



QUARTERLY REPORT 2

September 2023 – February 2024

Diamyd Medical AB (publ), Fiscal year 2023/2024



Precision Medicine for Autoimmune Diabetes in Pivotal Phase 3

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>

September 1, 2023 – February 29, 2024

- Operating income: MSEK 2.1 (2.6) second quarter: MSEK 1.2 (1.6)
- Net result: MSEK -62.0 (-57.9), second quarter: MSEK -29.3 (-25.0)
- Result per share: SEK -0.7 (-0.8), second quarter: SEK -0.3 (-0.3)
- Cash flow from operating activities: MSEK -63.2 (-52.4), second quarter: MSEK -35.4 (-25.4)
- Cash and short-term investments at February 29, 2024: MSEK 137.1 (101.6)

Significant events during the second quarter, December 1, 2023 – February 29, 2024

- Diamyd Medical received FDA Fast Track designation for Diamyd®

Other events during the second quarter

- Diamyd Medical announced presentation of new genetic data at ASIT summit in Boston, MA
- Publication in Diabetologia highlighted AI's potential for Type 1 Diabetes screening
- In-depth analysis of Diamyd Phase II trial further supported value of preserved insulin secretion
- Diamyd Medical gained market research findings to guide U.S. commercial strategy
- Diamyd® Phase 3 trial key interim analysis was announced to be presented in July
- Precision Medicine patent for the prevention and treatment of autoimmune diabetes was granted in South Korea

Significant events after the second quarter

- The Board resolved on a rights issue of approximately SEK 114 million

“The recent granting of Fast Track designation by the U.S. FDA for our flagship product Diamyd® is a milestone that both accelerates the path to bringing our innovative treatment to patients with Type 1 Diabetes and validates the urgent need for our therapy.”

Ulf Hannelius, CEO



Comments by CEO Ulf Hannelius

Dear Shareholders,

The recent granting of Fast Track designation by the U.S. FDA for our flagship product Diamyd® is a milestone that both accelerates the path to bringing our innovative treatment to patients with Type 1 Diabetes and validates the urgent need for our therapy. This status enhances our ability to work closely with the FDA to expedite the review process, bringing us closer to making a tangible impact on the lives of those diagnosed with Type 1 Diabetes.

In the wake of receiving the Fast Track designation for Diamyd® and the very positive momentum in the field, the decision to launch a rights issue is a forward-looking move designed to harmonize with our anticipated milestones and the existing warrant structure. The rights issue of SEK 114 million is relatively small compared to our market value, it is without underwriters and associated costs, and it provides the opportunity to lay a robust foundation for long-term financial planning.

The precision medicine Phase 3 trial DIAGNODE-3 remains a cornerstone of our efforts to advance the field of Type 1 Diabetes treatment through antigen-specific immunotherapy. We are poised for an interim analysis this summer based on approximately 70 patients and their progression in C-peptide, the marker for endogenous insulin producing capacity, at 6 months. The analysis is blinded to not interfere with the pivotal nature of the trial but will provide information about the progression of the trial and thereby the likelihood of the trial meeting its endpoints. In parallel, we anticipate reaching another significant milestone with 100 patients randomized this April and associated milestone payments from our partnership with JDRF. A few days ago, the clinical team also reported that we have now screened more than 300 patients, which underlines the operational momentum in the study.

The collaboration with JDRF not only underscores our commitment to pioneering innovative treatments but also highlights the collective drive to address the complexities of Type 1 Diabetes.

Last week I had the opportunity and privilege to present new genetic data from DIAGNODE-3 as well as how they align with data from our previous trials at the Antigen Specific Immune Tolerance Summit in Boston. The presentation shed light on the nuanced relationship between genetics, age, gender, and the incidence of Type 1 Diabetes. These insights are vital, as they elucidate the heterogeneous nature of Type 1 Diabetes and the rationale behind the findings from our previous phase 3 program with Diamyd® and why our current targeted approach has a high likelihood of success. It reinforces the imperative for a precision medicine approach, particularly with antigen-specific immunotherapy, which aims to specifically reprogram the immune system.

Furthermore, the progress at our biomanufacturing facility in Umeå is another key pillar of our strategy. In parallel to the work aiming to have the biomanufacturing facility GMP ready during this year, the team is actively working with engineering runs, technical batches that are critical before transitioning into manufacturing of clinical batches. The expansion of our team, where several positions are currently advertised, is also central to scaling up our production capabilities, ensuring that we can meet the future demand for Diamyd® efficiently and effectively.

The last months have been marked by noteworthy achievements and strategic decisions that pave the way for an exciting future. As CEO, I am profoundly optimistic about what lies ahead for Diamyd Medical while also humble in the face of the operational challenges. I am deeply grateful for the continued support of our shareholders, the dedication of our team, and the collaboration of our partners. Diamyd Medical stands at a pivotal juncture, marked by significant regulatory, scientific and operational advancements.

Together, we are making strides towards transforming the landscape of Type 1 Diabetes treatment.

Stockholm, March 27, 2024

Ulf Hannelius, President and CEO

Significant events during the second quarter

December 1, 2023 – February 29, 2024

FDA granted Fast Track designation for Diamyd®

The U.S. Food and Drug Administration (FDA) granted Fast Track designation for Diamyd® (rhGAD65/alum) that is being investigated to improve glycemic control in recently diagnosed stage 3 Type 1 Diabetes patients with the genotype HLA DR3-DQ2. The FDA grants Fast Track designation to facilitate the development and expedite the review of medicines to treat serious conditions and fill an unmet medical need. Fast Track designation is intended to bring promising medicines to patients sooner.

Other events during the second quarter

December 1, 2023 – February 29, 2024

Diamyd Medical announced that new genetic data were to be presented at the ASITT summit in Boston, MA

Diamyd Medical was invited as a speaker at the 7th Antigen Specific Immune Tolerance summit in Boston, MA, on March 18-20, 2024. CEO Ulf Hannelius presented in March up-to-date HLA haplotype frequency data in Type 1 Diabetes collected as part of the ongoing precision medicine Phase 3 trial DIAGNODE-3.

Publication in Diabetologia highlighted AI's potential for Type 1 Diabetes screening

An article in Diabetologia was published as a result of a conference organized in Malmö in May 2022 by the ASSET consortium (www.asset.healthcare) where key factors and opportunities around the integration of Artificial Intelligence (AI) in early Type 1 Diabetes screening were discussed. The publication highlighted the need for precision in risk assessment and individualized monitoring plans. The article also highlighted the overall feasibility and cost-effectiveness of screening. The ASSET consortium is financed by the Swedish innovation agency VINNOVA and coordinated by Diamyd Medical.

In-depth analysis of Diamyd Phase II trial further supported value of preserved insulin secretion

An in-depth analysis of the continuous glucose monitoring data from the phase 2b trial DIAGNODE-2 with Diamyd® sheds new light on the importance of residual beta cell function in individuals recently diagnosed with Type 1 Diabetes. Most notably, the results show highly statistically significant and positive associations between residual beta cell function measured as stimulated C-peptide and reduction of the number and severity of hyperglycemic events, in other words episodes of high blood glucose levels, as well as improvements in glucose control during mealtime. The results lend further support to the clinical relevance of therapeutically preserving C-peptide in Type 1 Diabetes, one of the two primary endpoints in the ongoing Phase 3 trial DIAGNODE-3.

Diamyd Medical gained market research findings to guide US commercial strategy

Market research including initial interviews with US health care practitioners as well as US payers demonstrated a strong willingness to consider prescribing the investigational precision medicine Diamyd® for Type 1 Diabetes and pricing in the range of USD 200,000. Diamyd® is currently being evaluated in the registrational Phase 3 trial DIAGNODE-3 in patients recently diagnosed with Type 1 Diabetes that carry the HLA DR3-DQ2 haplotype.

Diamyd® precision medicine Phase 3 trial key interim analysis in July

Diamyd Medical announced that the upcoming interim analysis of the transformational gene-based precision medicine Phase 3 trial, DIAGNODE-3, for type 1 diabetes is planned for July 2024. This precision medicine trial employs the antigen-specific immunotherapy Diamyd® and the interim assessment, focusing on the preservation of endogenous insulin production as measured by C-peptide levels at 6 months follow-up, will include data from 70-80 patients presently enrolled in DIAGNODE-3. The analysis is an important milestone, providing insights into the trial's progress towards achieving its primary goals.

Precision Medicine patent for the prevention and treatment of autoimmune diabetes was granted in South Korea

The patent, granted by the South Korean Patent Office and valid until 2035, safeguards the application of GAD autoantigen in treating or preventing autoimmune diabetes, specifically in individuals with the HLA DR3-DQ2 gene. GAD, the key component in Diamyd®, an antigen-specific immunotherapy is currently under evaluation in the registrational Phase III trial DIAGNODE-3.

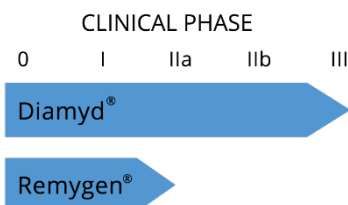
Significant events after the second quarter

The Board of Directors in Diamyd Medical resolved on a rights issue of approximately SEK 114 million

The Board resolved, pursuant to the authorization granted by the Company's annual general meeting held on November 30, 2023, on a rights issue of a maximum of 9,494,799 units, consisting of shares and warrants, corresponding to approximately SEK 114 million. The subscription price in the rights issue was set to SEK 12.00 per unit, corresponding to SEK 12.00 per share (the warrants are issued free of charge). Each A-unit contains one (1) share of series A and one (1) warrant of series TO 4 A. Each B-unit contains one (1) share of series B and one (1) warrant of series TO 4 B. Shareholders in Diamyd Medical on the record date have for each ten (10) held shares, regardless of share class, preferential right to subscribe for one (1) new unit of the same share class in the rights issue. Chairman of the Board of Directors and founder, Anders Essen-Möller, has committed to subscribing for units equivalent to approximately SEK 1 million. In addition, CEO Ulf Hannelius has committed to subscribe for his pro rata share of the rights issue, corresponding to approximately SEK 0.4 million, and other senior executives have committed to subscribe for units equivalent to approximately SEK 0.2 million. In total, the rights issue is thus covered by subscription commitments equivalent to approximately SEK 1.6 million, corresponding to approximately 1.4 percent of the rights issue.

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 immunomodulating precision medicine therapy for the treatment and prevention of autoimmune diabetes (type 1 diabetes and LADA, Latent Autoimmune Diabetes in Adults).

Clinical data indicate the potential of Diamyd® to halt or stop the autoimmune destruction of insulin-producing beta cells in individuals that carry the HLA DR3-DQ2 haplotype. 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 as significantly reduce the complications of type 1 diabetes. Topline results from the Phase IIb trial DIAGNODE-2 demonstrated a significant treatment effect of Diamyd® in the predefined genetic patient group. A confirming Phase III trial, DIAGNODE-3, is on-going.

Remygen® is an oral GABA-based regenerative and immunomodulatory drug candidate for the treatment of autoimmune- and type 2 diabetes. The safety of Remygen® has been demonstrated in a Phase 1/2 clinical trial with Remygen® in patients who have had type 1 diabetes for several years. In addition to safety, the study also collected data on restoring or stimulating the body's insulin production and preventing hypoglycaemia.



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 precision medicine immunotherapy aimed at stopping the immune system's attack on insulin-producing beta cells in autoimmune diabetes, is evaluated in the Phase III trial DIAGNODE-3 and in the Phase II trial DiaPrecise.

Ongoing clinical trials

Trials with Diamyd® in lymph nodes

- **DIAGNODE-3 - DIAMYD® IN LYMPH NODES WITH ORAL SUPPLEMENTATION OF VITAMIN D**

The placebo-controlled Phase III trial DIAGNODE-3 will include approximately 330 individuals aged 12 to 29 who have been recently diagnosed with Type 1 Diabetes and who carry the genetically defined haplotype HLA DR3-DQ2. The trial is currently ongoing at 50 clinics in eight European countries and the United States, where about 40% of all individuals with Type 1 Diabetes are estimated to carry the current haplotype. After an initial month in which all trial participants receive vitamin D, the individuals will be randomized 2:1, ie two out of three trial participants will receive three intralymphatic injections of Diamyd® and one in three will receive the corresponding placebo at one-month intervals, with one primary reading 24 months after trial start. The design provides, based on efficacy data from previous studies on the HLA-restricted patient population, a high probability of reaching the primary endpoints; preservation of stimulated C-peptide and lower HbA1c. The Coordinating Investigator for the trial is Professor Johnny Ludvigsson at Linköping University. The Sponsor of the trial is Diamyd Medical.

DiaPrecise - DIAMYD® IN LYMPH NODES

DiaPrecise is an open-label clinical trial where Diamyd® (GAD-alum) is given directly into a lymph node in 10 to 16 children aged 8 to 18 years who are at high risk of being diagnosed with clinical Type 1 Diabetes (so called Stage 1 or Stage 2 Type 1 Diabetes), and who also carry the genetically defined haplotype HLA DR3-DQ2, associated with clinical response to Diamyd®. The aim of the trial is to evaluate the safety and feasibility of two or three intralymphatic injections with Diamyd® as well as the effect on the immune system and clinical parameters including endogenous insulin production and blood glucose control. The Principal Investigator of DiaPrecise is Dr. Markus Lundgren, Researcher at the Department of Clinical Sciences at Lund University and consultant pediatrician at Kristianstad hospital, Sweden. Sponsor of the trial is Diamyd Medical.

Biomanufacturing in Umeå

A new facility for manufacturing of biological products is being set up in Umeå, the Capital of Västerbotten County in Sweden. The primary purpose is the manufacture of recombinant GAD65, the active pharmaceutical ingredient in the investigational medicine Diamyd®, an antigen-specific immunotherapy currently in late-stage clinical development. The long-term goal for the facility is to produce enough GAD65 to meet the market demand for Diamyd®, as well as to be a key player in the production of biological substances for other drug projects. The 24 000 square feet site, comprising of clean rooms, laboratory facilities, warehousing and office space, will facilitate full control, predictability and scalability of the manufacturing technology of the active pharmaceutical ingredient manufacturing technology. Diamyd Medical has chosen Cytiva's configurable single-use bioprocess manufacturing platform FlexFactory for the process that is based on a baculovirus-insect cell expression system. Small-scale experimental production of GAD65 is established at the manufacturing facility and large-scale production is being set up with the aim of having the biomanufacturing facility operational during 2024. Additional biomanufacturing projects will be evaluated to make full use of the site, platform, analytical laboratory and competencies.



The employees at the facility are experts in e.g. cell culture and protein purification, paving the way for the development for future precision medicine treatments of type 1 diabetes.

Key figures for the Group

	3 months Dec-Feb 2023/24	3 months Dec-Feb 2022/23	6 months Sep-Feb 2023/24	6 months Sep-Feb 2022/23	12 months Sep-Aug 2022/23
Research and development costs, MSEK	-17.0	-13.6	-34.7	-35.3	-69.9
Liquid assets and short-term investments	137.1	101.6	137.1	101.6	127.5
Solidity, %	80	89	80	89	82
Result per share, before and after dilution, SEK	-0.3	-0.3	-0.7	-0.8	-1.5
Liquidity and short-term investment per share, SEK	1.4	1.3	1.4	1.3	1.5
Equity per share, SEK	1.9	2.0	1.9	2.0	2.0
Total Cash flow per share, SEK	-0.4	-0.4	0.0	-0.2	0.1
Share price per closing, SEK	14.7	14.3	14.7	14.3	9.8
Number of shares per closing	94 947 996	76 926 939	94 947 996	76 926 939	85 782 314
Average numbers of shares	94 947 996	76 926 939	91 221 290	76 926 939	78 285 572
Average number of employees	26	21	26	20	22

Consolidated statement of comprehensive income

KSEK	Note	3 months Dec-Feb 2023/24	3 months Dec-Feb 2022/23	6 months Sep-Feb 2023/24	6 months Sep-Feb 2022/23	12 months Sep-Aug 2022/23
OPERATING INCOME						
Net income		26	113	60	324	546
Other operating income	2	1 138	1 528	2 087	2 285	3 201
TOTAL OPERATING INCOME		1 164	1 641	2 147	2 609	3 747
OPERATING EXPENSES						
External research and development costs		-16 978	-13 586	-34 663	-35 290	-69 909
External patent- and license costs		-793	-1 121	-1 936	-1 806	-3 634
Personnel costs	3	-7 420	-5 816	-15 336	-11 750	-25 658
Other external costs	4	-3 309	-3 440	-6 955	-6 806	-14 037
Other operating expenses		-37	-387	-276	-854	-1 486
Depreciation and impairment of						
Material and immaterial assets		-1 353	-1 131	-2 656	-2 353	-4 869
Result of shares in participations		-1 221	-1 111	-2 297	-2 178	-4 960
TOTAL OPERATING EXPENSES		-31 111	-26 592	-64 119	-61 037	-124 553
OPERATING RESULT		-29 947	-24 951	-61 971	-58 428	-120 806
Interest income and similar profit items		1 187	-18	2 019	506	4 735
Interest expense and similar loss items		-491	0	-2 083	-3	-3
RESULT BEFORE TAXES		-29 251	-24 970	-62 035	-57 926	-116 073
Income tax		-	-	-	-	-
NET RESULT FOR THE PERIOD		-29 251	-24 970	-62 035	-57 926	-116 073

Consolidated balance sheet

KSEK	Note	29 Feb 2024	28 Feb 2023	31 Aug 2023
ASSETS				
NON-CURRENT ASSETS				
<i>Intangible assets</i>				
Patents		-	-	-
<i>Tangible assets</i>				
	5			
Land and buildings		35 494	21 937	28 959
Constructions in progress		162	3 257	825
Machinery and inventory		20 825	24 080	22 538
<i>Financial assets</i>				
	6			
Deferred tax		1 474	1 598	1 536
Participation in associated companies		8 270	13 285	10 567
Other long-term receivables		456	626	573
TOTAL NON-CURRENT ASSETS		66 681	64 783	64 999
CURRENT ASSETS				
Trade receivables		-	86	59
Other receivables		2 774	2 687	3 996
Prepaid expenses and accrued income		19 872	6 544	9 221
Short term investments		-	-	-
Liquid assets		137 148	101 602	127 533
TOTAL CURRENT ASSETS		159 794	110 919	140 809
TOTAL ASSETS		226 475	175 701	205 808
EQUITY AND LIABILITIES				
EQUITY				
Share capital		9 630	7 802	8 700
Statutory reserve		200	200	200
Share premium reserve non-restricted		532 760	390 507	460 286
Profit or loss brought forward		-299 337	-184 130	-183 716
Net result for the period		-62 035	-57 926	-116 073
TOTAL EQUITY		181 218	156 453	169 397
PROVISIONS				
Pensions and other obligations		566	744	692
TOTAL PROVISIONS		566	744	692
LONG TERM-LIABILITIES				
Other long-term liabilities		24 148	-	15 865
TOTAL LONG-TERM LIABILITIES		24 148	-	15 865
CURRENT LIABILITIES				
Trade payables		5 625	6 753	4 886
Other payables		10 165	7 827	9 431
Prepaid income and accrued expenses		4 752	3 923	5 537
TOTAL CURRENT LIABILITIES		20 543	18 503	19 854
TOTAL EQUITY AND LIABILITIES		226 475	175 701	205 808

Consolidated statement of cash flow

KSEK	Note	3 months Dec-Feb 2023/24	3 months Dec-Feb 2022/23	6 months Sep-Feb 2023/24	6 months Sep-Feb 2022/23	12 months Sep-Aug 2022/23
OPERATING ACTIVITIES						
Operating profit/loss		- 29 947	-24 951	- 61 971	-58 428	-120 806
Interest received		1 187	105	2 019	292	1 051
Interest paid		-2	0	- 8	-3	-3
<i>Non-cash flow items</i>						
Depreciation		1 353	1 131	2 656	2 353	4 869
Other non-cash flow items		1 425	1 111	2 741	2 178	5 374
CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL		- 25 983	-22 604	- 54 563	-53 608	-109 515
Increase (-) decrease (+) receivables		- 1 633	-1 648	- 9 370	4 025	66
Increase (+) decrease (-) payables		- 7 814	-1 131	689	-2 864	-1 513
NET CASH FLOW FROM OPERATING ACTIVITIES		- 35 431	-25 383	- 63 245	-52 447	-110 962
INVESTING ACTIVITIES						
Investment in material assets		- 3 474	-3 844	- 6 815	-5 879	-11 442
Investment in financial assets		-	-	-	-	-64
Matured short-term investments		-	-	-	39 907	39 907
NET CASH FLOW FROM INVESTING ACTIVITIES		- 3 474	-3 844	- 6 815	34 028	28 401
FINANCING ACTIVITIES						
New issue		-	-	77 908	-	75 271
Issue expense		- 209	-	- 4 504	-	-4 594
Long-term liabilities		-	-	8 283	-	15 865
NET CASH FLOW FROM FINANCING ACTIVITIES		- 209	-	81 687	-	86 542
TOTAL CASH FLOW FOR THE PERIOD		- 39 114	-29 227	11 627	-18 418	3 981
Cash and cash equivalents at beginning of period		176 720	130 922	127 533	119 761	119 761
Net foreign exchange difference		- 458	-92	- 2 013	259	3 791
CASH AND CASH EQUIVALENTS AT END OF PERIOD		137 148	101 602	137 148	101 602	127 533

Consolidated 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, 2022	7 802	200	390 507	-184 130	214 379
Net result	-	-	-	-116 073	-116 073
New issue	898	-	74 373	-	75 271
Issue expenses	-	-	-4 594	-	-4 594
Incentive program LTI 2022	-	-	-	414	414
CLOSING BALANCE AUGUST 31, 2023	8 700	200	460 286	-299 789	169 397
OPENING BALANCE SEPTEMBER 1, 2023	8 700	200	460 286	-299 789	169 397
Net result	-	-	-	-62 035	-62 035
New issue	930	-	76 979	-	77 908
Issue expenses	-	-	-4 504	-	-4 504
Incentive program LTI 2022	-	-	-	452	452
CLOSING BALANCE FEBRUARY 29, 2024	9 630	200	532 760	-361 372	181 218

Income statement for the parent company

KSEK	Note	3 months Dec-Feb 2023/24	3 months Dec-Feb 2022/23	6 months Sep-Feb 2023/24	6 months Sep-Feb 2022/23	12 months Sep-Aug 2022/23
OPERATING INCOME						
Net income		130	181	294	405	690
Other operating income	2	1 138	1 628	2 087	2 179	3 094
TOTAL OPERATING INCOME		1 268	1 809	2 382	2 584	3 784
OPERATING EXPENSES						
External research and development costs		-16 978	-13 586	-34 663	-35 290	-69 909
External patent- and license costs		-793	-1 121	-1 936	-1 806	-3 634
Personnel costs	3	-7 420	-5 816	-15 336	-11 750	-25 658
Other external costs	4	-3 829	-3 822	-7 995	-7 313	-15 089
Other operating expenses		-37	-387	-276	-854	-1 486
Depreciation and impairment of Material and immaterial assets		-901	-857	-1 800	-1 666	-3 466
TOTAL OPERATING EXPENSES		-29 958	-25 588	-62 006	-58 680	-119 242
OPERATING RESULT		-28 690	-23 779	-59 625	-56 096	-115 458
Impairment of participation in associated companies		-	-	-	-	-11 781
Interest income and similar profit items		1 401	110	2 453	706	5 335
Interest expense and similar loss items		-491	0	-2 083	-3	-3
RESULT BEFORE TAXES		-27 780	-23 669	-59 254	-55 393	-121 906
Taxes		-	-	-	-	-
NET RESULT FOR THE PERIOD		-27 780	-23 669	-59 254	-55 393	-121 906

Balance sheet for the parent company

KSEK	Note	29 Feb 2024	28 Feb 2023	31 Aug 2023
ASSETS				
NON-CURRENT ASSETS				
<i>Intangible assets</i>				
Patents		-	-	-
<i>Tangible assets</i>				
Machinery and inventory		20 597	23 823	22 296
<i>Financial assets</i>				
Shares in subsidiaries		20 900	15 900	15 900
Long-term receivables from subsidiaries		18 000	15 000	18 000
Participation in associated companies	6	16 686	28 403	16 686
Other long-term receivables		456	626	573
TOTAL NON-CURRENT ASSETS		76 638	83 751	73 455
CURRENT ASSETS				
Trade receivables		-	111	-
Receivables subsidiaries		1 195	129	727
Other receivables		2 127	2 296	3 771
Prepaid expenses and accrued income		19 863	6 517	9 200
Short term investments		-	-	-
Liquid assets		135 244	97 145	124 918
TOTAL CURRENT ASSETS		158 429	106 198	138 616
TOTAL ASSETS		235 067	189 949	212 071
EQUITY AND LIABILITIES				
EQUITY				
<i>Restricted equity</i>				
Share capital		9 630	7 802	8 700
Statutory reserve		200	200	200
<i>Non-restricted equity</i>				
Share premium reserve non-restricted		532 760	390 507	460 286
Profit or loss brought forward		-290 516	-169 476	-169 062
Net result for the period		-59 254	-55 393	-121 906
TOTAL EQUITY		192 820	173 640	178 217
PROVISIONS				
Pensions and other obligations		566	744	692
TOTAL PROVISIONS		566	744	692
LONG TERM-LIABILITIES				
Other long-term liabilities		24 148	-	15 865
TOTAL LONG-TERM LIABILITIES		24 148	-	15 865
CURRENT LIABILITIES				
Trade payables		4 110	5 294	3 839
Other payables		8 621	6 417	7 820
Payables subsidiaries		50	-	100
Prepaid income and accrued expenses		4 752	3 853	5 537
TOTAL CURRENT LIABILITIES		17 533	15 565	17 296
TOTAL EQUITY AND LIABILITIES		235 067	189 949	212 071

Notes

Note 1 – General information and accounting principles

This interim report includes the parent company Diamyd Medical AB (publ), Corp. Reg. No. 556242-3797 and the subsidiary Diamyd Biomanufacturing AB, Corp. Reg. No. 559041-0931. Unless otherwise stated, all amounts are in thousands of Swedish kronor (KSEK). Figures, if not otherwise stated, refer to the Group.

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 2 – Other operating income

Other operating income consists mainly of grants related to VINNOVA (Swedish innovation agency) financed projects.

Note 3 – Long-term Incentive program, LTI 2022

The Company has as of February 29, 2024, allocated 28 participants rights to performance shares in accordance with LTI 2022. A total of 280 000 rights to performance shares have been allocated. LTI 2022 rights are measured on the allotment date at fair value of allocated equity instruments. As of February 29, 2024, social costs for LTI 2022 amount to MSEK 0.0 and personnel costs 0.45 MSEK for the period. The personnel cost is based on the allocation value, simulated with the Monte Carlo method.

Note 4 – Related-party transactions

During the period companies represented by immediate family members of the main owner and Executive Chairman Anders Essen-Möller were contracted as consultants. Total compensation for consultancy services and salaries to immediate family members amounted to KSEK 993 (724), and Anders Essen-Möller through a company owned by Essen-Möller has been compensated by KSEK 463 (463). Pricing has been set by the arm's length principle.

Group and parent company

KSEK	Sep-Feb 2023/24	Sep-Feb 2022/23	Sep-Aug 2022/23
Consultant fees and salaries to related parties	993	724	1 548
Consultant fees to Board members	463	463	976

Note 5 – Material assets

Group

KSEK	29 Feb 2023/24	28 Feb 2022/23	31 Aug 2022/23
<i>Land and buildings</i>			
Opening acquisition value	32 199	24 476	24 476
Investments in existing property	6 714	-	7 723
Reclassifications	662	-	-
Closing acquisition value	39 375	24 476	32 199
Opening accumulated depreciation	-3 240	-1 866	-1 866
Depreciation, period	-841	-673	-1 374
Closing accumulated depreciation	-4 081	-2 539	-3 240
Closing carrying amount	35 494	21 937	28 959

KSEK	29 Feb 2023/24	28 Feb 2022/23	31 Aug 2022/23
<i>Constructions in progress</i>			
Opening acquisition value	825	-	-
Purchases	-	3 257	825
Reclassifications	-662	-	-
	162	3 257	825

KSEK	29 Feb 2023/24	28 Feb 2022/23	31 Aug 2022/23
<i>Machinery and inventory</i>			
Opening acquisition value	28 872	27 381	27 381
Purchases, machinery and inventory	101	2 622	2 894
Reclassification machinery and inventory	-	-1 403	-1 403
Closing acquisition value	28 974	28 600	28 872
Opening accumulated depreciation	-6 334	-4 242	-4 242
Depreciation, period	-1 815	-1 681	-3 495
Reclassification depreciation	-	1 403	1 403
Closing accumulated depreciation	-8 149	-4 520	-6 334
Closing carrying amount	20 825	24 080	22 538

Note 6 – Financial assets

Group

Financial assets have been reduced by MSEK 24.0 in the consolidated balance sheet, due to the adjustment for accumulated results from shares in the associated company NextCell Pharma AB. The effect for the period is MSEK -2.3. The result is disclosed with a three-month delay.

Parent company

Diamyd Medical AB 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. As of February 29, 2024, the carrying amount was approximately MSEK 15.4. Diamyd Medical's share of the equity as well as share of the votes was as of the same date approximately 12.5 %. Diamyd Medical holds 25 % of the shares in the artificial intelligence company MainlyAI AB (corporate registration no 559258-7358). As of February 29, 2024, the carrying amount was MSEK 1.3.

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 2022/2023. 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, March 27, 2024

Anders Essen-Möller
Chairman of the Board

Erik Nerpin
Vice Chairman of the Board

Maria-Teresa Essen-Möller
Board member

Torbjörn Bäckström
Board member

Mark A. Atkinson
Board member

Karin Hehenberger
Board member

Ulf Hannelius
President & CEO

Karin Rosén
Board member

Financial Calendar

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June 26, 2024

Year-end Report

October 9, 2024

About Diamyd Medical

Diamyd Medical develops precision medicine therapies for the prevention and treatment of Type 1 Diabetes and LADA (Latent Autoimmune Diabetes in Adults). Diamyd® is an antigen-specific immunomodulatory therapeutic for the preservation of endogenous insulin production that has been granted Orphan Drug Designation in the U.S. as well as Fast Track Designation (Feb-2024) by the U.S. FDA. DIAGNODE-3, a confirmatory Phase III trial is actively recruiting patients with recent-onset Type 1 Diabetes in eight European countries and in the US. Significant results have previously been shown in a large genetically predefined patient group - in a large-scale meta-analysis as well as in the Company's prospective European Phase IIb trial, where Diamyd® was administered directly into a superficial lymph node in children and young adults with recently diagnosed Type 1 Diabetes. Injections into a superficial lymphnode can be performed in minutes and is intended to optimize the immune response. A biomanufacturing facility is under development in Umeå, Sweden, for the manufacture of recombinant GAD65 protein, the active ingredient in the antigen-specific immunotherapy Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® as a component in the treatments of metabolic diseases. Diamyd Medical is a major shareholder in the stem cell company NextCell Pharma AB as well as in the artificial intelligence company MainlyAI AB.

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.

Further information is available on <https://www.diamyd.com>

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