QUARTERLY REPORT 3

September 2019 – May 2020

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

Diamyd Medical AB (publ)
Kungsgatan 29 • SE-111 56 Stockholm • Phone 08-661 00 26
www.diamyd.com • info@diamyd.com

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

September 1, 2019 – May 31, 2020

- Net result: MSEK 23.2 (-26.8), whereof third quarter MSEK -7.2 (-7.9). 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 0.3 (-0.4), third quarter SEK -0.1 (-0.1)
- Cash flow from operating activities: MSEK 24.1 (-28.5), third quarter: MSEK -6.8 (-9.1)
- Cash and cash equivalents at May 31, 2020: MSEK 81.5 (70.5)

Significant events third quarter, March – May 2020

- DiAPREV-IT2: Results presented from clinical trial with Diamyd® in children at high risk for type 1 diabetes
- Diamyd Medical fully subscribes to its pro rata share in NextCell Pharma's rights issue
- ReGenerate-1: Promising findings from the first part of a clinical trial with Remygen®
- The European and Japanese Patent Offices granted patents for administration of the diabetes vaccine into the lymph node
- Diamyd Medical opened up for vaccine manufacturing in Umeå, Sweden
- GADinLADA: New trial with Diamyd® in autoimmune diabetes started recruiting patients in Norway

"The topline results from DIAGNODE-2 will comprise both the primary clinical endpoint and the most important secondary clinical endpoints, as well as the results for the genetically defined subgroups. These results will have an impact on the final design of any upcoming late stage development trials, including the patient population that we will target for the drug label."

Ulf Hannelius, CEO

Comments by CEO Ulf Hannelius

We are currently looking forward to the topline results from our ongoing Phase IIb trial DIAGNODE-2. In this innovative trial, the diabetes vaccine Diamyd® is administered into a superficial lymph node. This novel administration route enhances the immunological effect of the vaccine by directly targeting the immunological site of action, and results from the pilot trial DIAGNODE-1 support superior clinical efficacy compared to the subcutaneous route used in previous trials.

Notably, we already know that a genetically defined subgroup of type 1 diabetes, a so-called disease endotype, has a very high likelihood of clinically responding to our diabetes vaccine Diamyd® when administered subcutaneously. This finding, released in December 2019, is based on a meta-analysis comprising of data from more than 500 patients treated with subcutaneous injections of Diamyd® in three previous placebo controlled randomized clinical trials.

Importantly, Battaglia et al. in the publication "Introducing the Endotype Concept to Address the Challenge of Disease Heterogeneity in Type 1 Diabetes, Diabetes Care, Jan 2020", co-authored by 17 of the world's most prominent key opinion leaders in the field, highlighted the existence of two disease endotypes of type 1 diabetes. These two endotypes were defined by the underlying autoimmunity associated with certain genotypes which is in line with our own findings described above regarding genetically defined subgroups.

There is consequently a strong and emerging case for precision medicine for type 1 diabetes where the aim is to zero in on the actual disease mechanism to tailor treatments for individual patients that are predicted to respond to the therapy. Precision medicine has already shown significant success in the oncology field where certain immunotherapeutic agents, most notably pembrolizumab (KEYTRUDA), target tumors that express specific biomarkers. It remains to be seen if the intralymphatic injections used in DIAGNODE-2 has the potential to work in a more broadly defined group of individuals with type 1 diabetes compared to subcutaneous injections, or if the upcoming results will also support the genetically defined responder subgroup.

To answer this question, the topline results from DIAGNODE-2 will comprise both the primary clinical endpoint and the most important secondary clinical endpoints, as well as the results for the genetically defined subgroups. These results will have an impact on the final design of any upcoming late stage development trials, including the patient population that we will target for the drug label.

This spring we also announced patent approvals in Europe and Japan for intralymphatic administration of Diamyd®. The approval provides patent protection in these important pharmaceutical markets until 2035 and complements our US patent protection for the therapeutic use of GAD that is valid until 2032. Patent application for intralymphatic administration of Diamyd® has also been granted in Australia and Russia, further strengthening our global patent portfolio.

In addition to the scientific, regulatory and operational progress with the diabetes vaccine Diamyd®, we could recently release positive preliminary results from the first stage of the clinical trial with the GABA study drug Remygen® which is ongoing at Uppsala University Hospital. Besides an improvement in glycemic control, treatment with Remygen® surprisingly normalized the response to hypoglycemia in individuals with long term type 1 diabetes. Preventing hypoglycemia is a significant unmet medical need in type 1 diabetes and if these promising results are replicated, we may have an opportunity to broaden the therapeutic platform around GABA. The main stage of the trial is now ongoing where patients will be treated with both low and high dose of Remygen® as well as with the combination of Remygen® and the GABA receptor modulator Alprazolam.

We recently announced that, to further cement our control of the Diamyd® asset, we are setting up our own facility in Umeå Sweden to manufacture GAD, the active component in Diamyd®. The 10,000 square feet facility will give us the opportunity to work directly with licensing partners as well as to build and scale our own commercial manufacturing capabilities. Logistically it is also a perfect match since our drug formulator APL resides in the building next door.

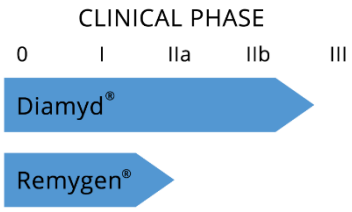
Finally, in these COVID-19 times we are all reminded of the importance of strong drug safety profiles. Unlike other drugs being developed for autoimmune diabetes, Diamyd® does not downregulate the immune system and therefore does not increase the risk of infections. Our diabetes vaccine has been evaluated without any safety concerns in trials encompassing more than 1,000 individuals, including healthy young children at risk of type 1 diabetes and in patients with recent-onset diabetes. This is a significant advantage going forward in our pursuit to achieve the best possible outcomes for patients with type 1 diabetes.

Stockholm, June 24, 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 third quarter

Mar 1, 2020 – May 31, 2020

Results from clinical trial with Diamyd® in children at high risk for type 1 diabetes

Results from the investigator initiated prevention trial DiAPREV-IT 2, where 26 healthy children at high risk for type 1 diabetes were treated with two subcutaneous injections of Diamyd® or placebo, showed that over the course of two years, one individual in the Diamyd® arm and two individuals in the placebo arm were diagnosed. No safety concerns were raised, and the safety profile was comparable between the active arm and the placebo arm. Mechanistic studies are still due to be conducted, and data from both DiAPREV-IT 1 and DiAPREV-IT 2 will be evaluated in a combined analysis.

Diamyd Medical fully subscribes to its pro rata share in NextCell Pharma's rights issue

Diamyd Medical announced that it will invest its pro rata share corresponding to approximately SEK 3.2 million in the associated company NextCell Pharma's ongoing rights issue, meaning that Diamyd Medical's book value of the holding in NextCell Pharma after the investment will increase from SEK 8.5 million to approximately SEK 11.7 million.

Promising findings from the first part of a clinical trial with Remygen®

The initial safety and dose escalation part of the Phase I/II trial ReGenerate-1 with Remygen® in individuals with long-term type 1 diabetes presented preliminary results showing that the trial participants' blood sugar control improved over the nine-day treatment period. The results also supported a surprising protective effect of Remygen® during hypoglycaemia, that is, during sharply lowered blood sugar levels. The findings in the trial are patent pending. The independent Data Safety Monitoring Board (DSMB) has previously approved the commencement of the main part of ReGenerate-1, which among other things evaluates Remygens® effect on restoring beta cell function.

The European and Japanese Patent Offices granted patent for intralymphatic administration of the diabetes vaccine Diamyd®

The granted patents are valid until 2035 and provides central protection for the diabetes vaccine Diamyd®. In particular, the patent protects the intralymphatic administration method that is being evaluated in the Phase IIb trial DIAGNODE-2 and which previously showed positive results in the Phase I/II trial DIAGNODE-1.

Vaccine manufacturing in Umeå

Diamyd Medical announced that a new manufacturing facility is being set up in Umeå by Diamyd Medical. The first priority of the new site is to receive the process technology for the manufacture of recombinant GAD65, the active ingredient in the therapeutic diabetes vaccine Diamyd®.

New trial with Diamyd® in autoimmune diabetes started recruiting patients in Norway

GADinLADA, the first clinical phase II trial with the diabetes vaccine Diamyd® administered directly into the lymph node in patients with LADA started recruitment at the Norwegian University of Science and Technology in Trondheim (NTNU), in cooperation with St. Olav's University Hospital, Trondheim. The trial will also be conducted in Sweden at the Center for Diabetes, the Academic Specialist Center. In total, the trial encompasses 15 patients between the ages of 30 to 70 years diagnosed with LADA within the last 12 months who are not yet on insulin therapy.

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.

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 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.

- **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 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. 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.

Key figures

	3 months Mar-May 2019/20	3 months Mar-May 2018/19	9 months Sep-May 2019/20	9 months Sep-May 2018/19	12 months Sep-Aug 2018/19
Research and development costs, MSEK	-1.8	-5.1	-7.5	-16.2	-22.4
Solidity, %	90	84	90	84	85
Result per share, SEK	-0.1	-0.1	0.3	-0.4	-0.5
Liquidity and short-term investment per share, SEK	1.2	1.0	1.2	1.0	0.8
Equity per share, SEK	1.2	1.0	1.2	1.0	0.9
Cash flow per share, SEK	-0.5	-0.1	0.2	0.3	0.3
Share price per closing, SEK	21.5	7.0	21.5	7.0	8.4
Number of shares per closing	69 169 796	69 169 796	69 169 796	69 169 796	69 169 796
Average number of shares	69 169 796	66 862 220	69 169 796	61 510 811	65 371 779
Average number of employees	7	6	7	6	6

Income statement

KSEK	Note	3 months Mar-May 2019/20	3 months Mar-May 2018/19	9 months Sep-May 2019/20	9 months Sep-May 2018/19	12 months Sep-Aug 2018/19
OPERATING INCOME						
Net income		97	943	263	1 323	1 568
Other operating income		8	25	770	56	69
Other compensation and income	1	-	-	43 174	-	-
TOTAL OPERATING INCOME		105	968	44 207	1 380	1 637
OPERATING EXPENSES						
External research and development costs	1	-1 751	-5 115	-7 486	-16 177	-22 359
External patent- and license costs		-1 427	-361	-2 422	-1 398	-1 693
Personnel costs	2	-2 399	-2 063	-6 736	-6 015	-7 891
Other external costs	2	-1 525	-1 277	-4 565	-4 381	-6 017
Other operating expenses		-13	-12	-36	-77	-105
Depreciation and impairment of material and immaterial assets		-35	-35	-105	-105	-140
TOTAL OPERATING EXPENSES		-7 154	-8 863	-21 350	-28 153	-38 206
OPERATING RESULT		**-7 049**	**-7 895**	**22 857**	**-26 773**	**-36 569**
Net Financial income/expense		-110	2	335	-70	-41
RESULT BEFORE TAXES		-7 159	-7 892	23 192	-26 843	-36 610
Taxes		-	-	-	-	-
NET RESULT FOR THE PERIOD		**-7 159**	**-7 892**	**23 192**	**-26 843**	**-36 610**

Balance sheet

KSEK	Note	31 May 2020	31 May 2019	31 Aug 2019
ASSETS				
NON-CURRENT ASSETS				
Intangible assets		240	379	345
Financial assets	3	11 979	8 789	11 979
TOTAL NON-CURRENT ASSETS		12 218	9 169	12 323
CURRENT ASSETS				
Trade receivables		0	478	214
Other receivables		1 112	1 811	1 215
Prepaid expenses and accrued income		444	4 644	3 736
Short term investments		29 984	40 018	20 012
Liquid assets		51 533	30 483	36 702
TOTAL CURRENT ASSETS		83 072	77 433	61 879
TOTAL ASSETS		**95 290**	**86 602**	**74 202**
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		-136 850	-100 240	-100 240
Net result for the period	1	23 192	-26 843	-36 610
TOTAL EQUITY		85 972	72 547	62 780
PROVISIONS				
Pensions and other obligations		777	777	777
Other provisions		-	5	-
TOTAL PROVISIONS		777	783	777
CURRENT LIABILITIES				
Trade payables		2 413	4 698	1 707
Other payables		259	721	563
Prepaid income and accrued expenses		5 869	7 853	8 374
TOTAL CURRENT LIABILITIES		8 541	13 272	10 644
TOTAL EQUITY AND LIABILITIES		**95 290**	**86 602**	**74 202**

Statement of cash flow

KSEK	Note	3 months Mar-May 2019/20	3 months Mar-May 2018/19	9 months Sep-May 2019/20	9 months Sep-May 2018/19	12 months Sep-Aug 2018/19
OPERATING ACTIVITIES						
Operating profit/loss	1	-7 049	-7 895	22 857	-26 773	-36 569
483Interest received		13	0	484	0	0
Interest paid		-123	-25	-149	-106	-124
Non-cash flow items						
Depreciation		35	35	105	105	140
Other non-cash flow items		5	-276	-734	-827	-832
CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL		**-7 119**	**-8 160**	**22 563**	**-27 601**	**-37 384**
Increase (-) decrease (+) receivables		412	-2 663	3 610	-3 854	-2 085
Increase (+) decrease (-) debts		-44	1 749	-2 104	2 911	284
NET CASH FLOW FROM OPERATING ACTIVITIES		**-6 751**	**-9 073**	**24 069**	**-28 543**	**-39 185**
INVESTING ACTIVITIES						
Investment in financial assets		-	-	-9 972	-1 484	-4 674
Investment in short term investments		-29 984	7	-	-9 983	10 024
NET CASH FLOW FROM INVESTING ACTIVITIES		-29 984	**7**	-9 972	**-11 467**	**5 350**
FINANCING ACTIVITIES						
New issue		-	-	-	58 403	58 403
Issue expenses		-	-	-	-2 024	-2 024
NET CASH FLOW FROM FINANCING ACTIVITIES		-	-	-	**56 380**	**56 380**
TOTAL CASH FLOW FOR THE PERIOD		**-36 735**	**-9 066**	**14 097**	**16 370**	**22 544**
Cash and cash equivalents at beginning of period		88 273	39 522	36 702	14 077	14 077
Net foreign exchange difference		-5	27	734	37	81
CASH AND CASH EQUIVALENTS AT END OF PERIOD		**51 532**	**30 483**	**51 532**	**30 483**	**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	-	-	-	23 192	23 192
CLOSING BALANCE MAY 31, 2020	**7 015**	**200**	**192 414**	**-113 658**	**85 972**

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, a payment of USD 5 million was made by Protein Sciences Corporation as support for transition of the manufacturing process which affected operating income by corresponding MSEK 43.2, as well as research and development costs by MSEK 2.0 due to reversion of previously disclosed manufacturing costs.

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 554 (792). As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 694 (637). Pricing has been set by the arm's length principle.

KSEK	Sep-May 2019/20	Sep-May 2018/19
Consultant fees and salaries to related parties	554	792
Consultant fees to Board members	694	637

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 May 31, 2020, 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, June 24, 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

Year-end Report*	October 7, 2020
Annual Report*	November 5, 2020
Annual General Meeting	November 26, 2020

*The reports will be available from these above dates at www.diamyd.com.

About Diamyd Medical

Diamyd Medical develops therapies for type 1 diabetes. The diabetes vaccine Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. 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. A new facility for vaccine manufacturing is being set up in Umeå with the first priority to receive the process technology 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® 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.

For more information, please contact:

Ulf Hannelius, President and CEO, phone: +46 736 35 42 41
Diamyd Medical AB (publ), Kungsgatan 29, SE-111 56 Stockholm, Sweden
Phone: +46 8 661 00 26 Fax: +46 8 661 63 68 E-mail: info@diamyd.com Reg. no: 556242-3797

The information was submitted for publication, through the agency of the contact person set out above, at 08.15 CET on June 24, 2020.