NextCell Pharma

Sector: Biotech

Blockbuster potential hidden in plain sight

Redeye initiates coverage of NextCell Pharma, a clinical-stage biotech company developing a cell therapy with disease-modifying potential in type 1 diabetes. Strong clinical data and upcoming phase II readouts in 2025–2026 could pave the way for an outlicensing deal, yet the valuation remains modest—offering a compelling opportunity.

Disease-modifying T1D candidate with blockbuster potential…

NextCell's lead candidate, ProTrans, currently in phase II clinical trials, has consistently demonstrated signs of halted disease progression in stage 3 type 1 diabetes patients. In the five-year follow-up of the ProTrans-2 trial, one injection maintained insulin production at 57% of baseline levels, compared to only 14% in the placebo group. Data from ProTrans-Repeat in December also showed signs of higher efficacy with two injections. Based on the robust data from previous trials, the outlook for positive results in the upcoming ProTrans-Young readout in Q2 2025 appears promising. Building on this outlook, we model a market launch of ProTrans in 2031, with a peak sales potential of USD1.4bn.

… supported by opportunity as a stem cell bank and ATMP service provider

In addition to its lead candidate and proprietary selection algorithm, NextCell operates Scandinavia's largest stem cell bank, generating approximately SEK9m in LTM sales with steady growth. The recent establishment of QVance, a subsidiary focused on quality analysis for the ATMP market, has already initiated partnerships and could contribute to revenue in the not-so-distant future.

We initiate coverage with a base case of SEK8 per share

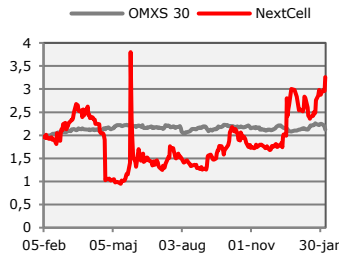
The current valuation appears undemanding, with implicit expectations pricing in a low probability of success for the ongoing trial—a stance contradicted by the accumulated clinical evidence of ProTrans. Since the rights issue in 2020 and the adjustment to the clinical program in 2021, there has been an inverse relationship between the valuation of the company and its clinical progress, a misconception by the market. Redeye initiates coverage with a base case valuation of SEK8 per share, alongside bull and bear case valuations of SEK13 and SEK0.5 per share, respectively. Our DCF approach is further validated by a peer group analysis. The interim readout of ProTrans-Young in April 2025 is a key near-term catalyst with the potential to significantly narrow the valuation gap.

Risk-Adjusted Key Financials (SEKm)	2022/2023	2023/2024	2024/2025e	2025/2026e	2026/2027e
Revenues	13,9	11,3	13,5	16,3	338,7
Revenue growth - YoY	123%	-19%	20%	21%	1981%
EBITDA	-40,6	-42,2	-45,3	-54,9	252,2
EBITDA margin	-293%	-375%	-335%	-338%	74%
EV/Revenues	5,3	4,1	14,7	12,2	0,6
EV/EBITDA	neg	neg	neg	neg	neg

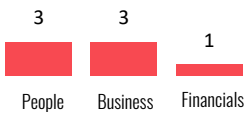
FAIR VALUE RANGE

BEAR	BASE	BULL
0.5	8	13

NXTCL VS OMXS30 – 12 MONTHS



REDEYE RATING



KEY STATS

Ticker	NXTCL
Market	First North
Share Price (SEK)	3.26
Market Cap (SEKm)	238
Net Debt (SEKm)	-34
Free Float (%)	91%
Avg. daily volume ('000)	272

Redeye, Mäster Samuelsgatan 42, 10tr, Box 7141, 103 87 Stockholm. Tel. +46 8-545 013 30, E-post: info@redeye.se

Investment case

A mispriced opportunity hidden in plain sight

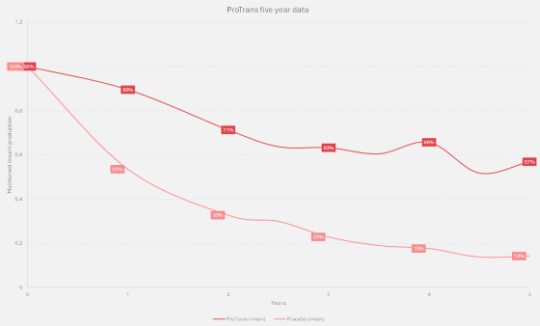
We judge that NextCell Pharma's shares have been overlooked by investors, and that the current valuation appears disconnected from the company's fundamentals. Having accumulated potentially disease-modifying data in type 1 diabetes, the phase II readouts (Q2 2025 and Q4 2026) present an opportunity for a materialized valuation upgrade, with good odds of success.

Good odds for readout and partnering

Historical probabilities in T1D trials imply phase II PoS of 52%. Anchored in reasonable market assumptions (launch 2031 and peak sales potential of USD1.4bn), the current valuation implies an implicit PoS in the phase II program of around 20%. We view this deviation as excessive and that a PoS aligning at least with the historical average seems reasonable. Positive readouts will likely also open up partnering opportunities, which is not reflected in the current valuation either.

Supportive analysis: Dose-dependent and disease-modifying effect

ProTrans have demonstrated a statistically significant, dose-dependent disease-modifying and clinically relevant effect in adults with stage 3 T1D, while also reporting no serious adverse events. A single infusion resulted in maintained insulin production at 57% of baseline levels after five years, compared to 14% in the placebo group. Moreover, the recent data from ProTrans-Repeat implied the potential for higher efficacy with two infusions.



The ongoing phase IIb trial, ProTrans-Young, aims to replicate and improve upon these results in younger age cohorts (7–11 and 12–18 years), positioning the candidate for a pivotal phase III trial, a potential outlicensing deal, and a broader patient group. NextCell also operates Scandinavia's largest stem cell bank and an ATMP service provider.

Challenge I: Binary risk remains

The readouts of ProTrans-Young represent a binary high-risk/reward scenario. Inconclusive or negative trial results would severely impair the company's value and partnering prospects as maintained safety and efficacy are critical for the continued development of ProTrans.

Challenge II: More capital is required

With SEK34m in liquid assets on the balance sheet in the most recent quarterly report, NextCell will require additional funding to bridge the gap until the full readout of the ProTrans-Young program at the end of 2026. This funding gap could be solved by the outstanding TO2 warrants with the potential of raising up to SEK113.5m in conjunction with the interim readout in Q2 2025.

DCF and peer analysis supports upside in the share

Our valuation derives from a risk-adjusted 2025-2040DCF model using a WACC of 14.5%. The SEK8 base case assumes phase II PoS of 60%, a USD650m deal in 2027, launch in 2031, and peak sales potential of USD1.4bn. Our SEK13 bull case sets the phase II PoS to 100%, reflecting the value of NextCell's following positive readouts. Conversely, the SEK0.5 bear case assumes negative readouts and a discontinued development in T1D. NextCell also trades at a clear discount compared to its peer group, providing further validation to our DCF value.

Catalysts

ProTrans-Young readout

The ProTrans-Young trial readout represents two significant catalysts for NextCell's share performance. The first, expected in H1 2025, is interim data that will provide insights into the company's lead candidate ProTrans' efficacy and safety in children aged 12–21 years. The second and most pivotal catalyst is anticipated by the end of 2026, with the release of the full data set from both age cohorts. Should these readouts confirm a disease-modifying effect with a maintained safety profile, NextCell would be positioned for a potential outlicensing deal.

Anticipated impact: Major

Time horizon: 12–18 months

Outlicensing deal

With positive readouts from ProTrans-Young, NextCell will have gathered a body of clinical data that we expect will generate interest enough to tie a partner to the project, which can take it through pivotal clinical trials and provide NextCell with an upfront payment as well as potential milestones and royalties. Anchored in related T1D deals, we estimate that a total deal value of up to USD650m could be on the table.

Anticipated impact: Major

Time horizon: 12–18 months

QVance – establishing a third arm

NextCell's subsidiary, QVance, specializes in quality analysis for advanced therapy medicinal products (ATMPs). The lab offers tailored services in quality control, product release, and analytical development, addressing the rapidly growing Nordic ATMP market, which is expanding at a ~15% CAGR. Achieving a commercial breakthrough and establishing stable revenue streams would significantly de-risk NextCell financially, and also support a higher valuation.

Anticipated impact: Moderate to major

Time horizon: 0–12 months

Selection of anticipated newsflow

Estimated trial timelines	2025		2026		2027	
	H1	H2	H1	H2	H1	H2
Clinical development	ProTrans-Young interim readout			ProTrans-Young readout	Partner and phase III start	
Other	TO2 warrants					

Source: Redeye research (estimates), NextCell (historical data)

Source: Redeye research (illustration), NextCell (data)

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Company introduction

Background description

NextCell is a Swedish biotechnology company founded in 2014 by researchers from the Karolinska Institute in Stockholm, Sweden. It is headquartered in Huddinge, near the institute, and employs approximately 15 people. About two-thirds of these employees work for the parent company, with the remainder in its two subsidiaries Cellaviva and QVance. The company focuses on developing advanced cell therapies based on mesenchymal stromal cells (MSCs) derived from the umbilical cord. Its core innovation includes a selection algorithm designed to assess the immunomodulatory abilities of these cells, ensuring that only those with the desired effects are chosen.

NextCell was initially established as Sweden's first and the Nordic region's only private stem cell bank, Cellaviva. Since 2015, Cellaviva has offered family storage of hematopoietic (blood-forming) and mesenchymal (connective tissue-forming) stromal cells, which have the potential for use in treating a wide range of diseases with the patient's own cells. It is the only stem cell bank authorized by the Health and Social Care Inspectorate (IVO) and generates recurring revenues.

As the company expanded its focus, it analyzed cells from various sources, parts of the umbilical cord and different donors to determine their suitability for different applications, culminating in the development of its proprietary selection algorithm. This work led to the creation of ProTrans, NextCell's lead candidate for Type 1 Diabetes (T1D). ProTrans has shown disease-modifying potential in clinical trials and mid-2024 demonstrated statistically significant five-year efficacy in T1D patients. The candidate is currently in phase II trials, with NextCell actively seeking a partner to advance it through pivotal studies.

In 2024, NextCell established QVance, a contract laboratory specializing in quality analysis for advanced therapy medicinal products (ATMPs), including cell and gene therapies. The company transferred its internal quality department to QVance, focusing on quality control, product release, and analytical development.

Selected company highlights

Year	Event
2024	
	Positive signs from repeat dosing in the ProTrans-Repeat trial
	ProTrans highlighted in Dagens Medicin
	Cellaviva and QVance (established in 2024) to be divested into subsidiaries
	SEK40m rights issue + SEK113m TO2 warrants
	ProTrans-2 demonstrated positive five-year disease-modifying outcomes compared to placebo
2023	
	Repeated treatment with ProTrans has been confirmed to be immunologically safe
	Presented on the International Society for Cell and Gene Therapy meeting in Paris and Advanced Therapies Europe
	NextCell's article explaining the result from its phase I/II-trial in T1D accepted in the scientific journal Diabetologia
2022	
	Start of ProTrans-Young, an investigator-initiated phase I/II-trial, evaluating treatment in pediatric patients with newly diagnosed T1D
	ProTrans demonstrates long-term effect in ProTrans-Repeat, ProTrans-Obs, and ProTrans-2 (three-year data)
	Participated in the International Society for Cell and Gene Therapy in San Francisco
2021	
	Clinical trials for the treatment of COVID-19 with ProTrans are started
2020	
	Positive data with statistical significance is published for ProTrans-2 SEK150m rights issue
2019	
	All patients treated with ProTrans-1 and ProTrans-Repeat demonstrated efficacy in an interim analysis of results from ProTrans-1 Start of ProTrans-2 and ProTrans-Repeat
2018	
	ProTrans-1 demonstrates safety in all three evaluated doses
2017	
	The first clinical trial with ProTrans is approved, named ProTrans-1
2016	
	First batch of the pharmaceutical candidate ProTrans produced according to GMP
2015	
	Launch of family savings of stem cells from umbilical cord blood and umbilical cord tissue
2014	
	Founded by scientists at Karolinska Institute, including Dr. Mathias Svahn (CEO) and Professor Edvard Smith (CMO)

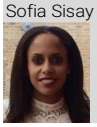
Source: Redeye research (illustration), NextCell (data)

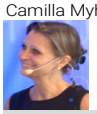
People and ownership

Management and board

NextCell is led by a team well-suited for its stage of development, characterized by a strong scientific focus on cell therapy and regenerative medicine with close ties to the Karolinska University Hospital/Institute. CEO and co-founder Mathias Svahn bring extensive expertise in stem cell research and biotechnology, having guided the company since 2015. He is supported by a management team and board of directors with deep experience in clinical development, life sciences business development, and finance. This collective expertise positions the company to effectively navigate the clinical development and partnering process for ProTrans. The company also benefits from a team of experienced Medical Advisers, including Per-Ola Carlsson the principal investigator of its clinical trials.

Management and board of directors

Name	Position	Shares	Options
Mathias Svahn 	CEO Born in 1976. Ph.D. and co-founder, background as scientific manager at KI and country medical manager at Roche. Joined NextCell Pharma in 2015.	1 034 184	624 179
Patrik Fagerholm 	CFO Born in 1967. M. Sc. in Finance and Business Administration. Responsible for the financial operations. Joined NextCell Pharma in 2021.	121 360	129 760
Lindsay Davies 	CSO Born in 1979. PhD with a long experience in stromal cell biology and development of cell therapies. In the role as CSO, Davies is responsible for the existing research portfolio as well as the development of new clinical treatments. Lindsay Davies joined NextCell Pharma in 2020.	0	n/a
Edvard Smith 	Medical director Born in 1951. Independent of the Company´s principal owner. Member of the Management as Medical Director. Professor of Molecular Genetics at the Department of Laboratory Medicine at Karolinska Institutet and Karolinska University Hospital, Huddinge. His research has resulted in the identification of several disease genes and to new treatments. Board member since 2014.	333 028	183 253
Sofie Falk Jansson 	CEO of Cellaviva Born in 1986. Experienced marketeer within business to consumer. Joined NextCell Pharma in 2018.	12 621	7 585
Sofia Sisay 	Head of Clinical Trials Born in 1981, Sofia Sisay possesses a PhD in Neuroscience, accompanied by a significant track record in orchestrating clinical studies and projects across both academic and industrial domains. In her role as Clinical Trial Manager, Sisay holds responsibility for the oversight of all ongoing clinical trials and has been entrusted with project leadership since the inception of NextCell's inaugural clinical trial. Sofia Sisay has been member of the NextCell Pharma team since 2022.	0	n/a

Name	Position	Shares	Options
Hans-Peter Ekre 	Chairman of the board Born in 1950. Independent of the Company and its principal owners. Background as investment manager at Karolinska Development and R&D manager at KabiPharmacia and Astra. Executive Chariman of the Board at Bactavia AB. Board member since 2014.	324 042	18 407
Edvard Smith 	Board Member Born in 1951. Independent of the Company´s principal owner. Member of the Management as Medical Director. Professor of Molecular Genetics at the Department of Laboratory Medicine at Karolinska Institutet and Karolinska University Hospital, Huddinge. His research has resulted in the identification of several disease genes and to new treatments. Board member since 2014.	333 028	183 253
Camilla Myhre Sandberg 	Board Member Born in 1967. Independent of the Company and its principal owners. Board member with a marketing background in cell therapy and regenerative medicine, CEO at Miris Holding AB. Board member since 2017.	0	n/a
Eva Sjökvist Saers 	Board Member Born 1962. Doctoral degree in pharmaceutical science from Uppsala University. Independent of the Company and its principal owners. Eva Sjökvist Saers has many years of experience from the pharmaceutical industry where she has worked in various leading positions within Astra/AstraZeneca, Apoteket AB and as CEO of the pharmaceutical company Apotek Produktion & Laboratorier AB (APL) for more than 10 years. Eva Sjökvist Saers is also Chairman of the strategic innovation program Swelife and has previously been Chairman of Apotekarsocieteten and Vice Chairman of SwedenBIO. Board member since 2021.	0	n/a

Source: NextCell (data), Redeye research (illustration)

Business strategy

NextCell's business strategy focuses on developing and commercializing cell-based therapies using its proprietary selection algorithm. The primary objective is for ProTrans to receive marketing approval for treating type 1 diabetes in collaboration with a partner. The first interim analysis from the ProTrans-Young study, involving 30 patients, is expected in the summer of 2025. This analysis is anticipated to confirm previous efficacy results and initiate detailed out-licensing discussions. The company's long-term strategy is to license additional drug candidates per indication, leveraging its proprietary selection algorithm. Variants of ProTrans are developed by adjusting 1) the selection algorithm parameters to align with the signaling pathways of the targeted disease, 2) dosing and treatment patterns, and 3) the optimal administration route depending on the condition. These adjustments lead to the classification of each treatment as a new drug. NextCell intends to continue developing cell therapies, like ProTrans, for other indications and progressively outlicense drug candidates after phase II trials (ProTrans-Young).

Beyond the ProTrans platform, NextCell's subsidiaries, Cellaviva and QVance, aim to provide predictable, recurring revenues by delivering high-quality services to underserved markets, enhancing the company's financial stability.

Competitive advantages

In line with the general outlook for biotech companies NextCell's primary competitive advantage is related to protection of intellectual property. The company's proprietary selection algorithm is protected by patents until 2039, ensuring long-term exclusivity for its approach. The company also holds a patent family covering methods, compositions, and medical uses of pooled allogeneic mesenchymal stromal cells, with granted patents in Europe, Japan, and Hong Kong valid until 2039. These patents target autoimmune and inflammatory diseases and conditions, including type 1 diabetes. Moreover, with a long-standing presence in the field, NextCell has cultivated in-house expertise in MSC research and development.

Value proposition

ProTrans offers a compelling value proposition for both patients and healthcare systems. As a disease-modifying treatment, it has the potential to preserve insulin production long-term, significantly improving glucose management. This advancement could reduce the risk of complications, enhance patients' quality of life, and potentially increase life expectancy. For society, ProTrans represents an opportunity to alleviate the financial burden of poor glucose management, delivering substantial health-economic benefits. It is also designed to be an off-the-shelf product, providing a logistical advantage by streamlining the treatment process for both patients and healthcare providers.

NextCell has identified a critical market gap in the analysis of cell and gene therapy drugs in the Nordics. Utilizing its in-house tools, clean rooms, and expertise, the company is well-positioned to support developers with GMP-compliant analyses. QVance was recently established as a subsidiary with the goal to become a one-stop shop for such services, addressing the current inefficiencies where tests and samples must be sent to multiple locations. This streamlined solution reduces resource allocation challenges and mitigates associated risks.

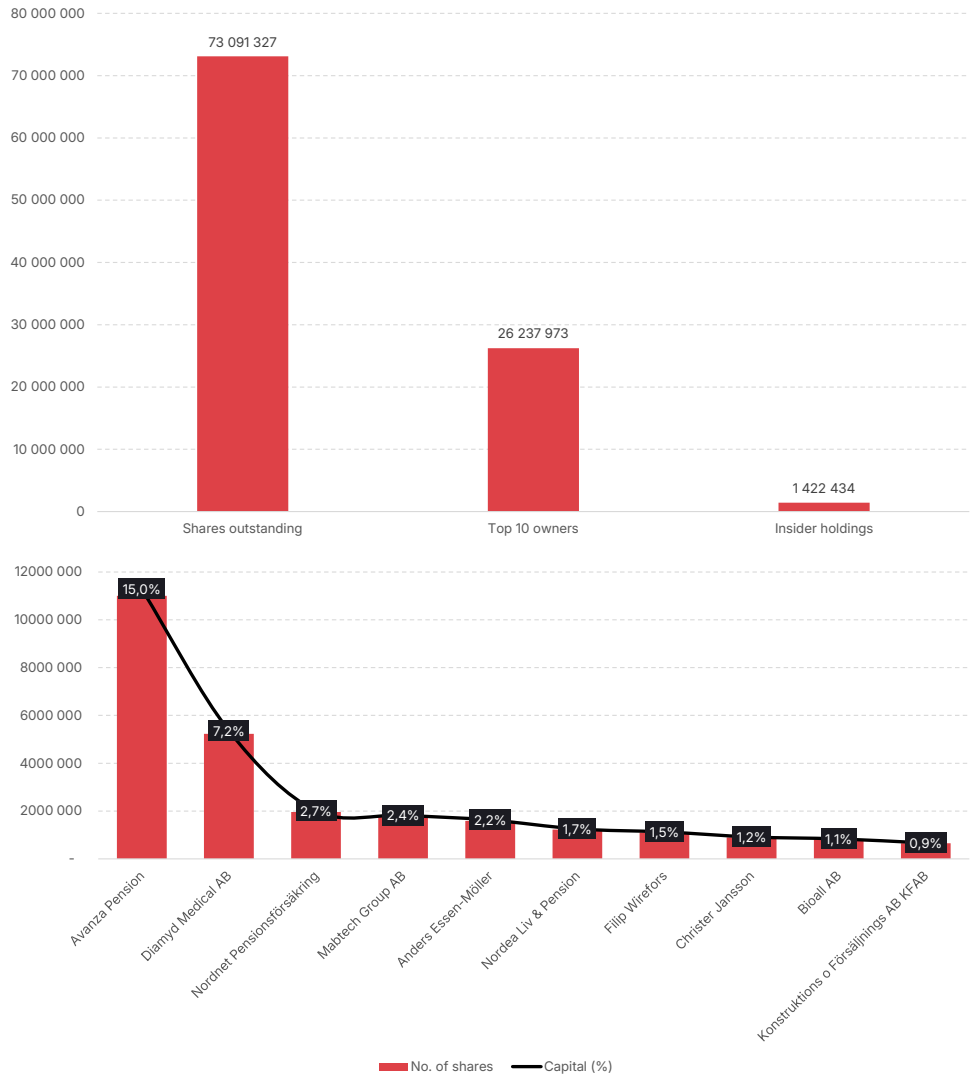
NextCell owns Cellaviva, Sweden's largest biobank for family stem cell storage, approved by Swedish authorities. Cellaviva enables families to bank a child's stem cells, providing access to a life-saving biological resource that is a perfect genetic match for the child. This proactive measure minimizes risks and complications compared to finding an external donor, offering a vital safeguard against unforeseen health challenges.

Ownership

We believe NextCell's ownership structure to be relatively typical for a clinical-stage biotech company, characterized by modest insider ownership and some institutional and industrial presence. The largest shareholders include industry peers such as Diamyd Medical—a Swedish-listed company developing antigen-specific immunomodulatory precision therapies for T1D—retail investors through Avanza Pension, and industry specialist Anders Essen-Möller. Essen-Möller, who also founded Diamyd Medical and previously served on NextCell's board of directors, is a notable shareholder. Together, these three entities represent approximately 30% of the company's equity.

Since the departure of Anders Essen Möller from the board of directors, the insider ownership is relatively low, amounting to approximately 2%, with the CEO Mathias Svahn being the largest owner of insiders holding c1.3% of the company according to holdings. Additionally, the management and board collectively hold 3.5% of the TO2 warrants, which are due for subscription in May 2025.

Shareholder structure



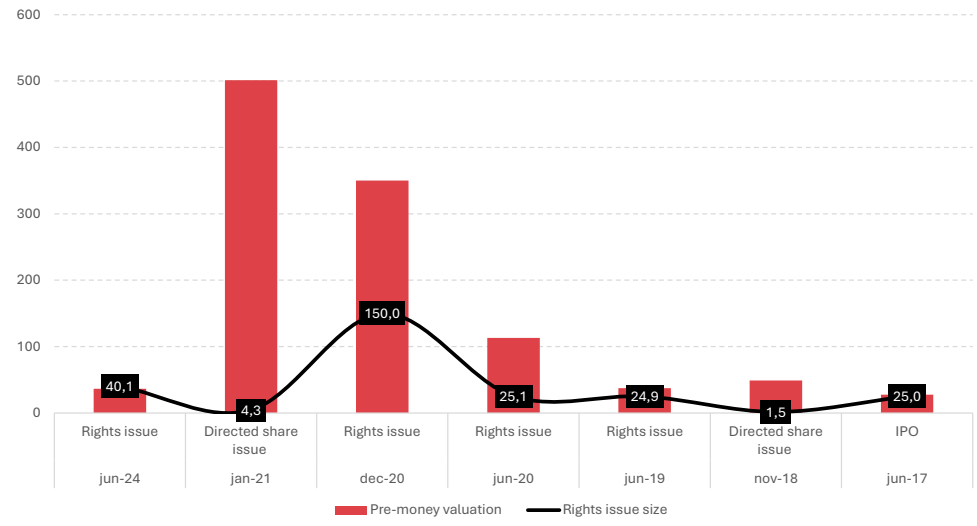
Source: Holdings (2025-01-15)

Financing Overview

NextCell has raised capital several times since its IPO in 2017, in line with the expectations and typical funding needs of a biotech company advancing a therapy through clinical development. These transactions have occurred at pre-money valuations ranging from SEK27m (at the IPO) to SEK501m (in a directed issue in 2021), playing a key role in advancing ProTrans to its current stage. The most recent capital raise, in June 2024, was conducted at a pre-money valuation of SEK36.4m.

The majority of capital raises have been rights issues. It has also twice carried out small directed issues, once in 2018 of SEK1.5m to Nordic Tech House, and once in 2021 targeting Polski Bank Komórek Macierzystych S.A (PBKM), the largest stem cell bank in Europe, where it raised SEK4m at a pre-money valuation of SEK501m.

Financing history



Source: NextCell (data), Redeye Research (chart structuring & calculations)

Since 2017, NextCell's financing rounds have shown a clear correlation between value creation and development progress, with the pre-money valuation increasing from SEK25m at the IPO to around SEK350m during the larger rights issue in 2020, reaching approximately SEK500m in 2021. However, the rights issue in June 2024 reversed this trend, showing an inverse relationship between clinical development progress and pre-money valuation. This is in our view counterintuitive, given the clinical data from ProTrans and over all advancements in the company. Typically, such a negative trend would imply unsatisfactory data or market concerns about a suboptimal financing solution—neither of which we believe applies to NextCell.

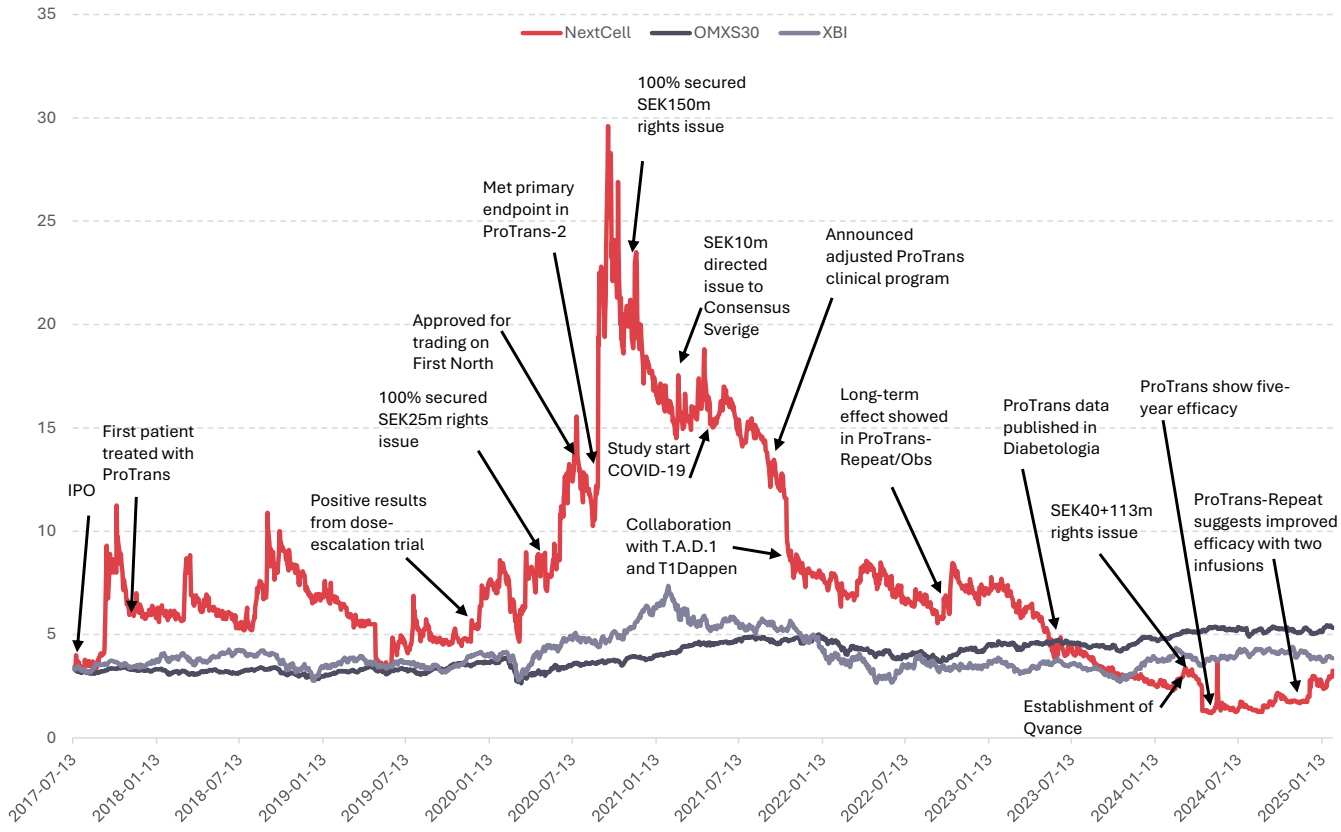
As outlined more elaborate on the next page, we believe this development is primarily driven by three key factors. First, the prevailing negative market sentiment toward biotech has weighed heavily on valuations across the sector. Second, the company's decision to expand the scope of the phase II trial, rather than proceeding directly to phase III. Lastly, NextCell has struggled to effectively communicate its equity story and differentiate itself among investors.

Share price discussion

Since its listing in 2017, NextCell's share price has exhibited high volatility, reflecting a high beta compared to both the OMXS30 index and the XBI ETF—a commonly used proxy for biotech sentiment. The stock has been primarily driven by ProTrans-related development milestones, peaking in Q3 2020 after meeting the primary endpoint in the ProTrans-2 trial.

However, following a SEK 150m rights issue and adjustments to its clinical program—delaying the phase III trial to include pediatric patients—the stock entered a prolonged decline. This aligns with broader biotech sentiment, as evidenced by the XBI ETF remaining well below its 2021 highs (down approximately 47%). The diminished risk appetite for small biotech companies in recent years has significantly weighed on valuations across the sector.

Unadjusted share price performance since IPO (SEK)



Source: Millistream (data), Redeye Research (chart structuring)

The extent of NextCell's share price decline appears largely disconnected from fundamentals, given the positive clinical development newsflow in recent years. We believe NextCell has struggled to effectively communicate its equity story to investors, leaving the case relatively "undiscovered" despite its advanced stage and promising data (currently a shareholder base of 3000 on Avanza).

However, the outlook for share price development throughout 2025 and beyond appears favorable. The forthcoming interim phase IIb readout in conjunction with a generally improving biotech could serve as catalysts for positive momentum. The accumulated data should support a relatively high probability of success, further reinforced by the stock's historical sensitivity to clinical milestones. Additionally, financing risks—often a key concern post-readout—are largely

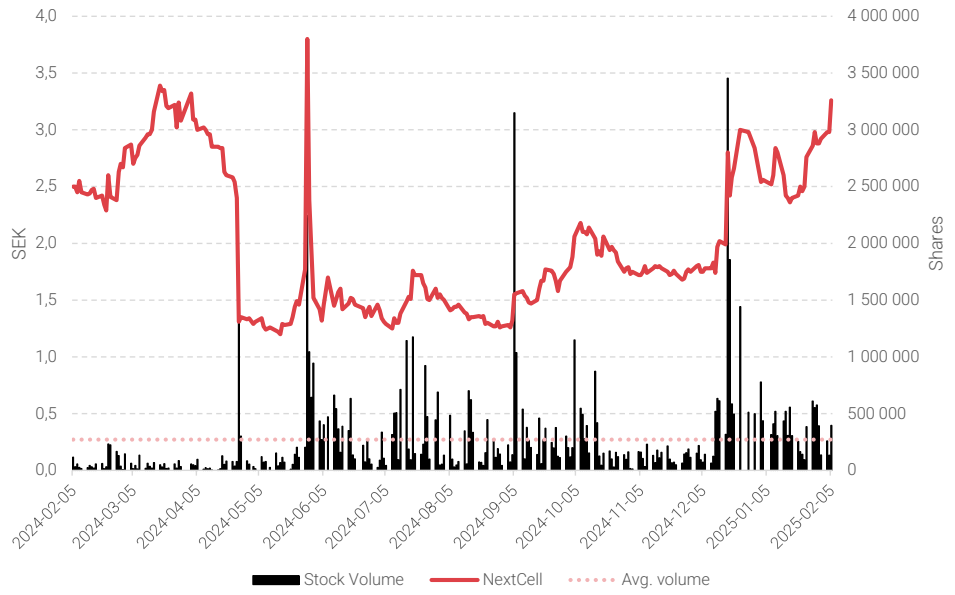
mitigated by the potential proceeds from TO2 warrants. These could provide up to SEK 113m in gross funding by May 2025, reducing financial uncertainty as a funding solution is at hand.

The primary share price catalysts for the share price will be the readouts of ProTrans-Young anticipated in Q2 2025 and Q4 2026. These readouts could mark transformative milestones for both the company and its valuation.

Volume

In the past twelve months the average turnover of shares amounts to approximately 272 thousands share per day, corresponding to approximately SEK500 thousand – which contributes to the volatility in the share price, with volume spikes being allocated to development and funding-related press releases.

Volume and share price development - 12 months



Source: Millistream (data), Redeye Research (chart structuring)

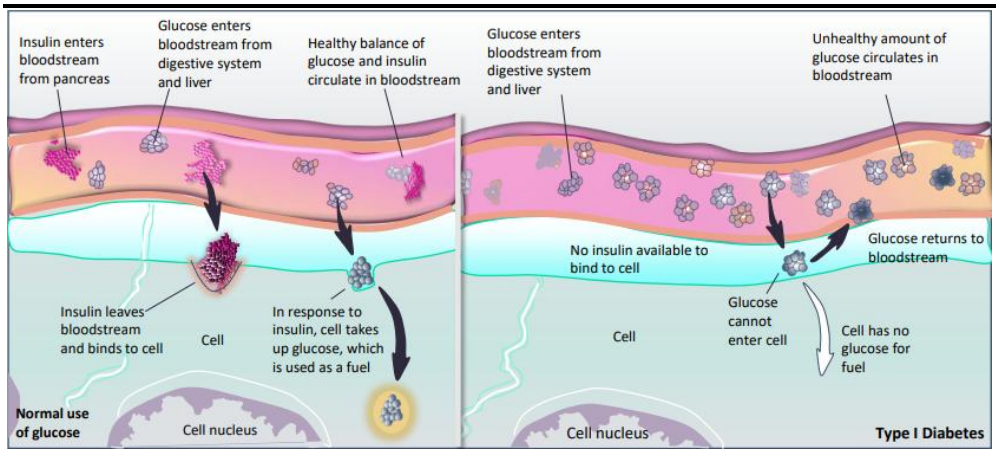
Pipeline and medical need

NextCell's flagship project, ProTrans, is a cell therapy utilizing mesenchymal stromal cells (MSCs) derived from umbilical cord tissue. Renowned for their regenerative and immunomodulatory properties, MSCs can differentiate into various cell types, including bone, cartilage, and fat cells. ProTrans is based on NextCell's patented selection algorithm and is designed to treat T1D by targeting the autoimmune processes driving disease progression, effectively slowing its advancement.

Type 1 Diabetes (T1D) Introduction

During digestion, the human body breaks down carbohydrates from foods like bread, rice, and pasta into various sugar molecules. One of these molecules is glucose, the body's primary energy source. Glucose is absorbed directly into the bloodstream after eating. With the help of the hormone insulin, glucose can enter the cells of the body's tissues. A simplification is that insulin acts as a key that opens the door (cells) to allow blood glucose to enter, as illustrated below:

Pathophysiology of T1D



Source: GlobalData - Harvard Health Publishing (illustration)

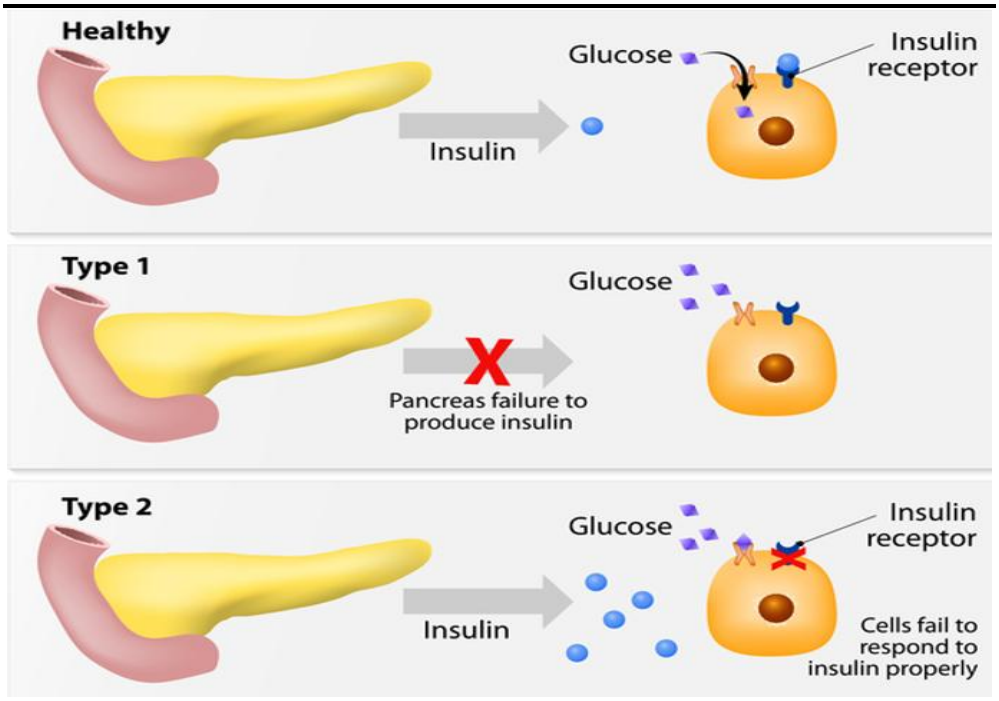
T1D and T2D, what is the difference…?

Diabetes mellitus refers to a group of metabolic disorders characterized by hyperglycemia (elevated blood glucose levels) caused by insufficient insulin secretion, impaired insulin sensitivity, or a combination of both. The two primary types are Type 1 diabetes (T1D) and Type 2 diabetes (T2D), which together account for approximately 90–95% of all diabetes cases in high-income countries. Of these, T1D represents about 5–10%. Other forms include gestational diabetes, which arises during pregnancy and typically resolves postpartum, and latent autoimmune diabetes in adults (LADA), a subtype of T1D diagnosed later in life.

T1D arises from a combination of genetic and environmental factors that trigger the production of islet-reactive autoantibodies. This autoimmune response leads the immune system to mistakenly attack insulin-producing beta cells in the pancreas, resulting in an absolute insulin deficiency as the patient's capacity to produce insulin is completely lost over time. In contrast, T2D is primarily driven by insulin resistance, often linked to conditions such as obesity and cardiovascular disease, leading to a relative insulin deficiency. T2D also includes a pre-diabetic phase where beta cell function can improve with effective blood sugar management.

ProTrans, NextCell's lead candidate, targets T1D by addressing the autoimmune mechanisms that underlie beta cell destruction. Its therapeutic effect is specific to this type of diabetes, where endogenous insulin production diminishes to eventually reach zero.

Diabetes mellitus overview



Source: Medline (illustration)

Etiology T1D

T1D is an autoimmune disease that permanently destroys the beta cells in the pancreatic islets, preventing the body from producing insulin, the hormone necessary for transporting glucose from the bloodstream into cells[1].

T1D is primarily caused by autoimmune-mediated destruction of insulin-producing pancreatic beta cells. Research on pancreatic tissue and peripheral blood lymphocytes indicates that a series of functional defects in the bone marrow, thymus, immune system, and beta cells all contribute to the disease's development, though the exact cause remains unknown to this day.

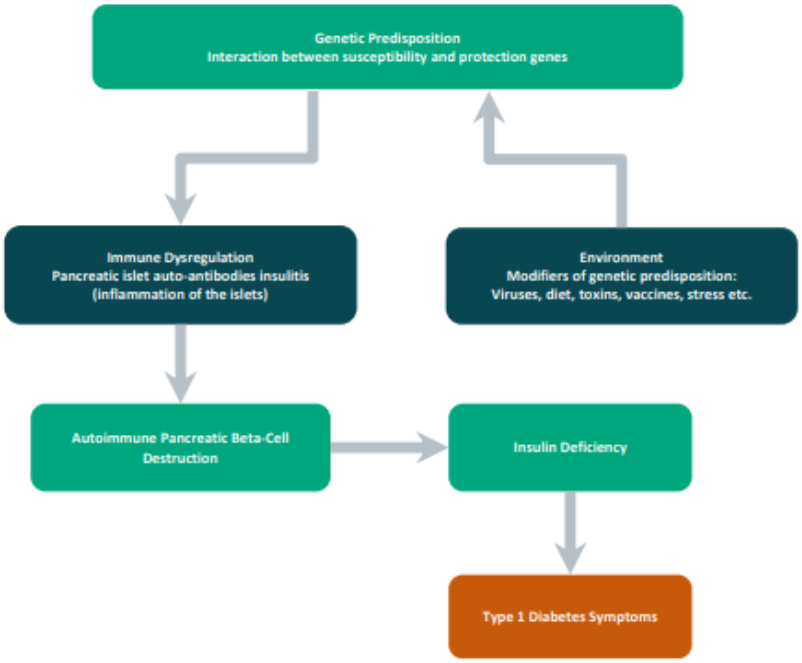
While multiple genetic loci are linked to T1D onset, environmental factors also play a crucial role in determining risk. Extensive familial and population genetic studies have shown a strong association between human leukocyte antigen (HLA) genes and T1D[2]. Specifically, HLA class II genes have been found to account for 30–50% of genetic T1D risk since their first association with diabetes in the 1970s, underscoring their role in the T-cell immune response[3].

Research shows that T1D risk increases from birth, peaks between ages 10–14, declines after puberty, and stabilizes in early adulthood[4]. Other environmental influences, such as diet, stress, and viruses, also contribute to the development of T1D in genetically predisposed individuals[5]. While several factors have been linked to T1D, none of the individual associations seem to be of a magnitude that could fully explain the increasing incidence of the disease. T1D appears to

[1] Vives-Pi, Rodríguez-Fernández, and Pujol-Autonell, 2015.
[2] Wang et al., 2017
[3] Cudworth and Woodrow, 1975; Santos et al., 2020
[4] Maahs et al., 2010
[5] Norris, Johnson, and Stene, 2020

be a heterogeneous disease, with its etiology, genetics, and phenotypic characteristics exhibiting significant variation.

T1D etiology

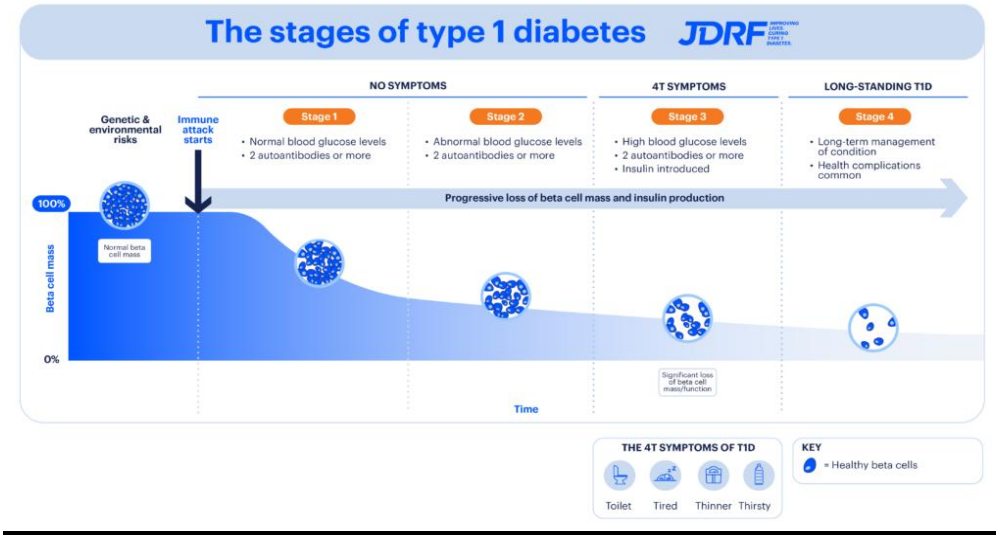


Source: Global data (picture)

A consensus statement from the Breakthrough T1D (previously JDRF), the American Diabetes Association (ADA), and the Endocrine Society has identified three stages of early T1D, followed by a fourth stage which essentially is the lifelong required monitoring and treatment.

- Stage 1 - Presence of autoimmunity, but the individual remains normoglycemic.
- Stage 2 - Evidence of glucose intolerance.
- Stage 3 - Symptomatic hyperglycemia (elevated blood sugar levels).
- Stage 4 - Glucose monitoring and insulin treatment

Diabetes mellitus overview



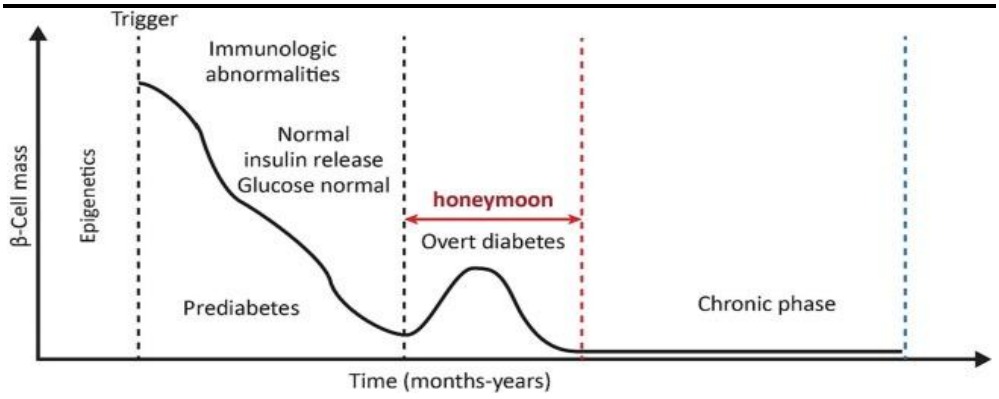
Source: Juvenile Diabetes Research Foundation - JDRF (illustration)

Insulin production continues a few years after diagnosis

After an initial diagnosis of T1D, patients often experience a "honeymoon phase," during which the remaining functional beta cells in the pancreas continue to produce some insulin, albeit at progressively diminishing levels. This phase, lasting from several months to over a year or more depending on individual variability, marks a period where endogenous insulin production partially supports blood glucose regulation.

During the honeymoon phase, patients typically require lower doses of exogenous insulin compared to those with fully depleted beta cell function. This residual insulin production can facilitate achieving target blood glucose levels, improve quality of life, and, if prolonged, may potentially reduce the risk of long-term complications associated with poorly managed glucose control. However, as the autoimmune process continues, beta cells are progressively destroyed, ultimately necessitating full reliance on external insulin for glycemic control.

Endogenous insulin production continues after diagnosis



Source: ScienceDirect (illustration)

In general, patients may lose up to 80% of their beta cell function by the time they are diagnosed, typically in stage 3 of T1D[6, 7]. However, this loss is highly variable and can differ considerably from one patient to another. Early-stage treatments targeting the preservation of beta cell function are thus likely to be most effective in patients with higher residual beta cell activity at the time of diagnosis.

Avoiding hyperglycemia is crucial to reduce long-term complications

Historically, the treatment of T1D has centred on symptom management through insulin injection since its discovery in 1921, with no approved disease-modifying treatments available until very recently. Therapeutic advancements have primarily focused on improving insulin formulations, such as developing rapid-acting insulin analogs and enhancing delivery methods, including introducing insulin pumps, which, with today's technology, try to resemble an artificial pancreas.

Effective T1D management relies on continuous blood glucose monitoring to guide insulin dosing. Patients utilize blood glucose monitors (BGMs) or continuous glucose monitors (CGMs) to track their glucose levels 24/7. These devices provide the essential data needed to adjust insulin doses through injections or insulin pumps, enabling patients to navigate the delicate balance between hyperglycemia (high blood sugar) and hypoglycemia (low blood sugar).

[6] Carlsson, PO., Espes, D., Sisay, S. et al. Umbilical cord-derived mesenchymal stromal cells preserve endogenous insulin production in type 1 diabetes: a Phase I/II randomised double-blind placebo-controlled trial. Diabetologia 66, 1431–1441 (2023). https://doi.org/10.1007/s00125-023-05934-3

[7] Klöppel G, Löhr M, Habich K, Oberholzer M, Heitz PU: Islet pathology and the pathogenesis of type 1 and type 2 diabetes mellitus revisited. Surv Synth Pathol Res 4:110–125,1985

Hyperglycemia is typically defined as blood glucose levels exceeding 180 mg/dL (10 mmol/L) over a prolonged period and is managed by insulin administration. Conversely, hypoglycemia, characterized by levels below 70 mg/dL (3.9 mmol/L), occurs when excessive insulin is administered. This creates a challenging cycle, as patients strive to maintain glucose levels within a healthy range while minimizing fluctuations that can lead to complications.

BGM (left) CGM (right)

Source: NextCell (illustration)

The American Diabetes Association (ADA) provides the following recommended treatment paradigm for T1D patients:

American Diabetes Association recommended treatment for T1D patients

Step	ADA
Lifestyle management	• Patients should be educated on how to match mealtime insulin doses to carbohydrate intake, fat and protein content, pre-meal glucose, and anticipated physical activity
Overall insulin regimen	• Most people with T1DM should be treated with multiple daily injections (MDI) of prandial (mealtime) and basal insulin, or continuous subcutaneous insulin infusion (insulin pump)
Basal insulin	• The guidelines note that the longer-acting insulins Toujeo and Tresiba may lower hypoglycemia risk compared to insulin glargine • NPH is a less preferred alternative
Mealtime insulin	• Most patients with T1DM should use RAA to reduce hypoglycemia risk • The guidelines note that Fiasp and Lyumjev may reduce prandial excursions better than RAA, and that inhaled insulin may cause less hypoglycemia and weight gain than RAA • Regular human insulin is a less preferred alternative
Mixed insulin	• While use of mixed insulin requires fewer injections for people with a strong preference for this and can lower cost, it is a less preferred alternative, with less flexibility and higher risk of hypoglycemia than others
Insulin pumps/CGM	• While most studies comparing pumps and MDI have been small and short in duration, a systemic review and meta-analysis concluded that pumps have modest advantages on lowering A1C (-0.3%) and for reducing severe hypoglycemia. However, there is no consensus on guiding the choice for a given individual. Still, the guidelines say that intensive insulin management using an insulin pump and CGM should be considered in most • Evidence for an advantage of closed-loop systems over sensor-augmented pumps, and closed-loop systems may be considered in patients capable of using them safely • CGM is standard of care for most with T1DM
Insulin-naïve type 1 diabetes patients	• No mention of use of specific insulins for insulin-naïve patients
Non-insulin treatment	• Pramlintide is approved for use in T1DM, with evidence for a modest reduction in A1C and weight • Results have been reported for metformin, GLP inhibitors (eg liraglutide), and SGLT-2 inhibitors as non-insulin treatments for T1DM; however, they are currently only approved for T2DM, and SGLT-2 inhibitors are associated with an increased risk of diabetic ketoacidosis. Risk and benefits continue to be evaluated
Surgical treatment	• Pancreas and islet transplantation can normalize glucose, but given the need for lifelong immunosuppression, should be reserved for patients undergoing simultaneous renal transplantation or for those with recurrent ketoacidosis or severe hypoglycemia despite intensive glycemic management

Source: American Diabetes Association (ADA)

Maintaining good metabolic control and stable glucose levels is crucial to reducing the risk of severe long-term complications. Suboptimal glycemic control can lead to serious issues, including organ damage, retinopathy, nephropathy, neuropathy, and cardiovascular disease. Physicians commonly use HbA1c as a key biomarker to monitor metabolic control in diabetes. HbA1c indicates the percentage of glycated hemoglobin in the blood, offering a measure of average blood glucose levels over the past 2–3 months. Elevated HbA1c levels are strongly linked to the progression of diabetes-related complications, making it essential to maintain levels within the target range to mitigate long-term risks. This measure is increasingly complemented by Time in Range (TIR), which assesses the percentage of time blood glucose levels remain within the target range, typically 3.9–10.0 mmol/L. TIR provides a more dynamic and nuanced understanding of glycemic control compared to HbA1c. Both metrics are frequently employed as endpoints in clinical trials for T1D therapies.

Preserving or enhancing endogenous insulin secretion in T1D patients offers a transformative approach to glycemic control. Endogenous insulin dynamically adjusts to blood glucose fluctuations in real-time, unlike exogenous insulin, which lacks this adaptive response. This dynamic regulation reduces the risks of hyperglycemia and hypoglycemia, leading to better glucose management and improved quality of life for patients.

Health economics

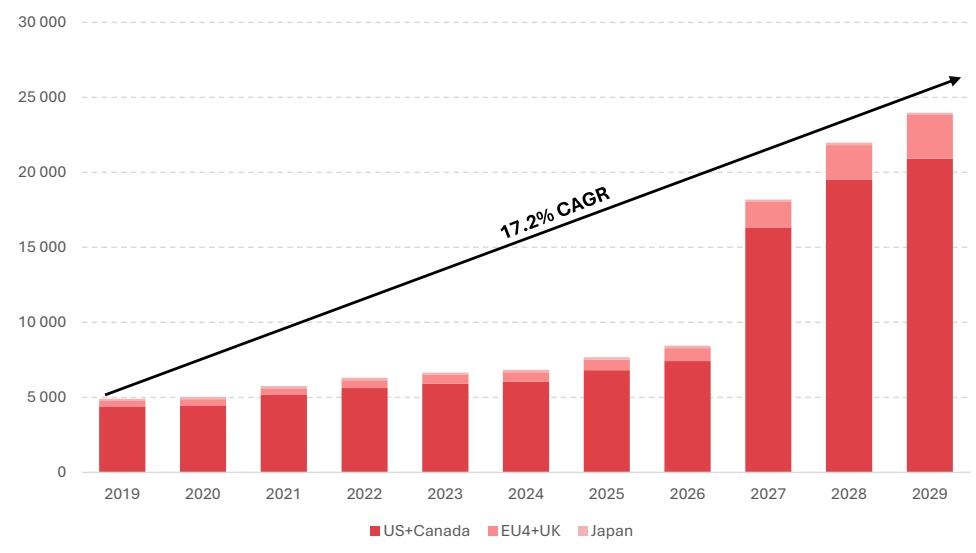
Quantifying the health-economic burden of T1D is challenging, given that it is associated with considerable indirect costs that both individuals and society bear. Moreover, most health economic studies have been focused on T2D or diabetes as a whole. However, studies are providing some insights into the scale of financial impact. For example, one study compared 1.6 million T1D patients with the corresponding number of patients without T1D and estimated a lifetime economic burden of T1D patients in the US to be approximately USD 813 billion[8], which amounts to more than USD500,000 per patient.

Moreover, another angle was highlighted in the UK, where a study by the NIH examined the economic impact of different HbA1c levels on diabetes management. It found that subjects with an HbA1c of 86 mmol/mol (10.0%) incur lifetime costs of £23,795. In contrast, maintaining an HbA1c of 42 mmol/mol (6.0%) could save £12,649, while also gaining 2.80 Quality-Adjusted Life Years (QALYs). This results in a net monetary benefit of £68,621 per person. Furthermore, reducing BMI provides a net benefit of £120 per person, and avoiding a single non-severe hypoglycemic event can save up to £197 per person[9]. These findings clearly highlight the significant economic burden of T1D and underscore the motivation for developing new therapeutics to improve blood glucose management

T1D therapeutics market size

As noted, T1D-related therapeutic sales have historically been driven by insulin, with additional contributions from therapeutics such as GLP-1 analogs and SGLT inhibitors. However, recent years have seen the approval of new treatments, including GLP-1s and disease-modifying therapies like teplizumab (Tzield) and Lantidra. The 8MM (US+Canada, EU4 + UK, and Japan) is projected to experience a CAGR of 17.2% in T1D-related therapeutic sales between 2019 and 2029, according to the GlobalData forecasts. In 2024, the US and Canada are expected to dominate the market, accounting for nearly 90% of total sales.

Estimated T1D therapeutic sales (USDm)



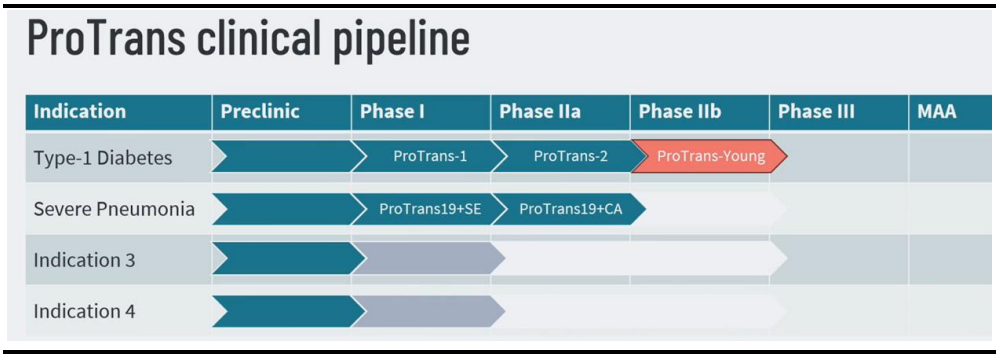
Source: GlobalData (data), Redeye research (chart structuring)

[8] Sussman M, Benner J, Haller MJ, Rewers M, Griffiths R. Estimated Lifetime Economic Burden of Type 1 Diabetes. Diabetes Technol Ther. 2020 Feb;22(2):121-130. doi: 10.1089/dia.2019.0398. PMID: 31886730.
[9] McEwan P, Bennett H, Bolin K, Evans M, Bergenheim K. Assessing the economic value of maintained improvements in Type 1 diabetes management, in terms of HbA_{1c}, weight and hypoglycaemic event incidence. Diabet Med. 2018 May;35(5):557-566. doi: 10.1111/dme.13590. Epub 2018 Feb 28. PMID: 29377320; PMCID: PMC5947585.

ProTrans

Beyond T1D, ProTrans has been explored in investigator-initiated trials for COVID-19, and other forms of virally induced pneumonia, in Sweden and Canada, though this pathway in Canada is no longer actively pursued on account of lack of funding from the sponsor. The company has also indicated that ProTrans may have potential in other autoimmune diseases, supported by the early-stage development of a preclinical, undisclosed project under the name NPC03. However, given the early stage of NPC03 and the discontinued COVID-19 studies, this report will focus on the T1D program, which unarguably constitutes the lion's share of the value of the company.

Pipeline overview



Source: NextCell (picture)

Stromal cells

Mesenchymal stromal cells, as used in ProTrans, were originally defined as a type of adult stem cell or mesenchymal stem cells. Today we understand that the connective tissue cells, or stroma, which are a heterogenous population of cells, including a small number of stem cells, are more effective in the development of immune-modulating cell therapies. This mixed population of stromal cells work in tight interplay with one another to ensure the maintenance and repair of tissues, as well as supporting the function of the individual tissue in which they reside in the body.

The application of stem cells has been focused on exploiting their ability to differentiate into various specialized tissues for regenerative medicine applications. However, stromal cells are far more effective at modulating the immune system than stem cells and this is why they have been employed in the development of cell therapies for autoimmunity, inflammation and immune dysregulation.

MSCs represent a promising approach for diabetes treatment, owing to their innate immunomodulatory, proangiogenic, and antifibrotic properties. These cells can be sourced from various connective tissues, but they are most commonly harvested from bone marrow, adipose tissue, or umbilical cord. Wharton's jelly MSCs (WJMSCs), a gelatinous substance derived from the umbilical cord, are particularly appealing due to their well-defined characteristics, abundance in the tissue, and rapid proliferation. Stromal cells maintain a memory of their tissue of origin and in vivo role even when removed from that environment and expanded in culture for the production of cell therapies. In the case of WJMSCs they have a memory to protect the foetus from the "foreign" cells of the mother, termed as foetal:maternal tolerance, which translates to a specific advantage in the development of allogeneic therapies and cell therapies where a clinical effect of tolerance eg in the case of dampening down inflammation or auto-destructive responses. Together, their ease of accessibility and

immunomodulatory capabilities make them suitable for use in allogeneic "off-the-shelf" therapies.

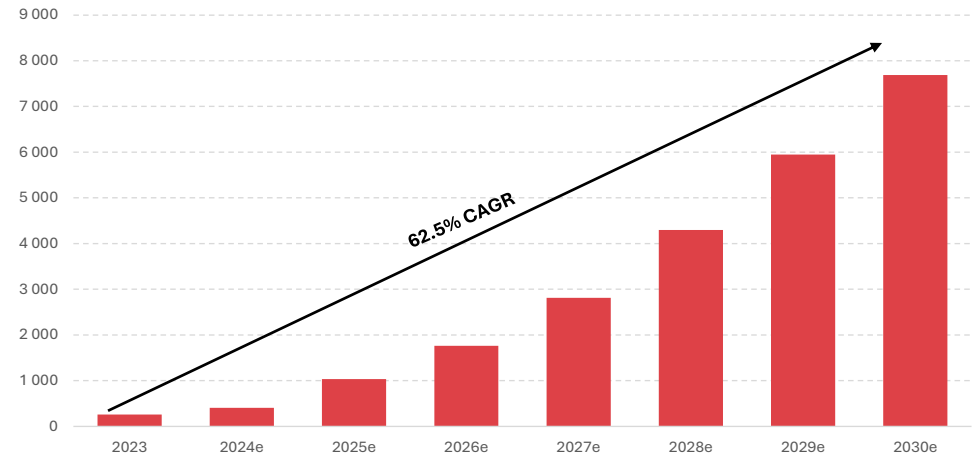
MSCs have been studied for their immunomodulatory effects in various diseases, including autoimmune disorders like multiple sclerosis and systemic lupus erythematosus (SLE). While numerous in vivo murine studies have explored the potential therapeutic benefits of MSCs in type 1 diabetes, clinical trials remain limited.

Cell therapy

Cell therapies are advanced medical treatments that involve the administration or transplantation of living cells into a patient to repair, replace, or regenerate damaged tissues and treat various diseases. These therapies are based on the idea that certain types of cells have regenerative, immune-modulating, or other therapeutic properties that can address underlying causes of illness, rather than merely alleviating symptoms. Cell therapies include a range of approaches, from using a patient's own cells (autologous therapy) to utilizing donor cells (allogeneic therapy). Common sources of therapeutic cells include stem cells, immune cells, and specialized progenitor cells.

A well-known subset of cell therapies includes hematopoietic stem cell transplantation (HSCT), widely used in cancer treatment to restore blood and immune cells after chemotherapy. Emerging forms, such as MSCs and chimeric antigen receptor T-cells (CAR-T), have gained attention for their potential to treat autoimmune diseases, heart conditions, and cancers, respectively. Cell therapies are subject to rigorous testing in clinical trials, given their complexity and the specific regulatory and manufacturing challenges they pose. Sales from approved cell therapy products are expected to increase dramatically from approximately USD250m in 2023 to around USD7.7bn by 2030, reflecting a CAGR of 62.5%.

Modality sales projection, Cell therapy (USDm)

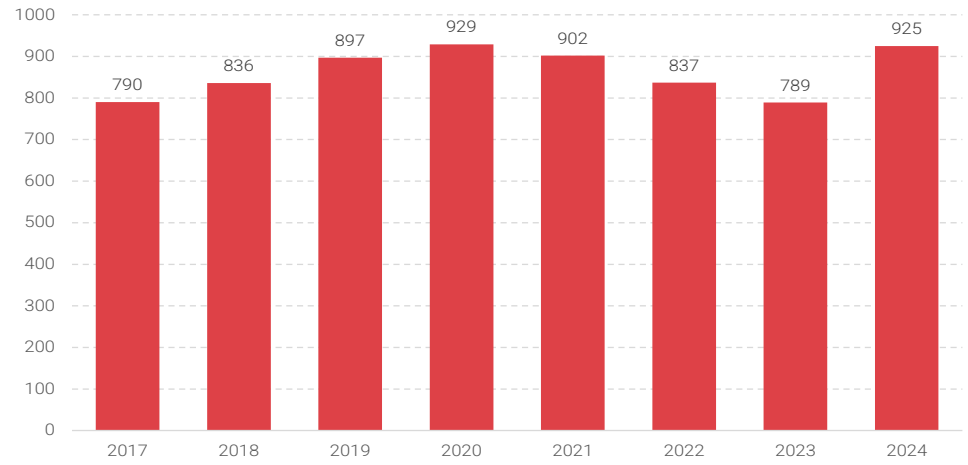


Source: GlobalData (data&estimates), Redeye research (chart structuring)

The cell therapy pipeline has expanded substantially over the past decade. According to the GlobalData database, over 700 clinical trials involving cell therapies have been initiated annually since 2017, highlighting the modality's increasing momentum. Some of these therapies are anticipated to reach blockbuster status, with projected sales exceeding USD1bn. As of Q3 2023, more than 1100 clinical trials globally have investigating MSCs, yet only around 10 MSC-based therapies have received regulatory approval. However, as recent as December 18, 2024, the Food and Drug Administration approved remestemcel-L-rknd (Ryoncil, Mesoblast, Inc.), an allogeneic bone marrow-derived mesenchymal stromal cell (MSC) therapy, for steroid-

refractory acute graft versus host disease (SR-aGVHD) in pediatric patients 2 months of age and older.

Cell therapy clinical trial initiations



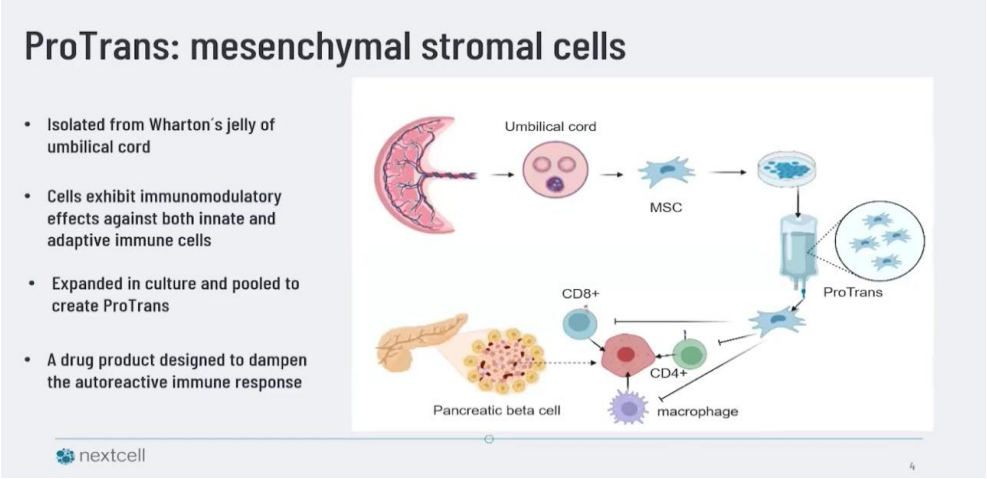
Source: Globaldata (data), Redeye research (chart structuring)

ProTrans in T1D

NextCell's ProTrans therapy is derived from umbilical cord tissue, specifically MSCs isolated from Wharton's jelly, known as WJMSCs. These cells are expanded in culture and pooled from five different donors to create ProTrans, an intravenous drug product. This pooling approach is designed to minimize batch-to-batch variability and optimize efficacy.

ProTrans harnesses the immunomodulatory properties of MSCs, which target both the innate and adaptive immune systems to suppress the autoimmune response associated with T1D. As an off-the-shelf solution, ProTrans is administered in an outpatient setting at the bedside with a fixed cell dose, allowing patients to be discharged within hours.

ProTrans - overview



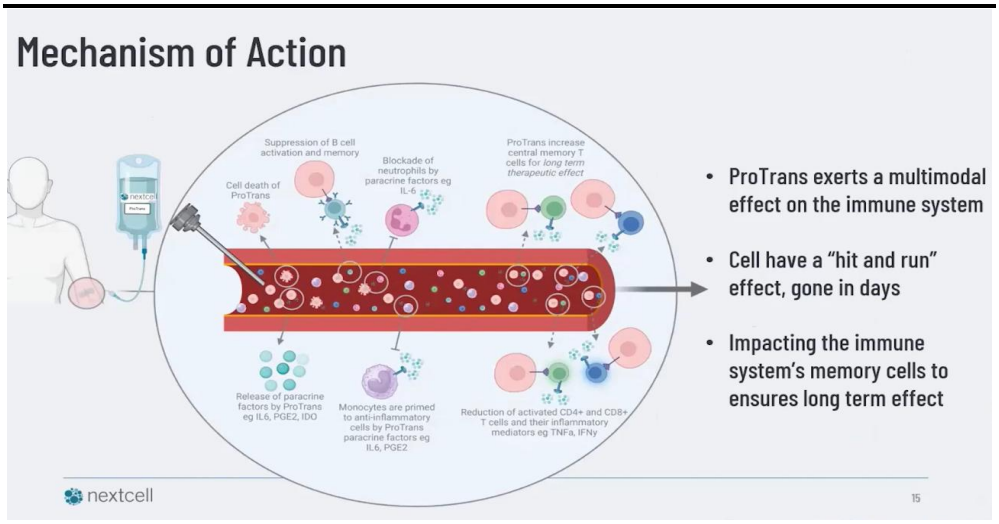
NextCell (illustration)

ProTrans functions through a multimodal, "hit-and-run" effect on the immune system. Although the infused cells are eliminated from the body within days post-infusion, they leave a lasting impact on the patient's immune system, enabling a long-term therapeutic effect. ProTrans has

been observed to suppress the activation of CD4 and CD8 T cells, which directly correlates with reduced inflammation through a decrease in inflammatory cytokines.

Moreover, ProTrans induces central memory T cells, which are essential for improving beta cell function in T1D. ProTrans also reduces T cell effector memory cells, which are central to the autoimmune response, potentially mitigating the immune-mediated destruction of beta cells. This mechanism allows patients to preserve a greater proportion of their insulin production over a prolonged period.

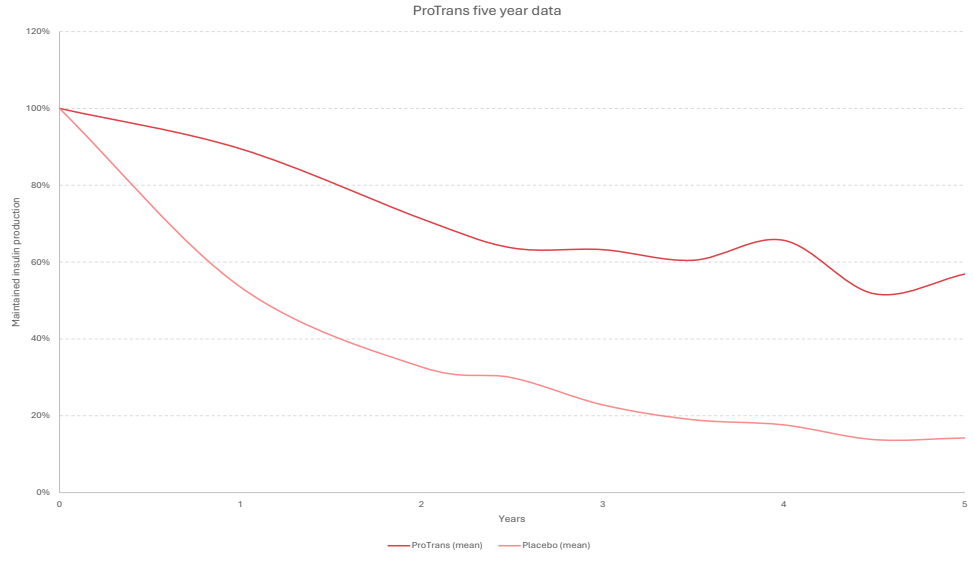
ProTrans – mechanism of action



Source: NextCell (illustration)

This effect supports patients with residual beta cell function, positioning ProTrans as well-suited for those recently diagnosed with T1D. Clinical trials have demonstrated its ability to slow disease progression in this population. In the combined phase I/IIa trial, NextCell demonstrated that patients retained approximately 57% of their baseline insulin production after five years, compared to only 14% in the placebo group. Further details on the clinical validation are presented in the coming chapter.

ProTrans five-year effect on maintained insulin production compared to placebo



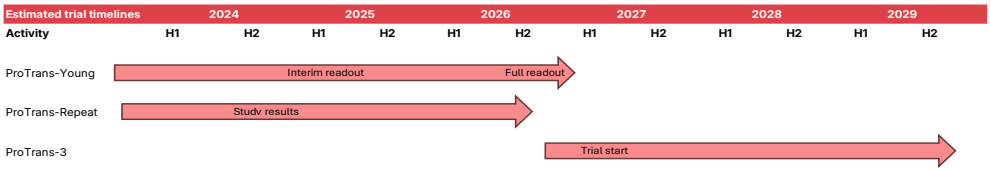
Source: NextCell (data), Redeye Research (illustration)

Clinical validation

ProTrans has been evaluated across several clinical trials, providing a robust dataset to support its development. Notably, the five-year data from the ProTrans-2 trial, reported in mid-2024, demonstrated a statistically significant and clinically meaningful improvement in outcomes compared to placebo, underscoring the candidate's long-term efficacy. Additionally, results from the ProTrans-Repeat trial, disclosed at the end of 2024, suggested that two injections of ProTrans may be more effective than a single dose, offering valuable insights into optimizing treatment protocols.

ProTrans clinical validation overview

Study name	Timeline	Year	Patients	Comment
T1D				
ProTrans-1	Completed	2018-2019	9	Open-label Phase I dose-escalation study. Showed safety and a dose-dependent effect on insulin production
ProTrans-2	Completed	2019-2020	15	Randomized, double-blind, placebo-controlled Phase II study - patients retained more than 50% insulin production
ProTrans-3	Planned	TBA	100-200	Upcoming pivotal Phase III trial is anticipated to serve as the foundation for conditional marketing approval.
ProTrans-Young	ongoing	2022-20	66	Investigator-initiated phase I/II trial on pediatric patients - >50% of patients treated
ProTrans-Repeat	ongoing	2019-2024e	15	Continuation of ProTrans-1 to verify effect of repeated treatment
ProTrans-OBS	ongoing	2019-2024	15	Long-term follow-up of 11 patients from ProTrans-2 - Five year data suggests disease modifying results



Source: NextCell (data), Redeye research (illustration)

NextCell's clinical trials are led by prominent experts in the T1D field, which provides additional validation of the scientific rationale of ProTrans. They are also active in other clinical stage T1D projects including Diamyd Medical's and Sana Biotechnology's. Per-Ola Carlsson has served as the principal investigator for all NextCell's T1D trials. He is a Chief Physician and specialist in Endocrinology and Diabetology, with more than 30 years of T1D research experience. He is also a Professor of Medical Cell Biology at the Department of Medical Cell Biology, Uppsala University, and holds a second professorship in Experimental Endocrinology at the Department of Medical Sciences, Academic Hospital in Uppsala.

In addition to Per-Ola Carlsson, Johnny Ludvigsson brings his extensive experience as a Senior Professor of Pediatrics at Linköping University. A distinguished pediatrician and researcher, Ludvigsson has authored over 400 scientific papers published in prestigious journals, including Nature, The Lancet, and The New England Journal of Medicine, with over 32,000 citations (Google Scholar). He founded The Swedish Child Diabetes Foundation in 1989, an organization supporting T1D research. Ludvigsson's expertise and involvement in late-stage T1D clinical trials should provide invaluable insights to the ProTrans-Young trial while also strengthening its scientific foundation as a co-investigator.

Completed clinical trials

Overall, the ProTrans-1 and ProTrans-2 trials together form a combined phase I/IIa study, conducted at the Karolinska University Hospital in Stockholm, Sweden. The program included a dose-escalation study followed by a randomized double-blind, placebo-controlled parallel study. The trials were designed to assess safety, optimal dosing, and efficacy in preserving

endogenous insulin production among T1D patients with recent diagnoses. A total of 24 participants were included, with nine being in the dose escalation part and 15 in the randomised, double-blinded, and placebo-controlled part. In addition to body weight, chronic infection, and unstable cardiovascular status-related exclusion criteria's the trial had the following inclusion criteria:

- T1D diagnosis <2 years before enrolment
- Age 18-40
- Fasting plasma C-peptide concentration >0.12 nmol/l

The ProTrans-Young/Repeat/OBS is largely continuation of the ProTrans-1/2 trials as described in the above picture.

Primary endpoint

The primary efficacy endpoint in ProTrans-1 and ProTrans-2 was the Δ (change) in C-peptide AUC during a mixed meal tolerance test (MMTT) one-year post-infusion compared to baseline. This metric is a key quantitative measure of beta-cell function, reflecting the body's ability to produce insulin in response to glucose intake. C-peptide is a byproduct of proinsulin cleavage, released in equal amounts with insulin from pancreatic beta cells. Measuring C-peptide provides a direct indicator of endogenous insulin production, as it reflects beta-cell function and is unaffected by external insulin therapy. Thus, the Δ in C-peptide AUC during a mixed meal tolerance test (MMTT) one-year post-infusion compared to baseline have been used as efficacy endpoints in diabetes clinical trials to evaluate treatments aimed at preserving or restoring endogenous insulin production, it was, for example used in the pivotal study for Tzield, the first approved disease-modifying T1D therapy.

A statistically significant effect on C-peptide AUC serves as strong evidence of a treatment's impact on beta-cell function and insulin production, making it a critical marker for assessing therapeutic efficacy in T1D.

ProTrans-1

The ProTrans-1 trial showed promising results in evaluating ProTrans as a potential disease-modifying treatment for T1D. This open-label, dose-escalation study involved nine patients and assessed three doses: 25, 100, and 200 million cells. All doses demonstrated a favorable safety profile, with no significant adverse events reported over one year, along with a dose-dependent effect. Based on these results, the highest dose was selected for the next phase of the trial.

At 12 months, the results showed a significant difference between groups. Placebo-treated patients experienced had maintained 53% of in C-peptide levels, while ProTrans-treated patients exhibited only a corresponding number of 89% ($p<0.05$), suggesting ProTrans may preserve endogenous insulin production—a critical factor in slowing disease progression.

Additionally, insulin requirements in the placebo group increased by a median of 10 units per day, whereas the ProTrans-treated group showed no increase. This highlights the potential of ProTrans to reduce reliance on exogenous insulin, an important factor for improving long-term patient outcomes. A dose-dependent effect was also observed, with the lowest dose group achieving better results than the placebo group.

ProTrans-1 (Δ) in C-peptide area under the curve

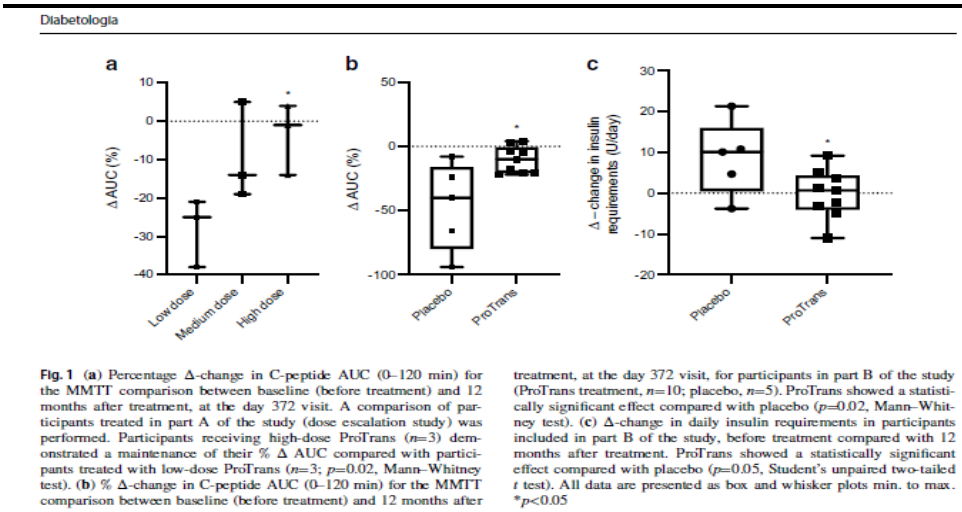


Fig. 1 (**a**) Percentage Δ-change in C-peptide AUC (0–120 min) for the MMTT comparison between baseline (before treatment) and 12 months after treatment, at the day 372 visit. A comparison of participants treated in part A of the study (dose escalation study) was performed. Participants receiving high-dose ProTrans (n=3) demonstrated a maintenance of their % Δ AUC compared with participants treated with low-dose ProTrans (n=3; p=0.02, Mann–Whitney test). (**b**) % Δ-change in C-peptide AUC (0–120 min) for the MMTT comparison between baseline (before treatment) and 12 months after treatment, at the day 372 visit, for participants in part B of the study (ProTrans treatment, n=10; placebo, n=5). ProTrans showed a statistically significant effect compared with placebo (p=0.02, Mann–Whitney test). (**c**) Δ-change in daily insulin requirements in participants included in part B of the study, before treatment compared with 12 months after treatment. ProTrans showed a statistically significant effect compared with placebo (p=0.05, Student's unpaired two-tailed t test). All data are presented as box and whisker plots min. to max. *p<0.05

Source: Carlsson, P.O., Espes, D., Sisay, S., Davies, L.C., Smith, C.I. & Svahn, M.G. (2023) 'Umbilical cord-derived mesenchymal stromal cells preserve endogenous insulin production in type 1 diabetes: a Phase I/II randomised double-blind placebo-controlled trial', Diabetologia, 24 May. doi:10.1007/s00125-023-05934-3.

ProTrans-2/OBS

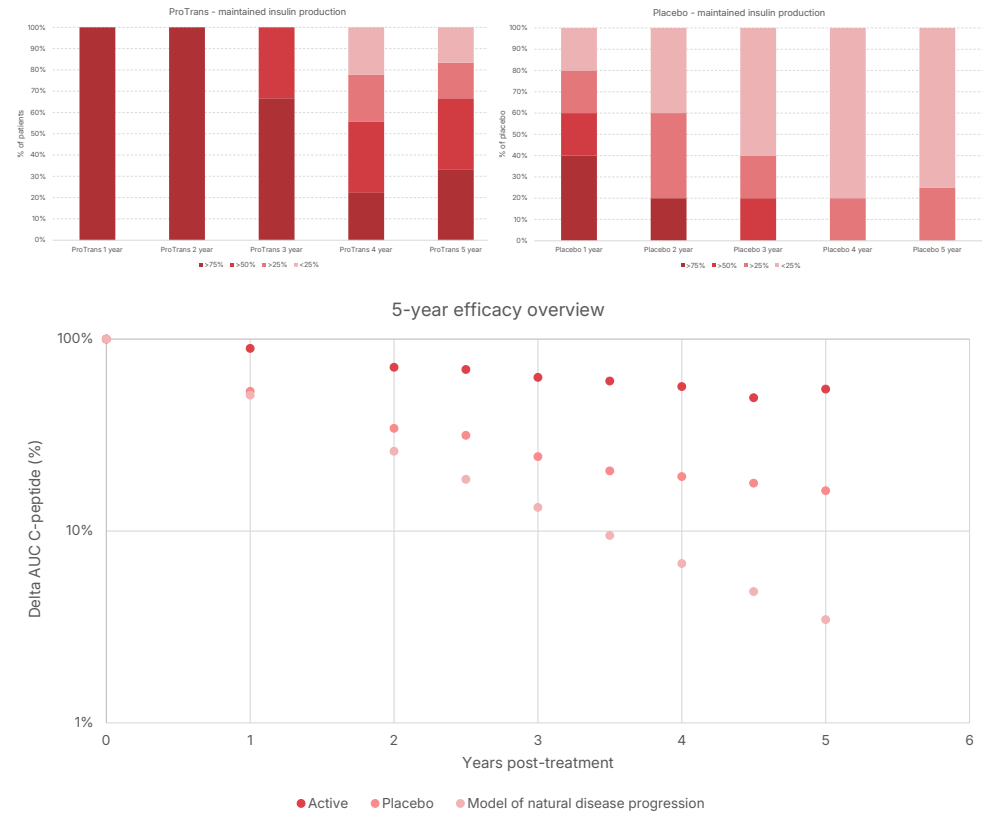
Following the results in ProTrans-1, the subsequent trial ProTrans-2 evaluated the highest dose in the phase I trial, in a randomized, placebo-controlled, double-blinded trial. In this part of the trial, fifteen participants were randomised, with ten being assigned to ProTrans treatment and five to the placebo group.

Results gave statistically significant indication that patients receiving a single infusion of ProTrans preserved the majority of their insulin production, maintaining approximately 63% after three years. In contrast, the placebo group only maintained a total of 23% in insulin production during the same period, highlighting ProTrans' potential to effectively slow disease progression. Notably, no serious adverse events related to the treatment were observed.

Of the 11 patients who completed the ProTrans-2 trial, 6 ProTrans-treated and 5 placebo-treated patients enrolled in the follow-up study, ProTrans-Obs. This non-interventional study tracks endogenous insulin production every six months, with safety monitored as a key endpoint.

The five-year follow-up data, presented in mid-2024, reported that ProTrans-treated patients maintained approximately 57% insulin production, compared to 14% in the placebo group. Scientific literature suggests that around 90% of insulin production is typically lost by year three, which aligns well with the placebo group. In contrast, ProTrans-treated patients demonstrated a marked preservation of pancreatic function. Importantly, more than 60% of ProTrans-treated patients retained over 50% of their baseline insulin production after five years, compared to 0% in the placebo group.

ProTrans five-year data



Source: NextCell (illustration)

The ProTrans results were published in Diabetologia, a scientific journal focused on diabetes and also the official journal of the European Association for the Study of Diabetes (EASD) in 2023, where it was also chosen as the "article of the month" demonstrating the perceived value to the field.

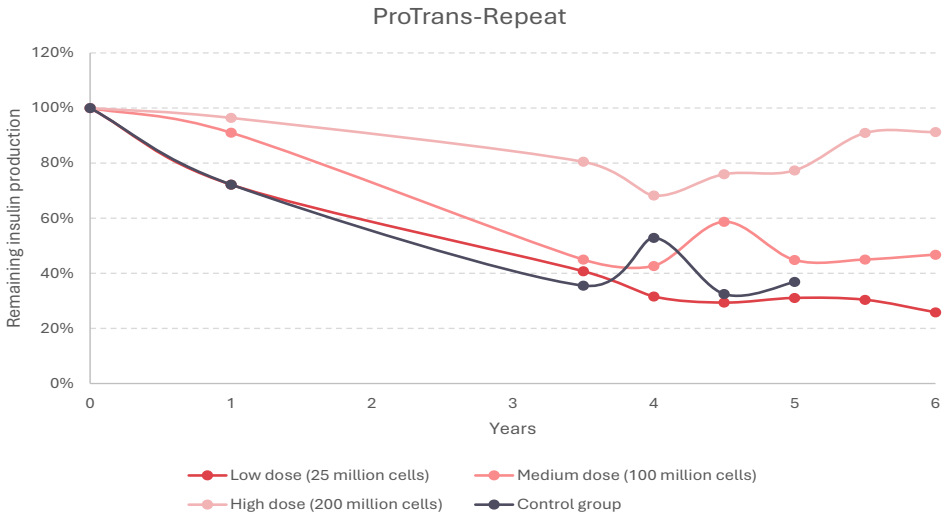
ProTrans-Repeat

ProTrans-Repeat, initiated in May 2019, is an open-label follow-up study aimed at evaluating whether a second treatment with ProTrans can prolong or maintain the therapeutic effects observed in the initial ProTrans-1 study over a longer period, while preserving the treatment's safety profile. Patients from ProTrans-1 were invited to participate in ProTrans-Repeat, providing an opportunity for further evaluation of ProTrans' potential to preserve endogenous insulin production in Type 1 Diabetes patients.

At the end of December 2024, NextCell announced that the high-dose group (n=3) retained, on average, 91% of their insulin production six years after treatment. Notably, two patients showed increases in insulin production by 23% and 34%, while the third patient experienced a significant loss in insulin production (approximately 85%). Given the limited sample size, these findings lack statistical significance. However, the overall result supports the potential of ProTrans, particularly highlighting the possibility of increased insulin production following repeat dosing over a prolonged timeframe, and further raises the bar ahead of the readout of ProTrans-Young.

No six-year data is available for the control group, as these patients were included later, at the start of the ProTrans-Repeat trial—1 to 1.5 years after the other participants. At inclusion, the duration of their Type 1 Diabetes diagnosis ranged from 2 months to over 2 years.

ProTrans-Repeat outcome



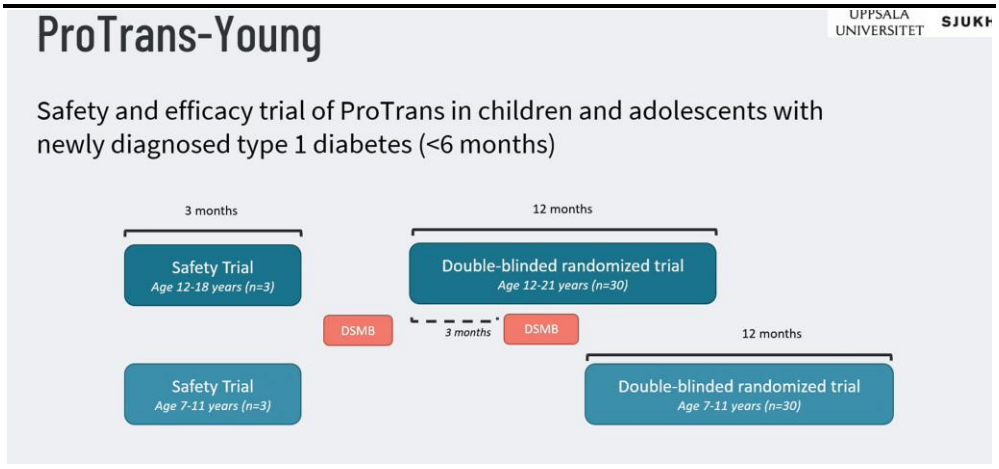
Source: NextCell (illustration)

Ongoing clinical trials

ProTrans-Young

The ProTrans-Young study, initiated in 2021, is an investigator-initiated phase I/II clinical trial led by Uppsala University in collaboration with Linköping and Lund/Malmö Universities. Its primary objective is to assess the safety and potential efficacy of ProTrans as a treatment for pediatric patients newly diagnosed with T1D.

ProTrans-Young trial overview



Source: NextCell (illustration)

The first part of the trial was an open-label safety study involving six children (ages 7–18) recently diagnosed with T1D. The positive safety profile observed led the safety committee to approve the progression to phase 2.

Part 2 of the trial is a randomized, placebo-controlled, double-blind trial assessing the efficacy and safety of ProTrans. The trial includes 60 patients divided into two age groups: 30 aged 12–21 and 30 aged 7–11, randomized 50/50 between placebo and active arms. Recruitment for the older group is complete, with the last patient treated in February 2024. A readout is expected in March/April 2025.

Following additional safety checks, recruitment for the younger group began in September 2024 and has progressed well. The company cites strong interest and positive word-of-mouth surrounding the trial. Full recruitment for this cohort is anticipated by summer 2025, with a full readout projected by the end of 2026.

This study is a key step in evaluating ProTrans as a potential disease-modifying treatment for type 1 diabetes in pediatric populations. Ongoing monitoring and recruitment are expected to provide valuable insights into the safety and effectiveness of the treatment in younger patients.

Additionally, literature implies that cell therapies, particularly for pediatric patients, could exhibit enhanced efficacy compared to adult populations. This is due to several factors related to children's physiological and immunological characteristics. In pediatric patients, particularly infants and young children, immune responses tend to be more robust and dynamic, potentially enhancing the efficacy of cell-based therapies and leading to improved therapeutic outcomes. This was exemplified by Mesoblast's MSC therapy RYONCIL, approved in December 2024 for steroid-refractory acute graft-versus-host disease (SR-aGVHD), which demonstrated sufficient efficacy for approval only in pediatric patients, as the results in adults were less compelling.

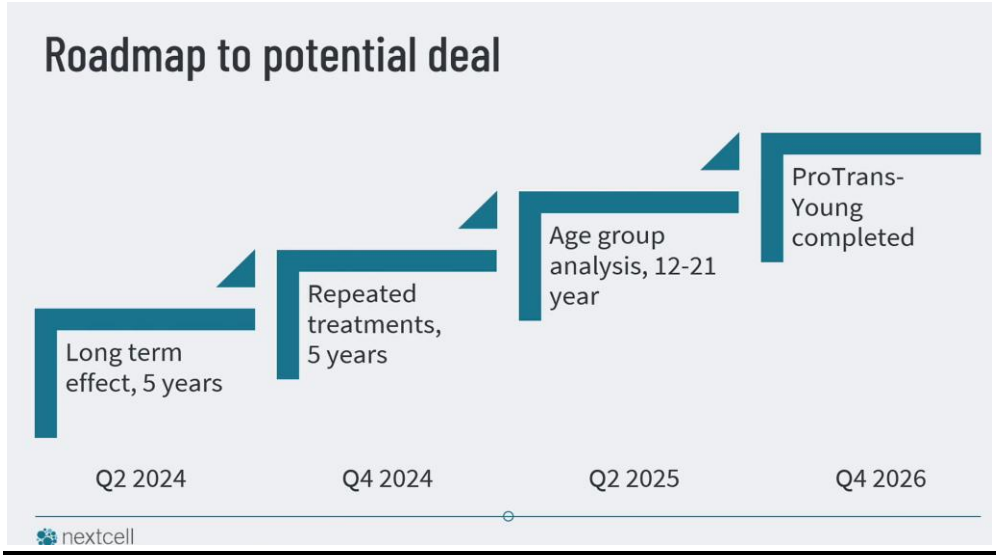
While speculative at this point, this may indicate improved efficacy in maintaining insulin production in the ProTrans-Young trial compared to results from the ProTrans-Young trial compared to the results from ProTrans-1/2/OBS.

Next step - phase III

Following the full data readout from ProTrans-Young, expected by the end of 2026, NextCell plans to advance ProTrans into a pivotal phase III trial. This trial is projected to enroll approximately 150 patients, aligning with the European Medicines Agency's (EMA) guidance that 144 participants would be sufficient based on ProTrans-2 data. The phase III trial will be critical in establishing the efficacy and safety of ProTrans on a larger scale, the final clinical development step towards a potential regulatory approval.

NextCell also intends to adjust the inclusion criteria, reducing the time since diagnosis to broaden patient eligibility. This modification could enhance treatment efficacy, as earlier intervention may allow patients to begin treatment with higher levels of endogenous insulin production, potentially improving outcomes given ProTrans' mechanism of action.

ProTrans roadmap



Source: NextCell (illustration)

ProTrans-Severe pneumonia

ProTrans has also been evaluated in two viral pneumonia COVID-19-related trials. The company was contacted by a group of French and Canadian scientists, which led to a phase II trial sponsored by McGill University in Canada in 2021. The study aimed to enroll 48 patients to assess ProTrans for treating severe COVID-19 pneumonia and preventing acute respiratory distress syndrome. However, the trial was never fully recruited and is currently not enrolling additional patients, effectively being shut down . In total, 19 patients were enrolled, and NextCell could potentially leverage the data related to safety and mechanism of action for other indications. Additionally, a similar trial was initiated in Sweden, but for viral pneumonia conditions including COVID-19, influenza A, respiratory syncytial virus (RSV) and human metapneumovirus (hMPV). However, the safety data from the ProTrans-2 trial was deemed insufficiently aligned with the requirements for a phase II study targeting the respiratory system. As a result, a dose-escalation trial was conducted instead. The phase II trial is terminated and now longer recruits patients, while the phase I trial is still open with one patient remaining to be enrolled in the high-dose cohort.

NPC03

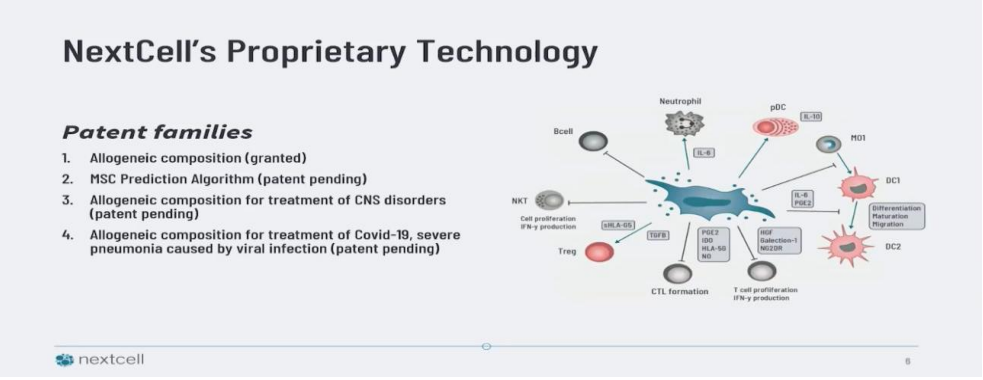
NextCell is actively exploring other indications, with preclinical development underway. While few details have been publicly disclosed, the company is pursuing an active patent process for applications in inflammation in the central nervous system (CNS) space. The patent family also covers areas such as transplantation rejection, anti-drug reactions, inflammatory diseases, and more. However, we believe it is unlikely that NextCell will allocate any considerable resources to this project before securing a partner for the T1D program and initiating a phase III trial. As such, substantial newsflow in this area is unlikely in the foreseeable future.

Patents

NextCell pursues an active IP strategy through four patent families. The selection algorithm, filed in 2019, is currently pending in Europe and the US, with potential maximum protection until 2039. The patent covering the allogenic composition for obtaining and isolating a pooled population of mesenchymal stromal cells (MSCs) from different donors, as well as their medical use in treating autoimmune and inflammatory diseases, including T1D, was also filed in 2019 and is protected until 2039.

A third patent family, filed in 2020, targets the allogenic composition for obtaining and isolating a pooled population of MSCs for use in central nervous system (CNS) disorders. This patent is pending with potential maximum protection until 2040, hinting at additional potential applications for ProTrans. The fourth patent family relates to isolated pooled allogenic MSC populations for the treatment and/or prevention of COVID-19 infection and associated symptoms. Filed in 2021, it is currently pending in several regions, including The US and Europe.

Patents families



Source: NextCell (illustration)

Competing T1D projects

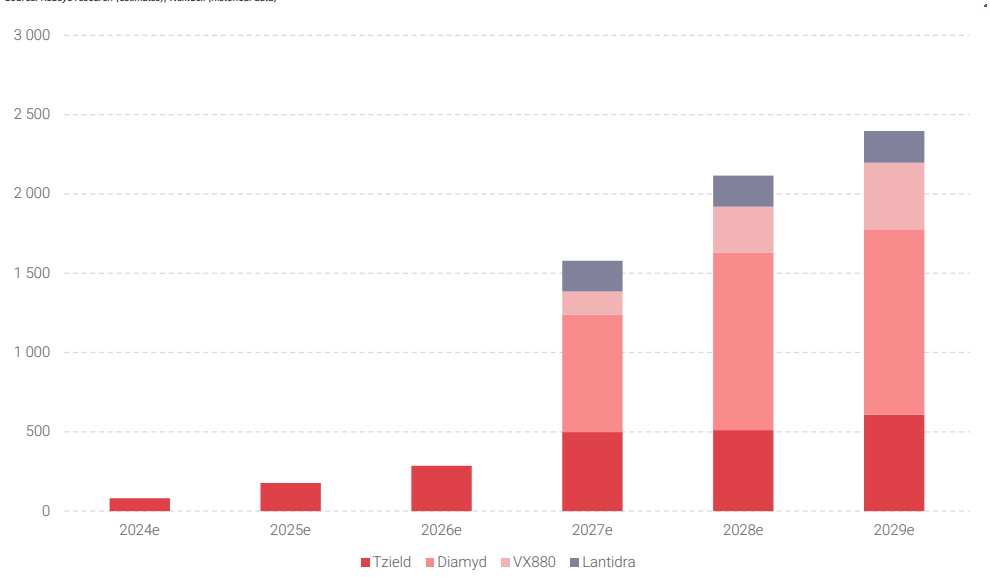
A handful of late-stage projects in the T1D pipeline focus on restoring or preserving insulin production in newly diagnosed patients. These include cell therapies, precision immunotherapies, and pancreatic islet transplantations, all aimed at achieving a disease-modifying effect. However, to trule "cure" the disease, a therapy would need to both halt disease progression, as seen with therapeutics like ProTrans, and restore insulin production, such as Lantidra or the Vertex projects. Importantly, this would need to be achieved without requiring immunosuppressive drugs, which are currently necessary for both Lantidra and VX-880.

Trials have utilized a wide variety of endpoints, and varying levels of data disclosure complicate direct comparisons. However, all things considered, it remains a significant market opportunity for safe and effective treatments that halt disease progression, particularly those with a strong safety profile, as this could facilitate combination therapy approaches. Assuming ProTrans continues to demonstrate sustained safety and efficacy in line with its results to date, we believe it is well-positioned, not least in terms of safety, not requiring any immunosuppression. According to the available estimates from GlobalData, these products is estimated to represent sales exceeding USD1.5bn already in 2027.

Competing projects overview and sales estimates

	Molecule	Stage	Comment
Lantidra	Pancreatic islet cellular therapy	Marketed	First-ever islet cell therapy (allogenic) approved for T1D. Aims to restore insulin production.
Tzield	Islet cell implant	Marketed	Approved to delay the onset of Stage 3 T1D. Acquired by Sanofi for USD2.9bn.
Diamyd	GAD65 antigen	Phase III	Ongoing pivotal trials. Precision immunotherapy aiming to stop autoimmune attack on beta cells
VX880/VX264	Stem-cell derived islet cells	Phase I/II	Ongoing phase I/II. Islet cell transplantation aimed at restoring insulin production.
IMCY-0098	Immunomodulatory peptide	Phase II	Ongoing phase II. Aims to stop auto-immune-mediated destruction of islet beta cells.
ProTrans	MSC therapy	Phase II	Ongoing phase II MSC cell therapy (allogenic). Aims to stop disease progression and maintain own insulin produc

Source: Redeye research (estimates), NextCell (historical data)



Source: Company documents (data), Globaldata (estimates), Redeye research (illustration)

Lantidra (Islet cell implant), CellTrans Inc. – Approved

Lantidra is an FDA-approved cell therapy for adults with Stage 3 T1D experiencing severe hypoglycemia despite intensive management. It involves infusing allogeneic (donor-derived) pancreatic islet cells into the hepatic (liver) portal vein to restore endogenous insulin production, with the goal of reducing or eliminating the need for exogenous insulin. Additional infusions may be administered based on patient response. However, it requires immunosuppressive medications, limiting its uptake severely.

Lantidra's primary mechanism of action is the secretion of insulin by the infused beta cells. In clinical trials, the therapy demonstrated the potential to achieve insulin independence in a subset of patients. Across two non-randomized, single-arm studies involving 30 participants with T1D and hypoglycemic unawareness:

- 21 participants achieved insulin independence for one year or more
- 11 participants remained insulin-free for 1-5 years
- 10 participants remained insulin-free for more than 5 years
- 5 participants did not achieve insulin independence at all

The most common adverse reactions include nausea, fatigue, anemia, diarrhea, and abdominal pain. Serious adverse events—linked to both the infusion procedure and the required immunosuppressive therapy—were observed in most participants. In some cases, adverse events led to the discontinuation of immunosuppressive treatment, resulting in the loss of islet cell function and insulin independence. These risks necessitate careful patient selection and thorough benefit-risk assessments.

Lantidra received FDA approval in 2023, with patient-directed labeling to ensure individuals are informed about its benefits and risks. While the therapy offers significant potential for long-term blood glucose control and reduced insulin dependency, its cost is approximately USD300-450,000 per treatment. While there are no official sales forecasts from the company, Globaldata estimates suggests sales exceeding USD500m in 2027.

Tzield (Anti-CD3 monoclonal antibody), Sanofi (Provention Bio)– Approved

Tzield is the first FDA approved therapy designed to delay the onset of clinical T1D in individuals at high risk (Stage 2). It is a monoclonal antibody that modulates the autoimmune attack on insulin-producing beta cells by targeting CD3 on T cells, effectively slowing the progression of beta cell destruction.

The safety and efficacy of TZIELD was investigated in a randomized, double-blind, event-driven, placebo-controlled study in 76 patients, 8 to 49 years of age with Stage 2 T1D, defined as having 2 or more T1D-related autoantibodies and dysglycemia on oral glucose tolerance testing. In this study, Stage 2 patients were randomized to receive TZIELD (n=44) or placebo (n=32) once daily, by intravenous infusion for 14 days. The primary efficacy endpoint was the time from randomization to stage 3 T1D diagnosis.

Developed by Provention Bio and now marketed in collaboration with Sanofi, Tzield has garnered significant attention as a disease-modifying T1D therapeutic. The treatment regimen consists of daily injections for 14 days and was approved by the FDA based on a pivotal clinical trial involving 76 patients at high risk of developing T1D. Results showed that patients treated with Tzield developed T1D approximately 50 months after receiving the medication, compared to 25 months in the placebo group. While not being the primary endpoint, it is also measured the loss of AUC mean C-pepide at 2 years compared to placebo, where the trial found that the loss of C-peptide was approximately 40%.

Tzield Clinical trial (TN-10) overview

Parameter	TZIELD N=44	Placebo N=32	Total N=76
Event numbers, n (%)			
Number of patients diagnosed with T1D	20 (45)	23 (72)	43 (57)
Number of censored patients	24 (55)	9 (28)	33 (43)
Censored due to reaching trial end: follow-up still ongoing at cutoff date	22 (50)	8 (25)	30 (39)
Censored due to discontinuation from study for reasons other than diagnosis	2 (5)	1 (3)	3 (4)
Follow-up time			
Median follow-up time (month)	50.6	49.9	50.6
Time to event summary statistics			
Median time to T1D diagnosis (month) (95% CI)	49.5 (32.1, NE)	24.9 (9.5, 48.6)	42.6 (25.9, 55.2)
Primary analysis: Cox proportional hazard model			
Hazard ratio (95% CI)		0.41 (0.22, 0.78)	
p-value		0.0066	

Source: FDA (data & illustration)

However, Tzield could face challenges in scaling its adoption as identifying appropriate candidates for the therapy is challenging, given that it seeks to treat stage 2 patients. MoreoverMoreover, its use requires careful monitoring due to the safety concerns related to immune modulation, infusion reactions, and infections.

Back in 2022, Provention Bio announced a wholesale cost of USD13,8500 per vial, resulting in an overall cost just below USD200,000 – however we find support for the list-price to even approach up to USD300,000. Globaldata estimates implies sales reaching USD500m by 2027. Provention Bio was acquired by Sanofi for a price tag of USD2.9bn in March 2023.

Diamyd (GAD65 antigen), Diamyd Medical – Phase III

Diamyd is a GAD65 antigen-based immunotherapy designed to halt the autoimmune attack on beta cells, potentially modifying the progression of T1D. Diamyd Medical previously conducted a phase III trial with this diabetes vaccine, but the candidate failed to meet its primary endpoint of preserving beta-cell function in newly diagnosed T1D patients. The failure was attributed to insufficient patient stratification and variability in treatment response, particularly due to genetic factors.

Currently, Diamyd is conducting an ongoing pivotal phase III clinical trials to evaluate the therapy's efficacy in preserving beta-cell function. In this new trial, Diamyd is targeting a genetically defined subgroup of T1D patients who carry the appropriate genetic biomarker, believed to respond more favorably to the therapy. This refined patient selection strategy aims to enhance efficacy outcomes and address the limitations observed in the previous trial. The approach reflects a more personalized medicine strategy, with the goal of improving the likelihood of demonstrating a clinical benefit.

The trial recruits individuals aged 8-18 with the HLA DR3-DQ2 haplotype and multiple islet autoantibodies (Stage 1 or Stage 2), indicating an increased risk of developing T1D. Subjects will be followed for a total of 12 months post-enrolment.

The FDA has provided Diamyd with positive feedback on the use of C-peptide as a surrogate endpoint, which is considered reasonably likely to predict clinical benefit. This opens the potential for accelerated approval based on significant treatment-related benefits on C-peptide

levels in response to administration of the drug. A surrogate endpoint is a marker—such as a laboratory measurement, radiographic image, physical sign, or other measure—that is thought to predict clinical benefit but is not itself a direct measure of clinical benefit.

VX-880/264 (Stem-cell derived islets), Vertex Pharmaceuticals (ViaCyte) – Phase II

Vertex Pharmaceuticals is pursuing innovative approaches to address the underlying causes of T1D by restoring insulin-producing cell function. Their projects VX-880 and VX-264 involve stem-cell derived islet cell transplantation aimed at re-establishing insulin production in T1D patients.

VX-880 is an allogeneic, stem cell-derived, fully differentiated insulin-producing islet cell therapy. Administered via infusion into the hepatic portal vein, it requires immunosuppressive therapy to prevent immune rejection. VX-880 aims to restore the body's ability to regulate glucose levels by reintroducing pancreatic islet cell function, including glucose-responsive insulin production. The ongoing phase 1/2 clinical trial is evaluating its safety and efficacy in T1D patients with impaired hypoglycemic awareness and severe hypoglycemia. The trial has expanded to additional sites in Norway, Switzerland, and the Netherlands. Notably, all 14 patients dosed in the trial had undetectable fasting C-peptide levels at baseline. Following the infusion of VX-880, all patients demonstrated islet cell engraftment and glucose-responsive insulin production by day 90. VX-880 has received PRIME designation from the European Medicines Agency (EMA) in March 2023 and Fast Track Designation from the U.S. FDA in March 2021.

VX-264 utilizes the same stem cells as VX-880, but these cells are encapsulated in a channel array device designed to shield the cells from the body's immune system. The device is surgically implanted in patients. The ongoing Phase 1/2 clinical trial of VX-264 aims to assess its safety, tolerability, and efficacy, with enrolment expected to include approximately 17 patients globally.

IMCY-0098 (Immunomodulatory peptide), Imcyse – Phase II

IMCY-0098 is an investigational peptide immunotherapy developed by Imcyse, positioned as a leading candidate in its portfolio to halt the progression of T1D. The therapy targets and eliminates specific immune cells involved in the autoimmune response against insulin-producing beta cells. In a phase I trial, IMCY-0098 was found to be well-tolerated, with no statistically significant differences in adverse events between the active and placebo groups.

Currently, IMCY-0098 is in phase II clinical trials, with the primary endpoint being the change from baseline in C-peptide levels, a marker of beta-cell function. Secondary endpoints include HbA1c levels, insulin use, and continuous glucose monitoring (CGM) levels. Efficacy proof-of-concept data were previously communicated to be anticipated during 2024, but there are no results visible on the company webpage or on clinicaltrials.gov.

Sales model and estimates

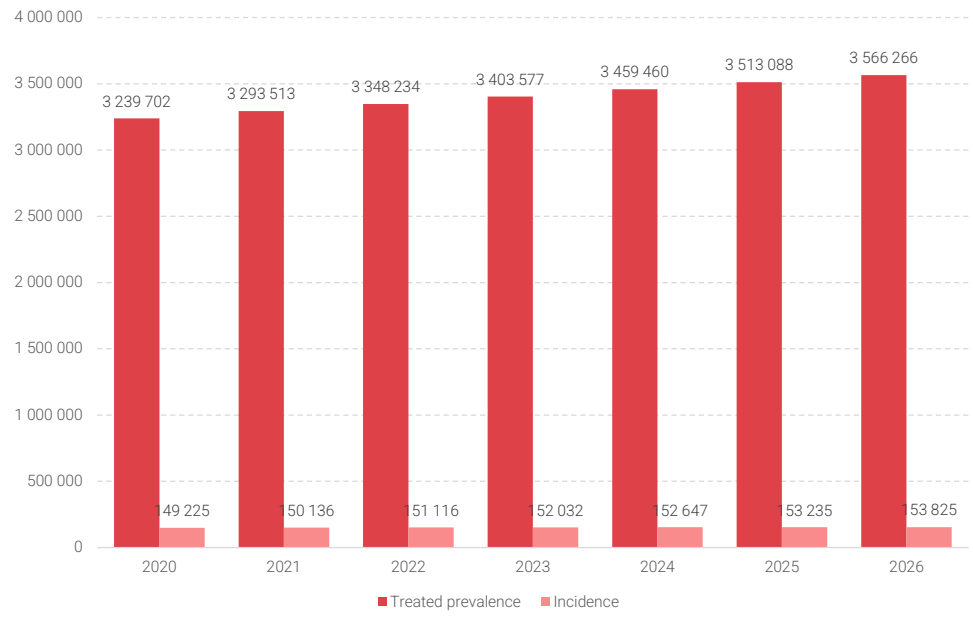
Our ProTrans sales model focuses solely on T1D, representing the company's primary value driver. While there is potential for expansion into additional indications, and NextCell has made clinical efforts in areas such as COVID-19, we believe the market currently assigns value only to the lead indication. However, if NextCell secures a partnership with ProTrans, we consider it likely that the company will evaluate the therapy in another indication within a few years. At that point, we would reassess and potentially incorporate additional indications into our sales model in future research updates.

T1D epidemiology & TAM

According to data from the Globaldata database, there are approximately a total of approximately 3.5 million diagnosed and treated T1D patients across the 8 major pharmaceutical markets (8MM), which constitute the US+Canada, EU4+UK (France, Germany, Italy, and Spain), and Japan in 2023.

ProTrans targets preserving insulin production in newly diagnosed T1D patients, and we base our market model on the incidence of Type 1 Diabetes (T1D) in the 8 major pharmaceutical markets (8MM): the US+Canada, EU4+UK (Germany, France, Italy, Spain, and the UK), and Japan. Using GlobalData's database, cross-verified with epidemiological studies, we estimate approximately 152,000 newly diagnosed T1D cases in the 8MM for 2023. Epidemiological data suggest an annual incidence growth of just under 3%, reaching approximately 184,000 patients by 2030, which is around when we expect an anticipated launch of ProTrans. The scientific literature points to incidence rates of approximately 19.3 per 100,000 people, which aligns with the data presented below which implies incidence rates of 20.2-20.7 per 100,000 in the 8MM.

Adressable patients in 8MM 2020-2026e



Source: Globaldata (data), Redeye research (illustration)

Licensing deal

NextCell aims to secure a partnership to advance ProTrans through pivotal clinical trials and ultimately commercialize the asset, a strategy we view as prudent given the substantial investment required for both the pivotal trial and commercialization. Consequently, our model

assumes that following the full data package in 2026, the company will out-license the global rights to ProTrans. In return, the partner would assume the remaining development costs, milestones, and royalties on net sales of the product.

To estimate the potential terms of a licensing deal for ProTrans, we analyze previous licensing agreements in the T1D space, ensuring our assumptions are aligned with market standards. Our research indicates that deal sizes range from a few million USD to several billion USD, with notable examples such as the acquisition of Provention Bio (Tzield). Most phase II/III deals tend to fall in the middle of this range, which also aligns with the average deal size in the space. This provides a useful benchmark for estimating the potential value of a licensing deal for ProTrans.

Selection of T1D licensing deals and acquisitions

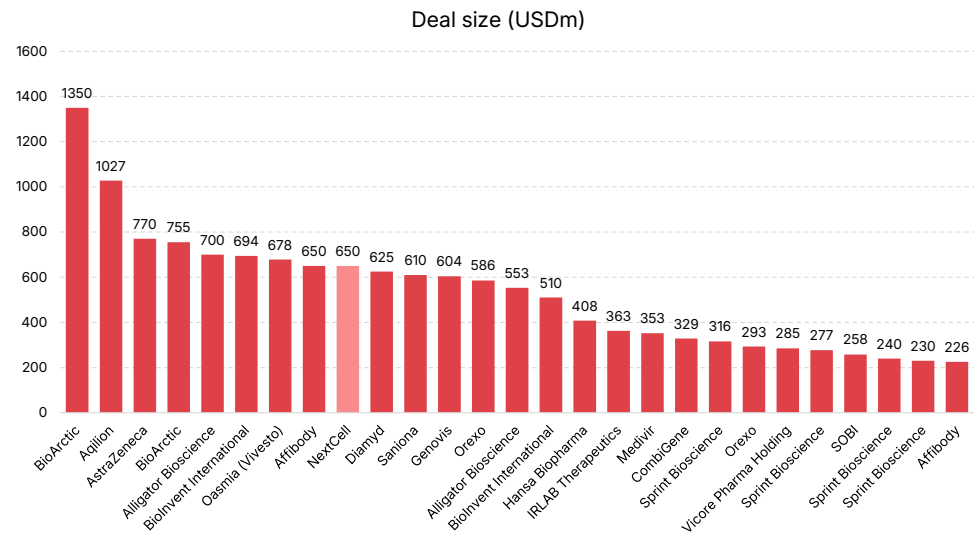
Year	Deal type	Upfront	Deal size	Phase	Region	Licensor/Target	Licensee/Buyer	Comment
2023-07-05	Option agreement	N/A	11	II	Global	Adocia SAS	Sanofi	Option agreement, Insulin-pramlintide
2023-04-27	Acqusition	N/A	2900	Market	Global	Provention Bio	Sanofi	Tzield, CD3 antibody to delay onset of T1D
2022-09-01	Licensing deal	3,5	39	Market	Global	Zealand Pharma	Novo Nordisk	Injectable for treatment of severe hypoglycemia
2020-09-01	Licensing deal	0,2	20	Preclinical	Global	University of Washington	Sana Biotechnology	Genetically engineered stem cell derived beta cells
2018-03-07	Licensing deal	20	534	Phase II	Global	Ligand Pharmaceuticals	Roivant Sciences	Oral drug targeting the glucagon receptor - T1D/T2D
2010-06-01	Licensing deal	50	1105	Phase I	Global	vTv Therapeutics Inc	Forest laboratories	Oral liver-selective glucokinase drug -T1D/T2D
2018-04-01	Licensing deal	63	473	Preclinical	Global	Sigilon Therapeutics	Eli Lilly and Co	Human stem cell-derived beta cell therapeutic
2010-10-18	Licensing deal	200	350	Phase III	Global	Biocon	Pfizer	Biocon's portfolio of insulin biosimilars
2009-06-14	Licensing deal	25	350	Phase I	Global	Tolerion Inc	Genentech	Immunotherapy vaccine candidate
2010-04-01	Licensing deal	N/A	335	Preclinical	Asia-Pacific	CureDM	Sanofi	Bioactive peptide sequence restoring pancreatic function
2022-07-11	Acqusition	N/A	320	Phase II	Global	ViaCyte	Vertex Pharmaceuticals	Stem cell-derived human pancreatic islets
2019-09-01	Acqusition	N/A	950	Preclinical	Global	Semma Therapeutics	Vertex Pharmaceuticals	Stem cell-derived human pancreatic islets
2010-06-22	Licensing deal	45	625	Phase III	Global	Diamyd Medical	Ortho-McNeil-Janssen Pharmaceuticals	GAD65 antigen-based therapy to prevent T1D
Average		**50,8**	**616,3**					
Median		**35,0**	**350,0**					

Source: GlobalData (data), Redeye research (chart structuring)

Deal prediction at this stage is challenging; however, given the disease-modifying potential of NextCell's therapy, we argue it is reasonable to expect at least in line with peer averages. This outlook also aligns with Diamyd Medical's USD625m deal secured in 2010. Consequently, we model a relatively backloaded deal valued at USD650m in 2027, including USD50m in upfront payments, with the partner assuming responsibility for subsequent clinical development and regulatory milestones.

To validate our assumption and ensure alignment with both local and global deal dynamics, we compare licensing deals in Swedish-listed biotech companies over the past 20 years. On average, deals involving Swedish companies are smaller compared to larger US-based transactions. This is largely due to better funding in US biotech, which allows for larger clinical trials and the ability to often target multiple indications simultaneously, among other factors.

Largest licensing deals in Swedish-listed biotech's since 2010



Source: GlobalData (data), Redeye research (chart structuring)

All things considered, the deal assumption discussed above would rank it among the top 10 largest licensing deals in Swedish biotech over the past 20 years. However, it's important to note that a significant portion of the milestones are typically tied to late-stage clinical development milestones and commercial milestones, often referred to as "Bio-dollars." These represent funding allocated to biotech projects, many of which fail to materialize into successful products due to unmet milestones, regulatory hurdles, or financial challenges, underscoring the high-risk and volatile nature of the industry.

Probability of success (PoS) and likelihood of approval (LoA)

A critical factor in evaluating drug candidates in clinical development is the Probability of Success (PoS) at each phase and the overall Likelihood of Approval (LoA). LoA is essential for risk-adjusting future cash flows, capturing the inherent uncertainties of clinical trials, and thus plays a pivotal role in the valuation of biotech companies. Given the strong clinical data supporting ProTrans, we consider it reasonable to base our estimates on historical success rates in T1D clinical trials, rather than solely on cell therapies, which typically have lower probabilities.

According to the GlobalData database, the historical PoS for diabetes projects stands at 52% in phase II, 60% in phase III, and 73% from pre-registration to approval, based on approximately 360 clinical trials. In contrast, cell therapies demonstrate significantly lower PoS: 29% in phase II, 15% in phase III, and 86% at the regulatory stage, derived from around 1,200 trials.

Probability of success and likelihood of approval in T1D and cell therapies

	Phase I	Phase II	III	Regulatory	Phase II LoA
All therapy areas	71%	46%	50%	83%	19%
T1D	68%	52%	60%	73%	23%
Cell therapy	75%	29%	15%	86%	4%
ProTrans	**100%**	**60%**	**60%**	**73%**	**26%**

Source: GlobalData (data), Redeye research (chart structuring)

For NextCell's phase II program, we set the PoS at 60%, drawing from historical probabilities within T1D trials and incorporating a slight premium to reflect the encouraging results from prior studies. This yields a LoA of 26%, used to risk-adjust our model.

Should the full phase II data package demonstrate positive results in 2026, the LoA would increase to 44%, a scenario illustrated by our bull case.

Clinical development timeline

The current timeline suggests the full phase II data package to be finalized by the end of 2026 and that NextCell will be able to tie a partner to the project by the first half of 2027, which would finance a pivotal phase III-trial.

All things considered, we model that the phase III-trial will require approximately 150 patients as indicated by the company, and that the patient enrolment will span approximately 1.5 years and that the follow-uptime will be 12 months after the last patient is enrolled. This would span approximately 3-3.5 years from start of phase III, until a potential marketing approval of ProTrans, which then would be possible by 2031.

Sales model

Please note that our model is built around calendar years and not NextCell's broken fiscal year.
Our sales model builds on the following assumptions:

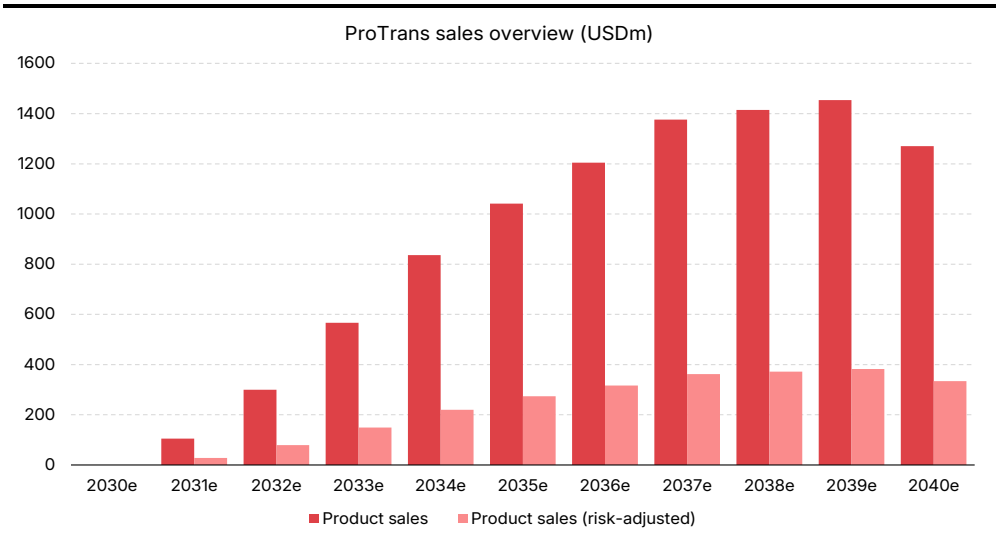
- We base our sales model on the T1D incidence between ages 7-40 in the 8MM (US+Canada, EU4+UK, and Japan)
- 60% probability that NextCell will secure a USD650m deal with low double-digit royalties (we assume 12%)
- Phase II PoS of 60% and a LoA of 26%
- A pivotal trial with ProTrans is initiated in 2027
- Launch in 2031
- At this stage, we model a peak market penetration of 15% of the addressable incidence per year (will be re-evaluated once more data is available)
- Net price of USD100 thousand
- Patent expiry 2039 initiating sales erosion

ProTrans T1D market model

ProTrans		2023	2024	2025e	2026e	2027e	2028e	2029e	2030e	2031e	2032e	2033e	2034e	2035e	2036e	2037e	2038e	2039e	2040e
Development stage		II	II	II	II	III	III	III	Regulatory	Market	Market	Market	Market	Market	Market	Market	Market	Market	Market
Probability		100%	100%	100%	100%	60%	60%	60%	36%	26%	26%	26%	26%	26%	26%	26%	26%	26%	26%
T1D - diagnosed incidence	US	102 676	105 551	108 506	111 545	114 668	117 878	121 179	124 572	128 060	131 646	135 332	139 121	143 017	147 021	151 138	155 369	159 720	164 192
	EU4+UK	44 909	46 166	47 459	48 788	50 154	51 558	53 002	54 486	56 012	57 580	59 192	60 850	62 553	64 305	66 105	67 956	69 859	71 815
	JP	4 447	4 572	4 700	4 831	4 966	5 105	5 248	5 395	5 546	5 702	5 861	6 025	6 194	6 368	6 546	6 729	6 918	7 111
Addressable patients 7-40 yo (TAM)	US	45 597	46 874	48 186	49 535	50 922	52 348	53 814	55 321	56 870	58 462	60 099	61 782	63 512	65 290	67 118	68 997	70 929	72 915
	EU4+UK	25 617	26 334	27 072	27 830	28 609	29 410	30 233	31 080	31 950	32 845	33 764	34 710	35 682	36 681	37 708	38 764	39 849	40 965
	JP	2 248	2 311	2 376	2 442	2 511	2 581	2 653	2 727	2 804	2 882	2 963	3 046	3 131	3 219	3 309	3 402	3 497	3 595
Market penetration	US	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	1,4%	3,8%	6,9%	9,9%	12,0%	13,5%	15,0%	15,0%	15,0%	12,8%
	EU4+UK	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	1,4%	3,8%	6,9%	9,9%	12,0%	13,5%	15,0%	15,0%	15,0%	12,8%
	JP	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	1,4%	3,8%	6,9%	9,9%	12,0%	13,5%	15,0%	15,0%	15,0%	12,8%
Treated patients	US	-	-	-	-	-	-	-	-	768	2 192	4 147	6 116	7 621	8 814	10 068	10 350	10 639	9 297
	EU4+UK	-	-	-	-	-	-	-	-	431	1 232	2 330	3 436	4 282	4 952	5 656	5 815	5 977	5 223
	JP	-	-	-	-	-	-	-	-	38	108	204	302	376	435	496	510	525	458
Net price	US	100 000	100 000	100 000	100 000	100 000	100 000	100 000	100 000	100 000	100 000	100 000	100 000	100 000	100 000	100 000	100 000	100 000	100 000
	EU4+UK	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000
	JP	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000	60 000
Product Sales (USDm)	US	-	-	-	-	-	-	-	-	77	219	415	612	762	881	1 007	1 035	1 064	930
	EU4+UK	-	-	-	-	-	-	-	-	26	74	140	206	257	297	339	349	359	313
	JP	-	-	-	-	-	-	-	-	2	6	12	18	23	26	30	31	32	27
Worldwide product sales (USDm)		-	-	-	-	-	-	-	-	105	300	567	836	1 042	1 205	1 376	1 415	1 454	1 271
Milestone payment (USDm)		-	-	-	49	-	49	-	81	-	81	-	65	-	98	-	98	-	130
Risk-adjusted royalties (SEKm)		-	-	-	-	-	-	-	-	36	103	195	288	358	415	474	487	500	437
Risk-adj. Milestones (SEKm)		-	-	-	319	-	192	-	192	-	140	-	112	-	168	-	168	-	224
Risk-adj. revenues (SEKm)		-	-	-	319	-	192	-	192	36	243	195	399	358	582	474	655	500	661

Source: GlobalData (data), Redeye research (chart structuring, estimates)

ProTrans T1D non risk-adj sales (USDm)



Source: Redeye research (estimates and illustration)

Sensitivity analysis peak sales (USDm)

Net price	Market penetration				
	5%	10%	15%	20%	25%
50 000	242	485	727	969	1 212
75 000	364	727	1 091	1 454	1 818
100 000	485	969	1 454	1 939	2 423
125 000	606	1 212	1 818	2 423	3 029
150 000	727	1 454	2 181	2 908	3 635

Source: Redeye research (estimates and illustration)

Additional opportunities with Cellaviva and QVance

In addition to its core centered around the T1D project with ProTrans, NextCell also operates the only stem cell bank in the Nordics and a recently established quality control service provider for cell and gene therapies and biologics. These two businesses are driven through two group subsidiaries, Cellaviva and QVance.

Cellaviva

Scandinavia's leading private stem cell bank

NextCell owns and operates Cellaviva, Sweden's first and the Nordic region's only private stem cell bank specializing in the family preservation of hematopoietic (blood-forming) and mesenchymal (tissue-forming) stem cells. It is the only stem cell bank in Sweden authorized by the Inspection for Health and Care (IVO).

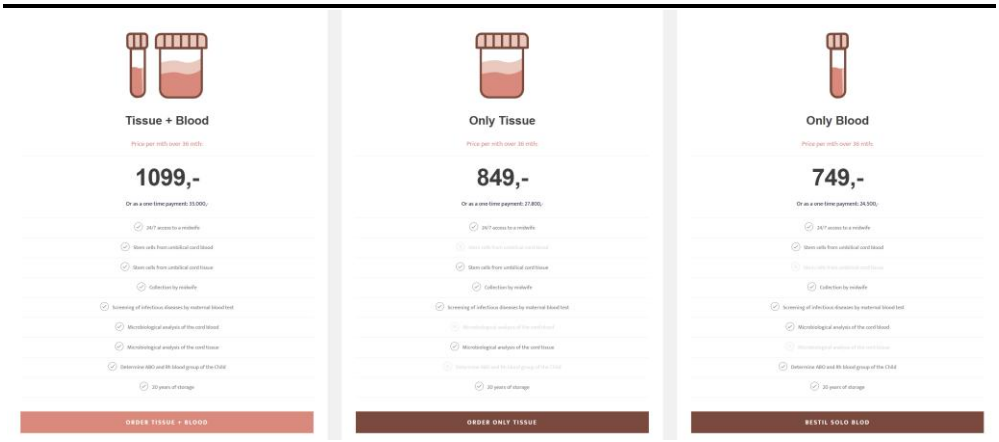
Since its establishment in September 2015 by NextCell's CEO, Mathias Svahn, Cellaviva has been a pioneer in the stem cell banking industry in the Nordics, initially offering its first product and subsequently expanding its services to include additional sources of stem cells. With annual revenues of approximately SEK10m, Cellaviva has demonstrated initial proof of a working business model and garnered a diverse customer base. The business became a self-sustaining but wholly-owned subsidiary in the autumn 2024. However, NextCell plans to provide financial support to ensure liquidity and drive growth. While the company is currently prioritizing growth over profitability, it has indicated a target of reaching break-even as early as 2025.

Since 2016, NextCell has maintained a strategic partnership with PBKM, Europe's largest stem cell bank, which merged with the German stem cell bank Vita34 in 2021. This collaboration encompasses all operational areas, with PBKM serving as a subcontractor for stem cell sample analyses and the manufacturing of ProTrans. Furthermore, PBKM acts as an insurance provider for Cellaviva's customers, ready to take over the management of stored stem cells if necessary.

Stem cell preservation could play a pivotal role in the treatment of serious diseases, which today lacks satisfactory options. By preserving stem cells from umbilical cord blood and the umbilical cord, families can enhance future treatment options and potentially reduce waiting times for vital therapies. Additionally, preserved stem cells can offer treatment opportunities for other family members in need.

After ordering the Cellaviva box, which is ready for delivery a few days after order. The process is by large taken care of by the company whereas the customer only needs to call the Cellaviva hotline and take the Cellaviva box to the place of birth and then the midwife will collect the stem cells from the umbilical cord, and after which Cellaviva handles for medical transportation to the lab, analyze, and freeze and store the stem cells, thus providing any unnecessary effort required by the parents.

Cellaviva offering



Source: Cellaviva website (2024-12-10)

In addition to its core stem cell storage offering, it also offers the following:

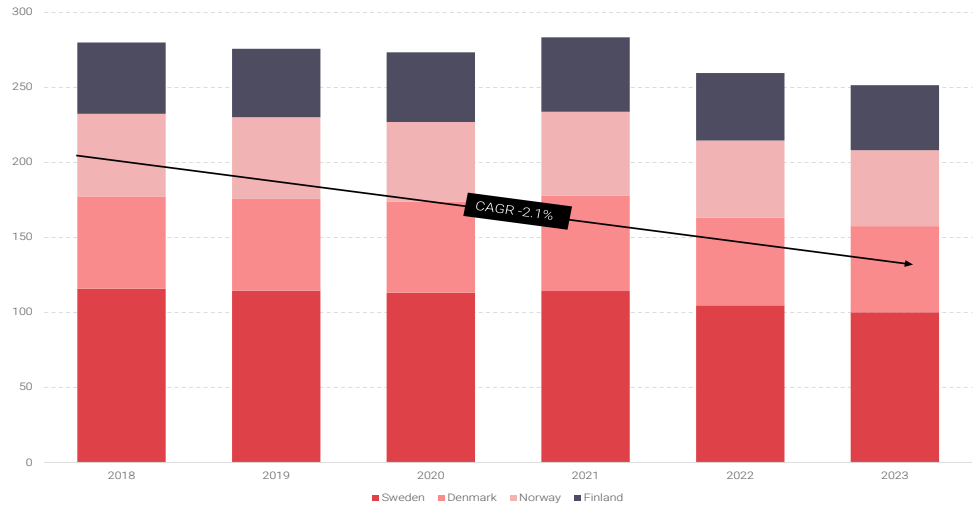
- **HLA typing analysis:** Used for identifying which people can safely donate stem cells, an organ, or bone marrow to a person in need of a transplant.
- **NIPT extended test:** A non-invasive prenatal diagnostic test used for determining the risk of foetus being born with certain genetic anomalies, such as down's syndrome or Edward's syndrome.

Targets a market of approximately 250 thousand births in the Nordics

Cellaviva's addressable market comprises approximately 250,000 births annually across the Nordics, a figure that has exhibited a CAGR of -2.1% since 2018. While there is potential for growth beyond the Nordic region, the company is unlikely to pursue this expansion in the near term due to the significant investment such a move would require.

The concept of preserving stem cells for newborns remains relatively new and underutilized in the Nordics, with a market penetration of less than 1% of births. In contrast, this figure is closer to 5% in countries like the US and southern Europe, illustrating room for growth if Cellaviva can effectively drive adoption. Where the concept of saving stem cells was introduced in the 1990's. Sweden had a bio-bank law which prevented external actors to enter the market, and also Sweden has relied on the public healthcare, and thus not being used to pay for healthcare.

Births in the Nordics (thousands)



Source: Statista (data), Redeye (chart structuring)

The business benefits from network effects, as many customers learn about the service through relatives or friends. Additionally, the company highlights that customers who choose Cellaviva for their first child are almost certain to use the service for subsequent children, with a retention rate close to 100%.

To improve market penetration, Cellaviva emphasizes the importance of raising awareness among healthcare providers and expectant families about the benefits of stem cell preservation. This strategy aligns with the broader potential of stem cell-based therapeutics, which could significantly enhance the perceived value of the service in the long term.

Sales model and assumptions

We base our model on the assumption that NextCell will continue to face some resistance in its effort to increase market penetration for stem cell banking, primarily due to market dynamics and the reluctance to pay for healthcare in the Nordics, as discussed above. However, we believe that as regenerative medicine matures, parents will increasingly recognize the advantages of the service. Over time, we expect market penetration for newborn stem cell banking in the Nordics to reach approximately 5%, aligning with levels seen in Southern Europe.

Hence, we model a scenario where Cellaviva continues on the current trajectory and grows approximately 20% CAGR over the coming years, reaching breakeven in H1 2026. Our valuation approach builds on a sales multiple of 2.5x (which we deem reasonable given the recurring nature and history of growth), on 2026e sales discounted back to present value using a WACC of 14.5%.

Our valuation approach builds on the following:

- 20% CAGR growth until 2026
- Sales multiple of 2.5x
- NPV discounted back to present value using a WACC of 14.5%.

Cellaviva NPV sensitivity analysis (SEKm)

Sales multiple	Two years sales CAGR 10%	15%	20%	25%	30%
1,5x	18,2	19,0	19,8	20,6	21,5
2,0x	24,2	25,3	26,4	27,5	28,6
2,5x	30,3	31,6	33,0	34,4	35,8
3,0x	36,3	38,0	39,6	41,3	42,9
3,5x	42,4	44,3	46,2	48,2	50,1

Source: Redeye research (estimates and illustration)

QVance

Background

Being one of the pioneers in cell therapy development in Sweden, and advancing ProTrans through clinical trials and phase III preparations, NextCell identified a gap in the Nordic region for comprehensive service providers catering to cell and gene therapy developers. To address this, the company launched QVance in 2024—a specialized contract laboratory for quality analysis of Advanced Therapy Medicinal Products (ATMPs)—leveraging its in-house equipment and expertise. This initiative included transitioning NextCell's internal quality department into the new entity.

QVance addresses a critical market need for specialized cell therapy drug testing services, including sterility assurance and contaminant detection. Many ATMP developers must send samples to multiple facilities, leading to inefficiencies and delays. By consolidating these processes, QVance streamlines release testing for cell therapy companies and hospitals, enhancing safety and operational efficiency.

Strategically positioned to meet the growing demand for ATMP quality analysis in the Nordics—an industry expanding at 15% annually and ranking among the fastest-growing globally—QVance provides tailored analytical services, quality control testing, product release, and analytical development. The laboratory features advanced instruments, clean rooms, and skilled personnel, serving both NextCell's internal projects and external clients. This positions QVance as a key emerging player in the Nordic ATMP ecosystem.

NextCell has committed to supporting QVance's growth, with plans to allocate liquid funds and an expected cost of SEK 6–7m in 2025. This initiative reflects NextCell's strategy to capitalize on the expanding ATMP market while establishing QVance as a trusted partner in advanced therapeutic quality assurance.

Partnership with bioMérieux

Since mid-November, QVance has partnered with bioMérieux Sweden to enhance quality control analytics for cell and gene therapy products in the Nordic region. This collaboration aims to strengthen QVance's microbiological testing capabilities for advanced therapies. According to the press release, the partnership will also grant QVance access to bioMérieux's customer base, enabling the use of advanced analytics technology. Additionally, the collaboration includes providing educational resources, such as webinars and training, to companies in the advanced therapies sector.

Sales model and assumptions

The primary driver of the share price remains ProTrans, with Cellaviva also playing a role. While the establishment of QVance in 2024 presents an appealing business case and could become a share price driver once it contributes meaningfully to revenue, a cautious approach is warranted given the binary risks in biotech investments. Therefore, we await further clarity on QVance's development before incorporating it into our forecasts and valuation.

We will reassess this decision as more information emerges regarding its progress, partnerships, and revenue potential.

Financials and estimates

Historical financials fiscal year 2019/2020-2023/2024

NextCell operates under broken fiscal year spanning from September to August i.e. FY 2023/2024 = 2023/09/01-2024/08/31. As a company in the clinical development phase, NextCell's revenues have been limited, and it has reported EBIT losses since its IPO. However, it has recurring and growing revenues from Cellaviva, and ongoing clinical trials in combination with personell costs is the primary cost drivers. This financial performance is expected and aligns with the typical challenges companies face at this stage of development.

Financial overview 2019/2020-2023/2024 (SEKm)

SEKm	2019/2020	2020/2021	2021/2022	2022/2023	2023/2024	2024/2025	LTM
Revenues	**4,2**	**4,4**	**6,2**	**13,9**	**11,3**	**16,6**	**9,4**
Cellaviva	3,6	4,1	5,6	10,0	10,6	11,0	9,2
Other operating income	0,6	0,4	0,6	3,8	0,6	0,6	0,2
OPEX	**-21,9**	**-29,3**	**-41,3**	**-55,0**	**-54,4**	**-53,4**	**-50,7**
Material and goods	-6,8	-10,0	-8,7	-11,0	-15,2	-15,7	-15,1
Other external costs	-7,2	-8,5	-19,1	-28,7	-21,9	-19,3	-19,3
Personnel costs	-7,5	-10,3	-12,7	-14,8	-16,3	-16,3	-14,7
Other operating costs	0,0	-0,1	-0,2	0,0	0,0	0,0	-0,1
EBITDA	**-17,3**	**-24,4**	**-34,6**	**-40,6**	**-42,2**	**-34,8**	**-39,8**
D&A	-0,4	-0,4	-0,5	-0,4	-1,0	-2,1	-1,5
EBIT	**-17,7**	**-24,9**	**-35,0**	**-41,1**	**-43,2**	**-36,8**	**-41,3**
EBIT margin	nm	nm	nm	nm	nm	nm	nm
Net income	**-17,7**	**-24,6**	**-34,6**	**-39,9**	**-42,0**	**-36,8**	**-40,2**
Shares outstanding	**23,4**	**34,4**	**34,4**	**34,4**	**73,1**	**73,1**	**73,1**

Source: NextCell (data)

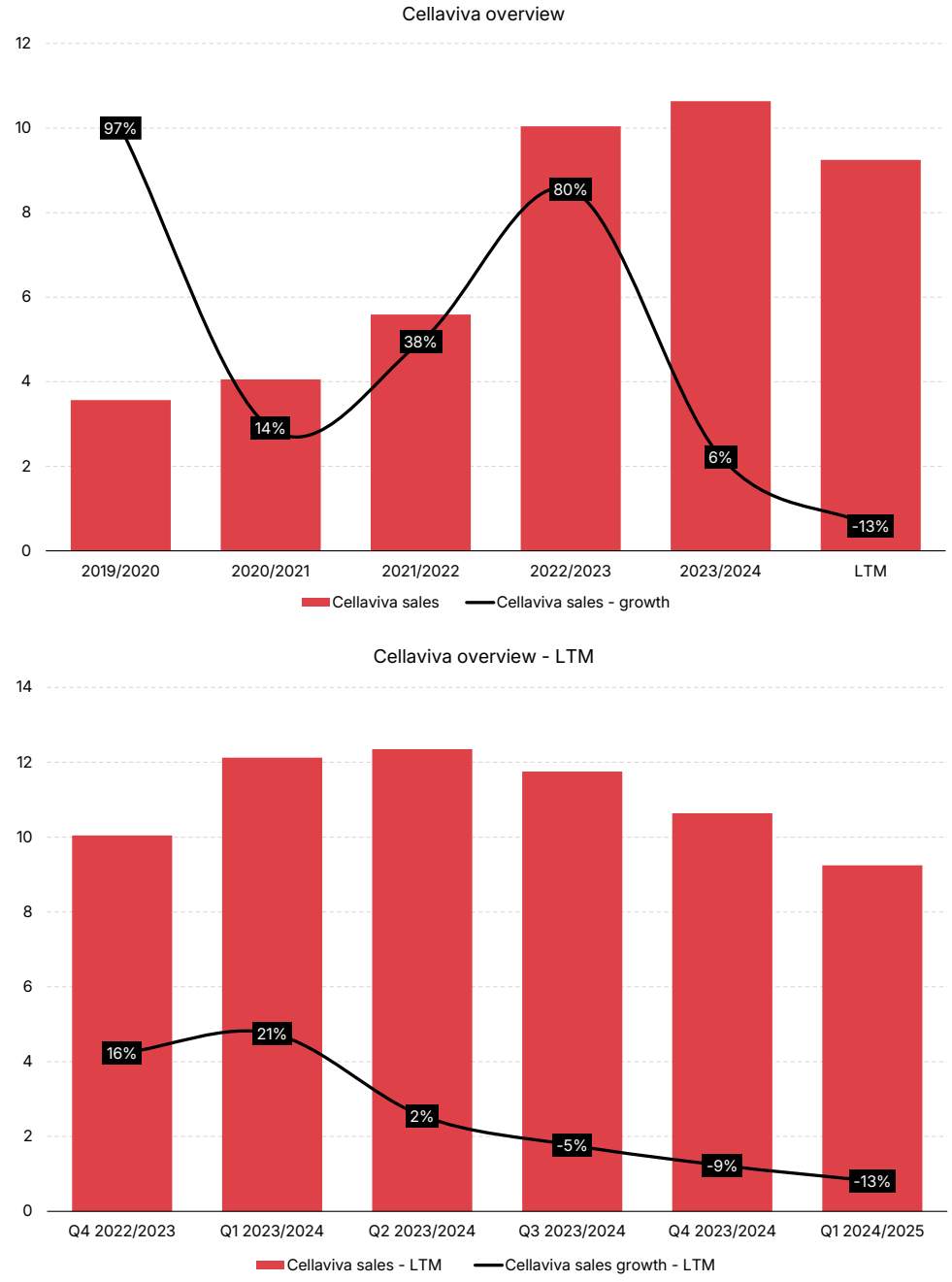
Revenues

NextCell's revenues primarily stem from Cellaviva sales, supplemented by occasional grants from organizations such as Vinnova, Sweden's innovation agency, which funds research and innovation projects. Cellaviva's sales have grown from SEK3.6m in 2019/2020 to SEK10.6m in 2023/2024, representing a 31% CAGR driven by increased market penetration. While the overall trend has been positive, growth has been uneven—nearly doubling in 2019/2020 and 2022/2023 due to operational improvements and expansion in Denmark. However, macroeconomic headwinds slowed growth to 6% in the latest fiscal year.

Looking ahead, growth initiatives are being rolled out, including Cellaviva's transition into an independent entity in 2024. The company highlights network effects and heightened awareness as key adoption drivers. Combined with relatively easier comparables following the muted growth in 2023/2024, these factors support a favorable outlook for continued expansion.

The recent slowdown in LTM sales is primarily due to a strong Q1 2023/2024, where Cellaviva reported SEK4.2m in sales, driven by increased stem cell banking activity, creating tough comparables.

Cellaviva sales overview (SEKm)

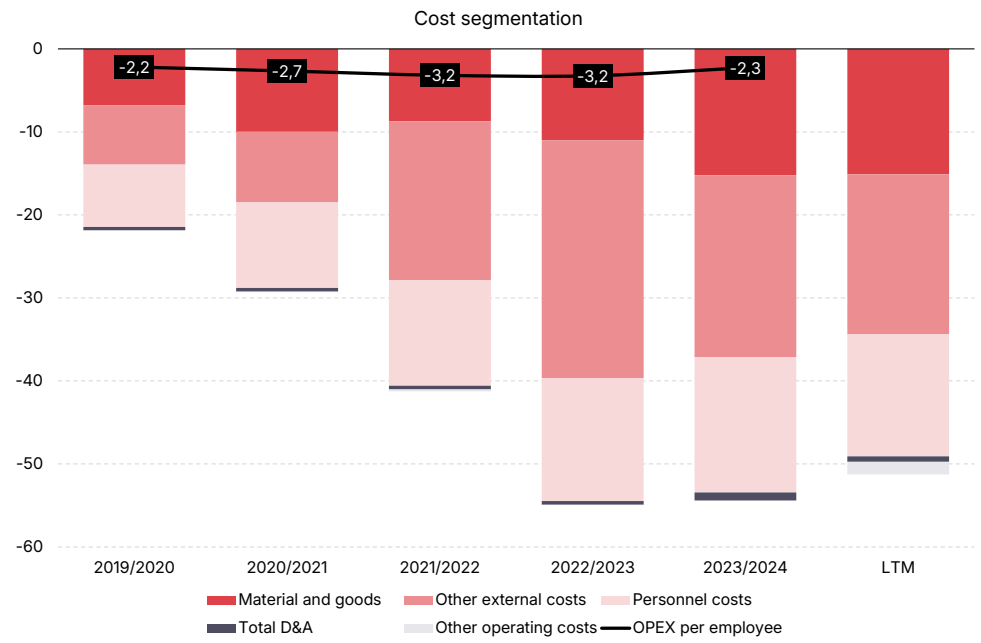


Source: NextCell (data)

Costs

On the cost side, the company has reported an increase in OPEX from approximately SEK-20m in 2019/2020 to just over SEK-50m in the past two years. The primary drivers of this increase relates to the ongoing clinical development of ProTrans, regulatory processes, and general cost increases due to an expanding organization, with employee numbers more than doubling from 10 in 2019/2020 to 24 in 2023/2024. Additional factors contributing to the expanding cost base includes the expansion of Cellaviva and the establishment of QVance.

Cost segmentation 2019/2020-2023/2024 (SEKm)

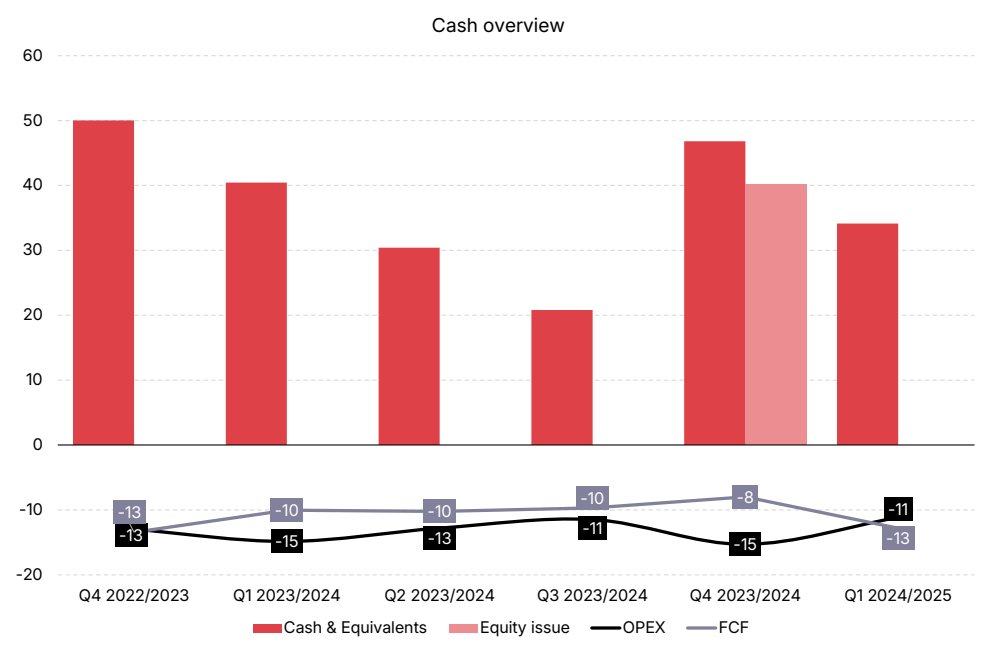


Source: NextCell (data)

Cash flow and cash conversion

In its year-end report, the company reported SEK34.1m in liquid assets. Over the past six quarters, both OPEX and FCF have consistently ranged between negative SEK10-15m per quarter. Despite ongoing clinical trials, these metrics have shown relatively small deviations.

Cash flow and liquidity overview (SEKm)



Source: NextCell (data)

Cash runway

Given current activities, we expect a modest increase in the cost base in the coming quarters, with a burn rate of approximately SEK15-20m, up from current levels of SEK10-15m. Based on the current cash position, the company has a runway of about two quarters. NextCell's TO2 warrants, maturing in May 2025, could raise SEK38-113m assuming full subscription, depending on the subscription price to be set in Q2 (SEK1-3). We estimate the company will need to raise at least SEK60m from the warrants to bridge the gap until the full ProTrans-Young readout and a potential upfront licensing deal in early 2027.

We assume that NextCell will present positive interim data, allowing for full subscription at the top of the price range for the TO2 warrants. This would raise SEK113.5m in gross proceeds through the issuance of 37.8m new shares, effectively funding the company through to the full ProTrans-Young readout, after which we anticipate a licensing deal with an upfront payment.

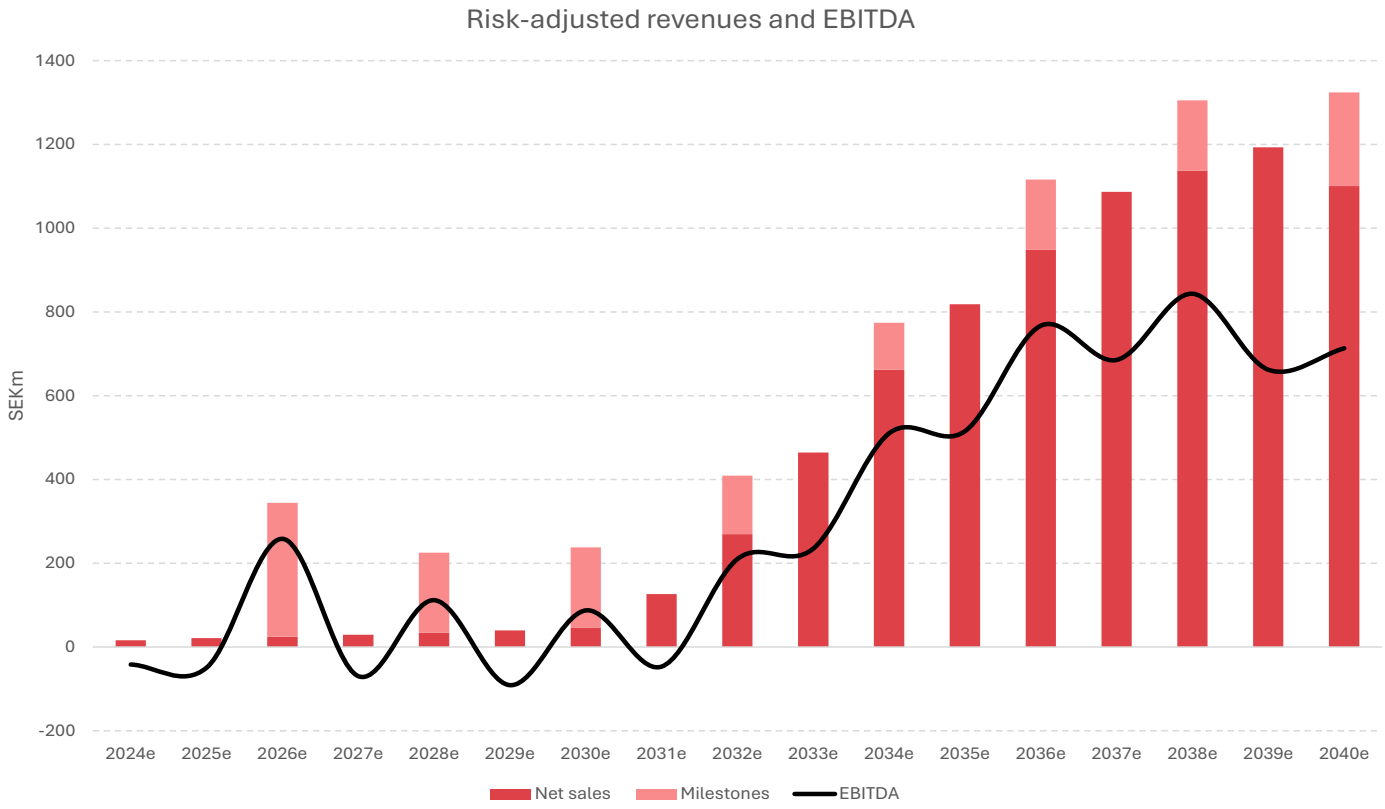
Gross proceeds from TO2 sensitivity analysis (SEKm)

		Sub. Price in warrants				
		1,0	1,5	2,0	2,5	3,0
Subscription %	20%	7,6	11,3	15,1	18,9	22,7
	40%	15,1	22,7	30,3	37,8	45,4
	60%	22,7	34,0	45,4	56,7	68,1
	80%	30,3	45,4	60,5	75,6	90,8
	100%	37,8	56,7	75,6	94,5	113,5

Source: NextCell (data)

Forecast period 2024-2040e

Risk-adjusted revenues and EBIT over forecast period (SEKm)



Source: Redeye research (estimates and illustration)

Valuation

DCF

At Redeye, we approach the valuation of a company using three scenarios: to provide a dynamic view of the case. In complement to our base case valuation, we also model both a pessimistic (bear case) and an optimistic (bull case) scenario. The differences in estimates between the scenarios are based on modifications of the assumptions used in our valuation process.

We apply a weighted average cost of capital (WACC) of 14.5%, based on (i) an equity risk premium derived from qualitative and quantitative aspects of the company using Redeye's company quality model and (ii) a risk-free interest rate of 2.5%. We also account for the expected dilution necessary for NextCell to reach the stage where it can outlicense ProTrans. Additionally, all projected revenues are risk-adjusted to reflect the anticipated remaining development risks.

Base case sum-of-the-parts (SEKm)

Project	Indication	Phase	Est. Launch	LoA	Peak sales (USDm)	Deal size (USDm)	rNPV (SEKm)
ProTrans	T1D	II	2031	26%	1 454	650	**891**
Cellaviva	N/A	N/A	N/A	N/A	N/A	N/A	**33**
QVance	N/A	N/A	N/A	N/A	N/A	N/A	**0**
Technology value (SEKm)							**924**
Net cash (SEKm)							**34**
Shared costs (SEKm)							**-80**
Equity value (SEKm)							**877**
Shares outstanding (million)							**73,1**
Diluted shares outstanding (million)							**110,9**
Equity value per share (SEK)							**7,9**

Source: NextCell (data)

Bear case SEK0.5

Our bear scenario assumes that the readout of ProTrans-Young is unsatisfactory and does not justify continued development of the project.

In this scenario, the remaining value in the company would primarily be tied to its cash position and subsidiaries. We estimate this value to be approximately cSEK0.5 per share.

Base case SEK8

Our base case builds on the following key assumptions for ProTrans:

- Phase II PoS 60% and LoA 26%
- USD650m deal
- Launch 2031
- Peak sales USD1.4bn

We assume 20% CAGR growth in Cellaviva until 2026 and apply a sales multiple of 2.5x discounted back to present value.

Bull case SEK13

In a bull case, we mirror the assumptions in our base case with one major deviation, we set the PoS to 100% in the phase II program, reflecting the anticipated value of the company following a successful readout of the full phase II data at the end of 2026.

Thus, the following applies to ProTrans:

- Phase II PoS 100% and LoA 44%
- USD650m deal
- Launch 2031
- Peak sales USD1.4bn

Peer group

While we recognize the limitations of peer comparisons, particularly due to the lack of perfect comparables, we have selected peers based on shared technologies, targeted patient populations, and development stages. In our peer group, we include 7 Swedish-listed biotech companies with similar or adjacent technologies and targeted indications to those of NextCell. This primary includes companies focusing on T1D/T2D, but also cancer, and other conditions through various biologics and gene/cell-therapy approaches. Diamyd Medical stands out as the most comparable peer to NextCell, particularly in terms of technology and therapeutic focus.

Peer cohort

Company	EV (SEKm)	Clinical projects	Lead indication	Phase	Comment
Corline Biomedical	188	1	Kidney tx	Phase I	Phase II-ready biologic candidate + medtech business
Diamyd Medical	1 614	2	T1D	Phase III	Precision medicine T1D vaccine
Elicera Therapeutics	90	2	DLBCL	Phase I	CAR-T cell therapy
Lipum	308	1	RA	Phase II	First-in-class biologic drug
Pila Pharma	100	1	T2D	Phase I	Small molecule T2D/Obesity drug
Saniona	913	3	Epilepsy	Phase I	Platform company with several targeted indications
SynAct Pharma	680	1	RA	Phase II	Ongoing phase IIb-trial in RA
Xintela	231	2	Osteoarthritis	Phase I	Stem cell-based therapies
Average	556	1,6			
Median	308	1,0			
NextCell	204	1,0	T1D	Phase II	

Source: Redeye research (chart structuring & description), Factset (data)

Given the company's accumulated clinical data and its more advanced development stage relative to most peers, a premium to the peer group average appears justified. However, a discount to Diamyd's EV is warranted, given the similarities of their lead assets and Diamyd's more advanced development stage, with an ongoing phase III trial. This supports an EV range above SEK550m but below SEK1600m, i.e. SEK4.4-14.5 (including full TO2 dilution) per share, which provides further support to our DCF valuation.

Sensitivity analysis

To add depth to our valuation of NextCell, we include a scenario analysis illustrating how adjustments to key assumptions impact the risk-adjusted net present value (rNPV) of the ProTrans T1D project. The middle values represent the assumptions currently applied in our base case scenario.

rNPV sensitivity analysis - ProTrans T1D

Deal value \ Deal probability	20%	40%	60%	80%	100%
350	507	595	681	768	854
500	545	669	792	916	1 039
650	583	743	904	1 064	1 225
800	620	817	1 015	1 212	1 410
950	657	891	1 126	1 361	1 595

Phase II PoS \ Market penetration	5%	10%	15%	20%	25%
20%	248	306	364	422	480
40%	401	518	634	750	866
60%	555	729	904	1 078	1 252
80%	708	941	1 173	1 406	1 638
100%	862	1 152	1 443	1 734	2 024

Source: Redeye research (estimates and illustration)

Summary Redeye Rating

The rating consists of three valuation keys, each constituting an overall assessment of several factors that are rated on a scale of 0 to 1 points. The maximum score for a valuation key is 5 points.

Rating changes in the report

People: 3

NextCell is led by a team well-suited for its stage of development, characterized by a strong scientific focus on cell therapy and regenerative medicine with close ties to the Karolinska University Hospital/Institute. CEO and co-founder Mathias Svahn bring extensive expertise in stem cell research and biotechnology, having guided the company since 2015. He is supported by a management team and board of directors with deep experience in clinical development, life sciences business development, and finance. This collective expertise positions the company to effectively navigate the clinical development and partnering process for ProTrans.

The company also benefits from a team of experienced Medical Advisers, including Per-Ola Carlsson the principal investigator of its clinical trials.

Business: 3

NextCell is a clinical-stage biotech company, complemented by its operation of Scandinavia's largest stem cell bank, Cellaviva. ProTrans is covered by patents until 2039, with the potential for additional protective barriers that could ensure long-term stability. Cellaviva provides the company with some near-term revenue and given the platform of ProTrans and the establishment of QVance, the company also has additional optionality and attractive reinvestment opportunities.

Financials: 1

On a group level, it generates some revenue from Cellaviva but is expected to remain loss-making for the foreseeable future and will primarily rely on equity funding. However, considerable revenue could be generated if an out-licensing deal for ProTrans is secured following the readout of the phase II program.

	2023/ 2024	2024/ 2025	2025/ 2026	2026/ 2027
INCOME STATEMENT				
Revenues	11	14	16	337
Operating Expenses	-54	-61	-74	-90
EBITDA	-42	-45	-55	251
D&A	-1	-2	-2	-3
EBIT	-43	-47	-58	247
Net Financial Items	1	0	0	0
EBT	-42	-47	-58	247
BALANCE SHEET				
Assets				
Current assets				
Cash & cash equivalents	47	106	48	232
Inventories	1	1	1	2
Accounts Receivable	2	3	4	4
Other Current Assets	12	18	18	28
Total Current Assets	61	126	72	265
Non-current assets				
Property, Plant & Equipment, Net	10	12	13	15
Goodwill	0	0	0	0
Intangible Assets	0	3	5	8
Right-of-Use Assets	0	0	0	0
Shares in Associates	0	0	0	0
Other Long-Term Assets	10	10	10	10
Total Non-Current Assets	21	25	29	33
Total Assets	81	151	100	298
Liabilities				
Current liabilities				
Short-Term Debt	0	0	0	0
Short-Term Lease Liabilities	0	0	0	0
Accounts Payable	6	9	14	16
Other Current Liabilities	4	5	7	7
Total Current Liabilities	10	14	21	23
Non-current liabilities				
Long-Term Debt	0	0	0	0
Long-Term Lease Liabilities	0	0	0	0
Other Long-Term Liabilities	4	4	4	4
Total Non-current Liabilities	4	4	4	4
Non-Controlling Interest	0	0	0	0
Shareholder's Equity	68	134	76	271
Total Liabilities & Equity	81	151	100	298
CASH FLOW				
EBT	-42	-47	-58	247
Cash Flow from changes in Working Ca	3	-3	4	-8
Operating Cash Flow	-38	-48	-51	191
Capital Expenditures	0	-4	-4	-4
Investment in Intangible Assets	0	-3	-2	-3
Investing Cash Flow	0	-6	-6	-7
Financing Cash Flow	35	113	0	0
Free Cash Flow	-38	-55	-57	183

DCF Valuation Metrics	**Sum FCF (SEKm)**
ProTrans	890
Cellaviva	33
NCP03	0
Technology value (SEKm)	923
Estimated net cash (SEKm)	34
Shared costs (SEKm)	-82
Equity value (SEKm)	875
Shares outstanding (million)	73,1
Diluted shares outstanding (million)	110,9
Fair Value per Share	7,9

	2023/ 2024	2024/ 2025e	2025/ 2026e	2026/ 2027e
GROWTH				
Revenue Growth	-19%	20%	21%	1981%
Basic EPS Growth	nm	nm	nm	nm
PROFITABILITY				
ROE	nm	nm	nm	nm
ROCE	nm	nm	nm	nm
ROIC	nm	nm	nm	nm
EBITDA Margin (%)	nm	nm	nm	nm
EBIT Margin (%)	nm	nm	nm	nm
Net Income Margin (%)	nm	nm	nm	nm
VALUATION				
Basic EPS	-0,6	-0,6	-0,7	2,8
P/E	nm	nm	nm	nm
EV/Revenue	4,1	11,8	9,1	0,6
EV/EBITDA	nm	nm	nm	nm
EV/EBIT	nm	nm	nm	nm

SHAREHOLDER STRUCTURE	CAPITAL %	VOTES %
Avanza Pension	15,0%	15,0%
Diamyd Medical AB	7,2%	7,2%
Nordnet Pensionsförsäkring	2,7%	2,7%
Mabtech Group AB	2,4%	2,4%
Anders Essen-Möller	2,2%	2,2%

SHARE INFORMATION	
Reuters code	NXTCL.ST
List	First North Stockholm
Share price	3,3
Total shares, million	73,1
Total shares, million (diluted)	110,9

MANAGEMENT & BOARD	
CEO	Mathias Svahn
CFO	Patrik Fagerholt
Chairman	Hans-Peter Ekre

ANALYSTS	Redeye AB
Filip Einarsson	Mäster Samuelsgatan 42, 10tr
Fredrik Thor	111 57 Stockholm

Redeye Rating and Background Definitions

Company Quality

Company Quality is based on a set of quality checks across three categories; PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive long-term earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of people behind a business is a significant part of understanding the long-term drive of the company. It all comes down to doing business with people you trust, or at least avoiding dealing with people of questionable character.

The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

Business

If you don't understand the competitive environment and don't have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won't succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.

The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company's financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.

The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

Redeye Equity Research team

Management

Tomas Otterbeck
tomas.otterbeck@redeye.se

Technology Team

Hjalmar Ahlberg
hjalmar.ahlberg@redeye.se

Henrik Alveskog
henrik.alveskog@redeye.se

Jacob Benon
jacob.benon@redeye.se

Mattias Ehrenborg
mattias.ehrenborg@redeye.se

Jessica Grunewald
jessica.grunewald@redeye.se

Antof Hoof
anton.hoof@redeye.se

Rasmus Jacobsson
rasmus.jacobsson@redeye.se

Fredrik Nilsson
fredrik.nilsson@redeye.se

Fredrik Reuterhäll
fredrik.reutarhall@redeye.se

Niklas Sävås
niklas.savas@redeye.se

Oskar Vilhelmsson
oskar.vilhelsson@redeye.se

Martin Wahlström
martin.wahlstrom@redeye.se

Editorial

Joel Karlsson
joel.karlsson@redeye.se

Jacob Benon
jacob.benon@redeye.se

Life Science Team

Oscar Bergman
oscar.bergman@redeye.se

Christian Binder
christian.binder@redeye.se

Filip Einarsson
filip.einarsson@redeye.se

Mats Hyttinge
mats.hyttinge@redeye.se

Filip Lindkvist
filip.lindkvist @redeye.se

Gustaf Meyer
gustaf.meyer@redeye.se

Richard Ramanius
richard.ramanius@redeye.se

Kevin Sule
kevin.sule@redeye.se

Fredrik Thor
fredrik.thor@redeye.se

Johan Unnerus
johan.unnerus@redeye.se

John Westborg
john.westborg@redeye.se

Disclaimer

Important information
Redeye AB ("Redeye" or "the Company") is a specialist financial advisory boutique that focuses on small and mid-cap growth companies in the Nordic region. We focus on the technology and life science sectors. We provide services within Corporate Broking, Corporate Finance, equity research and investor relations. Our strengths are our award-winning research department, experienced advisers, a unique investor network, and the powerful distribution channel redeye.se. Redeye was founded in 1999 and since 2007 has been subject to the supervision of the Swedish Financial Supervisory Authority.
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Redeye does not issue any investment recommendations for fundamental analysis. However, Redeye has developed a proprietary analysis and rating model, Redeye Rating, in which each company is analyzed and evaluated. This analysis aims to provide an independent assessment of the company in question, its opportunities, risks, etc. The purpose is to provide an objective and professional set of data for owners and investors to use in their decision-making.

Redeye Rating (2025-02-05)

Rating	People	Business	Financials
5p	5	7	1
3p - 4p	127	114	37
0p - 2p	20	31	114
Company N	152	152	152

Duplication and distribution

CONFLICT OF INTERESTS

Filip Einarsson owns shares in the company : No
Fredrik Thor owns shares in the company : No
Redeye performs/have performed services for the Company and receives/have received compensation from the Company in connection with this.