



QUARTERLY REPORT

September 2013 – November 2013

Diamyd Medical AB (publ), Fiscal year 2013/2014

Reporting period September 1, 2013 – November 30, 2013

- Net sales amounted to MSEK 0.2 (0)
- Loss before tax amounted to MSEK -4.8 (profit 0.9)
- Liquid assets and short term investments amounted to MSEK 61 (19) as of November 30, 2013

Significant events during the reporting period

- Major owner increased holdings in Diamyd Medical

Significant events after the reporting period

- More than half of the patients treated in diabetes study with the diabetes vaccine Diamyd®
- Diamyd Medical clarified media reports on diabetes study

CEO comments

Diamyd Medical was able to start the New Year by announcing that more than half of the planned total of 60 patients in the DIABGAD-1 study had been enrolled. Children and adolescents with newly diagnosed type 1 diabetes are currently being recruited to the study at about ten pediatric diabetes clinics throughout Sweden. Enrolment of the final patients is expected to be completed by summer 2014, and presentation of the initial results from the study is expected in 2015. The study is being led by Professor Ludvigsson at Linköping University.

In the DIABGAD-1 study, our diabetes vaccine Diamyd® is being combined with the anti-inflammatory drug ibuprofen and relatively high doses of vitamin D to investigate whether the treatment can preserve the patients' endogenous insulin production. Even a modest degree of endogenous insulin production reduces the risk of acute and long-term diabetes complications.

The Swedish researcher-initiated DiAPREV-IT study started in 2009 and aims to evaluate whether the diabetes vaccine Diamyd® can prevent or delay type 1 diabetes in children who are at high risk of developing clinical symptoms of the disease. The initial results from the DiAPREV-IT-study are also expected in 2015.

Additional researcher-initiated studies involving the diabetes vaccine Diamyd® are being discussed with various researchers groups and newly produced diabetes vaccine is now available for new studies. For example, a trial is being planned in the US in which the intention is to combine Diamyd® with GABA. The combination has shown favorable results in preclinical studies and the Company has in-licensed the rights for the use of GABA in connection with diabetes and other inflammation-related conditions. The study protocol and an agreement between Diamyd Medical and the researchers' university must be finalized before an application can be submitted to the US Food and Drug Administration (FDA).

Professor Ludvigsson's research group is continuing to analyze the extensive material collected in the earlier European Phase III study and an earlier Swedish Phase II study of Diamyd®. In December 2013, they published a scientific paper relating to the analysis of results from 148 Swedish children and adolescents with type 1 diabetes who participated in the earlier studies. The authors' conclusion is that treatment with two doses of the GAD-based diabetes vaccine is safe and that, versus placebo, it preserves insulin production 30 months after treatment (GAD-treatment of children and adolescents with recent-onset Type 1 diabetes preserves residual insulin secretion after 30 months, *Diabetes Metab Res Rev.* 2013 Dec 3. Epub ahead of print). Such new analyses based on the substantial database with patient data that Diamyd Medical has compiled over the years, add to strengthen the interest in the diabetes vaccine and researcher-initiated studies of Diamyd®.

On the second trading day of the year, the Diamyd share rose by 30 percent during heavy trading after widespread distribution of a newspaper article about the so called TEDDY study. The article described the TEDDY study, in which researchers are closely monitoring thousands of children from birth to ascertain who will and who will not develop type 1 diabetes, with the purpose of determining what triggers type 1 diabetes. To clarify for the stock market that the diabetes vaccine Diamyd® is not being tested as part of the TEDDY study, the company published a press release, after which the share price declined again.

In December, I was in Lorne in Australia and attended the scientific IDS conference dedicated to diabetes immunology research. The conference is an ideal opportunity to hear about the latest findings and to network with leading researchers in the field. In his opening plenary lecture, Doctor Jay Skyler described how the key to successfully treating type 1 diabetes will be to attack the disease from several angles simultaneously by combining various therapeutics, and that an autoantigen-specific treatment such as Diamyd® will constitute an essential component in future combination therapies.

Stockholm, January 22, 2014

Peter Zerhouni
President and CEO Diamyd Medical AB (publ)

Significant events during the reporting period

Major owner increased holdings in Diamyd Medical

Bertil Lindkvist increased his holdings in Diamyd Medical. Bertil Lindkvist's holdings in Diamyd Medical amounted to 2 979 286 B-shares as of September 24, 2013, which corresponds to 15.1 percent of the capital and 10.5 percent of the votes.

Significant events after the reporting period

More than half of the patients treated in diabetes study with the diabetes vaccine Diamyd®

Children and adolescents aged 10 to 18 years with newly diagnosed type 1 diabetes are now being recruited to a study with Diamyd® to investigate whether the treatment can preserve the patients' endogenous insulin production. Of the 60 patients being recruited at about ten pediatric diabetes clinics in Sweden more than half have been treated.

Diamyd Medical clarified media reports on diabetes study

On January 2, 2014 Dagens Industri and many other Swedish media published an article that originally came from TT News Agency on the TEDDY study, which is an international, multicenter study aiming to determine the causes of type 1 diabetes. Diamyd Medical clarified in a press release on January 3, 2014, that Diamyd Medical has no direct connection to the TEDDY study that the article describes. Diamyd Medical's drug candidate Diamyd® is not being tested in the TEDDY study.

Business overview

Diamyd Medical is a Swedish diabetes company.

Since 1994, the Company has been engaged in the development of the diabetes vaccine Diamyd® for the treatment and prevention of autoimmune diabetes. Diamyd® and the active substance GAD is Diamyd Medical's primary development project and is estimated to have the potential to become a key piece of the puzzle in a future solution to prevent, treat or cure type 1 diabetes and other forms of autoimmune diabetes.

Two Swedish researcher-initiated Phase II studies with Diamyd® are ongoing. One study evaluates whether the diabetes vaccine can prevent type 1 diabetes in children who are at high risk of developing the disease, while the other study evaluates whether Diamyd® in combination with relatively high doses of vitamin D and ibuprofen can preserve the body's own ability to regulate the blood sugar level in children and adolescents newly diagnosed with type 1 diabetes.

The Company concluded in May 2013 an exclusive licensing agreement with the University of California at Los Angeles (UCLA) relating to a patent portfolio for the use of GABA (gamma-aminobutyric acid) to treat and prevent type 1 and type 2 diabetes and other inflammatory disorders such as metabolic syndrome, rheumatoid arthritis and allergy.

Diamyd Medical also has holdings in the gene therapy company Periphagen Holdings, Inc. (US).

Diamyd Medical's Series B share is traded on NASDAQ OMX 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

Financial information

Net sales – Net sales during the first quarter amounted to MSEK 0.2 (0).

Costs – Costs were MSEK -5.2 (0.8) during the first quarter.

Result – Loss before tax for the first quarter was MSEK -4.8 (profit 0.9).

Financial position and liquidity – Liquid assets and short term investments were MSEK 61 (19) as of November 30, 2013.

Equity – As of November 30, 2013, the equity amounted to MSEK 55.4 (161.5), resulting in a solidity of 87 (97) percent. During the previous fiscal year a dividend of MSEK 109 was made to former parent company.

Organization – The average number of employees during the period was 7 (7).

Income statement

KSEK	Note	3 months Sep-Nov 2013/14	3 months Sep-Nov 2012/13	12 months Sep-Aug 2012/13
OPERATING INCOME				
Net income		171	-	100
Other operating income		24	-	65
TOTAL OPERATING INCOME		195	-	165
OPERATING EXPENSES				
External research and development costs	1	-2 236	794	-3 519
External patent- and license costs		-250	-190	-756
Personnel costs	2,3	-1 821	493	-5 231
Other external costs	2	- 840	-224	-3 433
Other operating expenses		-48	-22	-103
Depreciation		-28	-39	-155
TOTAL OPERATING EXPENSES		-5 222	812	-13 197
OPERATING LOSS		-5 028	812	-13 032
Net Financial income/expense		211	95	399
NET LOSS FOR THE PERIOD		-4 816	907	-12 633
Taxes		-	-	-
NET LOSS FOR THE PERIOD		-4 816	907	-12 633

Balance sheet

KSEK	Not	30 Nov 2013	30 Nov 2012	31 Aug 2013
ASSETS				
NON-CURRENT ASSETS				
Intangible assets		125	-	-
Tangible assets		61	201	85
Financial assets	4	652	146 575	639
TOTAL NON-CURRENT ASSETS		838	146 775	724
CURRENT ASSETS				
Trade receivables		58	-	-
Other receivables		1 331	1 281	972
Prepaid expenses and accrued income		456	491	603
Short terms investments		19 912	-	-
Liquid assets		41 096	19 386	65 518
TOTAL CURRENT ASSETS		62 853	21 158	67 093
TOTAL ASSETS		63 691	167 933	67 817
EQUITY AND LIABILITIES				
EQUITY				
<i>Restricted equity</i>				
Share capital		2 000	1 000	2 000
Statutory reserve		200	200	200
<i>Non-restricted equity</i>				
Share premium reserve non-restricted		19 291	-	19 386
Profit or loss brought forward	4	38 707	160 265	51 340
Net loss for the period		-4 816	907	-12 633
TOTAL EQUITY		55 382	162 372	60 293
NON-CURRENT LIABILITIES				
Other liabilities		810	786	795
TOTAL NON-CURRENT LIABILITIES		810	786	795
CURRENT LIABILITIES				
Trade payables		2 804	627	1 448
Other payables		901	1 109	674
Prepaid income and accrued expenses		3 794	3 039	4 607
TOTAL CURRENT LIABILITIES		7 499	4 775	6 729
TOTAL EQUITY AND LIABILITIES	5	63 691	167 933	67 817

Statement of cash flow

KSEK	Note	3 mån Sep-Nov 2013/14	3 mån Sep-Nov 2012/13	12 mån Sep/Aug 2012/13
CASH FLOW FROM OPERATIONS BEFORE CHANGES IN WORKING CAPITAL				
Operating profit/loss		-5 028	813	-13 032
Interest and foreign exchange difference received		148	79	425
Interest and foreign exchange difference paid		-1	-	-31
<i>Non-cash flow items</i>				
Depreciation		28	-	155
Other non-cash flow items		23	-2 072	-1 903
NET CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL		-4 829	-1 180	-14 386
Increase (-) decrease (+) receivables		473	-174	23
Increase (-) decrease (+) liabilities		73	-1 272	648
NET CASH FLOW FROM OPERATING ACTIVITIES		-4 283	- 2 626	-13 715
CASH FLOW FROM INVESTING ACTIVITIES				
Investment in immaterial and material assets, net		-129	39	-
Increase (-) decrease (+) short term investments, net		-19 912	-	-
Changes in transactions between former Group companies	4	-	200	36 882
NET CASH FLOW FROM INVESTING ACTIVITIES		-20 041	239	36 882
CASH FLOW FROM FINANCING ACTIVITIES				
Rights issue		-	-	20 705
Issue expenses		-95	-	-319
Changes in transactions between former Group companies		-	-200	-
NET CASH FLOW FROM FINANCING ACTIVITIES		-95	-200	20 386
TOTAL CASH FLOW FOR THE PERIOD		-24 419	-2 587	45 553
Cash and cash equivalents at beginning of period		65 518	21 960	21 960
Net foreign exchange difference		-3	13	5
CASH AND CASH EQUIVALENTS AT END OF PERIOD		41 096	19 386	65 518

Changes in Equity

KSEK	Share Capital	Statutory Reserve	Share premium reserve non restricted	Other non- restricted equity	Total Shareholder' equity
OPENING BALANCE SEPTEMBER 1, 2012	1 000	200	-	162 337	163 537
Net loss for the year	-	-	-	-12 633	-12 633
Rights issue	1 000	-	19 705	-	20 705
Issue expenses	-	-	-319	-	-319
Dividend to former Group companies	-	-	-	-109 000	-109 000
Employee options	-	-	-	-1 997	-1 997
CLOSING BALANCE AUGUST 31, 2013	2 000	200	19 386	38 707	60 293
OPENING BALANCE SEPTEMBER 1, 2013	2 000	200	19 386	38 707	60 293
Net loss for the period	-	-	-	-4 816	-
Issue expenses	-	-	-95	-	-
CLOSING BALANCE NOVEMBER 30, 2013	2 000	200	19 291	33 891	55 382

Notes

Accounting principles

Diamyd Medical's interim report has been prepared in accordance with the Annual Accounts Act (Chapter 9. Interim Report) and the Swedish Accounting Standards Board's general advice, except for BFNAR 2008:1 Annual Report for smaller companies (K2-rules).

Note 1 – External research and development costs

The previous year's amount includes reversal of reserved costs equivalent to MSEK 2.

Note 2 – Related-party transactions

During the period companies represented by immediate family members of the Chairman of the Board were contracted as consultants. Total compensation during the period amounted to KSEK 225 (67) excluding VAT and was attributable to IT-services. Pricing has been set by the arm's length principle. Remuneration of immediate family members of the Chairman amounted to KSEK 212 (182) during the period. 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 2013/14	Sep-Nov 2012/13
Salaries to related parties	212	182
Consultant fees to related parties	225	67

Note 3 – Personnel costs

The comparative year's amount includes a positive amount of MSEK 2.1 related to the previous employee option plan.

Note 4 – Distribution of Diamyd Therapeutics AB (current Diamyd Medical AB)

At an Extraordinary General Meeting in the former Diamyd Medical AB (current Mertiva AB) on April 22, 2013, it was decided to distribute the subsidiary Diamyd Therapeutics AB (new Diamyd Medical AB) with the diabetes operations to the shareholders and at the same time the Company assumed the name Diamyd Medical AB. The new Diamyd Medical was capitalized with approximately MSEK 50. The intercompany receivables of MSEK 146 between the former parent company Diamyd Medical and the former subsidiary Diamyd Therapeutics was in connection with the distribution settled by cash MSEK 37 and a dividend to the former parent company of MSEK 109 was made.

Note 5 – Equity and liabilities

All of the Company's debts are non-interest-bearing.

Key figures

	3 months Sep-Nov 2013/14	3 months Sep-Nov 2012/13	12 months Sep/Aug 2012/13
Research and development costs, MSEK	-2.2	0.8	-3.5
Solidity, %	87	97	89
Earnings per share, before and after dilution, SEK	-0.2	0	-0.6
Liquid assets and short term investments per share, SEK	3.1	1.0	3.3
Shareholders' equity per share, before and after dilution, SEK	2.8	8.2	3.1
Cash flow per share, SEK	-1.2	-0.1	2.2
Share price per closing, SEK	3.2	NA	2.7
Share price/Shareholders' equity per share, SEK	1.1	NA	0.9
Number of shares per closing	19 719 422	1 000 000	19 719 422
Average number of shares, before and after dilution	19 719 422	1 000 000	12 530 049

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.

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 2012/2013. 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 interim report has not been reviewed by the Company's auditors.

Stockholm, January 22, 2014

Anders Essen-Möller
Chairman of the Board

Erik Nerpin
Board member

Maria-Teresa Essen-Möller
Board member

Peter Zerhouni
President and CEO

Financial calendar

Quarterly report 2 2013/2014:	April 9, 2014
Quarterly report 3 2013/2014:	July 2, 2014
Year-end report 2013/2014:	October 15, 2014

For more information please contact:

Peter Zerhouni, President and CEO Diamyd Medical AB (publ). Phone: +46 8 661 00 26

Diamyd Medical AB (publ), Kungsgatan 29, SE-111 56 Stockholm, Sweden
Phone: +46 8 661 00 26 Fax: +46 8 661 63 68 E-mail: info@diamyd.com Reg no: 556242-3797

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