

DIAMYD MEDICAL

YEAR-END REPORT

September 2016 – August 2017

Diamyd Medical AB (publ), Fiscal year 2016/2017



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. Four clinical studies are ongoing with Diamyd[®]. The Company's trial DIAGNODE-2, where the diabetes vaccine is administered directly into the lymphatic node, is expected to start recruiting patients this fall. Diamyd Medical also develops Remygen[®], a proprietary GMP manufactured oral GABA-based study drug. 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. An exclusive license for GABA for the treatment of diabetes and inflammatory diseases constitutes alongside with the diabetes vaccine and Remygen[®] key assets in Diamyd Medical. 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.

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. Further information is available on the Company's website: www.diamyd.com.

The period September 1, 2016 – August 31, 2017 in brief

- R&D-expenses amounted to MSEK -12.9 (-6.2) of which the fourth quarter constituted MSEK -3.1 (-1.9)
- Net result amounted to MSEK -25.6 (-32.0) of which the fourth quarter amounted to MSEK -6.5 (-4.8). Previous year's result was charged with an impairment in associated company of MSEK -13.5
- Result per share, before and after dilution, amounted to SEK -0.7 (-1.3) of which the fourth quarter constituted SEK -0.1 (-0.2)
- Cash flow from operating activities amounted to MSEK -25.8 (-17.8) of which the fourth quarter constituted MSEK -9.8 (-4.1)
- Liquid assets and short-term investments amounted per August 31 to MSEK 85.7 (31.4)

Significant events during the reporting period

- Diamyd Medical ordered additional Diamyd[®] drug substance
- Diamyd Medical and Cardiff University to collaborate on study monitoring immune response in lymph node cells after administration of Diamyd[®]
- Additional preliminary interim results from intralymphatic trial with Diamyd[®] published as part of scientific correspondence in NEJM
- The Swedish Medical Products Agency approved conduction of the DIAGNODE-2 trial
- Two doses of Diamyd[®] showed safety in 5-year prevention trial in children at high risk for type 1 diabetes
- Continued positive interim reports from the DIAGNODE-1 trial. The trial was fully recruited.
- Diamyd Medical subscribed for MSEK 1.9 in NextCell Pharma's listing issue

Significant events after the reporting period

- Information was given about strategic development of the study drug Remygen[®]
- Phase II trial DIAGNODE-2 with the diabetes vaccine Diamyd[®] approved to start in all participating countries

CEO comments

Dear Shareholders and Readers,

Given the strategic decisions taken over the past year and the company's strong cash position following the successful new share issue this spring, we have significantly accelerated our operations during the quarter.

During the quarter national competent authorities from all of the participating countries (Spain, Sweden and Czech Republic) approved the conduction of the DIAGNODE-2 trial. The Investigator Meeting we arranged last week in Barcelona, at which the trial protocol was presented and discussed, was well attended and appreciated. The enthusiasm for the upcoming trial is high and stems from the promising preliminary results from the ongoing open DIAGNODE-1 trial, where Diamyd® is administered directly into the lymph node. After the decision was taken in the spring to conduct our own follow-up trial, our organization has in collaboration with our partners and contract manufacturers made an ambitious achievement moving the project forward on an aggressive timeline with a focus on starting as early as possible and efficient patient recruitment.

During the quarter we have also reached another milestone. We have established the formulation of our GABA study drug, filed a patent application on the formulation, and named it Remygen®. Manufacturing according to GMP (Good Manufacturing Process) has been validated and various pilot formulations were evaluated during the summer both at test-tube level and in a pharmacokinetic study. Remygen® is based on one of these formulations with specific desirable properties in terms of release and uptake. A consultative meeting regarding Remygen® and clinical trials was held with the Medical Products Agency in September and the first clinical trial will focus on beta cell growth in a selected population of type 1 diabetes patients. The ongoing GABA and Diamyd® trial at the University of Alabama at Birmingham focusing on recently diagnosed type 1 diabetes is progressing as planned with 74 of the 95 participants now enrolled and 41 having completed the trial.

On the business front, we are pursuing two courses of action. With the diabetes vaccine Diamyd® the Company is aiming to enter into licensing agreements for intralymphatic administration with the possibility of option agreements before the results from DIAGNODE-2 and for Remygen® to enter into licensing agreements or collaboration agreements. During the quarter, we participated at the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) conferences, the two largest diabetes conferences in the US and Europe, as well as at the Nordic Life Science Days in Sweden. These conferences continue to devote greater attention to type 1 diabetes and the field is open to new treatment possibilities that apply lessons learned from the treatment of, inter alia, rheumatoid arthritis and other autoimmune diseases, for which a number of drugs are currently being marketed. With the preliminary results from DIAGNODE-1 and the impending start of DIAGNODE-2, we have an attractive package to offer our potential partners. In conjunction with the above, additional recombinant GAD was ordered toward the tail-end of summer from our US contract manufacturer.

Stockholm, October 11, 2017

Ulf Hannelius

President and CEO of Diamyd Medical AB (publ)

Significant events during the reporting period

Diamyd Medical ordered additional Diamyd® drug substance

Diamyd Medical ordered additional recombinant GAD-protein, the clinical grade drug substance which is the main component in the diabetes vaccine Diamyd® from its contract manufacture. The order was placed to ensure access to drug substance for future clinical trials and possible early market launch. The order totaled approximately USD 750 000 (approximately MSEK 6.1) for which a cash installment was paid. Final payment will be made at approved delivery, either through Diamyd Medical Series B shares or cash, as then decided by Diamyd Medical.

Diamyd Medical and Cardiff University to collaborate on study monitoring immune response in lymph node cells after administration of Diamyd®

Diamyd Medical entered into a collaboration with Cardiff University on a new study with the diabetes vaccine Diamyd®. The aim of the study is to optimize methods based on ultrasound guided lymph node biopsies for monitoring the cellular immune response to immunotherapy. The study is financed by Cardiff University while Diamyd Medical is supplying the study drug.

Additional preliminary interim results from intralymphatic trial with Diamyd® published as part of scientific correspondence in NEJM

New immunological data from the DIAGNODE-1 trial, an open clinical pilot trial where the diabetes vaccine Diamyd is administered directly into the lymph node in combination with treatment with vitamin D, published as part of a correspondence in the medical periodical New England Journal of Medicine, showed a predominant Th2 response when the diabetes vaccine Diamyd® is administered directly into the lymph node being stronger than observed when injecting it under the skin.

Continued positive interim reports from the DIAGNODE-1 trial, which was fully recruited

A third interim report from DIAGNODE-1, when nine patients have been followed for 6 months, preliminarily showed that the treatment appears to be safe and tolerable. The clinical progression in the patients is positive in terms of the body's own capacity to produce insulin, as well as long-term blood sugar and insulin dose. Two of the three patients that have been followed for 6 months are children (12–18 years of age).

A fourth interim report from the trial showed a positive clinical progression in terms of the body's own capacity to produce insulin, as well as long-term blood sugar and insulin dose when half of the patients have been followed for 15 months.

DIAGNODE-1 was fully recruited after 12 patients. Diamyd Medical, together with Professor Johnny Ludvigsson at Linköping University, Principal investigator and Sponsor, decided to close the recruitment of patients in the DIAGNODE-1 trial to begin the follow-up of patients and focus on the larger follow-up trial DIAGNODE-2.

Diamyd Medical received approval from the Swedish Medical Products Agency for DIAGNODE-2

The Swedish Medical Products Agency approved the conduction of DIAGNODE-2. Submission of applications to the respective Competent Authorities in Spain and the Czech Republic are ongoing, as well as to the relevant Ethics Committees.

Two doses of Diamyd® showed safety in 5-year prevention trial in children at high risk for type 1 diabetes

Final results from DiAPREV-IT 1, a placebo-controlled clinical pilot trial led by Associate Professor MD Helena Elding Larsson, Lund University, where the diabetes vaccine Diamyd® for the first time is given to a group of individuals at high risk of developing type 1 diabetes were presented. Overall, the results showed that the treatment was safe and tolerable, and that fewer subjects than expected, 16 out of 50 compared to expected 25 out of 50, had developed type 1 diabetes in the 5-year follow-up of the trial. However, no significant difference was seen between children receiving placebo and those who received the active substance. The trial results were presented by Associate Professor Elding Larsson at the Diabetes Conference of the American Diabetes Associations (ADA) 77th Scientific Sessions in San Diego, USA.

Diamyd Medical subscribed for MSEK 1.9 in NextCell Pharma's listing issue

The Company subscribed for an additional SEK 1 million in the new issue in NextCell Pharma AB ahead of their IPO in July on Aktietorget. The Company invested in total approximately MSEK 1.9 in the listing issue.

Significant events after the reporting period

Information is given on the strategic development of the study drug Remygen®

A preliminary patent application was 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 approved 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.

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 cure should not be underestimated. 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. Four researcher-initiated 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.

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

A placebo-controlled trial, where Diamyd® is 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 combined 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 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 aim of the trial is to evaluate whether Diamyd® can delay or prevent the participants from presenting with type 1 diabetes. The trial is led by Dr. Helena Elding Larsson at Lund University, Sweden.

Key figures

	3 months Jun-Aug 2017	3 months Jun-Aug 2016	12 months Sep-Aug 2016/17	12 months Sep-Aug 2015/16
Research and development expenses, MSEK	-3.1	-1.9	-12.9	-6.2
Solidity, %	88	77	88	77
Result per share, before and after dilution, SEK	-0.1	-0.2	-0.7	-1.3
Liquid assets and short- term investments per share, before and after dilution, SEK	1.5	1.1	1.5	1.1
Shareholders' equity per share, before and after dilution, SEK	1.5	1.0	1.5	1.0
Cash flow per share, before and after dilution, SEK	0.9	-0.2	0.8	0.4
Share price per closing, SEK	3.0	7.0	3.0	7.0
Number of shares per closing	56 333 904	29 492 562	56 333 904	29 492 562
Average number of shares	50 483 849	29 492 562	33 783 517	24 939 761
Average number of employees	6	7	5	7

Income statement

KSEK	Note	3 months Jun-Aug 2017	3 months Jun-Aug 2016	12 months Sep-Aug 2016/17	12 months Sep-Aug 2015/16
OPERATING INCOME					
Net income		316	168	922	757
Other operating income		70	203	113	286
TOTAL OPERATING INCOME		386	371	1 035	1 043
OPERATING EXPENSES					
External research and development costs		-3 080	-1 942	-12 871	-6 220
External patent- and license costs		-245	-222	-1 740	-911
Personnel costs	1	-1 905	-1 796	-7 031	-7 671
Other external costs	1	-1 442	-1 206	-4 658	-4 514
Other operating expenses		-25	-29	-150	-137
Depreciation and impairment of material and immaterial assets	2	-26	-26	-106	-13 649
TOTAL OPERATING EXPENSES		-6 722	-5 222	-26 555	-33 102
OPERATING RESULT		-6 336	-4 851	-25 520	-32 059
Net Financial income/expense		-164	-57	35	51
RESULT BEFORE TAXES		-6 501	-4 794	-25 555	-32 008
Taxes		-	-	-	-
NET RESULT FOR THE PERIOD		-6 501	-4 794	-25 555	-32 008

Balance sheet

KSEK	Note	31 Aug 2017	31 Aug 2016
ASSETS			
NON-CURRENT ASSETS			
Intangible assets		268	374
Financial assets	2	7 305	4 453
TOTAL NON-CURRENT ASSETS		7 573	4 827
CURRENT ASSETS			
Trade receivables		147	215
Other receivables		692	379
Prepaid expenses and accrued income		4 508	961
Short term investments		30 031	4 999
Liquid assets		55 694	26 397
TOTAL CURRENT ASSETS		91 073	32 951
TOTAL ASSETS		98 647	37 778
EQUITY AND LIABILITIES			
EQUITY			
<i>Restricted equity</i>			
Share capital		5 714	2 991
Statutory reserve		200	200
<i>Non-restricted equity</i>			
Share premium reserve non-restricted		137 038	56 803
Profit or loss brought forward		-30 731	1 277
Net loss for the period		-25 555	-32 008
TOTAL EQUITY		86 666	29 263
PROVISIONS			
Pensions and other obligations		777	777
Other provisions	3	1 813	2 433
TOTAL PROVISIONS		2 591	3 210
CURRENT LIABILITIES			
Trade payables		6 368	1 221
Other payables		584	494
Prepaid income and accrued expenses		2 438	3 591
TOTAL CURRENT LIABILITIES		9 390	5 305
TOTAL EQUITY AND LIABILITIES		98 647	37 778

Statement of cash flow

KSEK	Not	3 months Jun-Aug 2017	3 months Jun-Aug 2016	12 month Sep-Aug 2016/17	12 months Sep-Aug 2015/16
OPERATING ACTIVITIES					
Operating profit/loss		-6 336	-4 850	-25 520	-32 059
Interest and foreign exchange difference received		-	25	-	43
Interest and foreign exchange difference paid		-68	0	-68	
<i>Non-cash flow items</i>					
Depreciation		26	26	106	106
Other non-cash flow items	2	-154	148	-619	13 515
CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL		-6 531	-4 651	-26 101	-18 395
Increase (-) decrease (+) receivables		-3 532	-310	-3 793	-623
Increase (+) decrease (-) debts		246	865	4 085	1 267
NET CASH FLOW FROM OPERATING ACTIVITIES		-9 816	-4 096	-25 808	-17 752
INVESTING ACTIVITIES					
Investment in financial assets		-1 855	-1 000	-2 852	-2 334
Investment in short term investments		-30 031	-	-25 032	7 999
NET CASH FLOW FROM INVESTING ACTIVITIES		-31 887	-1 000	-27 885	5 665
FINANCING ACTIVITIES					
New issue	4	88 816	-	88 816	22 119
Issue expenses		-3 515	-	-5 858	-373
NET CASH FLOW FROM FINANCING ACTIVITIES		-85 301	-	-82 958	21 747
TOTAL CASH FLOW FOR THE PERIOD		43 598	-5 096	29 265	9 660
Summa likvida medel vid periodens början		12 214	31 492	26 397	16 729
Kursdifferens i likvida medel		-117	1	32	8
CASH AND CASH EQUIVALENTS AT END OF PERIOD		55 695	26 397	55 695	26 397

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, 2015		2 243	200	35 804	1 276	39 524
Net result		-	-	-	-32 008	-32 008
New issue		748	-	21 372	-	22 120
Issue expenses		-	-	-373	-	-373
CLOSING BALANCE AUGUST 31, 2016		2 291	200	56 803	-30 732	29 263
OPENING BALANCE SEPTEMBER 1, 2016		2 291	200	56 803	-30 732	29 263
Net result		-	-	-	-25 555	-25 555
New issue	4	2 722	-	91 223	-	93 945
Issue expenses	5	-	-	-10 987	-	-10 987
CLOSING BALANCE AUGUST 31, 2017		5 713	200	137 039	-56 287	86 666

Notes

Accounting principles

Interim and annual reports are prepared with the application of the Annual Accounts Act and the Swedish Accounting Standards Board BFNAR 2012: 1 Annual Report and Consolidated accounts (K3).

Note 1 – Related-party transactions

During the year companies represented by immediate family members of the main owner and Board member Anders Essen-Möller were contracted as consultants. The consultancy services were attributable to IT-services and clinical consulting. Total compensation for consultancy services and salaries to immediate family members amounted to 849(1 552) KSEK. As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 838(0). Board member Torbjörn Bäckström has been compensated by KSEK 28(0) for scientific consulting services. Pricing has been set by the arm's length principle.

KSEK	Sep-Aug 2016/17	Sep-Aug 2015/16
Consultant fees and salaries to related parties	849	1 552
Consultant fees to Board members	866	-

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. During the year Diamyd Medical increased its shareholding in the company and as of August 31, 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 August 31, approximately 13.8 %. The previous carrying amount of the holding, corresponding to MSEK 13.5 was impaired previous fiscal year which yielded a non-recurring effect on the result of MSEK -13.5. 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.

Note 4 – New issue

Diamyd Medical received in a new issue proceeds of MSEK 88.8 before issue costs. The new issue was in the form of units, each with a share of either Series A or Series B and a remunerated warrant of the same series. 26 841 342 shares were issued whereof 852 074 shares of Series A and 25 989 268 shares of Series B. The number of shares in Diamyd Medical increased to 56 333 904. A total of 852 074 warrants for A shares and 25 989 268 warrants for B shares were issued. Each two warrants for Series A shares or Series B shares entitles the holder to subscribe for one corresponding new share at the issue price of SEK 4.55, during the period 1-30 November 2018.

Note 5 – Issue expenses

Total issue expenses amounted to KSEK 10 977, of which KSEK 5 129 constituted compensation to underwriters and financial adviser paid in the form of Series B shares and warrants for Series B shares in Diamyd Medical.

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 2015/2016. No significant changes in the Company's risk assessment have occurred since the Annual Report was issued.

Statement

The Board of Directors and the CEO certify that the Year-end report gives a fair overview of the business, position and profit or loss of the Company and describes the principal risks and uncertainties that face the Company.

This report has not been reviewed by the Company's auditors.

Stockholm, October 11, 2017

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

Annual Report 2016/2017:	November 9, 2017
Quarterly Report 1 2017/2018:	January 24, 2018
Quarterly Report 2 2017/2018:	March 28, 2018
Quarterly Report 3 2017/2018:	June 27, 2018
Year-End Report 2017/2018:	October 10, 2018

Annual General Meeting

The Annual General Meeting for the fiscal year 2016/2017 will be held on November 30, 2017, at 3:00 p.m., Hotel Kung Carl, Birger Jarlsgatan 21 in Stockholm

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 08.17 CET on October 11, 2017.

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.