b>		<b>-39 288</b>	<b>-12 976</b>	<b>-86 324</b>
<b>OPERATING RESULT</b>		<b>-39 232</b>	<b>-12 870</b>	<b>-85 880</b>
Net Financial income/expense	3	1 468	117 786	145 925
<b>RESULT BEFORE TAXES</b>		<b>-37 764</b>	<b>104 916</b>	<b>60 046</b>
Taxes		-	-	-
<b>NET RESULT FOR THE PERIOD</b>		<b>-37 764</b>	<b>104 916</b>	<b>60 046</b>



# Balance sheet for the parent company

KSEK	Note	30 Nov 2021	30 Nov 2020	31 Aug 2021
<b>ASSETS</b>				
NON-CURRENT ASSETS				
Intangible assets		30	170	65
Tangible assets		23 676	3 702	5 553
Financial assets		57 070	12 368	32 846
<b>TOTAL NON-CURRENT ASSETS</b>		<b>80 777</b>	<b>16 241</b>	<b>38 464</b>
CURRENT ASSETS				
Trade receivables		24	93	51
Other receivables		4 141	1 219	1 594
Prepaid expenses and accrued income		4 476	363	21 953
Short term investments		20 004	30 004	-
Liquid assets		220 438	143 058	139 376
<b>TOTAL CURRENT ASSETS</b>		<b>249 082</b>	<b>174 737</b>	<b>162 974</b>
<b>TOTAL ASSETS</b>		<b>329 859</b>	<b>190 977</b>	<b>201 438</b>
<b>EQUITY AND LIABILITIES</b>				
EQUITY				
<i>Restricted equity</i>				
Share capital		7 802	7 015	7 259
Statutory reserve		200	200	200
<i>Non-restricted equity</i>				
Share premium reserve non-restricted		390 507	192 414	248 895
Profit or loss brought forward		-67 095	-127 141	-127 141
Net result for the period		-37 764	104 916	60 046
<b>TOTAL EQUITY</b>		<b>293 650</b>	<b>177 405</b>	<b>189 258</b>
PROVISIONS				
Pensions and other obligations		2 514	777	777
<b>TOTAL PROVISIONS</b>		<b>2 514</b>	<b>777</b>	<b>777</b>
CURRENT LIABILITIES				
Trade payables		14 365	3 213	5 572
Other payables		3 178	836	1 039
Prepaid income and accrued expenses		16 152	8 746	4 792
<b>TOTAL CURRENT LIABILITIES</b>		<b>33 695</b>	<b>12 795</b>	<b>11 402</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>329 859</b>	<b>190 977</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 326 (223). As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 231 (231). Pricing has been set by the arm's length principle.

	Sep-Nov 2020/21	Sep-Nov 2020/21
KSEK		
Consultant fees and salaries to related parties	326	223
Consultant fees to Board members	231	231

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

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

## Note 4 – 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. The registered office is in Huddinge, Stockholm County. As of November 30, 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 12.5 %. Diamyd Medical holds 20 % of the shares in the artificial intelligence company Mainly AI AB (corporate registration no 559258-7358). As of November 30, 2021, the carrying amount was 1.2 MSEK.

# 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, January 26, 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

Quarterly Report 2	March 30, 2022
Quarterly Report 3	June 22, 2022
Year-end Report	October 5, 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. Preparations for a confirmatory Phase III trial are 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:

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