



MEMORANDUM

**Diamyd Medical 4Q25 (F1Q26) Interim results for immunomodulatory precision therapy for T1D expected in under two months; insulin-based antigen treatment receives patent approvals – January 28, 2026**

**Executive Highlights**

- **Diamyd Medical announced results from its 4Q25 (F1Q26) report today through a [press release](#).** CEO Dr. Ulf Hannelius commented on the company’s focus on advancing retogatein, an antigen-specific immunomodulatory precision therapy for the treatment and prevention of T1D. While the company has previously referred to retogatein as Diamyd, the World Health Organization’s International Nonproprietary Names (INN) Program and the United States Adopted Names Council (USAN) assigned retogatein as the global non-proprietary name [earlier this month](#). As background, retogatein is a GAD65 protein-containing molecule for people with detectable GAD65 antibodies and the HLA DR3-DQ2 haplotype, which affects about 40% of people with T1D.
  - Diamyd Medical is entering the final stage of the pivotal phase 3 [DIAGNODE-3](#) trial (n=330) of retogatein. The trial has completed screening in the US and EU, with expected enrollment of approximately 310-320 patients with the HLA DR3-DQ2 haplotype.
  - Interim results of the DIAGNODE-3 trial are expected in less than two months (March 2026), which could support a Biologics License Application (BLA) under the FDA’s accelerated approval pathway. Following a Type C meeting, the FDA accepted the company’s proposal to change the timepoint for the primary efficacy readout from 24 to 15 months.
- **Diamyd Medical's insulin-based antigen treatment for people with T1D carrying the HLA DR4-DQ8 genetic marker** received patent approval in Eurasia and Hong Kong in [September 2025](#) and [October 2025](#), respectively. The patent is effective until 2038. These grants follow patent approvals in 11 markets, including South Korea in [January 2025](#) and the EU in [April 2025](#). Insulin-based antigen treatment for those with HLA DR4-DQ8 builds on retogatein, as the company estimates that 90% of people with T1D have at least one of the two genetic markers (HLA DR3-DQ2 and HLA DR4-DQ8).
- **On the financial front**, Diamyd Medical exited the quarter with \$26.5 million (SEK 233 million) in cash and short-term investments. This value compares to \$17 million (SEK 153 million) during the same period last year.

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## Top Highlights

### 1. Phase 3 DIAGNODE-3 trial results expected in less than two months; full trial results accepted for accelerated readout

Diamyd Medical is entering the final stage of the pivotal phase 3 [DIAGNODE-3](#) trial (n=330) of retogatein, a GAD65 protein-containing molecule for people with detectable GAD65 antibodies and the HLA DR3-DQ2 haplotype, which affects about 40% of people with T1D. While the company has previously referred to retogatein as Diamyd, the World Health Organization's International Nonproprietary Names (INN) Program and the United States Adopted Names Council (USAN) assigned retogatein as the global non-proprietary name [earlier this month](#). In today's press release, CEO Dr. Ulf Hannelius provided the following updates to the DIAGNODE-3 trial.

- **The trial has completed screening in the US and EU, with expected enrollment of approximately 310-320 patients with the HLA DR3-DQ2 haplotype.** Dr. Hannelius called this progress a “monumental achievement” that reflects coordination across teams in the EU and the US.
- **Interim results of the DIAGNODE-3 trial are expected in March 2026**, which could support a Biologics License Application (BLA) under the FDA's accelerated approval pathway. This readout will be based on results from approximately 170 individuals who, by that time, will have completed their 15-month visit, with C-peptide as the primary endpoint. Dr. Hannelius said the interim analysis will mark a key milestone as the company prepares for the next phases in regulatory, manufacturing, and pre-commercial operations.
- **Progress with the DIAGNODE-3 trial has been further strengthened by the company's discussions with the FDA.** [Last month](#), the company announced that the acceleration of the primary efficacy readout of DIAGNODE-3 trial by nine months. Following a Type C meeting, the FDA accepted the company's proposal to change the timepoint for the primary efficacy readout from 24 to 15 months. As well, the company has completed five independent safety reviews by the Data Safety Monitoring Board, supporting retogatein's safety profile. Looking ahead, Dr. Hannelius emphasized that the company's focus remains on fulfilling clinical and regulatory approaches with “rigor and transparency.”

### 2. Ongoing DiaPrecise trial of retogatein for presymptomatic T1D

The phase 2 [DiaPrecise](#) trial (n=16) of retogatein in people with stage 1 and stage 2 T1D continues to progress, following the completion of the first safety review in [April 2025](#). As background, the trial assesses the safety of retogatein in children and adolescents with presymptomatic T1D, aiming to position retogatein as an immunotherapy to delay or prevent the onset of clinical T1D. In [2Q25](#), the company announced that following treatment of the initial three participants in the trial, the Data Safety Monitoring Board reported no safety concerns related to the treatment, supporting continued enrollment in the study. According to [ClinicalTrial.gov](#), the trial is currently enrolling patients in Sweden, with an estimated completion date of December 2026.

### 3. Insulin-based antigen treatment for T1D receives patent approval by the Eurasian Patent Office and Hong Kong

Diamyd Medical's insulin-based antigen treatment for people with T1D carrying the HLA DR4-DQ8 genetic marker received patent approval in Eurasia and Hong Kong in [September 2025](#) and [October 2025](#), respectively. The patent is effective until 2038. These grants follow patent approvals in 11 markets, including South Korea in [January 2025](#) and the EU in [April 2025](#).

Dr. Hannelius said that people with T1D who have the HLA DR4-DQ8 genetic marker may particularly benefit from insulin-specific immunotherapy. Insulin-based antigen treatment for those with HLA DR4-DQ8 builds on retogatein, as the company estimates that 90% of people with T1D have at least one of the two genetic markers (HLA DR3-DQ2 and HLA DR4-DQ8).

## Close Concerns' Questions

1. How is Diamyd Medical increasing education and awareness about screening for HLA DR4-DQ8 and HLA DR3-DQ2?
2. What factors influenced the FDA's decision to accelerate the duration of the DIAGNODE-3 trial?
3. In what other regions will Diamyd Medical pursue patent approval for insulin-based antigen treatment?
4. How are patients treating the news that they may be positive for the HLA DR4-DQ8 gene? Once they find out they are positive, what should they do to keep up to date with news about the therapy's regulatory path?

-- by *Esther Min, Monica Oxenreiter, and Kelly Close*