



QUARTERLY REPORT 1

September 2017 – November 2017

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



Diamyd Medical continues to show promising results from the DIAGNODE-1 trial where the diabetes vaccine Diamyd[®] is given into the lymph node. 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.

September 1, 2017 – November 30, 2017

- R&D-expenses amounted to MSEK -7.6 (-2.0). The cost increase compared with the previous year relates to the preparation of the DIAGNODE-2 trial and production of GAD-65
- Net result amounted to MSEK -10.8 (-4.3)
- Result per share, before and after dilution, amounted to SEK -0.2 (-0.1)
- Cash flow from operating activities amounted to MSEK -12.1 (-4.7)
- Liquid assets and short-term investments amounted as of November 30 to MSEK 73.7 (26.4)

Significant events during the reporting period

- Phase II-trial DIAGNODE-2 open to include patients
- Results of the investigator-initiated prevention trial DiAPREV-IT 2 is brought forward to 2020
- The GABA portfolio is strengthened with new license
- Strategic development of the study drug Remygen™
- Phase II trial DIAGNODE-2 with the diabetes vaccine Diamyd® approved to start in all participating countries

Significant events after the reporting period

- The diabetes vaccine Diamyd® shows continued positive clinical course when four patients have been followed for 30 months and when all twelve patients have been followed for six months



“The last two months were dominated by new and promising results from DIAGNODE-1, the ongoing investigator-initiated trial where the diabetes vaccine Diamyd® is administered to the lymph node in recently diagnosed patients suffering from Type 1 diabetes.”

Ulf Hannelius, CEO

CEO comments

Dear Shareholders and Readers,

The last two months were dominated by new and promising results from DIAGNODE-1, the ongoing investigator-initiated trial where the diabetes vaccine Diamyd® is administered to the lymph node in recently diagnosed patients suffering from Type 1 diabetes. The treatment aims to interrupt the immune system's attack on the insulin-producing cells and in this way preserve the remaining endogenous insulin production at the time of diagnosis. The value of such treatment is considerable for both patients and society, as even a minor ability to produce insulin means patients find it easier to manage their blood sugar levels, which can substantially reduce future complications, such as cardiovascular diseases, renal failure and impaired vision. In addition, the risk of acute hypoglycemia, meaning low blood sugar that may lead to unconsciousness or at worst a fatal outcome, may be decreased if some of the patient's endogenous insulin producing capacity is being preserved.

All twelve patients participating in the DIAGNODE-1 trial have now been followed for 6 months, half of the patients for 15 months and four for 30 months since start of the trial, and we can now see a disease progression suggesting the vaccine is slowing down the immune system's destruction of the insulin-producing cells. At 6 months, the average decrease of the patients' own insulin production measured as the stimulated C-peptide was 1.7 % (compared with 15 % in untreated patients of the same age according to published research), at 15 months 10.8% (compared with 35%), and at 30 months 32% (compared with 50% or more). This is in line with observations in our own previous trials with patients receiving placebo, inactive treatment. In the ongoing investigator initiated DIAGNODE-1, patients are on average injecting less insulin compared to at the start of the trial, and maintaining better blood sugar levels, which provides further confirmation of results suggesting that the intralymphatic treatment with the vaccine has a positive and long-term effect on the disease progression. Previously published immunological data¹ also shows that intralymphatic treatment produces a strong and desired immunological response.

Our highest priority now is DIAGNODE-2, the follow-up placebo-controlled Phase II trial comprising a total of 80 patients, where our goal is to complete enrollment within 12 months. The first DIAGNODE-2 clinic opened for enrollment in mid-November and 15 out of 17 clinics in Sweden, Spain and the Czech Republic are now open. Information about the trial is given not only by the different clinics but also through campaigns in social media and in local newspapers.

Our commitment toward our shareholders is to increase the value of your investment. I would like to thank you for your trust and look forward to reporting on the progress of our ongoing projects.

Stockholm, January 24, 2018

Ulf Hannelius,

President and CEO

¹ Ludvigsson J, Tavira B, Casas R. More on Intralymphatic Injection of Autoantigen in Type 1 Diabetes. *N Engl J Med.* 2017 Jul 27;377(4):403-5. doi: 10.1056/NEJMc1703468.

Significant events during the reporting period

Phase II-trial DIAGNODE-2 open to include patients

The diabetes vaccine Diamyd® for intralymphatic administration will be delivered to the clinics participating in the pivotal trial DIAGNODE-2 that can begin screening patients. The trial comprises about 80 patients from Spain, the Czech Republic and Sweden 12–24 diagnosed with type 1 diabetes during the last 6 months.

The results of the investigator-initiated prevention trial DiAPREV-IT 2 is brought forward to 2020

The Swedish Medical Products Agency approves a change to the trial led by Associate Professor Helena Elding Larsson, Lund University, where the diabetes vaccine Diamyd® is administered subcutaneously and vitamin D orally to a group of individuals at high risk of being diagnosed with type 1 diabetes. The change entails that the recruitment will stop at 26 children instead of 80 children and that the childrens' metabolic and immunological parameters will be followed in total for 2 years after the first injection instead of 5 years.

The GABA portfolio is strengthened with new license

Diamyd Medical concludes a new exclusive licensing agreement with University of California, Los Angeles (UCLA) Technology Development Group on behalf of UC Regents. The license relates to new patent applications for the therapeutic use of GABA (gamma-aminobutyric acid) with positive allosteric modulators of the GABAA receptor to enhance beta cell regeneration, survival and immunomodulation.

Strategic development of the study drug Remygen™

A preliminary patent application is filed on the formulation and release characteristics of the GABA-based study drug Remygen™. Based on feedback from a scientific meeting with the Swedish Medical Products Agency, and in collaboration with Diamyd Medical's scientific network, the Company will commence designing the first clinical trial based on Remygen™.

Phase II trial DIAGNODE-2 with the diabetes vaccine Diamyd® approved to start in all participating countries

Spanish and Czech Competent Authorities and the relevant Ethics Committees approves Diamyd Medical's application to conduct DIAGNODE-2, a pivotal follow-up placebo-controlled Phase II trial with the diabetes vaccine Diamyd® to be tested in children and young adults recently diagnosed type 1 diabetes. Previously, the trial has been approved by the Swedish Medical Products Agency and the Ethics Committee.

Significant events after the reporting period

The diabetes vaccine Diamyd® shows continued positive clinical course after 30 months and when all patients have been followed for 15 months

Positive effects such as lower insulin requirements and improved blood glucose levels are observed for the first four diabetes patients that have been followed for 30 months in the DIAGNODE-1 trial. Safety looks good and no serious side effects have been reported.

Positive results are also reported from the trial when all patients have been followed for 6 months. A clinically relevant and positive progression can be 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 have been reported.

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. The patients are followed for 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. 15-month results are expected during the first quarter of 2018.

- **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 Sep-Nov 2017	3 months Sep-Nov 2016	12 months Sep-Aug 2016/17
Research and development expenses, MSEK	-7.6	-2.0	-12.9
Solidity, %	87	74	88
Result per share, before and after dilution, SEK	-0.2	-0.1	-0.7
Liquid assets and short- term investments per share, before and after dilution, SEK	1.3	0.9	1.5
Shareholders' equity per share, before and after dilution, SEK	1.3	0.8	1.5
Cash flow per share, before and after dilution, SEK	-0.2	0	0.8
Share price per closing, SEK	3.4	6.8	3.0
Number of shares per closing	56 333 904	29 492 562	56 333 904
Average number of shares	56 333 904	29 492 562	34 783 517
Average number of employees	6	5	5

Income statement

	3 months Sep-Nov 2017	3 months Sep-Nov 2016	12 months Sep-Aug 2016/17
OPERATING INCOME			
Net income	586	438	922
Other operating income	70	15	113
TOTAL OPERATING INCOME	655	452	1 035
OPERATING EXPENSES			
External research and development costs	-7 571	-2 010	-12 871
External patent- and license costs	-366	-170	-1 740
Personnel costs	1 -2 069	-1 600	-7 031
Other external costs	1 -1 362	-1 061	-4 658
Other operating expenses	-84	-28	-150
Depreciation and impairment of material and immaterial assets	-26	-26	-106
TOTAL OPERATING EXPENSES	-11 479	-4 896	-26 555
OPERATING RESULT	-10 824	-4 445	-25 520
Net Financial income/expense	-54	109	35
RESULT BEFORE TAXES	-10 770	-4 336	-25 555
Taxes	-	-	-
NET RESULT FOR THE PERIOD	-11 770	-4 336	-25 555

Balance sheet

KSEK	Note	30 Nov 2017	30 Nov 2016	31 Aug 2017
ASSETS				
NON-CURRENT ASSETS				
Intangible assets		242	347	268
Financial assets	2	7 305	4 881	7 305
TOTAL NON-CURRENT ASSETS		7 547	5 228	7 573
CURRENT ASSETS				
Trade receivables		342	118	147
Other receivables		942	1 086	692
Prepaid expenses and accrued income		4 307	702	4 508
Short term investments		30 048	-	30 031
Liquid assets		43 658	26 423	55 694
TOTAL CURRENT ASSETS		79 297	28 328	91 073
TOTAL ASSETS		86 843	33 556	98 647
EQUITY AND LIABILITIES				
EQUITY				
<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		137 038	56 803	137 038
Profit or loss brought forward		-56 286	-30 731	-30 731
Net loss for the period		-10 770	-4 336	-25 555
TOTAL EQUITY		75 896	24 926	86 666
PROVISIONS				
Pensions and other obligations		777	777	777
Other provisions	3	1 658	2 278	1 813
TOTAL PROVISIONS		2 436	3 055	2 591
CURRENT LIABILITIES				
Trade payables		4 012	1 606	6 368
Other payables		711	574	584
Prepaid income and accrued expenses		3 789	3 395	2 438
TOTAL CURRENT LIABILITIES		8 512	5 574	9 390
TOTAL EQUITY AND LIABILITIES		86 843	33 556	98 647

Statement of cash flow

KSEK	3 months Sep-Nov 2017	3 months Sep-Nov 2016	12 months Sep-Aug 2016/17
OPERATING ACTIVITIES			
Operating profit/loss	-10 824	-4 445	-25 520
Interest received	-	0	-
Interest paid	-68	0	-68
<i>Non-cash flow items</i>			
Depreciation	26	26	106
Other non-cash flow items	-155	155	-619
CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL			
	-11 020	-4 573	-26 101
Increase (-) decrease (+) receivables	-243	-350	-3 793
Increase (+) decrease (-) debts	-878	269	4 085
NET CASH FLOW FROM OPERATING ACTIVITIES			
	-12 141	-4 653	-25 808
INVESTING ACTIVITIES			
Investment in financial assets	-	-427	-2 852
Investment in short term investments	-17	4 999	-25 032
NET CASH FLOW FROM INVESTING ACTIVITIES			
	-17	4 572	-27 885
FINANCING ACTIVITIES			
New issue	-	-	88 816
Issue expenses	-	-	-5 858
NET CASH FLOW FROM FINANCING ACTIVITIES			
	-	-	-82 958
TOTAL CASH FLOW FOR THE PERIOD			
	-12 158	-83	29 265
Summa likvida medel vid periodens början	55 695	26 397	26 397
Kursdifferens i likvida medel	121	109	32
CASH AND CASH EQUIVALENTS AT END OF PERIOD			
	43 658	26 423	55 695

Changes in Equity

KSEK	Note	Share Capital	Statutory Reserve	Share premium reserve non restricted	Other non-restricted equity	Total Shareholders' equity
OPENING BALANCE SEPTEMBER 1, 2016		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
CLOSING BALANCE AUGUST 31, 2017		5 713	200	137 039	-56 287	86 666
OPENING BALANCE SEPTEMBER 1, 2017		5 713	200	137 039	-56 287	86 666
Net result		-	-	-	-10 770	-10 770
CLOSING BALANCE NOVEMBER 30, 2017		5 713	200	137 039	-67 057	75 896

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 309 (258) KSEK. As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 209 (222). Pricing has been set by the arm's length principle.

KSEK	Sep-Nov 2017	Sep-Nov 2016
Consultant fees and salaries to related parties	309	258
Consultant fees to Board members	209	222

Note 2 – Financial assets

Diamyd Medical owns shares in NextCell Pharma AB (corporate registration no 556965-8361) who develops stem cell therapies. The registered office is in Huddinge, Stockholm County. As of November 30, 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 November 30, approximately 13.8 %. Diamyd Medical holds approximately 8.5% of the medical device company Companion Medical, Inc., based in San Diego, USA. 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 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, January 24, 2018

Erik Nerpin
Chairman of the Board

Anders Essen-Möller
Board member

Maria-Teresa Essen-Möller
Board member

Torbjörn Bäckström
Board Member

Ulf Hammelius
President & CEO

Financial calendar

Quarterly Report 2 2017/2018:	March 28, 2018
Quarterly Report 3 2017/2018:	June 27, 2018
Year-End Report 2017/2018:	October 10, 2018

About Diamyd Medical

The diabetes vaccine Diamyd[®], for antigen-specific immunotherapy is based on the from UCLA exclusively licensed GAD-molecule. Diamyd[®] 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[®]. Diamyd Medical also develops Remygen[™], a proprietary GMP manufactured oral GABA-based study drug. A 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.

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 24, 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.