



# YEAR-END REPORT

September 2014 – August 2015

Diamyd Medical AB (publ), Fiscal year 2014/2015

## Reporting period, June 1, 2015 – August 31, 2015

- Net result amounted to MSEK -4.2 (-3.3)
- Net result per share amounted to SEK -0.2 (-0.1)
- Cash flow from operating activities amounted to MSEK -4.1 (-3.2)
- Liquid assets and short term investments amounted at the end of the period to MSEK 29.7 (35.7)

## Full year, September 1, 2014 – August 31, 2015

- Net result amounted to MSEK -21.4 (-16.0)
- Result per share amounted to SEK -1.0 (-0.8)
- Cash flow from operating activities amounted to MSEK -18.6 (-16.7)

## Significant events during the reporting period

- New Diamyd Medical-licensed patent was issued
- Diamyd Medical's associated company Cellaviva launched its service for private family saving of stem cells
- Diamyd Medical licensed candidate drug for diabetes and gluten intolerance

## CEO comments

In recent years, Diamyd Medical has undergone a transition from being one company with one key development project into one company with several projects. Our in-licensed technologies for GAD, GABA and Gliadin are all, both individually and in combination, particularly relevant for driving us toward the vision – a cure for type 1 diabetes. In passing, our patent portfolio has also been developed to become relevant for other disorders than type 1 diabetes, such as gluten intolerance, type 2 diabetes, metabolic syndrome and, perhaps, autoimmune diseases in general.

It is becoming increasingly clear that GABA, best known as an inhibitory neurotransmitter, also plays a key role vis-à-vis metabolism and hormonal regulation. Our GABA patent portfolio, which comprises patents and patent applications in-licensed from the University of California, Los Angeles (UCLA), was supplemented during the year with our own preliminary GABA-related patent applications. We were extremely pleased when a patent protecting the use of the combination of GABA and preproinsulin or fragments thereof, in other words parts of the insulin molecule, was approved during the year. This combination has demonstrated substantially improved blood sugar regulation in animal models. Similarly good results have been reached in animal models with the combination of GABA and our in-licensed autoantigen GAD, which has also demonstrated a significant effect in certain subgroups of patients in a European Phase III trial when used alone. Is the conclusion that autoimmune disorders in general can be improved through a combination treatment that includes GABA together with relevant autoantigens?

That GAD is one of the most important autoantigens with regard to autoimmune diabetes has been established for a long time. Nonetheless, a new patent was approved during the year that protects the use of GAD for, inter alia, autoimmune diabetes until the beginning of 2032. Six different trials are currently ongoing for the GAD-based diabetes vaccine Diamyd®. The trials should be viewed as pilot trials. More than 1,000 patients have now participated in various trials with the diabetes vaccine Diamyd®, which have contributed to our important database with good safety data. GAD is required to produce GABA through an enzymatic pathway. Our molecules are related to each other.

A third area – gluten intolerance – is also related to type 1 diabetes. The genetic disposition at greatest risk for type 1 diabetes is also that with the highest risk for gluten intolerance. A gluten-free diet and treatment with the gluten protein Gliadin and Gliadin derivatives have demonstrated positive results in animal models for diabetes and gluten intolerance. For this reason, we recently licensed a new patent that protects the use of Gliadin to prevent or treat type 1 diabetes, and submitted a preliminary patent application as protection for GABA in combination with Gliadin to cure gluten intolerance.

Diamyd Medical is involved in the stem cell field, primarily through our 39 percent holding in the cord blood banking company Cellaviva. We are open to new opportunities in the area, since we believe that stem cell technology could become extremely important to treat genetic disorders and autoimmune diseases as well as some congenital conditions such as spinal cord injuries, where stem cells can replace lost tissue from the donor or close relatives, such as siblings.

New fiscal year from September 1. Interest from Big Pharma. New investigator-financed studies are under discussion. The results from the first pilot trial with ibuprofen, vitamin D and GAD are expected to be available this calendar quarter.

Thank you for your interest and support in the fight against diabetes!

*Stockholm, October 14, 2015*

Anders Essen-Möller, *President and CEO Diamyd Medical AB (publ)*

# Significant events during the reporting period

## June 1, 2015 – August 31, 2015

### **New Diamyd Medical-licensed patent issued**

Diamyd Medical announced that the University of California, Los Angeles, UCLA, had been granted a key patent for a combo treatment for type 1 diabetes with GABA and proinsulin or an immunogenic fragment thereof. Immunogenic fragments include C-peptide, proinsulin and other insulin molecules. This adds to Diamyd Medical's patent estate of exclusively licensed intellectual property using GABA for treatment and interception of type 1 diabetes and inflammatory diseases including type 2 diabetes, metabolic syndrome and rheumatoid arthritis. The Company also exclusively licenses UCLA patents for GAD65 (a major autoantigen in type 1 diabetes) for which the last patent expires 2032.

### **Diamyd Medical's associated company Cellaviva launched service for private family saving of stem cells**

Diamyd Medical's associated company Cellaviva AB launched its service in which expecting parents in Sweden can save stem cells from their newborn child. Stem cells from the baby's umbilical cord are saved and stored for at least 20 years in Cellaviva's biobank.

### **Diamyd Medical licensed candidate drug for diabetes and gluten intolerance**

Diamyd Medical entered into an exclusive license agreement for using the gluten protein Gliadin for the treatment and prevention of type 1 diabetes. Diamyd Medical aims at evaluating combination regimens of Gliadin with compounds and antigens, such as for example GABA and GAD, for shutting off the inflammatory component in type 1 diabetes, gluten intolerance and other inflammatory diseases, for which preliminary patent applications have been filed. The world market for a successful new drug for treatment and prevention of autoimmune diabetes and gluten intolerance (celiac disease) is considered to be several billion US dollars.

## Antigen Based Therapy (ABT) and combination trials

Type 1 diabetes is a devastating disease which requires daily treatment with insulin to sustain life. The importance of finding a cure should not be underestimated. The GAD-based diabetes vaccine Diamyd® is considered to be the furthest developed Antigen Based Therapy (ABT) in the world for treating autoimmune diabetes. Diamyd® has been used in clinical studies with more than 1,000 patients and has shown a good safety profile. In a European Phase III trial Diamyd® showed good clinical effect in several subgroups, and a limited overall 16% efficacy (p=0.10) in preserving endogenous insulin secretion. Subsequent development is focused on combination trials to enhance efficacy. Diamyd® is easy to administer in any clinical setting. The potential annual market is estimated to several billion dollars per year.

Six researcher initiated clinical trials are ongoing combining Diamyd® with various other immunomodulatory compounds; etanercept, ibuprofen, vitamin D and GABA.

- **DIABGAD- 1 - COMBINING DIAMYD® WITH IBUPROFEN AND VITAMIN D INTERVENTION TRIAL**

A placebo-controlled trial, where Diamyd® is being tested in combination with ibuprofen and vitamin D. The trial comprises a total of 64 patients between the ages of 10 and 18, recently diagnosed with type 1 diabetes, and will continue for a total of 30 months. The aim of the combination treatment is to preserve the body's own capacity to produce insulin. The trial runs at nine clinics in Sweden and is led by Professor Johnny Ludvigsson at Linköping University, Sweden. 15 month results from the trial are due in the fourth quarter of 2015.

- **DIAGNODE -1 -DIAMYD® IN LYMPH GLANDS IN COMBINATION WITH VITAMIN D INTERVENTION TRIAL**

An open label trial, where Diamyd® is administered directly into lymph nodes in combination with treatment with vitamin D. The trial comprises five patients between the ages of 18 and 30 newly diagnosed with type 1 diabetes, and will continue for a total of 30 months. The aim of the trial is to evaluate the safety of the combination treatment and the effect on the immune system and the patients' insulin producing capacity. The trial is led by Professor Johnny Ludvigsson at Linköping University, Sweden. The first patient was included in the trial in February 2015.

- **GABA/ DIAMYD® - COMBINING DIAMYD® WITH GABA INTERVENTION TRIAL**

A placebo-controlled trial, where Diamyd® is being tested in combination with GABA. The trial comprises 75 patients between the ages of 4 and 18 recently diagnosed with type 1 diabetes, and will continue for a total of 12 months. The aim of the combination treatment is to preserve the body's residual capacity to produce insulin. The trial is led by Professor Kenneth McCormick at the University of Alabama at Birmingham, USA. The first patient was included in the trial in March 2015.

- **EDCR IIa - COMBINING DIAMYD® WITH ETANERCEPT AND VITAMIN D INTERVENTION TRIAL**

An open label trial, where Diamyd® is combined with etanercept and vitamin D. The trial comprises 20 patients between the ages of 8 and 18 who have been newly diagnosed with type 1 diabetes, and will continue for a total of 30 months. The aim of the trial is to evaluate the safety of the combination treatment and the effect on the immune system and the patients' insulin producing capacity. The trial is led by Professor Johnny Ludvigsson at Linköping University, Sweden. The first patient was included in May 2015.

- **DiAPREV-IT 1- DIAMYD® PREVENTION TRIAL**

A placebo-controlled trial, where Diamyd® is being tested in children at high risk of developing type 1 diabetes, meaning that they have been found to have an ongoing autoimmune process but do not yet have any clinical symptoms of diabetes. A total of 50 participants from the age of four have been enrolled in the trial, which will last for five years. The aim of the trial is to evaluate whether Diamyd® can delay or prevent the participants from presenting with type 1 diabetes. The trial is led by Dr. Helena Elding Larsson at Lund University, Sweden. Five year results are expected at the end of 2016.

- **DiAPREV-IT 2 - COMBINING DIAMYD® WITH VITAMIN D PREVENTION TRIAL**

A placebo-controlled trial, where Diamyd® is being tested in combination with vitamin D in children at high risk of developing type 1 diabetes, meaning that they have been found to have an ongoing autoimmune process but do not yet have any clinical symptoms of diabetes. A total of 80 participants between the ages of 4 and 18 will be enrolled in the trial, which will last for five years. The aim of the trial is to evaluate whether Diamyd® can delay or prevent the participants from presenting with type 1 diabetes. The trial is led by Dr. Helena Elding Larsson at Lund University, Sweden. The first patient was included in March 2015.

## Business overview

Diamyd Medical is dedicated to working toward a cure for type 1 diabetes and LADA. Diamyd Medical's projects include development of combination regimens with the GAD-based diabetes vaccine Diamyd® for arresting the destruction of insulin-producing beta cells. The Company exclusively licenses UCLA-rights to GAD65, the active ingredient in the vaccine, for which the last patent expires in 2032. The Company also exclusively licenses UCLA patents for using GABA for the treatment of diabetes and other inflammation-related conditions. Additionally, Diamyd Medical exclusively licenses the gluten protein Gliadin for the treatment and prevention of type 1 diabetes.

Diamyd Medical is one of the major shareholders in the stem cell company Cellaviva AB, which is establishing a Swedish commercial bank for private family saving of stem cells in umbilical cord blood and other sources of stem cells. Stem cells can be expected to be used in 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](http://www.diamyd.com).

## Key figures

	<b>3 months Jun-Aug 2014/15</b>	<b>3 months Jun-Aug 2013/14</b>	<b>12 months Sep-Aug 2014/15</b>	<b>12 months Sep-Aug 2013/14</b>
Research and development costs, MSEK	-1.1	-1.0	-9.7	-5.5
Solidity, %	85	85	85	87
Result per share, SEK	-0.2	-0.1	-1.0	-0.8
Liquid assets and short term investments per share, SEK	1.3	1.3	1.3	1.6
Shareholders' equity per share, SEK	1.8	1.8	1.8	2.0
Cash flow per share, SEK	-0.4	-0.1	-0.4	-2.0
Share price per closing, SEK	8.9	3.5	8.9	3.5
Share price/Shareholders' equity per share, SEK	5.0	2.0	5.0	1.7
Number of shares per closing	22 119 422	19 719 422	22 119 422	19 719 422
Average number of shares	22 044 422	19 719 422	20 510 929	19 719 422
Average number of employees	6	7	6	7

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.

# Income statement

KSEK	Note	3 months Jun-Aug 2014/15	3 months Jun-Aug 2013/14	12 months Sep-Aug 2014/15	12 months Sep-Aug 2013/14
<b>OPERATING INCOME</b>					
Net income		117	158	513	443
Other operating income		33	63	699	116
<b>TOTAL OPERATING INCOME</b>		<b>150</b>	<b>221</b>	<b>1 212</b>	<b>559</b>
<b>OPERATING EXPENSES</b>					
External research and development costs		-1 076	-1 042	-9 686	-5 465
External patent- and license costs		-342	-253	-1 351	-1 262
Personnel costs	1	-1 433	-1 315	-7 366	-6 716
Other external costs	1	-1 021	-972	-4 106	-3 614
Other operating expenses		-19	-31	-246	-126
Depreciation		-6	-6	-26	-108
<b>TOTAL OPERATING EXPENSES</b>		<b>-3 998</b>	<b>-3 619</b>	<b>-22 780</b>	<b>-17 291</b>
<b>OPERATING LOSS</b>		<b>-3 848</b>	<b>-3 398</b>	<b>-21 568</b>	<b>-16 732</b>
Net Financial income/expense		-434	143	171	698
<b>RESULT BEFORE TAXES</b>		<b>-4 282</b>	<b>-3 255</b>	<b>-21 397</b>	<b>-16 034</b>
Taxes		-	-	-	-
<b>NET RESULT FOR THE PERIOD</b>		<b>-4 282</b>	<b>-3 255</b>	<b>-21 397</b>	<b>-16 034</b>

# Balance sheet

KSEK	Note	31 Aug 2015	31 Aug 2014
<b>ASSETS</b>			
NON-CURRENT ASSETS			
Intangible assets		480	106
Tangible assets		-	-
Financial assets	2	15 661	13 705
<b>TOTAL NON-CURRENT ASSETS</b>		<b>16 141</b>	<b>13 811</b>
CURRENT ASSETS			
Trade receivables		196	79
Other receivables		235	702
Prepaid expenses and accrued income		346	758
Short term investments		12 998	10 960
Liquid assets		16 279	24 715
<b>TOTAL CURRENT ASSETS</b>		<b>30 504</b>	<b>37 214</b>
<b>TOTAL ASSETS</b>		<b>46 545</b>	<b>51 025</b>
<b>EQUITY AND LIABILITIES</b>			
EQUITY			
<i>Restricted equity</i>			
Share capital		2 243	2 000
Statutory reserve		200	200
<i>Non-restricted equity</i>			
Share premium reserve non-restricted		35 808	19 292
Profit or loss brought forward		22 674	38 707
Net loss for the period		-21 397	-16 034
<b>TOTAL EQUITY</b>		<b>39 524</b>	<b>44 165</b>
NON-CURRENT LIABILITIES			
Other liabilities		806	841
<b>TOTAL NON-CURRENT LIABILITIES</b>		<b>806</b>	<b>841</b>
CURRENT LIABILITIES			
Trade payables		935	1 309
Other payables		277	248
Prepaid income and accrued expenses		5 103	4 462
<b>TOTAL CURRENT LIABILITIES</b>		<b>6 315</b>	<b>6 019</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>46 645</b>	<b>51 025</b>

# Statement of cash flow

KSEK	Note	3 months Jun-Aug 2014/15	3 months Jun-Aug 2013/14	12 months Sep-Aug 2014/15	12 months Sep-Aug 2013/14
<b>CASH FLOW FROM OPERATIONS BEFORE CHANGES IN WORKING CAPITAL</b>					
Operating profit/loss		-3 848	-3 399	-21 812	-16 732
Interest and foreign exchange difference received		-294	110	114	703
Interest and foreign exchange difference paid		0	-1	-2	-2
<i>Non-cash flow items</i>					
Depreciation		7	7	26	108
Other non-cash flow items		-646	-78	2 139	-91
<b>NET CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL</b>					
		<b>-4 781</b>	<b>-3 361</b>	<b>-19 535</b>	<b>-16 014</b>
Increase (-) decrease (+) receivables		226	370	636	61
Increase (+) decrease (-) liabilities		501	-229	344	-737
<b>NET CASH FLOW FROM OPERATING ACTIVITIES</b>					
		<b>-4 054</b>	<b>-3 220</b>	<b>-18 555</b>	<b>-16 690</b>
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>					
Investment in immaterial and material assets, net		-400	-	-400	-130
Investment in financial assets	2	-68	-	-2 007	-13 055
Increase (-) decrease (+) short term investments, net		-4 999	-	-2 038	-10 960
<b>NET CASH FLOW FROM INVESTING ACTIVITIES</b>					
		<b>-5 467</b>	<b>-</b>	<b>-4 444</b>	<b>-24 145</b>
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>					
New issue		-	-	15 000	-
Issue expenses		-3	-	-44	-95
<b>NET CASH FLOW FROM FINANCING ACTIVITIES</b>					
		<b>-3</b>	<b>-</b>	<b>14 956</b>	<b>-95</b>
<b>TOTAL CASH FLOW FOR THE PERIOD</b>					
		<b>-9 524</b>	<b>-3 220</b>	<b>-8 044</b>	<b>-40 930</b>
Cash and cash equivalents at beginning of period		26 215	27 804	24 715	65 518
Net foreign exchange difference		38	131	58	127
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>					
		<b>16 729</b>	<b>24 715</b>	<b>16 729</b>	<b>24 715</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, 2013</b>	<b>2 000</b>	<b>200</b>	<b>19 386</b>	<b>38 707</b>	<b>60 293</b>
Net result for the period	-	-	-	-16 034	-16 034
Issue expenses	-	-	-94	-	-94
<b>CLOSING BALANCE AUGUST 31, 2014</b>	<b>2 000</b>	<b>200</b>	<b>19 292</b>	<b>22 673</b>	<b>44 165</b>
<b>OPENING BALANCE SEPTEMBER 1, 2014</b>	<b>2 000</b>	<b>200</b>	<b>19 292</b>	<b>22 673</b>	<b>44 165</b>
Net result for the period	-	-	-	-21 397	-21 397
New issue	243	-	16 557	-	16 800
Issue expenses	-	-	-44	-	-44
<b>CLOSING BALANCE MAY 31, 2015</b>	<b>2 243</b>	<b>200</b>	<b>35 804</b>	<b>1 372</b>	<b>39 524</b>

# Notes

## Accounting principles

From fiscal year 2014/2015 interim and annual reports are prepared with the application of the Annual Accounts Act and the Swedish Accounting Standards Board BFNAR 2012: 1 Annual Report and Consolidated accounts (K3). Previously, the Annual Accounts Act and the Swedish Accounting Standards Board's general advice, except for BFNAR 2008: 1 Annual Report for smaller companies (K2 rules) were applied. The transition has been made in accordance with the provisions of BFNAR 2012: 1 Chapter 35, which includes, where appropriate, comparative figures for 2013/2014 adjusted to K3.

## Note 1 – Related-party transactions

During the year companies represented by immediate family members of the CEO 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 CEO during the year amounted to KSEK 1 510 (1 504). 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 2014/2015	Sep-Aug 2013/2014
Consultant fees and salaries to related parties	1 510	1 504
Consultant fee to Board member	-	63

## Note 2 – Financial assets

Diamyd Medical acquired during the last fiscal year shares in 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 was as of August 31, 2015 39 %, and valued at cost, approximately MSEK 12.2.

Diamyd Medical holds approximately 8.5% of the medical device company Companion Medical, Inc., based in San Diego, USA. The holding is valued at cost, approximately MSEK 2.8.

# 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 2013/2014. 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 report has not been reviewed by the Company's auditors.

Stockholm, October 14, 2015

Anders Essen-Möller, President & CEO, Board member

Erik Nerpin, Chairman of the Board

Maria-Teresa Essen-Möller, Board member

Fredrik Åhlander, Board member

## Financial calendar

Annual Report 2014/2015:	November 5, 2015
Quarterly Report 1 2015/2016:	January 20, 2016
Quarterly Report 2 2015/2016:	April 6, 2016
Quarterly Report 3 2015/2016	June 29, 2016
Year-End Report 2015/2016	October 12, 2016

## Annual General Meeting

The Annual General Meeting for the fiscal year 2014/2015 will be held on November 26, 2015, at 3:00 p.m., Hotel Kung Carl, Birger Jarlsgatan 21 in Stockholm

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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.*