YEAR-END REPORT

September 2019 – August 2020

Diamyd Medical AB (publ), Fiscal year 2019/2020

Significant effect of Diamyd® demonstrated in a large predefined patient group, covering about 40-50 percent of all type 1 diabetes patients

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, 2019 – August 31, 2020

- Net result: MSEK 9.7 (-36.6), whereof fourth quarter MSEK -13.5 (-9.8). The increase compared to previous year is a one-off effect due to a payment of corresponding MSEK 48.0 from the previous GAD65 manufacturer as support for transition of the manufacturing process.
- Result per share: SEK 0.1 (-0.5), fourth quarter SEK -0.2 (-0.1)
- Cash flow from operating activities: MSEK 16.2 (-39.2), fourth quarter: MSEK -7.9 (-10.6)
- Cash and cash equivalents at August 31, 2020: MSEK 68.4 (56.7). After the reporting period, MUSD 13.9 corresponding to MSEK 120 was received from divestment of shares in Companion Medical.

Significant events fourth quarter, June 1, 2020–August 31, 2020

- A Remygen® clinical trial was expanded to evaluate prevention of hypoglycaemia
- Companion Medical Inc., in which Diamyd Medical is a shareholder, was announced to be acquired by Medtronic plc
- Results highlighting efficacy of the diabetes vaccine Diamyd® in genetically defined groups of type 1 diabetes patients were published in the scientific journal Diabetologia

Significant events after the reporting period

- Diamyd Medical received USD 13.9 million 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

"The focus forward into Phase III and beyond is aligned with genetics-based Precision Medicine - targeting the right individual with the right treatment at the right time."

Ulf Hannelius, CEO

Comments by CEO Ulf Hannelius

On September 14 we had the pleasure to announce the topline results from DIAGNODE-2, the European multicenter Phase IIb trial in 109 individuals recently diagnosed with type 1 diabetes. The results show, in line with comprehensive insights from previous trials and scientific publications, that **the diabetes vaccine Diamyd® (GAD-alum) has a positive and significant disease-modifying effect on the preservation of endogenous insulin production compared to placebo in a genetically predefined patient group**. The focus forward into Phase III and beyond is aligned with genetics-based Precision Medicine - targeting the right individual with the right treatment at the right time.

Specifically and importantly, the topline results from DIAGNODE-2 make it clear that to receive a significant treatment benefit with Diamyd® one should target individuals with HLA-type DR3-DQ2. Equally, there seems to be no benefit in individuals that do not present with this HLA type. These results are in line with the large scale meta study that we first announced in December 2019 and later were published this August in Diabetologia. That study showed that based on data from more than 500 patients from three placebo-controlled trials, the HLA-type significantly influences the effect of Diamyd® and a positive effect is seen in individuals carrying the specific HLA type DR3-DQ2.

The notion of targeting individuals with HLA DR3-DQ2 is further supported by a combined analysis of two investigator-initiated prevention trials, DiaPrevIT-1 and DiaPrevIT-2, that we press released in August this year. While the individual trials did not support a benefit of Diamyd® to prevent or prolong time to diagnosis in healthy at-risk children, the combined analysis showed a clear trend that the preventive benefit of Diamyd® is seen in individuals that are positive for HLA DR3-DQ2. We also now know that the three individuals who all received a significant benefit following a fourth intralymphatic booster injection in the pilot trial DIAGNODE-1 were HLA DR3-DQ2 positive.

Furthermore, these results make sense from a scientific perspective. HLA DR3-DQ2 has previously been associated with autoimmunity against GAD, the active component in Diamyd®. This is significant as the HLA region codes for the molecules that bind and present antigens to antigen reactive immune cells, a central mechanism regulating immunity that now is shown to be susceptible for immunomodulation and the target for therapeutic antigen-specific vaccines like Diamyd®.

It should also be emphasized that despite the COVID-19 pandemic, DIAGNODE-2 has not met with any operational disruptions, which is a true testament to the safety and convenience of the treatment as well as to the competence and engagement of the clinics and collaborators involved in the trial. A safe, convenient, and effective disease- modifying treatment is imperative to reach therapeutic and commercial success in the type 1 diabetes field.

Going forward, the detailed results from DIAGNODE-2 will be published in a scientific journal and we are accelerating our design efforts for a pivotal Phase III trial. This trial will incorporate all the knowledge around Diamyd® and especially the HLA aspect and the administration route, and we are planning interactions with the FDA to align the trial design and evaluate potential expedited regulatory pathways for Diamyd®.

To summarize, it has been a truly pivotal year for Diamyd Medical.

Stockholm, October 7, 2020

Ulf Hannelius, *President and CEO*

Significant events during the fourth quarter

June 1, 2020 – August 31, 2020

Clinical trial with Remygen® was expanded to evaluate prevention of hypoglycaemia

The Swedish Medical Products Agency approved an amendment to ReGenerate-1 to investigate Remygen®'s preventive effects on hypoglycaemia (severely reduced blood sugar level) in individuals with long-term type 1 diabetes.

Medtronic announced plans to acquire Companion Medical

Companion Medical, Inc. of which Diamyd Medical is a shareholder, and Medtronic plc, jointly announced the acquisition of Companion Medical by Medtronic.

Results published highlighting efficacy of the diabetes vaccine Diamyd® in genetically defined groups of type 1 diabetes patients

Diabetologia (the journal of the European Association for the Study of Diabetes EASD) published results from a meta study that demonstrates a highly significant and clinically relevant effect of Diamyd Medical's lead drug candidate Diamyd® (GAD-alum) on preserving endogenous insulin production in genetically defined groups of type 1 diabetes patients. The meta study, first reported in December 2019, comprises more than 500 patients from three placebo controlled randomized clinical trials conducted in Europe and the USA assessing the therapeutic diabetes vaccine Diamyd®. The publication is co-authored by Dr. Ulf Hannelius, Diamyd Medical, Professor Craig Beam, Western Michigan University and Professor Johnny Ludvigsson, Linköping University.

Significant events after the reporting period

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

In connection with the previously announced 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

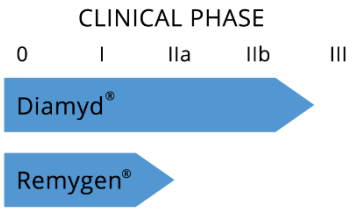
Diamyd Medical announced the topline results from the placebo-controlled Phase IIb trial DIAGNODE-2, where the diabetes vaccine Diamyd® (GAD-alum) was injected directly into a lymph node in individuals with recently diagnosed type 1 diabetes. In line with previous large-scale analysis of trials involving 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, this 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. Importantly, no related severe adverse events were observed in the trial. Based on these results, Diamyd Medical will 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.

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 Jun-Aug 2019/20	3 months Jun-Aug 2018/19	12 months Sep-Aug 2019/20	12 months Sep-Aug 2018/19
Research and development costs, MSEK	-6.3	-6.2	-13.8	-22.4
Solidity, %	81	85	81	85
Result per share, SEK	-0.2	-0.1	0.1	-0.5
Liquidity and short-term investment per share, SEK	1.0	0.8	1.0	0.8
Equity per share, SEK	1.0	0.9	1.0	0.9
Cash flow per share, SEK	0.1	0.1	0.3	0.3
Share price per closing, SEK	39.6	8.4	39.6	8.4
Number of shares per closing	69 169 796	69 169 796	69 169 796	69 169 796
Average number of shares	69 169 796	69 169 796	69 169 796	65 371 779
Average number of employees	9	6	7	6

Income statement

KSEK	Note	3 months Jun-Aug 2020	3 months Jun-Aug 2019	12 months Sep-Aug 2019/20	12 months Sep-Aug 2018/19
OPERATING INCOME					
Net income		78	247	341	1 568
Other operating income		14	12	784	69
Other compensation and income	1	-	-	43 174	-
TOTAL OPERATING INCOME		92	260	44 298	1 637
OPERATING EXPENSES					
External research and development costs	1	-6 323	-6 182	-13 810	-22 359
External patent- and license costs		-2 066	-295	-4 488	-1 693
Personnel costs	2	-2 459	-1 877	-9 195	-7 891
Other external costs	2	-2 293	-1 638	-6 858	-6 017
Other operating expenses		-23	-29	-59	-105
Depreciation and impairment of material and immaterial assets		-44	-35	-149	-140
TOTAL OPERATING EXPENSES		-13 208	-10 056	-34 559	-38 206
OPERATING RESULT		**-13 117**	-9 796	**9 739**	-36 569
Net Financial income/expense		-366	26	-30	-41
RESULT BEFORE TAXES		-13 482	-9 769	9 709	-36 610
Taxes		-	-	-	-
NET RESULT FOR THE PERIOD		**-13 482**	-9 769	**9 709**	-36 610

Balance sheet

KSEK	Note	31 Aug 2020	31 Aug 2019
ASSETS			
NON-CURRENT ASSETS			
Intangible assets		205	345
Tangible assets		1 970	-
Financial assets	3	15 196	11 979
TOTAL NON-CURRENT ASSETS		17 370	12 323
CURRENT ASSETS			
Trade receivables		79	214
Other receivables		3 594	1 215
Prepaid expenses and accrued income		358	3 736
Short term investments		9 995	20 012
Liquid assets		58 367	36 702
TOTAL CURRENT ASSETS		72 394	61 879
TOTAL ASSETS		**89 764**	**74 202**
EQUITY AND LIABILITIES			
EQUITY			
Restricted equity			
Share capital		7 015	7 015
Statutory reserve		200	200
Non-restricted equity			
Share premium reserve non-restricted		192 414	192 414
Profit or loss brought forward		-136 850	-100 240
Net result for the period	1	9 709	-36 610
TOTAL EQUITY		72 489	62 780
PROVISIONS			
Pensions and other obligations		777	777
Other provisions		-	-
TOTAL PROVISIONS		777	777
CURRENT LIABILITIES			
Trade payables		7 254	1 707
Other payables		699	563
Prepaid income and accrued expenses		8 544	8 374
TOTAL CURRENT LIABILITIES		16 497	10 644
TOTAL EQUITY AND LIABILITIES		**89 764**	**74 202**

Statement of cash flow

KSEK	Note	3 months Jun-Aug 2020	3 months Jun-Aug 2019	12 months Sep-Aug 2019/20	12 months Sep-Aug 2018/19
OPERATING ACTIVITIES					
Operating profit/loss	1	-13 118	-9 796	9 739	-36 569
Interest received		-453	0	31	0
Interest paid		123	-17	-26	-124
Non-cash flow items					
Depreciation		44	35	149	140
Other non-cash flow items		9	-5	-725	-832
CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL		**-13 395**	**-9 783**	**9 168**	**-37 384**
Increase (-) decrease (+) receivables		-2 477	1 769	1 134	-2 085
Increase (+) decrease (-) debts		7 957	-2 627	5 853	284
NET CASH FLOW FROM OPERATING ACTIVITIES		**-7 915**	**-10 642**	**16 154**	**-39 185**
INVESTING ACTIVITIES					
Investments in material and immaterial assets		-1 979	-	-1 979	
Investment in financial assets		-3 217	-3 190	-3 217	-4 674
Investment in short term investments		19 989	20 006	10 017	10 024
NET CASH FLOW FROM INVESTING ACTIVITIES		14 793	**16 817**	4 821	**5 350**
FINANCING ACTIVITIES					
New issue		-	-	-	58 403
Issue expenses		-	-	-	-2 024
NET CASH FLOW FROM FINANCING ACTIVITIES		-	-	-	**56 380**
TOTAL CASH FLOW FOR THE PERIOD		**6 878**	**6 175**	**20 975**	**22 544**
Cash and cash equivalents at beginning of period		51 532	30 483	36 702	14 077
Net foreign exchange difference		-44	44	690	81
CASH AND CASH EQUIVALENTS AT END OF PERIOD		**58 367**	**36 702**	**58 367**	**36 702**

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, 2018	5 713	200	137 337	-100 241	43 011
Net result	-	-	-	-36 610	-36 610
New issue	1 302	-	57 101	-	58 403
Issue expenses	-	-	-2 024	-	-2 024
CLOSING BALANCE AUGUST 31, 2019	7 015	200	192 414	-136 851	62 780
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**

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

In February 2020, MUSD 5 was received from Protein Sciences Corporation. The payment referred to the repayment of an advance invoice of MUSD 0.5 - approximately MSEK 4.8, of which half was booked as research and development costs and the remainder as prepaid expenses. The remaining MUSD 4.5 was received as support for transition of the manufacturing process. The payment has 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 748 (975). As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 926 (899). Pricing has been set by the arm's length principle.

KSEK	Sep-Aug 2019/20	Sep-Aug 2018/19
Consultant fees and salaries to related parties	748	975
Consultant fees to Board members	926	899

Note 3 – 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, 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%. As of August 31, 2020, Diamyd Medical held approximately 4.5% of the medical device company Companion Medical, Inc. The holding was valued at cost, approximately MSEK 2.8. After the end of the financial year, the holding was divested and proceeds of MUSD 13.9, corresponding to approximately MSEK 120, were received.

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 2018/2019. 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 7, 2020

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

Annual General Meeting	November 26, 2020
Quarterly Report 1	January 20, 2021
Quarterly Report 2	March 31, 2021
Quarterly Report 3	June 23, 2021
Year-end Report	October 6, 2021

Annual Report

The Annual Report for 2019 /20 is expected to be available on November 5, 2020, via Diamyd Medical AB's website (https://www.diamyd.com).

Annual General Meeting

The Annual General Meeting will be held on November 26, 2020, at 5:00 p.m., Finlandshuset , Snickarbacken 4 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 metastudy as well as in the Company's European Phase IIb trial DIAGNODE-2, where the diabetes vaccine is 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.
Further information is available on https://www.diamyd.com.

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