

# QUARTERLY REPORT

September 2013 - May 2014

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

### Reporting period March 1, 2014 - May 31, 2014

- Net sales amounted to MSEK 0 (0)
- Loss before tax amounted to MSEK -3.6 (-4.0)
- Liquid assets and short term investments amounted to MSEK 39 (48) as of May 31, 2014

### First nine months, September 1, 2013 - May 31, 2014

- Net sales amounted to MSEK 0.3 (0)
- Loss before tax amounted to MSEK -12.8 (-8.3)

### Significant events during 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
- Diamyd Medical invested in a US medical device company

### Significant events after the reporting period

• Clinical study with Diamyd Medical's diabetes vaccine fully recruited

### **CEO** comments

At the beginning of June, the final participants were included in the researcher-initiated study DIABGAD-1 following intensive and successful recruitment efforts. Slightly more than 60 children and adolescents with newly diagnosed type 1 diabetes are participating in the study and testing our diabetes vaccine, Diamyd<sup>®</sup>, in a unique combination with vitamin D and ibuprofen. We strongly believe in attacking the disease process in type 1 diabetes from several angles simultaneously by combining Diamyd<sup>®</sup> with other drugs and this is one of the first such studies anywhere in the world. The Phase II study will also evaluate the effect of a double dose of Diamyd<sup>®</sup>. The aim of the treatment is to preserve the patients' endogenous insulin production. Now that the last participant has been treated, we know that the first planned analysis focusing on immunological markers can be initiated at the end of 2014 and, accordingly, the results presented at the start of 2015.

The study is being led by Professor Johnny Ludvigsson at Linköping University. Professor Ludvigsson is ranked as one of the world's ten most distinguished researchers of type 1 diabetes according to a recent analysis based on scientific publications in the field over the last ten years. Professor Mark Atkinson, who is a member of Diamyd Medical's Scientific Advisory Board, is found at second place in the top-ten list and Diamyd Medical also collaborates with several other top names. The list was published in June at the annual US diabetes conference that was held in San Francisco and which brought together over 17,000 participants. As usual, Diamyd Medical was there to network and to discuss possibilities for future collaborations.

At the same time, there is an ongoing researcher-initiated pilot study with Diamyd®, called DiAPREV-IT, which is testing whether the diabetes vaccine can prevent or delay type 1 diabetes in healthy children who are at high risk of developing the disease. Simply delaying the onset of the disease with the help of the diabetes vaccine would be a major medical success. The pilot study currently comprises 50 children aged four and upwards and the research team at Lund University conducting DiAPREV-IT would like to test the concept on more children to increase the probability of being able to demonstrate a statistically significant preventive effect of the diabetes vaccine. The research team is in discussions with the Swedish Medical Products Agency and Diamyd Medical about the most appropriate way of increasing the sample size by means of additional children.

Efforts continue to launch additional researcher-initiated clinical trials with Diamyd® and we have well-advanced plans in place with several teams of researchers.

In April, we invested in two exciting startups. The first and largest investment was in Sweden's first commercial stem cell bank for private family saving of umbilical cord blood and other sources of stem cells. Diamyd procured a 46-percent holding for an investment of MSEK 11.5. The company has taken the name Cellaviva and is in the process of establishing its operations in close proximity to Karolinska Institutet's cell therapy and regenerative medicine programs.

The second investment was in Companion Medical, a newly started medical technology company in San Diego, in the US, which develops advanced technical devices for people living with insulin-treated diabetes. For competitive reasons, Companion Medical does not want us to reveal exactly what it is developing, more than that it comprises a cost-effective system combining the best features of existing solutions for delivering insulin to the body together with advanced data management. It was our presence in the global diabetes world that generated the opportunity for us to invest in Companion with its highly skilled and experienced team. In addition to a ten-percent ownership stake, Diamyd Medical also gains the distribution rights for its future products in the Nordic region. The investment makes it possible to broaden our diabetes portfolio in the long term and to enter the medical technology market.

Stockholm, July 2, 2014

Peter Zerhouni
President and CEO Diamyd Medical AB (publ)

# Significant events during the reporting period March 1, 2014 – May 31, 2014

#### 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.

### Diamyd Medical invested in a US medical device company

Diamyd Medical entered into an agreement to purchase 10 percent of the American start-up med-tech company Companion Medical, Inc. for corresponding approximately SEK 1.6 million. Companion Medical develops advanced technical devices for people living with insulin treated diabetes. Diamyd Medical will have a seat on the Board of Companion Medical as well as the distribution rights to Companion Medical's future products in the Nordic countries.

# Significant events after the reporting period

#### Clinical study with Diamyd Medical's diabetes vaccine fully recruited

Diamyd Medical announced that all participants had been included in a Phase II clinical study, DIABGAD-1, in which Diamyd Medical's diabetes vaccine Diamyd<sup>®</sup>, in a unique combination with other drugs, is tested in children and adolescents recently diagnosed with type 1 diabetes. The first results from the researcher-initiated study will thereby be available in the beginning of 2015.

### **Business overview**

Diamyd Medical is a Swedish diabetes company.

The Company's primary development project consists of the GAD-based diabetes vaccine Diamyd® for the treatment and prevention of autoimmune diabetes. Two Swedish researcher-initiated Phase II studies with Diamyd® are currently 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.

In 2013 the Company concluded an exclusive licensing agreement with the University of California in Los Angeles (UCLA) relating to a patent portfolio for the therapeutic use of GABA (gamma-aminobutyric acid) and GABA receptor agonists for the treatment and prevention of type 1 and type 2 diabetes and other inflammation-related conditions, such as metabolic syndrome, rheumatoid arthritis and allergies.

In April 2014, Diamyd Medical entered an agreement with a group of founding partners and Karolinska Institutet Holding AB, in order to establish 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 interests in the gene therapy company Periphagen Holdings, Inc. (US) and Companion Medical, 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 third quarter amounted to MSEK 0 (0). Net sales during the first nine months amounted to MSEK 0.3 (0).

**Costs** - Costs were MSEK -3.8 (-4.1) during the third quarter. Costs were MSEK -13.6 (-8.6) during the first nine months.

**Result** – Loss before tax for the third quarter was MSEK –3.6(-4.0). Loss before tax for the first nine months was MSEK -12.8 (-8.3).

**Financial position and liquidity -** Liquid assets and short term investments were MSEK 39 (48) as of May 31, 2014.

**Equity** - As of May 31, 2014, the equity amounted to MSEK 47.4 (44.2), resulting in a solidity of 87 (86) percent.

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

## Income statement

KSEK	Note	3 months Mar-May 2013/14	3 months Mar-May 2012/13	9 months Sep-May 2013/14	9 months Sep-May 2012/13	12 months Sep-Aug 2012/13
OPERATING INCOME						
Net income		33	39	285	39	100
Other operating income		12	-1	30	8	65
TOTAL OPERATING INCOME		45	38	315	47	165
OPERATING EXPENSES						
External research and development costs	1	-1 087	-849	-4 423	-2 335	-3 519
External patent- and license costs		-180	-202	-1 009	-560	-756
Personnel costs	2,3	-1 739	-1 957	-5 402	-3 465	-5 231
Other external costs	2	-710	-1 081	-2 642	-2 098	-3 433
Other operating expenses		-30	-5	-71	-38	-103
Depreciation		-43	-38	-101	-116	-155
TOTAL OPERATING EXPENSES		-3 789	-4 132	-13 648	-8 612	-13 197
OPERATING LOSS		-3 744	-4 094	-13 333	-8 565	-13 032
Net Financial income/expense		170	103	554	218	399
LOSS BEFORE TAXES		-3 574	-3 991	-12 779	-8 347	-12 633
Taxes		-	-	-	-	-
NET LOSS FOR THE PERIOD		-3 574	-3 991	-12 779	-8 347	-12 633

# Balance sheet

KSEK	Note	31 May 2014	31 May 2013	31 Aug 2013
ASSETS				
NON-CURRENT ASSETS				
Intangible assets		112	-	-
Tangible assets		0	123	85
Financial assets	4	13 695	639	639
TOTAL NON-CURRENT ASSETS		13 807	762	724
CURRENT ASSETS				
Trade receivables		45	49	-
Other receivables		1 060	1 560	972
Prepaid expenses and accrued income		779	757	603
Short terms investments		10 960	9 964	-
Liquid assets		27 804	38 329	65 518
TOTAL CURRENT ASSETS		40 648	50 659	67 093
TOTAL ASSETS		54 455	51 421	67 817
EQUITY AND LIABILITIES				
EQUITY				
Restricted equity		• • • • •	4.000	
Share capital		2 000	1 000	2 000
Statutory reserve Non-restricted equity		200	200	200
Share premium reserve non-restricted		19 291	_	19 386
Profit or loss brought forward		38 708	51 340	51 340
Net loss for the period		-12 779	-8 347	-12 633
TOTAL EQUITY		47 420	44 193	60 293
NON-CURRENT LIABILITIES				
Other liabilities		828	795	795
TOTAL NON-CURRENT LIABILITIES		828	795	795
CURRENT LIABILITIES				
Trade payables		1 680	653	1 448
Other payables		416	1 322	674
Prepaid income and accrued expenses		4 110	4 458	4 607
TOTAL CURRENT LIABILITIES		6 207	6 433	6 729
TOTAL EQUITY AND LIABILITIES	6	54 455	51 421	67 817

# Statement of cash flow

KSEK	Note	3 months Mar-May 2013/14	3 months Mar- May 2012/13	9 months Sep-May 2013/14	9 months Sep- May 2012/13	12 months Sep/Aug 2012/13
CASH FLOW FROM OPERATIONS BEFORE CHANGES IN WORKING CAPITAL						
Operating profit/loss		-3 744	-4 094	-13 333	-8 565	-13 032
Interest and foreign exchange difference received		221	49	594	285	425
Interest and foreign exchange difference paid		-	40	-1	-31	-31
Non-cash flow items						
Depreciation		43	38	101	116	155
Other non-cash flow items		-	3	-14	-1 928	-1 903
NET CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL		-3 480	-3 964	-12 653	-10 123	-14 386
Increase (-) decrease (+) receivables		443	-37	-308	-791	23
Increase (-) decrease (+) liabilities		-1 045	436	-508	377	648
NET CASH FLOW FROM OPERATING ACTIVITIES		-4 082	-3 565	-13 469	-10 537	-13 715
CASH FLOW FROM INVESTING ACTIVITIES						
Investment in immaterial and material assets, net		-	-	-129	-	-
Investment in financial assets	4	-13 055	-	-13 055	-	-
Increase (-) decrease (+) short term investments, net Changes in transactions between former Group		6 981	-9 964	-10 960	-9 964	-
companies	5	-	36 882	-	36 882	36 882
NET CASH FLOW FROM INVESTING ACTIVITIES		-6 074	26 918	-24 144	26 918	36 882
CASH FLOW FROM FINANCING ACTIVITIES						
Rights issue		-	-	-	-	20 705
Issue expenses		-	-	-95	-	-319
NET CASH FLOW FROM FINANCING ACTIVITIES		0	0	-95	0	20 386
TOTAL CASH FLOW FOR THE PERIOD		-10 156	23 353	-37 708	-16 381	43 553
Cash and cash equivalents at beginning of period		37 964	14 949	65 518	21 960	21 960
Net foreign exchange difference		-4	27	-6	-12	5
CASH AND CASH EQUIVALENTS AT END OF PERIOD		27 804	38 329	27 804	38 329	65 518

# **Changes in Equity**

KSEK	Share Capital	Statutory Reserve	Share premium reserve non restricted	Other non- restricted equity	Total Shareholdesr' 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, 2012	1 000	200	-	162 337	163 537
Net loss for the period	-	-	-	-8 347	-4 357
Dividend to former Group companies				-109 000	-109 000
Employee options	-	-	-	-1 997	-1 997
CLOSING BALANCE MAY 31, 2013	1 000	200	0	42 993	44 193
OPENING BALANCE SEPTEMBER 1, 2013	2 000	200	19 386	38 707	60 293
Net loss for the period	-	-	-	-12 779	-12 779
Issue expenses	-	-	-94	-	-94
CLOSING BALANCE MAY 31 , 2014	2 000	200	19 292	25 928	47 420

### **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 1 123 (762). 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	Sep-Aug
KSEK	2013/2014	2012/2013	2012/2013
Consultant fees and salaries to related parties	1 123	762	1 270
Consultant fee to Board member	-	-	125

### 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 - Financial assets

During the third quarter Diamyd Medical acquired 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 Huddinge, Stockholm County. Diamyd Medical's share of the equity as well as share of the votes is 46.3 %, which is 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, approximately MSEK 1.6.

### Note 5 – 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 6 - Equity and liabilities

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

# Key figures

	3 months	3 months	9 months	9 months	12 months
	Mar-May	Mar-May	Sep-May	Sep-may	Sep/Aug
	2013/14	2012/13	2013/14	2012/13	2012/13
Research and development costs, MSEK	-1.1	-0.8	-3.3	-2.3	-3.5
Solidity, %	87	86	87	86	89
Earnings per share, before and after dilution, SEK	-0.2	-0.2	-0.6	-0.4	-0.6
Liquid assets and short term investments per share, SEK	2.0	2.4	2.0	2.4	3.3
Shareholders' equity per share, before and after					
dilution, SEK	2.4	2.2	2.4	2.2	3.1
Cash flow per share, SEK	-0.5	1.2	-1.9	1.2	2.2
Share price per closing, SEK	3.4	2.7	3.4	2.7	2.7
Share price/Shareholders' equity per share, SEK	1.4	1.2	1.4	1.2	0.9
Number of shares per closing	19 719 422	9 859 711	19 719 422	9 859 711	19 719 422
Average number of shares, before and after dilution	19 719 422	9 859 711	19 719 422	9 859 711	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, July 2, 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

The Year-end report for fiscal year 2013/2014 will be published on October 15, 2014.

### For more information please contact:

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