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INITIATING COVERAGE
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Sweden
Healthcare

Research analysts:
Ludvig Svensson

Diamyd Medical

Share price: SEK9.4

Fair value range: SEK14.0–23.0

Targeting the root of autoimmune diabetes

Diamyd Medical is a Swedish biopharma company developing Diamyd, a first-in-class antigen-specific immunotherapy for type 1 diabetes (T1D) currently in Phase III development. Diamyd targets the autoimmune cause of T1D to preserve insulin production by teaching the immune system to tolerate GAD65, a protein active in insulin-producing beta cells and often the target of autoimmunity in T1D. Over 1,000 patients, both newly diagnosed and those at earlier stages of T1D, have been treated with Diamyd across 15 studies in the US and Europe, demonstrating a strong safety profile with more than 99% of participants completing the treatment.

The company is conducting a Phase III trial in T1D patients who carry the HLA DR3-DQ2 haplotype, present in up to 50% of the population. Positive interim results in July 2024 showed potential for the Phase III trial meeting its endpoint related to preservation of endogenous insulin production. A second interim analysis, expected in March 2026, will be the next key catalyst, with the potential to significantly move the share price. Positive results could support a BLA under the FDA's accelerated approval pathway, making Diamyd the first T1D therapy to reach the US market this way, in 2027.

Commercially, the opportunity with the Diamyd immunotherapy is substantial. The company's market research estimates an annual addressable population of ~60,000 in the US alone in its launch indication, which coupled with a high price point represents a blockbuster opportunity. Our model assumes a 2026 partnership deal worth SEK4,300m, including an upfront of SEK500m and 40% revenue share. Based on these key assumptions, we arrive at a fair value range of SEK14–23 per share, with the upcoming DIAGNODE-3 interim readout and potential partnership being the most important share price catalysts. This readout is crucial for the company's future, and a positive outcome could significantly de-risk the asset and boost investor confidence. Also, the company's fully-owned facility secures in-house production of Diamyd, supporting contract manufacturing and pipeline expansion.

Changes in this report

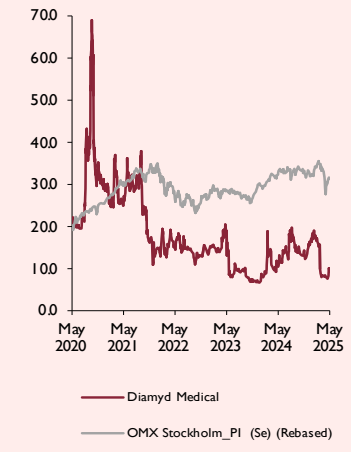
	From	To	Chg
EPS adj. 2025e	-1.52	-1.27	+17%
EPS adj. 2026e	-1.78	0.54	+130%
EPS adj. 2027e	-1.62	0.36	+122%

Key facts

No. shares (m)	137.3
Market cap. (USDm)	134
Market cap. (SEKm)	1,295
Net IB Debt. (SEKm)	-211
Adjustments (SEKm)	0
EV (2025e) (SEKm)	1,084
Free float	90.7%
Avg. daily vol. ('000)	609
Risk	High Risk
Fiscal year end	August
Share price as of (CET)	08 May 2025 00:00

Key figures (SEK)	2024	2025e	2026e	2027e
Sales (m)	0	0	233	170
EBITDA (m)	-136	-146	101	70
EBIT (m)	-147	-153	94	63
EPS	-1.60	-1.27	0.54	0.36
EPS adj.	-1.60	-1.27	0.54	0.36
DPS	0.00	0.00	0.00	0.00
Sales growth Y/Y	-76%	-92%	+chg	-27%
EPS adj. growth Y/Y	-chg	+chg	+chg	-33%
EBIT margin	n.m.	n.m.	40.2%	37.0%
P/E adj.	n.m.	n.m.	17.4	25.9
EV/EBIT	neg.	neg.	10.9	15.4
EV/EBITA	neg.	neg.	10.9	15.4
EV/EBITDA	neg.	neg.	10.1	13.9
P/BV	6.7	5.2	4.0	3.5
Dividend yield	0.0%	0.0%	0.0%	0.0%
FCF yield	-11.0%	-13.6%	5.1%	3.5%
Equity/Total Assets	67.2%	79.6%	81.9%	85.0%
ROCE	-96.0%	-77.5%	32.8%	18.1%
ROE adj.	-96.3%	-77.7%	26.1%	14.4%
Net IB debt/EBITDA	1.0	1.4	-2.7	-4.6

Share price - 5Y



High/Low (12M) SEK19.7/7.6

Perf.	3M	6M	12M	YTD
Abs.	-43.5	-28.3	-10.3	-42.4
Rel.	-35.5	-23.8	-6.5	-40.6

Source: Carnegie Research, FactSet, Millistream & company data

Equity story

Near term: 6–12m

In the short term, the biggest catalyst we see for Diamyd Medical's share price will be the interim results from the DIAGNODE-3 trial, which we expect in March 2026. This readout is crucial for the company's future, and a positive outcome could significantly de-risk the Diamyd asset and boost investor confidence.

Long term: 5Y+

The company's long-term success hinges on Diamyd receiving market approval and the company striking an attractive licensing deal with a commercially strong partner, enabling it to generate revenue through milestones and royalties. These funds could then support ongoing R&D efforts for pipeline projects.

3 Key risks to investment case:

- Failure in clinical trials
- Partner dependence
- Financing

Company description

Diamyd Medical is a Swedish biotech company developing treatments for autoimmune diabetes.

Key industry drivers

- Precision medicine gaining traction
- Regulatory tailwinds
- First approval of disease modifying therapy

Industry Outlook

- Significant potential in untapped market. The company estimates an annual addressable population of 60,000 in the US alone in its launch indication, which coupled with a high price point represents a blockbuster opportunity.

Largest shareholders

Avanza Pension	12.2%
Bertil Lindkvist	8.2%
Nordnet Pension	5.0%

Cyclicality

Cyclicality: N/A

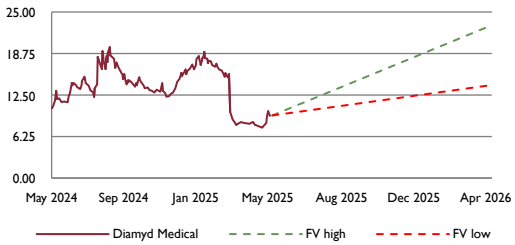
Key peers

Ascelia Pharma, Egetis Therapeutics

Valuation and methodology

Our fair value range is based on DCF-based sum-of-the-parts valuations. Our assumptions include a partnership deal for Diamyd in 2026 with a total value of SEK4,300m, comprising an upfront payment of SEK500m, contingent on positive top-line results from the interim analysis from DIAGNODE-3 in March 2026. Additionally, we estimate Diamyd Medical will receive 40% of net sales for Diamyd in a revenue share agreement.

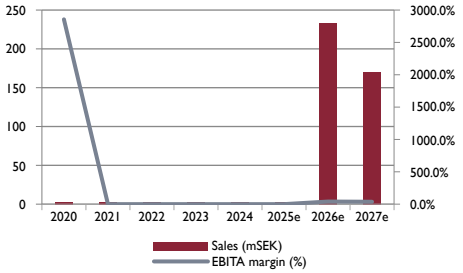
Upside/downside spectrum 12m



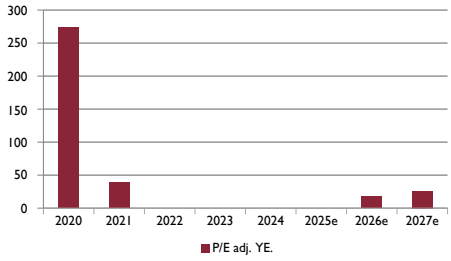
The lower end of our fair value range is based on our DCF-based SOTP model using a WACC of 20%.

The upper end of our fair value range is based on our DCF-based SOTP model using a WACC of 13%.

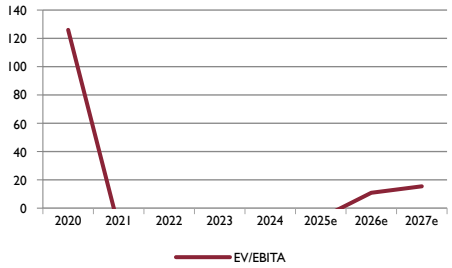
Key metrics



PE 12m forward



Long term valuation trend



Source: Carnegie Research & company data

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Investment thesis

Diamyd Medical is a Swedish biopharmaceutical company pioneering precision medicine for type 1 diabetes (T1D). The company is developing Diamyd, a first-in-class antigen-specific immunotherapy designed to slow or even stop the progression of autoimmune T1D. T1D is an autoimmune disease that advances through three stages – starting with pre-symptomatic (early) stages 1 and 2, and culminating in symptomatic (clinical) stage 3 diabetes, almost always requiring insulin therapy. Unlike current diabetes treatments that focus on symptom management, Diamyd targets the underlying immune response to help preserve insulin production and therefore can address all T1D stages. In total, over 1,000 patients across stage 1–3 T1D have been exposed to Diamyd within clinical studies in the US and Europe, and more than 99% participants have completed the treatment across 15 studies, showcasing a very benign safety profile.

Over a decade ago, Diamyd Medical faced a major setback in the development of Diamyd, then in Phase III trials for T1D. At the time, the company had a partnership with Johnson & Johnson, which brought both funding and credibility to the project. However, the European Phase III trial failed to show a benefit in preserving beta-cell function, and the US Phase III trial was halted in early 2012 due to a low likelihood of success. Following these failures, Diamyd Medical underwent a major restructuring, and by mid-2012, J&J terminated its partnership. We believe this setback still lingers over the company's reputation today.

In the years that followed, Diamyd Medical revisited its clinical data and discovered that treatment response varied depending on the patient's genetic profile. This led to a new focus on individuals with the HLA DR3-DQ2 haplotype, found in up to 50% of T1D patients. Building on these insights, the company successfully completed a Phase IIb trial and showed preservation of endogenous insulin production in this subgroup.

Now, over a decade later, the company is conducting a new pivotal Phase III trial, DIAGNODE-3. This trial is evaluating the efficacy of Diamyd in newly diagnosed T1D patients (stage 3) who carry the HLA DR3-DQ2 genotype. In July 2024, the company announced a positive outcome from an interim analysis deigned to detect futility (i.e. whether it is unlikely the treatment will show meaningful benefit) from the trial, indicating the potential to preserve insulin production in T1D patients, measured as the surrogate endpoint "C-peptide". The interim analysis was based on data from 74 patients over six months, and to preserve trial integrity the results were only reviewed by an independent Data Safety Monitoring Board that confirmed the trial's potential to deliver significant results for the full study size and recommended continuing continuation as planned.

Next up, a second interim efficacy analysis, expected in March 2026, will evaluate 15-month data from 170 patients. This is an important event. If positive, these results could support a BLA under the FDA's accelerated approval pathway, allowing Diamyd to reach the market faster. This would make Diamyd Medical the first company globally to bring a T1D treatment to market through accelerated approval in the US. For the European market, the European Medicines Agency (EMA) has stated that only one Phase III trial is needed for approval but has not currently granted any accelerated pathway to market.

Diamyd Medical's wholly-owned Umeå facility is a strategic asset providing full control over the production of recombinant GAD65, the active ingredient in Diamyd, ensuring quality and scalability for late-stage clinical trials and future commercialization. In addition to securing the supply chain for Diamyd, the facility opens up revenue-generating opportunities through contract manufacturing, in-house analytical services, and future pipeline expansion, positioning Diamyd Medical as a scalable biotech platform. The 24,000-square-foot facility is fully operational, housing cleanrooms, a quality control lab, and process development capabilities, with process characterisation and GMP certification by the Swedish Medical Products Agency set for 2025 – key milestones ahead of a BLA submission and subsequent FDA inspection.

Market wise, the initial opportunity for Diamyd is substantial, driven by a clearly defined patient group and high unmet need. We estimate around 48,000 newly diagnosed T1D cases annually in the US, with approximately 35% carrying the HLA DR3-DQ2 haplotype. Also, an additional opportunity exists among recently diagnosed patients who retain beta cell function for up to two years following diagnosis. Combined, the company sees an annual addressable population of 60,000 in the US alone. This does not factor in potential off-label and indication expansion opportunities for the product, as well as market potential outside the US.

Diamyd Medical's own market research suggests that Diamyd could achieve peak annual sales well above blockbuster levels (>USD1bn) in the US alone. Our sales model is based on recently diagnosed patients and we assume peak sales of ~USD900m by 2033, building on a 30% market penetration and a price of USD150,000 in the US in this group. Important catalysts for sales estimates upgrades include securing a strong commercial partner for launch and generating additional clinical data demonstrating durable efficacy.

We assign Diamyd in the initial T1D indication a 65% likelihood of approval, which is based on the historic probability within the endocrine/autoimmune space but adjusted upwards due to the orphan drug status. We assume a partnership deal for Diamyd in 2026 worth SEK4,300m, including an upfront payment following positive interim DIAGNODE-3 results. We also estimate Diamyd Medical will earn 40% of Diamyd net sales. If our estimates hold, and a licensing deal materialises in 2026, the company will turn cash flow positive already in 2026.

Based on these key assumptions, we initiate coverage with a fair value range of SEK14–23 per share, using a DCF model with a WACC between 20% and 13%. We currently exclude the company's pipeline product Remygen from our valuation due to the lack of a clear development plan. The upcoming DIAGNODE-3 interim readout and potential partnership are the most important share price catalysts that we see.

Company introduction

Diamyd Medical develops therapies for autoimmune diabetes, targeting the disease's root cause. Its lead candidate, Diamyd, is currently being evaluated in a Phase III trial.

Diamyd Medical is a Swedish biotech company developing treatments for autoimmune diabetes. Unlike many traditional approaches that focus on managing symptoms, the company aims to address the root cause of these diseases: the immune system attacking the body's insulin-producing beta cells.

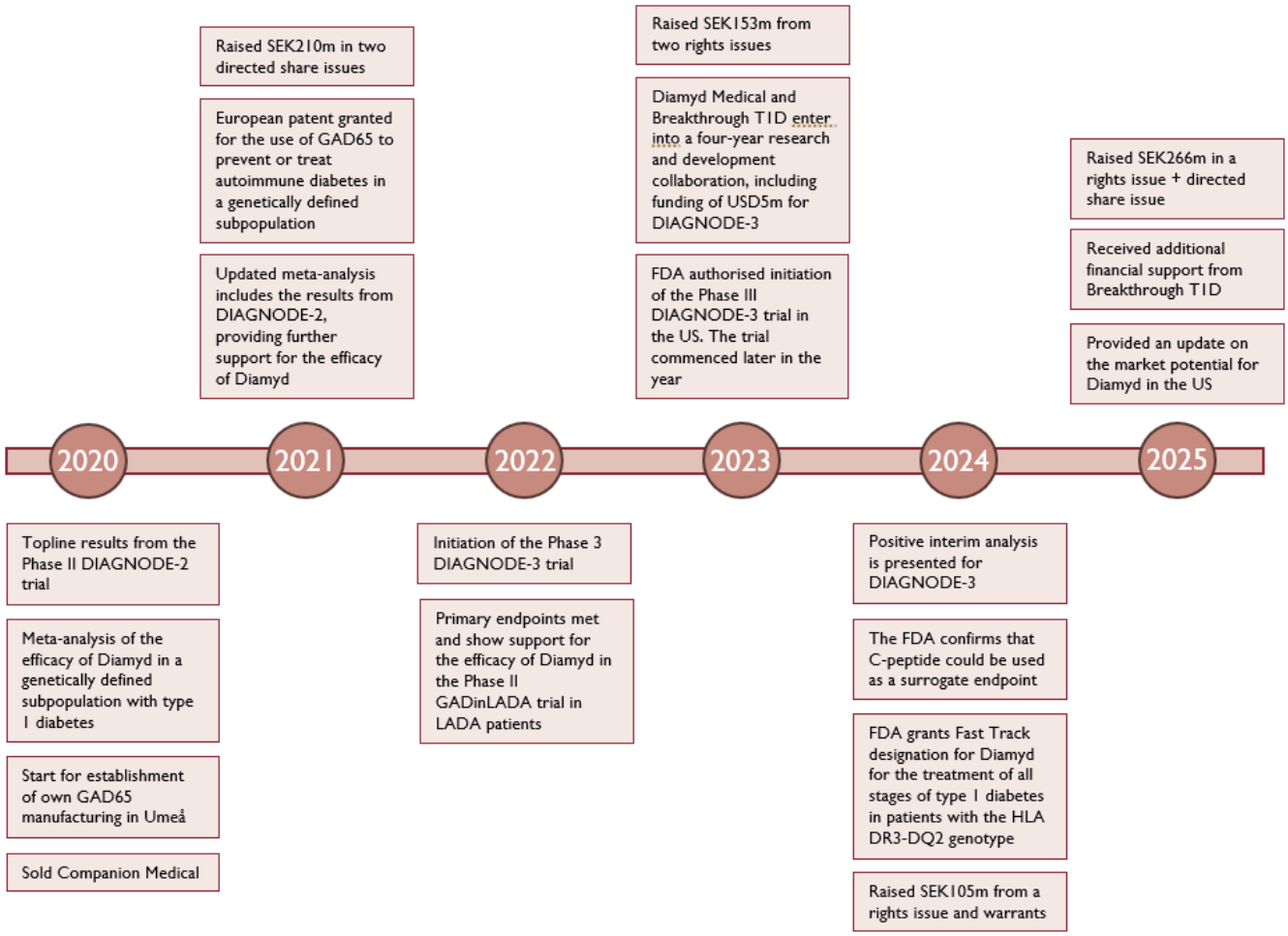
At the core of Diamyd Medical's efforts is its lead product, Diamyd, an antigen-specific immunotherapy designed to modulate the immune system to tolerate GAD65-directed autoimmunity in order to slow or stop disease progression in patients across all stages of T1D. The therapy is currently being evaluated in a Phase III clinical trial (DIAGNODE-3), targeting patients with stage 3 T1D carrying the HLA DR3-DQ2 genotype.

Worth to highlight is that Diamyd Medical has a partnership with Breakthrough T1D, a leading global organisation dedicated to T1D research. As part of this collaboration, Breakthrough T1D is supporting Diamyd Medical pivotal study, DIAGNODE-3, through a four-year research and development partnership. This includes USD6.75m in funding to help drive the trial forward. Also, Breakthrough T1D assists the company with such things as patient recruitment and regulatory applications.

Company history

Diamyd Medical was founded in mid-1990s by Anders Essen-Möller after his daughter was diagnosed with T1D. Motivated by the need for better treatments and a potential cure, he founded the company to develop innovative therapies for autoimmune diabetes. Anders-Essen Möller secured key intellectual property rights through an exclusive licence from the University of California, Los Angeles (UCLA) and the company started conducting research on Diamyd.

Historical timeline for Diamyd Medical (2020–25)



Source: Company Reports, Carnegie Research

Over a decade ago, Diamyd Medical's Phase III trial failed, prompting the halt of its US study in 2011. As a result, Johnson & Johnson terminated their partnership, leading to a major restructuring of the company.

Over a decade ago, Diamyd Medical faced a major setback in its development of Diamyd, which was then in late-stage development for T1D. At the time, Diamyd had a partnership with Johnson & Johnson, which had invested in the development of Diamyd through a licensing agreement signed in 2010. The licensing agreement with J&J was signed about one year ahead of the Phase III readout. This collaboration had brought both funding and credibility to the project, as J&J saw potential in Diamyd's ability to alter the course of T1D.

The company suffered a blow when its European Phase III trial showed no significant benefit in preserving beta-cell function. The company continued its US Phase III trial, but in 2011, it decided to halt the study, realising that the likelihood of achieving a meaningful outcome was too low. The failure of these trials forced the company to reassess its strategy, and later that year, it announced a major restructuring. After the discouraging results, J&J terminated its agreement with Diamyd Medical in mid-2011, effectively ending its financial support for the project.

In the following years, Diamyd Medical spent time going through the data set and found that patients responded to the treatment differently depending on their genetic profile. With these findings, the company went on conducting a Phase IIb trial, which showed positive results in patients with the HLA DR3-DQ2 haplotype, thus validating the precision medicine concept based on HLA genetics. It is now once again being evaluated in a Phase III trial, with decisive interim data expected in March 2026.

Diamyd – the company's leading project

Diamyd targets autoimmune diabetes by retraining the immune system to stop attacking insulin-producing beta cells. Using GAD65, it aims to preserve natural insulin production, potentially slowing or preventing disease progression.

Diamyd is an immunotherapy designed to slow or prevent the progression of T1D by targeting the autoimmune attack on insulin-producing beta cells. It is based on GAD65, a protein found in pancreatic beta cells involved in cell signalling. In T1D, the immune system often erroneously targets GAD65 and launches an attack on beta cells. This autoimmune response is a key factor in contributing to the loss of beta cell function.

Diamyd is currently the only drug in Phase III development for T1D. It has received Fast Track designation from the FDA for the treatment of stage 1, 2, and 3 T1D. Additionally, it has been granted orphan drug status for stage 3 T1D. In short, T1D develops in three stages. In stage 1, autoantibodies appear as the immune system attacks beta cells, but blood sugar remains normal, and there are no symptoms. In stage 2, blood sugar levels become irregular, though symptoms are still absent. By stage 3, the disease is fully diagnosed, with hyperglycaemia, elevated HbA1c, and the need for insulin therapy.

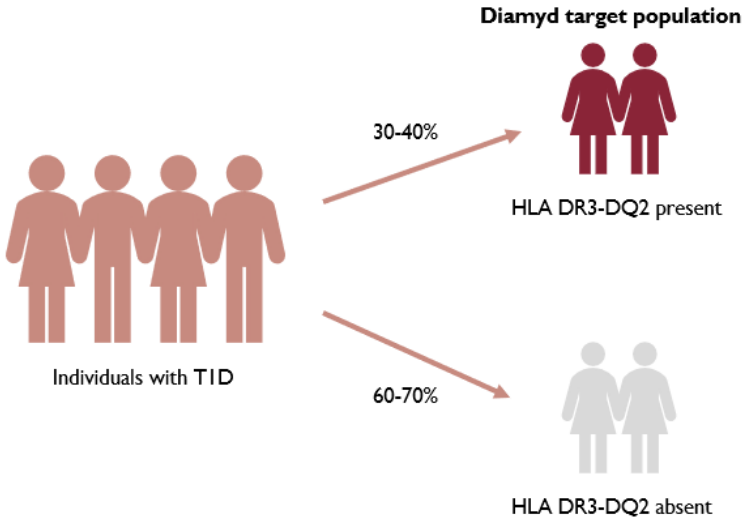
In the immune system's reaction to GAD65, the production of anti-GAD65 autoantibodies (GADA) is often induced. These autoantibodies are often detectable long before someone develops symptoms of T1D, making them a valuable early marker for predicting the disease. When a person tests positive for GADA it usually means their immune system is actively destroying beta cells. This process eventually leads to insulin dependence. GADA is also found in latent autoimmune diabetes in adults (LADA), a slow-progressing form of autoimmune diabetes that can initially look like T2D but that the field today increasingly sees as slowly-progressing T1D in adults.

Since GAD65 is one of the main targets of the immune system in T1D, the hypothesis is that GAD65 in a controlled way could "teach" the immune system to tolerate it instead of attacking it. This is the idea behind Diamyd. The therapy involves the targeted delivery of recombinant GAD65 to desensitise the immune system and prevent further damage to insulin-producing cells. If successful, this approach could help preserve some natural insulin production, reducing the severity of diabetes and potentially delaying full insulin dependence.

Another exciting possibility for Diamyd is its potential use as a preventive therapy, targeting the early stages of T1D. Results from the investigator-initiated DiAPREV-IT trials have been promising, hinting that Diamyd might help delay or even prevent the onset of the disease (clinical, stage 3 T1D) in high-risk individuals. Currently the company is conducting a pilot-trial DIAPRECISE in this indication. Securing approval for preventive use, however, may be challenging, as it would likely require large, long-term studies to demonstrate a statistically significant effect.

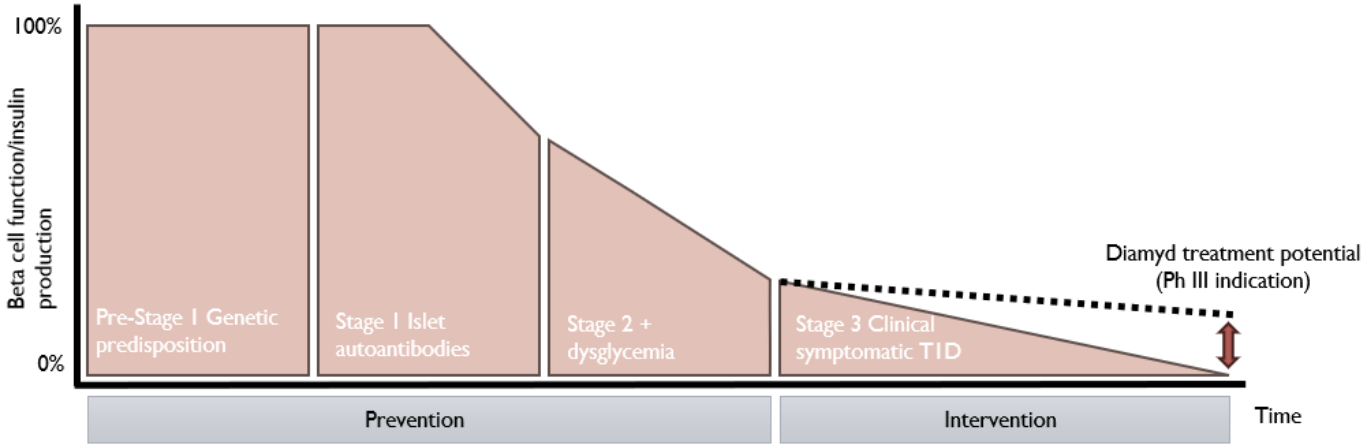
Diamyd is administered through intralymphatic injections, with three doses given four weeks apart. A radiologist or trained professional performs the procedure, using ultrasound guidance to deliver the injections directly into a superficial lymph node. This precise approach targets the immune system effectively, and the pain level is comparable to that of a routine blood draw.

Target patient population for Diamyd



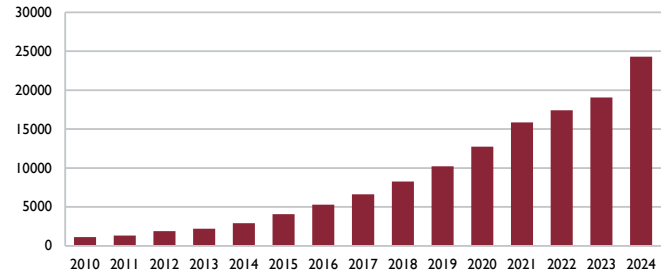
Source: Company material, Carnegie Research

Illustrative decline of functional beta cell mass in autoimmune diabetes



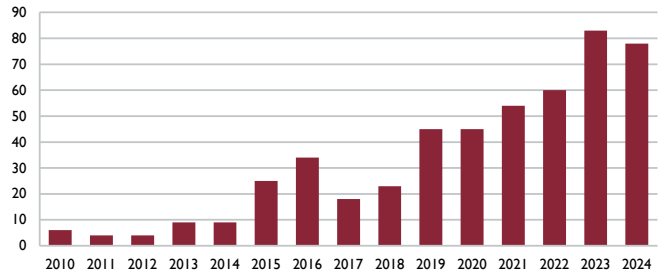
Source: Company material, Carnegie Research

Annual publication volume on precision medicine



Source: PubMed, Carnegie Research

Annual publication volume on precision medicine & Type 1 diabetes



Source: PubMed, Carnegie Research

Preserving natural insulin production in T1D helps stabilise blood sugar, reduces insulin needs, lowers the risk of severe hypoglycaemia, and protects against long-term complications like eye, kidney, nerve, and heart disease.

Why is it important to preserve endogenous insulin production?

Preserving a T1D patient's ability to produce their own insulin is an important treatment goal because it makes managing the disease easier and helps prevent complications. Even a small amount of natural insulin production can help regulate blood sugar levels more effectively, leading to fewer extreme highs and lows. This means patients experience more stable blood sugar levels, require less injected insulin, and are at a lower risk of severe hypoglycaemia. Keeping some beta-cell function also provides long-term benefits, including a lower risk of complications like eye disease, kidney damage, nerve issues, and heart problems (Steffes et al, 2003).

A 2022 study (Nowak et al.) found that Diamyd responders maintained better C-peptide levels, correlating with lower HbA1c. This highlights the importance of preserving natural insulin production and supports C-peptide as a key trial endpoint for beta-cell preservation therapies.

Correlation between C-peptide and HbA1c

C-peptide is a biomarker for endogenous insulin secretion. It is commonly used as a surrogate endpoint in clinical trials assessing investigational beta cell-preserving therapies.

A study from Nowak et al, 2022, provides evidence on the relationship between C-peptide levels and blood sugar control (HbA1c) in T1D. This individual patient meta-analysis examined data from four randomised controlled trials of Diamyd in individuals recently diagnosed with T1D. The study assessed the correlation between C-peptide and HbA1c, stratifying patients based on the presence of the HLA DR3-DQ2 and whether they received two injections or three to four injections of either Diamyd or a placebo. The primary outcome measured was the difference in C-peptide levels between the Diamyd and placebo groups after 15 months of treatment.

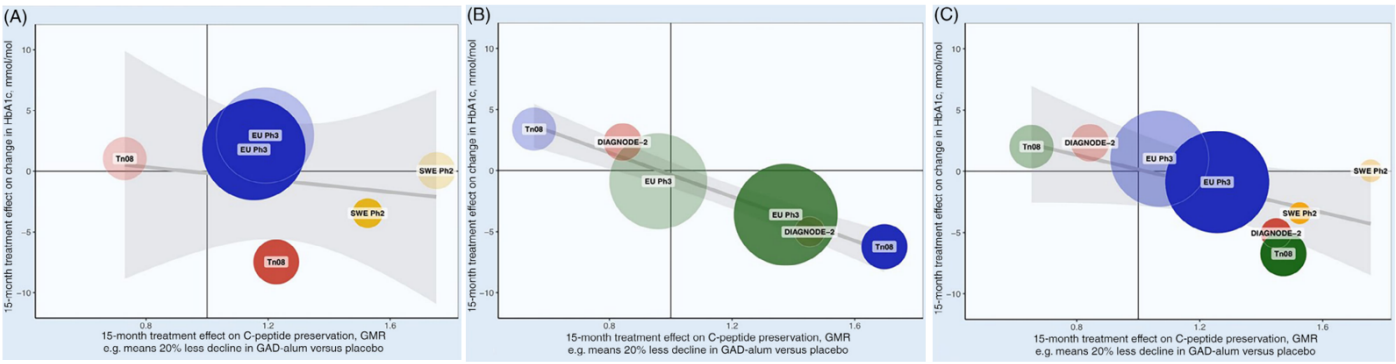
Results showed that patients that responded well to Diamyd maintained better C-peptide levels, which in turn correlated with lower HbA1c. This suggests that even preserving a small amount of natural insulin production can have a meaningful impact on glucose management. It also reinforces the idea that C-peptide could be used as a primary endpoint in clinical trials, as it provides a clear indication of whether a treatment is helping to slow beta-cell loss.

Fact box: Surrogate endpoints

Surrogate endpoints in clinical trials are substitutes for direct measures of clinical outcomes. Instead of waiting for the actual clinical event (e.g., death, heart attack, disease progression), researchers use a biomarker or intermediate outcome that is correlated with the real clinical outcome. FDA and EMA can allow drugs to be approved based on surrogate endpoints, particularly in accelerated approvals. In the case of Diamyd, C-peptide is considered by the FDA a surrogate endpoint reasonably likely to predict clinical benefit of preserving endogenous insulin production. HbA1c, a measure of the patient's average blood sugar levels over the past 2–3 months, is a validated surrogate endpoint also used in the DIAGNODE-3 trial.

The picture below shows the correlation between C-peptide (x-axis) and HbA1c (y-axis). Each circle represents a randomised controlled trial, with larger circles indicating larger sample sizes. A treatment effect is considered beneficial when C-peptide values are greater than 1 on the x-axis and HbA1c values are below 0 on the y-axis. Panels A, B, and C represent different dosing groups: A (two), B (three-four), and C (all combined).

Association between C-peptide and HbA1C, change from baseline to month 15 compared with placebo



Source: Nowak et al, 2022., Carnegie Research

The company has opened a biomanufacturing facility in Umeå, Sweden, to produce GAD65, the key ingredient in its diabetes treatment. The facility enhances production control, efficiency, and scalability, and is being set up according to GMP standards with the aim to supporting clinical trials and future demand for the drug.

Production facility in Umeå

Diamyd Medical has established a biomanufacturing facility in Umeå, Sweden, to produce recombinant GAD65, the active ingredient in Diamyd. The facility, covering around 24,000 square feet, includes clean rooms, laboratories, warehousing, and office spaces, and is designed to meet the company's needs for clinical trial production and potential future demand.

Previously, the production of GAD65 was outsourced to the US. By moving manufacturing to Umeå, Diamyd Medical aims to gain more control over the production process and bring expertise in cell culture and protein purification closer to its operations. This transition is intended to improve efficiency and ensure a reliable supply of the product. The facility is equipped with Cytiva's FlexFactory platform, a bioprocess manufacturing system that supports production using a baculovirus-insect cell expression system. This system is designed to provide a scalable and controlled environment for manufacturing while adhering to Good Manufacturing Practice (GMP) standards.

In addition to its primary focus on GAD65 production for Diamyd, the facility has the capacity to support other biopharmaceutical projects, leveraging its infrastructure and technical capabilities.

Proof of concept and clinical data

Diamyd has conducted 15 clinical studies with over 1,000 patients, maintaining a treatment completion of >99%.

Diamyd has been evaluated in several clinical studies over the past years. In our view, the meta-analysis and Phase IIb study with Diamyd represents the most important milestones in the company's R&D efforts. In total, over 1000 patients have been exposed to Diamyd within clinical studies and treatment completion >99% across 15 studies. There have not been any major safety events in the clinical development. The most common adverse events include transient tenderness at injection site, injection site edema, mild injection site pain and injection site reaction that commonly resolve within seven days.

Completed clinical trials

Trial	Type	Indication	Product	Participants	Sponsor	Results	Completion
DIAGNODE-B	Phase 2b	Has type 1 diabetes and the HLA DR3-DQ2 genotype, and has previ ously been treated with Diamyd	Diamyd	6	Linköping University	The primary endpoints of safety and tolera bility were met after 12 months and the trial showed support for a mild disease pro gression up to 8 years from type 1 diabetes diagnosis.	2023
ReGenerate-1 P	Phase 1/ Phase 2	Type 1 diabetes	Remygen	35	Uppsala University	Remygen met the primary safety end point but there was no clear support for a sustained treatment effect on increased endogenous insulin production.	2023
GADinLADA	Phase 1/ Phase 2	Newly diagnosed LADA	Diamyd	15	NTU Trondheim	The trial showed positive results and the participants remained insulin-independent 12 months after treatment, among those with the HLA DR3-DQ2 genotype.	2022
DIAGNODE-2	Phase 2b	Newly diagnosed type 1 diabetes	Diamyd	109	Diamyd Medical	The trial showed positive results and sig nificant treatment efficacy for Diamyd® in patients with the HLA DR3-DQ2 genotype.	2021
Meta-analysis	N/A	Newly diagnosed type 1 diabetes	Diamyd	521	Diamyd Medical	Retrospective meta-analysis of three earlier clinical trials showed significant impact of the HLA genotype on the clinical effect of Diamyd®. Laid the foundation for the preci sion medicine approach for Diamyd® among patients with the HLA DR3-DQ2 genotype.	2020
DIAGNODE-1	Phase 1/ Phase 2	Newly diagnosed type 1 diabetes	Diamyd	12	Linköping University	The trial showed positive results and the par ticipants showed a decrease in the need for exogenous insulin and close to normal blood glucose levels.	2018

Source: Company Data, Carnegie Research

Phase IIb trial

The Phase IIb trial of Diamyd in 109 young T1D patients showed no overall benefit in preserving C-peptide levels. However, those with the HLA DR3-DQ2 haplotype had significant improvements in C-peptide and HbA1c

This Phase IIb trial was a randomised, double-blind, placebo-controlled study designed to test whether intralymphatic injections of Diamyd, combined with vitamin D supplementation, could help preserve beta-cell function in young people with recently diagnosed T1D. A total of 109 participants, aged 12 to 24, who had been diagnosed with T1D within the past six months, were enrolled and randomly assigned to receive either the active treatment or a placebo. The study included a prespecified genetic analysis to see if patients carrying the HLA DR3-DQ2 haplotype responded differently to treatment.

Those in the treatment group received three injections of 4 µg Diamyd at one-month intervals, along with daily oral vitamin D for four months. The primary endpoint in the study was to track changes in stimulated serum C-peptide levels over 15 months. Secondary outcomes included changes in HbA1c levels, insulin use, and immune system responses to see if the treatment had broader effects on disease progression.

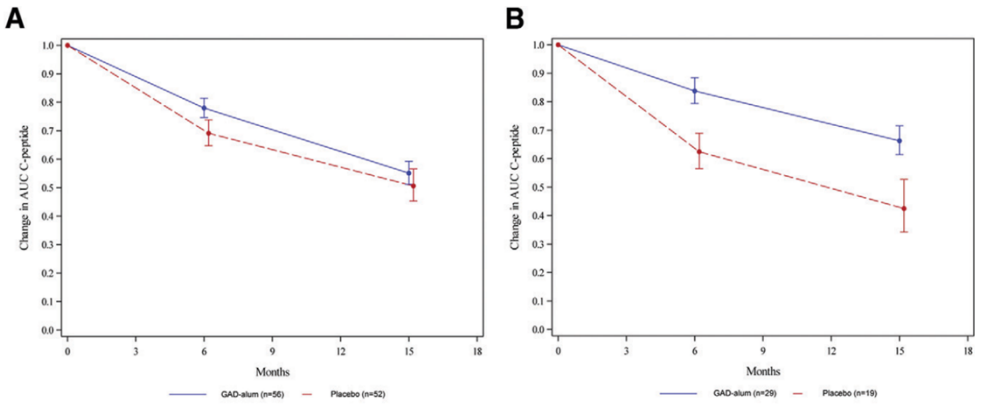
The results did not show any difference between the Diamyd group and placebo in the global study population on the primary endpoint (C-peptide). However, patients with the HLA DR3-DQ2 haplotype did see a statistically significant benefit on the primary endpoint, with better

preservation of C-peptide levels compared to placebo. Also, a strong trend for improved HbA1c levels was seen in this subgroup as well as statistically significant improvement in glycaemic control measured as more Time-in-Range (glycaemic target range), less time in hyperglycaemia and less glycaemic variability.

In the graphs below, we see the effect on C-peptide over time in the global study population (A) and in the HLA DR3-DQ2 subgroup (B). We can clearly see that the confidence intervals overlap both at the 9-month and 15-month timepoint for the global study population (which means that it is not statistically significant), while the effect is significant at both time periods in the HLA DR3-DQ2 subgroup (B). The increased effectiveness in the HLA DR3-DQ2 subgroup seems to be driven by a greater preservation of C-peptide in the treatment group, but may also be affected by a steeper drop in the placebo group compared to the global study population. We find some support among studies that patients with HLA DR3-DQ2 tend to have a more aggressive disease, which may be an explanation behind the steeper drop in the curve.

We believe that these findings are very promising. This is the first time the company showed benefit with Diamyd in the HLA DR3-DQ2 population in a prospective setting. In our view, it provides a clear rationale for the ongoing Phase III study, which uses the same primary endpoint.

Primary endpoint (change in stimulated serum C-peptide)



Source: Ludvigsson et al., 2021

One of the limitations in this study, in our view, is that the sample size, particularly in the genetic subgroup, was relatively small, increasing the risk that the observed effect could be due to chance (type 1 error). The follow-up period of 15 months is also relatively short, leaving uncertainty about whether the benefits seen in the genetic subgroup would persist over time. Additionally, because vitamin D was included in the treatment regimen, it remains unclear whether the observed effects were driven by GAD-alum alone or if vitamin D played a role.

Meta-analysis and the HLA DR3-DQ2 haplotype

A 2020 meta-analysis found Diamyd significantly preserved C-peptide in HLA-DR3-DQ2 carriers, with a dose-dependent effect, but showed no benefit in others. This supports targeting Diamyd to HLA-DR3-DQ2 patients rather than the broader T1D population.

There is growing recognition that genetics, particularly HLA genotype, plays a key role not just in determining who develops T1D, but also in how the disease progresses. It is also likely that these genetic factors influence how well antigen-specific immunotherapies like Diamyd work.

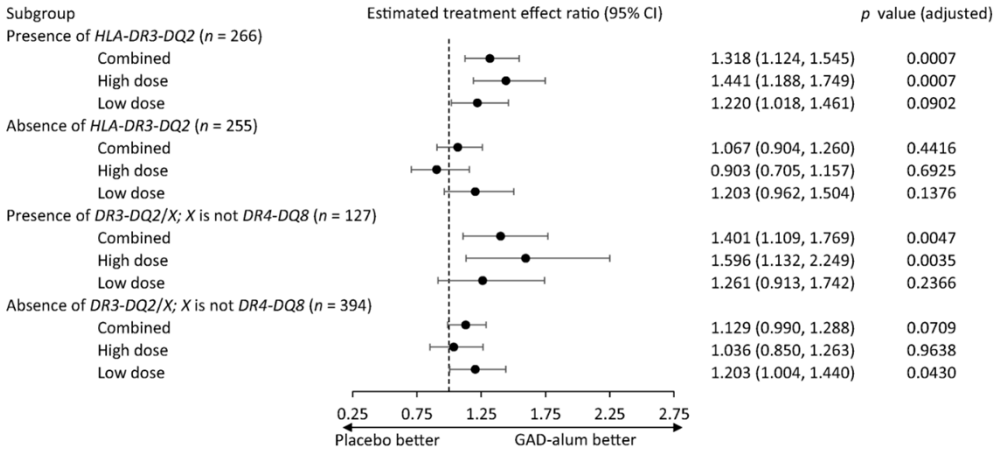
A meta-analysis by Hannelius et al., published in Diabetologia in October 2020, explored the impact of Diamyd on preserving pancreatic beta-cell function in individuals with recently diagnosed T1D. The design of the trial included combined analysis of data from three randomised, placebo-controlled clinical trials, involving a total of 521 participants who were recently diagnosed with T1D. These individuals were divided based on their genetic profile, whether they carried the HLA-DR3-DQ2 or HLA-DR4-DQ8 haplotype. Participants received

either two, three, or four injections of Diamyd, or a placebo, and the primary outcome measured was the change in C-peptide levels over 15 months.

Results showed that almost all subgroups across all dose levels favoured Diamyd treatment over placebo. A significant and dose-dependent effect was observed in patients carrying the HLA-DR3-DQ2. Also, in this subgroup of patients, the higher dose of Diamyd performed better than the lower dose. Patients who did not carry the HLA-DR3-DQ2 haplotype did not exhibit any significant benefit from Diamyd, reinforcing the idea that the treatment may not be universally effective but could be optimised based on individual genetic risk factors.

Our conclusion from the results from this study is that there is a clear rationale for Diamyd to target the subgroup of patients carrying the HLA-DR3-DQ2 haplotype, rather than a global T1D diabetes population. Furthermore, the company has from its studies concluded that there is a potential "super responder" group consisting of patients who carry HLA-DR3-DQ2, but not the HLA-DR4-DQ8 haplotype.

Efficacy of Diamyd associated with HLA-DR3-DQ2 in recently diagnosed T1D patients



Source: Hannelius et al., 2020, Carnegie Research

DIAGNODE-3 study

The DIAGNODE-3 trial is a Phase III study evaluating Diamyd's ability to preserve insulin production in newly diagnosed T1D patients with the HLA DR3-DQ2 haplotype. Positive interim results from 74 participants support the trial's continuation, with further analysis due in 2026 potentially enabling an accelerated FDA approval.

The DIAGNODE-3 trial is a Phase III, placebo-controlled study designed to evaluate the efficacy and safety of Diamyd in individuals recently diagnosed with T1D who carry the HLA DR3-DQ2 haplotype. This genetic marker, present in up to 50% of T1D patients in Western countries, represents a key subgroup for targeted treatment. The study is being conducted in the US and eight European countries: Sweden, Spain, the Czech Republic, the Netherlands, Germany, Poland, Hungary, and Estonia. In total, the study involves approximately 60 clinics worldwide, which ensures a robust data collection from a representative patient population.

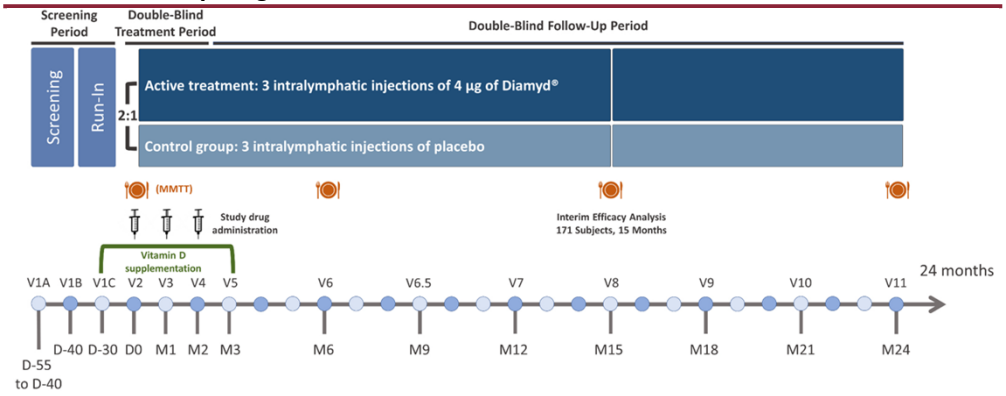
The study is a 2-arm, randomised, double-blind, placebo-controlled, multi-centre, clinical trial. At the first screening visit, patients will undergo HLA genotyping. Those found to carry the HLA DR3-DQ2 haplotype will proceed to a second screening visit for additional procedures. Eligible participants will receive three injections of Diamyd or a placebo into an inguinal lymph node, with one month apart, along with oral vitamin D supplementation.

The trial aims to enrol approximately 330 participants, aged 12 to 28, all diagnosed with T1D within the past six months. Patients will be randomly assigned to receive either Diamyd or a placebo. The primary objective is to assess the treatment's ability to preserve the body's own insulin production over a 24-month period, with stimulated C-peptide levels and changes in HbA1c levels serving as primary endpoints. Secondary endpoints include change in time in glycaemic target range, proportion of patients with a stimulated c-peptide above a set clinically

relevant limit (0.2 nmol/L), proportion of patients with a HbA1c <7% (53mmol/mol), change in daily insulin requirements, change in number of hypoglycaemic events (< 3.0 mmol/L), incidence of hypoglycaemic important glycaemic events.

The company has publicly shared that it has now screened more than 600 patients in the DIAGNODE-3 trial. Given that it has now recruited more than 220 patients, it implies that at least about 40% of general T1D patients fit the criteria of the study. This could be a good indicator of how big a share of the T1D diabetes population will be eligible for treatment with Diamyd in a commercial setting.

DIAGNODE-3 study design



Source: Ludvigsson et al., 2022

Positive interim data in 2024 – a significant milestone

In July 2024, an interim analysis of DIAGNODE-3 showed promising results for preserving insulin production, and the independent safety board recommended the trial continue as planned.

In July 2024, the company announced positive results from an interim analysis of the DIAGNODE-3 trial. The analysis focused was designed to detect futility of the trial by focusing on the likelihood of achieving one of the trial's key goals: preserving the body's ability to produce insulin, measured through stimulated C-peptide levels. The analysis looked at six-month data from 74 patients and to maintain the trial integrity the result was assessed by an independent Data Safety Monitoring Board (DSMB). Based on the data, the DSMB concluded that the trial has potential to achieve its objectives and gave a green light to continue the trial as planned.

The path forward towards market approval

An interim DIAGNODE-3 analysis is due by March 2026. Positive results could lead to FDA accelerated approval, making Diamyd Medical the first to bring a T1D therapy to market this way. The EMA requires only one Phase III trial but has not yet granted an accelerated pathway.

Another interim analysis for efficacy is now planned, with results expected in March 2026. This analysis focuses on data from 171 participants who have completed their 15-month assessments. If these results are positive, they could serve as the basis for a Biologics License Application (BLA) under the FDA's accelerated approval pathway. Importantly, the FDA, has, in a historic decision, approved this pathway for Diamyd, recognising stimulated C-peptide levels as a reasonably likely surrogate endpoint for clinical benefit. This provides an opportunity to potentially bring Diamyd to market faster than would be possible through a traditional approval pathway. This makes Diamyd Medical the first company in the world with the potential to bring its T1D treatment to market through an accelerated approval process in the US.

The EMA has communicated that only one Phase III study is required for approval. However, it has not granted an accelerated pathway to market. We believe there is a possibility that the EMA could reconsider this process if the company delivers positive interim data in March 2026 and the FDA moves forward with an accelerated approval. The FDA and EMA often align in their regulatory decisions. A comparative study from 2019 found that the two agencies reached the same approval decision in 91–98% of cases (Kashoki et al., 2019).

Biologic rationale behind HLA DR3-DQ2 and Diamyd treatment

Diamyd is most effective in patients with the HLA-DR3-DQ2 haplotype, where autoimmunity targets GAD. clinical and biological data support using GAD-based therapy specifically for this genetic group.

As the connection between HLA-DR3-DQ2 and the treatment effect with Diamyd is based on clinical data generated though a post-hoc analysis, we find it particularly relevant to question if there is any biologic rational behind this connection.

HLA-DR3-DQ2 is not only associated with an increased risk of T1D but also with primary autoimmunity. Individuals with this haplotype often develop autoantibodies first specifically against GAD, while those with the other major haplotype, HLA-DR4-DQ8, are more prone to develop antibodies first against insulin. The hypothesis is that if an individual is more reactive to GAD65, immune modulation by treatment with GAD to induce tolerance is more likely to succeed. However, if an individual is less reactive to GAD65 and more reactive to e.g. insulin, a GAD-based treatment may not be as effective.

This theory was further reinforced last summer when the "oral insulin study" was published. The study showed that patients with HLA-DR4-DQ8 responded better to oral insulin treatment (Zhao et al., 2024).

So, in conclusion, the progression of T1D depends on the patient's genetic profile, with different antigens playing a key role. For individuals with the HLA DR3-DQ2 haplotype, the GAD antigen is most relevant. In contrast, for those with the HLA DR4-DQ8 haplotype, insulin becomes the primary antigen driving the disease.

Overall, this provides further support for the idea that an individual's HLA type influences the drivers of autoimmunity and, consequently, which type of antigen-based treatment would be most effective. In the future, the company plans to expand its platform to also include patients where insulin is the driver of T1D. If successful, this would significantly grow Diamyd's reach – from covering around 30–40% of people with T1D today to potentially up to 90% of all patients.

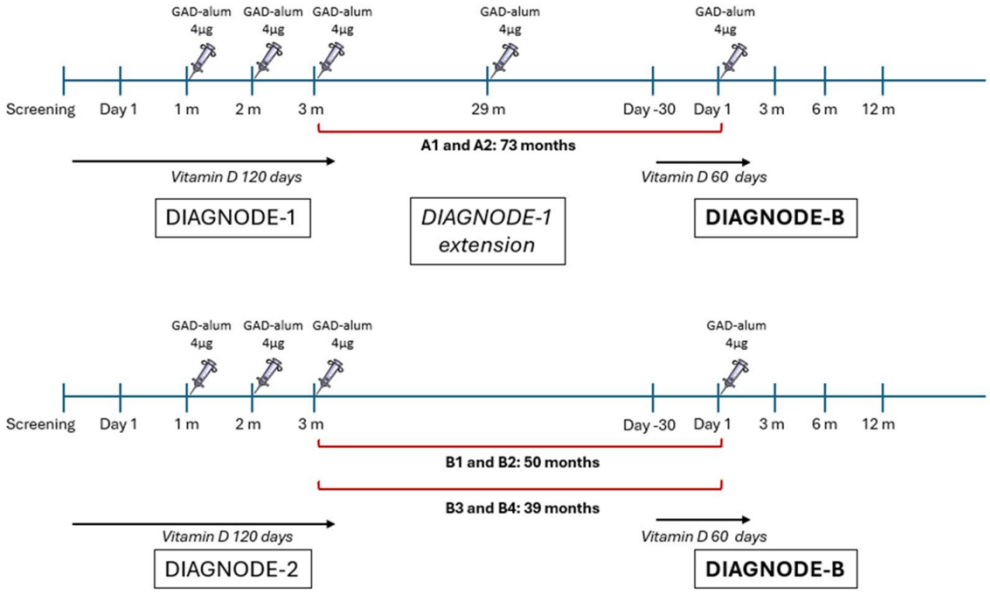
DIAGNODE B

The DIAGNODE-B pilot trial tested an additional Diamyd injection in six HLA-DR3-DQ2 patients from prior trials. It was well-tolerated, with stable C-peptide levels, improved HbA1c, and reduced insulin use.

The DIAGNODE-B pilot trial was an open-label Phase I/II study designed to explore whether an additional intralymphatic injection of Diamyd is safe and feasible for people with T1D who had previously received the treatment. The study included six participants, all carrying the HLA DR3-DQ2 haplotype, who had previously taken part in either the DIAGNODE-1 or DIAGNODE-2 trials. Each participant received a single additional 4 µg dose of Diamyd injected into an inguinal lymph node, along with daily vitamin D supplementation for two months, beginning one month before the injection.

The main goal was to assess the safety and tolerability of redosing Diamyd over a 12-month period. Secondary measures looked at changes in beta-cell function, tracked through stimulated C-peptide levels in a Mixed-Meal Tolerance Test (MMTT), as well as monitoring HbA1c levels, insulin use, and immune system responses.

Design of DIAGNODE-B clinical trial



Source: Casas et al, 2025., Carnegie Research

The results showed that the re-dosing with Diamyd was well-tolerated, with no serious side effects reported. Most participants maintained stable C-peptide levels, indicating little decline in beta-cell function over the study period. There were also signs of improved blood sugar control, as shown by stable or slightly improved HbA1c levels and a reduction in daily insulin requirements. Immune system tests revealed an increase in cytokine responses, particularly IL-13, after the redosing.

However, the study had some limitations. The sample size was small, and there was no control group, making it difficult to draw firm conclusions. Additionally, the duration of diabetes varied among participants at the time of redosing, which could have influenced the results.

DiaPrecise

Initiated in 2024, the DiaPrecise trial is aimed at assessing the safety of Diamyd in children. It is a Phase II open-label trial evaluating Diamyd in children aged 8 to 18 years who are at high risk (Stage 1 or Stage 2) of developing T1D and carry the HLA DR3-DQ2 genotype. The study aims to assess the safety and feasibility of two or three intralymphatic injections of Diamyd, while also evaluating its impact on the immune system, endogenous insulin production, and blood sugar control. The trial is currently screening for subjects with 10–16 expected to be included. The company reported in April 2025 that the trial has cleared its first safety milestone following treatment of the initial three participants.

Diabetes

Diabetes includes a group of diseases where the body struggles to produce or use insulin properly, leading to high blood sugar levels. T1D is autoimmune, where the immune system attacks insulin-producing cells, while type 2 occurs when the body becomes less sensitive to insulin. If left untreated, diabetes can cause serious, life-threatening conditions.

Diabetes is a collective term for a group of diseases characterised by elevated blood sugar levels caused by the body's inability to produce or respond to the hormone insulin. Insulin is a vital hormone that regulates the ability of cells to absorb energy in the form of sugar (glucose) from the blood. The disease is usually divided into two types: autoimmune diabetes (T1D) and T2D. In T1D, the body's immune system attacks its own insulin-producing cells in the pancreas. In T2D diabetes, the cells in the body have developed a reduced sensitivity to insulin, meaning the available insulin cannot be effectively used.

In a healthy individual, the body regulates blood sugar with the help of two hormones: insulin and glucagon, which are secreted by beta cells and alpha cells in the pancreas, respectively. In diabetes, there is an imbalance between insulin and glucagon. Insulin is essential for the body's cells to absorb and use sugar (glucose) from food to produce chemical energy (ATP).

In diabetes, sugar is not absorbed by the cells but remains in the blood, causing blood sugar levels to rise. The energy needs inside the cells are compensated by extracting energy from fat and protein, which releases ketones as a byproduct of fat breakdown. When these ketones are further processed in the liver, acetone is produced, lowering the blood's pH level. If this process continues for a long time, it can affect the brain and eventually lead to diabetic coma (ketoacidosis). The high blood sugar levels caused by diabetes are harmful to the body's organs and are strongly linked to an increased risk of complications, including eye problems, kidney issues, and cardiovascular disease.

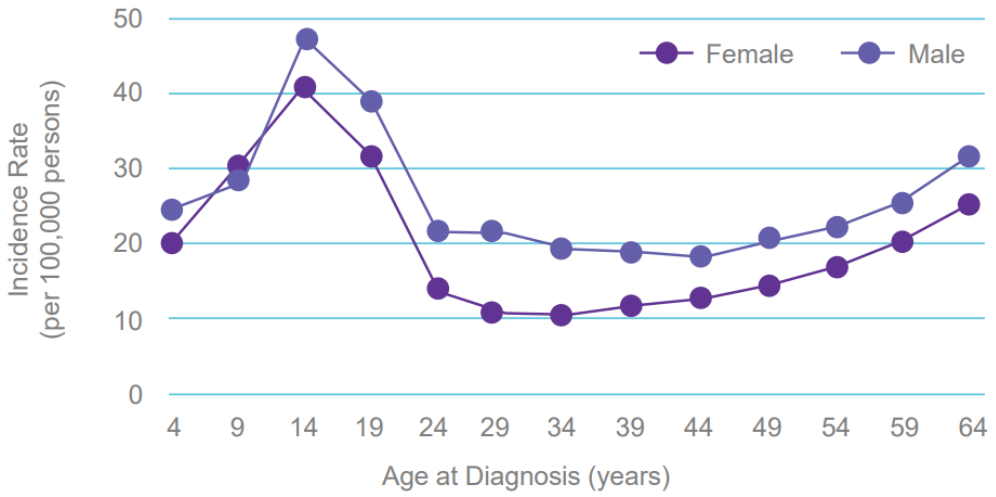
Type 1 diabetes (T1D)

Type 1 diabetes is a chronic condition where the immune system destroys insulin-producing beta cells, often starting long before symptoms appear. It progresses through three stages: silent autoimmunity, impaired glucose regulation, and full-blown diabetes, requiring lifelong insulin therapy.

T1D is a chronic disease that requires around-the-clock management and primarily affects children and young people. In T1D, the body's immune system attacks the insulin-producing beta cells, which are gradually destroyed. The incidence of T1D peaks at approximately 12 years of age, and children diagnosed by age 10 years have a reduced life expectancy by 16 years (Rawshani et al., 2018). Currently, there are no approved medications that can restore the body's ability to produce its own insulin.

Even in the early stages of the autoimmune attack, when the body's blood sugar regulation is still normal, ongoing beta cell directed autoimmunity can be detected through diabetes-related autoantibodies. At a later stage, reduced glucose regulation becomes apparent due to the decreasing number of insulin-producing beta cells, indicating the impact of the autoimmune destruction process. The immune system's breakdown of beta cells begins long before the patient experiences symptoms. Clinical symptoms and a T1D diagnosis typically occur only when 10–20% of beta cell function remains. At this point, the body can no longer produce sufficient insulin, leading to a life-threatening condition.

Incidence rates for type 1 diabetes by age at diagnosis and sex, US, 2001–15

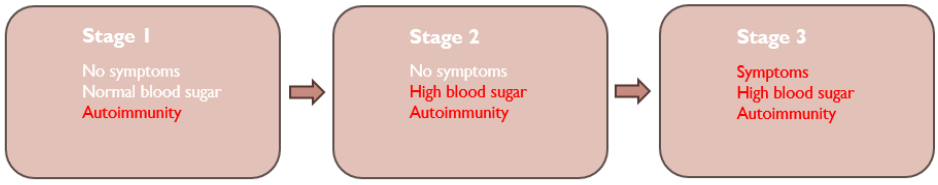


Source: Rawshani et al., 2018, Provention Bio Corporate Presentation

Type 1 diabetes progresses in three stages. In the first stage, autoantibodies appear as the immune system attacks beta cells, but blood sugar remains normal, and there are no symptoms. In the second stage, blood sugar levels become irregular, though symptoms are still absent. By the third stage, the disease is fully diagnosed, with hyperglycaemia, elevated HbA1c, and the need for insulin therapy.

Over the past 30–40 years, we have come to understand that T1D progresses through distinct stages, rather than appearing suddenly. This insight has shifted the way we think about the disease and how it might be treated or even delayed. In the **first stage**, the immune system begins to attack pancreatic beta cells, and specific autoantibodies can be detected. Despite this, blood sugar levels stay within normal ranges, and people have no symptoms. This stage is typically discovered through screening, often in those with a family history of the disease, and while the person remains symptom-free, the risk of developing diabetes is significantly higher. The **second stage** is marked by ongoing autoimmunity and the emergence of irregularities in blood sugar levels. Glucose regulation starts to falter, showing signs like impaired fasting glucose or glucose intolerance, yet symptoms of diabetes still have not appeared. At this point, the beta cells are struggling, hinting at the progression toward the symptomatic phase of T1D. By the **third stage,** T1D is clinically diagnosed. This is when the typical symptoms appear. Blood tests will reveal hyperglycaemia and elevated HbA1c levels, indicating significant beta-cell loss. Insulin therapy becomes essential at this stage to control blood sugar and manage the disease. From this point on, patients require lifelong insulin treatment.

The disease progression in T1D



Source Company Material, Carnegie Research

One of the first symptoms of diabetes is often a significant increase in urine production (polyuria). Other signs include excessive thirst (polydipsia), dry mouth, extreme fatigue, weight loss, acetone-scented breath, and difficulties with depth perception. Without correction through insulin therapy, the condition becomes fatal.

Since the body does not produce enough insulin, the affected individual must learn to manage the life-sustaining treatment required around the clock with externally supplied insulin, either through injections or a pump. To ensure the body receives the correct amount of insulin to maintain blood sugar balance, blood sugar levels are monitored consistently.

Both excessively high and low levels can be acutely life-threatening. Low blood sugar levels can result in hypoglycaemia, which may lead to coma, brain damage, or even sudden death. High blood sugar levels, on the other hand, indicate a lack of insulin and require intensive care to prevent fatal outcomes. Prolonged elevated blood sugar levels over time lead to serious and costly complications, such as cardiovascular diseases, kidney failure, blindness, and amputations.

Living with T1D can mean up to 35 fewer years of healthy life, and a life span that is 15–20 years shorter than average. People with T1D also face a tenfold increased risk of cardiovascular disease. So, in targeting T1D, Diamyd is not just addressing the condition itself, it is also tackling a major driver of cardiovascular disease.

Adult-onset T1D or Latent autoimmune diabetes in adults (LADA)

LADA is a slow-progressing form of autoimmune diabetes often mistaken for type 2 diabetes. It initially responds to lifestyle changes and oral medications but typically requires insulin therapy within a few years. LADA affects adults and likely accounts for 6–20% of type 2 diabetes cases.

Latent autoimmune diabetes in adults (LADA) is a form of diabetes similar to T1D, as insulin production is destroyed due to an autoimmune reaction – meaning the body attacks and breaks down its insulin-producing beta cells. Like T1D, the exact cause of LADA remains unknown but is believed to result from a combination of genetic predisposition and external factors. LADA typically affects adults and is sometimes mistaken for type 2 diabetes because its progression is slower than classical T1D, and patients are not initially dependent on external insulin. In the early stages, LADA can often be managed with lifestyle changes and oral medications that lower blood sugar levels. However, after a few years, insulin injections are usually required. It is estimated that 6–20% of all individuals diagnosed with T2D may actually have LADA.

According to the latest guidelines from the American Diabetes Association, individuals with LADA are now officially classified as having T1D. LADA is essentially a slowly progressing form of T1D that develops in adults. That said, we recognise that many physicians and endocrinologists may still view LADA as a T2D variant, simply because it typically appears later in life.

In its US market update published in January, the company estimates that LADA affects approximately 7% of the 1.2m adults diagnosed annually with T2D in the US. This would imply a patient population north of 80,000 patients, which is a similar or even larger opportunity than the T1D population.

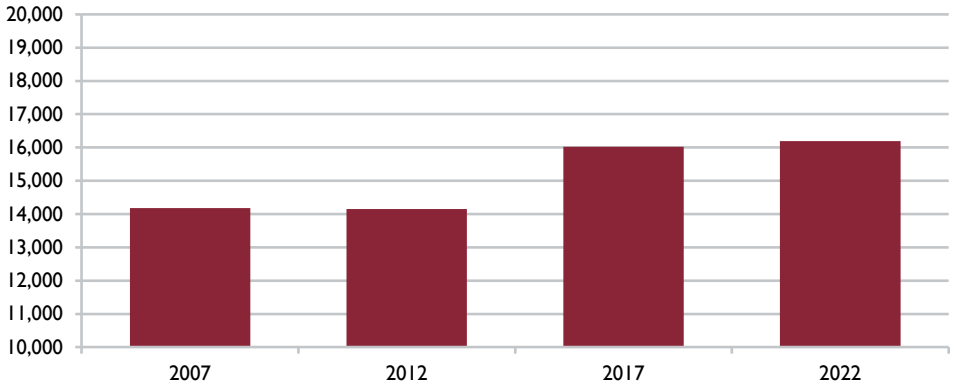
The regulatory pathway

The best-case scenario would be if LADA patients were included in a potential label for Diamyd based on the DIAGNODE-3 study. However, in our view, regulatory authorities, particularly the FDA, tend to take a conservative approach. We anticipate that an additional study exclusively recruiting LADA patients will be required for approval in this patient group. That said, some off-label use in LADA patients may occur before official approval is granted.

Burden of diabetes

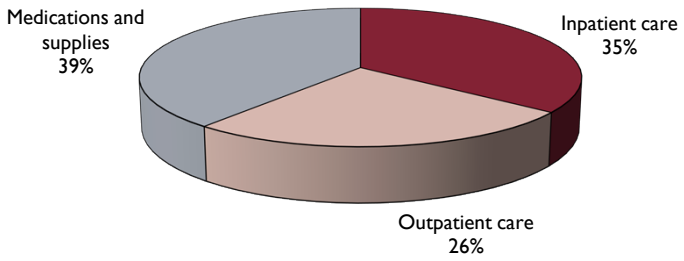
In a Diabetes Care article from 2017, the total cost of diagnosed diabetes was estimated at USD327bn, which includes USD237bn in direct medical costs and USD90bn in reduced productivity. Care for people diagnosed with diabetes accounts for one in four healthcare dollars in the US. Additionally, diabetes reduces the quality of life, leading to daily management challenges, mental health issues such as depression, and long-term disability. This burden affects not only patients but also their families and caregivers.

Annual healthcare cost per person with diabetes in the US (USD)



Source: Parker et al. 2023, Carnegie Research

Distribution of costs for a diabetes patient



Source: Parker et al. 2023, Carnegie Research

Market overview

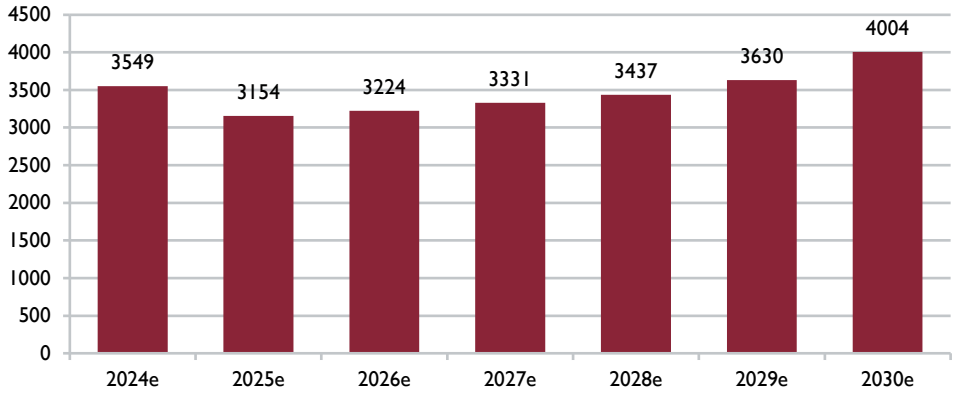
Insulin remains the standard treatment for T1D, given its availability, affordability, and safety. The T1D market is much smaller than T2D, which has surged with GLP-1 therapies like Ozempic. T1D drug sales exceed USD3bn annually, projected to surpass USD4bn, driven by TZIELD, with potential growth from new therapies like Diamyd.

The foundation of type 1 diabetes (T1D) treatment is insulin therapy, because people with T1D cannot produce enough or any insulin on their own. Insulin has been off patent for many years, making it widely available and relatively affordable. It also has an extremely documented safety profile. While there have been numerous attempts to develop novel therapies for T1D, success has been limited, and insulin remains the standard of care. We believe it will continue to do so for the foreseeable future.

When it comes to market potential, T1D is significantly smaller than type 2 diabetes (T2D). This is largely due to the much higher prevalence of T2D, which affects a far greater number of people worldwide. Additionally, the T2D market has experienced a major boost in recent years with the introduction of semaglutide (Ozempic, Wegovy) and other GLP-1 receptor agonists, driving strong growth and investment in the sector.

According to data and analyst estimates from Evaluate Pharma, the top 10 products for T1D currently generate over USD3bn in annual global sales. This number is expected to surpass USD4bn, largely driven by increased sales of TZIELD. However, these projections do not account for a potential launch of Diamyd or other therapies under development, which could further impact the market size.

Estimated global market size of T1D, top 10 products (USDm)



Source: EvaluatePharma, Carnegie Research

TZIELD

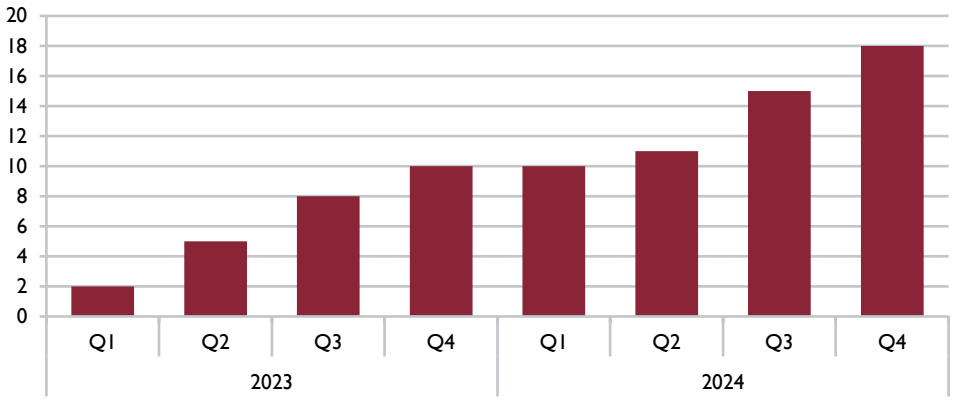
TZIELD, FDA approved in November 2022, is the first drug to delay stage 3 T1D in at-risk patients. Marketed by Sanofi, it is also in a Phase III trial for newly diagnosed T1D. Despite a slow US launch, with EUR54m sales in 2024, uptake is expected to grow, with forecasts exceeding USD570m by 2030.

TZIELD is a biologic drug designed to delay the progression to stage 3 T1D in adults and children aged eight and older who are at risk (stage 2 T1D). The FDA approved it in November 2022, making it the first and only approved treatment for preventing the onset of stage 3 T1D. Marketed by Sanofi, TZIELD was also studied in a phase III trial to evaluate its potential for treating newly diagnosed stage 3 T1D patients. The product is not yet approved in Europe.

TZIELD was launched in the US market in late 2022 following its approval. However, its market uptake has been slower than expected. In its first year (2023), sales reached EUR25m, and while that number grew to EUR54m in 2024, it was not as good as analysts' initial projections.

One reason for TZIELD's relatively slow launch is the lack of established screening programmes to identify patients in stage 2 T1D. Since this is the first disease-modifying treatment approved for T1D, limited clinician awareness and patient education have also likely played a role in its slower-than-expected adoption. According to Evaluate Pharma consensus estimates, the uptake for TZIELD is likely to improve in the coming years and in 2030 sales are forecast to exceed USD570m.

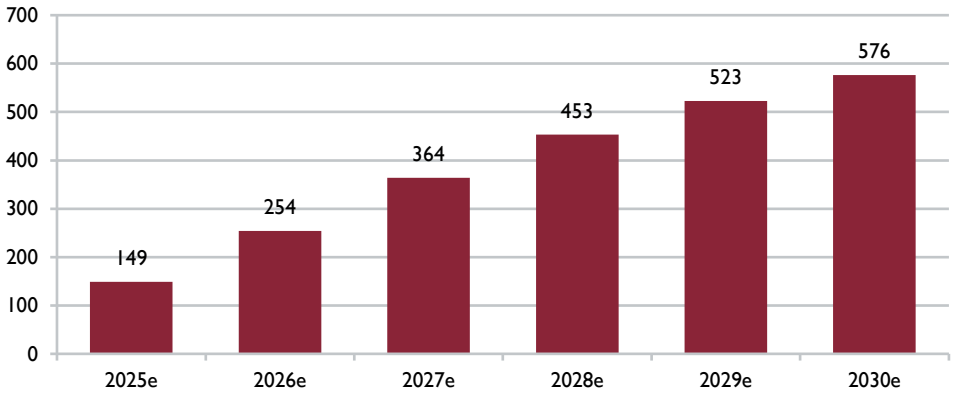
TZIELD sales (EURm)*



*Q1,Q2,Q3 2023 unknown but sums up to EUR15m

Source: Company Reports, Carnegie Research

TZIELD consensus sales estimates (USDm)



Source: EvaluatePharma, Carnegie Research

Cell therapies

Cell therapies show promise for T1D but pose no immediate threat to Diamyd due to manufacturing challenges, scalability issues, and high costs, limiting near-term adoption.

Cell therapies are promising new approaches to treating T1D, focusing on tackling the root cause of the disease. Generally, the goal is to restore or replace lost insulin-producing beta cells or even reprogram other cells to take over their function, potentially offering a long-term solution for people with T1D.

While promising, we do not see cell therapies as a significant threat to Diamyd's market potential at this stage. The manufacturing and scaling of these therapies remain complex, making large-scale production of functional beta cells from stem cells or donor sources both technically challenging and costly. Beyond production hurdles, we believe cost is another major barrier for a broader adoption of these treatments. Given the complex manufacturing process and the specialised care required for patients, cell therapies are likely to come with a hefty price tag. Also, we do not believe cell therapies will be used for stage 1 and 2 T1D.

Here are some of the, in our view, most important cell therapies for T1D:

UP421

Sana Biotechnology, a US-based biotech company, is developing UP421 – a donor-derived allogeneic islet cell therapy aimed at treating T1D without the need for immunosuppression. In a recent update, the company shared results from a single patient who received the therapy. Four weeks after the islet cells were transplanted into the patient's arm, the treatment showed no signs of immune rejection and was associated with steady c-peptide production, suggesting that the transplanted cells were functioning as intended. While this is in an early stage, we believe it an interesting approach as it represents a potential cure for T1D.

Lantidra

In 2023, the FDA approved Lantidra, the first cell therapy for the treatment of T1D. Lantidra is a cell therapy made from insulin-producing cells taken from deceased donors. It helps adults with T1D who struggle with severe or frequent low blood sugar (hypoglycaemia), especially those who cannot sense when their blood sugar is dropping. The transplanted cells work by producing insulin, helping to regulate blood sugar levels.

Despite its potential, Lantidra's market adoption has faced challenges. Since its FDA approval in June 2023, Lantidra has been available exclusively at the University of Illinois Hospital (UIH) in Chicago. Since the therapy relies on donor islet cells, finding a suitable match through the United Network for Organ Sharing can limit availability. Lantidra is expected to generate sales of USD200m by 2029, according to GlobalData patient-based forecasts.

VCTX211

VCTX211 is a stem cell therapy developed by CRISPR Therapeutics and ViaCyte. It is currently in Phase I/II development. The therapy uses gene-edited, donor-derived cells to create insulin-producing cells that can evade the immune system – potentially eliminating the need for lifelong immunosuppression. The goal of this therapy is to restore the body's natural ability to produce insulin in response to blood sugar levels. According to Evaluate Pharma consensus, this drug is expected to reach sales of over USD220m in 2030.

VX-880

VX-880 is an experimental treatment from Vertex Pharmaceuticals. It works by infusing patients with lab-grown, insulin-producing islet cells, with the goal of restoring the body's natural ability to control blood sugar levels. Following promising data in a Phase I/II trial, this therapy is now going to be evaluated in a pivotal trial.

Remygen – the company's second project

Remygen is an oral GABA-based therapy aiming to regenerate insulin-producing cells and treat T1D and T2D. Diamyd Medical holds exclusive rights to GABA patents from UCLA and has advanced the programme through preclinical and clinical studies.

Remygen is an oral regenerative and immunomodulatory therapy aimed at treating autoimmune diabetes and T2D by stimulating the growth of insulin-producing cells, thereby increasing patients' own insulin production. The goal is to provide treatment for both T1D and T1D, where a common issue is the deficiency of insulin-producing cells.

GABA (gamma-aminobutyric acid) is a neurotransmitter in the central nervous system. Preclinical studies have shown that GABA can improve beta cell function and contribute to the regeneration of insulin-producing beta cell tissue, leading to better blood sugar control. Research has also indicated that GABA may enhance insulin sensitivity, regulate inflammation in metabolic syndrome, and help mitigate the progression of other inflammatory diseases, such as rheumatoid arthritis.

The company believes that there is a big interest in GABA from major pharmaceutical companies. GABA could pave the way for a new class of diabetes medications with a unique mechanism of action for the treatment of both autoimmune and T2D.

In 2013, Diamyd Medical signed an agreement for exclusive rights to a portfolio of GABA-related patents with the University of California, Los Angeles (UCLA) in the US. Since then, the company has further developed the value of GABA through preclinical and clinical studies in T1D.

We note that the company is currently prioritising Diamyd and its precision medicine antigen-specific platform while evaluating the next development step including potential partnerships for Remygen.

Financials

Income statement

Sales

Geographical scope: When estimating sales for Diamyd, we include the US and the EU4 (Germany, France, Spain, Italy) + the UK in our model. The US and Europe have many similarities in their regulatory framework, and we believe that clinical data generated in each region can be leveraged for market submissions in both markets. We see RoW as an option for potential upside to our estimates.

Patient population: Although the incidence rate of T1D and the proportion of patients with the HLA DR3-DQ2 haplotype vary significantly between countries, a large-scale study conducted in the US between 2001 and 2015 estimated the annual incidence of T1D (ages 0–64) at approximately 64,000 new cases. The Centers for Disease Control and Prevention (CDC) reports that approximately 23% of these cases go undiagnosed, suggesting that the number of diagnosed cases is around 49,000 per year. In its updated US market potential calculation, Diamyd Medical estimates an annual diagnosis rate of 47,000 patients, which closely aligns with these figures. Based on this data, we assume an annual 48,000 diagnosed cases in the US. Due to the lack of reliable data for Europe, we choose to extrapolate the incidence data found in the study mentioned earlier to the European population, resulting in a diagnosed population of approximately 45,000 patients annually in the EU4+UK.

Regarding the prevalence of the HLA DR3-DQ2 genotype and GADA in T1D patients, we have seen studies indicating that up to 50% of individuals with T1D carry this genetic marker (Kircher et al., 2017). In the DIAGNODE-3 trial, the company reports having screened over 600 patients and successfully recruited more than 220 participants. This suggests that about 35% of the general T1D population has met the study's eligibility criteria, which we believe provides a useful estimate of the potential share of T1D patients who could qualify for Diamyd treatment commercially. We assume 35%, which implies a population of 17,000 and 16,000 in the US and EU4+UK, respectively. We understand that the company sees potential in treating patients who are not newly diagnosed but still produce some of their own insulin. While this in our view makes sense, we also acknowledge that this group is not part of the Phase III protocol, and we have chosen not to include them in our model for now. This is an opportunity of upside in our estimates.

Although the DIAGNODE-3 study, and consequently a potential label for Diamyd, will only cover patients aged 12 and older, we suspect that doctors may still prescribe it off-label for younger children. However, we believe that an additional study will be necessary to obtain official approval for paediatric use in the US. The company is currently pursuing the DiaPrecise trial, which is evaluating the safety of Diamyd in a younger paediatric population, in stage 1/ stage 2 T1D.

While a label expansion into LADA patients would increase the TAM significantly, we currently exclude this patient population from our estimates. We currently assume it would require an additional trial only including LADA patients to receive a market approval for this population. We do however acknowledge that there is a possibility that LADA patients may get included in the label given that ADA now sees LADA as a form of T1D.

Below we have conducted a sensitivity analysis in which we have evaluated the market potential in the US for Diamyd with different scenarios in terms of prevalence numbers and list price. We can see that the market potential is significant, especially if both T1D and LADA patients get included in a potential label. However, investors should remember that these calculations assume a market penetration of 100% and that 35% of patients have the HLA DR3-DQ2 genotype and does not factor in any discounts on the list price.

US market potential sensitivity analysis, prevalence and list price

		Prevalence						
		50,000	65,000	80,000	95,000	110,000	125,000	140,000
List price (USD)	75,000	1313	1706	2100	2494	2888	3281	3675
	100,000	1750	2275	2800	3325	3850	4375	4900
	125,000	2188	2844	3500	4156	4813	5469	6125
	150,000	2625	3413	4200	4988	5775	6563	7350
	175,000	3063	3981	4900	5819	6738	7656	8575
	200,000	3500	4550	5600	6650	7700	8750	9800
	225,000	3938	5119	6300	7481	8663	9844	11025

Source: Carnegie Research

Market penetration: The share of the target patient population that will receive Diamyd may be the most challenging factor to estimate. According to the company's market research, it is estimated that Diamyd could achieve a market penetration of 30% in a base case.

In the first year or two, we believe adoption mainly will be driven by diabetes specialists and endocrinologists who are familiar with the therapy, primarily clinics which participated in the Phase III trial. We argue that the requirement for routine HLA screening, in combination with the anticipated high cost for the therapy could lead to a more conservative initial uptake. In the initial launch phase of high-cost drugs, it is common that health insurance companies to require "prior authorisation" before approving reimbursement coverage. We believe a strong commercial partner will be key to driving sales by securing reimbursement and raising awareness among healthcare providers – especially about the importance of preserving patients' natural insulin production. On the other hand, the benign safety profile, the easy administration, and low frequency of injections are positive factors that speak in favour of a rapid market uptake of the drug.

Looking further down the road, we assume that market penetration could reach 30% and 20% in US and EU4+UK, respectively, in a more mature stage. However, success will hinge on ensuring routine HLA screening, demonstrating cost-effectiveness, and securing physician trust in the treatment. We believe that, if the data is encouraging enough, Diamyd could serve as a backbone treatment in combination therapies for T1D. Its benign safety profile makes it especially well-suited for this role. This means that, even if other treatments get approved, it does not have to be a negative development if they work through different mechanisms of action and could provide additive effects.

Pricing: We assume a list price for Diamyd of USD150,000 per year in the US and USD105,000 per year in EU4+UK. Drug list prices in Europe tend to be 25–30% of the US price, but the discrepancy is often smaller for high-cost drugs and orphan drugs (Ways and Means Committee, 2019). In 2024, Diamyd Medical conducted market research in the US by interviewing physicians, as well as national and regional payers. The findings suggested a potential price range of USD194,000–240,000 for a full treatment with Diamyd. While we are not familiar with what assumptions this builds on in terms of treatment efficacy and potential cost savings, we see this as a high price point, which could limit a broad uptake in the target population. On the other hand, the willingness to pay for orphan drugs is typically high and T1D does have broad coverage among insurance companies in the US.

We assume average gross-to-net discounts of 20% and 10% in the US and EU4+UK, respectively. In our experience, the discounts tend to be less in Europe due to a less market-oriented healthcare system. The company is guiding for a maximum of 20% in the US market.

Conclusion: When taken together, this leads to estimated global peak sales of ~USD900m for Diamyd in the initial indication. Note that we have taken a considerably more conservative stance

on peak sales for Diamyd compared to the company's own projections. We will review our assumptions as we see clinical data and a credible commercial partner that could launch the product.

Sales model, Diamyd for T1D

		2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
US																		
Diagnosed T1D cases		48000	48376	48748	49115	49477	49835	50188	50537	50881	51220	51555	51885	52211	52532	52849	53161	53469
Growth (%)	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Share HLA DR3-DQ2 positive	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%
Adressable patient population		16800	16932	17062	17190	17317	17442	17566	17688	17808	17927	18044	18160	18274	18386	18497	18606	18714
Launch curve					0.03	0.12	0.25	0.35	0.60	0.85	1.00	0.80	0.64	0.45	0.31	0.25	0.20	0.16
Market penetration	30%				1%	4%	8%	11%	18%	26%	30%	24%	19%	13%	9%	8%	6%	5%
Treated patients					155	623	1308	1844	3184	4541	5378	4331	3487	2456	1730	1392	1120	901
List price (USD)	150000				150000	150000	150000	150000	150000	150000	150000	150000	150000	150000	150000	150000	150000	150000
Growth (%)	0%				0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Gross to net (%)	20%				20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Net price (USD)					120000	120000	120000	120000	120000	120000	120000	120000	120000	120000	120000	120000	120000	120000
US sales (USDm)					**19**	**75**	**157**	**221**	**382**	**545**	**645**	**520**	**418**	**295**	**208**	**167**	**134**	**108**
EU4+UK																		
Diagnosed T1D cases		45000	45432	45860	46283	46701	47115	47524	47928	48328	48723	49113	49498	49879	50255	50626	50992	51354
Growth (%)	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Share HLA DR3-DQ2 positive	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%
Adressable patient population		15750	15901	16051	16199	16345	16490	16633	16775	16915	17053	17189	17324	17458	17589	17719	17847	17974
Launch curve					0.00	0.03	0.06	0.18	0.40	0.62	0.79	0.85	0.95	1.00	0.50	0.25	0.13	0.06
Market penetration	20%				0%	1%	1%	4%	8%	12%	16%	17%	19%	20%	10%	5%	3%	1%
Treated patients					6	98	198	599	1342	2097	2694	2922	3292	3492	1759	886	446	225
List price (USD)	105000				105000	105000	105000	105000	105000	105000	105000	105000	105000	105000	105000	105000	105000	105000
Growth (%)	0%				0	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Gross to net (%)	10%				10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
Net price (USD)					94500	94500	94500	94500	94500	94500	94500	94500	94500	94500	94500	94500	94500	94500
EU4+UK sales (USDm)					**1**	**9**	**19**	**57**	**127**	**198**	**255**	**276**	**311**	**330**	**166**	**84**	**42**	**21**

Source: Carnegie Research

Below, we have conducted sensitivity analyses to visualise the impact of changes in two key parameters: market penetration and list price. While our estimates indicate peak sales of ~USD650m in the US, using Diamyd Medical's own assumptions would indicate peak sales well above USD1.0bn in this market.

US peak sales sensitivity analysis, market penetration and list price

		Market penetration (%)						
		10%	20%	25%	30%	35%	40%	50%
List price (USD)	75,000	108	215	269	323	376	430	538
	100,000	143	287	359	430	502	574	717
	125,000	179	359	448	538	627	717	896
	150,000	215	430	538	645	753	861	1076
	175,000	251	502	627	753	878	1004	1255
	200,000	287	574	717	861	1004	1147	1434
	225,000	323	645	807	968	1129	1291	1613

Source: Carnegie Research

EU4+UK peak sales sensitivity analysis, market penetration and list price

		Market penetration (%)						
		5%	10%	15%	20%	25%	30%	50%
List price (USD)	75,000	59	118	177	236	295	354	589
	85,000	67	134	200	267	334	401	668
	95,000	75	149	224	299	373	448	746
	105,000	82	165	247	330	412	495	825
	115,000	90	181	271	361	452	542	903
	125,000	98	196	295	393	491	589	982
	135,000	106	212	318	424	530	636	1061

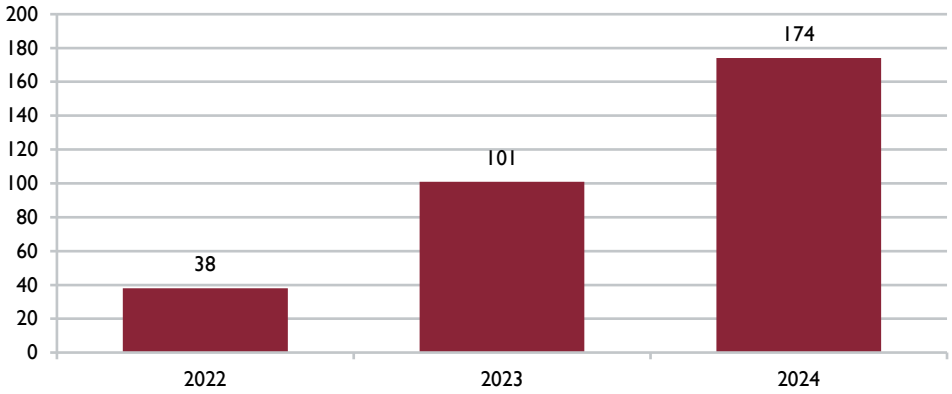
Source: Carnegie Research

The Nefecon case

While IgA nephropathy and T1D are very different disease areas, we believe that the launch of Calliditas' drug Nefecon offers an interesting comparison. Nefecon was the first-ever approved treatment for IgA nephropathy, a rare kidney disease. Similar to what could happen with Diamyd, Nefecon received accelerated approval in the US and Europe based on a surrogate endpoint – in this case, proteinuria (protein in the urine).

When Nefecon entered the market, there was significant discussion within the medical community about whether improvements in proteinuria would translate into long-term clinical benefits. We argue that a similar dynamic could apply to C-peptide levels in Diamyd's case. This means that, under an accelerated approval scenario, market uptake for Diamyd could be relatively modest at first, with broader adoption likely dependent on a full approval demonstrating long-term benefits in blood sugar control, and other important endpoints.

TARPEYO sales development since launch (USDm)

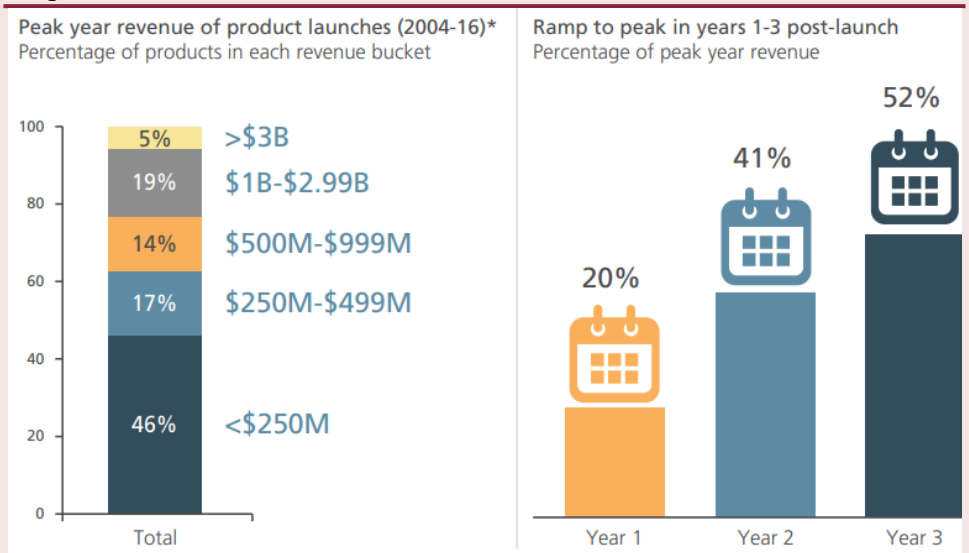


Source: Carnegie Research

Drug launch statistics for the US market

A drug is considered a blockbuster if it generates USD1bn or more in annual sales. Only a small fraction ever achieve that milestone. A study by L.E.K. Consulting analysed over 450 new molecular entity (NME) launches in the US to assess their commercial success. It found that since 2004, the average peak US revenue for newly launched drugs has been around USD800m, but only one in five surpassed the USD1bn threshold. Over half of the drugs examined failed to reach USD250m in peak US sales.

Drug launch statistics for the US market



Source: L.E.K. Launch Monitor, EvaluatePharma

Deals

The T1D space has historically seen some big licensing deals. The substantial total addressable market (TAM) has drawn interest from pharmaceutical companies willing to invest in next-generation treatments. However, such deals have remained relatively scarce in recent years, particularly in the later stages of development. Below, we highlight some notable licensing agreements struck during Phase III clinical trials.

Selected deals within the type 1 diabetes space

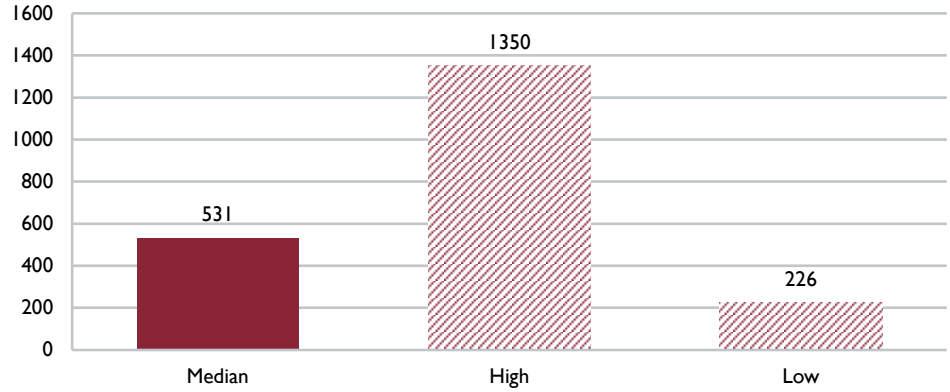
Year	Deal type	Upfront	Deal size	Phase	Licensor	Licensee
2015	Licensing deal	300	1720	III	Lexicon Pharmaceuticals	Sanofi
2010	Licensing deal	100	1245		Rigel Pharmaceuticals	AstraZeneca
2010	Licensing deal	200	350	III	Biocon	Pfizer
2010	Licensing deal	45	625	III	Diamyd Medical	J&J
2007	Licensing deal	41	1104	III	MacroGenics	Ely Lily
	Average	**137**	**1009**			
	Median	**100**	**1104**			

Source: Evaluate Pharma, Company PR, Carnegie Research

We also want to highlight a notable deal from March 2023, when Sanofi acquired Provention Bio. This acquisition included the global rights to commercialise TZIELD, a newly approved disease-modifying therapy. The deal was valued at USD2.9bn, representing a 273% premium over Provention Bio's share price at the time.

While the global T1D space has seen some impressive deal sizes, Swedish biotech has not seen the same kind of blockbuster deals over the past 15 years. While Sweden has a strong life sciences scene, the deal sizes have been noticeably smaller compared to international peers. One reason could be that fewer Swedish biotech's reach the late-stage development needed to attract major licensing agreements. Another factor is possibly a more conservative investment climate, especially compared to the US market.

Largest deals in Swedish biotech last 15 years, deal value (USDm)



Source: Company PR, Carnegie Research

In our projections for a potential licensing deal, we anticipate that Diamyd Medical will secure a partnership with a commercial player following the interim data readout in 2026. Under this agreement, we expect the partner to gain global commercial rights to sell Diamyd, while Diamyd Medical would receive an upfront payment, milestone payments, and royalties on net sales. We assume that Diamyd Medical retains manufacturing responsibilities.

To estimate the potential size of such a deal, we have looked at the deals Calliditas made for Nefecon in Europe and Japan. However, given that we assume Diamyd will also be outlicensed for the US market, we have adjusted for a larger deal size. Our assumptions include an upfront payment of SEK500m, a total deal value of SEK4.3bn, and revenue share of 40%.

Likelihood of approval

In 2020, the largest study to date on the likelihood of a drug in clinical development reaching the market was published. The study included data from 7,455 different clinical programmes conducted between 2006 and 2015, aiming to determine what historical data tells us about the actual probability of obtaining regulatory approval (Bio, Biomedtracker, Amplion, 2020).

Empirical probabilities of reaching the market

Likelihood of Approval	Phase I to Approval		Phase II to Approval		Phase III to Approval		NDA/BLA to Approval	
	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA
Hematology	283	26.1%	197	35.7%	114	63.0%	50	84.0%
Infectious disease	916	19.1%	569	27.5%	283	64.5%	133	88.7%
Ophthalmology	267	17.1%	201	20.1%	100	45.2%	40	77.5%
Other	301	16.3%	205	24.4%	89	61.5%	43	88.4%
Metabolic	241	15.3%	146	25.1%	62	55.6%	27	77.8%
Gastroenterology*	156	15.1%	115	20.0%	59	55.9%	26	92.3%
Allergy	107	14.7%	70	21.8%	30	67.0%	16	93.8%
Endocrine	791	13.2%	492	22.4%	250	55.9%	107	86.0%
Respiratory	428	12.8%	278	19.6%	82	67.3%	37	94.6%
Urology	108	11.4%	87	20.0%	35	61.2%	14	85.7%
Autoimmune	837	11.1%	540	17.0%	221	53.5%	86	86.0%
All Indications	**9985**	**9.6%**	**6403**	**15.3%**	**2541**	**49.6%**	**1050**	**85.3%**
Neurology	1304	8.4%	842	14.2%	377	47.8%	161	83.2%
Cardiovascular	632	6.6%	423	11.2%	186	46.7%	76	84.2%
Psychiatry	451	6.2%	297	11.6%	128	49.0%	58	87.9%
Oncology	3163	5.1%	1941	8.1%	525	33.0%	176	82.4%

Source: Bio, Biomedtracker, Amplion, 2020

In the case of Diamyd, we believe it is most relevant to consider the historic probability within the endocrine/autoimmune space, which would give a LoA of about 55%. However, drugs with accelerated pathways have shown to have a higher probability of success. We choose to apply a LoA of 65% that Diamyd will reach the market.

Cost of goods sold

It is challenging to model cost of goods sold when we do not know the structure of a potential licensing deal for Diamyd. For now, we assume that Diamyd Medical enters a revenue-sharing deal with a commercial partner for Diamyd, where the company retains manufacturing responsibilities while the partner handles commercialisation. Under this structure, we assume that the company would not recognise revenue at the point of sale to the partner but would instead receive a 40% share of net sales, aligning its earnings with the partner's commercial execution. Diamyd Medical would then recognise COGS when the drug is produced and delivered to the partner.

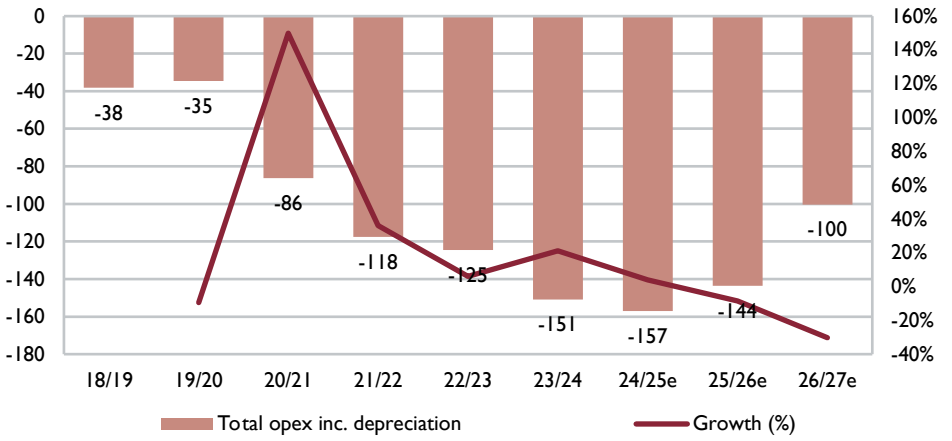
We do not have exact figures on Diamyd's manufacturing costs, but we expect the anticipated high price point in the US to result in strong gross margins for the company. Generally, biologics tend to have lower margins than small-molecule drugs due to their more complex manufacturing process. That said, we estimate the company's cost of goods sold (COGS) will be around 15% of Diamyd's sales.

Operating expenses

For a biotech company like Diamyd Medical, research and development make up the bulk of operating expenses. Costs have risen significantly since the launch of the global Phase III trial, DIAGNODE-3, as the company relies on contract manufacturing organisations (CMOs) and contract research organisations (CROs) to conduct the study. We expect operating expenses to remain at their current levels until patient recruitment is complete, which we anticipate happening in 2026. After that, the company will continue to incur costs related to preparing its market submission in the US.

If striking a licensing deal, we believe it is likely that the company will ramp up its efforts to develop its pipeline projects, but we believe that operating expenses would still decline relative to current levels.

Opex development (SEKm)



Source: Company Reports, Carnegie Research

Net financials

Diamyd Medical has no interest-bearing long-term debt on its balance sheet, and consequently interest payments are negligible.

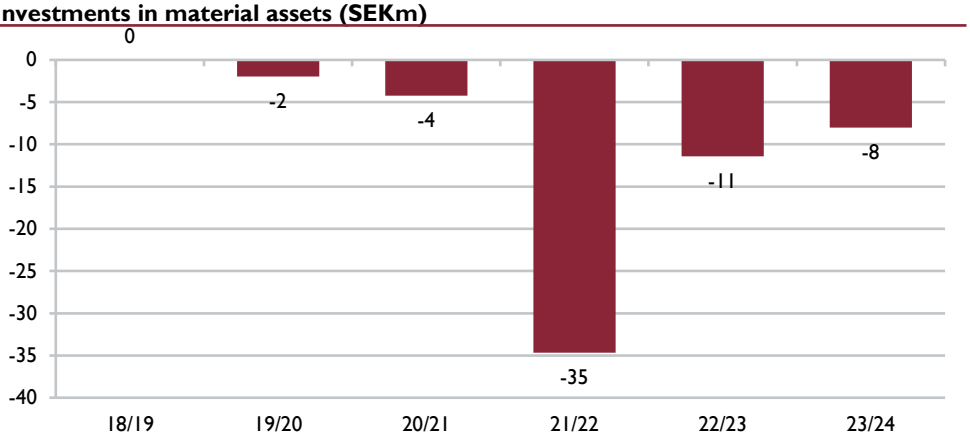
Cash flow and balance sheet

Investments/capex

The company has made substantial investments in building and expanding its manufacturing facility in Umeå, Sweden, to produce GAD65, the key component of its immunotherapy. In April 2020, the company began setting up a 24,000-square-foot production facility, which includes clean rooms, laboratories, and office space. Since then, the company has continued to invest in the facility with the goal of having it production-ready for commercial use ahead of a potential market launch of Diamyd.

In its prospectus for the recent rights issue, the use of proceeds stated that ~20% of the issue will be used for the continued development of the company's production facility in Umeå for production of GAD65. Given the issue size of SEK224m, it implies that about SEK45m will be invested in the facility going forward.

Investments in material assets (SEKm)



Source: Company Reports, Carnegie Research

Depreciation/amortisation

Diamyd Medical's non-current assets primarily consist of tangible assets such as property and machinery, which typically are depreciated over a long period of time. Depreciation has averaged about SEK7m annually over the past three years.

Working capital

Since Diamyd Medical has not yet launched any products, it does not bind much working capital. As it is likely to seek a partner for launching Diamyd and not have to carry the responsibility of sales and distribution, we believe that the business can be run in an asset-light manner even in a commercial stage. We assume a future partner will hold and manage most of the inventory to support demand for the product, while Diamyd Medical will be responsible for manufacturing.

Financing

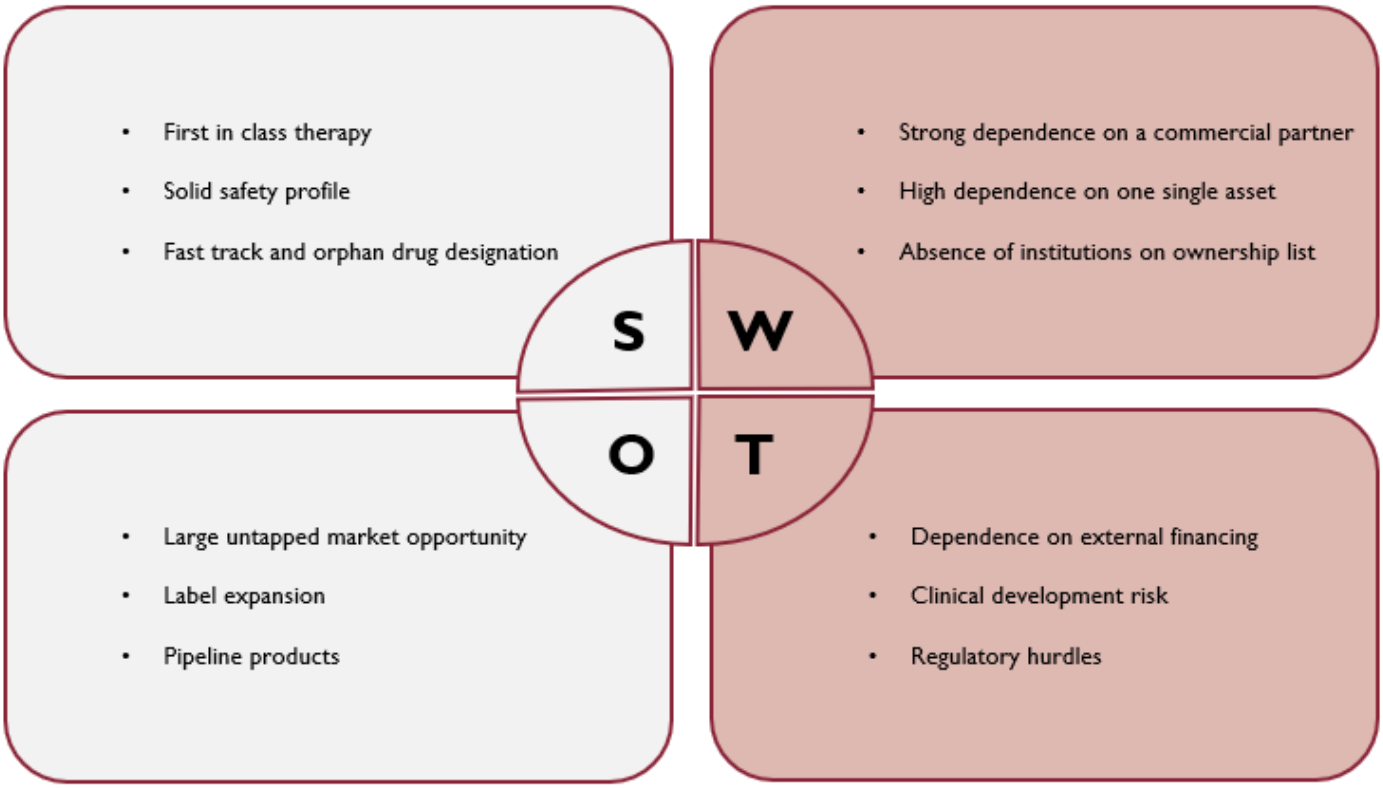
At the end of February 2025, Diamyd Medical held ~SEK104m in cash. The company has recently conducted a rights issue plus directed share issue which brought in another ~SEK266m in gross proceeds. We believe that these funds will be enough to fund operations until the company finds a partner, which we have modelled in 2026 following data from the upcoming interim analysis from the DIAGNODE-3 trial. After this, we believe that there will be no need for additional capital injections.

Warrant programme

As part of its rights issue in April 2025, the company introduced a new warrant programme. Investors who subscribed for shares in the issue also received TO5 warrants. These warrants give holders the opportunity to purchase additional shares in the company during a defined subscription window. Specifically, two TO5 warrants – whether of series A or B – can be exchanged for one new share of the corresponding share class. The subscription period runs from 16–30 April 2026, with a fixed exercise price of SEK20 per share.

SWOT

SWOT analysis



Source: Carnegie Research

Valuation

Our fair value range is based on DCF-based sum-of-the-parts valuations. Conducting a peer valuation on Diamyd Medical is challenging due to the lack of sales and positive EBIT, which makes valuation multiples irrelevant. Also, there are not currently a lot of other Scandinavian companies in Phase III development.

In our model, we project peak sales of ~USD900m for Diamyd in T1D. We assign the project a 65% likelihood of approval (LoA). Due to the absence of a clear development plan for Remygen, we have not yet included it in our valuation model.

Our assumptions include a partnership deal for Diamyd in 2026 with a total value of SEK4,300m, comprising an upfront payment of SEK500m, contingent on positive top-line results from the interim analysis from DIAGNODE-3 in March 2026. Additionally, we estimate Diamyd Medical will receive 40% of net sales for Diamyd in a revenue-share agreement. We reach a fair value range of SEK14–23 per share. The lower end of our fair value range is based on our DCF model using a WACC of 20%, and the upper end is based on our DCF model using a WACC of 13%.

Project	Launch	Probability	Peak sales (USDm)	Valuation approach	NPV (SEKm)	NPV/share (SEK)
Diamyd	2027	65%	900	DCF, WACC 20%	1766	13
Unallocated costs					-136	-1
Enterprise Value (EV), SEKm					**1630**	**12**
Est. net cash Q2 (24/25), adjusted for share issues					359	3
Total NPV					**1989**	**14**

Source: Carnegie Research

Project	Launch	Probability	Peak sales (USDm)	Valuation approach	NPV (SEKm)	NPV/share (SEK)
Diamyd	2027	65%	900	DCF, WACC 13%	2963	22
Unallocated costs					-223	-2
Enterprise Value (EV), SEKm					**2740**	**20**
Est. net cash Q2 (24/25), adjusted for share issues					359	3
Total NPV					**3099**	**23**

Source: Carnegie Research

NPV/share sensitivity analysis, WACC and LoA

		WACC (%)						
		13%	14%	16%	17%	18%	19%	20%
LoA (%)	100%	34	32	28	26	24	23	21
	75%	26	24	21	20	19	17	16
	70%	24	23	20	19	17	16	15
	65%	23	21	18	17	16	15	14
	55%	19	18	16	15	14	13	12
	50%	18	16	15	14	13	12	11
	45%	16	15	13	12	12	11	11

Source: Carnegie Research

Risks

Clinical development risk: In terms of companies in clinical development, the greatest risk is always that they fail in their clinical studies. There is also a risk that the authorities do not approve an application for clinical studies or to advance further with ongoing studies.

Commercialisation risk: The company has not yet commercialised any projects, such as via licensing deals, partnerships, or through its own development, or launched any drugs. It thus has not made any sales or generated any revenues.

Partner dependence: A significant risk in Diamyd Medical's investment case is its dependence on securing a strong commercial partner to successfully bring Diamyd to market. While the company has expertise in research and development, commercialising a drug in the diabetes field is challenging as it demands significant resources for marketing, distribution, and sales infrastructure. If the company fails to secure a capable partner, it may struggle to launch Diamyd on its own, leading to delays in market entry and limited revenue potential.

Financing risk: Like many biotech companies, Diamyd Medical relies on substantial funding to support its research, clinical trials, and operations. It could mean additional capital raises in the future.

Risks related to key staff: The company has a compact management structure and is highly dependent on key executives. If it were to lose some of its key staff, this would damage the company's future development.

Intellectual property

The company holds key patents for its diabetes treatments, including US protection for GAD65 use until 2032 and additional patents in multiple regions valid until 2035. As a biologic, it also benefits from market exclusivity in the US and Europe.

Diamyd Medical has secured key intellectual property rights through an exclusive licence from the University of California, Los Angeles (UCLA), which provides US patent protection for the use of GAD65 to treat diabetes until 2032. This patent offers an important layer of protection for the company's technology in the US market.

The company also holds patents in Europe, Eurasia, Israel, Japan, South Korea, Hong Kong, and South Africa for the prevention and treatment of autoimmune diabetes in individuals with the HLA DR3-DQ2 genotype, valid until 2038, additional countries pending. Additional patent applications have been filed for treating autoimmune diabetes with insulin-based antigens, including claims covering HLA DR4-DQ8, either independently or combined with HLA DR3-DQ2, approved in Europe and South Korea, additional countries pending.

Intralymphatic administration of Diamyd is another area of patent protection, with approvals in Europe, Japan, Russia, Israel, Australia, China, and Canada, valid until 2035, and applications pending in other regions. This method, which demonstrated positive outcomes in the Phase IIb DIAGNODE-2 trial, is currently under evaluation in the ongoing Phase III DIAGNODE-3 trial.

Also, as a biologic therapy, Diamyd also benefits from 12 years of market exclusivity in the US and 10 years in Europe, providing additional commercial protection independent of its patent portfolio.

Sustainability

The company is committed to sustainability, tackling environmental impacts, improving healthcare access, and advancing diabetes research. Through projects like ALISTAIR and ASSET, it is optimising production, including diverse groups in trials, and enhancing early detection for better outcomes.

Diamyd Medical is working to integrate sustainability into its operations within the life sciences sector, guided by the United Nations' 2030 Agenda for Sustainable Development and its Sustainable Development Goals (SDGs). These principles influence the company's pharmaceutical value chain, spanning research, development, manufacturing, distribution, and patient care.

While pharmaceutical processes can have environmental impacts, such as waste generation and greenhouse gas emissions, Diamyd Medical recognises the importance of addressing these challenges while delivering health benefits through its therapies. The company acknowledges the environmental footprint of its activities, including the production of recombinant GAD protein at its Umeå facility and the handling of clinical trial samples in Europe and the US. To better understand and mitigate these impacts, Diamyd Medical participated in the VINNOVA-funded ALISTAIR project, which analysed its production processes, energy consumption, and waste management practices. This initiative also explored the potential use of artificial intelligence to optimise sustainability efforts, aiming to reduce greenhouse gas emissions and improve resource efficiency.

In addition to environmental efforts, Diamyd Medical is taking steps to improve healthcare access and equity. In the US, the company is working to involve underrepresented populations, including ethnic minorities, in its clinical trials. Research has shown that these groups often experience poorer diabetes management and have limited access to new technologies. By collaborating with clinics that serve these communities, Diamyd Medical aims to create a more diverse participant base and generate broader insights into its treatments.

The company is also contributing to advancements in clinical trial design. Through partnerships with organisations like the Critical Path Institute (C-Path), it is working to optimise trial methodologies for disease-modifying therapies in T1D. This includes using biomarkers and data-driven tools to improve participant selection and increase the relevance of clinical outcomes. These efforts are intended to support the development of more effective therapies.

Appendix – Management

Ulf Hannelius, Chief Executive Officer

Born in 1975. PhD in Molecular Biology from Karolinska Institutet in Stockholm and Executive MBA from Stockholm School of Economics. Prior experience from business development in the biotech and medtech industries as well as from academic research in the fields of genetics and molecular biology. Chairman of Diamyd Biomanufacturing AB, Board member in MainlyAI AB. Joined Diamyd Medical in 2015, CEO since 2016.

Martina Widman, Chief Operating Officer

Born in 1981. M.Sc. in Mechanical Engineering from the Royal Institute of Technology in Stockholm, with a specialisation in Biomedical Engineering. Prior experience of clinical operation from the pharmaceutical industry. Joined Diamyd Medical in 2008.

Anna Styrud, Chief Financial Officer

Born in 1961. B.Sc. in Business Administration from Uppsala University. Prior experience includes Treasurer of Vasakronan AB and various positions in finance and control within real estate and engineering industry. Board member in Diamyd Biomanufacturing AB. Joined Diamyd Medical in 2010.

Anton Lindqvist, Chief Scientific Officer

Born in 1980. M.Sc in Molecular Biotechnology Engineering from Uppsala University. Research experience from University of Pittsburgh, Uppsala University, the Royal Institute of Technology and Karolinska Institutet. Prior experience in managing technical development at several bio-tech companies. Joined Diamyd Medical in 2013.

Maja Johansson, Chief Operating Officer, Manufacturing Site

Born in 1962. PhD in Biochemistry from Umeå University and Associate professor in neuroendocrinology. Prior experience from biotech companies. Board member in Diamyd Biomanufacturing AB. Joined Diamyd Medical in 2020.

Appendix – Board of directors

Anders Essen-Möller, Chairman

Born in 1941. M.Sc. Founder of and CEO during 1996–07 of Diamyd Medical and Chairman 2007 –2015. Independent of the Company, major owner. Founder of Synectics Medical AB, sold to Medtronic, Inc. in 1996. Chairman of NextCell Pharma AB.

Erik Nerpin, Vice Chairman

Born in 1961. Lawyer. Self-employed with Advokatfirman Nerpin AB. Independent of the Company and its principal owners. Board member since 2012. Board assignments in listed companies: Chairman of Kancera AB, Hilbert Group AB, edyoutech AB and Neovici Holding AB and board member in Effnetplattformen Holding AB.

Maria-Teresa Essen-Möller, Board Member

Born in 1970. M.Sc. in Business Administration. Independent to the company, not independent to its principal owners. Previous experience includes CEO of Health Solutions AB, Digital Marketing Manager at Sanofi and Account Director at Creuna. Board member since 2009.

Torbjörn Bäckström, Board Member

Born in 1948. MD, PhD. CEO of Umecrine AB. Independent of the company and its principal owners. Board member since 2017. Head of Neurosteroid Research Centre in Umeå and Professor Emeritus in the Department of Clinical Science, Obstetrics and Gynecology at Umeå University.

Mark Atkinson, Board Member

Born in 1961. PhD. Professor of Diabetes Research, Department of Pathology, Immunology and Laboratory Medicine, University of Florida, US. American Diabetes Association Eminent Scholar for Diabetes Research. Director, UF Diabetes Institute, University of Florida. Independent of the company and its principal owners. Board member since 2018.

Karin Hehenberger, Board Member

Born in 1972. M.D., Ph.D, Karolinska Institute, Post-doc at the Joslin Center, Harvard Medical School. Chief Medical Officer, Patient Care America, President and founder of Lyfebulb, Member of the 3B Future Health Ventures Scientific Advisory board, board member AADI pharmaceuticals (Nasdaq), board member Anacardio AB, board member Rolf Luft Foundation for Diabetes research, board member American Diabetes Association NY/NJ Community Board. Independent of the company and its principal owners. Board member since 2021.

Karin Rosén, Board Member

Born in 1967. M.D., Ph.D, Lund University, Sweden. More than two decades of experience from senior leadership positions in Global Clinical Development and US & Global Medical Affairs with Horizon Therapeutics, GlaxoSmithKline, Aimmune Therapeutics and Genentech, part of the Roche group. Independent of the company and its principal owners. Board member since 2023.

Financial statements

Profit & loss (SEKm)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
Sales	0	2	0	0	0	1	0	0	233	170
COGS	0	0	0	0	0	0	0	0	0	-12
Gross profit	**0**	**2**	**0**	**0**	**0**	**1**	**0**	**0**	**233**	**158**
Other income & costs	0	-38	10	-85	-111	-116	-136	-146	-133	-88
Share in ass. operations and JV	0	0	0	0	0	0	0	0	0	0
EBITDA	**0**	**-36**	**10**	**-85**	**-111**	**-116**	**-136**	**-146**	**101**	**70**
Depreciation PPE	0	0	0	-1	-4	-5	-11	-7	-7	-7
Depreciation lease assets	0	0	0	0	0	0	0	0	0	0
Amortisation development costs	0	0	0	0	0	0	0	0	0	0
Amortisation other intangibles	0	0	0	0	0	0	0	0	0	0
Impairments / writedowns	0	0	0	0	0	0	0	0	0	0
EBITA	**0**	**-37**	**10**	**-86**	**-115**	**-121**	**-147**	**-153**	**94**	**63**
Amortization acquisition related	0	0	0	0	0	0	0	0	0	0
Impairment acquisition related	0	0	0	0	0	0	0	0	0	0
EBIT	**0**	**-37**	**10**	**-86**	**-115**	**-121**	**-147**	**-153**	**94**	**63**
Share in ass. operations and JV	0	0	0	0	0	0	0	0	0	0
Net financial items	0	0	0	146	5	5	-5	0	0	0
of which interest income/expenses	0	0	0	0	0	0	0	0	0	0
of which interest on lease liabilities	0	0	0	0	0	0	0	0	0	0
of which other items	0	0	0	146	5	5	-5	0	0	0
Pre-tax profit	**0**	**-37**	**10**	**60**	**-110**	**-116**	**-152**	**-153**	**94**	**63**
Taxes	0	0	0	0	0	0	0	0	-19	-13
Post-tax minorities interest	0	0	0	0	0	0	0	0	0	0
Discontinued operations	0	0	0	0	0	0	0	0	0	0
Net profit	**0**	**-37**	**10**	**60**	**-110**	**-116**	**-152**	**-153**	**74**	**50**
Adjusted EBITDA	0	-36	10	-85	-111	-116	-136	-146	101	70
Adjusted EBITA	0	-37	10	-86	-115	-121	-147	-153	94	63
Adjusted EBIT	0	-37	10	-86	-115	-121	-147	-153	94	63
Adjusted net profit	0	-37	10	60	-110	-116	-152	-153	74	50
Sales growth Y/Y	na	+chg	-78.3%	-25.8%	79.4%	20.3%	-76.2%	-92.3%	2333333.3%	-27.0%
EBITDA growth Y/Y	na	-chg	+chg	-chg	-chg	-chg	-chg	-chg	+chg	-30.5%
EBITA growth Y/Y	na	-chg	+chg	-chg	-chg	-chg	-chg	-chg	+chg	-32.8%
EBIT growth Y/Y	na	-chg	+chg	-chg	-chg	-chg	-chg	-chg	+chg	-32.8%
EBITDA margin	nm	na	na	na	na	na	na	na	43.2%	41.1%
EBITA margin	nm	nm	na	nm	nm	nm	nm	nm	40.2%	37.0%
EBIT margin	nm	na	na	na	na	na	na	na	40.2%	37.0%
Tax rate	na	na	na	na	na	na	na	na	20.6%	20.6%

Cash flow (SEKm)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
EBITDA	0	-36	10	-85	-111	-116	-136	-146	101	70
Paid taxes	0	0	0	0	0	0	0	0	-19	-13
Change in NWC	0	-2	7	-25	18	-1	8	-8	4	-4
Non cash adjustments	0	-1	-1	0	0	6	-2	0	0	0
Discontinued operations	0	0	0	0	0	0	0	0	0	0
Total operating activities	**0**	**-39**	**16**	**-109**	**-93**	**-111**	**-129**	**-154**	**86**	**53**
Capex tangible assets	0	0	-2	-4	-35	-11	-8	-22	-20	-7
Capitalised development costs	0	0	0	0	0	0	0	0	0	0
Capex - other intangible assets	0	0	0	0	0	0	0	0	0	0
Acquisitions/divestments	0	0	0	0	0	0	0	0	0	0
Other non-cash adjustments	0	5	7	-9	-47	35	-15	0	0	0
Total investing activities	**0**	**5**	**5**	**-13**	**-81**	**24**	**-23**	**-22**	**-20**	**-7**
Net financial items	0	0	0	146	5	5	-5	0	0	0
Lease payments	0	0	0	0	0	0	0	0	0	0
Dividend paid and received	0	0	0	0	0	0	0	0	0	0
Share issues & buybacks	0	56	0	57	142	71	127	255	0	0
Change in bank debt	0	0	0	0	0	0	0	0	0	0
Other cash flow items	0	0	0	0	0	16	15	0	0	0
Total financing activities	**0**	**56**	**0**	**203**	**147**	**91**	**137**	**255**	**0**	**0**
Operating cash flow	0	-39	16	-109	-93	-111	-129	-154	86	53
Free cash flow	0	-39	14	32	-123	-118	-143	-176	66	46
Net cash flow	0	23	21	80	-28	4	-15	79	66	46
Change in net IB debt	0	23	21	80	-28	4	-15	79	66	46
Capex / Sales	nm	0.0%	580.4%	1670.0%	7632.6%	2095.6%	6173.1%	220000.0%	8.6%	4.1%
NWC / Sales	nm	-174.7%	-2631.2%	-53.6%	459.3%	-1337.3%	-7625.0%	-91229.5%	-3.1%	-4.2%

Fiscal year end: August

Source: Carnegie Research & company data

Financial statements, cont.

Balance sheet (SEKm)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
Acquired intangible assets	0	0	0	0	0	0	0	0	0	0
Other fixed intangible assets	0	0	0	0	0	0	0	0	0	0
Capitalised development	0	0	0	0	0	0	0	0	0	0
Tangible assets	0	0	2	6	46	52	49	64	77	77
Lease assets	0	0	0	0	0	0	0	0	0	0
Other IB assets (1)	0	0	0	0	0	0	0	0	0	0
Other non-IB assets	0	12	15	33	18	13	9	9	9	9
Fixed assets	**0**	**12**	**17**	**38**	**64**	**65**	**58**	**73**	**86**	**86**
Inventories (2)	0	0	0	0	0	0	0	0	0	0
Receivables (2)	0	0	0	0	0	0	0	0	0	0
Prepaid exp. & other NWC items (2)	0	5	4	24	13	13	27	27	30	29
IB current assets (1)	0	20	10	0	40	0	0	0	0	0
Other current assets	0	0	0	0	0	0	0	0	0	0
Cash & cash equivalents (1)	0	37	58	139	120	128	132	212	277	323
Current assets	**0**	**62**	**72**	**163**	**173**	**141**	**159**	**239**	**308**	**352**
Total assets	**0**	**74**	**90**	**201**	**237**	**206**	**217**	**311**	**394**	**438**
Shareholders' equity	0	63	72	189	214	169	146	248	322	372
Minorities	0	0	0	0	0	0	0	0	0	0
Other equity	0	0	0	0	0	0	0	0	0	0
Total equity	**0**	**63**	**72**	**189**	**214**	**169**	**146**	**248**	**322**	**372**
Deferred tax	0	0	0	0	0	0	0	0	0	0
LT IB debt (1)	0	0	0	0	0	0	0	0	0	0
Other IB provisions (1)	0	0	0	0	0	0	0	0	0	0
Lease libilities	0	0	0	0	0	0	0	0	0	0
Other non-IB liabilities	0	1	1	1	1	17	32	32	32	32
LT liabilities	**0**	**1**	**1**	**1**	**1**	**17**	**32**	**32**	**32**	**32**
ST IB debt (1)	0	0	0	0	0	0	0	0	0	0
Payables (2)	0	2	7	6	10	5	17	17	19	17
Accrued exp. & other NWC items (2)	0	9	9	6	12	15	23	15	21	17
Other ST non-IB liabilities	0	0	0	0	0	0	0	0	0	0
Liabilities - assets held for sale	0	0	0	0	0	0	0	0	0	0
Current liabilities	**0**	**11**	**16**	**11**	**21**	**20**	**40**	**32**	**40**	**34**
Total equity and liabilities	**0**	**74**	**90**	**201**	**237**	**206**	**217**	**311**	**394**	**438**
Net IB debt (=1)	0	-56	-68	-139	-159	-127	-132	-211	-277	-323
Net working capital (NWC) (=2)	0	-5	-12	12	-8	-7	-13	-5	-9	-5
Capital employed (CE)	0	64	73	190	215	170	146	248	323	373
Capital invested (CI)	0	-5	-10	18	38	46	36	59	68	72
Equity / Total assets	nm	85%	81%	94%	91%	82%	67%	80%	82%	85%
Net IB debt / EBITDA	nm	1.5	-6.8	1.6	1.4	1.1	1.0	1.4	-2.7	-4.6

Per share data (SEK)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
Adj. no. of shares in issue YE (m)	0.00	69.17	69.17	71.57	76.93	85.97	104.1	137.3	137.3	137.3
Diluted no. of Shares YE (m)	0.00	69.17	69.17	71.57	76.93	85.97	104.1	137.3	137.3	137.3
EPS	na	-1.06	0.14	0.85	-1.48	-1.43	-1.60	-1.27	0.54	0.36
EPS adj.	na	-1.06	0.14	0.85	-1.48	-1.43	-1.60	-1.27	0.54	0.36
CEPS	na	-1.06	0.14	0.86	-1.42	-1.37	-1.48	-1.21	0.59	0.42
DPS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BVPS	na	0.91	1.05	2.64	2.79	1.97	1.40	1.81	2.35	2.71

Performance measures	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
ROE	nm	-116.8%	14.4%	45.9%	-54.6%	-60.5%	-96.3%	-77.7%	26.1%	14.4%
Adj. ROCE pre-tax	na	na	14.2%	45.6%	-54.4%	-60.3%	-96.0%	-77.5%	32.8%	18.1%
Adj. ROIC after-tax	na	na	-126.3%	-2283.5%	-413.9%	-289.5%	-358.1%	-320.5%	116.8%	71.3%

Valuation	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
FCF yield	0.0%	-3.0%	1.1%	2.5%	-9.5%	-9.1%	-11.0%	-13.6%	5.1%	3.5%
Dividend yield YE	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Dividend payout ratio	na	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Dividend + buy backs yield YE	nm	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
EV/Sales YE	nm	>50	>50	>50	>50	>50	>50	>50	4.36	5.71
EV/EBITDA YE	nm	neg.	>50	neg.	neg.	neg.	neg.	neg.	10.1	13.9
EV/EBITA YE	nm	neg.	>50	neg.	neg.	neg.	neg.	neg.	10.9	15.4
EV/EBITA adj. YE	nm	neg.	>50	neg.	neg.	neg.	neg.	neg.	10.9	15.4
EV/EBIT YE	nm	neg.	>50	neg.	neg.	neg.	neg.	neg.	10.9	15.4
P/E YE	na	nm	>50	38.4	nm	nm	nm	nm	17.4	25.9
P/E adj. YE	na	nm	>50	38.4	nm	nm	nm	nm	17.4	25.9
P/BV YE	na	8.94	36.68	12.38	5.08	4.95	11.66	5.22	4.02	3.48
Share price YE (SEK)	7.66	8.11	38.4	32.8	14.2	9.74	16.3	9.43		

Fiscal year end: August

Source: Carnegie Research & company data

Disclosures and disclaimers

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Valuation, methodology, and assumptions

Commissioned research reports include the analyst's assessment of a fair value range over the coming six to 12 months based on various fundamental valuation methods. A commonly used method is DCF valuation, where future cash flows are discounted to today. Analysts may also use different valuation multiples, e.g. P/E ratio and EV/EBIT multiples, relative to industry peers. For companies where it is appropriate, a fair value range can also be based on the analyst's assessment of a fair ratio relative to the net asset value of the company. Fair value ranges represent the assessment of the analyst(s) at the time of writing

Frequency of update

Carnegie's research analysis consists of case-based analyses, which implies that the frequency of the analytical report may vary over time. Unless otherwise expressly stated in the report, the analysis is updated when considered necessary by the research department, for example in the event of significant changes in market conditions or events related to the issuer/the financial instrument.

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