

QUARTERLY REPORT 3

September 2014 - May 2015

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

Reporting period, March 1, 2015 - May 31, 2015

- Net result amounted to MSEK -7.3 (-3.6)
- Net result per share amounted to SEK -0.4 (-0.2)
- Cash flow from operating activities amounted to MSEK -4.8 (-4.1)
- Liquid assets and short term investments amounted at the end of the period to MSEK 34.2 (38.8)

First nine months, September 1, 2014 - May 31, 2015

- Net result amounted to MSEK -17.2 (-12.8)
- Result per share amounted to SEK -0.9 (-0.6)
- Cash flow from operating activities amounted to MSEK -14.6 (-24.1)

Significant events during the reporting period

- DIAMYD®/GABA. First patient included in US Diamyd® and GABA diabetes study
- DiAPREV-IT 2. New study started with the diabetes vaccine Diamyd® to stop type 1 diabetes in children
- DIABGAD. Diamyd Medical announced that immunological results from a study with Diamyd[®] were to be presented in April
- Diamyd Medical received SEK 15 million in a direct issue
- Diamyd Medical announced that the Company contributes to JDRF initiative to increase understanding of type 1 diabetes
- DIABGAD. Immunological markers affected after six months in a first combination study with the diabetes vaccine Diamyd[®]
- Diamyd Medical increased investment in stem cell activity
- EDCR started first patient included in new study combining the diabetes vaccine Diamyd[®] with etanercept
- Diamyd Medical increased investment in Companion Medical

CEO comments

Diamyd Medical tackles autoimmune type 1 diabetes on three fronts: drug development, stem cell technology and medical devices. During the last quarter, the Company has advanced its positions in all of these areas. In addition to efforts to identify partners for the diabetes vaccine Diamyd®, the following were also noteworthy: a) three new studies with the diabetes vaccine Diamyd® (DiAPREV-IT 2, Diamyd®/GABA, and EDCR IIa) recruited their first patients; b) Diamyd®+vitamin D+ibuprofen has been well tolerated during the first six months' treatment as part of the DIABGAD study (immunological results); c) additional shares were acquired in the stem cell company Cellaviva, and; d) more shares were purchased in the medical devices company Companion Medical. In addition, a private placement brought in SEK 15 million to Diamyd Medical.

Diamyd Medical sees many values in using resources to try to extend the life of and improve quality of life for people with type 1 diabetes. Type 1 diabetes is a life-long autoimmune disease, where the body's own immune system breaks down the cells in the body that produce the vital hormone insulin. Each day, the blood sugar level is checked with frequent measurements and, each day, insulin must be added through injections or a pump to sustain life. Still, these patients risk severe complications from the disease, both in the short term and the long term. Type 1 diabetes is estimated to cost around SEK 100 billion annually in the US alone and, currently, there is no approved treatment in the market that can interrupt or prevent the autoimmune process. All things considered, this makes diabetes one of the greatest opportunities of our age, from both a humanitarian and a business perspective. New products in the diabetes field that improve conditions for patients have enormous financial potential.

The diabetes vaccine Diamyd® is, to the Company's knowledge, "first in class" in terms of antigen-based therapeutics being developed for type 1 diabetes. Diamyd® has demonstrated a good safety profile in studies with more than 1,000 participants. In a European phase III study conducted in nine countries with 334 newly diagnosed children, Diamyd® showed an efficacy of 16 percent (p=0.10) with regard to preserving the body's capacity to produce insulin. Even small improvements in the ability to preserve the body's ability to produce insulin are considered significant advances in protecting against complications later in life. The Company's strategy is now, in various smaller studies, to combine the diabetes vaccine Diamyd® with other substances and devices with market approval with the aim of identifying a treatment that synergistically strengthens the efficacy of the diabetes vaccine. Three such studies are currently ongoing in which Diamyd® is being combined with substances such as GABA, etanercept, ibuprofen and vitamin D for children recently diagnosed with type 1 diabetes. In a fourth study with adult patients, Diamyd® is administered directly into lymph nodes, again in combination with treatment with vitamin D. Furthermore, two studies are ongoing with Diamyd® to evaluate whether it can prevent or delay type 1 diabetes in children who are at high risk of developing the disease.

Stem cell technology is advancing at a rapid pace. The Company's commitment in this area builds on the vision of a combination treatment with tolerance induction for the insulin-producing beta cells, paired with treatment with autologous differentiated stem cells to replace lost beta cell mass that could finally mean a cure for type 1 diabetes. Diamyd Medical now owns 39 percent of the stem cell company Cellaviva and is open to additional collaborative undertakings in this and other areas to win the fight against type 1 diabetes.

Thank you for your interest.

Stockholm, July 1, 2015

Anders Essen-Möller

President and CEO Diamyd Medical AB (publ)

Significant events during the reporting period

First patient included in US Diamyd® and GABA diabetes study

The first patient was randomized and dosed in a pioneering study combining the diabetes vaccine Diamyd[®] with GABA in children with new onset type 1 diabetes. The aim of the combination therapy is to preserve the body's residual capacity to produce insulin.

New study started with the diabetes vaccine Diamyd® to stop type 1 diabetes in children

DiAPREV-IT 2 started. In the new study, the second of its kind, the diabetes vaccine Diamyd® is tested to prevent or delay the onset of type 1 diabetes in children at very high risk of presenting with the disease.

Immunological results from a study with Diamyd® in April

Diamyd Medical announced that immunological results from DIABGAD were to be presented at an international diabetes congress (IDS) in Munich on April 12 to 16, 2015.

Diamyd Medical received SEK 15 million in a direct issue

Diamyd Medical accepted an offer from a group of international institutional investors, previously not shareholders in Diamyd Medical, to issue 2,000,000 new B shares in a direct placement at 7.50 SEK per share. Total proceeds to the Company amounted to SEK 15 million.

Diamyd Medical announced that the Company contributes to JDRF initiative to increase understanding of type 1 diabetes

Diamyd Medical joined a research initiative aimed at increasing the understanding of the natural progression of type 1 diabetes in order to transform and accelerate drug development for the disease. Diamyd Medical will contribute data from the control (placebo) arm of its European Phase III study with the diabetes vaccine Diamyd[®]. The data will be made available to the research community in an open access database together with similar data from other late stage studies in type 1 diabetes.

Immunological markers affected after six months in a first combination study with the diabetes vaccine Diamyd®

A first evaluation, after six months, of immunological markers in DIABGAD was performed. Both anti-inflammatory and inflammatory immunological markers are affected by the Diamyd® treatment. The safety profile is good, with regards to the combination of Diamyd® with vitamin D and ibuprofen, as well as the combination of single or double doses of Diamyd® with vitamin D. Metabolic results, such as the treatment's effect on the ability to produce insulin, are expected to be ready for presentation by end of 2015 when all patients have completed their 15-month follow-up.

Diamyd Medical increased investment in stem cell activity

Diamyd Medical invested an additional SEK 0.8 million in Cellaviva AB, Sweden's first commercial biobank for stem cells.

EDCR started - first patient included in new study combining the diabetes vaccine Diamyd® with etanercept

The first patient was included in a new study, EDCR, in which the diabetes vaccine Diamyd® is combined with two other approved agents, the immunosuppressive drug etanercept and vitamin D, with the aim to evaluate the safety of the combination treatment as well as its impact on the immune system in children and adolescents newly diagnosed with type 1 diabetes. With the start of EDCR a total of six clinical studies are now ongoing where alternative approaches with Diamyd® are being tested, either in combination with other agents or by administering the diabetes vaccine at an earlier stage in the disease process, prior to type 1 diabetes diagnosis.

Diamyd Medical increased investment in Companion Medical

Diamyd Medical increased its investment in Companion Medical by USD 150,000. This was done in connection with a financing transaction in which Eli Lilly invested USD 3 million in Companion.

About the diabetes vaccine 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. Diamyd® is considered to be the world's furthest developed Antigen Based Therapy (ABT) for treating the disease. Diamyd® has been used in clinical studies with more than 1,000 patients and has shown a good safety profile. In a European Phase III study Diamyd® showed good clinical effect in several subgroups, and a limited overall 16% efficacy (p=0.10) in preserving endogenous insulin secretion. To enhance the overall effect, combination treatments with Diamyd® and other approved agents are being pursued. Diamyd® is easy to administer in any clinical setting. The potential annual market is estimated to several billion dollars.

Six researcher-initiated clinical studies with Diamyd® in different treatment regimens are ongoing:

DIABGAD-1 - COMBINING DIAMYD® WITH IBUPROFEN AND VITAMIN D

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. The study runs at nine clinics in Sweden and is led by Professor Johnny Ludvigsson at Linköping University, Sweden. 15 month results from the study are due in the fourth quarter of 2015.

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

An open label study, where Diamyd® is administered directly into lymph nodes in combination with treatment with vitamin D. The study comprises five patients between the ages of 18 and 30 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 led by Professor Johnny Ludvigsson at Linköping University, Sweden. The first patient was included in the study in February 2015.

• DIAMYD®/GABA - COMBINING DIAMYD® WITH GABA

A placebo-controlled study, where Diamyd® is being tested in combination with GABA. The study comprises 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 led by Professor Kenneth McCormick at the University of Alabama at Birmingham, USA. The first patient was included in the study in March 2015.

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

An open label study, where Diamyd® is combined with etanercept and vitamin D. The study 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 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 led by Professor Johnny Ludvigsson at Linköping University, Sweden. The first patient was included in May 2015.

• DiAPREV-IT 1- DIAMYD®

A placebo-controlled study, where Diamyd® is being tested 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. 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 led by Dr. Helena Elding Larsson at Lund University, Sweden. Five year results are expected at the end of 2016.

• DiAPREV-IT 2 - COMBINING DIAMYD® WITH VITAMIN D

A placebo-controlled study, 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. 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 led by Dr. Helena Elding Larsson at Lund University, Sweden. The first patient was included in March 2015.

Business overview

Diamyd Medical is dedicated to working toward a cure for type 1 diabetes and LADA. The Company's projects include development of combination regimens with the GAD-based diabetes vaccine Diamyd® for arresting the destruction of insulin-producing beta cells. The Company exclusively licenses UCLA-rights to GAD65, the active ingredient in the vaccine, for which the last patent expires in 2032. Additionally, the Company exclusively licenses UCLA patents for using GABA for the treatment of diabetes and other inflammation-related conditions.

Diamyd Medical is one of the major shareholders 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 can be 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'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 Mar- May 2014/15	3 months Mar-May 2013/14	9 months Sep-May 2014/15	9 months Sep-May 2013/14	12 months Sep-Aug 2013/14
Research and development costs, MSEK	-4.3	-1.1	-8.6	-4.4	-5.5
Solidity, %	83	87	83	87	87
Result per share, SEK	-0.4	-0.2	-0.9	-0.6	-0.8
Liquid assets and short term investments per share, SEK	1.6	1.8	1.6	1.8	1.6
Shareholders' equity per share, SEK	1.9	2.2	1.9	2.2	2.0
Cash flow per share, SEK	0.0	-0,5	0.1	-1.9	-2.0
Share price per closing, SEK	9.1	3.4	9.1	3.4	3.5
Share price/Shareholders' equity per share, SEK	4.7	1.6	4.7	1.6	1.7
Number of shares per closing	21 819 422	19 719 422	21 819 422	19 719 422	19 719 422
Average number of shares	20 493 335	19 719 422	19 994 147	19 719 422	19 719 422
Average number of employees	6	7	7	7	7

When calculating key figures it is assumed that the number of shares for the comparative year shall be the number of shares for the fiscal year.

Income statement

KSEK	Note	3 months Mar-May 2014/15	3 months Mar-May 2013/14	9 months Sep-May 2014/15	9 months Sep-May 2013/14	12 months Sep-Aug 2013/14
OPERATING INCOME						
Net income		172	33	396	285	443
Other operating income		35	12	667	30	116
TOTAL OPERATING INCOME		207	45	1 063	315	559
OPERATING EXPENSES						
External research and development costs		-4 337	-1 087	-8 610	-4 423	-5 465
External patent- and license costs		-170	-180	-1 009	-1 009	-1 262
Personnel costs	1	-1 960	-1 739	-5 934	-5 402	-6 716
Other external costs	1	-1 037	-710	-2 985	-2 642	-3 614
Other operating expenses		-22	-30	-226	-71	-126
Depreciation		-6	-43	-19	-101	-108
TOTAL OPERATING EXPENSES		-7 532	-3 789	-18 783	-13 648	-17 291
OPERATING LOSS		-7 325	-3 744	-17 721	-13 333	-16 732
Net Financial income/expense		70	170	509	554	794
RESULT BEFORE TAXES		-7 254	-3 574	-17 212	-12 779	-15 938
Taxes		-	-	-	-	-
NET RESULT FOR THE PERIOD		-7 254	-3 574	-17 212	-12 779	-15 938

Balance sheet

KSEK	Note	31 May 2015	31 May 2014	31 Aug 2014
ASSETS			-	
NON-CURRENT ASSETS				
Intangible assets		86	112	106
Tangible assets		-	0	-
Financial assets	2	16 246	13 695	13 801
TOTAL NON-CURRENT ASSETS		16 332	13 807	13 907
CURRENT ASSETS				
Trade receivables		86	45	79
Other receivables		506	1 060	702
Prepaid expenses and accrued income		297	779	758
Short term investments		7 998	10 960	10 960
Liquid assets		26 214	27 804	24 715
TOTAL CURRENT ASSETS		35 102	40 648	37 214
TOTAL ASSETS		51 434	54 455	51 121
EQUITY AND LIABILITIES EQUITY				
Restricted equity				
Share capital		2 213	2 000	2 000
Statutory reserve Non-restricted equity		200	200	200
Share premium reserve non-restricted		34 487	19 291	19 292
Profit or loss brought forward		22 770	38 708	38 707
Net loss for the period		-17 212	-12 779	-15 938
TOTAL EQUITY		42 458	47 420	44 261
NON-CURRENT LIABILITIES Other liabilities		908	828	841
TOTAL NON-CURRENT LIABILITIES		908	828	841
CURRENT LIABILITIES				
Trade payables		1 126	1 680	1 309
Other payables		351	416	248
Prepaid income and accrued expenses		6 591	4 110	4 462
TOTAL CURRENT LIABILITIES		8 068	6 207	6 019
TOTAL EQUITY AND LIABILITIES		51 434	54 455	51 121

Statement of cash flow

KSEK	Note	3 months Mar-May 2014/15	3 months Mar-May 2013/14	9 months Sep-May 2014/15	9months Sep-May 2013/14	12 months Sep-Aug 2013/14
CASH FLOW FROM OPERATIONS BEFORE CHANGES IN WORKING CAPITAL						
Operating profit/loss		-7 325	-3 744	-17 721	-13 333	-16 732
Interest and foreign exchange difference received		22	221	428	594	703
Interest and foreign exchange difference paid		-	-	-2	-1	-2
Non-cash flow items						
Depreciation		6	43	19	101	108
Other non-cash flow items		163	-	72	-14	-91
NET CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL		-7 134	-3 480	-17 204	-12 653	-16 014
Increase (-) decrease (+) receivables		-214	443	410	-308	61
Increase (+) decrease (-) liabilities		2 506	-1 045	2 195	-508	-737
NET CASH FLOW FROM OPERATING ACTIVITIES		-4 842	-4 082	-14 599	-13 469	-16 690
CASH FLOW FROM INVESTING ACTIVITIES						
Investment in immaterial and material assets, net		-	-	-	-129	-130
Investment in financial assets	2	-1 690	-13 055	-2 007	-13 055	-13 055
Increase (-) decrease (+) short term investments, net		-8 229	6 981	2 731	-10 960	-10 960
NET CASH FLOW FROM INVESTING ACTIVITIES		9 919	-6 074	724	-24 144	-24 145
CASH FLOW FROM FINANCING ACTIVITIES						
New issue		15 450	-	15 450	-	-
Issue expenses		-31	-	-41	-95	-95
NET CASH FLOW FROM FINANCING ACTIVITIES		15 419	-	15 409	-95	-95
TOTAL CASH FLOW FOR THE PERIOD		658	-10 156	1 534	-37 708	-40 930
Cash and cash equivalents at beginning of period		25 880	37 964	24 715	65 518	65 518
Net foreign exchange difference		-324	-4	-35	-6	127
CASH AND CASH EQUIVALENTS AT END OF PERIOD		26 214	27 804	26 214	27 804	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	2 000	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, 2013	2 000	200	19 386	38 707	60 293
Net result for the period	-	-	-	-12 779	-12 779
Issue expenses	-	-	-94	-	-94
CLOSING BALANCE MAY 31, 2014	2000	200	19 292	25 928	47 420
OPENING BALANCE SEPTEMBER 1, 2014	2 000	200	19 292	22 769	44 261
Net result for the period	-	-	-	-17 212	-17 212
New issue	213	-	15 237	-	15 450
Issue expenses	-	-	-41	-	-41
CLOSING BALANCE MAY 31, 2015	2 010	200	34 487	5 654	42 458

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 CEO 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 CEO during the first nine months amounted to KSEK 1 125 (1 123). 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.

	Sep-May	Sep-May
KSEK	2014/2015	2013/2014
Consultant fees and salaries to related parties	1 125	1 123

Note 2 - Financial assets

Diamyd Medical acquired during the last fiscal year shares in 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 Huddinge, Stockholm County. Diamyd Medical's share of the equity as well as share of the votes was as of May 31, 2015 39 %, and valued at cost, approximately MSEK 11.9.

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, adjusted for closing rate, approximately MSEK 3.3.

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, July 1, 2015

Anders Essen-Möller, President & CEO, Board member Erik Nerpin, Chairman of the Board

Maria-Teresa Essen-Möller, Board member Fredrik Åhlander, Board member

Financial calendar

Year-End Report 2014/2015

October 14, 2015

For more information please contact:

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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.