



## QUARTERLY REPORT 3

September 2020 – May 2021

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



### 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 previous financial year.*

## September 1, 2020 – May 31, 2021

- Net result: MSEK 87.3 (23.2), third quarter -32.7 (-7.2). 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 1.3 (0.3), third quarter SEK -0.5 (-0.1)
- Cash flow from operating activities: MSEK -50.4 (24.1), third quarter: MSEK -21.4 (-6.8)
- Cash and cash equivalents at May 31, 2021: MSEK 194.2 (81.5)

## Significant events during the third quarter, March 1, 2021–May 31, 2021

- Diamyd® Phase IIb trial results published in Diabetes Care
- Karin Hehenberger joined the Board of Directors
- A global CRO was contracted for a Phase III trial with the diabetes vaccine Diamyd®
- A clinical trial in LADA with Diamyd® was fully recruited
- A directed share issue raised proceeds of SEK 60 million
- Diamyd Medical selected Cytiva's FlexFactory platform to make precision medicine type 1 diabetes vaccine

## Significant events after the reporting period

- 24-month follow-up of Phase IIb Diamyd® clinical trial indicated continued positive treatment effect post 15 months
- Diamyd Medical was elected to present Diamyd® meta-analysis results on October 1 at the EASD diabetes conference



“The findings and the publication in Diabetes Care strongly support the diabetes vaccines’s efficacy in preserving beta cell function in individuals carrying the DR3-DQ2 genes.”

Ulf Hannelius, CEO

## Comments by CEO Ulf Hannelius

Up to half of all patients diagnosed with type 1 diabetes carry the diabetes susceptibility genes HLA DR3-DQ2.

These individuals have a high likelihood of responding to Diamyd® treatment. Last month's publication of the peer-reviewed article highlighting the topline clinical and immunological findings from DIAGNODE-2 in the leading diabetes journal *Diabetes Care*, has significantly increased the awareness and visibility for the novel precision medicine approach we are pursuing and has so far generated international coverage and further opportunities to present at scientific conferences. Most importantly, the findings and the publication in *Diabetes Care* strongly support the diabetes vaccine's efficacy in preserving beta cell function in individuals carrying the DR3-DQ2 genes.

That the antigen-specific immunotherapy Diamyd® shows a positive and clinically relevant disease modifying effect in individuals that carry the so-called HLA haplotype DR3-DQ2, was shown 2019 in a meta-analysis comprising data from previous clinical studies using Diamyd®. These findings were later published as a peer-reviewed article in *Diabetologia*. Independently, about the same time, Battaglia M, Ahmed S, Anderson MS, et al, reported that HLA is associated with the first appearing autoantibody, be it HLA DR4-DQ8 with IAA first or DR3-DQ2 with GADA first, opening up the notion that type 1 diabetes are of two different endotypes: "proinsulin autoimmune-DR4 (PADR4 Diabetes) and "GAD autoimmune-DR3" (GADR3 Diabetes). After the announcement of the meta-analysis, we amended the then ongoing DIAGNODE-2 trial and prespecified the HLA analysis in the clinical protocol and statistical analysis plan. When the database was locked, code broken and results from DIAGNODE-2 were subsequently announced in the autumn of 2020, data confirmed what the meta-analysis had shown, the responders to Diamyd® treatment are defined by the individual's carrying the DR3DQ2 HLA haplotype.

We have subsequently updated the large-scale meta-analysis with data from DIAGNODE-2 and have now results based on data from more than 600 individuals that have participated in four placebo controlled double blinded clinical trials in Europe and the US. In individuals carrying the HLA DR3-DQ2 haplotype we see highly significant preservation of endogenous insulin production measured as stimulated C-peptide and significant lowering of HbA1c, a measure of blood glucose control. These data have laid the groundwork for our First in Class precision medicine approach including focusing on Accelerated Approval and Conditional Marketing Approval from FDA and EMA. We are also evaluating the possibility of receiving orphan designation in Europe for the HLA DR3-DQ2 restricted patient population to complement the orphan designation we already have in the US for the preservation of residual insulin production. These regulatory frameworks provide advantages that can accelerate the approval process for novel therapies.

In parallel, the Confirmatory Phase 3 trial that we are moving ahead with in Europe and the US has a highly robust design as we shall include only individuals carrying the DR3DQ2 HLA haplotype.

The 24-month extension in DIAGNODE-2 that were recently announced, included 15 individuals positive for HLA DR3-DQ2 treated with intralymphatic Diamyd®, positively indicates that the positive effect of Diamyd® remains post 15 months. The actively treated individuals followed their expected slope with only 22% reduction in endogenous insulin production between months 15 and 24. The 8 individuals in the placebo arm carrying HLA DR3-DQ2 had lost during the same period 38%. While it is a small and non-random sample precluding any statistical testing, the data provide further comfort to our Phase 3 design that will follow all participants for 24 months in alignment with regulatory requirements.

From a scientific perspective our findings are highly relevant for how antigen-based therapies and vaccines are developed. HLA is the most polymorphic region in the human genome and is central to how we react to endogenous and exogenous antigens such as autoantigens, allergens, and viruses. This is because the HLA region codes for the proteins that bind to and present antigens to immune cells. Importantly, HLA DR3-DQ2 is one of the most common genetic risk factors for type 1 diabetes and has been associated with autoimmunity against GAD, the very same antigen that is used as the active component in the diabetes vaccine Diamyd®.

The work with the manufacturing facility is progressing at full speed. I am impressed with all the logistics and testing and millions of other ongoing activities in Umeå to establish our own drug substance manufacturing. I would like to stress again the importance of pharmaceutical manufacturing as a top priority in these times.

Moving forward we also see a big opportunity to broaden the use of Diamyd® into the prevention space, treating individuals that are at risk of being diagnosed with type 1 diabetes in the future. The two previous pilot trials, DiAPREV-IT-1 and 2, where subcutaneous injections of Diamyd® were evaluated in children at high risk of type 1 diabetes, support the same notion that we see in recent onset individuals, namely that HLA DR3-DQ2 associates with a delay of overt diabetes onset, and we are currently evaluating the best path forward in the prevention space. In addition, we are pursuing the autoimmune form of type 2 diabetes, or latent autoimmune diabetes in adults (LADA), as it is also called. Like type 1 diabetes there are no disease modifying treatments for type 2 diabetes and we are expecting the first clinical and immunological results from the GADinLADA trial in the beginning of next year.

All in all - the past quarter has been fundamental in advancing the precision diabetes vaccine Diamyd®.

*Stockholm, June 23, 2021*

Ulf Hannelius, *President and CEO*

## Significant events during the third quarter

### March 1, 2021 – May 31, 2021

#### **Diamyd® Phase IIb trial results published in Diabetes Care**

Diabetes Care published the results of DIAGNODE-2, a Phase IIb trial that evaluated intralymphatic administration of Diamyd Medical's lead drug candidate Diamyd® (GAD-alum) in individuals recently diagnosed with type 1 diabetes. Results showed, in line with a published large-scale meta-analysis of clinical data, that while no treatment benefit was seen in the full patient population, three intralymphatic injections of Diamyd® had a significant and positive effect on the preservation of insulin producing capacity in the predefined subgroup of individuals that carry the HLA DR3-DQ2 haplotype. In this subgroup of patients, more than 50% greater preservation of insulin producing capacity was observed at 15 months from baseline in those that received active treatment compared to placebo.

#### **Karin Hehenberger joined the Board of Directors**

Karin Hehenberger, MD, PhD, joined the Board of Directors of Diamyd Medical as affiliated member, to be proposed for election to the Board at its next General Meeting of Shareholders. Dr Hehenberger has a vast experience from both medical and financial executive positions within the fields of diabetes and other chronic diseases.

#### **A global CRO was contracted for Phase III trial with the diabetes vaccine Diamyd®**

Diamyd Medical contracted the global contract research organization (CRO) ICON plc for DIAGNODE-3, a placebo-controlled Phase III precision medicine trial with the diabetes vaccine Diamyd®. 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. The trial is expected to begin recruiting patients later this year.

#### **A clinical trial in LADA with Diamyd® was fully recruited**

The clinical Phase II trial GADinLADA, where the diabetes vaccine Diamyd® is administered directly into the lymph node in patients with the autoimmune form of diabetes LADA (Latent Autoimmune Diabetes in Adults), was fully recruited. The first results from the trial are planned to be announced in early 2022.

#### **A directed share issue raised proceeds of SEK 60 million**

Diamyd Medical completed a directed share issue of 2 400 000 B-shares at a price of SEK 25 per share. Through the directed share issue gross proceeds of SEK 60 million were received. The share issue was subscribed by qualified investors.

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

Diamyd Medical installs 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.

## Significant events after the reporting period

### 24-month follow-up of Phase IIb Diamyd® clinical trial indicated continued positive treatment effect post 15 months

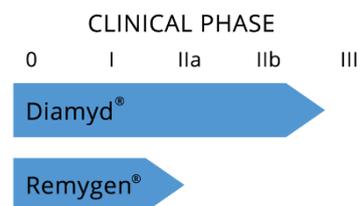
50 out of the 109 individuals in DIAGNODE-2 who were included in an extension study had been followed for a total of 24 months. The actively treated individuals carrying HLA DR3-DQ2, in total 15 individuals, followed their expected trajectory from 15 to 24 month, showing no indication of diminishing treatment effect compared to their progression up to 15 months. As also expected, safety at 24 months looked good with no difference in adverse events between actively treated and placebo treated individuals.

### Diamyd Medical was elected to present Diamyd® meta-analysis results at the EASD diabetes conference

A scientific abstract detailing the latest findings from a meta-analysis based on data from more than 600 individuals with type 1 diabetes participated in clinical trials with the diabetes vaccine Diamyd® (GAD-alum) has been elected to be presented orally on October 1 at the 57th EASD Annual Meeting (European Association for the Study of Diabetes).

## 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.



## 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, 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.

### Trial with Diamyd® in lymph node

- **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. First results from the trial are planned to be announced in early 2022. 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.

## Upcoming clinical trial

### Trial with Diamyd® in lymph node

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

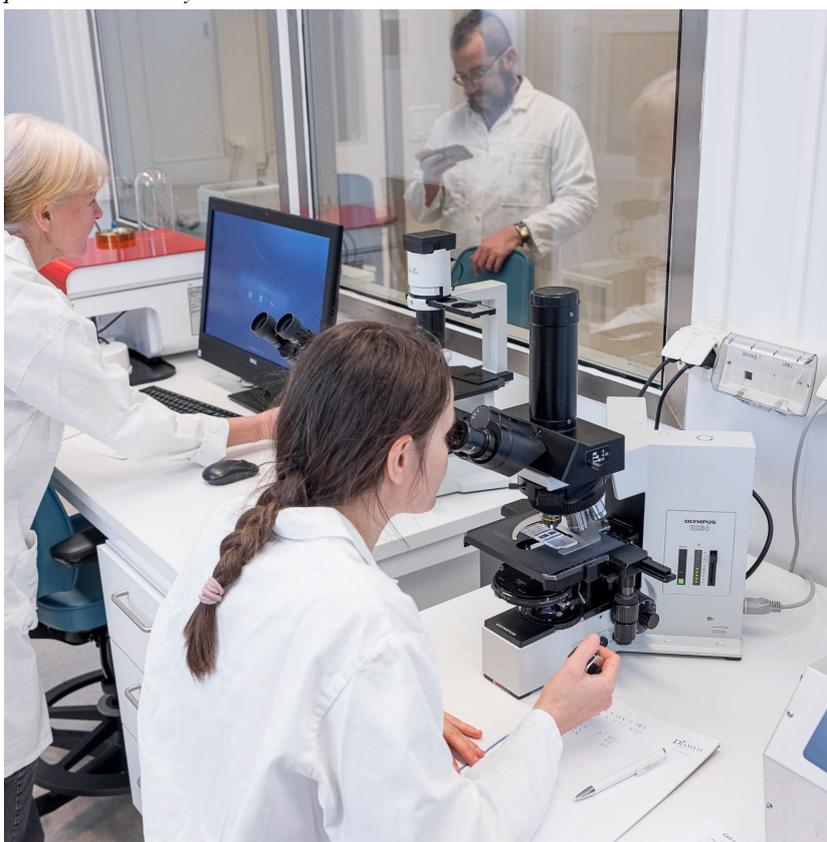
The placebo-controlled Phase III trial DIAGNODE-3 will include approximately 330 individuals aged 12 to 28 who have been recently diagnosed with type 1 diabetes and who carry the genetically defined haplotype HLA DR3-DQ2. The trial will be conducted at approximately 50 clinics in Europe and the United States, 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 end-points; 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.

# 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 Mar-May 2020/21	3 months Mar-May 2019/20	9 months Sep- May 2020/21	9 months Sep-May 2019/20	12 months Sep-Aug 2019/20
Research and development costs, MSEK	-24.1	-1.8	-36.2	-7.5	-13.8
Solidity, %	91	90	91	90	81
Result per share, SEK	-0.5	-0.1	1.3	0.3	0.1
Liquidity and short-term investment per share, SEK	2.7	1.2	2.7	1.2	1.0
Equity per share, SEK	3.0	1.2	3.0	1.2	1.0
Cash flow per share, SEK	0.4	-0.5	1.4	0.2	0.3
Share price per closing, SEK	31.7	21.5	31.7	21.5	39.6
Number of shares per closing	71 569 796	69 169 796	71 569 796	69 169 796	69 169 796
Average number of shares	69 248 917	69 169 796	69 196 170	69 169 796	69 169 796
Average number of employees	15	7	12	7	7

## Income statement

KSEK	Note	3 months Mar-May 2020/21	3 months Mar-May 2019/20	9 months Sep-May 2020/21	9 months Sep-May 2019/20	12 months Sep-Aug 2019/20
<b>OPERATING INCOME</b>						
Net income		137	97	202	263	341
Other operating income		20	8	75	770	784
Other compensation and income	1	0	-	-	43 174	43 174
<b>TOTAL OPERATING INCOME</b>		<b>157</b>	<b>105</b>	<b>277</b>	<b>44 207</b>	<b>44 298</b>
<b>OPERATING EXPENSES</b>						
External research and development costs	1	-24 124	-1 756	-36 173	-7 486	-13 810
External patent- and license costs		-633	-1 427	-2 089	-2 422	-4 488
Personnel costs	2	-4 994	-2 399	-12 023	-6 736	-9 195
Other external costs	2	-2 641	-1 525	-6 663	-4 565	-6 858
Other operating expenses		-85	-13	-187	-36	-59
Depreciation and impairment of material and immaterial assets		-332	-35	-674	-105	-149
<b>TOTAL OPERATING EXPENSES</b>		<b>-32 809</b>	<b>-7 154</b>	<b>-57 810</b>	<b>-21 350</b>	<b>-34 559</b>
<b>OPERATING RESULT</b>		<b>-32 652</b>	<b>-7 049</b>	<b>-57 532</b>	<b>22 857</b>	<b>9 739</b>
Net Financial income/expense	3	-21	-110	144 825	335	-30
<b>RESULT BEFORE TAXES</b>		<b>-32 672</b>	<b>-7 159</b>	<b>87 293</b>	<b>23 192</b>	<b>9 709</b>
Taxes		-	-	-	-	-
<b>NET RESULT FOR THE PERIOD</b>		<b>-32 672</b>	<b>-7 159</b>	<b>87 293</b>	<b>23 192</b>	<b>9 709</b>

## Balance sheet

KSEK	Note	31 May 2021	31 May 2020	31 Aug 2020
<b>ASSETS</b>				
NON-CURRENT ASSETS				
Intangible assets		100	240	205
Tangible assets		9 138	-	1 970
Financial assets	4	32 846	11 979	15 196
<b>TOTAL NON-CURRENT ASSETS</b>		<b>42 084</b>	<b>12 218</b>	<b>17 370</b>
CURRENT ASSETS				
Trade receivables		159	0	79
Other receivables		1 584	1 112	3 594
Prepaid expenses and accrued income		542	444	358
Short term investments		40 008	29 984	9 995
Liquid assets		154 186	51 533	58 367
<b>TOTAL CURRENT ASSETS</b>		<b>196 480</b>	<b>83 072</b>	<b>72 394</b>
<b>TOTAL ASSETS</b>		<b>238 564</b>	<b>95 290</b>	<b>89 764</b>
<b>EQUITY AND LIABILITIES</b>				
EQUITY				
<i>Restricted equity</i>				
Share capital		7 259	7 015	7 015
Statutory reserve		200	200	200
<i>Non-restricted equity</i>				
Share premium reserve non-restricted		248 998	192 414	192 414
Profit or loss brought forward		-127 141	-136 850	-136 850
Net result for the period	1	87 293	23 192	9 709
<b>TOTAL EQUITY</b>		<b>216 608</b>	<b>85 972</b>	<b>72 489</b>
PROVISIONS				
Pensions and other obligations		777	777	777
<b>TOTAL PROVISIONS</b>		<b>777</b>	<b>777</b>	<b>777</b>
CURRENT LIABILITIES				
Trade payables		2 680	2 413	7 254
Other payables		649	259	699
Prepaid income and accrued expenses		17 850	5 869	8 544
<b>TOTAL CURRENT LIABILITIES</b>		<b>21 179</b>	<b>8 541</b>	<b>16 497</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>238 564</b>	<b>95 290</b>	<b>89 764</b>

# Statement of cash flow

KSEK	Note	3 months Mar-May 2021	3 months Mar-May 2020	9 months Sep-May 2020/21	9 months Sep-May 2019/20	12 months Sep-Aug 2019/20
<b>OPERATING ACTIVITIES</b>						
Operating profit/loss	1	-32 652	-7 049	-57 532	22 857	9 739
Interest received		1	13	3	484	31
Interest paid		-17	-123	-39	-149	-26
<i>Non-cash flow items</i>						
Depreciation		332	35	674	105	149
Other non-cash flow items		64	5	112	-734	-
<b>CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL</b>						
		-32 272	-7 119	-56 782	22 563	9 893
Increase (-) decrease (+) receivables		-164	412	1 746	3 610	1 134
Increase (+) decrease (-) debts		10 999	-44	4 681	-2 104	5 853
<b>NET CASH FLOW FROM OPERATING ACTIVITIES</b>						
		<b>-21 437</b>	<b>-6 751</b>	<b>-50 355</b>	<b>24 069</b>	<b>16 880</b>
<b>INVESTING ACTIVITIES</b>						
Investment in material and immaterial assets		-5 374	-	-7 738	-	-1 979
Investment in financial assets	4	-1 200	-	-20 477	-	-3 217
Divestment of financial assets	3	-	-	2 827	-	-
Gain sold financial asset		-	-	144 414	-	40 001
Investment in short term investments		-7	-29 984	-30 013	-9 972	-29 984
<b>NET CASH FLOW FROM INVESTING ACTIVITIES</b>						
		<b>-6 581</b>	<b>-29 984</b>	<b>89 012</b>	<b>-9 972</b>	<b>4 821</b>
<b>FINANCING ACTIVITIES</b>						
New issue		60 000	-	60 000	-	-
Issue expenses		-3 173	-	-3 173	-	-
<b>NET CASH FLOW FROM FINANCING ACTIVITIES</b>						
		<b>56 827</b>	<b>-</b>	<b>56 827</b>	<b>-</b>	<b>-</b>
<b>TOTAL CASH FLOW FOR THE PERIOD</b>						
		<b>28 809</b>	<b>-36 735</b>	<b>95 484</b>	<b>14 097</b>	<b>21 701</b>
Cash and cash equivalents at beginning of period		125 446	88 273	58 367	36 702	36 702
Net foreign exchange difference		-68	-5	336	734	-35
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>						
		<b>154 186</b>	<b>51 532</b>	<b>154 186</b>	<b>51 532</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				87 293	87 293
New issue	243	-	59 757	-	60 000
Issue expenses	-	-	-3 173	-	-3 173
CLOSING BALANCE MAY 31, 2021	7 259	200	248 998	-39 847	216 608

## 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 677 (554). As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 799 (694). 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-May 2020/21	Sep-May 2019/20
Consultant fees and salaries to related parties	677	554
Consultant fees to Board members	799	694

### 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. As of May 31, 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 %. Diamyd Medical holds 20 % of the shares in the artificial intelligence company Mainly AI AB (corporate registration no 559258-7358). As of May 31, 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 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, June 23, 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

Karin Hehenberger  
Affiliated Board member

Ulf Hammelius  
President & CEO

## Financial Calendar

Year-end Report	October 6, 2021
Annual Report	November 11, 2021
Annual General Meeting	December 2, 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 meta-study as well as in the Company's European Phase IIIb 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. Preparations for a confirmatory Phase III trial in the US and Europe are on-going, to start recruiting patients later in 2021. 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>.

**For more information, please contact:**

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

Diamyd Medical AB (publ), Kungsgatan 29, SE-111 56 Stockholm, Sweden

Phone: +46 8 661 00 26 Fax: +46 8 661 63 68 E-mail: 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 23, 2021.