



Press release, November 13, 2025

Information about the Annual Report 2024/2025

Diamyd Medical today publishes its Annual Report for 2024/25. The Company is in an expansive phase where positive feedback has been received from the US Food and Drug Administration (FDA) regarding the possibility of earlier market approval. The Annual Report is published in Swedish. The English version is expected to be published around December 5, 2025.

- The development in type 1 diabetes has never had greater momentum, supported by a regulatory environment increasingly favoring disease-modifying therapies. With the FDA's fast track and orphan drug designations for our investigational therapy Diamyd®, the recognition of C-peptide as a surrogate marker that can support an accelerated approval pathway, and the approval of the disease-modifying drug TZIELD® (teplizumab), there is now clear regulatory alignment and growing payer recognition of the value of preserving the body's own insulin production. Diamyd Medical is leading the development of precision medicine and antigen-specific immunotherapy for type 1 diabetes. The antigen-specific immunotherapy Diamyd® combines genetic precision, a favorable safety profile, and clinical usability, defining a new class of targeted treatments that address the underlying cause of the disease.

At the end of the fiscal year Diamyd Medical had 277,2 (132,4) MSEK in cash and short-term investments. The company's total equity corresponded to 280,0 (145,9) MSEK.

About Diamyd Medical

Diamyd Medical develops precision medicine therapies to prevent and treat Type 1 Diabetes. Diamyd® is an investigational antigen-specific immunomodulatory therapeutic for the preservation of endogenous insulin production specifically for individuals carrying a HLA DR3-DQ2 gene. Diamyd® has been granted Orphan Drug Designation in the U.S. as well as Fast Track Designation by the U.S. FDA for the treatment of Stage 3 (symptomatic) Type 1 Diabetes. Diamyd® has also been granted Fast Track Designation for the treatment of Stage 1 and 2 (pre-symptomatic) Type 1 Diabetes. DIAGNODE-3, a confirmatory Phase III trial with potential for an accelerated approval pathway in the US is actively recruiting individuals with recent-onset Stage 3 Type 1 Diabetes at 57 clinics in eight European countries and in the US. Significant results in preserving endogenous insulin production have previously been shown in a large genetically predefined group of individuals with Stage 3 Type 1 Diabetes – both in a largescale meta-analysis as well as in the Company's prospective European Phase IIb trial. The DIAGNODE-3 trial is only including individuals that carry the common genotype known as HLA DR3-DQ2, which constitutes approximately 40 % of individuals with Type 1 Diabetes in Europe and the US. 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 is a shareholder in the stem cell company NextCell Pharma AB and 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.

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