



# QUARTERLY REPORT

September 2013 – February 2014

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

## Reporting period December 1, 2013 - February 28, 2014

- Net sales amounted to MSEK 0.1 (0)
- Loss before tax amounted to MSEK -4.4 (-5,3)
- Liquid assets and short term investments amounted to MSEK 56 (15) as of February 28, 2014

## First half year September 1, 2013 - February 28, 2014

- Net sales amounted to MSEK 0.3 (0)
- Loss before tax amounted to MSEK -9.2 (-4.4)

## Significant events during the reporting period

- More than half of the patients treated in diabetes study with the diabetes vaccine Diamyd® in combination with vitamin D and ibuprofen
- Diamyd Medical clarified media reports on diabetes study
- Application to double unique prevention study with Diamyd's diabetes vaccine submitted to the Swedish MPA

## Significant events after the reporting period

- Diamyd Medical's former sister company Periphagen, Inc. (former Diamyd, Inc.) secured new financing
- Diamyd Medical entered the stem cell field with investment in Swedish cord blood bank

## CEO comments

Recent times have been eventful for Diamyd Medical and we were able to report two items of good news in quick succession the past week. Together with a group of founding partners and Karolinska Institutet Holding AB, we will establish Sweden's first commercial stem cell bank for private family saving of umbilical cord blood and other sources of stem cells. The intention is also to collect stem cells from umbilical cord tissue and make these available for research purposes, not least for research into type 1 diabetes. With the new venture Diamyd Medical enters the expansive field of stem cells. The financial risk is considered limited given the many examples of established private cord blood banks in other countries. Through the initiative of a research bank, we hope to contribute to substantial progress in the future use of stem cells in various therapies.

At birth, there is a unique opportunity to collect young stem cells from the umbilical cord, which are otherwise discarded. Private family saving of umbilical cord blood has been possible in the US for more than 20 years and is offered in most European countries, although such a service is not yet available in Sweden. I myself investigated the possibilities when my children were born a few years ago but it was too complicated since the only way would be for me to personally bring the equipment necessary to the delivery room, collect the blood and subsequently send it overseas for processing, freezing and storage since this service didn't exist in Sweden.

Hans-Peter Ekre, who has extensive experience and a broad network in the Swedish life science field, will lead the project. Together with the knowledgeable and experienced group of founding partners, as well as Karolinska Institutet Holding AB, we are looking forward to building a professional and robust activity.

Last week, we could also report that our former colleagues at Periphagen in Pittsburgh had secured funding for the continued development of their gene therapy platform. Periphagen was previously part of the Diamyd Group, where it was known as Diamyd, Inc., but was bought out by the US management in autumn 2012. I was delighted to hear that a life science fund has decided to initially invest USD 6.5 million and we congratulate the team at Periphagen! Diamyd Medical still has financial interests in Periphagen and these are dependent on the continued development of the platform. Diamyd Medical's shareholding, which amounted to 10 percent, has been reduced as a result of the investment by the fund, but our other financial interests in Periphagen remain and the possibility of receiving a return on these has increased.

Diamyd Medical could receive up to USD 9 million in milestone payments to be disbursed on the achievement of certain development targets. Furthermore, Diamyd Medical will receive 10 percent of upfront payments and other payments that Periphagen may receive from future partners, as well as royalties on future sales of drugs based on the gene therapy technology. Diamyd Medical also has a claim of USD 1 million and retains certain rights to utilize Periphagen's technology in the field of diabetes.

Two researcher-initiated clinical studies of our diabetes vaccine Diamyd® are currently in progress. We expect patient enrolment to DIABGAD-1, where Diamyd® is combined with vitamin D and ibuprofen, to be concluded before the summer, meaning that the first results can be presented in 2015. The results of the DiAPREV-IT prevention study are also expected in 2015. DiAPREV-IT is a relatively small study and the research team at Lund University conducting the study is planning to expand the number of participating children with a high risk of presenting with type 1 diabetes. This will increase the chance of being able to demonstrate a preventive effect of the diabetes vaccine and enhance the scientific value of the study.

*Stockholm, April 9, 2014*

Peter Zerhouni  
*President and CEO Diamyd Medical AB (publ)*

## Significant events during the reporting period December 1, 2013 – February 28, 2014

### **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 had been treated as of January 7, 2014.

### **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.

### **Application to double unique study with Diamyd's diabetes vaccine submitted to the Swedish MPA**

The research group at Lund University, that runs DiAPREV-IT, a clinical study evaluating if the diabetes vaccine Diamyd® can prevent or delay the onset of type 1 diabetes in children at high risk of developing the disease, has applied to the Swedish Medical Products Agency to expand the study with an additional 50 children. The first part of the study, which also comprises 50 children, is fully recruited and results are expected in 2015.

## Significant events after the reporting period

### **Diamyd Medical's former sister company secured new financing**

Diamyd Medical holds shares in the US gene therapy company Periphagen Holdings, Inc. Periphagen announced the successful completion of a financing transaction where a life science fund invests up to USD 16 million, of which USD 6.5 million has been closed.

### **Diamyd Medical entered the stem cell field with investment in Swedish cord blood bank**

Diamyd Medical signed an agreement with a group of founding partners and Karolinska Institutet Holding AB, by which Diamyd Medical agrees to invest SEK 11.5 million for the establishment of a commercial cord blood bank in Sweden for private family saving of umbilical cord blood and other sources of stem cells. The intention is also to collect and make available stem cells from umbilical cord tissue for research purposes in order to advance the fields of stem cells and regenerative medicine, including research within type 1 diabetes.

# 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 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 signed in April 2014 an agreement with a group of founding partners and Karolinska Institutet Holding AB, by which Diamyd Medical agrees to invest SEK 11.5 million for the establishment of a commercial cord blood bank in Sweden for private family saving of umbilical cord blood and other sources of stem cells. The intention is also to collect and make available stem cells from umbilical cord tissue for research purposes in order to advance the fields of stem cells and regenerative medicine, including research within type 1 diabetes.

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](http://www.diamyd.com)

## Financial information

**Net sales** – Net sales during the second quarter amounted to MSEK 0.1 (0). Net sales during the first half year amounted to MSEK 0.3 (0).

**Costs** – Costs were MSEK -4.7 (-5.2) during the second quarter. Costs were MSEK -9.6 (-4.5) during the first half year.

**Result** – Loss before tax for the second quarter was MSEK -4.4 (-5.3). Loss before tax for the first half year was MSEK -9.2 (-4.4).

**Financial position and liquidity** – Liquid assets and short term investments were MSEK 56 (15) as of February 28, 2014.

**Equity** – As of February 28, 2014, the equity amounted to MSEK 51.0 (157.2), resulting in a solidity of 86 (96) 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 Dec-Feb 2013/14	3 months Dec-Feb 2012/13	6 months Sep-Feb 2013/14	6 months Seb-Feb 2012/13	12 months Sep-Aug 2012/13
<b>OPERATING INCOME</b>						
Net income		81	1	252	2	100
Other operating income		9	7	19	7	65
<b>TOTAL OPERATING INCOME</b>		<b>90</b>	<b>8</b>	<b>271</b>	<b>9</b>	<b>165</b>
<b>OPERATING EXPENSES</b>						
External research and development costs	1	-1 100	-2 281	-3 336	-1 486	-3 519
External patent- and license costs		-579	-168	-829	-358	-756
Personnel costs	2,3	-1 841	-2 280	-3 662	-1 508	-5 231
Other external costs	2	-1 092	-464	-1 932	-906	-3 433
Other operating expenses		-8	-11	-41	-33	-103
Depreciation		-31	-39	-59	-78	-155
<b>TOTAL OPERATING EXPENSES</b>		<b>-4 651</b>	<b>-5 243</b>	<b>-9 859</b>	<b>-4 369</b>	<b>-13 197</b>
<b>OPERATING LOSS</b>		<b>-4 561</b>	<b>-5 284</b>	<b>-9 588</b>	<b>-4 471</b>	<b>-13 032</b>
Net Financial income/expense		172	20	383	114	399
<b>NET LOSS FOR THE PERIOD</b>		<b>-4 389</b>	<b>-5 264</b>	<b>-9 205</b>	<b>-4 357</b>	<b>-12 633</b>
Taxes		-	-	-	-	-
<b>NET LOSS FOR THE PERIOD</b>		<b>-4 389</b>	<b>-5 264</b>	<b>-9 205</b>	<b>-4 357</b>	<b>-12 633</b>

## Balance sheet

KSEK	Note	28 Feb 2014	28 Feb 2013	31 Aug 2013
<b>ASSETS</b>				
NON-CURRENT ASSETS				
Intangible assets		119	-	-
Tangible assets		36	161	85
Financial assets	4	659	146 518	639
<b>TOTAL NON-CURRENT ASSETS</b>		<b>814</b>	<b>146 679</b>	<b>724</b>
CURRENT ASSETS				
Trade receivables		58	-	-
Other receivables		1 272	1 443	972
Prepaid expenses and accrued income		991	896	603
Short terms investments		17 971	-	-
Liquid assets		37 964	14 949	65 518
<b>TOTAL CURRENT ASSETS</b>		<b>58 227</b>	<b>17 289</b>	<b>67 093</b>
<b>TOTAL ASSETS</b>		<b>59 040</b>	<b>163 968</b>	<b>67 817</b>
<b>EQUITY AND LIABILITIES</b>				
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	38 708	160 340	51 340
Net loss for the period		-9 205	-4 357	-12 633
<b>TOTAL EQUITY</b>		<b>50 994</b>	<b>157 183</b>	<b>60 293</b>
NON-CURRENT LIABILITIES				
Other liabilities		819	790	795
<b>TOTAL NON-CURRENT LIABILITIES</b>		<b>819</b>	<b>790</b>	<b>795</b>
CURRENT LIABILITIES				
Trade payables		2 461	1 244	1 448
Other payables		773	1 059	674
Prepaid income and accrued expenses		3 994	3 692	4 607
<b>TOTAL CURRENT LIABILITIES</b>		<b>7 228</b>	<b>5 995</b>	<b>6 729</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	5	<b>59 040</b>	<b>163 968</b>	<b>67 817</b>

# Statement of cash flow

KSEK	Note	3 mån Dec-Feb 2013/14	3 mån Dec- Feb 2012/13	6 mån Sep-Feb 2013/14	6 mån Sep- Feb 2012/13	12 mån Sep/Aug 2012/13
<b>CASH FLOW FROM OPERATIONS BEFORE CHANGES IN WORKING CAPITAL</b>						
Operating profit/loss		-4 562	-5 284	-9 589	-4 471	-13 032
Interest and foreign exchange difference received		224	157	372	236	425
Interest and foreign exchange difference paid		-	-71	-1	-71	-31
<i>Non-cash flow items</i>						
Depreciation		31	78	59	78	155
Other non-cash flow items		-37	141	-14	-1 931	-1 903
<b>NET CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL</b>						
		<b>-4 344</b>	<b>-4 979</b>	<b>-9 173</b>	<b>-6 159</b>	<b>-14 386</b>
Increase (-) decrease (+) receivables		-1 225	-579	-752	-753	23
Increase (-) decrease (+) liabilities		464	1 213	537	-59	648
<b>NET CASH FLOW FROM OPERATING ACTIVITIES</b>						
		<b>-5 105</b>	<b>-4 345</b>	<b>-9 388</b>	<b>-6 971</b>	<b>-13 715</b>
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>						
Investment in immaterial and material assets, net		-	-39	-129	-	-
Increase (-) decrease (+) short term investments, net		1 970	-	-17 941	-	-
Changes in transactions between former Group companies	4	-	-200	-	-	36 882
<b>NET CASH FLOW FROM INVESTING ACTIVITIES</b>						
		<b>1 970</b>	<b>-239</b>	<b>-18 070</b>	<b>0</b>	<b>36 882</b>
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>						
Rights issue		-	-	-	-	20 705
Issue expenses		-	-	-95	-	-319
Changes in transactions between former Group companies		-	200	-	-	-
<b>NET CASH FLOW FROM FINANCING ACTIVITIES</b>						
		<b>0</b>	<b>200</b>	<b>-95</b>	<b>0</b>	<b>20 386</b>
<b>TOTAL CASH FLOW FOR THE PERIOD</b>						
		<b>-3 135</b>	<b>-4 384</b>	<b>-27 553</b>	<b>-6 971</b>	<b>45 553</b>
Cash and cash equivalents at beginning of period		41 096	19 386	65 518	21 960	21 960
Net foreign exchange difference		3	-54	-1	-41	5
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>						
		<b>37 964</b>	<b>14 948</b>	<b>37 964</b>	<b>14 948</b>	<b>65 518</b>

## Changes in Equity

KSEK	Share Capital	Statutory Reserve	Share premium reserve non restricted	Other non-restricted equity	Total Shareholders' equity
<b>OPENING BALANCE SEPTEMBER 1, 2012</b>	<b>1 000</b>	<b>200</b>	<b>-</b>	<b>162 337</b>	<b>163 537</b>
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
<b>CLOSING BALANCE AUGUST 31, 2013</b>	<b>2 000</b>	<b>200</b>	<b>19 386</b>	<b>38 707</b>	<b>60 293</b>
<b>OPENING BALANCE SEPTEMBER 1, 2012</b>	<b>1 000</b>	<b>200</b>	<b>-</b>	<b>162 337</b>	<b>163 537</b>
Net loss for the period	-	-	-	-4 357	-4 357
Employee options	-	-	-	-1 997	-1 997
<b>CLOSING BALANCE FEBRUARY 28, 2013</b>	<b>1 000</b>	<b>200</b>	<b>0</b>	<b>155 983</b>	<b>157 183</b>
<b>OPENING BALANCE SEPTEMBER 1, 2013</b>	<b>2 000</b>	<b>200</b>	<b>19 386</b>	<b>38 707</b>	<b>60 293</b>
Net loss for the period	-	-	-	-9 205	-9 205
Issue expenses	-	-	-94	-	-94
<b>CLOSING BALANCE FEBRUARY 28, 2014</b>	<b>2 000</b>	<b>200</b>	<b>19 292</b>	<b>29 502</b>	<b>50 994</b>



# 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. 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 757 (318). 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-Feb 2013/14	Sep-Feb 2012/13
Consultant fees and salaries to related parties	757	318

## 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

	<b>3 months Dec-Feb 2013/14</b>	<b>3 months Dec-Feb 2012/13</b>	<b>6 months Sep-Feb 2013/14</b>	<b>6 months Sep-Feb 2012/13</b>	<b>12 months Sep/Aug 2012/13</b>
Research and development costs, MSEK	-1.1	-2.3	-3.3	-1.5	-3.5
Solidity, %	86	96	86	96	89
Earnings per share, before and after dilution, SEK	-0.2	0	-0.5	-0.2	-0.6
Liquid assets and short term investments per share, SEK	2.8	0.8	2.8	0.8	3.3
Shareholders' equity per share, before and after dilution, SEK	2.6	8.2	2.6	8.2	3.1
Cash flow per share, SEK	-0.2	-0.1	-1.4	-0.4	2.2
Share price per closing, SEK	3.4	NA	3.4	NA	2.7
Share price/Shareholders' equity per share, SEK	1.3	NA	1.3	NA	0.9
Number of shares per closing	19 719 422	1 000 000	19 719 422	1 000 000	19 719 422
Average number of shares, before and after dilution	19 719 422	1 000 000	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, April 9, 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 3 2013/2014: July 2, 2014

Year-end report 2013/2014: October 15, 2014

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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.*