



# YEAR END REPORT

September 2012 – August 2013

Diamyd Medical AB (publ), former Diamyd Therapeutics AB  
Fiscal year 2012/2013

## Reporting period, June 1, 2013 – August 31, 2013

- Net sales amounted to MSEK 0.1 (0)
- Loss before tax amounted to MSEK -4.3 (-4.2)
- Liquid assets amounted to MSEK 65.5 (22.0) as of August 31, 2013

## Full year, September 1, 2012 – August 31, 2013

- Net sales amounted to MSEK 0.1 (0.5)
- Loss before tax amounted to MSEK -12.6 (-16.3)

## Significant events during the reporting period

### June 1, 2013 – August 31, 2013

- Diamyd Medical's rights issue was oversubscribed and raised approximately MSEK 21
- Diamyd Medical expanded its Scientific Advisory Board

## Significant events after the reporting period

- Major owner increased holdings in Diamyd Medical

## CEO Comments

After an intense period in May and June with the listing on First North, and an oversubscribed rights issue, Diamyd Medical's focus has shifted to business development activities and the production of a new batch of the diabetes vaccine Diamyd®. Our current inventory needs to be renewed and the manufacturing process has evolved since we last made a batch for clinical use.

Having sufficient inventory of fresh diabetes vaccine available is vital for our strategy of collaborating with externally funded research groups to establish additional clinical pilot studies with Diamyd®. Both in combination with other drugs to achieve a strong beta cell preserving effect, and by treating earlier in the disease process to try to prevent the onset of type 1 diabetes and other autoimmune diabetes altogether.

Manufacturing of the new batch was carried out late September in the Netherlands and was completed without problems. Pharmaceutical manufacturing is subject to a strict regulatory framework called Good Manufacturing Practice (GMP), which sets high quality standards. Currently a wide range of tests are performed on the product to confirm that it meets all manufacturing specifications. We expect that the new vials with the diabetes vaccine Diamyd® will be released for use in clinical trials later this autumn.

We work in parallel with several academic research groups who have ideas for new studies with the diabetes vaccine. The advantage of this approach is that we can test more hypotheses than if we were to conduct and fund all studies with the diabetes vaccine ourselves. The downside compared to company-funded studies, is that it takes more time since we are dependent upon the scientists actively working on the projects and seeking and receiving grants, at the same time as they are busy with their regular work at their respective hospitals.

Two researcher-initiated studies with Diamyd® are already in progress. The study DIABGAD-1 evaluates treatment with the diabetes vaccine in combination with the anti-inflammatory drug ibuprofen and relatively high doses of vitamin D. The study was launched earlier this year and more than a third of the planned 60 patients have been enrolled. Also, since 2009 a researcher-initiated study is in progress with children at high risk of developing type 1 diabetes, with the aim to prevent the onset of the disease.

Regarding business development, we are working hard to evaluate new opportunities for collaboration and deals in the field of diabetes. We have participated in several international diabetes meetings and will also be represented at the annual ISPAD Meeting (International Society for Pediatric and Adolescent Diabetes) next week, which this year will take place in Gothenburg. Also next week, at the Nordic Life Science Days in Stockholm, we will present Diamyd Medical to potential investors and partners from around the world.

*Stockholm, October 10, 2013*

Peter Zerhouni

*President and CEO Diamyd Medical AB (publ)*

## Significant events during the reporting period

### June 1, 2013 – August 31, 2013

#### **Diamyd Medical's rights issue was oversubscribed and raised approximately MSEK 21**

Diamyd Medical's share issue with preferential rights for the Company's shareholders was oversubscribed. The Company received proceeds of MSEK 20.7 before issue expenses.

#### **Diamyd Medical expanded its Scientific Advisory Board**

The Company's Scientific and Medical Advisory Board was expanded with three internationally leading experts on GABA and diabetes: Dr. Bryndis Birnir at Uppsala University, Dr. Brooke Ligon and Dr. Qinghua Wang at Toronto University.

## Significant events after 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.

## Business overview

Diamyd Medical is a Swedish diabetes company. The Company was formerly called Diamyd Therapeutics and was spun off from Mertiva AB (formerly Diamyd Medical AB) in April 2013.

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 has been traded on NASDAQ OMX First North since May 20, 2013 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 for the fourth quarter were MSEK 0.1 (0). Net sales for the full year were MSEK 0.1 (0.5).

**Costs** – Costs were MSEK -4.6 (-4.0) in the fourth quarter. Costs for the full year were MSEK -13.2 (-18.4).

**Result** – Loss before tax for the fourth quarter was MSEK -4.3 (-4.2). Loss before tax for the full year was MSEK -12.6 (-16.3).

**Financial position and liquidity** – Liquid assets were MSEK 65.5 (22.0) as of August 31, 2013. During the period the Company received proceeds of MSEK 20.7 before issue expenses from a rights issue.

**Equity** – As of August 31, 2013, the Company's equity amounted to MSEK 60.3 (163.5), resulting in a solidity of 89 (96) percent. During the financial year a dividend of MSEK 109 was made to former parent company. See also Note 3.

**Number of shares** – Number of shares amounted to 19,719,422 as of August 31, 2013. During the fiscal year the number of shares increased by 8,859,711 in connection to a split and by 9,859,711 in connection to a rights issue.

**Organization** – The average number of employees during the year was 7 (10). At the end of the fiscal year the number of employees was 7 (7).

# The Company's Income statement

KSEK	Note	3 months Jun-Aug 2012/13	3 months Jun-Aug 2011/12	12 months Sep-Aug 2012/13	12 months Sep-Aug 2011/12
<b>OPERATING INCOME</b>					
Net sales		61	-	100	514
Other operating income		57	-	65	1,086
<b>TOTAL OPERATING INCOME</b>		<b>118</b>	<b>-</b>	<b>165</b>	<b>1,600</b>
<b>OPERATING EXPENSES</b>					
External research and development costs		-1,184	-1,262	-3,519	-5,250
External patent and license expenses		-196	-217	-756	-877
Personal costs	1	-1,766	-2,026	-5,231	-8,332
Other external expenses	1	-1,335	-403	-3,433	-1,639
Other operating expenses		-65	-120	-103	-2,126
Depreciation tangible assets		-39	3	-155	-185
<b>TOTAL OPERATING EXPENSES</b>		<b>-4,585</b>	<b>-4,025</b>	<b>-13,197</b>	<b>-18,409</b>
<b>OPERATING LOSS</b>		<b>-4,467</b>	<b>-4,025</b>	<b>-13,032</b>	<b>-16,809</b>
Net Financial Income/Expense	2	181	-139	399	514
<b>LOSS BEFORE TAXES</b>		<b>-4,286</b>	<b>-4,164</b>	<b>-12,633</b>	<b>-16,295</b>
Taxes		-	53	-	53
<b>NET LOSS FOR THE PERIOD</b>		<b>-4,286</b>	<b>-4,111</b>	<b>-12,633</b>	<b>-16,242</b>
Earnings per share before dilution, SEK		-0.3	-4.11	-1.9	-16.2
Earnings per share after dilution, SEK		-0.3	-4.11	-1.9	-16.2
Number of shares per closing day		19,719,422	1,000,000	19,719,422	1,000,000
Average number of shares before dilution		16,075,616	1,000,000	6,523,277	1,000,000
Average number of shares after dilution		16,075,616	1,000,000	6,523,277	1,000,000

# The Company's Balance sheet

KSEK	Note	31 Aug 2013	31 Aug 2012
<b>ASSETS</b>			
NON-CURRENT ASSETS			
Tangible assets		85	239
Financial assets	3	639	146,572
<b>TOTAL NON-CURRENT ASSETS</b>		<b>724</b>	<b>146,811</b>
CURRENT ASSETS			
Other receivables		972	1,011
Prepaid expenses and accrued income		603	587
Liquid assests		65,518	21,960
<b>TOTAL CURRENT ASSETS</b>		<b>67,093</b>	<b>23,558</b>
<b>TOTAL ASSETS</b>		<b>67,817</b>	<b>170,369</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
SHAREHOLDERS' EQUITY			
<b>Restricted equity</b>			
Share capital		2,000	1,000
Statutory reserve		200	200
<b>Non-restricted equity</b>			
Share premium reserve non-restricted		19,386	-
Profit or loss brought forward	3	51,340	178,579
Net loss for the year		-12,633	-16,242
<b>TOTAL NON-CURRENT LIABILITIES</b>		<b>60,293</b>	<b>163,537</b>
<b>NON-CURRENT LIABILITIES</b>			
Other liabilities		795	782
<b>TOTAL NON-CURRENT LIABILITIES</b>		<b>795</b>	<b>782</b>
<b>CURRENT LIABILITIES</b>			
Trade payables		1,448	777
Other payables		674	1,196
Prepaid income and accrued expenses		4,607	4,077
<b>TOTAL CURRENT LIABILITIES</b>		<b>6,729</b>	<b>6,050</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>4</b>	<b>67,817</b>	<b>170,369</b>

# The Company's Statement of cash flow

KSEK	Note	3 months	3 months	12 months	12 months
		Jun-Aug 2012/13	Jun-Aug 2011/12	Sep-Aug 2012/13	Sep-Aug 2011/12
<b>CASH FLOW FROM OPERATIONS BEFORE CHANGES IN WORKING CAPITAL</b>					
Operating profit/loss		-4,467	-4,025	-13,032	-16,809
Interest and foreign exchange difference received		140	-	425	438
Interest and foreign exchange difference paid		-	-948	-31	-5
Non- cash flow items					
Depreciation		39	-3	155	185
Other non-cash flow items		25	668	-1,903	524
<b>NET CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL</b>					
		<b>-4,263</b>	<b>-4,309</b>	<b>-14,386</b>	<b>-15,667</b>
Increase (-) decrease (+) receivables		814	3,688	23	53
Increase (+) decrease (-) liabilities		271	-3,403	648	-51,588
<b>NET CASH FLOW FROM OPERATING ACTIVITIES</b>					
		<b>-3,178</b>	<b>-4,023</b>	<b>-13,715</b>	<b>-67,202</b>
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>					
Increase (-) decrease (+) short term investments, net		9,964	-	-	-
Changes in transactions between former Group companies	3	-	54	36,882	78,662
Sale of equipment		-	-	-	16
<b>NET CASH FLOW FROM INVESTING ACTIVITIES</b>					
		<b>9,964</b>	<b>54</b>	<b>36,882</b>	<b>78,678</b>
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>					
Rights issue		20,705	-	20,705	-
Issue expenses		-319	-	-319	-
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>					
		<b>20,386</b>	<b>-</b>	<b>20,386</b>	<b>-</b>
<b>TOTAL CASH FLOW FOR THE PERIOD</b>					
		<b>27,172</b>	<b>-3,969</b>	<b>43,553</b>	<b>11,476</b>
Cash and cash equivalents at beginning of period		38,329	25,151	21,960	10,415
Net foreign exchange difference		17	779	5	69
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>					
		<b>65,518</b>	<b>21,960</b>	<b>65,518</b>	<b>21,960</b>

## Changes in Equity

KSEK	Share Capital	Statutory reseve	Share premium reserve non restricted	Other non- restricted equity	Total shareholders' equity
<b>OPENING BALANCE SEPTEMBER 1, 2011</b>	<b>1,000</b>	<b>200</b>	-	<b>178,356</b>	<b>179,556</b>
Net loss for the year	-	-	-	-16,242	-16,242
Employee options	-	-	-	223	223
<b>CLOSING BALANCE AUGUST 31, 2012</b>	<b>1,000</b>	<b>200</b>	-	<b>162,337</b>	<b>163,537</b>
<b>OPENING BALANCE SEPTEMBER 1, 2012</b>	<b>1,000</b>	<b>200</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 costs	-	-	-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>



# Notes

## Accounting principles

Diamyd Medical's year-end 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 – Related-party transactions

During the year companies represented by immediate family members of the Chairman of the Board were contracted as consultants. Total compensation during the year amounted to KSEK 456 (382) excluding VAT and was attributable to IT-services. During the year KSEK 125 (0) has been expensed regarding legal consultation performed by board member Erik Nerpin, lawyer. Pricing has been set by the arm's length principle. Remuneration of immediate family members of the Chairman amounted to KSEK 814 (850) during the year. 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-Aug 2012/13	Sep-Aug 2011/12
Salaries to related parties	814	850
Consultant fees to related parties	456	382
Consultant fees to Board members	125	-

## Note 2 – Net Financial Income/Expense

Net Financial Income/Expense for the year amounts to MSEK 0.4 and consists of interest income on liquid assets and short term investments.

## Note 3 – 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 4 – Equity and liabilities

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

## Key figures

	<b>3 months</b>	<b>3 months</b>	<b>12 months</b>	<b>12 months</b>
	<b>Jun-Aug</b>	<b>Jun-Aug</b>	<b>Sep-Aug</b>	<b>Sep-Aug</b>
	<b>2012/13</b>	<b>2011/12</b>	<b>2012/13</b>	<b>2011/12</b>
Research and development costs, MSEK	-1.2	-1.3	-3.5	-5.2
Solidity, %	89	96	89	96
Earnings per share before dilution, SEK	-0.3	-4.1	-1.9	-16.2
Earnings per share after dilution, SEK	-0.3	-4.1	-1.9	-16.2
Liquid assets per share, SEK	3.3	22.0	3.3	22.0
Shareholders' equity per share before dilution, SEK	3.8	163.5	9.2	163.5
Shareholders' equity per share after dilution, SEK	3.8	163.5	9.2	163.5
Cash flow per share, SEK	1.4	-4.0	2.2	11.5
Share price per closing, SEK	2.7	NA	2.7	NA
Share price/shareholders' equity per share, SEK	0.7	NA	0.3	NA
Number of shares per closing	19,719,422	1,000,000	19,719,422	1,000,000
Average number of shares before dilution	16,075,616	1,000,000	6,523,277	1,000,000
Average number of shares after dilution	16,075,616	1,000,000	6,523,277	1,000,000

## Risks

The Company'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 Company Description prepared in connection to the listing on NASDAQ OMX First North. No significant changes in the Company's risk assessment have occurred since the Company Description 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 year-end report has not been reviewed by the Company's auditors.

Stockholm, October 10, 2013

Anders Essen-Möller,  
*Chairman of the Board*

Erik Nerpin,  
*Board member*

Maria-Teresa Essen-Möller,  
*Board member*

Peter Zerhouni,  
*President and CEO*

## Financial calendar

Annual Report 2012/2013:	November 1, 2013
Quarterly report 1 2013/2014:	January 22, 2014
Quarterly report 2 2013/2014:	April 9, 2014
Quarterly report 3 2013/2014:	July 2, 2014
Year-end report 2013/2014:	October 15, 2014

## Annual General Meeting

The Annual General Meeting for the fiscal year 2012/2013 will be held on November 22, 2013, at 3:00 p.m., Finlandshuset Konferens, Snickarbacken 4 in Stockholm.

**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.*