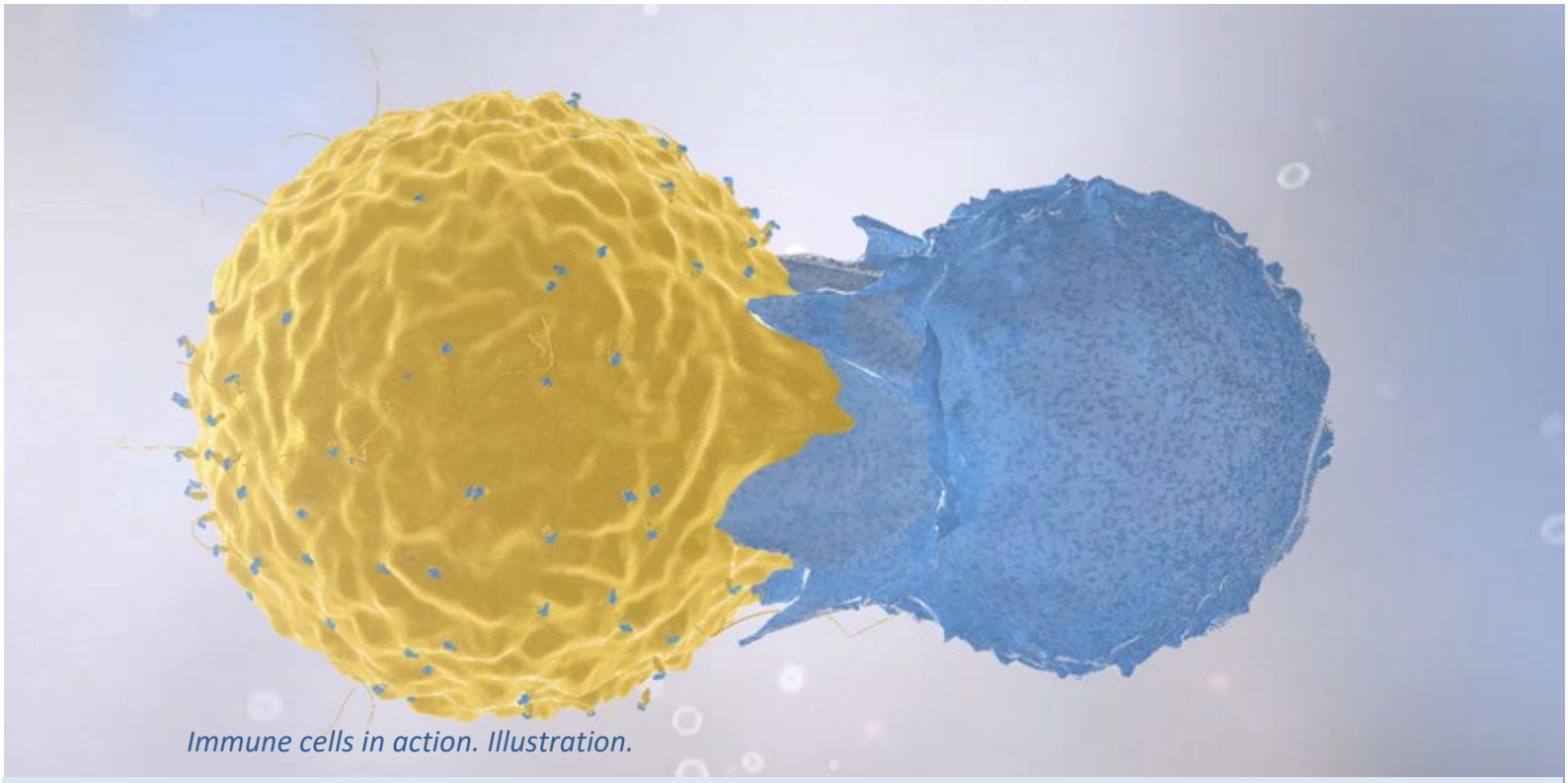
QUARTERLY REPORT 3

September 2018 – May 2019

Diamyd Medical AB (publ), Fiscal year 2018/2019



Immune cells in action. Illustration.

DIAGNODE-2 is fully recruited. Results are expected in Q3 2020.

Diamyd Medical's B-share is traded on Nasdaq First North 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, 2018 – May 31, 2019

- Net income: MSEK 1.3 (0.6), whereof third quarter MSEK 0.9 (0). The change refers to increased sales of GAD-protein for pre-clinical research.
- Net result: MSEK -26.8 (-32.5), whereof third quarter MSEK -7.9 (-12.6)
- Result per share: SEK -0.4 (-0.6), third quarter SEK -0.1 (-0.3)
- Cash flow from operating activities: MSEK -28.5 (-32.6), third quarter MSEK -9.1 (-9.6)
- Liquid assets and short-term investments as of May 31, 2019: MSEK 70.5 (52.8)

Significant events March 1, 2019 – May 31, 2019

- Swedish MPA approved new treatment arm with Remygen® and Alprazolam in Phase I/II trial ReGenerate-1
- DIAGNODE-2, the European Phase IIb trial with the diabetes vaccine Diamyd®, was fully recruited
- Results were presented from the EDCR IIa trial with Diamyd® given subcutaneously
- Immunological findings supporting intralymphatic treatment with Diamyd® were presented at a diabetes meeting in Stockholm
- Diamyd Medical announced strategic activities for 2019 and 2020
- New publication supported Diamyd Medical's patent rights around GABA

Significant events after the reporting period

- Diamyd Medical's intralymphatic diabetes therapy attracts increased interest
- Diamyd Medical fully subscribed to its pro rata share in NextCell Pharma's rights issue
- New interim report at 30 months and after extra injection supported long-term effect of intralymphatic Diamyd®

"The results have been received with great interest during partner discussions and show the potential of intralymphatic injections of Diamyd®."

Ulf Hannelius, CEO

Comments by CEO Ulf Hannelius

This June, over 15,000 representatives from industry, health care and academia within the diabetes field, gathered in San Francisco for the 79th Scientific Sessions organized by the American Diabetes Association (ADA). The conference marked a significant step forward for the field and strengthens the case for Diamyd Medical's mission to cure type 1 diabetes.

Prior to ADA, Diamyd Medical communicated both clinical and immunological results supporting the mechanistic rational and long-term effect of Diamyd® in newly diagnosed patients. The seven patients that had been followed for 30 months in the DIAGNODE-1 trial were in partial disease remission, with well controlled blood sugar levels and low requirements of insulin use. Three of these patients had received a fourth injection, a booster, at month 32. Intriguingly, we also saw increased endogenous insulin production between months 32 and 37 in these patients! The results have been received with great interest during partner discussions and show the potential of intralymphatic injections of Diamyd® to not only slow down but also to actually reverse the disease progression in a safe and specific manner.

With these promising results, I am very pleased to note advances in diabetes research that were presented by other organizations during ADA. Especially important for the type 1 diabetes field were results from a prevention trial presented by the research organization TrialNet, showing that a two-week immunosuppressive therapy with an anti-CD3 monoclonal antibody can delay the time to diagnosis for high risk individuals by approximately two years. Although treatment with anti-CD3 is associated with side effects and requires hospitalization, the positive findings support the notion of immunotherapy in type 1 diabetes. This in turn reflects very positively on the work Diamyd Medical is pursuing. Antigen-specific immunotherapy for type 1 diabetes is on top of mind. I am also encouraged by the fact that there was a session dedicated to autoimmune diabetes in adults (LADA) that highlighted the urgent need for disease-modifying therapies for this large and often misdiagnosed patient population. Defined by autoimmunity against the antigen GAD, autoimmune diabetes in adults represents an indication that fits very well with GAD-specific immunotherapy. Researchers are interested, Big Pharma is interested. There is great potential here for Diamyd®.

In addition to the advances made with Diamyd®, the Remygen® program is progressing well. Recently, the Swedish MPA approved an amendment to the ongoing ReGenerate-1 trial in Uppsala to add a treatment arm that combines our drug candidate Remygen® with the receptor modulating drug Alprazolam. This gives us the possibility to not only evaluate two different doses of Remygen® but also the combination with receptor modulators that preclinical studies have shown to further enhance GABA's effect of beta cell regeneration and immunomodulation.

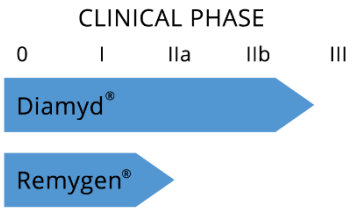
In May, Diamyd Medical reached a significant operational milestone when DIAGNODE-2 was reported fully enrolled. Specific regulatory activities are ongoing that prepare and build the case for potential earlier marketing approval for Diamyd®. In parallel, partner discussions are advancing well. With the positive advances we are making I feel confident in finding a partner that has the required know-how, resources and dedication to build and execute the best possible commercial strategy for Diamyd® together with us.

Stockholm, June 26, 2019

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 three 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 diabetes and type 2 diabetes.

Preclinical data indicate GABA's potential to stimulate growth and function of insulin-producing beta cells. Increased GABA concentrations activate GABA-specific cell surface receptors leading to effects on the cells in the pancreas.

By stimulating the growth of insulin-producing cells, Remygen® has the potential to reverse the disease progression in autoimmune diabetes 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

March 1, 2019 – May 31, 2019

Swedish Medical Products Agency approved new treatment arm with Remygen® and Alprazolam in Phase I/II trial ReGenerate-1

The approval entails that ReGenerate-1, with Diamyd Medical's GABA-based investigational drug Remygen®, will be expanded from the original two treatment arms encompassing Remygen® administration, with a third treatment arm in which 12 patients receive Remygen® in combination with the GABA receptor modulator Alprazolam.

Fully recruited European Phase IIb trial with the diabetes vaccine Diamyd®

All patients in Diamyd Medical's European Phase IIb trial DIAGNODE-2, where the diabetes vaccine Diamyd® (rhGAD65/alum) is given directly into the lymph node, were randomized and the trial was fully recruited. In total, 109 of originally 106 planned patients has been included. The patients will be followed for 15 months and topline results are expected in the third quarter 2020.

Results presented from the EDCR IIa trial where Diamyd® was given subcutaneously

30-month results from EDCR IIa, an investigator initiated pilot trial in which the diabetes vaccine Diamyd® was given subcutaneously combined with etanercept and vitamin D, showed that the treatment was safe and tolerable. No serious side effects had been reported. As expected, based on previously reported 15-month results, the results at 30 months showed no clear positive effect on the clinical course of the disease.

Immunological findings supporting intralymphatic treatment with Diamyd® were presented at a diabetes meeting in Stockholm

A new analysis of results from the DIAGNODE-1 trial that supports the association between immunological and clinical response following intralymphatic administration of Diamyd® was presented on April 11 at the Scandinavian Society for Study of Diabetes meeting in Stockholm.

Diamyd Medical announced strategic activities for 2019 and 2020

The Company announced that preparations for a Conditional Marketing Authorization Application in Europe end of 2020 are underway, including regulatory, manufacturing and commercial activities as well as preparations for a Phase III clinical trial in Europe and the US, to be completed post-approval in support of an accelerated approval process.

Publication supported Diamyd Medical's patent rights around GABA

A scientific article published in Journal of Diabetes Research supported previous findings that form the basis of patent applications that Diamyd Medical exclusively licenses from University of California, Los Angeles (UCLA). The study showed that treatment with GABA in combination with the GABA receptor modulating agent Alprazolam provides increased effect on the survival and growth of insulin-producing cells in animals.

Significant events after the reporting period

Diamyd Medical's intralymphatic diabetes therapy attracts increased interest

Progress in immunotherapy for type 1 diabetes reported during the ADA (American Diabetes Association) meeting in San Francisco is positively interpreted for Diamyd Medical as well as for the whole field working to prevent and treat type 1 diabetes.

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

Diamyd Medical pro rata share corresponds to approximately SEK 3.2 million in the associated company NextCell Pharma's rights issue, meaning that Diamyd Medical's book value of the holding in NextCell Pharma after the investment increases from approximately SEK 5.3 million to approximately SEK 8.5 million.

New interim report at 30 months and after extra injection supported long-term effect of intralymphatic Diamyd®

The first seven patients that have been followed for the entire 30-month period in DIAGNODE-1 continued to show a positive clinical course and were in partial remission. Partial remission in type 1 diabetes is characterized by low external insulin requirement and near to normal long-term blood sugar levels. Three of the seven patients had also received an extra intralymphatic injection of Diamyd® after their 30-month visit. These three patients showed an increase in endogenous insulin production between the 30 and 37month visits. The treatment appeared safe and no serious side effects had been reported.

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 diabetic patients 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. In addition to these, Diamyd® is evaluated in various combinations and modes of administration in ongoing investigator-initiated trials.

Trials with Diamyd® intralymphatically

- **DIAGNODE -2 – DIAMYD® IN LYMPH NODES IN COMBINATION WITH VITAMIN D**
  A follow-up double-blind randomized clinical trial where Diamyd® is administered directly into a lymph node in combination with treatment with vitamin D. The trial encompasses 109 patients from Sweden, the Czech Republic, Spain and the Netherlands, aged 12–24 years that have recently been diagnosed with type 1 diabetes and will continue for a total of 15 months. Results are expected to be presented in the third quarter of 2020. The trial is a follow up of DIAGNODE-1. 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.

- **DIAGNODE -1 – DIAMYD® IN LYMPH NODES IN COMBINATION WITH VITAMIN D**
  An open label investigator-initiated clinical trial, where Diamyd® is administered directly into a lymph node in combination with treatment with vitamin D. The trial comprises twelve patients between the ages of 12 and 30 newly diagnosed with type 1 diabetes and will continue for a total of 30 months. 30 months results are expected to be presented in the first quarter of 2020. The aim of the trial is to evaluate the safety of the combination treatment and the effect on the immune system and the patients' insulin producing capacity. The trial is led by Professor Johnny Ludvigsson at Linköping University.

Trials with Remygen® and GABA/Diamyd®

- **REGENERATE-1 – REMYGEN® /APRAZOLAM**
  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.

- **GABA/DIAMYD® – COMBINING DIAMYD® WITH GABA**
  A placebo-controlled investigator-initiated clinical trial, where Diamyd® is given subcutaneously and being tested in combination with GABA. In accordance with agreement with Jansen Research & Development and JDRF the trial has expanded to comprise 101 patients between the ages of 4 and 18 recently diagnosed with type 1 diabetes. The trial will continue for a total of 12 months and results are expected to be presented in the last quarter of 2019. The aim of the combination treatment is to preserve the body's residual capacity to produce insulin. The trial is led by Professor Kenneth McCormick at the University of Alabama at Birmingham, USA.

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.

Key figures

	3 months Mar-May 2019	3 months Mar-May 2018	9 months Sep-May 2018/19	9 months Sep-May 2017/18	12 months Sep-Aug 2017/18
Research and development costs, MSEK	-5.1	-8.5	-16.2	-21.2	-29.1
Solidity, %	84	84	84	84	78
Result per share, SEK	-0.1	-0.2	-0.4	-0.6	-0.8
Liquidity and short-term investment per share, SEK	1.0	0.9	1.0	0.9	0.8
Equity per share, SEK	1.0	1.0	1.0	1.0	0.8
Cash flow per share, SEK	-0.1	0.0	0.3	-0.4	-0.7
Share price per closing, SEK	7.0	4.2	7.0	4.2	7.9
Number of shares per closing	69 169 796	56 333 904	69 169 796	56 333 904	56 333 904
Average number of shares	66 862 220	56 333 904	64 091 861	56 333 904	34 783 517
Average number of employees	6	6	6	6	6

Income statement

KSEK	Note	3 months Mar-May 2019	3 months Mar-May 2018	9 months Sep-May 2018/19	9 months Sep-May 2017/18	12 months Sep-Aug 2017/18
OPERATING INCOME						
Net income		943	34	1 323	636	726
Other operating income		25	2	56	89	93
TOTAL OPERATING INCOME		968	36	1 380	725	819
OPERATING EXPENSES						
External research and development costs		-5 115	-8 518	-16 177	-21 241	-29 118
External patent- and license costs		-361	-757	-1 398	-1 667	-2 109
Personnel costs	1	-2 063	-2 064	-6 015	-6 109	-7 831
Other external costs	1	-1 277	-1 223	-4 381	-3 974	-5 408
Other operating expenses		-12	-27	-77	-182	-259
Depreciation and impairment of material and immaterial assets		-35	-35	-105	-96	-131
TOTAL OPERATING EXPENSES		-8 863	-12 624	-28 153	-33 269	-44 855
OPERATING RESULT		**-7 895**	**-12 587**	-26 773	**-32 543**	**-44 036**
Net Financial income/expense		2	29	-70	30	83
RESULT BEFORE TAXES		**-7 892**	-12 559	**-26 843**	-32 514	**-43 953**
Taxes		-	-	-	-	-
NET RESULT FOR THE PERIOD		**-7 892**	**-12 559**	**-26 843**	**-32 514**	**-43 953**

Balance sheet

KSEK	Note	31 May 2019	28 May 2018	31 Aug 2018
ASSETS				
NON-CURRENT ASSETS				
Intangible assets		379	519	484
Financial assets	2	8 789	7 305	7 305
TOTAL NON-CURRENT ASSETS		9 169	7 824	7 789
CURRENT ASSETS				
Trade receivables		478	37	108
Other receivables		1 811	1 273	624
Prepaid expenses and accrued income		4 644	2 821	2 346
Short term investments		40 018	20 018	30 035
Liquid assets		30 483	32 795	14 077
TOTAL CURRENT ASSETS		77 433	56 945	47 191
TOTAL ASSETS		**86 602**	**64 769**	**54 981**
EQUITY AND LIABILITIES				
EQUITY				
Restricted equity				
Share capital		7 015	5 714	5 714
Statutory reserve		200	200	200
Non-restricted equity				
Share premium reserve non-restricted		192 414	137 032	137 337
Profit or loss brought forward		-100 240	-56 286	-56 286
Net loss for the period		-26 843	-32 514	-43 953
TOTAL EQUITY		72 547	54 145	43 011
PROVISIONS				
Pensions and other obligations		777	777	777
Other provisions		5	1 107	832
TOTAL PROVISIONS		783	1 885	1 609
CURRENT LIABILITIES				
Trade payables		4 698	2 149	1 211
Other payables		721	812	537
Prepaid income and accrued expenses		7 853	5 778	8 613
TOTAL CURRENT LIABILITIES		13 272	8 739	10 361
TOTAL EQUITY AND LIABILITIES		**86 602**	**64 769**	**54 981**

Statement of cash flow

KSEK	3 months Mar-May 2019	3 months Mar-May 2018	9 months Sep-May 2018/19	9 months Sep-May 2017/18	12 months Sep-Aug 2017/18
OPERATING ACTIVITIES					
Operating profit/loss	-7 895	-12 588	-26 773	-32 543	-44 036
Interest received	0	74	0	203	285
Interest paid	-25	-45	-106	-173	-202
Non-cash flow items					
Depreciation	35	35	105	96	131
Other non-cash flow items	-276	-276	-827	-706	-981
CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL	**-8 160**	**-12 800**	**-27 601**	**-33 124**	**-44 804**
Increase (-) decrease (+) receivables	-2 663	-527	-3 854	1 217	2 269
Increase (+) decrease (-) debts	1 749	3 689	2 911	-651	971
NET CASH FLOW FROM OPERATING ACTIVITIES	**-9 073**	**-9 638**	**-28 543**	**-32 558**	**-41 564**
INVESTING ACTIVITIES					
Investment in material and immaterial assets	-	-178	-	-347	-347
Investment in financial assets	-	-	-1 484	-	-
Investment in short term investments	7	10 025	-9 983	10 013	-4
NET CASH FLOW FROM INVESTING ACTIVITIES	7	**-9 846**	-11 467	**9 665**	**-352**
FINANCING ACTIVITIES					
New issue	-	-	58 403	-	-
Issue expenses	-	-	-2 024	-7	298
NET CASH FLOW FROM FINANCING ACTIVITIES	-	-	56 380	**-7**	**298**
TOTAL CASH FLOW FOR THE PERIOD	**-9 066**	**208**	**16 370**	**-22 900**	**-41 617**
Cash and cash equivalents at beginning of period	39 522	32 587	14 077	55 695	55 695
Net foreign exchange difference	27	0	37	0	-1
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**30 483**	**32 795**	**30 483**	**32 795**	**14 077**

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, 2017	5 713	200	137 039	-56 287	86 666
Net result	-	-	-	-43 953	-43 953
Issue expenses	-	-	298	-	298
CLOSING BALANCE AUGUST 31, 2018	5 713	200	137 337	-100 241	43 011
OPENING BALANCE SEPTEMBER 1, 2018	**5 713**	**200**	**137 337**	**-100 241**	**43 011**
Net result	-	-	-	-26 843	-26 843
New issue	1 302	-	57 101	-	58 403
Issue expenses	-	-	-2 024	-	-2 024
CLOSING BALANCE MAY 31, 2019	**7 015**	**200**	**192 414**	**-127 083**	**72 547**

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. The consultancy services were attributable to IT-services. Total compensation for consultancy services and salaries to immediate family members amounted to KSEK 792 (732). As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 637 (559). Pricing has been set by the arm's length principle.

KSEK	Sep-May 2018/19	Sep-May 2017/18
Consultant fees and salaries to related parties	792	732
Consultant fees to Board members	637	559

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 May 31, 2019, the carrying amount was approximately MSEK 5.3 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 2017/2018. 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, June 26, 2019

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 2, 2019
Annual Report	October 31, 2019
Annual General Meeting	November 21, 2019

About Diamyd Medical

Diamyd Medical develops the diabetes vaccine Diamyd®, for antigen-specific immunotherapy to preserve the endogenous insulin production. Diamyd® has demonstrated good safety in trials with more than 1,000 patients as well as effect in some pre-specified subgroups. Besides the Company's own European Phase-II trial DIAGNODE-2 where the diabetes vaccine is administered directly into the lymph node, there are three investigator initiated clinical trials ongoing with 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. An investigator-initiated trial with GABA and Diamyd® in patients recently diagnosed with type 1 diabetes is also ongoing at the University of Alabama at Birmingham, USA. 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 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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This information is information that Diamyd Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out above, at 08.15 CET on June 26, 2019.