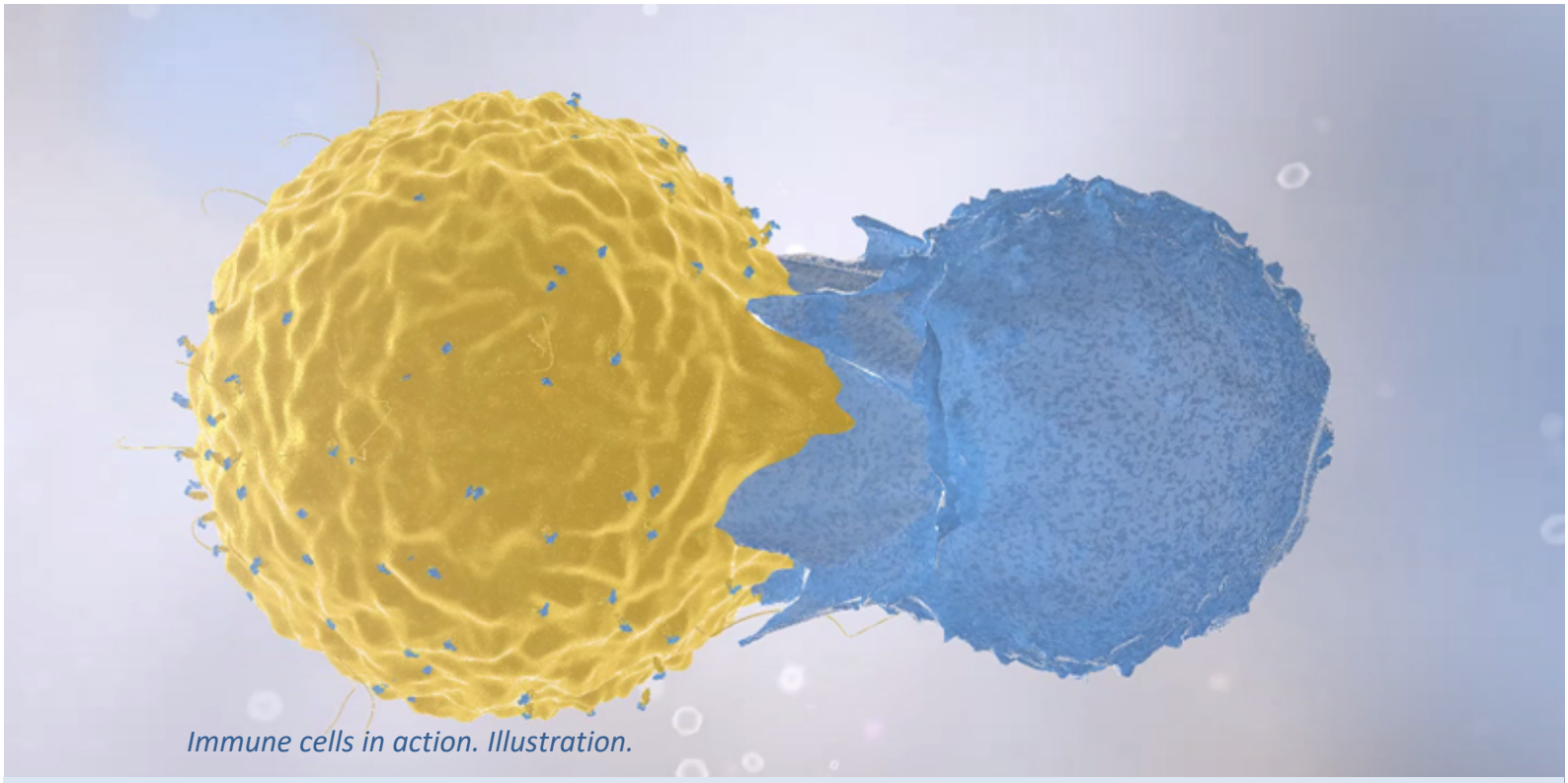
YEAR-END REPORT

September 2018 – August 2019

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



Immune cells in action. Illustration.

To preserve and regain the body's own insulin production

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, 2018 – August 31, 2019

- Net income: MSEK 1.6 (0.8), whereof the fourth quarter MSEK 0.3 (0.1). The change refers to increased sales of GAD-protein for pre-clinical research.
- Net result: MSEK -36.6 (-44.0), whereof the fourth quarter MSEK -9.8 (-11.7)
- Result per share: SEK -0.5 (-0.8), fourth quarter SEK -0.1 (-0.2)
- Cash flow from operating activities: MSEK -39.2 (-41.6), fourth quarter MSEK -10.6 (-9.0)
- Liquid assets and short-term investments as of August 31, 2019: MSEK 56.7 (44.1)

Significant events June 1, 2019 – August 31, 2019

- Diamyd Medical fully subscribed to its pro rata share in NextCell Pharma's rights issue
- DIAGNODE-1: Increase in endogenous insulin production following extra intralymphatic injection with Diamyd®

Significant events after the reporting period

- 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®

"With Diamyd® in late stage development - the world's furthest advanced antigen-specific diabetes therapeutic, Remygen® in early clinical phase, and a strong IP position, we look forward to further strengthening our value proposition during the forthcoming year."

Ulf Hannelius, CEO

Comments by CEO Ulf Hannelius

We systematically build our value proposition around intralymphatic administration of Diamyd®. The clinical results from DIAGNODE-1 provide proof of concept of a strong, clinically relevant effect for preserving the patient's own insulin production. Moreover, immunological results indicate a response as in immunological tolerance. In addition, a recently published feasibility study based on interviews and questionnaires highlighted the ease of use for intralymphatic injections in a clinical routine setting. The administration takes seconds, is simple, safe and the patient is free to leave the clinic within an hour.

The innovative, strategic choice in 2017 to focus on intralymphatic (IL) administration seems to be very successful. With safety from Diamyd® trials in more than 1000 patients, where injections under the skin (subcutaneous, SC) resulted in positive efficacy trends and significant efficacy in certain prespecified subgroups, three IL administrations one month apart, have resulted in that 11 out of 12 type 1 diabetes patients in the DIAGNODE-1 trial are in partial remission mode 15 months after treatment. As expected, SC administration of Diamyd® in the recently reported GABA/GAD investigator-initiated trial at the University of Alabama in Birmingham, confirmed these prior results, whereas the GABA part of the trial indicated an important effect on glucagon secretion. This trial started in 2015 before the higher potency of intranodal administration was known and it now seems clear that additional doses including IL administration, as is being pursued in DIAGNODE-1 and DIAGNODE-2 is required to achieve the desired effect with Diamyd®. We are excited to advance this innovative and promising therapeutic approach for patients suffering from autoimmune diabetes and it may be of interest to point out that a similar development is ongoing within the allergy space. Here, minute amounts of allergen are administered three times into a lymph node, resulting in, compared to conventional long-term SC or oral regimens, significantly faster and safer desensitization to several allergens.

Highlighting our second therapeutic platform based on GABA, the investigator initiated trial in Alabama reported important results from treatment with a GABA food supplement in a population of recent-onset type 1 diabetes patients. While trial limitations were observed, especially regarding patient adherence to the oral GABA supplement as well as an unusually strong response in a few placebo patients, strong trends for effects on lowering glucagon levels were seen in both treatment arms compared to placebo. This is interesting as we now have the very first clinical results in humans showing that GABA influences the pancreatic islets in patients with diabetes. Glucagon is a most important regulatory response to low blood glucose levels and an integral component in both type 1 and type 2 diabetes pathology. The role of glucagon in diabetes was highlighted in several large sessions at a recent EASD conference in Barcelona, Spain. Diamyd Medical's proprietary formulation of GABA, Remygen®, is being evaluated in the ReGenerate-1 trial at this time, and together with the data from the trial in Alabama we aim at much more precisely define the product profile around Remygen® - and advance it towards market.

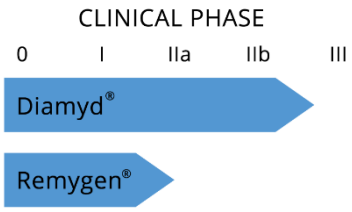
We have the world's furthest advanced antigen-specific diabetes therapeutic (Diamyd®) in late stage development; one additional compound (Remygen®) in early clinical phase, both of which are supported by strong safety and a significant unmet medical need. With our strong IP position and ongoing regulatory activities our goal is to further strengthen the foundation of the company ahead of results from DIAGNODE-2.

I would like to thank all patients, shareholders, collaborators and employees, for your engagement and confidence that makes all this possible.

Stockholm, October 2, 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- 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 fourth quarter

June 1, 2019 – August 31, 2019

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

Diamyd Medical pro rata share corresponded 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 increased from approximately SEK 5.3 million to approximately SEK 8.5 million.

Increase in endogenous insulin production following extra intralymphatic injection with Diamyd®

The first seven patients that had 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.

Significant events after the reporting period

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 in Barcelona, Spain. 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 lymphnode as in the ongoing DIAGNODE trials) 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 will be offered longer participation in the European Phase IIb trial with the diabetes vaccine Diamyd®

Following approval from the Competent Authorities and Ethics Committees in Spain, the Czech Republic, Sweden and the Netherlands, Diamyd Medical can offer the patients participating in the diabetes trial DIAGNODE-2 who have not yet performed their last visit at 15 months, 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, as previously announced, 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. The pilot study was based on interviews with and answers to questionnaires from selected radiologists and answers to questionnaires from selected study nurses participating in the ongoing DIAGNODE-2 trial where the antigen-specific immunotherapy Diamyd® is administered directly into a lymph node.

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® 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. Those patients who have not yet performed their last visit at 15 months will be offered to participate in an extension for another 9 months. 15-month 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.

Trial with Remygen® (GABA)

- **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.

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 Jun-Aug 2019	3 months Jun-Aug 2018	12 months Sep-Aug 2018/19	12 months Sep-Aug 2017/18
Research and development costs, MSEK	-6.2	-7.9	-22.4	-29.1
Solidity, %	85	78	85	78
Result per share, SEK	-0.1	-0.2	-0.5	-0.8
Liquidity and short-term investment per share, SEK	0.8	0.8	0.8	0.8
Equity per share, SEK	0.9	0.8	0.9	0.8
Cash flow per share, SEK	0.1	-0.3	0.3	-0.7
Share price per closing, SEK	8.4	7.9	8.4	7.9
Number of shares per closing	69 169 796	56 333 904	69 169 796	56 333 904
Average number of shares	69 169 796	56 333 904	65 371 779	56 333 904
Average number of employees	6	6	6	6

Income statement

KSEK	Note	3 months Jun-Aug 2019	3 months Jun-Aug 2018	12 mon Sep-Aug 2018/19	12 months Sep-Aug 2017/18
OPERATING INCOME					
Net income		247	90	1 568	726
Other operating income		12	4	69	93
TOTAL OPERATING INCOME		260	94	1 637	819
OPERATING EXPENSES					
External research and development costs		-6 182	-7 877	-22 359	-29 118
External patent- and license costs		-295	-719	-1 693	-2 109
Personnel costs	1	-1 877	-1 722	-7 891	-7 831
Other external costs	1	-1 638	-1 434	-6 017	-5 408
Other operating expenses		-29	-77	-105	-259
Depreciation and impairment of material and immaterial assets		-35	-35	-140	-131
TOTAL OPERATING EXPENSES		-10 056	-11 864	-38 206	-44 855
OPERATING RESULT		**-9 796**	**-11 770**	**-36 569**	**-44 036**
Net Financial income/expense		26	53	-41	83
RESULT BEFORE TAXES		**-9 769**	-11 716	**-36 610**	**-43 953**
Taxes		-	-	-	-
NET RESULT FOR THE PERIOD		**-9 769**	**-11 716**	**-36 610**	**-43 953**

Balance sheet

KSEK	Note	31 Aug 2019	31 Aug 2018
ASSETS			
NON-CURRENT ASSETS			
Intangible assets		345	484
Financial assets	2	11 979	7 305
TOTAL NON-CURRENT ASSETS		12 323	7 789
CURRENT ASSETS			
Trade receivables		214	108
Other receivables		1 215	624
Prepaid expenses and accrued income		3 736	2 346
Short term investments		20 012	30 035
Liquid assets		36 702	14 077
TOTAL CURRENT ASSETS		61 879	47 191
TOTAL ASSETS		**74 202**	**54 981**
EQUITY AND LIABILITIES			
EQUITY			
Restricted equity			
Share capital		7 015	5 714
Statutory reserve		200	200
Non-restricted equity			
Share premium reserve non-restricted		192 414	137 337
Profit or loss brought forward		-100 240	-56 286
Net loss for the period		-36 610	-43 953
TOTAL EQUITY		62 780	43 011
PROVISIONS			
Pensions and other obligations		777	777
Other provisions		-	832
TOTAL PROVISIONS		777	1 609
CURRENT LIABILITIES			
Trade payables		1 707	1 211
Other payables		563	537
Prepaid income and accrued expenses		8 374	8 613
TOTAL CURRENT LIABILITIES		10 644	10 361
TOTAL EQUITY AND LIABILITIES		**74 202**	**54 981**

Statement of cash flow

KSEK	3 months Jun-Aug 2019	3 months Jun-Aug 2018	12months Sep-Aug 2018/19	12 months Sep-Aug 2017/18
OPERATING ACTIVITIES				
Operating profit/loss	-9 796	-11 493	-36 569	-44 036
Interest received	0	82	0	285
Interest paid	-17	-29	-124	-202
Non-cash flow items				
Depreciation	35	35	140	131
Other non-cash flow items	-5	-276	-832	-981
CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL	**-9 783**	**-11 680**	**-37 384**	**-44 804**
Increase (-) decrease (+) receivables	1 769	1 052	-2 085	2 269
Increase (+) decrease (-) debts	-2 627	1 621	284	971
NET CASH FLOW FROM OPERATING ACTIVITIES	**-10 642**	**-9 006**	**-39 185**	**-41 564**
INVESTING ACTIVITIES				
Investment in material and immaterial assets	-	-	-	-347
Investment in financial assets	-3 190	-	-4 674	-
Investment in short term investments	20 006	-10 017	10 024	-4
NET CASH FLOW FROM INVESTING ACTIVITIES	**16 817**	**-10 017**	**5 350**	**-352**
FINANCING ACTIVITIES				
New issue	-	-	58 403	-
Issue expenses	-	298	-2 024	298
NET CASH FLOW FROM FINANCING ACTIVITIES	-	**298**	56 380	**298**
TOTAL CASH FLOW FOR THE PERIOD	**6 175**	**-18 725**	**22 544**	**-41 617**
Cash and cash equivalents at beginning of period	30 483	32 795	14 077	55 695
Net foreign exchange difference	44	7	81	-1
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**36 702**	**14 077**	**36 702**	**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	-	-	-	-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**

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 year 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 975 (939). As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 899 (733). Pricing has been set by the arm's length principle.

KSEK	Sep-Aug 2018/19	Sep-Aug 2017/18
Consultant fees and salaries to related parties	975	939
Consultant fees to Board members	899	733

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 August 31, 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 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 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 2, 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

Annual General Meeting	November 21, 2019
Quarterly Report 1	January 22, 2020
Quarterly Report 2	March 25, 2020
Quarterly Report 3	June 24, 2020
Year-end Report	October 7, 2020

Annual Report

The Annual Report for 2018 /19 is expected to be available on October 31, 2019, via Diamyd Medical AB's website (https://www.diamyd.com).

Annual General Meeting

The Annual General Meeting for the fiscal year 2018/2019 will be held on November 21, 2019, at 5:00 p.m., Hotel Kung Carl, Birger Jarlsgatan 21 in Stockholm.

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 two other 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. 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.
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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 October 2, 2019.