



YEAR END REPORT

September 2013 – August 2014

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

Reporting period, June 1, 2014 - August 31, 2014

- Net sales amounted to MSEK 0.2 (0.1)
- Loss before tax amounted to MSEK -3.3 (-4.3)
- Liquid assets and short term investments amounted to MSEK 35.7 (65.5) as of August 31, 2014

Full year, September 1, 2013 - August 31, 2014

- Net sales amounted to MSEK 0.4 (0.1)
- Loss before tax amounted to MSEK -16.0 (-12.6)

Significant events during the reporting period

- Clinical study with Diamyd Medical's diabetes vaccine fully recruited
- Diamyd Medical reinforces focus on business development
- Study with Diamyd Medical's diabetes vaccine awarded EU-funding

Significant events after the reporting period

- Diamyd-licensed technology cures diabetes in pre-clinical model
- New method to give Diamyd® will be tested in adults with type 1 diabetes
- Diamyd Medical and Protein Sciences deepen commitment to develop new treatment for diabetes

CEO comments

Diamyd Medical has made a flying start to the autumn and the company is a hive of activity. Among all these activities, we will manufacture fresh GAD protein at our long-term partner Protein Sciences Corporation. The GAD protein is the active substance in the diabetes vaccine Diamyd[®], which is being developed for the treatment and prevention of autoimmune diabetes. Since a portion of the payment is being made in Diamyd shares, Protein Sciences will become a strategic and one of the largest shareholders in Diamyd Medical. Having a well-established manufacturing process for Diamyd[®] in place represents a substantial value and further deepening the relationship with Protein Sciences in this manner is very positive for ensuring long-term manufacturing.

We are meeting increasing interest for conducting studies with the diabetes vaccine so it is strategically important that we keep the production process updated and, continuously, ensure that GAD protein and ready-for-use Diamyd[®] are available for clinical trials. Diamyd[®] is the Antigen-Based Therapy (ABT) that is at the forefront of development and can be used on children due to its favorable safety profile demonstrated in extensive earlier clinical trials. Together with researchers, we strongly believe in attacking the disease process for type 1 diabetes from several angles simultaneously by combining Diamyd[®] with other drugs and we are preparing such combination trials together with half a dozen different groups. The preparations for several of these have progressed as far as discussions with the regulatory authorities.

A new investigator-initiated trial with Diamyd[®] recently received approval from the Swedish Medical Products Agency and is being launched. In analogy to the development in allergy therapy, where the administration of allergen into lymph nodes significantly improved the efficacy, in this study, a low dose of Diamyd[®] will be administered directly into lymph nodes in combination with vitamin D treatment. Initially, this exciting concept will be tested on a small group of adult patients recently diagnosed with type 1 diabetes. The entire study will be conducted at Linköping University under Professor Johnny Ludvigsson.

Another investigator-initiated combination trial where discussions are ongoing with the US Food and Drug Administration (FDA) pertains to the combination of Diamyd[®] and gamma amino butyric acid (GABA). Last year, Diamyd Medical secured a license from the University of California, Los Angeles (UCLA) to the exclusive intellectual rights for GABA for the treatment of diabetes, among other conditions. The idea of combining GABA with Antigen-Based Therapy (ABT) for type 1 diabetes gained further support from a scientific paper at the beginning of September. In the paper, scientists at UCLA confirmed previous findings, that combination therapy with GABA and ABT acts synergistically when treating non-obese diabetic (NOD) mice, a model for type 1 diabetes. The new paper concludes that the use of GABA in combination with ABT also has potential for type 1 diabetes intervention in humans.

In parallel with the planning of new trials, one of the world's first combination trials is ongoing in Sweden – DIABGAD-1. Slightly more than 60 children and adolescents with newly diagnosed type 1 diabetes are participating in the trial and testing Diamyd[®] in a unique combination with vitamin D and ibuprofen. The trial received a nice contribution corresponding to about SEK 1.1 million in EU funding at the end of August. The expectation is to be able to present the results from the first six months of the trial at the start of 2015 with a focus on immunological markers. Later in 2015, the 15-month results should also be available from the trial and these will be able to say more about the effects of the treatment on the patients' ability to produce their own insulin.

Having widened the Company's focus areas during the fiscal year through investments in the Swedish company Cellaviva, which is establishing a bank for umbilical cord blood and stem cell research, and the US medical technology company Companion Medical, we are now looking to leverage the increasing interest in Diamyd[®] and investing energy in identifying collaboration partners.

Stockholm, October 15, 2014

Peter Zerhouni
President and CEO Diamyd Medical AB (publ)

Significant events during the reporting period

June 1, 2014 – August 31, 2014

Clinical study with Diamyd Medical's diabetes vaccine fully recruited

All participants have been included in a Phase II clinical study, DIABGAD-1, in which Diamyd Medical's diabetes vaccine Diamyd[®], 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.

Diamyd Medical reinforces focus on business development

Diamyd Medical's lead candidate therapeutic Diamyd[®] for treatment and prevention of type 1 diabetes experiences an increased interest. Consensus is that the disease must be attacked by inducing tolerance to beta cell auto-antigens at a time when the inflammatory components of the immune system are kept at bay. Diamyd[®] is the furthest developed beta cell specific auto-antigen (GAD65 formulated in alum) available and the Company is currently in discussion with half a dozen parties about new combination studies. Diamyd Medical is therefore preparing to meet this increased interest by reinforcing its focus on business development. To make available further management resources for this, the Board has asked the Company Chairman, Anders Essen-Möller, to assume responsibility for Diamyd Medical's external communication, with the aim of meeting the interest from potential partners and other stakeholders.

Study with Diamyd Medical's diabetes vaccine awarded EU-funding

The ongoing combination study DIABGAD-1 has been awarded EUR 120 000, corresponding to about SEK 1.1 million, in EU-funding. The grant comes from an FP7 project where Linköping University and Diamyd Medical are included. The DIABGAD study aims to evaluate whether vitamin D and ibuprofen act synergistically with the diabetes vaccine Diamyd[®] in order to preserve the insulin producing capacity in children newly diagnosed with type 1 diabetes. The first results from the study are expected to be presented in the beginning of 2015.

Significant events after the reporting period

Diamyd-licensed technology cures diabetes in pre-clinical model

Researchers at UCLA have confirmed earlier findings that combinations of GABA and Antigen Based Therapy (ABT) works synergistically as a treatment in the NOD mouse model of type 1 diabetes. Diamyd Medical is the exclusive licensee for the commercialization of UCLA's GABA technology for metabolic diseases including in diabetes.

New method to give Diamyd[®] will be tested in adults with type 1 diabetes

A new way to give Diamyd[®] will be tested in a clinical study with five adults newly diagnosed with type 1 diabetes. The investigator initiated study has been approved by the Swedish MPA. In analogy to the development in allergy therapy, where the administration of allergen into lymph nodes has significantly improved the efficacy, Diamyd[®] will in this study be administered directly into lymph nodes in combination with treatment with vitamin D.

Diamyd Medical and Protein Sciences deepen commitment to develop new treatment for diabetes

Protein Sciences has broadened its commitment to diabetes and become a strategic and significant shareholder in Diamyd Medical, its long-time partner in this domain. Protein Sciences will manufacture product for upcoming late stage clinical trials for type 1 diabetes involving Diamyd Medical's recombinant GAD (glutamic acid decarboxylase) protein made using Protein Sciences' proprietary Baculovirus Expression Vector System (BEVS) technology. The diabetes vaccine Diamyd[®] (GAD formulated with alum) has been evaluated as a monotherapy for type 1 diabetes in a Phase III study and data suggests that Diamyd[®] may be a critical component of combination therapies that pairs the tolerance-inducing GAD antigen with anti-inflammatory agents for the treatment and prevention of type 1 diabetes. This is being evaluated in ongoing and upcoming Phase II studies.

Business overview

Diamyd Medical is dedicated to fight type 1 diabetes and to work towards a cure for the disease. Diamyd Medical's current projects include development of combination regimens for arresting the successive destruction of insulin producing beta cells using the Company's GAD65-based diabetes vaccine Diamyd[®], such as Diamyd[®] + Vitamin D with or without an anti-inflammatory compound; and Diamyd[®] + GABA, for which Diamyd Medical licenses exclusive intellectual rights from the University of California in Los Angeles (UCLA).

Diamyd[®] has been used in trials totaling more than one thousand patients with an excellent safety profile. Diamyd[®] has shown an overall 16% efficacy (p=0.1) versus placebo regarding preservation of the patients' endogenous insulin secretion in a European Phase III trial and is currently being further developed in combination regimens with other therapeutic compounds. Diamyd[®] is easy to administer in any clinical setting.

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 produce insulin in children and adolescents newly diagnosed with type 1 diabetes.

Diamyd Medical has further acquired 46% of the stem cell company Cellaviva AB that is establishing a Swedish commercial bank for private family saving of umbilical cord blood and other sources of stem cells. Stem cells are required for 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.

Financial information

Net sales – Net sales during the fourth quarter amounted to MSEK 0.2 (0.1). Net sales for the full year amounted to MSEK 0.4 (0.1).

Costs – Costs were MSEK -3.6 (-4.6) during the fourth quarter. Costs were MSEK -17.3 (-13.2) for the full year.

Result – Loss before tax for the fourth quarter was MSEK -3.3 (-4.3). Loss before tax for the full year was MSEK -16.0 (-12.6).

Financial position and liquidity – Liquid assets and short term investments were MSEK 35.7 (65.5) as of August 31, 2014.

Equity – As of August 31, 2014, the equity amounted to MSEK 44.2 (60.3), resulting in a solidity of 87 (89) percent.

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

Income statement

KSEK	Note	3 months Jun-Aug 2013/14	3 months Jun-Aug 2012/13	12 months Sep-Aug 2013/14	12 months Sep-Aug 2012/13
OPERATING INCOME					
Net income		158	61	443	100
Other operating income		63	57	116	65
TOTAL OPERATING INCOME		221	118	559	165
OPERATING EXPENSES					
External research and development costs	1	-1 042	-1 184	-5 465	-3 519
External patent- and license costs		-253	-196	-1 262	-756
Personnel costs	2,3	-1 315	-1 766	-6 716	-5 231
Other external costs	2	-972	-1 335	-3 614	-3 433
Other operating expenses		-31	-65	-126	-103
Depreciation		-6	-39	-108	-155
TOTAL OPERATING EXPENSES		-3 619	-4 585	-17 291	-13 197
OPERATING LOSS		-3 398	-4 467	-16 732	-13 032
Net Financial income/expense		143	181	698	399
LOSS BEFORE TAXES		-3 255	-4 286	-16 034	-12 633
Taxes		-	-	-	-
NET LOSS FOR THE PERIOD		-3 255	-4 286	-16 034	-12 633

Balance sheet

KSEK	Note	31 Aug 2014	31 Aug 2013
ASSETS			
NON-CURRENT ASSETS			
Intangible assets		106	-
Tangible assets		-	85
Financial assets	4	13 705	639
TOTAL NON-CURRENT ASSETS		13 811	724
CURRENT ASSETS			
Trade receivables		79	-
Other receivables		702	972
Prepaid expenses and accrued income		758	603
Short term investments		10 960	-
Liquid assets		24 715	65 518
TOTAL CURRENT ASSETS		37 214	67 093
TOTAL ASSETS		51 025	67 817
EQUITY AND LIABILITIES			
EQUITY			
<i>Restricted equity</i>			
Share capital		2 000	2 000
Statutory reserve		200	200
<i>Non-restricted equity</i>			
Share premium reserve non-restricted		19 292	19 386
Profit or loss brought forward		38 707	51 340
Net loss for the period		-16 034	-12 633
TOTAL EQUITY		44 165	60 293
NON-CURRENT LIABILITIES			
Other liabilities		841	795
TOTAL NON-CURRENT LIABILITIES		841	795
CURRENT LIABILITIES			
Trade payables		1 309	1 448
Other payables		248	674
Prepaid income and accrued expenses		4 462	4 607
TOTAL CURRENT LIABILITIES		6 019	6 729
TOTAL EQUITY AND LIABILITIES	6	51 025	67 817

Statement of cash flow

KSEK	Note	3 months Jun-Aug 2013/14	3 months Jun-Aug 2012/13	12 months Sep-Aug 2013/14	12 months Sep-Aug 2012/13
CASH FLOW FROM OPERATIONS BEFORE CHANGES IN WORKING CAPITAL					
Operating profit/loss		-3 399	-4 467	-16 732	-13 032
Interest and foreign exchange difference received		110	140	703	425
Interest and foreign exchange difference paid		-1	-	-2	-31
<i>Non-cash flow items</i>					
Depreciation		7	39	108	155
Other non-cash flow items		-78	25	-91	-1 903
NET CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL					
		-3 361	-4 263	-16 014	-14 386
Increase (-) decrease (+) receivables		370	814	61	23
Increase (-) decrease (+) liabilities		-229	271	-737	648
NET CASH FLOW FROM OPERATING ACTIVITIES					
		-3 220	-3 178	-16 690	-13 715
CASH FLOW FROM INVESTING ACTIVITIES					
Investment in immaterial and material assets, net		-	-	-130	-
Investment in financial assets	4	-	-	-13 055	-
Increase (-) decrease (+) short term investments, net		-	9 964	-10 960	-
Changes in transactions between former Group companies	5	-	-	-	36 882
NET CASH FLOW FROM INVESTING ACTIVITIES					
		-	9 964	-24 145	36 882
CASH FLOW FROM FINANCING ACTIVITIES					
Rights issue		-	20 705	-	20 705
Issue expenses		-	-319	-95	-319
NET CASH FLOW FROM FINANCING ACTIVITIES					
		-	20 386	-95	20 386
TOTAL CASH FLOW FOR THE PERIOD					
		-3 220	27 172	-40 930	43 553
Cash and cash equivalents at beginning of period		27 804	38 329	65 518	21 960
Net foreign exchange difference		131	17	127	5
CASH AND CASH EQUIVALENTS AT END OF PERIOD					
		24 715	65 518	24 715	65 518

Changes in Equity

KSEK	Share Capital	Statutory Reserve	Share premium reserve non restricted	Other non-restricted equity	Total Shareholders' 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	-	-	-	-16 034	-16 034
Issue expenses	-	-	-94	-	-94
CLOSING BALANCE AUGUST 31 , 2014	2 000	200	19 292	22 673	44 165

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 – 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. During the year KSEK 63 (62) has been accounted for regarding legal consultation performed by board member Erik Nerpin, lawyer. 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 year amounted to KSEK 1 504 (1 270). 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 2013/2014	Sep-Aug 2012/2013
Consultant fees and salaries to related parties	1 504	1 270
Consultant fee to Board member	63	62

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

Diamyd Medical acquired during the third quarter 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 Solna, 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 Jun-Aug 2013/14	3 months Jun-Aug 2012/13	12 months Sep-Aug 2013/14	12 months Sep-Aug 2012/13
Research and development costs, MSEK	-1.0	-1.2	-5.5	-3.5
Solidity, %	87	89	87	89
Earnings per share, before and after dilution, SEK	-0.2	-0.2	-0.8	-0.6
Liquid assets and short term investments per share, SEK	1.8	3.3	1.8	3.3
Shareholders' equity per share, before and after dilution, SEK	2.2	3.1	2.2	3.1
Cash flow per share, SEK	-0.5	1.4	-0.4	2.2
Share price per closing, SEK	3.5	2.7	3.5	2.7
Share price/Shareholders' equity per share, SEK	1.6	0.9	1.6	0.9
Number of shares per closing	19 719 422	19 719 422	19 719 422	19 719 422
Average number of shares, before and after dilution	19 719 422	16 075 616	19 719 422	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 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 interim report has not been reviewed by the Company's auditors.

Stockholm, October 15, 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

Annual Report 2013/2014:	November 6, 2014
Quarterly Report 1 2014/2015:	January 21, 2015
Quarterly Report 2 2014/2015:	April 1, 2015
Quarterly Report 3 2014/2015	July 1, 2015
Year-End Report 2014/2015	October 14, 2015

Annual General Meeting

The Annual General Meeting for the fiscal year 2013/2014 will be held on November 27, 2014, at 3:00 p.m., Näringslivets Hus, Storgatan 19 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.