



YEAR-END REPORT

September 2020 – August 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 – August 31, 2021

- Net result: MSEK 60.0 (9.7), fourth quarter -27.4 (-13.5). Profit from divestment of shares in Companion Medical, Inc. during the year improved the net result by MSEK 144.4
- Result per share: SEK 0.9 (0.1), fourth quarter SEK -0.4 (-0.2)
- Cash flow from operating activities: MSEK -109.5 (16.9), fourth quarter: MSEK -59 (-7.9)
- Cash and cash equivalents at August 31, 2021: MSEK 139.4 (68.4)

After the reporting period gross proceeds of SEK 150 million were raised via a directed share issue.

Significant events during the fourth quarter, June 1, 2021–August 31, 2021

- Manufacturing: Small-scale experimental production of GAD65 was established in the Umeå facility
- Robust treatment effect of Diamyd® were shown in additional analyses
- Precision medicine patent for prevention and treatment of autoimmune diabetes was secured
- 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 at the EASD diabetes conference

Significant events after the reporting period

- Diamyd Medical and partners were awarded SEK 40 million in VINNOVA funding
- A new analysis supporting the effect of Diamyd® elected to be presented at scientific conference
- DIAGNODE-3: First regulatory approval to start the Phase III trial was received
- DIAGNODE-3: Start of the Phase III trial in the US was paused pending clarification of FDA questions
- Manufacturing: Acquisition of property with manufacturing facility in Umeå
- SEK 150 million was raised via a directed share issue



“We will make sure to work closely with the FDA and other authorities to advance Diamyd® as fast as possible.”

Ulf Hamelius, CEO

Comments by CEO Ulf Hannelius

This past financial year we have significantly advanced the therapeutic diabetes vaccine Diamyd®. With a focus on our Diamyd platform precision medicine supported by clinical results from several international placebo controlled randomized trials, we are 1) Moving ahead with a pivotal phase 3 trial in individuals newly diagnosed with type 1 diabetes (T1D) carrying the genetic HLA DR3-DQ2 haplotype, 2) Advancing our efforts to treat individuals at-risk for T1D through an innovation milieu financially supported by the Swedish government, 3) Evaluating Diamyd® in individuals diagnosed with Latent Autoimmune Diabetes in Adults (LADA) and 4) Progressing at high speed the build-up of our own manufacturing facility in Umeå. These activities are supported by a strong financial position that give us a runway into 2023.

During the past quarter we announced new sensitivity analyses that support the robustness of our clinical results with Diamyd® that show a significant and clinically relevant effect on preserving endogenous insulin production and lowering blood glucose in individuals that carry the HLA DR3-DQ2 haplotype. In addition, we announced new positive results from the phase 2b trial DIAGNODE-2 that show that individuals positive for the HLA DR3-DQ2 haplotype and treated with Diamyd® measure significantly shorter time with elevated blood glucose and significantly more time with normal blood glucose (TIR, Time In Range). These findings are very comforting and strongly support the design of the precision medicine phase 3 trial DIAGNODE-3. Work is ongoing to start the trial in Europe and the US. We recently received the greenlight from the Swedish MPA and we are expecting to hear from the authorities in the other European countries within the coming months. The trial protocol has also been submitted to the US FDA and here we still have some outstanding questions from the FDA that need clarification before the trial can start in the US. We will make sure to work closely with the FDA and other authorities to advance Diamyd® as fast as possible. On the prevention side we recently achieved a major milestone as we together with a stellar team of collaborators received in total MSEK 40 from the governmental innovation office VINNOVA for the five-year innovation milieu ASSET (AI for Sustainable Prevention of Autoimmunity in the Society). The focus of ASSET is to predict the individual's risk of being diagnosed with T1D and to evaluate therapeutic efforts to delay or prevent progression to diagnosed T1D. This is a very exciting and ambitious long-term project that I believe will produce results that are significant for both Diamyd Medical, our partners, and the broader field of T1D and autoimmune diseases.

We are also looking forward to the first results from the GADinLADA trial where intralymphatic injections of Diamyd® are evaluated in individuals diagnosed with LADA. This is an important and large indication that is genetically similar to T1D but is still often diagnosed and treated like type 2 diabetes (T2D). With the very promising results from T1D we see great promise in broadening the use of Diamyd® also for LADA, an indication that represents up to 10% of all individuals diagnosed with T2D. In parallel with these clinical efforts, the work to set up our own manufacturing facility in Umeå Sweden is progressing according to plan. The small-scale experimental manufacturing is in place, and we soon expect to have the large-scale equipment installed. The main aim is to get the manufacturing process GMP certified, and the facility approved to have new material in place for a potential application for accelerated market approval and commercialization. Also, to further secure our long-term control of the manufacturing strategy we recently acquired the property where we have our manufacturing facility. This will provide us opportunities going forward to scale-up and broaden our activities in Umeå in alignment with market demand and sustainability goals.

Finally, in addition to the recent non-dilutive grant from VINNOVA that will support the prevention efforts with Diamyd®, we have also strengthened our cash position. During the financial year we received MSEK 148 from the divestment of Companion Medical and MSEK 60 from a directed share issue. We recently conducted an additional direct issue, of SEK 150, which in all make sure we can continue to advance at full pace and reach several important milestones.

I would like to thank all our shareholders, partners, collaborators and employees for your support and valuable work.

Stockholm, October 13, 2021

Ulf Hannelius, *President and CEO*

Significant events during the fourth quarter

June 1, 2021 – August 31, 2021

GAD65 manufacturing facility on track for Diamyd® vaccine production

Small-scale experimental production of the recombinant human protein GAD65, the active component in the therapeutic diabetes vaccine Diamyd®, was established at the manufacturing facility in Umeå. Large-scale production is being set up primarily using Cytiva equipment. The future CGMP certified production process at the facility is a key part of Diamyd Medical's regulatory strategy for potential future conditional and accelerated market approvals.

Additional analyses showed robust treatment effect of the therapeutic vaccine Diamyd®

Diamyd Medical conducted, as part of interactions with regulatory agencies, two new analyses on the large meta-analysis dataset of 627 individuals that participated in four previous placebo controlled clinical trials evaluating the efficacy and safety of the therapeutic diabetes vaccine Diamyd®. Both analyses supported the clinical relevance and significance of the treatment benefits of Diamyd®, which further support the design of the Phase III trial DIAGNODE-3 which is planned to start recruiting patients later this year.

Diamyd Medical secured precision medicine patent for prevention and treatment of autoimmune diabetes

The European Patent Office has informed Diamyd Medical that the Company's patent application regarding prevention and treatment of autoimmune diabetes in individuals carrying the HLA DR3-DQ2 gene will be granted. The patent is valid until 2035 and provides central protection in Europe for the treatment or prevention of genetically defined autoimmune diabetes using GAD, which is the active component in the therapeutic diabetes vaccine Diamyd®. The patent claims cover the patient population in which Diamyd® has shown efficacy and is targeted in the upcoming Phase III trial DIAGNODE-3.

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).

Significant events after the reporting period

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

The Swedish governmental innovation agency VINNOVA provides 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.

Analysis that supports the effect of the diabetes vaccine Diamyd® will be presented at a the ISPAD conference

A new analysis showing the effect of the diabetes vaccine Diamyd® (GAD-alum) in reducing the time a patient has high blood glucose, was selected to be presented at the ISPAD conference (The International Society of Pediatric and Adolescent Diabetes), which this year will be held on 13-15 October. The analysis is based on data from Continuous Glucose Monitoring (CGM) and will be presented by Professor Johnny Ludvigsson, Principal Investigator of the clinical trial DIAGNODE-2.

First regulatory approval received to start the Phase III trial DIAGNODE-3 with the diabetes vaccine Diamyd®

The Swedish Medical Products Agency gave approval for the start of DIAGNODE-3, a placebo-controlled precision medicine Phase III 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.

FDA paused the start of DIAGNODE-3 in the US

The start of the Phase III trial 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. Diamyd Medical will be notified of which questions that are outstanding within 30 days.

Acquisition of property with manufacturing facility in Umeå

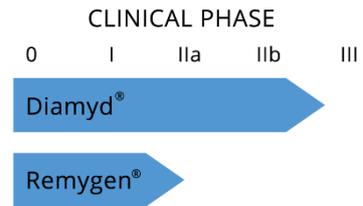
Diamyd Medical announced the acquisition of the property in Umeå, Sweden, where production of the recombinant protein GAD65, the active component in the therapeutic diabetes vaccine Diamyd® is being established. The property is acquired for a purchase price of SEK 24.5 million and comprises approximately 20 000 square feet including the 10 000 square feet Diamyd Medical rents today, 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. The price corresponded to a discount of approximately 17.0 percent calculated on the volume weighted average price on the Nasdaq First North Growth Market for the preceding 30 trading days. Through the directed share issue, the Company received gross proceeds of SEK 150 million. The directed share issue was subscribed by qualified investors.

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 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 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. The first results from the trial are planned to be announced in early 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.



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 Jun-Aug 2020/21	3 months Jun-Aug 2019/20	12 months Sep-Aug 2020/21	12 months Sep-Aug 2019/20
Research and development costs, MSEK	-20.7	-6.3	-56.9	-13.8
Solidity, %	94	81	94	81
Result per share, SEK	-0.4	-0.2	0.9	0.1
Liquidity and short-term investment per share, SEK	1.9	1.0	1.9	1.0
Equity per share, SEK	2.6	1.0	2.6	1.0
Cash flow per share, SEK	-0.2	0.1	1.2	0.3
Share price per closing, SEK	33.7	39.6	33.7	39.6
Number of shares per closing	71 569 796	69 169 796	71 569 796	69 169 796
Average number of shares	71 569 796	69 169 796	69 794 454	69 169 796
Average number of employees	16	7	14	7

Income statement

KSEK	Note	3 months Jun-Aug 2020/21	3 months Jun-Aug 2019/20	12 months Sep-Aug 2020/21	12 months Sep-Aug 2019/20
OPERATING INCOME					
Net income		51	78	253	341
Other operating income		116	14	191	784
Other compensation and income	1	-	-	0	43 174
TOTAL OPERATING INCOME		167	92	444	44 298
OPERATING EXPENSES					
External research and development costs	1	-20 687	-6 323	-56 860	-13 810
External patent- and license costs		-412	-2 066	-2 501	-4 488
Personnel costs	2	-4 150	-2 459	-16 174	-9 195
Other external costs	2	-2 794	-2 293	-9 457	-6 858
Other operating expenses		-364	-23	-551	-59
Depreciation and impairment of material and immaterial assets		-235	-44	-782	-149
TOTAL OPERATING EXPENSES		-28 642	-13 208	-86 324	-34 559
OPERATING RESULT		-28 475	-13 117	-85 880	9 739
Net Financial income/expense	3	1 100	-366	145 925	-30
RESULT BEFORE TAXES		-27 374	-13 482	60 046	9 709
Taxes		-	-	-	-
NET RESULT FOR THE PERIOD		-27 374	-13 482	60 046	9 709

Balance sheet

KSEK	Note	31 Aug 2021	31 Aug 2020
ASSETS			
NON-CURRENT ASSETS			
Intangible assets		65	205
Tangible assets		5 553	1 970
Financial assets	4	32 846	15 196
TOTAL NON-CURRENT ASSETS		38 464	17 370
CURRENT ASSETS			
Trade receivables		51	79
Other receivables		1 594	3 594
Prepaid expenses and accrued income		21 953	358
Short term investments		-	9 995
Liquid assets		139 376	58 367
TOTAL CURRENT ASSETS		162 974	72 394
TOTAL ASSETS		201 438	89 764
EQUITY AND LIABILITIES			
EQUITY			
<i>Restricted equity</i>			
Share capital		7 259	7 015
Statutory reserve		200	200
<i>Non-restricted equity</i>			
Share premium reserve non-restricted		248 895	192 414
Profit or loss brought forward		-127 141	-136 850
Net result for the period	1	60 046	9 709
TOTAL EQUITY		189 258	72 489
PROVISIONS			
Pensions and other obligations		777	777
TOTAL PROVISIONS		777	777
CURRENT LIABILITIES			
Trade payables		5 572	7 254
Other payables		1 039	699
Prepaid income and accrued expenses		4 792	8 544
TOTAL CURRENT LIABILITIES		11 402	16 497
TOTAL EQUITY AND LIABILITIES		201 438	89 764

Statement of cash flow

KSEK	Note	3 months Jun-Aug 2021	3 months Jun-Aug 2020	12 months Sep-May 2020/21	12 months Sep-Aug 2019/20
OPERATING ACTIVITIES					
Operating profit/loss	1	-28 475	-13 118	-85 880	9 739
Interest received		0	-453	0	31
Interest paid		-32	123	-71	-26
<i>Non-cash flow items</i>					
Depreciation		235	44	782	149
Other non-cash flow items		248	9	362	-
CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL					
		-28 024	-13 395	-84 806	9 893
Increase (-) decrease (+) receivables		-21 312	-2 477	-19 566	1 134
Increase (+) decrease (-) debts		-9 777	7 957	-5 095	5 853
NET CASH FLOW FROM OPERATING ACTIVITIES					
		-59 113	-7 915	-109 468	16 880
INVESTING ACTIVITIES					
Investment in material and immaterial assets		3 513	-1 979	-4 225	-1 979
Investment in financial assets	4	-	-3 217	-20 477	-3 217
Divestment of financial assets	3	-	-	2 827	-
Gain sold financial asset		-	-	144 414	40 001
Investment in short term investments		40 008	19 989	9 995	-29 984
NET CASH FLOW FROM INVESTING ACTIVITIES					
		43 521	14 793	132 533	4 821
FINANCING ACTIVITIES					
New issue		-	-	60 000	-
Issue expenses		-103	-	-3 276	-
NET CASH FLOW FROM FINANCING ACTIVITIES					
		-103	-	56 724	-
TOTAL CASH FLOW FOR THE PERIOD					
		-15 695	6 878	79 789	21 701
Cash and cash equivalents at beginning of period		154 186	51 532	58 367	36 702
Net foreign exchange difference		884	-44	1 221	-35
CASH AND CASH EQUIVALENTS AT END OF PERIOD					
		139 376	58 367	139 376	58 367

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				60 046	60 046
New issue	243	-	59 757	-	60 000
Issue expenses	-	-	-3 276	-	-3 276
CLOSING BALANCE AUGUST 31, 2021	7 259	200	248 895	-67 095	189 258

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 1 040 (748). As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 926 (926). 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-Aug 2020/21	Sep-Aug 2019/20
Consultant fees and salaries to related parties	1 040	748
Consultant fees to Board members	1 031	926

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 August 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 12.5 %. Diamyd Medical holds 20 % of the shares in the artificial intelligence company Mainly AI AB (corporate registration no 559258-7358). As of August 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 Year-end 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, October 13, 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 Hannelius
President & CEO

Financial Calendar

Annual General Meeting	December 2, 2021
Quarterly Report 1	January 26, 2022
Quarterly Report 2	March 30, 2022
Quarterly Report 3	June 22, 2022
Year-end Report	October 5, 2022

Annual Report

The Annual Report for 2020/2021 is expected to be available on November 11, 2021, via Diamyd Medical AB's website (<https://www.diamyd.com>).

Annual General Meeting

The Annual General Meeting will be held on December 2, 2021, at 5:00 p.m. at Hotel Kung Carl in Stockholm

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:

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