QUARTERLY REPORT 1

September 2014 – November 2014

Diamyd Medical AB (publ), Fiscal year 2014/2015

Reporting period, September 1, 2014 – November 30, 2014

- Net result amounted to MSEK -5.9 (-4.8)
- Result per share amounted to SEK -0.3 (-0.2)
- Cash flow from operating activities amounted to MSEK -5.8 (-4.3)
- Liquid assets and short term investments amounted to MSEK 29.8 (61.0) at the end of the period

Significant events during the reporting period

- Diamyd-licensed technology, GABA in combination with Antigen Based Therapy, cures diabetes in pre-clinical model
- Diamyd® administered directly into lymph nodes will be tested in adults with type 1 diabetes
- Diamyd Medical and Protein Sciences deepen commitment to develop new treatment for diabetes
- Pioneering study combining the diabetes vaccine Diamyd® with GABA in children with type 1 diabetes approved by the US FDA
- New study to prevent type 1 diabetes with the Diamyd® diabetes vaccine approved by the Swedish Medical Products Agency
- Diamyd® in combination with vitamin D and etanercept approved for testing in children and adolescents with type 1 diabetes
- Treatment with GABA enhances transplanted human beta cell mass in preclinical model of type 1 diabetes

Significant events after the reporting period

- Diamyd Medical's patent protection extended by ten years to 2032

CEO comments

Following an intense autumn with many positives, Diamyd Medical was able to start the New Year with yet more good news. On January 6, 2015, the United States Patent and Trademark Office granted a new patent for GAD65 for the treatment of autoimmune diseases, including diabetes. The GAD65 protein is the active substance in the Diamyd® diabetes vaccine and Diamyd Medical has an exclusive license for the new patent from the University of California, Los Angeles (UCLA). The term of the new patent runs into January 2032, which is more than ten years longer than previous US patent protection for the diabetes vaccine. The longer term should provide time for the remaining development of Diamyd® and many years of marketing in the US without competition. Diamyd® is the furthest developed Antigen Based Therapy for type 1 diabetes in the world.

In December, two new batches of GAD65 protein were manufactured by Protein Sciences in the US. Preliminary analyses indicate that the production went well even if much analytical work remains before the material can be released for use. In accordance with the production agreement from September 2014, Diamyd Medical has issued 100,000 Series B shares to Protein Sciences. Protein Sciences will receive a further 300,000 Series B shares upon release of the material. In addition, a cash amount was paid to Protein Sciences for the manufacturing, which explains the higher costs for the period compared with earlier periods.

The end product Diamyd® is comprised of GAD65 protein from Protein Sciences formulated with the vaccine adjuvant alum. Thus far, the formulation has been done in batches of 3,000 vials by Octoplus in the Netherlands, however, they have recently informed their clients that they plan to phase out their contract manufacturing services. We have a large stock of ready-for-use diabetes vaccine that will suffice until autumn 2017 for all studies, so we have plenty of time to select a new contract manufacturer for the final formulation.

The initial results of the DIABGAD-1 combination study are expected to be presented in the spring. The study encompasses a total of 64 patients between the ages of ten and 18 who have been recently diagnosed with type 1 diabetes. The study will continue for a total of 30 months, but an initial evaluation will take place now after six months with focus on immunological markers. The immunological markers can provide an indication of how the treatment has affected the immune system. However, in this patient group, six months is too short a time for relevant differences to arise between the treatment groups in terms of the clinically most interesting variables, for example, the patients' ability to produce insulin. The 15-month results from the study, that may be available by the end of 2015, will show what effect the treatment has had on the ability to produce insulin.

DIABGAD-1 is a researcher-initiated study with the Diamyd® diabetes vaccine, in which a group of participants also receive the anti-inflammatory substance ibuprofen. In addition, several of the groups of participating children receive vitamin D to further steer the immune system in the right direction and, concurrently, strengthen the beta cells. The aim of the combination treatment is to preserve the body's remaining capacity to produce insulin. The study is taking place at nine clinics in Sweden and is led by Professor Johnny Ludvigsson at Linköping University.

In addition to DIABGAD-1, the researcher-initiated DiAPREV-IT study is ongoing in southern Sweden and its results are expected at the end of next year. The study comprises 50 children that have been found to have an ongoing autoimmune process, but do not yet have any clinical symptoms of diabetes, and aims to evaluate whether treatment with Diamyd® can delay or prevent the participants from presenting with type 1 diabetes. In the autumn, four new researcher-initiated studies with the Diamyd® diabetes vaccine were approved in Sweden and the US. Intense efforts are ongoing with getting these studies started and we expect several of them to start recruiting participants in the first quarter of 2015.

Stockholm, January 21, 2015

Peter Zerhouni

President and CEO Diamyd Medical AB (publ)

Significant events during the reporting period

Diamyd-licensed technology cures diabetes in pre-clinical model
Researchers at UCLA have confirmed earlier findings that combinations of GABA and Antigen Based Therapy (ABT) works synergistically as a treatment in the NOD mouse model of type 1 diabetes. Diamyd Medical is the exclusive licensee for the commercialization of UCLA's GABA technology for metabolic diseases including diabetes.

New method to give Diamyd® will be tested in adults with type 1 diabetes
A new way to give Diamyd® will be tested in a clinical study with five adults newly diagnosed with type 1 diabetes. The investigator initiated study has been approved by the Swedish MPA. In analogy to the development in allergy therapy, where the administration of allergen into lymph nodes has significantly improved the efficacy, Diamyd® will in this study be administered directly into lymph nodes in combination with treatment with vitamin D.

Diamyd Medical and Protein Sciences deepen commitment to develop new treatment for diabetes
Protein Sciences has broadened its commitment to diabetes and become a strategic and significant shareholder in Diamyd Medical, its long-time partner in this domain. Protein Sciences will manufacture product for upcoming late stage clinical trials for type 1 diabetes involving Diamyd Medical's recombinant GAD (glutamic acid decarboxylase) protein made using Protein Sciences' proprietary Baculovirus Expression Vector System (BEVS) technology.

Pioneering study combining the diabetes vaccine Diamyd® with GABA in children with type 1 diabetes approved by the US FDA
An investigator initiated study combining the diabetes vaccine Diamyd® and GABA in children with new onset type 1 diabetes has been approved by the US Food and Drug Administration. Diamyd Medical and University of Alabama at Birmingham has entered a Clinical Trial Agreement regarding the study, which will be conducted at Children's of Alabama in Birmingham, USA. The combination has shown promising results in preclinical studies

New study to prevent type 1 diabetes with the Diamyd® diabetes vaccine approved by the Swedish Medical Products Agency
The Swedish Medical Products Agency has approved the planned new investigator initiated study with the Diamyd® diabetes vaccine in 80 children at high risk of presenting with type 1 diabetes. The aim is to test whether the diabetes vaccine can prevent or delay the onset of type 1 diabetes in the children.

New concept with the Diamyd® diabetes vaccine approved for testing in children and adolescents with type 1 diabetes
The Swedish Medical Products Agency has approved another new researcher-initiated combination study with the Diamyd® diabetes vaccine. In the study, Diamyd® will be combined with two other agents – vitamin D and the immunosuppressive drug etanercept. This was the fourth researcher-initiated clinical trial with the Diamyd® diabetes vaccine to receive regulatory approval in the autumn of 2014. Two other clinical studies with the diabetes vaccine are already ongoing.

Diamyd-licensed technology enhances transplanted human beta cell mass in preclinical model of type 1 diabetes
A new scientific paper in the December issue of the journal Diabetes shows that GABA enhances transplanted human beta cell mass in the NOD mouse model of type 1 diabetes. Diamyd Medical licenses exclusive rights from the University of California for the therapeutic use of GABA for the treatment of diabetes and other inflammation-related conditions.

Significant events after the reporting period

Diamyd Medical's patent protection extended to 2032 in pivotal decision
The Regents of the University of California on behalf of its Los Angeles Campus (UCLA) has been granted another key US patent for its GAD65 technology on which the Diamyd® diabetes vaccine is based. The term of the new patent runs into 2032, which is approximately ten years longer than current US patents. Diamyd Medical is the exclusive licensee to the new patent.

About the Diamyd® diabetes vaccine

Diamyd® is being developed with the objective of preventing, delaying or stopping the autoimmune attack on beta cells in type 1 diabetes and other forms of autoimmune diabetes and thus preserve the body's own ability to produce insulin. Ongoing development work is aimed at enhancing the efficacy of the treatment by combining Diamyd® with other agents and to treat earlier in the disease process. New approaches are being evaluated in several clinical studies together with different teams of researchers. Two researcher-initiated clinical studies with Diamyd® are ongoing and an additional four are being launched.

- **DIABGAD-1.** A placebo-controlled study, where Diamyd® is being tested in combination with ibuprofen and vitamin D. The study comprises a total of 64 patients between the ages of 10 and 18 recently diagnosed with type 1 diabetes, and will continue for a total of 30 months. The aim of the combination treatment is to preserve the body's residual capacity to produce insulin. All of the participants have been enrolled in the study and the initial six-month results, focusing on immunological markers, are expected to be presented in the spring of 2015. The study runs at nine clinics in Sweden and is led by Professor Johnny Ludvigsson at Linköping University.

- **DIAPREV-IT.** A placebo-controlled study, where Diamyd® is being tested in children with early stages of 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. A total of 50 participants from the age of four have been enrolled in the study, which will last for five years. The aim of the study is to evaluate whether Diamyd® can delay or prevent the participants from presenting with type 1 diabetes. The study is taking place in Sweden led by Dr. Helena Elding Larsson at Lund University. Results are expected at the end of 2016.

- **DIAMYD®/GABA.** A placebo-controlled study, where Diamyd® is being tested in combination with GABA. The study will comprise 75 patients between the ages of 4 and 18 recently diagnosed with type 1 diabetes, and 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 study is taking place in the US led by Professor Kenneth McCormick at the University of Alabama at Birmingham and is in the start-up phase.

- **DIAPREV-IT 2.** A placebo-controlled study, where Diamyd® is being tested in combination with vitamin D in children with early stages 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. A total of 80 participants between the ages of 4 and 18 will be enrolled in the study, which will last for five years. The aim of the study is to evaluate whether Diamyd® can delay or prevent the participants from presenting with type 1 diabetes. The study is taking place in Sweden led by Dr. Helena Elding Larsson and is in the start-up phase.

- **DIAGNODE.** An open label study, where Diamyd® is administered directly into lymph nodes in combination with treatment with vitamin D. The study will comprise five patients between the ages of 18 and 30 who have been newly diagnosed with type 1 diabetes, and will continue for a total of 30 months. The aim of the study is to evaluate the safety of the combination treatment and the effect on the immune system and the patients' insulin producing capacity. The study is taking place in Sweden led by Professor Johnny Ludvigsson and is in the start-up phase.

- **EDCR IIa.** An open label study, where Diamyd® is combined with etanercept and vitamin D. The study will comprise 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 study is to evaluate the safety of the combination treatment and the effect on the immune system and the patients' insulin producing capacity. The study is taking place in Sweden led by Professor Johnny Ludvigsson and is in the start-up phase.

Business overview

Diamyd Medical is dedicated to fighting type 1 diabetes and to working toward a cure for the disease. Its projects include development of combination regimens with the GAD-based Diamyd® diabetes vaccine for arresting the successive destruction of insulin-producing beta cells. Diamyd Medical has an exclusive license to patent rights held by the UCLA related to the GAD molecule. The company has also an exclusive license from UCLA for GABA for the treatment of diabetes and other inflammation-related conditions.

Diamyd Medical is a shareholder in the stem cell company Cellaviva AB, which is establishing a Swedish commercial bank for private family saving of stem cells in umbilical cord blood and other sources of stem cells. Stem cells are expected to be used in Personalized Regenerative Medicine (PRM), for example, to restore beta cell mass in diabetes patients where autoimmunity has been arrested. Diamyd Medical also has an ownership stake in the US medical technology company Companion Medical, Inc., and a minor shareholding and other financial interests in the US gene therapy company Periphagen Holdings, Inc.

Diamyd Medical's Series B share is traded on Nasdaq Stockholm First North under the ticker DMYD B. Remium Nordic AB is the Company's Certified Adviser. Further information is available on the Company's website: www.diamyd.com.

Key figures

	3 months Sep-Nov 2014/15	3 months Sep-Nov 2013/14	12 months Sep-Aug 2013/14
Research and development costs, MSEK	-3.2	-2.2	-5.5
Solidity, %	86	87	87
Result per share, before and after dilution, SEK	-0.3	-0.2	-0.8
Liquid assets and short term investments per share, SEK	1.5	3.1	1.8
Shareholders' equity per share, before and after dilution, SEK	1.9	2.8	2.2
Cash flow per share, SEK	-0.2	-1.2	-2.1
Share price per closing, SEK	6.1	3.2	3.5
Share price/Shareholders' equity per share, SEK	3.1	1.1	1.6
Number of shares per closing	19 719 422	19 719 422	19 719 422
Average number of shares, before and after dilution	19 719 422	19 719 422	19 719 422
Average number of employees	7	7	7

Income statement

KSEK	Note	3 months Sep-Nov 2014/15	3 months Sep-Nov 2013/14	12 months Sep-Aug 2013/14
OPERATING INCOME				
Net income		87	171	443
Other operating income		417	24	116
TOTAL OPERATING INCOME		504	195	559
OPERATING EXPENSES				
External research and development costs		-3 186	-2 236	-5 465
External patent- and license costs		-266	-250	-1 262
Personnel costs	1	-1 849	-1 821	-6 716
Other external costs	1	-1 160	-840	-3 614
Other operating expenses		-109	-48	-126
Depreciation		-6	-28	-108
TOTAL OPERATING EXPENSES		-6 576	-5 222	-17 291
OPERATING LOSS		**-6 072**	**-5 028**	**-16 732**
Net Financial income/expense		180	211	794
RESULT BEFORE TAXES		-5 892	-4 816	-15 938
Taxes		-	-	-
NET RESULT FOR THE PERIOD		**-5 892**	**-4 816**	**-15 938**

Balance sheet

KSEK	Note	**30 Nov 2014**	30 Nov 2013	31 Aug 2014
ASSETS				
NON-CURRENT ASSETS				
Intangible assets		99	125	106
Tangible assets		-	61	-
Financial assets	2	13 933	652	13 801
TOTAL NON-CURRENT ASSETS		14 032	838	13 907
CURRENT ASSETS				
Trade receivables		44	58	79
Other receivables		649	1 331	702
Prepaid expenses and accrued income		334	456	758
Short term investments		7 991	19 912	10 960
Liquid assets		21 817	41 096	24 715
TOTAL CURRENT ASSETS		30 835	62 853	37 214
TOTAL ASSETS		**44 867**	**63 691**	**51 121**
EQUITY AND LIABILITIES				
EQUITY				
Restricted equity				
Share capital		2 000	2 000	2 000
Statutory reserve		200	200	200
Non-restricted equity				
Share premium reserve non-restricted		19 289	19 291	19 292
Profit or loss brought forward		22 769	38 707	38 707
Net loss for the period		-5 892	-4 816	-15 938
TOTAL EQUITY		38 366	55 382	44 261
NON-CURRENT LIABILITIES				
Other liabilities		862	810	841
TOTAL NON-CURRENT LIABILITIES		862	810	841
CURRENT LIABILITIES				
Trade payables		1 457	2 804	1 309
Other payables		53	901	248
Prepaid income and accrued expenses		4 129	3 794	4 462
TOTAL CURRENT LIABILITIES		5 639	7 499	6 019
TOTAL EQUITY AND LIABILITIES		**44 867**	**63 691**	**51 121**

Statement of cash flow

KSEK	Note	3 months Sep-Nov 2013/14	3 months Sep-Nov 2013/14	12 months Sep-Aug 2013/14
CASH FLOW FROM OPERATIONS BEFORE CHANGES IN WORKING CAPITAL				
Operating profit/loss		-6 071	-5 028	-16 732
Interest and foreign exchange difference received		352	148	703
Interest and foreign exchange difference paid		-2	-1	-2
Non-cash flow items				
Depreciation		7	28	108
Other non-cash flow items		-133	23	-91
NET CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL		**-5 847**	**-4 829**	**-16 014**
Increase (-) decrease (+) receivables		445	473	61
Increase (+) decrease (-) liabilities		-390	73	-737
NET CASH FLOW FROM OPERATING ACTIVITIES		**-5 792**	**-4 283**	**-16 690**
CASH FLOW FROM INVESTING ACTIVITIES				
Investment in immaterial and material assets, net		-	-129	-130
Investment in financial assets	2	-206	-	-13 055
Increase (-) decrease (+) short term investments, net		2 970	-19 912	-10 960
NET CASH FLOW FROM INVESTING ACTIVITIES		**2 764**	**-20 041**	**-24 145**
CASH FLOW FROM FINANCING ACTIVITIES				
Issue expenses		-2	-95	-95
NET CASH FLOW FROM FINANCING ACTIVITIES		**-2**	**-95**	**-95**
TOTAL CASH FLOW FOR THE PERIOD		**-3 030**	**-24 419**	**-40 930**
Cash and cash equivalents at beginning of period		24 715	65 518	65 518
Net foreign exchange difference		133	-3	127
CASH AND CASH EQUIVALENTS AT END OF PERIOD		**21 818**	**41 096**	**24 715**

Changes in Equity

KSEK	Share Capital	Statutory Reserve	Share premium reserve non restricted	Other non-restricted equity	Total Shareholders' equity
OPENING BALANCE SEPTEMBER 1, 2013	2000	200	19 386	38 707	60 293
Net result for the period	-	-	-	-15 938	-15 938
Issue expenses	-	-	-94	-	-94
CLOSING BALANCE AUGUST 31, 2014	2 000	200	19 292	22 769	44 261
OPENING BALANCE SEPTEMBER 1, 2014	**2 000**	**200**	**19 292**	**22 769**	**44 261**
Net result for the period	-	-	-	-5 892	-5 892
Issue expenses	-	-	-2	-	-2
CLOSING BALANCE NOVEMBER 30, 2014	**2 000**	**200**	**19 289**	**16 877**	**38 366**

Notes

Accounting principles

From fiscal year 2014/2015 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). Previously, the Annual Accounts Act and the Swedish Accounting Standards Board's general advice, except for BFNAR 2008: 1 Annual Report for smaller companies (K2 rules) were applied. The transition has been made in accordance with the provisions of BFNAR 2012: 1 Chapter 35, which includes, where appropriate, comparative figures for 2013/2014 adjusted to K3.

Note 1 – Related-party transactions

During the period companies represented by immediate family members of the Chairman of the Board were contracted as consultants. The consultancy services were attributable to IT-services. Pricing has been set by the arm's length principle. Total compensation for consultancy services and salaries to immediate family members of the Chairman during the period amounted to KSEK 361 (437). No other members of the Board of Directors, key executives or their immediate family members have been directly or indirectly involved in any business transaction with the Company that is or was unusual in its character or terms and conditions and took place during the period. Neither has the Company given any loans, provided any guarantees or surety to or for the benefit of any member of the Board of Directors, key executives or auditors in the Company.

KSEK	Sep-Nov 2014/2015	Sep-Nov 2013/2014
Consultant fees and salaries to related parties	361	437

Note 2 – Financial assets

Diamyd Medical acquired during the last fiscal year shares in the new company Cellaviva AB. Cellaviva AB is establishing a stem cell bank for private family saving of umbilical cord blood and other sources of stem cells. Cellaviva's corporate registration number is 556965-8361. The registered office is in Solna, Stockholm County. Diamyd Medical's share of the equity as well as share of the votes was as of November 30, 2014 46.3%, and valued at cost, approximately MSEK 11.5.

Diamyd Medical also acquired 10% of the start-up medical device company Companion Medical, Inc., based in San Diego, USA. The holding is valued at cost, adjusted for closing rate, approximately MSEK 1.8.

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 2013/2014. 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 21, 2015

Anders Essen-Möller, Chairman of the Board

Maria-Teresa Essen-Möller, Board member

Peter Zerhouni, President & CEO

Erik Nerpin, Board member

Fredrik Åhlander, Board member

Financial calendar

Quarterly Report 2 2014/2015:	April 1, 2015
Quarterly Report 3 2014/2015	July 1, 2015
Year-End Report 2014/2015	October 14, 2015

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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.