QUARTERLY REPORT 1

September 2019 – November 2019

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

Developing 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

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

September 1, 2019 – November 30, 2019

- Net income: MSEK 0.1 (0.3)
- Net result: MSEK -6.8 (-8.5)
- Result per share: SEK -0.1 (-0.2)
- Cash flow from operating activities: MSEK -6.1 (-10.8)
- Liquid assets and short-term investments as of November 30, 2019: MSEK 50.6 (31.8)

Significant events first quarter, September– November

- ReGenerate-1: Positive safety review of Remygen® gave clearance to start next part of Phase I/II trial in type 1 diabetes patients
- Manufacturing process may be moved to a new manufacturer
- Agreement for intralymphatic Diamyd® trial in LADA patients
- Preliminary results were presented from a GABA/Diamyd® trial
- DIAGNODE-2: Patients will be offered longer participation in the European Phase IIb trial with the diabetes vaccine Diamyd®
- DIAGNODE-2: Feasibility study supported the use of intralymphatic injections of Diamyd®

Significant events after the reporting period

- DIAGNODE-1: Positive Top-line results from Phase I/II trial with intralymphatic Diamyd®
- ReGenerate-1: The main part of the Phase I/II trial with Remygen® in type 1 diabetes started
- Significant effect of Diamyd® in Type 1 diabetes shown in comprehensive analysis of previous phase III and phase II trials

"Recent clinical results and analyses provide strong support for the efficacy of the diabetes vaccine Diamyd® and significantly decreases the risk in the clinical development program for our type 1 diabetes therapy"

Ulf Hannelius, CEO

Comments by CEO Ulf Hannelius

I am proud to say that the first quarter of the financial year 2019/2020 has substantially strengthened Diamyd Medical as a company. Recent clinical results and analyses provide strong support for the efficacy of the diabetes vaccine Diamyd® and significantly decreases the risk in the clinical development program for our type 1 diabetes therapy.

In December, we announced results from a comprehensive analysis based on more than 530 type 1 diabetes patients who participated in three previous placebo controlled randomized trials with Diamyd®. The analysis, a collaborative effort between Diamyd Medical, academic researchers and clinicians, is based on the hypothesis that the efficacy of the Diamyd®-therapy differs depending on the presence or absence of certain genes. These genes code for the HLA molecule that in turn determines how antigens are recognized and presented by the immune system. The field has long known that genetic variations in the HLA molecule constitute one of the most significant risk factors for type 1 diabetes and other autoimmune diseases. Only in recent years has this led to the realization that these genes may also be central to defining different subgroups of patients in order to tailor treatments based on the patient's underlying disease mechanism, so-called precision medicine.

Against this background, it is of the utmost interest that the results indeed show that the effect of Diamyd® is influenced by the patient's HLA genes. About 50% of all patients included in the analysis have HLA genes that associate with the best effect of the vaccine. More specifically, the highest doses (3 or 4 subcutaneous injections) of Diamyd® in this subgroup of patients, give a statistically significant treatment effect. Patients that received a higher dose of Diamyd® are estimated to have on average up to 60% more insulin producing capacity compared to placebo at 15 months from baseline.

These results give us the opportunity to precisely identify the patients that have a high likelihood of responding to Diamyd®. Moreover, they also provide answers to questions that were raised following the phase III trial which did not meet its primary end point in 2011. A previous large-scale analysis (published in the beginning of 2017) showed that Diamyd® with a very high probability has a positive but limited (approximately 16-20%) biological effect on preserving the insulin producing capacity compared to placebo. The new analysis focusing on specific subgroups shows that the effect is both positive AND clinically relevant when targeting the right patient group. Furthermore, it is encouraging that additional doses of Diamyd® lead to better efficacy. This ties very nicely to our Diamyd®-program; the recently announced topline results from DIAGNODE-1 and the European DIAGNODE-2 trial with three intralymphatic injections of Diamyd®, where we expect to present results the third quarter later this year.

The topline results from DIAGNODE-1, also presented in December, showed that the patients had well controlled blood glucose levels and used less insulin than expected. What is perhaps even more exiting is that a fourth booster injection, given to three patients 30 months after baseline, preserved the insulin producing capacity for a whole year. This shows that additional doses of Diamyd® administered into the lymph node seem to lead to improved efficacy and goes well with the dose-response relationship seen in the comprehensive analysis mentioned above.

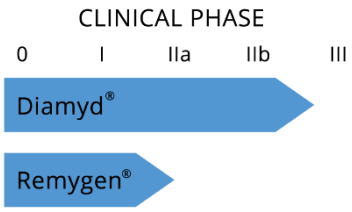
The new insights into Diamyd® in type 1 diabetes treatment are significant and we benefit from them in all aspects of our work including defining the analysis plan for DIAGNODE-2, planning for the upcoming phase III program and in our discussions with potential partners. We have a very interesting and intense period ahead of us.

Stockholm, January 22, 2020

Ulf Hannelius, *President and CEO*

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 immunotherapy for the treatment of autoimmune diabetes (type 1 diabetes).

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.

Intralymphatic treatment with Diamyd® is now being investigated in a clinical Phase IIb trial (DIAGNODE-2), with the aim of confirming the previously demonstrated clinical effect from a pilot trial in type 1 diabetes patients (DIAGNODE-1).

Remygen® is an oral regenerative and immunomodulatory therapy 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.

Remygen® is now being investigated in a clinical Phase I/II trial (ReGenerate-1), where clinical efficacy is evaluated with the aim of optimizing treatment ahead of registration-based trials.

Significant events during the first quarter

September 1, 2019 – November 30, 2019

Positive safety review of Remygen® gave clearance to start next part of Phase I/II trial in type 1 diabetes patients

The initial safety and dose escalation part of the Phase I/II trial with Remygen® in type 1 diabetes patients, ReGenerate-1, was completed. The safety data from the six patients included in the first part of the trial was evaluated by an independent Data Safety Monitoring Board (DSMB) who recommended that the main study could start.

Manufacturing process may be moved to a new manufacturer

Diamyd Medical's manufacturing process of rhGAD65, the active ingredient in the diabetes vaccine Diamyd®, may be moved to a new manufacturer. Protein Sciences has offered to support Diamyd Medical in a transition of the current process to a new manufacturer, the details of which will need to be discussed and agreed on by the parties.

Diamyd Medical entered agreement for intralymphatic Diamyd® trial in LADA patients

The agreement with the Norwegian University of Science and Technology in Trondheim (NTNU) refers to a first, investigator initiated clinical Phase II trial with the diabetes vaccine Diamyd® administered directly into the lymph node in a limited number of patients newly diagnosed with LADA (Latent Autoimmune Diabetes in Adults).

Preliminary results were presented from a GABA/Diamyd® trial

Preliminary results from the US investigator initiated GABA/Diamyd® trial were presented by Professor Kenneth McCormick at University of Alabama at Birmingham, Principal Investigator and Sponsor of the trial, at the annual meeting of the EASD. Initial analyses indicated that GABA alone or in combination with two 20 µg Diamyd® injections under the skin (in contrast to three injections into a lymph node as in the ongoing DIAGNODE trial) to recent onset type 1 diabetes patients does not significantly affected insulin production, blood glucose values or insulin dose compared to placebo. A potential positive effect of GABA on lowering glucagon levels was observed. No serious side effects were reported. In-depth metabolic analyses and immunological results are expected to follow.

Patients offered longer participation in the European Phase IIb trial with the diabetes vaccine Diamyd®

Patients participating in the diabetes trial DIAGNODE-2 who have not yet performed their last visit at 15 months, are offered to be included in a 9 month extension of the trial, which means that these patients will be followed for a total of 24 months. Top-line results of the trial will be presented after 15 months, in the third quarter of 2020. The purpose of the longer follow-up is to further strengthen the regulatory package with safety and efficacy data prior to a potential earlier market application.

Feasibility study supported the use of intralymphatic injections of Diamyd®

A feasibility study performed as a Master Thesis at Uppsala University and supervised by Diamyd Medical, supported the use of ultrasound guided intralymphatic injections for clinical routine use.

Significant events after the reporting period

Positive Top-line results from Phase I/II trial with intralymphatic Diamyd®

When all 12 patients had been followed throughout the 30-month period in the open-label trial DIAGNODE-1, the patients showed on average a positive clinical course with a near normal long-term blood sugar and a low need for externally supplied insulin. The three patients who received an extra Diamyd® injection into the lymph node after their 30-month visit showed a maintained own insulin production between the 30- and 43-month visits, as well as lower long-term blood sugar and insulin requirements compared to baseline. Safety looked good and no serious side effects had been reported.

The main part of the Phase I/II trial ReGenerate-1 with Remygen® started

Four patients had already been included in the trial and additional patients were scheduled to be included in December and January. Compilation of metabolic results from the completed safety and dose escalation part of the trial awaits a final experimental analysis and is expected to be announced in early 2020.

Significant effect of Diamyd® in Type 1 diabetes shown in a comprehensive analysis of previous Phase III and Phase II trials

A new analysis based on data from more than 530 individual patients from previous Phase III and II trials in Europe and US with the diabetes vaccine Diamyd® identified genetically defined subgroups of type 1 diabetes patients that showed a positive and statistically significant dose-dependent treatment response.

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

Trial 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 and will continue for a total of 15 months. As of autumn 2019, those patients who have not performed their last visit at 15 months are invited to participate in a nine months extension of the trial. 15-month results are expected to be presented in the third quarter of 2020. The aim of the trial is to evaluate the patients' remaining insulin producing capacity. Coordinating Investigator is Professor Johnny Ludvigsson at Linköping University, Sweden. Diamyd Medical is the Sponsor of the trial.

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. The primary aim of the trial is to in a smaller dose escalation section evaluate the safety of Remygen®. The main trial also evaluates whether the insulin-producing cells can be regenerated using Remygen®, and in the combination of Remygen® and Alprazolam. The trial is led by Professor Per-Ola Carlsson at Uppsala University, Sponsor of the trial.

Other ongoing trial with Diamyd®

- **DiAPREV-IT 2 – COMBINING DIAMYD® WITH VITAMIN D**
  A placebo-controlled investigator-initiated clinical trial, where Diamyd® is given subcutaneously and being tested in combination with vitamin D in children at high risk of developing type 1 diabetes, meaning that they have been found to have an ongoing autoimmune process but do not yet have any clinical symptoms of diabetes. The trial includes 26 children and results are expected in the beginning of 2020. The aim of the trial is to evaluate whether Diamyd® can delay or prevent the participants from presenting with type 1 diabetes. The trial is led by Dr. Helena Elding Larsson at Lund University, Sweden, Sponsor of the trial.

Key figures

	3 months Sep-Nov 2019	3 months Sep-Nov 2018	12 months Sep-Aug 2018/19
Research and development costs, MSEK	-2.7	-4.9	-22.4
Solidity, %	84	73	85
Result per share, SEK	-0.1	-0.2	-0.5
Liquidity and short-term investment per share, SEK	0.7	0.6	0.8
Equity per share, SEK	0.8	0.6	0.9
Cash flow per share, SEK	0.2	0.1	0.3
Share price per closing, SEK	7.5	6.4	8.4
Number of shares per closing	69 169 796	56 333 904	69 169 796
Average number of shares	69 169 796	56 333 904	65 371 779
Average number of employees	7	6	6

Income statement

KSEK	Note	3 months Sep-Nov 2019	3 months Sep-Nov 2018	12 mon Sep-Aug 2018/19
OPERATING INCOME				
Net income		118	261	1 568
Other operating income		13	25	69
TOTAL OPERATING INCOME		131	287	1 637
OPERATING EXPENSES				
External research and development costs		-2 734	-4 881	-22 359
External patent- and license costs		-444	-410	-1 693
Personnel costs	1	-2 136	-1 951	-7 891
Other external costs	1	-1 514	-1 460	-6 017
Other operating expenses		-12	-17	-105
Depreciation and impairment of material and immaterial assets		-35	-35	-140
TOTAL OPERATING EXPENSES		-6 876	-8 754	-38 206
OPERATING RESULT		**-6 744**	**-8 467**	**-36 569**
Net Financial income/expense		-39	-58	-41
RESULT BEFORE TAXES		**-6 783**	-8 525	**-36 610**
Taxes		-	-	-
NET RESULT FOR THE PERIOD		**-6 783**	**-8 525**	**-36 610**

Balance sheet

KSEK	Note	30 Nov 2019	30 Nov 2018	31 Aug 2019
ASSETS				
NON-CURRENT ASSETS				
Intangible assets		310	449	345
Financial assets	2	11 979	8 789	11 979
TOTAL NON-CURRENT ASSETS		12 288	9 239	12 323
CURRENT ASSETS				
Trade receivables		214	225	214
Other receivables		942	1 832	1 215
Prepaid expenses and accrued income		2 255	3 932	3 736
Short term investments		-	10 005	20 012
Liquid assets		50 584	21 750	36 702
TOTAL CURRENT ASSETS		53 995	37 743	61 879
TOTAL ASSETS		**66 283**	46 982	74 202
EQUITY AND LIABILITIES				
EQUITY				
Restricted equity				
Share capital		7 015	5 714	7 015
Statutory reserve		200	200	200
Non-restricted equity				
Share premium reserve non-restricted		192 414	137 238	192 414
Profit or loss brought forward		-136 850	-100 240	-100 240
Net loss for the period		-6 783	-8 525	-36 610
TOTAL EQUITY		55 997	34 387	62 780
PROVISIONS				
Pensions and other obligations		777	777	777
Other provisions	3	-	556	-
TOTAL PROVISIONS		777	1 334	777
CURRENT LIABILITIES				
Trade payables		1 977	4 325	1 707
Other payables		644	678	563
Prepaid income and accrued expenses		6 888	6 257	8 374
TOTAL CURRENT LIABILITIES		9 509	11 261	10 644
TOTAL EQUITY AND LIABILITIES		**66 283**	46 982	74 202

Statement of cash flow

KSEK	3 months Sep-Nov 2019	3 months Sep-Nov 2018	12months Sep-Aug 2018/19
OPERATING ACTIVITIES			
Operating profit/loss	-6 744	-8 467	-36 569
Interest received	0	0	0
Interest paid	-18	-58	-124
Non-cash flow items			
Depreciation	35	35	140
Other non-cash flow items	-	-276	-832
CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL	**-6 727**	**-8 766**	**-37 384**
Increase (-) decrease (+) receivables	1 755	-2 909	-2 085
Increase (+) decrease (-) debts	-1 136	900	284
NET CASH FLOW FROM OPERATING ACTIVITIES	**-6 108**	**-10 775**	**-39 185**
INVESTING ACTIVITIES			
Investment in financial assets	-	-1 484	-4 674
Investment in short term investments	20 012	20 030	10 024
NET CASH FLOW FROM INVESTING ACTIVITIES	**20 012**	**18 546**	**5 350**
FINANCING ACTIVITIES			
New issue	-	-	58 403
Issue expenses	-	-98	-2 024
NET CASH FLOW FROM FINANCING ACTIVITIES	-	**-98**	**56 380**
TOTAL CASH FLOW FOR THE PERIOD	**13 903**	**7 673**	22 544
Cash and cash equivalents at beginning of period	36 702	14 077	14 077
Net foreign exchange difference	-21	0	81
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**50 584**	**21 750**	**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	-	-	-	-6 783	-6 783
CLOSING BALANCE NOVEMBER 30, 2019	**7 015**	**200**	**192 414**	**143 633**	**55 997**

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 – 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 277 (233). As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 231(175). Pricing has been set by the arm's length principle.

KSEK	Sep-Nov 2019	Sep-Nov 2018
Consultant fees and salaries to related parties	277	233
Consultant fees to Board members	231	175

Note 2 – 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, 2019, the carrying amount was approximately MSEK 8.5. 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 also holds approximately 5.6% of the medical device company Companion Medical, Inc., based in San Diego, USA. Companion Medical develops technical devices for people with insulin treated diabetes. The holding is valued at cost, approximately MSEK 2.8.

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 quarterly 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 22, 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

Quarterly Report 2	March 25, 2020
Quarterly Report 3	June 24, 2020
Year-end Report	October 7, 2020

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. Diamyd® has demonstrated good safety in trials encompassing more than 1,000 patients as well as significant effect in some pre-specified subgroups. Results from 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, are expected to be presented in the third quarter of 2020. Diamyd Medical also develops the GABA-based investigational drug Remygen® for regeneration of endogenous insulin production. 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 and has holdings in the medtech company Companion Medical, Inc., San Diego, USA.

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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