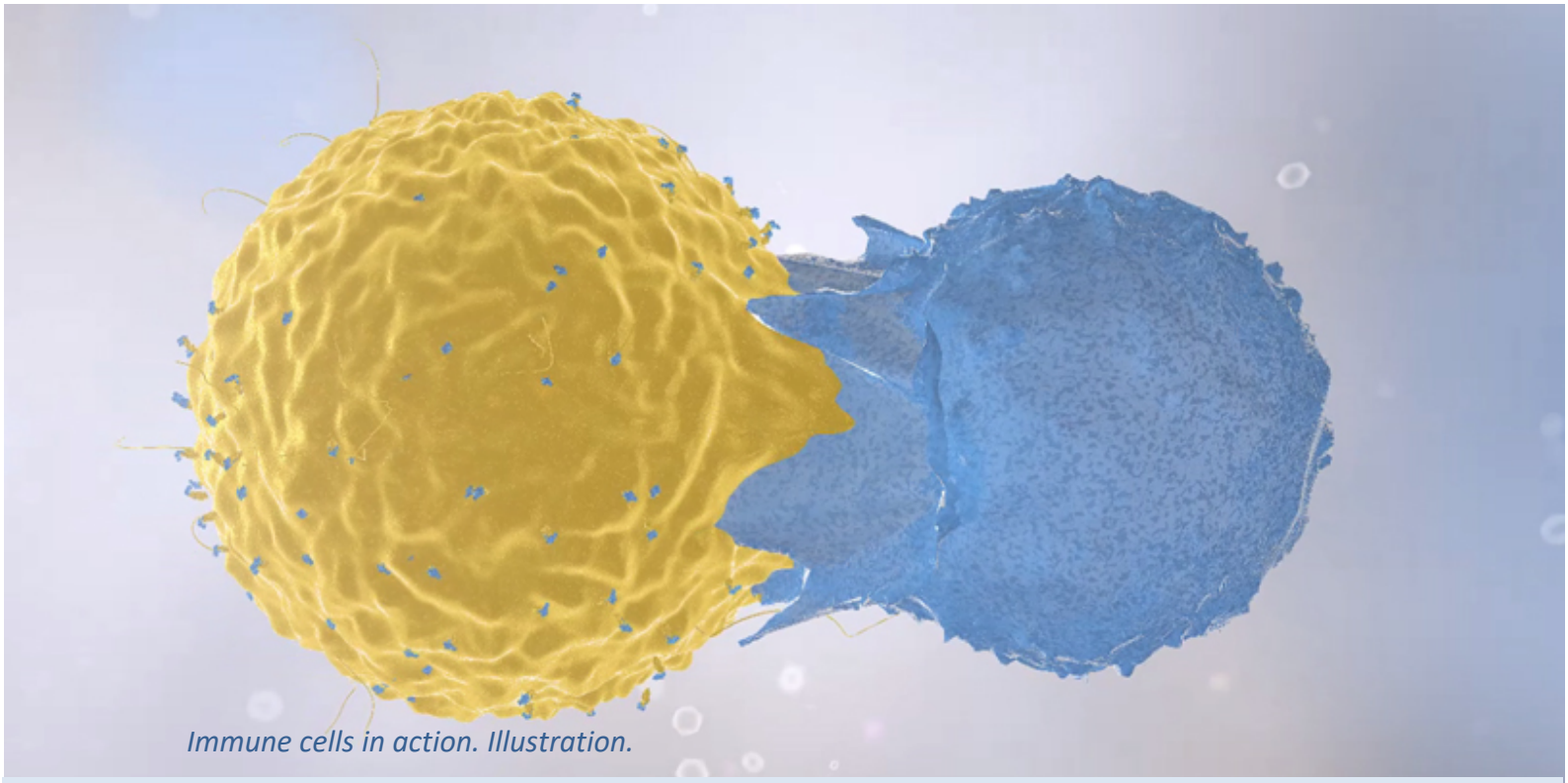
QUARTERLY REPORT 1

September 2018 – November 2018

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



Immune cells in action. Illustration.

Continued strong results from DIAGNODE-1

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.

First quarter, September 1– November 30, 2018

- Net result: MSEK -8.5 (-10,8).
- Result per share: SEK -0.2 (-0.2)
- Cash flow from operating activities: MSEK -10.8 (-12.1)
- Liquid assets and short-term investments as of November 30: MSEK 31.8 (73.7). After the reporting period MSEK 58.4 were raised through exercise of warrants.

Significant events September 1, 2018 – November 30, 2018

- Eleven out of twelve Type 1 diabetes patients treated with intralymphatic Diamyd® in Partial Remission at 15 months
- Internationally renowned diabetes expert joined Diamyd Medical's Board of Directors
- Immunological results supporting intralymphatic treatment with Diamyd® were presented at the Immunology of Diabetes Society Congress
- Diamyd Medical clarified the goal of applying for earlier market approval for Diamyd®
- Positive 15-month results were announced from the diabetes trial DIAGNODE-1

Significant events after the reporting period

- 75 percent of the patients have been enrolled in Diamyd Medical's European Phase II trial
- Diamyd Medial raised SEK 58.4 million through redemption of warrants

"Our top strategic priority is to prepare for a marketing application for Diamyd®."

Ulf Hannelius, CEO

Comments by CEO Ulf Hannelius

Dear Shareholders and Readers,

I am pleased to report significant clinical, strategic and financial progress for this quarter. In November we reported that 11 out of 12 patients treated with intralymphatic Diamyd® in the DIAGNODE-1 trial are in partial remission about 18 months after diagnosis of type 1 diabetes. This is notable as partial remission, defined as the patient having a well-controlled blood sugar level and a low requirement for external insulin, is seen in patients that have had the disease for more than a year. The fact that retained endogenous insulin production, lower blood sugar levels AND lower insulin requirements can be seen, is very attractive. Importantly, and as highlighted during several recent partnering meetings, this efficacy profile clearly satisfies the commercial requirements set by larger pharmaceutical companies. From a competitive standpoint it should be mentioned that very few candidate compounds that have been evaluated in clinical trials have achieved similar indications of effect, while our antigen specific Diamyd® therapeutic points at both superior safety profile and patient convenience (three injections only).

CEO Ulf Hannelius, Company founder Board director Anders Essen-Moller and Professor Mark Atkinson, January 2019

We are enormously proud that Professor Mark Atkinson, one of the world's most respected type 1 diabetes researchers and key opinion leaders agreed to join our Board of Directors in November. Mark is actively contributing with his expertise and joined us for several important meetings with potential partners recently during the JP Morgan Healthcare week in San Francisco.

We are confident in the Diamyd® program, and Mark is adept at highlighting the unique strengths of the program while also providing increased international visibility to our company.

Our cash position was strengthened through the redemption of warrants in November. The raised SEK 58 million means that the ongoing DIAGNODE-2 trial is fully financed until results in the third quarter of 2020.

Our top strategic priority during this financial year is to prepare for a marketing application for Diamyd®. These regulatory activities are performed in parallel with the ongoing clinical program, with the aim to file by the end of 2020 together with one or a few strategic partners, in order to maximize the potential in the program as well as the shareholder value.

With several upcoming milestones including full recruitment of DIAGNODE-2, results from booster injections in DIAGNODE-1 and our GABA program with the ongoing ReGenerate-1 trial in Uppsala, we have an exciting period ahead.

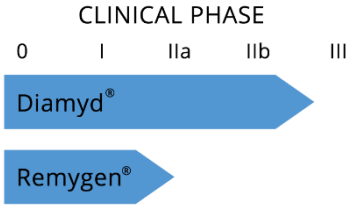
Stockholm, January 23, 2019

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. The effect is achieved primarily by increasing the levels of GABA in the blood and thus activating GABA receptors that affect the function and growth of insulin-producing 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 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, 2018 – November 30, 2018

Eleven out of twelve Type 1 diabetes patients treated with intralymphatic Diamyd® are in Partial Remission at 15 months

An analysis ahead of the conference 1st Antigen Specific Immune Tolerance Europe in London December 2018 showed that 92% (11 out of 12) of the DIAGNODE-1 trial participants were in Partial Remission at 15 months from start of the trial. This can be compared to a large international study in 3 657 children and adolescents with type 1 diabetes, where approximately 20% of the patients were in partial remission 12 to 18 months after diagnosis. Partial remission in type 1 diabetes is characterized by low external insulin requirement and near to normal long-term blood sugar levels.

Internationally renowned diabetes expert joined Diamyd Medical's Board of Directors

One of the world's most prominent diabetes experts, Professor Mark Atkinson, American Diabetes Association Eminent Scholar for Diabetes Research; Director, UF Diabetes Institute; University of Florida, Gainesville, FL, USA, was elected as member Diamyd Medical's Board of Director's at the Annual General Meeting of Shareholders on November 15, 2018. Re-elected were; for Chairman: Erik Nerpin, and for Directors: Anders Essen-Möller, Torbjörn Bäckström, and Maria-Teresa Essen-Möller.

Immunological results that support intralymphatic treatment with Diamyd® were presented at the Immunology of Diabetes Society Congress

Results of intralymphatic treatment with the diabetes vaccine Diamyd® indicating the induction of a long-term immune response that supports the positive clinical results shown in the DIAGNODE-1 trial were presented at the international conference Immunology of Diabetes Society Congress 2018 in London.

Diamyd Medical clarified the goal of applying for earlier market approval for Diamyd®

Diamyd Medical announced that the Company's goal is to submit a marketing application for the diabetes vaccine Diamyd® in late 2020.

Positive 15-month results with Diamyd® in Type 1 diabetes

When all patients had been followed for 15 months in the diabetes trial DIAGNODE-1, where the diabetes vaccine Diamyd® is given directly into the lymph node, a clearly positive and clinically relevant effect was seen in improving the clinical course and maintaining the endogenous insulin production in newly diagnosed type 1 diabetes.

Significant events after the reporting period

75 percent of patients enrolled in Diamyd Medical's European Phase II trial

Three quarters, 80 out of 106 patients has been included in the European Phase II trial DIAGNODE-2, where the diabetes vaccine Diamyd® is administered directly into the lymph node.

Diamyd Medical raised SEK 58.4 million in funds through redemption of warrants

During 1 to 30 November 2018, holders of warrants of series TO 1 B and TO 2 A of Diamyd Medical AB were able to subscribe for shares through warrants. A total of 426 037 A shares and 12 409 855 B shares were subscribed for, which means a subscription rate of 95.6 percent. Diamyd Medical raised approximately SEK 58.4 million before issue costs. After registration with the Swedish Companies Registration Office of the new shares, the number of shares in Diamyd Medical amounts to a total of 69 159 726, of which 2 556 223 A shares and 66 613 573 B shares.

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**
  DIAGNODE-2 is a follow-up double-blind randomized clinical trial where Diamyd® is administered directly into lymph nodes in combination with treatment with vitamin D. The trial encompasses approximately 106 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. 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. Diamyd Medical is the Sponsor of the trial.

- **DIAGNODE -1 – DIAMYD® IN LYMPH NODES IN COMBINATION WITH VITAMIN D**
  An open label clinical trial, where Diamyd® is administered directly into lymph nodes 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. The trial was fully recruited in June 2017. 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, Sweden.

Trials with Remygen® and GABA/Diamyd®

- **REGENERATE-1 – REMYGEN®**
  ReGenerate-1 is an open-label, investigator-initiated clinical trial with Remygen®. The trial includes 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®. The trial is led by Professor Per-Ola Carlsson at Uppsala University.

- **GABA/DIAMYD® – COMBINING DIAMYD® WITH GABA**
  A placebo-controlled 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 95 patients between the ages of 4 and 18 recently diagnosed with type 1 diabetes. The trial will continue for a total of 12 months. 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 trials with Diamyd®

- **EDCR IIa – COMBINING DIAMYD® WITH ETANERCEPT AND VITAMIN D**
  An open label clinical trial, where Diamyd® is given subcutaneously and being tested in combination with etanercept and vitamin D. The trial comprises 20 patients between the ages of 8 and 18 who have been newly diagnosed with type 1 diabetes and will continue for a total of 30 months. 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, Sweden.

- **DiAPREV-IT 2 – COMBINING DIAMYD® WITH VITAMIN D**
  A placebo-controlled 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. 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 Sep-Nov 2018	3 months Sep-Nov 2017	12 months Sep-Aug 2017/18
Research and development costs, MSEK	-4.9	-7.6	-29.1
Solidity, %	73	87	78
Result per share, before and after dilution, SEK	-0.2	-0.2	-0.8
Liquidity and short-term investments per share, Before and after dilution, SEK	0.6	1.3	0.8
Equity per share, before and after dilution, SEK	0.6	1.3	0.8
Cash flow per share, before and after dilution, SEK	0.1	-0.2	-0.7
Share price per closing, SEK	6.4	3.4	7.9
Number of shares per closing	56 333 904	56 333 904	56 333 904
Average number of shares	56 333 904	56 333 904	56 333 904
Average number of employees	6	6	6

Income statement

KSEK	Note	3 months Sep-Nov 2018	3 months Sep-Nov 2017	12 months Sep-Aug 2017/18
OPERATING INCOME				
Net income		261	586	726
Other operating income		25	70	93
TOTAL OPERATING INCOME		287	655	819
OPERATING EXPENSES				
External research and development costs		-4 881	-7 571	-29 118
External patent- and license costs		-410	-366	-2 109
Personnel costs	1	-1 951	-2 069	-7 831
Other external costs	1	-1 460	-1 362	-5 408
Other operating expenses		-17	-84	-259
Depreciation and impairment of material and immaterial assets		-35	-26	-131
TOTAL OPERATING EXPENSES		-8 754	-11 479	-44 855
OPERATING RESULT		**-8 467**	-10 824	-44 036
Net Financial income/expense		-58	54	83
RESULT BEFORE TAXES		**-8 525**	-10 770	-43 953
Taxes		-	-	-
NET RESULT FOR THE PERIOD		**-8 525**	-10 770	-43 953

Balance sheet

KSEK	Note	30 Nov 2018	30 Nov 2017	31 Aug 2018
ASSETS				
NON-CURRENT ASSETS				
Intangible assets		449	242	484
Financial assets	2	8 789	7 305	7 305
TOTAL NON-CURRENT ASSETS		9 239	7 547	7 789
CURRENT ASSETS				
Trade receivables		225	342	108
Other receivables		1 832	942	624
Prepaid expenses and accrued income		3 932	4 307	2 346
Short term investments		10 005	30 048	30 035
Liquid assets		21 750	43 658	14 077
TOTAL CURRENT ASSETS		37 743	79 297	47 191
TOTAL ASSETS		**46 982**	86 843	54 981
EQUITY AND LIABILITIES				
EQUITY				
Restricted equity				
Share capital		5 714	5 714	5 714
Statutory reserve		200	200	200
Non-restricted equity				
Share premium reserve non-restricted		137 238	137 038	137 337
Profit or loss brought forward		-100 240	-56 286	-56 286
Net loss for the period		-8 525	-10 770	-43 953
TOTAL EQUITY		34 387	75 896	43 011
PROVISIONS				
Pensions and other obligations		777	777	777
Other provisions	3	556	1 658	832
TOTAL PROVISIONS		1 334	2 436	1 609
CURRENT LIABILITIES				
Trade payables		4 325	4 012	1 211
Other payables		678	711	537
Prepaid income and accrued expenses		6 257	3 789	8 613
TOTAL CURRENT LIABILITIES		11 261	8 512	10 361
TOTAL EQUITY AND LIABILITIES		**46 982**	86 843	54 981

Statement of cash flow

KSEK	3 months Sep-Nov 2018	3 months Sep-Nov 2017	12 months Sep-Aug 2017/18
OPERATING ACTIVITIES			
Operating profit/loss	-8 467	-10 824	-44 036
Interest received	0	-	285
Interest paid	-58	-68	-202
Non-cash flow items			
Depreciation	35	26	131
Other non-cash flow items	-276	-155	-981
CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL	**-8 766**	**-11 020**	-44 804
Increase (-) decrease (+) receivables	-2 909	-243	2 269
Increase (+) decrease (-) debts	900	-878	971
NET CASH FLOW FROM OPERATING ACTIVITIES	**-10 775**	**-12 141**	-41 564
INVESTING ACTIVITIES			
Investment in material and immaterial assets	-	-	-347
Investment in financial assets	-1 484	-	-
Investment in short term investments	20 030	-17	-4
NET CASH FLOW FROM INVESTING ACTIVITIES	**18 546**	**-17**	-352
FINANCING ACTIVITIES			
Issue expenses	-98	-	298
NET CASH FLOW FROM FINANCING ACTIVITIES	**-98**	-	298
TOTAL CASH FLOW FOR THE PERIOD	**7 673**	**-12 158**	-41 617
Cash and cash equivalents at beginning of period	14 077	55 695	55 695
Net foreign exchange difference	0	121	-1
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**21 750**	**43 658**	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	2 991	200	56 803	-30 732	29 263
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	-	-	-	-8 525	-8 525
Issue expenses	-	-	-98	-	-98
CLOSING BALANCE NOVEMBER 30, 2018	**5 713**	**200**	**137 239**	**-108 766**	**34 387**

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 233 (309) KSEK. As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 175 (209). Pricing has been set by the arm's length principle.

KSEK	Sep-Nov 2018	Sep-Nov 2017
Consultant fees and salaries to related parties	233	309
Consultant fees to Board members	175	209

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 2018, the carrying amount was approximately MSEK 5.4 Diamyd Medical's share of the equity as well as share of the votes was as of November 30, 2018, approximately 13.1%. 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.

Note 3 – Provisions

The amount constitutes mainly of accrued research and development costs.

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, January 23, 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

Quarterly Report 2	March 27, 2019
Quarterly Report 3	June 26, 2019
Year-End Report	October 2, 2019

About Diamyd Medical

Diamyd Medical is dedicated to finding a cure for diabetes and other serious inflammatory diseases through pharmaceutical development and investments in stem cell and medical technology.

Diamyd Medical develops the diabetes vaccine Diamyd®, for antigen-specific immunotherapy based on the exclusively licensed GAD-molecule. Diamyd® has demonstrated good safety in studies 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 four investigator initiated clinical trials ongoing with Diamyd®. Diamyd Medical also develops Remygen®, an oral GABA-based candidate drug which in June 2018 was approved by the Swedish Medical Agency for clinical trial. An investigator-initiated placebo-controlled trial with GABA and Diamyd® in patients recently diagnosed with type 1 diabetes is ongoing at the University of Alabama at Birmingham.

Exclusive licenses for GABA and positive allosteric modulators of GABA receptors for the treatment of diabetes and inflammatory diseases constitutes alongside with the diabetes vaccine Diamyd® and Remygen® key assets. Diamyd Medical is also 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 and in the gene therapy company Periphagen, Inc., Pittsburgh, USA. FNCA Sweden AB is the Company's Certified Adviser. E-mail: info@fnca.se Tel: 08-528 003 99.

For more information, please contact:
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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 January 23, 2019.

Note: This document has been prepared in both Swedish and English. The Swedish version shall govern in case of differences between the two documents. The document contains certain statements about the Company's operating environment and future performance. These statements should only be regarded as reflective of prevailing interpretations. No guarantees can be made that these statements are free from errors.