QUARTERLY REPORT 1

September 2020 – November 2020

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

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

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

September 1, 2020 – November 30, 2020

- Net result: MSEK 104.9 (-6.8). The increase compared to previous year is a one-off effect of corresponding MSEK 117.5 due to profit from divestment of shares in Companion Medical, Inc.
- Result per share: SEK 1.5 (-0.1)
- Cash flow from operating activities: MSEK -14.1 (-6.1)
- Cash and cash equivalents at November 30, 2020: MSEK 173.0 (50.6)

Significant events first quarter, September 1, 2020–November 30, 2020

- Diamyd Medical invested its pro rata share in NextCell Pharma's rights issue
- USD 13.8 million were received after divestment in Companion Medical
- Phase IIb topline results demonstrated a significant treatment effect of Diamyd® in a predefined genetic patient group covering about 40-50% of all type 1 diabetes patients
- Analyses of prevention trials and intralymphatic pilot trial with the diabetes vaccine Diamyd® supported a positive efficacy trend in genetically defined groups of type 1 diabetes patients

Significant events after the reporting period

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

"The collected genetic and immunological insights support the possibility that we may be able to truly individualize the treatment."

Ulf Hannelius, CEO

Comments by CEO Ulf Hannelius

Following the announcement of the topline results from the phase IIb trial DIAGNODE-2 with Diamyd® in September 2020, we have focused on additional data analyses, manufacturing activities and regulatory activities to take Diamyd® and the company to the next level.

The notion that individuals carrying certain HLA genotypes have a very high likelihood of responding to Diamyd® treatment has received further support from the recently updated meta-analysis that we announced last week. The analysis now includes the data from DIAGNODE-2 and encompasses data from 627 individuals that have participated in randomized clinical trials with Diamyd®.

The findings from the analysis show that the two variables that influence the clinical effect of Diamyd® the most are 1) the HLA genotype and 2) the dosing regimen. This is comforting additional knowledge to what we already knew about our diabetes vaccine, as we can control for both factors when designing and conducting trials. It is also reassuring that baseline glycemic values, in other words the patient's blood glucose and insulin dose at study start, do not seem to influence the positive effect of Diamyd®.

In addition, as we announced in December, the first immunological results from DIAGNODE-2 also showed significant differences between the genetically defined patient groups. The collected genetic and immunological insights support the possibility that we may be able to truly individualize the treatment through tailored trials and using real world data.

I am pleased to see that our other programs are advancing according to plan. For the Remygen® (GABA) activities, the first ReGenerate-1 trial participants have been treated for a month with high dose Remygen® and the combination of Remygen® and Alprazolam, and the safety committee has given the greenlight for the trial to proceed as planned. Our manufacturing facility we are establishing in Umeå is being received very positively by the local life science community which gives us a great opportunity to find top talent to join our company. I am also pleased with our strong cash position, which is especially due to the proceeds that we have received through the sale of Companion Medical, Inc. to Medtronic. This puts us in a good position to advance all our operations.

In parallel to the significant scientific advances, it is very promising that the JDRF, a leading global organization funding type 1 diabetes research, has launched a screening education and awareness campaign in the United States that focuses on early detection of type 1 diabetes using autoantibody screening. This may strongly support the development of preventive treatments, and with the existing safety and efficacy data from trials in both recently diagnosed and at-risk individuals I see here an area with great potential for Diamyd®.

Stockholm, January 20, 2021

Ulf Hannelius, *President and CEO*

Significant events during the first quarter

September 1, 2020 – November 30, 2020

Diamyd Medical fully subscribed for its pro rata share in a rights issue in NextCell Pharma

The pro rata share corresponded to approximately SEK 19.3 million, which means that the book value of the holding in NextCell Pharma after the investment increases from approximately SEK 11.7 million to approximately SEK 31 million.

Diamyd Medical received USD 13.9 million in connection with divestment in Companion Medical

In connection to the acquisition of Companion Medical, Inc. by Medtronic plc., Diamyd Medical received approximately USD 13.9 million, corresponding to SEK 120 million. Depending on achievement of certain future milestones, some additional payments may be possible, and will then be communicated if they occur.

Phase IIb topline results demonstrated a significant treatment effect of Diamyd® in a predefined genetic patient group covering about 40-50% of all type 1 diabetes patients

Diamyd Medical announced the topline results from the placebo-controlled Phase IIb trial DIAGNODE-2, where the diabetes vaccine Diamyd® (GAD-alum) was injected directly into a lymph node in individuals with recently diagnosed type 1 diabetes. In line with previous large-scale analysis of trials involving subcutaneous administration of Diamyd®, the results, encompassing a total of 109 patients, showed a statistically significant effect in the predefined HLA (Human Leukocyte Antigen) group of trial participants. Specifically, the trial demonstrated a preservation of beta cell function at 15 months post-diagnosis, as measured by meal stimulated C-peptide. The primary endpoint, defined as meal stimulated C-peptide in the entire trial population was not met. No related severe adverse events were observed in the trial. Based on these results, Diamyd Medical would pursue the HLA restricted responder group in an upcoming pivotal Phase III program.

Analyses of prevention trials and intralymphatic pilot trial with the diabetes vaccine Diamyd® supported a positive trend in genetically defined groups of type 1 diabetes patients

A combined analysis of two previous clinical prevention trials, DiAPREV-IT 1 and 2 in healthy children at high risk of type 1 diabetes, as well as additional insights from the open label pilot trial DIAGNODE-1 in children and young adults newly diagnosed with type 1 diabetes, while not reaching statistical significance, were consistent with the recently published large-scale responder analysis which showed a highly significant and clinically relevant effect of the diabetes vaccine Diamyd® in individuals positive for genotypes that include HLA DR3-DQ2.

Significant events after the reporting period

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

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

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

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

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

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

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

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

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

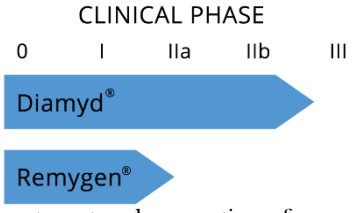
The project will design, test and build a sustainability framework powered by artificial intelligence (AI) for Diamyd Medical's production facility in Umeå, Sweden.

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

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

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 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. The effect is achieved by antigen-specific reprogramming of immune cells by administration of low doses of Diamyd® in superficial lymph nodes. By maintaining the endogenous insulin production, Diamyd® has the potential to make a significant difference in the daily life of patients as well significantly reduce the complications of type 1 diabetes. Topline results from the Phase IIb trial DIAGNODE-2 has demonstrated a significant treatment effect of Diamyd® in a 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 immunotherapy aimed at stopping the immune system's attack on insulin-producing beta cells in autoimmune diabetes, is evaluated in the Phase IIb trial DIAGNODE-2 and in the Phase II trial GADinLADA.

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

Trials with Diamyd® in lymph node

- **DIAGNODE -2 – DIAMYD® IN LYMPH NODES WITH ORAL SUPPLEMENTATION OF VITAMIN D**
  A follow-up double-blind randomized clinical trial where Diamyd® is administered directly into a lymph node with oral supplements of vitamin D. The trial encompasses 109 patients from Sweden, the Czech Republic, Spain and the Netherlands, aged 12–24 years who have recently been diagnosed with type 1 diabetes. The 15-month results were presented on September 14, 2020, demonstrating a significant treatment effect of Diamyd® in a predefined patient group. As of autumn 2019, patients who had not yet completed their last visit at 15 months were offered to participate in an extension of the trial for another 9 months. 53 patients agreed to participate in the extension trial and 15 of these patients have already been followed for 24 months. Results of this extended trial should be available in Q3 2021. Coordinating Investigator is Professor Johnny Ludvigsson at Linköping University, Sweden. Diamyd Medical is the Sponsor of the trial.

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

Trial with Remygen® (GABA)

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

Manufacturing of GAD65 in Umeå

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

Site Manager Maja Johansson giving a guided tour to parts of the Company Board and Management at the production facility in Umeå, Sweden in September 2020.

Key figures

	3 months Sep-Nov 2020	3 months Sep-Nov 2019	12 months Sep-Aug 2019/20
Research and development costs, MSEK	-6.9	-2.7	-13.8
Solidity, %	93	84	81
Result per share, SEK	1.5	-0.1	0.1
Liquidity and short-term investment per share, SEK	2.5	0.7	1.0
Equity per share, SEK	2.6	0.8	1.0
Cash flow per share, SEK	1.2	0.2	0.3
Share price per closing, SEK	32.2	7.5	39.6
Number of shares per closing	69 169 796	69 169 796	69 169 796
Average number of shares	69 169 796	69 169 796	69 169 796
Average number of employees	10	7	7

Income statement

KSEK	Note	3 months Sep-Nov 2020	3 months Sep-Nov 2019	12 months Sep-Aug 2019/20
OPERATING INCOME				
Net income		81	118	341
Other operating income		0	13	784
Other compensation and income	1	24	-	43 174
TOTAL OPERATING INCOME		106	131	44 298
OPERATING EXPENSES				
External research and development costs	1	-6 897	-2 734	-13 810
External patent- and license costs		-519	-444	-4 488
Personnel costs	2	-3 375	-2 136	-9 195
Other external costs	2	-1 999	-1 514	-6 858
Other operating expenses		-27	-12	-59
Depreciation and impairment of material and immaterial assets		-158	-35	-149
TOTAL OPERATING EXPENSES		-12 976	-6 876	-34 559
OPERATING RESULT		**-12 870**	-6 744	9 739
Net Financial income/expense	3	117 786	-39	-30
RESULT BEFORE TAXES		104 916	-6 783	9 709
Taxes		-	-	-
NET RESULT FOR THE PERIOD		**104 916**	-6 783	9 709

Balance sheet

KSEK	Note	30 Nov 2020	30 Nov 2019	31 Aug 2020
ASSETS				
NON-CURRENT ASSETS				
Intangible assets		170	310	205
Tangible assets		3 702	-	1 970
Financial assets	4	12 368	11 979	15 196
TOTAL NON-CURRENT ASSETS		**16 241**	**12 288**	17 370
CURRENT ASSETS				
Trade receivables		93	214	79
Other receivables		1 219	942	3 594
Prepaid expenses and accrued income		363	2 255	358
Short term investments		30 004	-	9 995
Liquid assets		143 058	50 584	58 367
TOTAL CURRENT ASSETS		174 737	53 995	72 394
TOTAL ASSETS		**190 977**	**66 283**	**89 764**
EQUITY AND LIABILITIES				
EQUITY				
Restricted equity				
Share capital		7 015	7 015	7 015
Statutory reserve		200	200	200
Non-restricted equity				
Share premium reserve non-restricted		192 414	192 414	192 414
Profit or loss brought forward		-127 141	-136 850	-136 850
Net result for the period	1	104 916	-6 783	9 709
TOTAL EQUITY		177 405	55 997	72 489
PROVISIONS				
Pensions and other obligations		777	777	777
Other provisions		-	-	-
TOTAL PROVISIONS		777	777	777
CURRENT LIABILITIES				
Trade payables		3 213	1 977	7 254
Other payables		836	644	699
Prepaid income and accrued expenses		8 746	6 888	8 544
TOTAL CURRENT LIABILITIES		12 795	9 509	16 497
TOTAL EQUITY AND LIABILITIES		**190 977**	**66 283**	**89 764**

Statement of cash flow

KSEK	Note	3 months Sep-Nov 2020	3 months Sep-Nov 2019	12 months Sep-Aug 2019/20
OPERATING ACTIVITIES				
Operating profit/loss		-12 870	-6 744	**9 739**
Interest received		1	0	**31**
Interest paid		-8	-18	**-26**
Non-cash flow items				
Depreciation		158	35	**149**
Other non-cash flow items		3	-	-
CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL		**-12 715**	**-6 727**	**9 893**
Increase (-) decrease (+) receivables		2 357	1 755	**1 134**
Increase (+) decrease (-) debts		-3 702	-1 136	**5 853**
NET CASH FLOW FROM OPERATING ACTIVITIES		**-14 061**	**-6 108**	**16 880**
INVESTING ACTIVITIES				
Investments in material and immaterial assets		-1 856	-	**-1 979**
Investment in financial assets		2 827	-	**-3 217**
Gain sold financial asset		117 533	-	-
Investment in short term investments		-20 009	20 012	**10 017**
NET CASH FLOW FROM INVESTING ACTIVITIES		98 495	**20 012**	**4 821**
FINANCING ACTIVITIES				
New issue		-	-	-
Issue expenses		-	-	-
NET CASH FLOW FROM FINANCING ACTIVITIES		-	-	-
TOTAL CASH FLOW FOR THE PERIOD		**84 434**	**13 903**	**21 701**
Cash and cash equivalents at beginning of period		58 367	36 702	**36 702**
Net foreign exchange difference		256	-21	**-35**
CASH AND CASH EQUIVALENTS AT END OF PERIOD		**143 058**	**50 584**	**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	7015	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	-	-	-	104 916	104 916
CLOSING BALANCE 30 NOVEMBER, 2020	**7 015**	**200**	**192 414**	**-22 224**	**177 405**

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 223 (277). 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.

KSEK	Sep-Nov 2020	Sep-Nov 2019
Consultant fees and salaries to related parties	223	277
Consultant fees to Board members	231	231

Note 3 – Net financial income/expense

The increase compared to previous year is a one-off effect due to profit, including exchange rate effect, of corresponding 117.5 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 November 30, 2020, the carrying amount was approximately MSEK 11.7. Diamyd Medical's share of the equity as well as share of the votes was as of the same date approximately 12.8 %. After the period, Diamyd Medical invested its pro rata share, MSEK 19.3, in a rights issue in NextCell Pharma, which means that the book value of the holding in NextCell Pharma after the investment amounts to approximately MSEK 31.0.

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, January 20, 2021

Erik Nerpin
Chairman of the Board

Anders Essen-Möller
Board member

Maria-Teresa Essen-Möller
Board member

Torbjörn Bäckström
Board Member

Mark A. Atkinson
Board member

Ulf Hannelius
President & CEO

Financial Calendar

Quarterly Report 2	March 31, 2021
Quarterly Report 3	June 23, 2021
Year-end Report	October 6, 2021

About Diamyd Medical

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

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