QUARTERLY REPORT 2

September 2019 – February 2020

Diamyd Medical AB (publ), Fiscal year 2019/2020

Developing therapies for type 1 diabetes

Diamyd Medical's B-share is traded on Nasdaq First North Growth Market under the ticker DMYD B.
Further information is available on https://www.diamyd.com

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Figures in parentheses relate to the corresponding period previous financial year.

September 1, 2019 – February 29, 2020

- Net result: MSEK 30.3 (-19.0), whereof second quarter MSEK 37.1 (-10.4). The increase is a one-off effect due to a payment of corresponding MSEK 48.0 from the previous GAD65 manufacturer as support for transition of the manufacturing process.
- Result per share: SEK 0.4 (-0.3), second quarter SEK 0.5 (-0.2)
- Cash flow from operating activities: MSEK 31.1 (-19.5), second quarter: MSEK 37.2 (-8.7)
- Cash and cash equivalents at February 29, 2020: MSEK 88.3 (79.6)

Significant events second quarter, December 2019 – February 2020

- Diamyd Medical entered agreement to facilitate transition of manufacturing
- DIAGNODE-1: Positive Top-line results from Phase I/II trial with intralymphatic Diamyd®
- ReGenerate-1: The main part of the Phase I/II trial with Remygen® in type 1 diabetes started
- Significant effect of Diamyd® in Type 1 diabetes shown in comprehensive analysis of previous phase III and phase II trials

Significant events after the reporting period

- GADinLADA: New trial with Diamyd® in autoimmune diabetes started recruiting patients in Norway

"Given the prevailing times, we are fortunate at Diamyd Medical to have solid finances and a strong position with the diabetes vaccine Diamyd®, our lead candidate."

Ulf Hannelius, CEO

Comments by CEO Ulf Hannelius

The last weeks we have seen the Corona virus disease (COVID-19) outbreak creating turmoil in the financial markets and affecting the global economy. Given the prevailing times, we are fortunate at Diamyd Medical to have solid finances and a strong position with the diabetes vaccine Diamyd®, our lead candidate.

First, SEK 88 million in cash and a current monthly burn rate of approximately SEK 3 million give us, with ongoing activities, a runway of at least two years. We will do our best to prioritize our resources wisely and to strengthen the foundation of the company, maximizing the value of our assets.

Second, our DIAGNODE-2 Phase IIb trial with Diamyd®, was fully recruited already by May 2019, and all patients received their three injections long before the viral outbreak. We are now working closely with our partners to make sure to smooth operations as we are moving closer to finalizing the trial later this year.

Third, it is important to know that the antigen-specific immunotherapy Diamyd® does not weaken the immune system, opposed to immunosuppressive treatments that may increase the risk of infections by viral or other pathogens and/or predispose the patient to complications due to these infections. The safety profiles of both Diamyd® and our second clinical asset Remygen® are clear strengths, and in these times and going forward this may prove to become one of the most crucial advantages for Diamyd Medical.

Fourth, with the comprehensive responder analysis announced in December last year, we have improved the probability of success for Diamyd®. The results, which identified the genetics for the best Diamyd® responders, were in agreement with the thoughts on precision medicine that were independently proposed in a recent scientific review (Introducing the Endotype Concept to Address the Challenge of Disease Heterogeneity in Type 1 Diabetes, Diabetes Care, January, 2020).

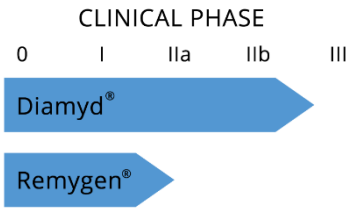
Last but not least, the DIAGNODE-2 results will be important in forming the final design of the pivotal Phase III program, and with the results from the responder analysis now at hand we have the confidence to move ahead in our preparations for building the commercial case for Diamyd®.

Stockholm, March 25, 2020

Ulf Hannelius, *President and CEO*

Two drugs in clinical development

Diamyd® and Remygen® are drugs in clinical development that focus on the underlying disease mechanisms of diabetes; the dysfunction and loss of insulin-producing beta cells in the pancreas.



Diamyd® is an antigen-specific immunotherapy for the treatment of autoimmune diabetes (type 1 diabetes).

Clinical data indicate the potential of the diabetes vaccine Diamyd® to halt or stop the autoimmune destruction of insulin-producing beta cells. The effect is achieved by antigen-specific reprogramming of immune cells by administration of low doses of Diamyd® in superficial lymph nodes.

By maintaining the endogenous insulin production, Diamyd® has the potential to make a significant difference in the daily life of patients as well significantly reduce the complications of type 1 diabetes.

Intralymphatic treatment with Diamyd® is now being investigated in a clinical Phase IIb trial (DIAGNODE-2), with the aim of confirming the previously demonstrated clinical effect from a pilot trial in type 1 diabetes patients (DIAGNODE-1).

Remygen® is an oral regenerative and immunomodulatory therapy for the treatment of autoimmune- and type 2 diabetes.

By stimulating the growth of insulin-producing cells, Remygen® has the potential to reverse the disease progression in autoimmune- and type 2 diabetes.

Remygen® is now being investigated in a clinical Phase I/II trial (ReGenerate-1), where clinical efficacy is evaluated with the aim of optimizing treatment ahead of registration-based trials.

Significant events during the second quarter

December 1, 2019 – February 29, 2020

Diamyd Medical entered agreement to facilitate transition of manufacturing

Diamyd Medical and Protein Sciences Corporation (PSC) entered into an agreement modifying their relationship, by which PSC will continue to support Diamyd Medical in its development of a diabetes vaccine but will no longer serve as its contract manufacturer. The agreement facilitates the transition of the manufacturing process of recombinant GAD65, the active ingredient in the diabetes vaccine Diamyd®, to a new manufacturer for future anticipated commercial manufacture. PSC will support Diamyd Medical with in cash, as well as certain raw materials and up to 150 man-hours of technical assistance for the transition process. The agreement has been made in light of the announcement by Diamyd Medical in October 2019 where PSC had informed Diamyd Medical that it was unable to meet Diamyd Medical's manufacturing needs for commercial supply. The payment was made in February 2020.

Positive Top-line results from Phase I/II trial with intralymphatic Diamyd®

When all 12 patients had been followed throughout the 30-month period in the open-label trial DIAGNODE-1, the patients showed on average a positive clinical course with a near normal long-term blood sugar and a low need for externally supplied insulin. The three patients who received an extra Diamyd® injection into the lymph node after their 30-month visit showed a maintained own insulin production between the 30- and 43-month visits, as well as lower long-term blood sugar and insulin requirements compared to baseline. Safety looked good and no serious side effects had been reported.

The main part of the Phase I/II trial ReGenerate-1 with Remygen® started

Four patients had been included in the trial and additional patients were scheduled to be included in December and January. Compilation of metabolic results from the completed safety and dose escalation part of the trial awaits a final experimental analysis and is expected to be announced during the second quarter of 2020.

Significant effect of Diamyd® in Type 1 diabetes shown in a comprehensive analysis of previous Phase III and Phase II trials

A new analysis based on data from more than 530 individual patients from previous Phase III and II trials in Europe and US with the diabetes vaccine Diamyd® identified genetically defined subgroups of type 1 diabetes patients that showed a positive and statistically significant dose-dependent treatment response.

Significant events after the reporting period

New trial with Diamyd® in autoimmune diabetes started recruiting patients in Norway

GADinLADA, the first clinical phase II trial with the diabetes vaccine Diamyd® administered directly into the lymph node in patients with LADA started recruitment at the Norwegian University of Science and Technology in Trondheim (NTNU), in cooperation with St. Olav's University Hospital, Trondheim. The trial will also be conducted in Sweden at the Center for Diabetes, the Academic Specialist Center, an academic specialist unit that is run in collaboration between the Health Care Services Stockholm County, Karolinska Institute and Karolinska University Hospital, and the recruitment is expected to start during the spring. In total, the trial encompasses 15 patients between the ages of 30 to 70 years diagnosed with LADA within the last 12 months who are not yet on insulin therapy.

Ongoing clinical trials

Type 1 diabetes is a devastating disease which requires daily treatment with insulin to sustain life. The importance of finding a drug that improves the prospects for patients with diabetes is of utmost importance. The effect of intralymphatic administration of Diamyd®, an antigen-specific immunotherapy aimed at stopping the immune system's attack on insulin-producing beta cells in autoimmune diabetes, is evaluated in the Phase IIb trial DIAGNODE-2. Remygen®, which aims to stimulate the growth of beta cells in patients with diabetes, is now evaluated in patients in a Phase I/II trial.

Trials with Diamyd® in lymph node

- **DIAGNODE -2 – DIAMYD® IN LYMPH NODES WITH ORAL SUPPLEMENTATION OF VITAMIN D**
  A follow-up double-blind randomized clinical trial where Diamyd® is administered directly into a lymph node with oral supplements of vitamin D. The trial encompasses 109 patients from Sweden, the Czech Republic, Spain and the Netherlands, aged 12–24 years who have recently been diagnosed with type 1 diabetes and will continue for a total of 15 months. As of autumn 2019, those patients who have not performed their last visit at 15 months are invited to participate in a nine months extension of the trial. 15-month results are expected to be presented in the third quarter of 2020. The aim of the trial is to evaluate the patients' remaining insulin producing capacity. Coordinating Investigator is Professor Johnny Ludvigsson at Linköping University, Sweden. Diamyd Medical is the Sponsor of the trial.

- **GADinLADA – DIAMYD® IN LYMPH NODES WITH ORAL SUPPLEMENTATION OF VITAMIN D**
  An open-label, investigator initiated clinical trial where Diamyd® is administered directly into a lymph node with oral supplements of vitamin D. The trial encompasses 15 patients aged 30-70 years diagnosed with LADA (Latent Autoimmune Diabetes in Adults) and not yet on inulin treatment. The aim with the trial is to evaluate the safety of intralymphatic treatment with Diamyd® in LADA patients and to continuously evaluate the immunological and clinical response during a one-year period. Sponsor of the trial is the Norwegian University of Science and Technology with Ingrid K Hals as sponsor representative.

Trial with Remygen® (GABA)

- **REGENERATE-1 – REMYGEN® /ALPRAZOLAM**
  An open-label, investigator initiated clinical trial with Remygen®. The trial includes approximately 36 patients aged 18-50 who have had type 1 diabetes for more than five years with low to non-existing insulin production. The primary aim of the trial is to in a smaller dose escalation section evaluate the safety of Remygen®. The main trial also evaluates whether the insulin-producing cells can be regenerated using Remygen®, and in the combination of Remygen® and Alprazolam. The trial is led by Professor Per-Ola Carlsson at Uppsala University, Sponsor of the trial.

Other ongoing trial with Diamyd®

- **DiAPREV-IT 2 – COMBINING DIAMYD® WITH VITAMIN D**
  A placebo-controlled investigator-initiated clinical trial, where Diamyd® is given subcutaneously and 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. The trial includes 26 children and results are expected in Q2 2020. 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, Sponsor of the trial.

Key figures

	3 months Dec-Feb 2019/20	3 months Dec-Feb 2018/19	6 months Sep-Feb 2019/20	6 months Sep-Feb 2018/19	12 months Sep-Aug 2018/19
Research and development costs, MSEK	-3.0	-6.2	-5.7	-11.1	-22.4
Solidity, %	91	86	91	86	85
Result per share, SEK	0.5	-0.2	0.4	-0.3	-0.5
Liquidity and short-term investment per share, SEK	1.3	1.2	1.3	1.2	0.8
Equity per share, SEK	1.3	1.2	1.3	1.2	0.9
Cash flow per share, SEK	0.5	0.3	0.7	0.4	0.3
Share price per closing, SEK	14.6	7.1	14.6	7.1	8.4
Number of shares per closing	69 169 796	69 169 796	69 169 796	69 169 796	69 169 796
Average number of shares	69 169 796	66 862 220	69 169 796	61 510 811	65 371 779
Average number of employees	7	6	7	6	6

Income statement

KSEK	Note	3 months Dec-Feb 2019/20	3 months Dec-Feb 2018/19	6 months Sep-Feb 2019/20	6 months Sep-Feb 2018/19	12 months Sep-Aug 2018/19
OPERATING INCOME						
Net income		48	97	166	358	1 568
Other operating income		749	28	762	53	69
Other compensation and income	1	43 174	-	43 174	-	-
TOTAL OPERATING INCOME		43 970	125	44 102	411	1 637
OPERATING EXPENSES						
External research and development costs	1	-2 991	-6 181	-5 725	-11 061	-22 359
External patent- and license costs		-552	-627	-995	-1 037	-1 693
Personnel costs	2	-2 201	-2 000	-4 337	-3 952	-7 891
Other external costs	2	-1 537	-1 643	-3 052	-3 105	-6 017
Other operating expenses		-11	-50	-23	-65	-105
Depreciation and impairment of material and immaterial assets		-35	-35	-70	-70	-140
TOTAL OPERATING EXPENSES		-7 326	-10 536	-14 202	-19 290	-38 206
OPERATING RESULT		**36 644**	**-10 411**	**29 900**	**-18 878**	**-36 569**
Net Financial income/expense		484	-14	445	-72	-41
RESULT BEFORE TAXES		37 128	-10 425	30 345	-18 951	-36 610
Taxes		-	-	-	-	-
NET RESULT FOR THE PERIOD		**37 128**	**-10 425**	**30 345**	**-18 951**	**-36 610**

Balance sheet

KSEK	Note	29 Feb 2020	28 Feb 2019	31 Aug 2019
ASSETS				
NON-CURRENT ASSETS				
Intangible assets		275	414	345
Financial assets	3	11 979	8 789	11 979
TOTAL NON-CURRENT ASSETS		12 253	9 204	12 323
CURRENT ASSETS				
Trade receivables		55	98	214
Other receivables		1 443	1 394	1 215
Prepaid expenses and accrued income		469	2 777	3 736
Short term investments		-	40 025	20 012
Liquid assets		88 273	39 522	36 702
TOTAL CURRENT ASSETS		90 239	83 817	61 879
TOTAL ASSETS		**102 493**	**93 020**	**74 202**
EQUITY AND LIABILITIES				
EQUITY				
Restricted equity				
Share capital		7 015	7 015	7 015
Statutory reserve		200	200	200
Non-restricted equity				
Share premium reserve non-restricted		192 414	192 414	192 414
Profit or loss brought forward		-136 850	-100 240	-100 240
Net result for the period	1	30 345	-18 951	-36 610
TOTAL EQUITY		93 125	80 440	62 780
PROVISIONS				
Pensions and other obligations		777	777	777
Other provisions		-	281	-
TOTAL PROVISIONS		777	1 058	777
CURRENT LIABILITIES				
Trade payables		1 363	4 057	1 707
Other payables		271	640	563
Prepaid income and accrued expenses		6 956	6 826	8 374
TOTAL CURRENT LIABILITIES		8 590	11 522	10 644
TOTAL EQUITY AND LIABILITIES		**102 493**	**93 020**	**74 202**

Statement of cash flow

KSEK	Note	3 months Dec-Feb 2019/20	3 months Dec-Feb 2018/19	6 months Sep-Feb 2019/20	6 months Sep-Feb 2018/19	12 months Sep-Aug 2018/19
OPERATING ACTIVITIES						
Operating profit/loss	1	36 644	-10 411	29 900	-18 878	-36 569
Interest received		2	0	2	0	0
Interest paid		-8	-53	-26	-82	-124
Non-cash flow items						
Depreciation		35	35	70	70	140
Other non-cash flow items		-759	-276	-739	-551	-832
CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL		**36 673**	**-10 705**	**29 946**	**-19 442**	**-37 384**
Increase (-) decrease (+) receivables		1 444	1 719	3 199	-1 191	-2 085
Increase (+) decrease (-) debts		-918	261	-2 054	1 162	284
NET CASH FLOW FROM OPERATING ACTIVITIES		**37 199**	**-8 725**	**31 090**	**-19 471**	**-39 185**
INVESTING ACTIVITIES						
Investment in financial assets		-	-	-	-1 484	-4 674
Investment in short term investments		-	-30 020	20 012	-9 990	10 024
NET CASH FLOW FROM INVESTING ACTIVITIES		-	**-30 020**	20 012	**-11 474**	**5 350**
FINANCING ACTIVITIES						
New issue		-	58 403	-	58 403	58 403
Issue expenses		-	-1 925	-	-2 024	-2 024
NET CASH FLOW FROM FINANCING ACTIVITIES		-	**56 478**	-	**56 380**	**56 380**
TOTAL CASH FLOW FOR THE PERIOD		**37 199**	**17 733**	51 102	**25 435**	**22 544**
Cash and cash equivalents at beginning of period		50 584	21 750	36 702	14 077	14 077
Net foreign exchange difference		490	39	469	10	81
CASH AND CASH EQUIVALENTS AT END OF PERIOD		**88 273**	**39 522**	**88 273**	**39 522**	**36 702**

Statement of changes in equity

KSEK	Share Capital	Statutory Reserve	Share premium reserve non restricted	Other non-restricted equity	Total Shareholders' equity
OPENING BALANCE SEPTEMBER 1, 2018	5 713	200	137 337	-100 241	43 011
Net result	-	-	-	-36 610	-36 610
New issue	1 302	-	57 101	-	58 403
Issue expenses	-	-	-2 024	-	-2 024
CLOSING BALANCE AUGUST 31, 2019	7 015	200	192 414	-136 851	62 780
OPENING BALANCE SEPTEMBER 1, 2019	**7 015**	**200**	**192 414**	**-136 851**	**62 780**
Net result	-	-	-	30 345	30 345
CLOSING BALANCE FEBRUARY 29, 2020	**7 015**	**200**	**192 414**	**-106 506**	**93 125**

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 – Other compensation and income, research and development costs

During the period a payment of USD 5 million was made by Protein Sciences Corporation as support for transition of the manufacturing process which affects operating income by corresponding MSEK 43.2, as well as research and development costs by MSEK 2.0 due to reversion of previously disclosed manufacturing costs.

Note 2 – Related-party transactions

During the period companies represented by immediate family members of the main owner and Board member Anders Essen-Möller were contracted as consultants. Total compensation for consultancy services and salaries to immediate family members amounted to KSEK 381 (525). As working Board member, Anders Essen-Möller has through a company owned by Essen-Möller been compensated by KSEK 463 (406). Pricing has been set by the arm's length principle.

KSEK	Sep-Feb 2019/20	Sep-Feb 2018/19
Consultant fees and salaries to related parties	381	525
Consultant fees to Board members	463	406

Note 3 – Financial assets

Diamyd Medical owns shares in NextCell Pharma AB (corporate registration no 556965-8361) who develops stem cell therapies and operates a stem cell bank for private family saving of stem cells. The registered office is in Huddinge, Stockholm County. As of February 29, 2020, the carrying amount was approximately MSEK 8.5. Diamyd Medical's share of the equity as well as share of the votes was as of the same date approximately 12.8%. Diamyd Medical also holds approximately 5.6% of the medical device company Companion Medical, Inc., based in San Diego, USA. Companion Medical develops technical devices for people with insulin treated diabetes. 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 2018/2019. 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 quarterly 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, March 25, 2020

Erik Nerpin
Chairman of the Board

Anders Essen-Möller
Board member

Maria-Teresa Essen-Möller
Board member

Torbjörn Bäckström
Board Member

Mark A. Atkinson
Board member

Ulf Hannelius
President & CEO

Financial Calendar

Quarterly Report 3	June 24, 2020
Year-end Report	October 7, 2020

The reports will be available from these above dates at www.diamyd.com.

About Diamyd Medical

Diamyd Medical develops therapies for type 1 diabetes. The diabetes vaccine Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. Diamyd® has demonstrated good safety in trials encompassing more than 1,000 patients as well as significant effect in some pre-specified subgroups. Results from the Company's European Phase IIb trial DIAGNODE-2, where the diabetes vaccine is administered directly into a lymph node in children and young adults with newly diagnosed type 1 diabetes, are expected to be presented in the third quarter of 2020. Diamyd Medical also develops the GABA-based investigational drug Remygen® for regeneration of endogenous insulin production. An investigator-initiated Remygen® trial in patients living with type 1 diabetes for more than five years is ongoing at Uppsala University Hospital. Diamyd Medical is one of the major shareholders in the stem cell company NextCell Pharma AB and has holdings in the medtech company Companion Medical, Inc., San Diego, USA.

Diamyd Medical's B-share is traded on Nasdaq First North Growth Market under the ticker DMYD B. FNCA Sweden AB is the Company's Certified Adviser; phone: +46 8-528 00 399, e-mail: info@fnca.se.
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