



## QUARTERLY REPORT 2

September 2017 – February 2018

Diamyd Medical AB (publ), Fiscal year 2017/2018



The diabetes vaccine Diamyd<sup>®</sup> continues to show promising results from the DIAGNODE-1 trial where the diabetes vaccine Diamyd<sup>®</sup> is given into the lymph node in patients with recently on set type 1 diabetes. The interest for the follow-up trial DIAGNODE-2 is considerable. The Company 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's B-share is traded on Nasdaq First North under the ticker DMYD B. Further information is available on the Company's website: [www.diamyd.com](http://www.diamyd.com).

## September 1, 2017 – February 28, 2018

- Net result amounted to MSEK -20.0 (-10.9), of which the second quarter constituted of MSEK -9.1 (-6.4). The change compared with the previous year relates to the DIAGNODE-2 trial which started this financial year and production of GAD-65
- Result per share, before and after dilution, amounted to SEK -0.4 (-0.4), of which the second quarter constituted of SEK -0.2 (-0.2)
- Cash flow from operating activities amounted to MSEK -22.9 (-10.5) of which the second quarter constituted of MSEK -10.8 (-5.9)
- Liquid assets and short-term investments amounted as of February 28 to MSEK 62.6 (20.6)

### Significant events during the second quarter, December 1, 2017 – February 28, 2018

- The GABA/Diamyd® trial in the US expected to be fully recruited this summer
- High interest from patients to participate in the DIAGNODE-2 trial
- Continued positive clinical course was shown in DIAGNODE-1 when four patients had been followed for 30 months and all patients for six months

### Significant events after the reporting period

- Diamyd® subcutaneously continued to show weaker results than when administered intralymphatically
- Continued positive clinical course was shown in DIAGNODE-1 when nine patients had been followed for 15 months



“So far, patient enrollment for DIAGNODE-2 has exceeded our expectations.”

Ulf Hannelius, CEO

# CEO comments

Dear Shareholders and Readers,

So far, patient enrollment for DIAGNODE-2 has exceeded our expectations. A total of 48 patients have been screened, which corresponds to nearly half of the number planned. Of these 48 patients screened, 29 have started the trial. To be able to respond to the considerable interest being shown in the trial, we increased the number of clinics in March. The most recent clinic to join the trial is the pediatrics clinic at the University Hospital of Umeå, which is now open for patient enrollment.

The other week, we announced new results from the ongoing DIAGNODE-1 trial, where a total of nine patients have completed their 15-month follow-up period. In connection with this, we met with potential partners. The results from DIAGNODE-1 remain positive, and confidential discussions are under way with some players regarding licensing of the Diamyd® diabetes vaccine for certain countries. The outcome of these discussions will largely depend on whether an agreement can be reached regarding the financial terms and on the prospective partners' expertise and involvement in the field of diabetes and pharmaceutical marketing. The progress we have made in the development of the diabetes vaccine has also made an impression on investigators, and we have identified an interest in initiating a trial involving a patient population with latent autoimmune diabetes in adults (LADA). Since our existing resources are primarily focused on the DIAGNODE-2 trial, we are currently proceeding with the application for grants for the trial together with collaboration partners. LADA patients represent a large and often incorrectly treated group of diabetics, who are often misdiagnosed as having type 2 diabetes but actually have a diagnosis that more closely resembles type 1 diabetes, where the disease progression involves an autoimmune attack on the insulin-producing cells.

Regarding Remygen™, our proprietary patent-pending GABA formulation, we are seeing growing interest in our program, partly from companies that have indicated an interest in entering into partnership at an early phase and thereby contributing to the design of the clinical development program. Intellectual property rights, meaning patents and trade secrets, play a very important role in such collaborations, since GABA is a previously known substance. We have a strong and growing patent portfolio; with our own applications and with the patent application we licensed from UCLA in early autumn 2017 where we have chosen to proceed in the US, Canada, Australia, Europe, China, Japan and South Korea. The application covers the combination of GABA and allosteric modulators to increase the efficacy in terms of growth and survival of insulin-producing cells, a highly attractive area for Diamyd Medical.

It may also be interesting to note that, in addition to the above-mentioned patent applications, Diamyd Medical has so far applied for a further seven proprietary patents, including a) antigen-specific treatment of individuals with certain genetic predisposition for type 1 diabetes, b) biomarkers to measure the effect of antigen-specific therapies and c) antigen-specific treatment of autoimmune diseases with concomitant inhibition of complement activation.

I would like to thank all shareholders and others for your interest in our struggle to change the paradigm for the treatment of diabetes.

*Stockholm, March 28, 2018*

Ulf Hammelius,

*President and CEO*

# Significant events during the second quarter

December 1, 2017 –February 28, 2018

## **The GABA/Diamyd® trial in the US fully recruited this summer**

In the placebo-controlled combination trial GABA/Diamyd® conducted at University of Alabama at Birmingham, US, 82 patients had been included, of which 48 had completed the entire trial. No serious side effects had been reported and the treatment appeared to be safe. The trial is expected to be fully recruited this summer.

## **High interest from patients to participate in the DIAGNODE-2 trial**

Diamyd Medical reported that five patients had been enrolled in the European phase II trial DIAGNODE-2 and several patients were scheduled for screening during the forthcoming weeks. Out of these first five patients, one patient had had the first intralymphatic injection of the diabetes vaccine Diamyd® (or its placebo) after a 30-day period of oral treatment with vitamin D (or its placebo).

## **Continued positive clinical course was shown in DIAGNODE-1 when four patients had been followed for 30 months and all patients for six months**

Positive effects such as lower insulin requirements and improved blood glucose levels were observed for the first four diabetes patients that had been followed for 30 months in the DIAGNODE-1 trial. Safety looked good and no serious side effects had been reported. Positive results were also reported from the trial when all patients have been followed for 6 months. A clinically relevant and positive progression was demonstrated in terms of the body's own capacity to produce insulin, as well as long-term blood sugar and insulin dose. No serious adverse events had been reported.

# Significant events after the reporting period

## **Diamyd® subcutaneously continued to show weaker results than when administered intralymphatically**

A preliminary 15-month interim report from EDCR IIa, an investigator initiated pilot trial where the diabetes vaccine Diamyd® is administered subcutaneously in combination with etanercept and vitamin D showed, when all 20 patients have been followed for fifteen months, that the treatment is safe and tolerable. No serious side effects had been reported. Results pertaining to the patients' own insulin production, HbA1c and external insulin requirements were, however, weaker in EDCR IIa than from the ongoing DIAGNODE-1 trial where the diabetes vaccine is administered directly into the lymph node.

## **Continued positive clinical course was shown from DIAGNODE-1 when nine patients had been followed for 15 months**

A sixth interim report from the investigator initiated DIAGNODE-1 trial, an open label clinical pilot trial in which the diabetes vaccine Diamyd® is given directly into the lymph node, showed a continued positive clinical course in terms the patients' own ability to produce insulin as well as long-term blood sugar and insulin dose when nine patients had been followed for 15 months.

## On-going clinical trials with Diamyd®

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 diabetes vaccine Diamyd® has been used in clinical trials with more than 1 000 patients and has shown a good safety profile. Diamyd® is easy to administer in any clinical setting. The potential annual market is estimated to several billion dollars per year. Five clinical trials are ongoing combining Diamyd® with various other immunomodulatory compounds; etanercept, vitamin D and GABA.

- **DIAGNODE -1 - DIAMYD® IN LYMPH GLANDS IN COMBINATION WITH VITAMIN D**

An open label 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.

- **DIAGNODE -2 - DIAMYD® IN LYMPH GLANDS IN COMBINATION WITH VITAMIN D**

DIAGNODE-2 is a follow-up double-blind randomized trial where Diamyd® is administered directly into lymph nodes in combination with treatment with vitamin D. The trial encompasses approximately 80 patients from Sweden, the Czech Republic and Spain, 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.

- **GABA/ DIAMYD® - COMBINING DIAMYD® WITH GABA**

A placebo-controlled 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.

- **EDCR IIa - COMBINING DIAMYD® WITH ETANERCEPT AND VITAMIN D**

An open label 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 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 Dec-Feb 2017/18	3 months Dec-Feb 2016/17	6 months Sep-Feb 2017/18	6 months Sep-Feb 2016/17	12 months Sep-Aug 2016/17
Research and development costs, MSEK	-5.2	-2.9	-12.7	-5.0	-12.9
Solidity, %	90	69	90	69	88
Result per share, before and after dilution, SEK	-0.2	-0.2	-0.4	-0.4	-0.7
Liquidity and short-term investments per share, Before and after dilution, SEK	1.1	0.7	1.1	0.7	1.5
Equity per share, before and after dilution, SEK	1.2	0.6	1.2	0.6	1.5
Cash flow per share, before and after dilution, SEK	-0.2	-0.2	-0.4	-0.2	0.8
Share price per closing, SEK	3.4	6.0	3.4	6.0	3.0
Number of shares per closing	56 333 904	29 492 562	56 333 904	29 492 562	56 333 904
Average number of shares	56 333 904	29 492 562	56 333 904	29 492 562	34 783 517
Average number of employees	6	5	6	5	5

## Income statement

KSEK	Note	3 months Dec-Feb 2017/18	3 months Dec-Feb 2016/17	6 months Sep-Feb 2017/18	6 months Sep-Feb 2016/17	12 months Sep-Aug 2016/17
<b>OPERATING INCOME</b>						
Net income		16	47	602	484	922
Other operating income		17	13	87	28	113
<b>TOTAL OPERATING INCOME</b>		<b>33</b>	<b>60</b>	<b>689</b>	<b>512</b>	<b>1 035</b>
<b>OPERATING EXPENSES</b>						
External research and development costs		-5 151	--2 860	--12 722	-5 025	-12 871
External patent- and license costs		-504	-838	-870	-1 007	-1 740
Personnel costs	1	-1 976	-1 680	-4 045	-3 280	-7 031
Other external costs	1	-1 389	-1 209	-2 751	-2 270	-4 658
Other operating expenses		-110	-30	-194	-61	-150
Depreciation and impairment of material and immaterial assets	2	-35	129	-61	257	-106
<b>TOTAL OPERATING EXPENSES</b>		<b>9 165</b>	<b>-6 489</b>	<b>-20 644</b>	<b>-11 386</b>	<b>26 555</b>
<b>OPERATING RESULT</b>		<b>-9 131</b>	<b>-6 429</b>	<b>-19 955</b>	<b>-10 874</b>	<b>-25 520</b>
Net Financial income/expense		-53	10	1	119	-35
<b>RESULT BEFORE TAXES</b>		<b>-9 185</b>	<b>-6 419</b>	<b>-19 955</b>	<b>-10 755</b>	<b>-25 555</b>
Taxes		-	-	-	-	-
<b>NET RESULT FOR THE PERIOD</b>		<b>-9 185</b>	<b>-6 419</b>	<b>-19 955</b>	<b>-10 755</b>	<b>-25 555</b>

# Balance sheet

KSEK	Note	28 Feb 2018	28 Feb 2017	31 Aug 2017
<b>ASSETS</b>				
<b>NON-CURRENT ASSETS</b>				
Intangible assets		376	321	268
Financial assets	2	7 305	4 881	7 305
<b>TOTAL NON-CURRENT ASSETS</b>		<b>7 681</b>	<b>5 205</b>	<b>7 573</b>
<b>CURRENT ASSETS</b>				
Trade receivables		19	61	147
Other receivables		680	698	692
Prepaid expenses and accrued income		2 905	395	4 508
Short term investments		30 043	-	30 031
Liquid assets		32 587	20 555	55 694
<b>TOTAL CURRENT ASSETS</b>		<b>66 234</b>	<b>21 710</b>	<b>91 073</b>
<b>TOTAL ASSETS</b>		<b>73 915</b>	<b>26 911</b>	<b>98 647</b>
<b>EQUITY AND LIABILITIES</b>				
<b>EQUITY</b>				
<i>Restricted equity</i>				
Share capital		5 714	2 991	5 714
Statutory reserve		200	200	200
<i>Non-restricted equity</i>				
Share premium reserve non-restricted		137 032	56 803	137 038
Profit or loss brought forward		-56 286	-30 731	-30 731
Net loss for the period		-19 955	-10 755	-25 555
<b>TOTAL EQUITY</b>		<b>66 704</b>	<b>18 508</b>	<b>86 666</b>
<b>PROVISIONS</b>				
Pensions and other obligations		777	777	777
Other provisions	3	1 383	2 123	1 813
<b>TOTAL PROVISIONS</b>		<b>2 160</b>	<b>2 900</b>	<b>2 591</b>
<b>CURRENT LIABILITIES</b>				
Trade payables		710	1 304	6 368
Other payables		682	571	584
Prepaid income and accrued expenses		3 659	3 628	2 438
<b>TOTAL CURRENT LIABILITIES</b>		<b>5 051</b>	<b>5 503</b>	<b>9 390</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>73 915</b>	<b>26 911</b>	<b>98 647</b>

# Statement of cash flow

KSEK	Not	3 months Dec-Feb 2017/18	3 months Dec-Feb 2016/17	6 months Sep-Feb 2017/18	6 months Sep-Feb 2016/17	12 months Sep-Aug 2016/17
<b>OPERATING ACTIVITIES</b>						
Operating profit/loss		-9 131	-6 429	-19 955	-10 874	-25 520
Interest received		219	6	129	2	-
Interest paid		-60	-	-128	0	-68
<i>Non-cash flow items</i>						
Depreciation		35	26	61	53	106
Other non-cash flow items		-276	-155	-430	-310	-619
<b>CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL</b>		<b>-9 303</b>	<b>-6 551</b>	<b>-20 324</b>	<b>-11 128</b>	<b>-26 101</b>
Increase (-) decrease (+) receivables		1 987	750	1 744	400	-3 793
Increase (+) decrease (-) debts		-3 461	-69	-4 340	200	4 085
<b>NET CASH FLOW FROM OPERATING ACTIVITIES</b>		<b>-10 778</b>	<b>-5 870</b>	<b>-22 919</b>	<b>-10 528</b>	<b>-25 808</b>
<b>INVESTING ACTIVITIES</b>						
Investment in material and immaterial assets		-169	-	-169	-	-
Investment in financial assets		-	-	-	-427	-2 852
Investment in short term investments		5	-	-12	4 999	-25 032
<b>NET CASH FLOW FROM INVESTING ACTIVITIES</b>		<b>-164</b>	<b>-</b>	<b>181</b>	<b>4 571</b>	<b>-27 885</b>
<b>FINANCING ACTIVITIES</b>						
New issue		-	-	-	-	88 816
Issue expenses		-7	-	-7	-	-5 858
<b>NET CASH FLOW FROM FINANCING ACTIVITIES</b>		<b>-7</b>	<b>-</b>	<b>-7</b>	<b>-</b>	<b>-82 958</b>
<b>TOTAL CASH FLOW FOR THE PERIOD</b>		<b>-10 949</b>	<b>-5 870</b>	<b>-23 107</b>	<b>-5 957</b>	<b>29 265</b>
Cash and cash equivalents at beginning of period		43 658	26 423	55 695	26 397	26 397
Net foreign exchange difference		-122	2	-1	115	32
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>		<b>32 587</b>	<b>20 555</b>	<b>32 587</b>	<b>20 555</b>	<b>55 695</b>

# Statement of changes in equity

KSEK	Note	Share Capital	Statutory Reserve	Share premium reserve non restricted	Other non-restricted equity	Total Shareholders' equity
<b>OPENING BALANCE SEPTEMBER 1, 2016</b>						
		2 991	200	56 803	-30 732	29 263
Net result		-	-	-	-25 555	-25 555
New issue		2 772	-	91 223	-	93 945
Issue expenses		-	-	-10 987	-	-10 987
<b>CLOSING BALANCE AUGUST 31, 2017</b>						
		5 713	200	137 039	-56 287	86 666
<b>OPENING BALANCE SEPTEMBER 1, 2017</b>						
		5 713	200	137 039	-56 287	86 666
Net result		-	-	-	-19 955	-19 955
Issue expenses		-	-	-7	-	-7
<b>CLOSING BALANCE FEBRUARY 28, 2018</b>						
		5 713	200	137 032	-76 242	66 704

## 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 523 (461) KSEK. As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 325 (421). Pricing has been set by the arm's length principle.

KSEK	Sep-Feb 2017/18	Sep-Feb 2016/18
Consultant fees and salaries to related parties	523	461
Consultant fees to Board members	325	421

### Note 2 – Financial assets

Diamyd Medical owns shares in NextCell Pharma AB (corporate registration no 556965-8361) who develops stem cell therapies and also operates a stem cell bank for private family saving of stem cells. The registered office is in Huddinge, Stockholm County. As of February 28, 2018, the carrying amount was approximately MSEK 3.9. Diamyd Medical's share of the equity as well as share of the votes was as of February 28, 2018, approximately 13.8 %. Diamyd Medical holds approximately 7.8 % 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.

## Warrants

In connection with a rights issue in 2017, 852 074 warrants were issued for Series A shares and 25 989 268 warrants for Series B shares. Holders of warrants are entitled to for two (2) warrants for Series A or B shares subscribe for one (1) new share of each kind in Diamyd Medical during the period 1-30 November 2018 at issue price 4.55 SEK per new share.

## 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 2016/2017. 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 28, 2018

Erik Nerpin  
Chairman of the Board

Anders Essen-Möller  
Board member

Maria-Teresa Essen-Möller  
Board member

Torbjörn Bäckström  
Board Member

Ulf Hannelius  
President & CEO

## Financial calendar

Quarterly Report 3 2017/2018: June 27, 2018

Year-End Report 2017/2018: October 10, 2018

## About Diamyd Medical

The diabetes vaccine Diamyd<sup>®</sup>, for antigen-specific immunotherapy is based on the from UCLA exclusively licensed GAD-molecule. Diamyd<sup>®</sup> has demonstrated good safety in studies of 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<sup>®</sup>. Diamyd Medical also develops Remygen<sup>™</sup>, a proprietary GMP manufactured oral GABA-based study drug. A placebo-controlled trial with GABA and Diamyd<sup>®</sup> 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<sup>®</sup> and Remygen<sup>™</sup> 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.

### 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 March 28, 2018.

*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.*