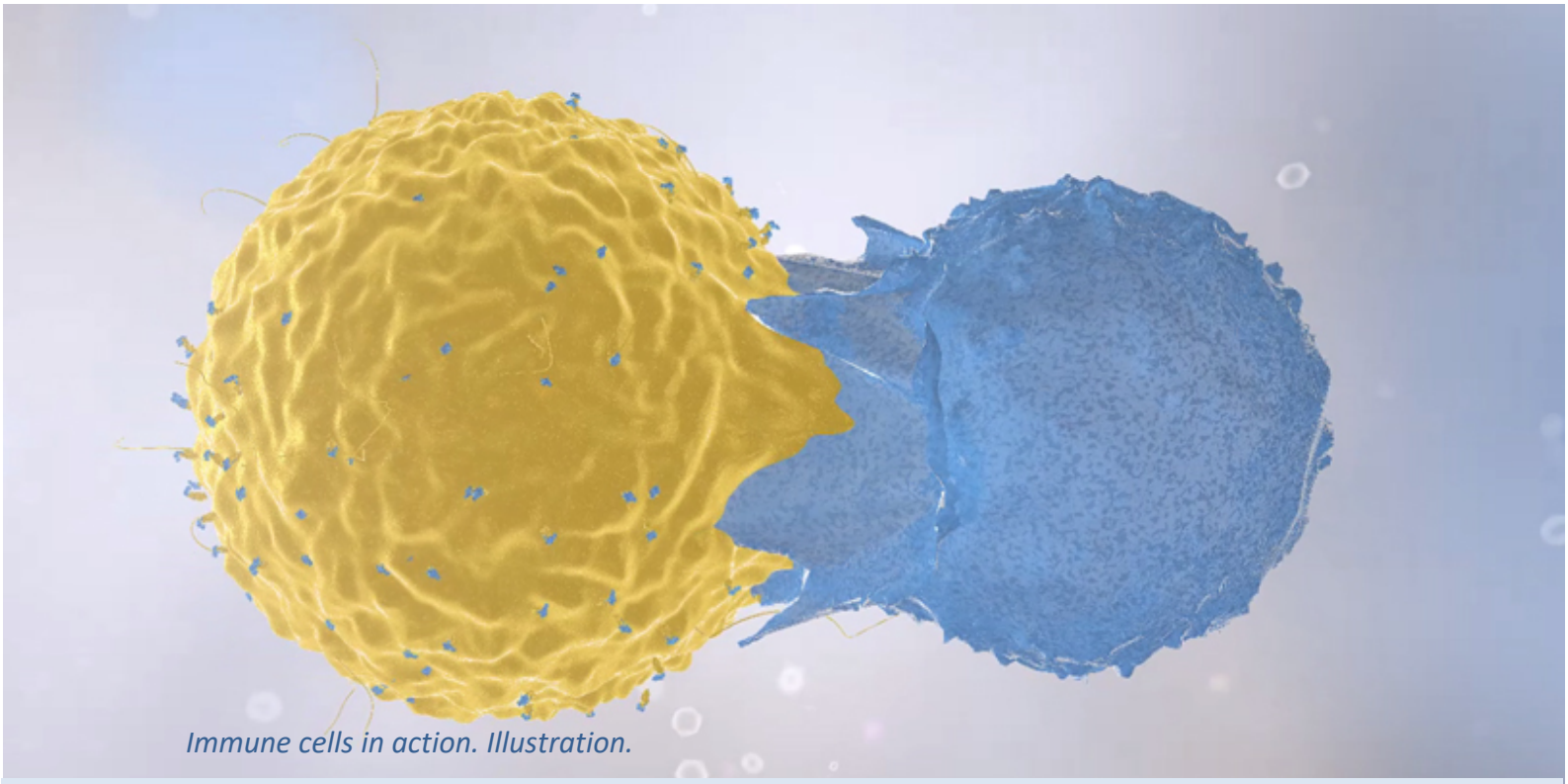
QUARTERLY REPORT 2

September 2018 – February 2019

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



Immune cells in action. Illustration.

DIAGNODE-2 towards full recruitment

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 – February 28, 2019

- Net result: MSEK -19.0 (-20.0), whereof second quarter MSEK -10.4 (-9.2)
- Result per share: SEK -0.3 (-0.4), second quarter SEK -0.2 (-0.2)
- Cash flow from operating activities: MSEK -19.5 (-22.9), second quarter MSEK -8.7 (-10.8)
- Liquid assets and short-term investments as of February 28, 2019: MSEK 79.6 (62.6)

Significant events December 1, 2018 – February 28, 2019

- 75 percent of the patients enrolled in DIAGNODE-2, the European Phase II trial with Diamyd®
- Diamyd Medial raised SEK 58.4 million through redemption of warrants

Significant events after the reporting period

- Diamyd Medical announced strategic activities for 2019 and 2020
- DIAGNODE-2 close to full recruitment
- New publication supports Diamyd Medical's patent rights around GABA

"We are seeing increased international visibility highlighting the work we are doing."

Ulf Hannelius, CEO

Comments by CEO Ulf Hannelius

Dear Shareholders and Readers,

Our European phase IIb trial DIAGNODE-2, where the diabetes vaccine Diamyd® is administered three times in a superficial lymph node is close to being fully recruited. Currently, 93 out of 106 patients have been randomized and in the beginning of March we were able to give the green light to the clinic in Rotterdam in the Netherlands to start recruiting. This together with high patient retention rate ensures that we keep our timelines and will close the trial for recruitment during the spring. Results are expected in the third quarter in 2020, and as previously communicated our aim is to file for a conditional marketing authorization in Europe end of 2020.

There are certain requirements for a therapy to be aligned with conditional marketing authorization in Europe. Firstly, the positive effects need to out-weigh the risks and there should be a clear public health benefit to making the product immediately available. Secondly, the applicant should be able to provide comprehensive data following conditional authorization in order to convert it to a full marketing authorization. And finally, the product needs to address a significant unmet medical need. Given the above, there is a clear case supporting an early market introduction for Diamyd®.

Today, there are no disease-modifying therapies available for type 1 diabetes patients. Recent reports both in Europe and in the US show that treatment goals are met by only a minority of patients despite an increased use of modern assistive devices and improvements in insulin technologies. The disease is associated with a significant decrease in life-expectancy due to short- and long-term complications as well as significant health economic costs.

Diamyd® is a therapeutic that has demonstrated very good safety in trials with more than 1,000 patients and there is strong support of a positive biological effect of the therapeutic. Most importantly, recent results based on intralymphatic administration of Diamyd® support an efficacy profile that is both clinically highly relevant as well as unique, and the treatment regimen is simple and therefore aligned with high patient acceptance.

Supported by these key insights we are moving forward with confidence and we are seeing increased international visibility highlighting the work we are doing. Recently an interview by the US non-profit T1DExchange was published featuring our efforts to cure type 1 diabetes. Diamyd Medical has also been invited to present the diabetes vaccine Diamyd® at the international scientific conference Vaccines Forum in Valencia in May.

As announced yesterday, regulatory meetings in Europe and the US are planned for 2019 and 2020. We also announced that we are planning for commercial activities including pricing and market access, designing a Phase III program, as well as making sure the commercial manufacturing capacity is aligned with market launch and expansion. Existing resources will be used for finalizing DIAGNODE-2 and for regulatory meetings, while activities associated with a Phase III program and commercial manufacturing and will be financed through with future partnerships and/or institutional investors.

Based on current results and the progress we are making it seems ever more likely that we will be able to make a significant positive impact in the lives of those affected by type 1 diabetes.

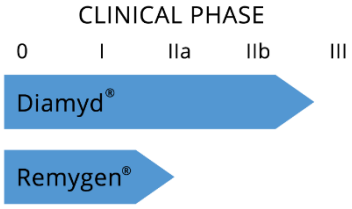
Stockholm, March 27, 2019

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 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 second quarter

December 1, 2018 – February 28, 2019

75 percent of patients enrolled in Diamyd Medical's European Phase IIb trial DIAGNODE-2

Three quarters, 80 out of 106 patients had been included in DIAGNODE-2, where the diabetes vaccine Diamyd® is administered directly into the lymph node with the aim to preserve the patients' endogenous insulin production

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.

Significant events after the reporting period

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.

DIAGNODE-2 close to full recruitment

Diamyd Medical announced that 91 patients were included in the DIAGNODE-2 trial. Results from the trial are expected during the third quarter of 2020.

Publication supports Diamyd Medical's patent rights around GABA

A scientific article published in Journal of Diabetes Research supports previous findings that form the basis of patent applications that Diamyd Medical exclusively licenses from University of California, Los Angeles (UCLA). The study shows 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.

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 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. 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 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®**
  An open-label, investigator-initiated clinical trial with Remygen®. The trial includes approximately 30 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 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 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. 30 months results are expected to be presented in the spring of 2019. 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.

- **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 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 Dec-Feb 2018/19	3 months Dec-Feb 2017/18	6 months Sep-Feb 2018/19	6 months Sep-Feb 2017/18	12 months Sep-Aug 2017/18
Research and development costs, MSEK	-6.2	-5.2	-11.1	-12.7	-29.1
Solidity, %	86	90	86	90	78
Result per share, before and after dilution, SEK	-0.2	-0.2	-0.3	-0.4	-0.8
Liquidity and short-term investments per share, Before and after dilution, SEK	1.2	1.1	1.2	1.1	0.8
Equity per share, before and after dilution, SEK	1.2	1.2	1.2	1.2	0.8
Cash flow per share, before and after dilution, SEK	0.3	-0.2	0.4	-0.4	-0.7
Share price per closing, SEK	7.1	3.4	7.1	3.4	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	61 510 811	56 333 904	34 783 517
Average number of employees	6	6	6	6	6

Income statement

KSEK	Note	3 months Dec-Feb 2018/19	3 months Dec-Feb 2017/18	6 months Sep-Feb 2018/19	6 months Sep-Feb 2017/18	12 months Sep-Aug 2017/18
OPERATING INCOME						
Net income		97	16	358	602	726
Other operating income		28	17	53	87	93
TOTAL OPERATING INCOME		125	33	411	689	819
OPERATING EXPENSES						
External research and development costs		-6 181	-5 151	-11 061	-12 722	-29 118
External patent- and license costs		-627	-504	-1 037	-870	-2 109
Personnel costs	1	-2 000	-1 976	-3 952	-4 045	-7 831
Other external costs	1	-1 643	-1 389	-3 105	-2 751	-5 408
Other operating expenses		-50	-110	-65	-194	-259
Depreciation and impairment of material and immaterial assets		-35	-35	-70	-61	-131
TOTAL OPERATING EXPENSES		-10 536	-9 165	-19 290	-20 644	-44 855
OPERATING RESULT		**-10 411**	**-9 131**	-18 878	**-19 955**	**-44 036**
Net Financial income/expense		-14	-53	-72	1	-83
RESULT BEFORE TAXES		**-10 425**	-9 185	**-18 951**	-19 955	**-43 953**
Taxes		-	-	-	-	-
NET RESULT FOR THE PERIOD		**-10 425**	**-9 185**	**-18 951**	**-19 955**	**-43 953**

Balance sheet

KSEK	Note	28 Feb 2019	28 Feb 2018	31 Aug 2018
ASSETS				
NON-CURRENT ASSETS				
Intangible assets		414	376	484
Financial assets	2	8 789	7 305	7 305
TOTAL NON-CURRENT ASSETS		9 204	7 681	7 789
CURRENT ASSETS				
Trade receivables		98	19	108
Other receivables		1 394	680	624
Prepaid expenses and accrued income		2 777	2 905	2 346
Short term investments		40 025	30 043	30 035
Liquid assets		39 522	32 587	14 077
TOTAL CURRENT ASSETS		83 817	66 234	47 191
TOTAL ASSETS		**93 020**	**73 915**	**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		-18 951	-19 955	-43 953
TOTAL EQUITY		80 440	66 704	43 011
PROVISIONS				
Pensions and other obligations		777	777	777
Other provisions	3	281	1 383	832
TOTAL PROVISIONS		1 058	2 160	1 609
CURRENT LIABILITIES				
Trade payables		4 057	710	1 211
Other payables		640	682	537
Prepaid income and accrued expenses		6 826	3 659	8 613
TOTAL CURRENT LIABILITIES		11 522	5 051	10 361
TOTAL EQUITY AND LIABILITIES		**93 020**	**73 915**	**54 981**

Statement of cash flow

KSEK	Not	3 months Dec-Feb 2018/19	3 months Dec-Feb 2017/18	6 months Sep-Feb 2018/19	6 months Sep-Feb 2017/18	12 months Sep-Aug 2017/18
OPERATING ACTIVITIES						
Operating profit/loss		-10 411	-9 131	-18 878	-19 955	-44 036
Interest received		0	129	0	129	285
Interest paid		-53	-60	-82	-128	-202
Non-cash flow items						
Depreciation		35	35	70	61	131
Other non-cash flow items		-276	-276	-551	-430	-981
CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL		**-10 705**	**-9 303**	**-19 442**	**-20 324**	**-44 804**
Increase (-) decrease (+) receivables		1 719	1 987	-1 191	1 744	2 269
Increase (+) decrease (-) debts		261	-3 461	1 162	-4 340	971
NET CASH FLOW FROM OPERATING ACTIVITIES		**-8 725**	**-10 778**	**-19 471**	**-22 919**	**-41 564**
INVESTING ACTIVITIES						
Investment in material and immaterial assets		-	-169	-	-169	-347
Investment in financial assets		-	-	-1 484	-	-
Investment in short term investments		-30 020	5	-9 990	-12	-4
NET CASH FLOW FROM INVESTING ACTIVITIES		-30 020	**-164**	-11 474	**181**	**-352**
FINANCING ACTIVITIES						
New issue		58 403	-	58 403	-	-
Issue expenses		-1 925	-7	-2 024	-7	298
NET CASH FLOW FROM FINANCING ACTIVITIES		56 478	**-7**	56 380	**-7**	**298**
TOTAL CASH FLOW FOR THE PERIOD		**17 733**	**-10 949**	**25 435**	**-23 107**	**-41 617**
Cash and cash equivalents at beginning of period		21 750	43 658	14 077	55 695	55 695
Net foreign exchange difference		39	-122	10	-1	-1
CASH AND CASH EQUIVALENTS AT END OF PERIOD		**39 522**	**32 587**	**39 522**	**32 587**	**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	-	-	-	-18 951	-18 951
New issue	1 302	-	57 101	-	58 403
Issue expenses	-	-	-2 024	-	-2 024
CLOSING BALANCE FEBRUARY 28, 2019	**7 015**	**200**	**192 414**	**-119 190**	**80 440**

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 525 (523). As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 406 (325). Pricing has been set by the arm's length principle.

KSEK	Sep-Feb 2018/19	Sep-Feb 2017/18
Consultant fees and salaries to related parties	525	523
Consultant fees to Board members	406	325

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 February 28, 2019, 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 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.

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