YEAR-END REPORT

September 2015 – August 2016

Diamyd Medical AB (publ), Fiscal year 2015/2016

Reporting period, June 1, 2016 – August 31, 2016

- Net result amounted to MSEK -4.8 (-4.2)
- Net result per share amounted to SEK -0.2 (-0.2)
- Cash flow from operating activities amounted to MSEK -4.1 (-4.1)
- Liquid assets and short term investments amounted at the end of the period to MSEK 31.4 (29.7)

Full year, September 1, 2015 – August 31, 2016

- Net result amounted to MSEK -32.0 (-21.4), of which impairment of holding in associated company amounted to MSEK -13.5 (0)
- Net result per share amounted to SEK -1.3 (-1.0)
- Cash flow from operating activities amounted to MSEK -17.8 (-18.3)

Significant events during the reporting period

- Diamyd Medical signs agreement with Janssen R&D, JDRF and UAB regarding ongoing GABA/GAD-trial
- Companion Medical receives FDA clearance
- Diamyd Medical and researchers at UCLA agree on a new preclinical trial
- The associated company Cellaviva withdraws new share issue. Diamyd Medical makes an impairment of its previous holding of MSEK 13.5. Cellaviva, that after the period changed name to NextCell Pharma AB, is refinanced and intends to increase its focus on the development of therapeutic stem cell products

Significant events after the reporting period

- Positive effect of Diamyd® is supported in new scientific article
- The Swedish Medical Products Agency approves extension of Diamyd® trial
- Board member of Diamyd Medical resigns from the Board
- Diamyd Medical expands activities to both type 1 and type 2 diabetes as well as rheumatoid arthritis with proprietary GABA drug
- The Phase II study EDCR IIa is fully enrolled and results from the prevention study DiAPREV-IT 1 are expected to be presented during the first quarter of 2017

CEO comments

Dear Shareholders,

We have now closed the books on an intensive and exciting fiscal year – a year in which my role as the new CEO of Diamyd Medical was characterized by a focus on strategy and business development. My goal has been to further strengthen the company's licensing possibilities and thus the core of our business model.

So what have we accomplished during the year and how will the results of this work benefit you as a shareholder? To achieve the goal of strengthening our licensing offering, we focused on three stages: 1) evaluating our existing assets, 2) developing the most promising of these assets, and 3) marketing these assets through active participation in conferences and partnering events.

Our flagship project is the diabetes vaccine Diamyd®, where we currently have six ongoing Phase II trials focused on preventing or curing autoimmune diabetes. Combination studies have continued to attract growing interest, a trend that was particularly noticeable at the largest diabetes conference of the year: the 76th American Diabetes Association (ADA) Scientific Sessions. Opinion makers in the field clearly advocate studies that are in line with Diamyd Medical's development strategy and the scientific basis for our clinical work on antigen-specific immunotherapy – most recently in an article published only a week ago in the scientific journal Diabetologia. In this article, a team of highly respected researchers in the area of type 1 diabetes demonstrate in a comprehensive analysis that the probability of the diabetes vaccine yielding a positive biological effect is very high. The preliminary results of ongoing studies during the fiscal year also demonstrated the feasibility of administering our vaccine directly into the lymph nodes – a patent-pending concept that we look forward with great interest to evaluating on a larger scale and in further detail.

We have clearly advanced our positions with respect to GABA, which has shown excellent potential to be developed into an attractive pharmaceutical for the treatment of diabetes and other inflammatory disorders. In other positive news, after a long period of negotiation, we were finally able to sign an agreement with JDRF, Janssen R&D and the University of Alabama concerning the ongoing GABA/Diamyd® study in Birmingham, Alabama. According to the agreement, resources will be provided to increase the number of patients enrolled in the GABA arm of the study and to analyze additional GABA-related biomarkers. The interest shown by the major players and opinion makers and the research showing the potential of GABA formed the basis for the recently announced expansion of our operations to include a proprietary GABA drug product. Our current focus on autoimmune diabetes is now being expanded to include type 2 diabetes and rheumatoid arthritis, where there is a significant need for better, safer drugs and intensifying competition for market shares among pharmaceutical giants. For Diamyd Medical, this means even greater interest in our offering.

Several milestones will be achieved during the coming year, including the final results from two ongoing Phase II trials with the diabetes vaccine Diamyd® during the first half of 2017 and preliminary results from ongoing open studies. Diamyd Medical will be represented at the most important conferences and partnering events, and the exciting expansion and introduction of a proprietary GABA drug product will attract greater news coverage and interest from potential partners. We are now entering the new fiscal year with a great sense of excitement and confidence, and I would like to thank you, our shareholders, for your continued trust.

Stockholm, October 12, 2016

Ulf Hannelius

President and CEO of Diamyd Medical AB (publ)

Significant events during the reporting period

Diamyd Medical signs agreement with Janssen R&D, JDRF and UAB regarding ongoing GABA/GAD-trial

Diamyd Medical signs an agreement with Janssen Research & Development, the Juvenile Diabetes Research Foundation (JDRF) and the University of Alabama at Birmingham regarding the ongoing clinical trial "Effect of GABA or Combination GABA/GAD on the Progression of Type 1 Diabetes Mellitus in Children". The agreement entails that Janssen Research & Development and JDRF will support the trial with approximately USD 600 000 to be used to study GABA-biomarkers and to increase the number of patients in the trial.

Companion Medical receives FDA clearance

Companion Medical, Inc. receives 510(k) clearance from the FDA for the InPen® system, an intelligent insulin administration system and smartphone application. Diamyd Medical owns 8.5% of Companion Medical and holds the distribution rights for future products in the Nordic countries.

Diamyd Medical and researchers at UCLA agree on new preclinical trial

Diamyd Medical agrees with researchers at the University of California, Los Angeles (UCLA) on the conduct of a new preclinical trial to evaluate if GABA in combination with both autoantigens GAD 65 and proinsulin improves efficacy even further. Strong synergistic effects have earlier been reported in an animal model with GABA in combination with either GAD65 or proinsulin. Diamyd Medical licenses exclusive rights from UCLA for the therapeutic use of GABA alone or in combination with antigens for the treatment of diabetes and other inflammation-related conditions.

Diamyd Medical's associated company Cellaviva withdraws new share issue. Diamyd Medical makes an impairment of its previous shareholding. Cellaviva is refinanced and intends to increase its focus on the development of therapeutic stem cell products

Diamyd Medical's associated company Cellaviva withdraws a new share issue due to low participation. Cellaviva, that after the period changed name to NextCell Pharma AB, is refinanced by approximately MSEK 8.2 through the exercise of a convertible loan of about MSEK 2.7 and a capital contribution of approximately MSEK 5.5, of which Diamyd Medical's shares amount to MSEK 1.3 and MSEK 1, respectively. NextCell Pharma intends to increase its focus on the development of therapeutic stem cell products. Diamyd Medical announces concurrently in its quarterly report that an impairment is made of the previous holding of approximately MSEK 13.5.

Significant events after the reporting period

Positive effect of Diamyd® is supported in new scientific article

A comprehensive analysis of previously published clinical studies shows that the diabetes vaccine Diamyd® with great probability reduces the loss of C-peptide, a measure of endogenous insulin production, by 15-20%. The analysis is made by internationally leading researchers in type 1 diabetes, and has been published in the journal Diabetologia. Diamyd Medical has previously announced, by press release February 2, 2015, that the basis for the now confirmed results was published in an abstract for a scientific conference.

The Swedish Medical Products Agency approves extension of Diamyd® trial

DIAGNODE-1, an open clinical pilot trial where the diabetes vaccine Diamyd® is tested by given directly into the lymph node, has been approved by the Swedish Medical Products Agency and the Ethics Committee to be expanded from nine to fifteen patients.

Board member of Diamyd Medical resigns from the Board

Board member Fredrik Åhlander has been convicted (accepted a punishment of 15 600 SEK in fines) for an insider offense. The offense occurred before Åhlander was elected to the Board of Diamyd Medical and did not concern the Diamyd Medical share. Fredrik Åhlander requests own resignation from Diamyd Medical's Board with immediate effect.

Diamyd Medical expands activities to both type 1 and type 2 diabetes as well as rheumatoid arthritis with proprietary GABA drug

Diamyd Medical announces that its activities will expand to include both type 1 and type 2 diabetes as well as rheumatoid arthritis, which is planned to be pursued through the development of a proprietary GABA drug product.

The Phase II study EDCR IIa is fully enrolled and results from the prevention study DiAPREV-IT 1 are expected to be presented during the first quarter of 2017

The phase II study EDCR IIa is fully enrolled and results from a first evaluation after 6 months are estimated to be presented during the second quarter of 2017. Diamyd Medical also announces that results from the placebo-controlled prevention study DiAPREV-IT 1 are expected to be presented during the first quarter of 2017.

Business overview

Diamyd Medical is dedicated to finding a cure for diabetes and other serious inflammatory diseases through pharmaceutical development and investments in stem cell and medical technology.

Diamyd Medical develops the diabetes vaccine Diamyd®, an antigen-specific immunotherapy based on the exclusively licensed GAD-molecule. At this time six clinical studies are ongoing with Diamyd®. GABA constitutes alongside with the diabetes vaccine a key asset in Diamyd Medical and the Company uses its GABA in-licensed technology to develop a proprietary GABA drug product. Diamyd Medical is one of the major shareholders in the stem cell company NextCell Pharma AB (previously named Cellaviva AB). Diamyd Medical also has holdings in the medtech company Companion Medical, Inc., San Diego, USA and in the gene therapy company Periphagen, Inc., Pittsburgh, USA.

Diamyd Medical's 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.

Development of proprietary GABA drug

As a further development of the potential of GABA, Diamyd Medical broadens its operations towards both type 1 and type 2 diabetes and rheumatoid arthritis, which is planned to be pursued by the development of a proprietary GABA-drug product. By producing its own GABA, Diamyd Medical will gain full control of product development. The first development stage of a GABA drug product will, with a preferred provider for GMP production and with preclinical studies, determine formulation technology and dosage. At a later stage the production can be scaled up in alignment with the clinical development strategy including formulation, administration and dosage of the drug.

On-going combination trials with Diamyd®

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 diabetes vaccine Diamyd® has been used in clinical studies with more than 1,000 patients and has shown a good safety profile. 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**
  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. 30 month results from the trial are expected during the first half year of 2017.

- **DIAGNODE -1 – DIAMYD® IN LYMPH GLANDS IN COMBINATION WITH VITAMIN D**
  An open label trial, where Diamyd® is administered directly into lymph nodes in combination with treatment with vitamin D. The trial comprises fifteen patients between the ages of 12 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**
  A placebo-controlled trial, where Diamyd® is being tested in combination with GABA. In accordance with agreement with Jansen Research & Development and JDRF the trial was recently expanded to comprise 95 patients between the ages of 4 and 18 recently diagnosed with type 1 diabetes. The trial 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 Dr. Alexandra Martin 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**
  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. All patients were included in September 2016 and 6 month results are expected during the second quarter of 2017.

- **DiAPREV-IT 1– DIAMYD®**
  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 during the first quarter of 2017.

- **DiAPREV-IT 2 – COMBINING DIAMYD® WITH VITAMIN D**
  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.

Key figures

	3 months Jun-Aug 2015/16	3 months Jun-Aug 2014/15	**12 months Sep-Aug 2015/16**	12 months Sep-Aug 2014/15
Research and development costs, MSEK	-1.9	-1.1	-6.2	-9.7
Solidity, %	77	85	77	85
Result per share, SEK	-0.2	-0.2	-1.3	-1.0
Liquid assets and short term investments per share, SEK	1.1	1.3	1.1	1.3
Shareholders' equity per share, SEK	0.99	1.8	0.99	1.8
Cash flow per share, SEK	-0.2	-0.4	0.4	-0.4
Share price per closing, SEK	7.0	8.9	7.0	8.9
Share price/Shareholders' equity per share, SEK	7.1	5.0	7.1	5.0
Number of shares per closing	29 492 562	22 119 422	29 492 562	22 119 422
Average number of shares	29 492 562	22 044 422	24 939 761	20 510 929
Average number of employees	7	6	7	6

Income statement

KSEK	Note	3 months Jun-Aug 2015/16	3 months Jun-Aug 2014/15	12 months Sep-Aug 2015/16	12 months Sep-Aug 2014/15
OPERATING INCOME					
Net income		168	117	757	513
Other operating income		203	33	286	699
TOTAL OPERATING INCOME		371	150	1 043	1 212
OPERATING EXPENSES					
External research and development costs		-1 942	-1 076	-6 220	-9 686
External patent- and license costs		-222	-342	-911	-1 351
Personnel costs	1	-1 796	-1 432	-7 671	-7 366
Other external costs	1	-1 206	-1 121	-4 514	-4 105
Other operating expenses		-29	-19	-137	-246
Depreciation and impairment of material and immaterial assets	2	-26	-6	-13 649	-26
TOTAL OPERATING EXPENSES		-5 222	-3 998	-33 102	-22 780
OPERATING RESULT		**-4 851**	**-3 848**	**-32 059**	**-21 568**
Net Financial income/expense		-57	-434	51	171
RESULT BEFORE TAXES		-4 794	-4 282	-32 008	-21 397
Taxes		-	-	-	-
NET RESULT FOR THE PERIOD		**-4 794**	**-4 282**	**-32 008**	**-21 397**

Balance sheet

KSEK	Note	**31 Aug 2016**	31 Aug 2015
ASSETS			
NON-CURRENT ASSETS			
Intangible assets		374	480
Financial assets	2	4 453	15 661
TOTAL NON-CURRENT ASSETS		4 827	16 141
CURRENT ASSETS			
Trade receivables		215	196
Other receivables		379	235
Prepaid expenses and accrued income		961	346
Short term investments		4 999	12 998
Liquid assets		26 397	16 729
TOTAL CURRENT ASSETS		32 951	30 504
TOTAL ASSETS		**37 778**	**46 645**
EQUITY AND LIABILITIES			
EQUITY			
Restricted equity			
Share capital		2 991	2 243
Statutory reserve		200	200
Non-restricted equity			
Share premium reserve non-restricted		56 803	35 804
Profit or loss brought forward		1 277	22 674
Net loss for the period		-32 008	-21 397
TOTAL EQUITY		29 263	39 524
PROVISIONS			
Pensions and other obligations		777	806
Other provisions	3	2 433	-
TOTAL PROVISIONS		3 210	806
CURRENT LIABILITIES			
Trade payables		1 221	935
Other payables		494	277
Prepaid income and accrued expenses		3 591	5 103
TOTAL CURRENT LIABILITIES		5 305	6 315
TOTAL EQUITY AND LIABILITIES		**37 778**	**46 645**

Statement of cash flow

KSEK	Note	3 months Jun-Aug 2015/16	3 months Jun-Aug 2014/15	12 months Sep-Aug 2015/16	12 months Sep-Aug 2014/15
CASH FLOW FROM OPERATIONS BEFORE CHANGES IN WORKING CAPITAL					
Operating profit/loss		-4 850	-3 848	-32 059	-21 568
Interest and foreign exchange difference received		25	-294	-43	114
Interest and foreign exchange difference paid		0	-	0	-2
Non-cash flow items					
Depreciation		26	7	106	26
Other non-cash flow items	2	148	-646	13 515	2 139
NET CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL		**-4 651**	**-4 781**	**-18 395**	**19 291**
Increase (-) decrease (+) receivables		-310	226	-623	636
Increase (+) decrease (-) liabilities		865	501	1 267	344
NET CASH FLOW FROM OPERATING ACTIVITIES		**-4 096**	**-4 054**	**-17 752**	**-18 311**
CASH FLOW FROM INVESTING ACTIVITIES					
Investment in immaterial and material assets, net		-	-400	-	-400
Investment in financial assets		-1 000	-68	-2 334	-2 007
Increase (-) decrease (+) short term investments, net		-	-4 999	7 999	-2 038
NET CASH FLOW FROM INVESTING ACTIVITIES		**-1 000**	**-5 467**	**5 665**	**-4 444**
CASH FLOW FROM FINANCING ACTIVITIES					
New issue		-	-	22 119	15 000
Issue expenses		-	-3	-373	-44
NET CASH FLOW FROM FINANCING ACTIVITIES		**-**	**-3**	**21 747**	**14 956**
TOTAL CASH FLOW FOR THE PERIOD		**-5 096**	**-9 524**	**9 660**	**7 800**
Cash and cash equivalents at beginning of period		31 492	26 215	16 729	24 715
Net foreign exchange difference		1	38	8	-186
CASH AND CASH EQUIVALENTS AT END OF PERIOD		**26 397**	**16 729**	**26 397**	**16 729**

Changes in Equity

KSEK	Share Capital	Statutory Reserve	Share premium reserve non restricted	Other non-restricted equity	Total Shareholders' equity
OPENING BALANCE SEPTEMBER 1, 2014	**2 000**	**200**	**19 292**	**22 673**	**44 165**
Net result for the period	-	-	-	-21 397	-21 397
New issue	243	-	16 557	-	16 800
Issue expenses	-	-	-44	-	-44
CLOSING BALANCE AUGUST 31, 2015	**2 243**	**200**	**35 804**	**1 276**	**39 524**
OPENING BALANCE SEPTEMBER 1, 2015	**2 243**	**200**	**35 804**	**1 276**	**39 524**
Net result for the period	-	-	-	-32 008	-32 008
New issue	748	-	21 372	-	22 120
Issue expenses	-	-	-373	-	-373
CLOSING BALANCE AUGUST 31, 2016	**2 991**	**200**	**56 804**	**-30 732**	**29 263**

Notes

Accounting principles

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).

Note 1 – Related-party transactions

During the year companies represented by immediate family members of the former CEO (present Board member) 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 Board member during the year amounted to KSEK 1 552 (1 510). 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-Aug	Sep-Aug
KSEK	2015/2016	2014/2015
Consultant fees and salaries to related parties	1 552	1 510

Note 2 – Financial assets

Diamyd Medical owns shares in NextCell Pharma AB, (previously Cellaviva AB), (corporate registration no 556965-8361) who operates a stem cell bank for private family saving of umbilical cord blood and other sources of stem cells. 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, 2016, approximately 21 %. The carrying amount of the holding, corresponding to MSEK 13.5 has been impaired in its entirety. The impairment has yielded a non-recurring effect on the result of MSEK -13.5. During the last quarter of the fiscal year Cellaviva has been refinanced through the exercise of a convertible loan of about MSEK 2.7 and a capital contribution of about MSEK 5.5, of which Diamyd Medical invested MSEK 1 which has been accounted for with the same amount.

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.

Note 3 – Provisions

The amount constitutes mainly of accrued research and development costs.

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 2014/2015. 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 report has not been reviewed by the Company's auditors.

Stockholm, October 12, 2016

Erik Nerpin Chairman of the Board	Anders Essen-Möller Board member	Maria-Teresa Essen-Möller Board member
	Ulf Hannelius President & CEO	

Financial calendar

Annual Report 2015/2016:	November 3, 2016
Quarterly Report 1 2016/2017:	January 25, 2017
Quarterly Report 2 2016/2017:	April 5, 2017
Quarterly Report 3 2016/2017	June 28, 2017
Year-End Report 2016/2017	October 11, 2017

Annual General Meeting

The Annual General Meeting for the fiscal year 2015/2016 will be held on November 24, 2016, at 3:00 p.m., Hotel Kung Carl, Birger Jarlsgatan 21 in Stockholm

For more information, please contact:
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This information is information that Diamyd Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out above, at 08.30 CET on October 12, 2016.

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.