# Mendus AB

## Initiation of coverage

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Inderes corporate customer

# Keeping cancer in check

Mendus is a clinical-stage biotechnology company developing cellular immunotherapies for cancer. The company aims to improve disease-free and overall survival in cancers with a high recurrence rate. Its lead product, vididencel, is being developed as maintenance therapy for acute myeloid leukemia (AML) and is about to enter a Phase II clinical trial. As a pre-revenue company, Mendus' risk profile is high, as unfavorable research results can lead to a permanent loss of capital. These risks are offset by significant upside potential if commercialization is successful. Our DCF model suggests upside for stock while relative valuation is in line with Nordic peers. The stock's upside could be realized via a partnering deal or Mendus becoming an acquisition target. We initiate coverage with an Accumulate recommendation and a target price of SEK 0.7 in line with a favorable risk/reward ratio.

### Near-term development is focused on a Phase II clinical trial in AML and building pivotal-stage readiness

Mendus has two whole cell-based cancer immunotherapies in clinical development. The lead product vididencel is being developed as a maintenance therapy for AML and ovarian cancer. Results from previous trials have shown a favorable safety profile and indicated possible efficacy. The company is about to initiate a Phase II clinical trial CADENCE in Q2'24 evaluating vididencel in combination with standard-of-care in AML maintenance. In parallel, the company is building pivotal-stage readiness for H2'25. In addition to AML, other programs include vididencel for ovarian cancer and ilixadencel for soft tissue sarcomas. Mendus has a cash runway until Q3'25, which should enable the company to conduct a data readout of the CADENCE trial and to acquire readiness to undertake a global registrational trial.

### Investment returns ultimately depend on the success of the clinical trials

We estimate Mendus' target market for its key indications to be approximately 9.5 BNUSD, growing at a CAGR of over 8% through the end of the decade. There is an urgent need for new therapies, and Mendus aims to differentiate itself in the market by establishing a position in the maintenance cancer therapies. In our view, Mendus has an advantage in terms of the products being difficult to copy, in the manufacturing capabilities, and in the fact that past and ongoing research has established a favorable safety profile of the therapies. Despite these advantages, the risk profile of Mendus remains high, not least due to the R&D risks, which expose investors to the risk of permanent loss of capital in the event of unfavorable clinical data. To compensate for this risk, the stock has significant upside potential if the clinical data are favorable, and the products are successfully commercialized.

### Risk-adjusted DCF model indicates upside for the stock while relative valuation is in line with Nordic peers

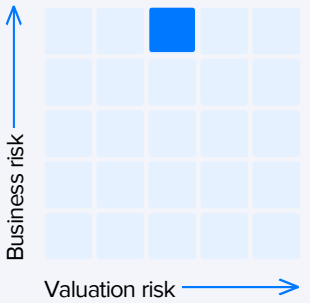
Our estimates are risk-adjusted to account for the R&D risks. We expect the launch of vididencel for the first indication (AML) in 2029, with further launches to follow in 2030 and 2031. We expect peak sales of ~4800 MSEK in 2038 (risk-adjusted peak sales of ~640 MSEK). Operating profit turns positive in 2032, followed by a period of high profitability and strong cash flows. Our DCF model indicates a net present value of SEK 0.7 per share. Relative valuation is in line with the Nordic Phase II immuno-oncology peers. The possibility of a favorable partnering deal or Mendus becoming an acquisition target brings an additional positive option for investors to realize value. We see a favorable risk/reward ratio that supports a positive recommendation.

## Recommendation

**Accumulate**
(prev. )

**0,70 EUR**
(prev. EUR)

**Share price:**
0,49




## Key indicators

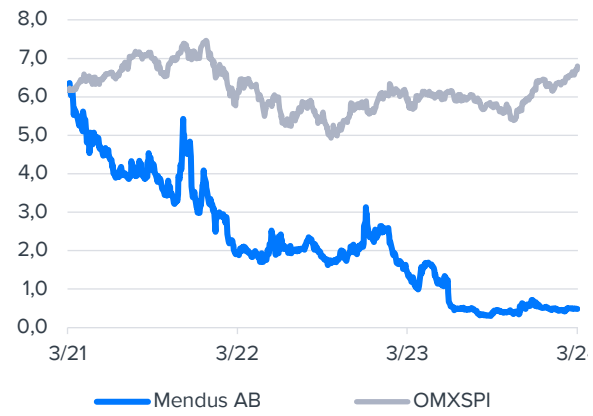
| | 2023 | 2024e | 2025e | 2026e |
|---|---|---|---|---|
| **Revenue** | 0,0 | 0,0 | 0,0 | 0,0 |
| **EBIT adj.** | -125,9 | -123,8 | -123,0 | -93,0 |
| **Net Income** | -126,9 | -126,2 | -126,0 | -96,0 |
| **EPS (adj.)** | -0,15 | -0,13 | -0,13 | -0,10 |
| | | | | |
| **P/E (adj.)** | neg. | neg. | neg. | neg. |
| **P/B** | 0,6 | 0,8 | 0,9 | 1,1 |
| **EV/EBIT (adj.)** | neg. | neg. | neg. | neg. |
| **EV/EBITDA** | neg. | neg. | neg. | neg. |
| **EV/S** | >100 | >100 | >100 | >100 |

Source: Inderes

## Guidance

Mendus does not provide guidance.

## Share price




Source: Millistream Market Data AB

## Value drivers

- Urgent need for new cancer treatments
- Target market is estimated to grow to USD 9.5 billion by 2030 (CAGR >8%)
- Very defensive sector with potential for high profitability
- Potential for globally sold products with annual revenue potential estimated in several billions SEK per indication.
- Potential can also materialize through a partnering agreement or an M&A deal.

## Risk factors

- Therapy development requires substantial upfront investment
- Failed development is likely to result in permanent loss of invested capital
- Success depends on the safety and efficacy of the therapy candidates, which may prove to be insufficient in clinical trials
- Even if market entry is successful, the market share, sales price and royalties involve significant uncertainties

| Valuation | 2024e | 2025e | 2026e |
|---|---|---|---|
| **Share price** | 0,49 | 0,49 | 0,49 |
| **Number of shares, millions** | 1007,2 | 1007,2 | 1007,2 |
| **Market cap** | 495 | 495 | 495 |
| **EV** | 420 | 546 | 642 |
| **P/E (adj.)** | neg. | neg. | neg. |
| **P/E** | neg. | neg. | neg. |
| **P/FCF** | neg. | neg. | neg. |
| **P/B** | 0,8 | 0,9 | 1,1 |
| **P/S** | >100 | >100 | >100 |
| **EV/Sales** | >100 | >100 | >100 |
| **EV/EBITDA** | neg. | neg. | neg. |
| **EV/EBIT (adj.)** | neg. | neg. | neg. |
| **Payout ratio (%)** | 0,0 % | 0,0 % | 0,0 % |
| **Dividend yield-%** | 0,0 % | 0,0 % | 0,0 % |

Source: Inderes

# Contents

# Mendus in brief

Mendus is a clinical-stage biotechnology company developing cellular immunotherapies for cancer. The company aims to improve disease-free and overall survival in cancers with a high recurrence rate. The lead program, vididencel, is being developed as a maintenance therapy for acute myeloid leukemia. Other programs include vididencel for ovarian cancer and ilixadencel for soft tissue sarcomas.

## 2021

Year of establishment through merger of Immunicum (Sweden) and DCPrime (the Netherlands)

## Lead product vididencel

Designed to boost immunity against cancer, to improve disease-free and overall survival following first-line treatment of the primary tumor.

## USD 9.5 billion[1] (2030)

Estimated size of the key markets

## >8% (CAGR 2023-2030)

Estimated growth of the key markets

## SEK -101 million

EBIT 2023

## 27

Personnel at the end of 2023

### 2022 – Building Mendus

- 2002: Establishment of Immunicum.
- 2013: Immunicum IPO on Nasdaq First North.
- 2015: Immunicum starts a Phase II MERECA trial for renal cell cancer with intratumoral immune primer ilixadencel.
- 2018: Phase II vididencel trial ADVANCE II initiated for acute myeloid leukemia by DCPrime.
- 2020: Merger of Immunicum and DCPrime to join forces in developing therapies based on dendritic cell biology.
- 2021: integration completed.
- 2021: Phase I/II trial ALISON started for ovarian cancer.
- 2022: name changed to Mendus.

### 2023 – Recent events

- Q4'23: Long-term follow-up results from the ADVANCE II vididencel monotherapy trial announced. Results suggest favorable safety profile and promising efficacy in acute myeloid leukemia.
- Initial data from the ALISON trial demonstrate the triggering of broad immune responses and support the favorable safety profile of vididencel.
- Long-term follow-up of the MERECA trial did not show a survival benefit. Mendus decides not to pursue metastatic renal cell cancer as an indication for ilixadencel.
- Initiation of a strategic partnership with NorthX Biologics for large-scale production of vididencel. The partnership builds essential capabilities for the upcoming trials and commercialization.

### 2024 and onwards

- H1'24: A Phase II CADENCE trial to start in partnership with ALLG1. The trial combines vididencel with the standard-of-care treatment as a maintenance therapy for acute myeloid leukemia.
- Preparations underway to be ready for a pivotal trial in H2'25.
- Technology transfer to NorthX planned to be ready by mid-2025.
- ALISON trial data readout and survival analysis to be released in 2024.
- Exploration of clinical development of ilixadencel in soft tissue sarcomas continues.
- Cash runway until Q3'25.

Source: Mendus / Inderes

1) iHealthCareAnalyst; Emergen research; Future Market Insights
2) The Australasian Leukaemia and Lymphoma Group

# Company description 1/2

**Mendus is a clinical stage biotechnology company developing cellular immunotherapies for cancer**

Mendus is a clinical stage biotechnology company developing cellular immunotherapies for cancer. The Company was formed in 2020 through a merger of Immunicum (Swe) and DCPrime (NL). Both companies were focused on developing therapies based on dendritic cell biology creating a rationale for the merger. Upon completion of the merger in 2021, the company changed its name to Mendus in 2022.

Mendus' core expertise lays in dendritic cell biology. The Company utilizes this expertise to design active immunotherapies based on living cells. The products are designed to build up long-lasting immunity against cancer. The Company is strategically focused on cancer maintenance therapies with the goal of prolonging disease-free survival and overall survival in cancers with high recurrence rate after first line treatment.

Mendus' current lead product vididencel (DCP-001) is derived from a proprietary cell line making the product off-the-shelf and highly scalable. Vididencel is primarily developed as a maintenance therapy for acute myeloid leukemia AML. Data released so far indicate that vididencel has a favorable safety profile and the Phase II ADVANCE II trial has shown promising signs of efficacy. The product has reached several regulatory milestones facilitating its development (see right margin).

Mendus has entered into a collaboration with the Autralasian Leukaemia and Lymphoma Group (ALLG) to expand the clinical development of vididencel.

This AMLM22-CADENCE (from here on CADENCE) trial is a randomized, controlled combination trial with oral azacitidine, currently the only approved AML maintenance drug.

The priority for the Company is to build readiness to undertake a pivotal-stage vididencel trial in AML by H2'25, supported by the data from the ADVANCE II and CADENCE trials. Mendus has entered into a manufacturing alliance with NorthX Biologics to establish the large-scale manufacturing of vididencel required for pivotal-stage development and market launch.

In addition to AML, Mendus is exploring vididencel in the solid tumor space in the ongoing ALISON Phase I trial in ovarian cancer. The results so far support the benign safety profile of the product and indicate an induction of immune responses in ovarian cancer patients. A primary data readout and a survival analysis of the ALISON trial are expected in H2'24.

The second clinical stage product is called ilixadencel which is an intratumoral immune primer based on donor-derived dendritic cells. Mendus is currently (as of April 2024) exploring the possibilities to develop ilixadencel in soft-tissue sarcomas (i.e. cancers originating from soft tissues).

As an investment case, Mendus is a pre-revenue company with high potential if the clinical development and subsequent market entry are successful. Investor returns may also be realized via favorable partnering or M&A deals. On the other hand, the risk profile is high, not least due to the R&D risks, which expose investors to possible permanent loss of capital in the event of unfavorable data.

## Mendus in a nutshell[1]

| | | |
|---|---|---|
| **The company** | **Mendus**<br>Formed through merger of Immunicum and DCPrime | |
| | **Sweden**<br>Administration | **Netherlands**<br>R&D |
| **Clinical stage therapies** | **Cellular immunotherapies**<br>Long-lasting immune response evoked against cancer by living cells | |
| | **vididencel**<br>For AML & OC[2] | **ilixadencel**<br>Immune system primer for STS[3] |
| **Regulatory milestones for vididencel** | FDA **Fast Track Designation** for AML maintenance therapy | |
| | **Orphan Drug Status** EU and US | |
| | Manufacturing process has **ATMP[4] certification** by EMA | |
| **Preclinical development** | **Natural killer cell platform**<br>Method for expansion of memory NK cells | |
| **Funding situation** | **Cash position MSEK 121 (Q4'23)**<br>Previous funding round of 317 MSEK in Summer 2023. Cash runway till Q3'25 | |

1) Pipeline status as of 4/2024
2) AML = Acute Myeloid Leukemia; OC = ovarian cancer
3) STS = Soft-tissue sarcomas
4) ATMP = Advanced Therapy Medicinal Product

Source: Mendus / Inderes

# Company description 2/2 - Pipeline

| Product | Indication<br>Main program: AML | Research phase: Preclinical | Phase I | Phase II | Phase III | Status | Next steps |
|---|---|---|---|---|---|---|---|
| **Vididencel**<br><br>Proprietary DCOne® cell line | **Acute myeloid leukemia (AML) maintenance**<br>Monotherapy | ADVANCE II | | | | Long-term follow up stage. | Follow-up to continue till 2025. |
| | **AML maintenance**<br>Combination with standard-of-care | CADENCE | | | | Trial launch Q2'24; readouts mid-2025 and late 2026. | Possible indication expansion later. |
| | **AML Maintenance**<br>Pivotal-stage Global registration trial | | | | | In preparation. | Preparation phase ongoing. Recruitment could start in H2'25. |
| | **Ovarian cancer**<br>Combination with Standard-of-care | ALISON | | | | Patient recruitment finished. | Primary data readouts in 2024; survival analysis H2'24. |
| **Ilixadencel**<br><br>Donor cells | **Soft-tissue sarcomas** | | | | | In preparation. | TBA |
| | **Multiple solid tumors**<br>Combination with TKI or PD-1i | MERECA (renal cell carcinoma) | | | | Phase II completed. | Mendus will not pursue metastatic renal cell carcinoma as an indication. |
| **Preclinical development**<br><br>Based on DCOne® | **Natural killer cell platform** | | | | | Preclinical development. | Potential new program or basis for collaboration. |

Source: Mendus / Inderes
TKI=Tyrosine kinase inhibitor

# Products 1/6 – Vididencel

### Vididencel is a cancer maintenance therapy

Vididencel (DCP-001) is a cellular immunotherapy developed using Mendus' proprietary cell line DCOne®. The product is based on living cells, and it works by boosting an immune response against cancer. The product is developed as a maintenance therapy meaning that it is administered to patients who have already received initial chemotherapy that has killed most of the cancer cells. However, residual cells can cause tumor recurrence, and this is the major cause of global cancer-related deaths. If patients have Measurable Residual Disease MRD (i.e. traces of cancer datable with sensitive methods) after the initial chemotherapy, the likelihood of cancer recurrence is higher and outlook for these patients worse.

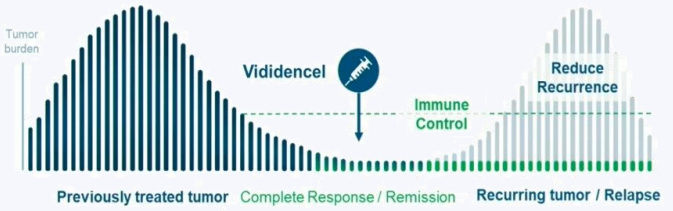
Vididencel aims to prolong the time until cancer recurrence and to improve overall survival of the patients. The product is an active immunotherapy (a vaccine essentially) which means that it is designed to evoke a long-lasting immune response against cancer. Active immunity, built up by the patients' own immune system, takes a few weeks to develop and therapeutic concepts based on active immunity will therefore be most effective in low-disease settings. If successful, an active immunotherapy approach has the potential for long-term eradication of cancer. In line with these principles and supported by the Phase I data in AML, vididencel has the greatest potential efficacy as a maintenance therapy.

We highlight that the concept of immunotherapy against cancer is already proven by the so-called checkpoint inhibitors. These antibody-based passive therapies activate the patient's immune system by blocking inhibitory pathways expressed by cancer cells. Checkpoint inhibitors have revolutionized cancer therapy since their introduction to clinical practice in the early 2010s by improving treatments outcomes. However, patients with blood-borne cancers have not yet benefitted of these drugs. The most recent setbacks have been with CD47 inhibitors in AML. Further, despite significant efforts, attempts to improve the checkpoint inhibitors' efficacy by combining them with other immunotherapies has been very limited. Mendus is strategically positioned to develop new immunotherapies in blood-borne tumors and solid cancers that are not, or poorly, responding to checkpoint inhibitors.

### Vididencel targets cancer from multiple directions exploiting several antigens

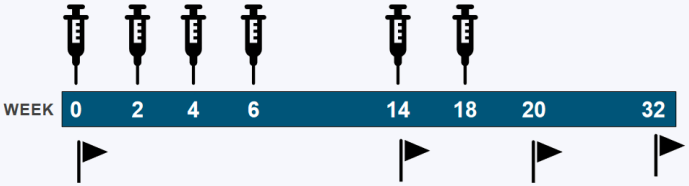
Vididencel's mechanism of action as an active cellular immunotherapy is quite different from checkpoint inhibitors or other immunotherapy approaches which typically rely on activating or inhibiting a specific receptor. Vididencel carries a wide range of known and unknown tumor antigens as well as other molecules that help activate a broad antitumor response. In other words, the immune response evoked by vididencel targets the cancer cells from multiple directions. This may result in the eradication of cancer with greater efficiency. Ideally, the immune response is long-lasting leading to durable clinical remissions.

**Vididencel aims to prolong disease-free survival**




Source: Mendus

**Vididencel administration schedule**




Source: Mendus
Flags indicate assessments of Measurable Residual Disease

# Products 2/6 - Vididencel

We emphasize that at this stage this theory needs to be validated in larger clinical trials. Nevertheless, current Phase II data on vididencel appear promising (see pages 10-11).

### Vididencel is a whole cell-based product

Vididencel manufacturing is based on Mendus' proprietary DCOne® cell line, which are leukemic cells that were selected for manufacturing purposes. The DCOne® cells are first expanded to large quantities in cell culture and then differentiated into a dendritic cell-like phenotype using Mendus' proprietary protocol. The final product is irradiated for safety purposes and stored frozen, so that it is available on-demand ("off-the-shelf") for clinical use. Mendus has developed a large-scale manufacturing process which is suitable for late-stage development and commercialization and this process is now transferred to NorthX for clinical-grade (GMP) production.

Vididencel is applied by injecting the product into the patient's skin (i.e., intradermal administration). Once injected, vididencel directly activates T-cells (alloreactive) in the skin, resulting in secretion of inflammatory mediators. These mediators in turn recruit antigen-presenting cells in the skin, which engulf the vididencel cells and become activated in the process. Once these events have taken place in the skin, the antigen-presenting cells migrate to the lymph nodes, where they further activate T-cells and initiate a broad anti-tumor response.

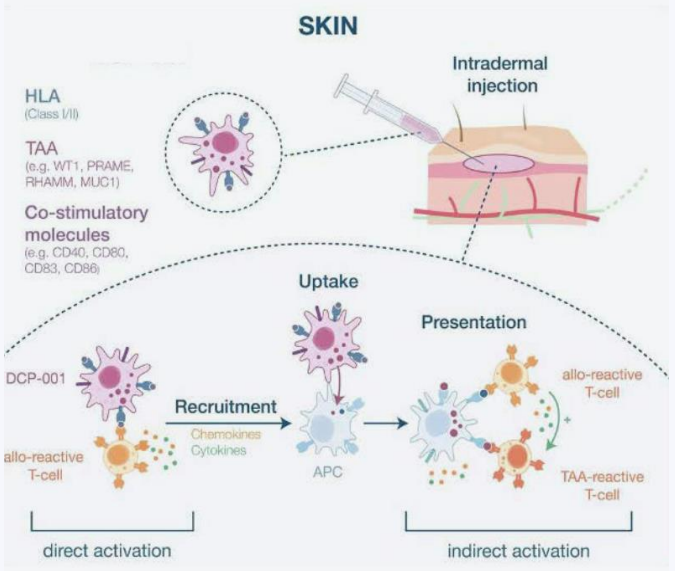
As a whole cell-based product, vididencel carries a wide range of known and unknown tumor antigens (molecular structures found on cancer cells but not normal cells). According to data published by Mendus, vididencel contains at least 4 tumor antigens (WT1, PRAME, RHAMM, MUC1). In reality, the living cells may contain a much higher number of antigens but measuring all of them is not feasible. In addition, vididencel contains co-stimulatory molecules (e.g. CD40 and CD80) that help further activate the immune system.

### Vididencel as a maintenance therapy for acute myeloid leukemia

Vididencel is being studied as a maintenance therapy for acute myeloid leukemia (AML). This means that vididencel is given to AML patients who are first treated with chemotherapy (first induction and then consolidation chemotherapy). Chemotherapy is typically effective in the short term: about 2 out of 3 patients experience a complete response, which is defined as a reduction of at least 95% of the cancer cells in the bone marrow, known as blasts. In addition, blood counts in circulation return to normal and there are no signs or symptoms of the disease. Such a patient with a positive response is said to be in remission.

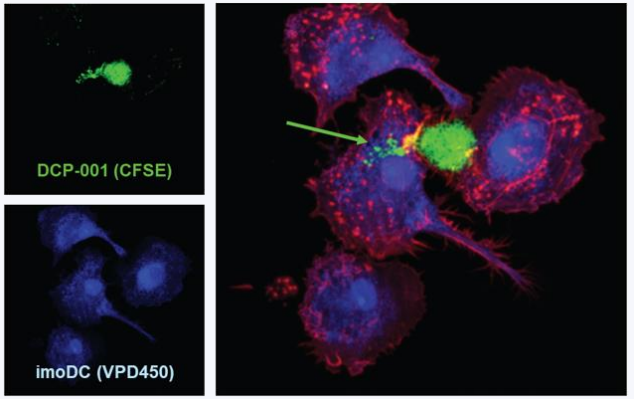
Unfortunately, remissions are often temporary, and patients relapse with new signs of cancer. There have been many attempts to prolong remission or ideally prevent relapse. Apart from hematopoietic stem cell transplantation (HSCT), unfortunately, few strategies have been successful and 5-year survival of AML still stands only at around 30%. . Patients who have Measurable Residual Disease MDR (i.e. traces of cancer detectable with sensitive molecular methods) have a higher risk of relapse and shorter life-expectancy.

### Vididencel activates T-cells to destroy cancer




TAA = Tumor associated antigen
Source: Mendus

### Vididencel[1] is engulfed by antigen presenting cells[2]




1) Green cells
2) Blue cells

Source: Mendus, Modified from Zuo et al., Cells (10), 2021

# Products 3/6 – Vididencel

The only currently approved AML maintenance treatment is oral azacitidine (Onureg®), which has been shown to prolong survival based on the QUAZAR AML-001 trial (see right). Although the improvement is reproducible, the effect is also rather small in size. As other treatment options are currently very limited, there is a clear need for new and better treatments.

To our understanding, Mendus has focused on developing vididencel as a maintenance therapy for several reasons: 1) the need for better maintenance treatments for AML patients; 2) vididencel has excellent tolerability and low number of adverse events which is important for patients weakened by intensive chemotherapy and for their quality of life; 3) active immunity takes time to build up, so vididencel is likely to only work in low-disease settings (i.e. relatively low number of cancer cells after chemotherapy) as indicated by data from earlier vididencel trials.

### ADVANCE II - Phase II trial indicates tolerability and preliminary efficacy in AML maintenance

The leading trial on vididencel to date has been ADVANCE II, a Phase II clinical trial evaluating vididencel monotherapy for the maintenance of AML in patients with Measurable Residual Disease MRD. The enrolled patients (n=20) achieved complete remission with MRD as a result of induction chemotherapy. The study is currently in long-term follow-up and the most recent data was published in December 2023. According to the data, the safety and tolerability profile of vididencel appears to be very favorable. The only adverse effects reported are at the site of injection and are mild in nature. Local side effects are to be expected and may be a result of the injection and not related to vididencel itself.

At the last reported read-out presented in December 2023, median follow-up was 31.6 months. Median relapse-free survival was 30.4 months and median overall survival was not reached, with the majority of patients (14/20) still alive in long-term follow-up. The survival data suggest that those patients who survive the first year seem likely to do well also in the long term. The durable clinical remissions following vididencel treatment were associated with broad immune responses, supporting the mode of action of vididencel as an active immunotherapy boosting long-term immunity that in turn keeps the residual cancer cells in check.

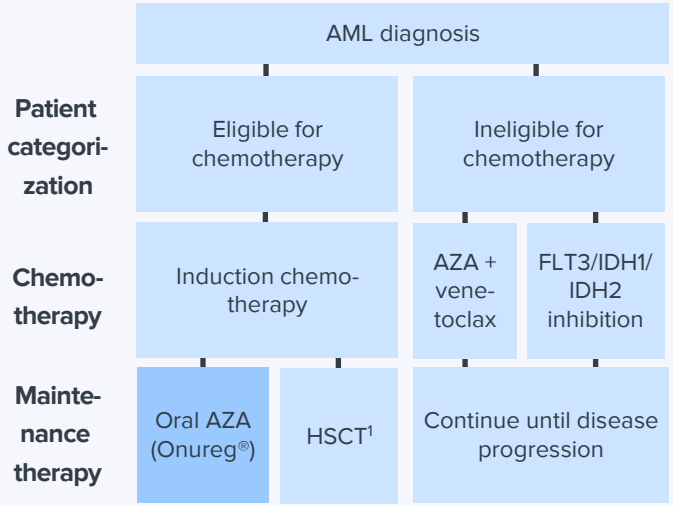
In the QUAZAR-AML registration trial for oral azacitidine, relapse-free survival in high-risk MRD-positive patients was 7.1 months vs 2.7 months for placebo and overall survival 14.6 vs 10.4 months, respectively. We caution that making direct comparisons between results from different trials may easily lead to erroneous conclusions. This is because of possible differences between the studies, such as patient selection and population characteristics may lead to different outcomes. Despite our caution, we think that the ADVANCE II data appear very promising in terms of both safety and efficacy and provide a solid foundation for Mendus to continue to develop vididencel.

### QUAZAR AML-001 trial, MRD-positive patients[1]

| | |
|---|---|
| **Patients** | 219 patients of which 103 received Onureg® |
| | >55 years of age in first remission |
| | Within 4 months of achieving first complete remission |
| | Not a candidate for stem cell transplantation |
| **Treatment** | 300 mg/day for 14 days/28 day cycle |
| | Continue until disease progression, unacceptable toxicity or allo-HSCT |
| **Relapse-free survival** | 7.1 months vs 2.7 in the control arm |
| **Overall survival** | 14.6 months vs 10.4 in the control arm |

Source: Roboz et al. Blood 139 (14), 2022.

### AML treatment scheme




1) HSCT = Hematopoietic Stem Cell Transplantation
Source: Mendus, Inderes

# Products 4/6 – Vididencel

When ADVANCE II was initiated, there were no treatment options available for AML maintenance. As a result, the ADVANCE II was designed and undertaken as a monotherapy trial. Since ADVANCE II began, oral azacitidine (Onureg®) was approved by the FDA and EMA and became standard-of-care. This created a rationale to combine vididencel with Onureg®. Vididencel and azacitidine have completely different modes of action, creating a rationale for effective combination therapy. Moreover, there is some evidence that immunotherapies and azacitidine may have synergistic effects. In addition, the favorable safety profile of vididencel makes it a solid candidate for combination therapy, reducing the risk of exacerbated side effects for the patients who have already undergone harsh chemotherapy. As the effect size of Onureg® in improving relapse-free and overall survival is relatively modest, there is room for vididencel to improve patient outcomes in combination with Onureg®.

### CADENCE trial combines vididencel with standard-of-care for AML

Mendus' lead program AMLM22-CADENCE combines vididencel with the standard-of-care Onureg® for AML maintenance. CADENCE is an adaptive, randomized, multi-center trial conducted in collaboration with the Australasian Lymphoma and Leukemia Group (ALLG). In Stage I, the study enrolls 40 patients (of which half receive vididencel) with the potential to expand up to 140 in Stage II. Enrolment is to begin in April 2024. The first Stage of the trial is expected to take 18-24 months. The time frame for the full 140 patients is expected to be 24-36 months. The CADENCE trial will serve as a steppingstone towards a pivotal clinical trial and safety data from the CADENCE trial may be used for the global registration dossier of vididencel based on positive FDA feedback.

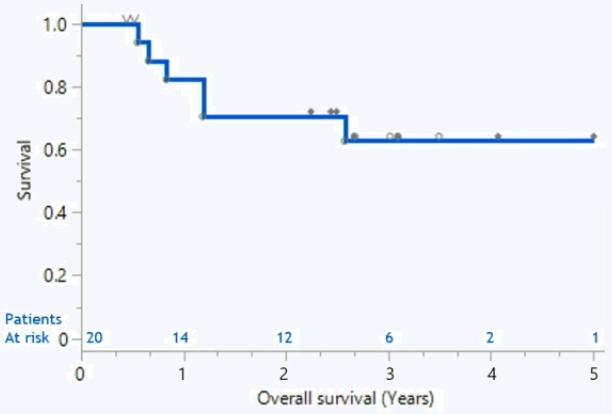
### Building readiness for a pivotal trial

In parallel with the CADENCE trial, Mendus is preparing for a pivotal vididencel trial for AML. The details and specific plans regarding this trial are not yet announced by Mendus. If successful, this registration trial would enable applying for market authorizations for global commercialization.

To enable the registration trial and commercial launch, Mendus has established a strategic manufacturing partnership with the Sweden-based specialized cell- and gene therapy manufacturer NorthX Biolologics. Mendus has already paid for the technology transfer as well as vididencel production for the pivotal trial. In the most recent business update March 2024, Mendus and NorthX stated that the production facility for vididencel has been established and that the transfer of the manufacturing process from Mendus to NorthX has started according to plan.

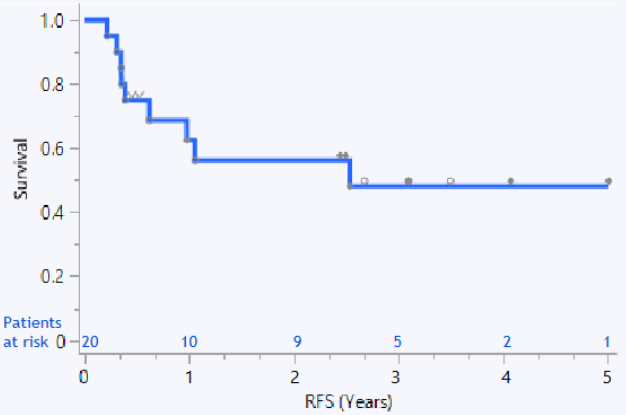
Based on the timelines for developing the registration trial protocol and establishing large-scale manufacturing, Mendus expects to be ready for pivotal-stage development of vididencel in AML in H2'25.

**Overall survival in ADVANCE II – data readout Q4'23**




Source: Mendus

**Relapse-free survival**




Source: Mendus

# Products 5/6 – Vididencel

## Vididencel for ovarian cancer

Mendus is exploring the possible application of vididencel in solid tumors in the Phase I ALISON trial in ovarian cancer. Ovarian cancer is the second most common gynecologic cancer in the United States (US Department of Health and Human Services). Similar to AML, ovarian cancer has a high recurrence rate after initial treatment, which is typically surgery followed by chemotherapy.

Available treatments become less effective after each round of recurrence. Therefore, maintenance therapies are needed to prolong progression-free survival and overall survival. PARP inhibitors are currently used for maintenance therapy. These drugs show better therapeutic outcomes with less toxicity compared to previous drugs. However, significant room for improvement remains for patient outcomes.

As with AML, Mendus is developing vididencel for ovarian cancer as a maintenance therapy. The ALISON trial has enrolled all 17 patients as of late 2023. The latest update on ALISON progression was published in November 2023. The data showed positive safety and tolerability and induction of broad immune responses in this indication, but the data are too early to draw any conclusions about clinical efficacy. Further readouts from ALISON are expected in 2024, including a primary read-out in H2'24.

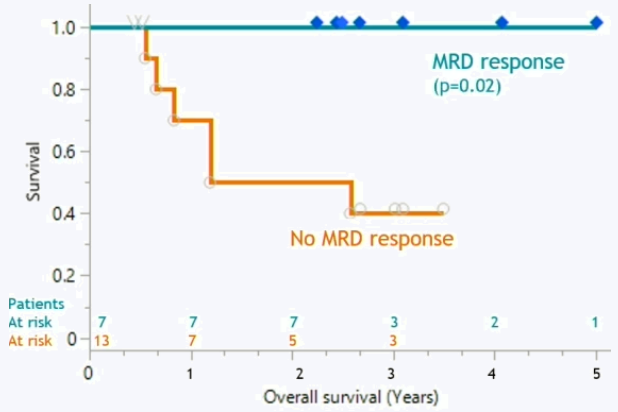
## Vididencel is protected strongly by patents and manufacturing secrets

Our understanding of Mendus' intellectual property rights is that the key patents around vididencel cover the DCOne® cell line and the manufacturing process. It is our understanding that the initial key patents will expire in the early 2030s[1]. Mendus has an active strategy to broaden and extend the patent protection for the platform and vididencel as a product. Since Mendus "owns" the DCOne® cell line, it creates a wide moat against competition. Mendus has physical control of the cell line, and it would be very difficult for competitors to gain access to DCOne®.

We emphasize that even after the expiration of key patents, vididencel is still strongly protected from competition. This is based on the physical control of the DCOne® cell line, the GMP Master and Working Cell Banks. Importantly, the company has developed extensive expertise in manufacturing and other technical aspects of vididencel, which according to our understanding, Mendus has deliberately not patented. This is to keep the many steps of the manufacturing process secret. It would be very difficult and time-consuming to replicate the manufacturing process without knowing the details of the manufacturing protocol, which likely involves multiple steps including specific treatments of the living cells. We believe that if these steps are not followed according to minute details the exact characteristics of vididencel cannot be reproduced.

We speculate that a highly skilled team could develop a product similar to vididencel in a few years. However, this product would have to go through the lengthy clinical trials and show superior safety and/or efficacy over the current standard-of-care. In summary, we believe Mendus' IPR is very solid, even beyond the expiration of key patents.

## Overall survival by MRD responce




Source: Mendus

## CADENCE trial – vididencel combined with azacitidine for AML

| | |
|---|---|
| **Study design[2]** | An adaptive, randomized, multi-center **Phase II** trial consisting of two stages. To evaluate **vididencel** in combination **with oral AZA** as a maintenance therapy in AML |
| **First stage** | **Safety** of vididencel in combination with AZA in 40 patients randomized to either receive vididencel + AZA or AZA alone |
| **Second stage** | **Efficacy** of the combination will be assessed in an additional 100 patients |
| **Protocol** | four biweekly intradermal injections, followed by 3 booster injections up to 6 months after start of treatment. |
| **Initiation** | **Recruiting to begin H1'24** pending ethical approval |

Source: Mendus

1) https://patents.google.com/patent/EP2931878B1/en
2) Approved by the ethics committee in March 2024.

# Products 6/6 – Ilixadencel

### Ilixadencel primes the immune system for an anti-tumor response

Mendus' second major asset, Ilixadencel, shares many similarities with the lead asset, vididencel, but also has important differences. Ilixadencel is manufactured using donor cells from a healthy individual. This means that the ability to expand the number of cells outside the body is limited (although still being relatively scalable) compared to cell lines such as DCOne®. Ilixadencel is composed of pro-inflammatory dendritic cells. When injected into the tumor, Ilixadencel induces an inflammatory environment that primes an immune response against the tumor.

Ilixadencel has been in Phase II clinical trials for several different types of solid tumors in combination with other anticancer agents. These include tyrosine kinase inhibitors and the immune checkpoint inhibitor pembrolizumab (Keytruda®). The most recent study evaluated the safety and efficacy of ilixadencel in metastatic renal cell carcinoma. However, according to the latest data released in Q4'23, ilixadencel did not improve overall survival in patients with metastatic renal cell carcinoma when combined with a tyrosine kinase inhibitor. Consequently, Mendus announced that the Company would not continue pursuing renal cell carcinoma as an indication for ilixadencel.

Despite the setback in metastatic renal cell cancer, Mendus believes ilixadencel has potential in difficult-to-treat cancers that are unresponsive to current therapies. As the next step in the development of ilixadencel, Mendus is evaluating the possibilities of ilixadencel in soft tissue sarcomas (STS), a group of tumors generally unresponsive to current available therapies after first-line treatment failure. The Company has seen initial encouraging clinical results in gastrointestinal stromal tumors, a subtype of STS. We expect the Company to provide further details on future clinical development of ilixadencel during 2024. As a key enabling step for future development, Mendus has worked to establish a more robust manufacturing process to support the supply of ilixadencel.

### Preclinical pipeline explores novel opportunities of DCOne® and therapy combinations

In addition to the clinical assets vididencel and ilixadencel, Mendus has a preclinical program to develop next generation immunotherapies based on the DCOne® cell line as well as combinations of cancer vaccines and intratumoral priming.

The company sees potential in utilizing the DCOne® platform to expand the so-called memory natural killer cells that could potentially be used in cancer immunotherapy. These cells are unique because of their longevity and resistance to immune suppression. The number of these cells correlates with improved clinical outcomes in blood-borne tumors suggesting that they may play a role in keeping cancer in check.

To our understanding, the preclinical projects are currently at a relatively early stage and are not yet mature enough to move to the clinical stage. However, we believe these development projects are important in building the long-term success of Mendus.

### Summary of the lead products

| | vididencel | Ilixadencel |
|---|---|---|
| **Mechanism of action** | Made from DCOne® vididencel is a live-cell cancer vaccine that is injected into the skin. The DC[1]-like cells induce an anti-tumor immune response. | Ilixadencel is made of live DC-like cells that are injected into the tumor. Ilixadencel primes the immune system to work against cancer. |
| **Indications** | Maintenance therapy for AML; ovarian cancer | Soft-tissue sarcomas |
| **Safety and efficacy** | Based on Phase II data, the safety profile is very favorable and benign.<br><br>Initial data on efficacy is promising. | Based on Phase I data, the safety profile is favorable and benign.<br><br>It is too early to draw conclusions regarding efficacy. |

Source: Inderes
1) DC = dendritic cell

# Business model 1/5

## Business model has high risk and high opportunity

The business model for developing these novel types of cell-based immunotherapies is very similar to that of drug development. Due to the nature of developing new medical treatments, the development phase before commercialization can take up to a decade or more and requires major upfront investments in basic and clinical research. The typical phases of development are presented in the table on right. In the past, Mendus has financed this development through a series of new share issues and investors should be prepared forpossible financing rounds also in the future.

The nature of drug development exposes the investor to not only regular business risks but also to a binary risk related to success or failure of the clinical trials. If the safety, tolerability and/or efficacy of a therapy does not prove to be superior to existing therapies, the development process will be halted, and the project is likely to be written off. This would result in permanent loss of capital. To offset the high risks, the potential rewards are also lucrative. The number of patients who would benefit from Menus' therapies is high and revenue per patient could exceed 1 MSEK. The business model is also scalable, as commercialization would most likely be realized through a partnering deal that would yield Mendus significant cash flows without major capital investment.

If the therapies developed have a sufficient efficacy and safety profile, doctors and hospitals will have a strong incentive to prescribe the treatment to their patients, especially in affluent Western countries.

## Developing novel therapies takes time and money

Similar to other companies developing new drugs or therapies, Mendus' business model is based on advancing clinical trials. Upon successful regulatory review, completion of the clinical program will allow commercialization of the treatment for one or several indications.

Clinical trials are typically divided into three phases (see table on right). In early development, the safety and efficacy profile of the therapy is unknown, and the likelihood of market entry is lowest. With positive results and regulatory approval, the company can move on to the next clinical phase, which increases the likelihood of market entry.

As the quality and quantity of scientific data increases, the probability of market success goes up. As a result, the value of the company is likely to go up as the probability of future cash flows increases. Conversely, if the research results are unfavorable, the value of the drug/treatment candidate may decline dramatically. The asset may still be useful, e.g., for another indication, but in practice a failed development often leads to the abandonment of the candidate. We currently view Mendus as a Phase II clinical development company, as the leading upcoming trial will be the Phase II CADENCE trial vididencel combined with standard-of-care azacitidine for AML maintenance therapy.

In addition to scientific and clinical research capabilities, conducting the clinical program requires funding and upscaled manufacturing of the live cells that are the basis of Mendus' products.

## Drug development phases

Early research | Clinical trials | Commercialization

| | Duration | Patients | Cost |
|---|---|---|---|
| **Basic research and drug development** | 2-4 years | - | ~10-20 MEUR |
| **Preclinical phase** – Cell cultures and animal models | 1 year | - | ~5 MEUR |
| **Phase I** – Safety and tolerability | 1-2 years | Dozens | ~2-5 MEUR |
| **Phase II*** - safety and preliminary efficacy | 2-3 years | Dozens - hundreds | ~10-15 MEUR |
| **Phase III** – extensive safety and efficacy | 2-3 years | Hundreds - thousands | ~20-50 MEUR |
| **Marketing authorization*** | 1 year | - | ~0.01-0.1 MEUR |
| **Post-marketing surveillance** | The safety and efficacy of the drug is monitored throughout its sales. Relevant authorities may require possible further research. | | |

* In certain cases, conditional marketing authorization may be granted before completion of Phase III studies

Source: Davis FS, Biotech Forecasting & Valuation, 2016. / Inderes

# Business model 2/5

### Vididencel is manufactured in collaboration with NorthX

Mendus recently entered a strategic collaboration with NorthX, a Swedish contract development and manufacturing organization, to scale up production. Vididencel is based on living cells that are manufactured in pouches containing liquid that supplies the cells with nutrients. Once the cells have multiplied, the batch is collected, purified and the cell product is frozen in vials ready for shipping. The final product is off-the-shelf meaning the frozen vial can be thawed at the site of use and applied immediately. Mendus' products are of allogenic origin which makes scaling production process, scalability, and logistics easier compared to autolougous (the patients own) cells.

Maintaining cell viability and product efficacy is not trivial, and to our knowledge, NorthX specializes in manufacturing cell and gene therapy products. The manufacturing protocol is complex compared to the chemical synthesis of a typical small-molecule drug or the production of biologic drugs (e.g. antibodies). Production capabilities must be scaled up significantly before large pivotal trials and eventual commercialization can begin. In our view, Mendus has been developing its manufacturing capabilities for years and the company is well prepared to upscale production and respond to the potential realization of risks associated with manufacturing the products. Outsourcing upscaled production to NorthX is feasible as it requires specific competencies. Building up Mendus' own manufacturing capabilities would require significant capital expenditure. We believe that Mendus' limited financial resources are better used to accelerate the clinical pipeline.

### Financing is at the heart of the business model

As a pre-revenue company, financing the clinical trials and manufacturing is central to Mendus' business model. In recent years, Mendus has spent approximately 50 to 90 MSEK on R&D, depending on the phases and capital intensity of its trials. This has been sufficient to carry out the Phase II trials, but a possible launch of pivotal Phase III trials would probably result in increased R&D spending as the number of patients is much higher resulting in costs of hundreds of millions of SEK per trial.

The success of the financing arrangements is therefore crucial to the implementation of the company's business model and strategy. With its limited resources, Mendus must prioritize the trials to find an optimal cost/benefit ratio. As stated by Mendus, the clear future priority (as of early 2024) for the Company is the vididencel Phase II CADENCE trial for AML in combination with azacitidine. Further, the pivotal vididencel trial for AML is a clear priority for the company. However, due to the costs of the trial a partnering deal or other non-dilutive funding arrangement may be needed to support this development financially. Nevertheless, Mendus is committed to building readiness to be able to undertake the pivotal trial. We note that Mendus is continuously evaluating scientific data and development priorities may change accordingly.

Most of Mendus' R&D funding to execute the planned pipeline are still unsecured. We believe that the company's options for financing research are licensing agreements, share issues, and possibly debt financing. To date, Mendus has financed its activities with share issues, the most recent of which was carried out in the summer of 2023, bringing in 317 MSEK. The share issue and subsequent exercise of warrants have secured Mendus' funding until Q3'25.

In the medium to long term, we expect Mendus to pursue a licensing deal with a larger pharmaceutical/biotech company. Such a deal typically includes an upfront payment to help fund the pipeline, milestone payments linked to progress of the clinical trials and commercialization, and licensing fees as a percentage of eventual sales. Funding the entire pipeline through new share issues would be highly dilutive and probably not in the best interest of shareholders.

### Considerable revenue and profitability potential

Regulatory authorities can grant marketing authorization to a drug or therapy if the developing company is able to prove adequate safety and efficacy relative to the severity of the disease and alternative drugs or therapies. Once approved, the drug is marketed and sold to hospitals and doctors who choose the drug they believe is best for their patients. If the drug development progresses favorably, the most likely scenario is that the company signs a licensing agreement with a larger pharmaceutical company in Phase II/III research.

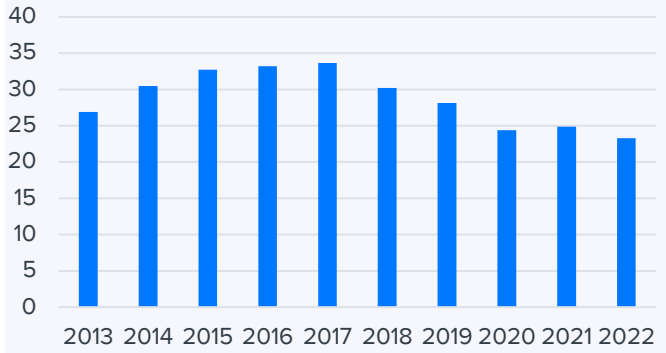
# Business model 3/5

The purpose of the agreement is to share research risks, costs and potential future returns with a larger partner. In addition, through licensing, Mendus would gain access to a global sales and distribution network.  In licensing agreements, the developer typically receives a royalty payment of roughly 20 % of sales and potential milestone payments, depending on the progress of research and sales. The value of these deals varies greatly and can reach even tens of billions of SEK in the most potential cases. The licensing model does not require significant investment by the company. Thus, license income can be expected to be highly profitable. A deal would also have a significant effect on the company's cash flow, as an upfront payment would likely cover most or all of the R&D funding requirements.

At the mature stage, biotechnology companies are typically highly profitable. Companies in the Bloomberg Global Mature Biotech Index have shown a median EBIT margin of 29.2% over the past ten years. This underscores the lucrative potential for profitability if market access is successfully achieved.

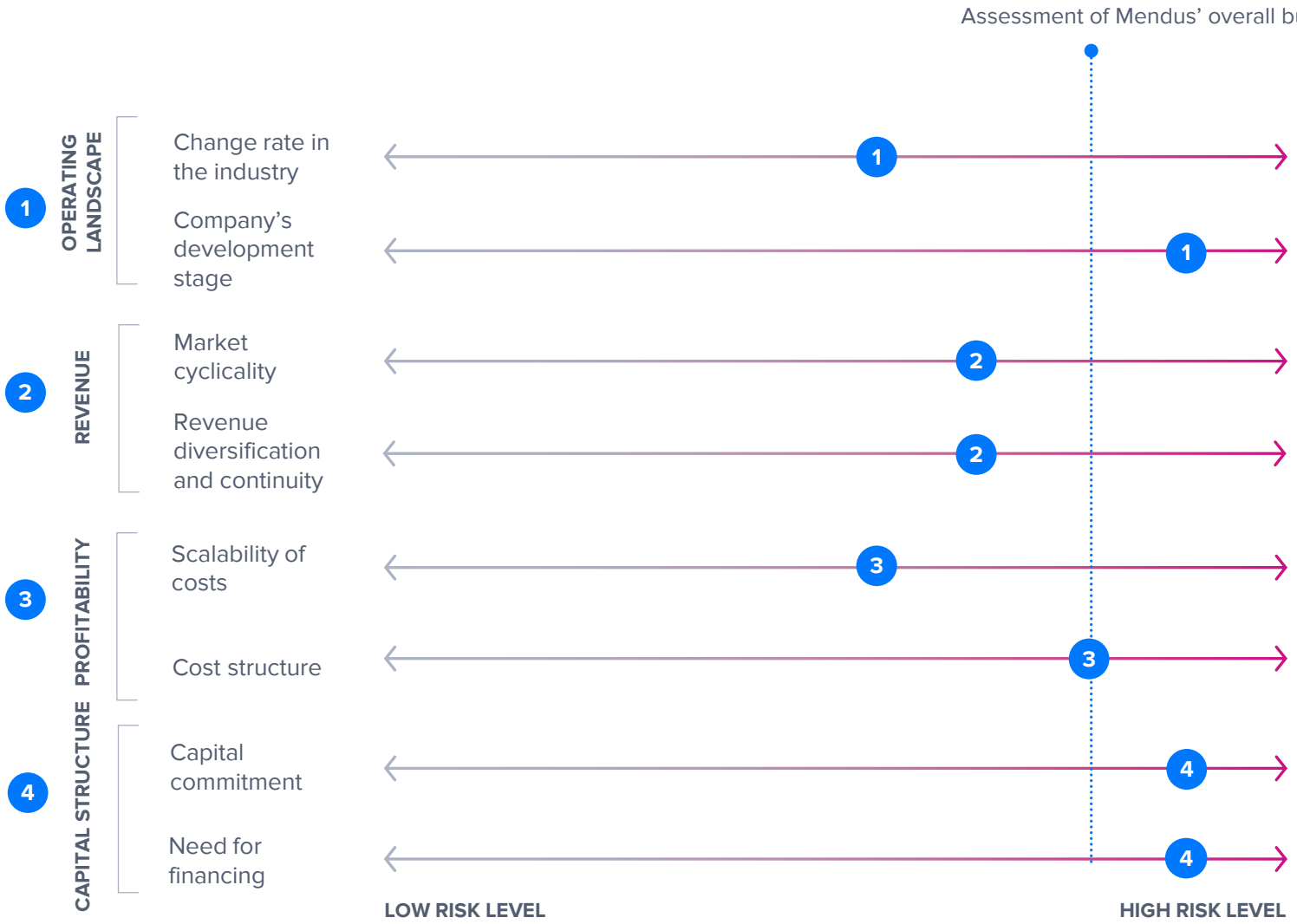
Another alternative for cash flow materialization is an M&A scenario, in which one of the major global biotechnology or pharmaceutical companies would acquire Mendus or one of its therapies to complement its pipeline. Such M&A deals have decreased in number and value since 2022, but at the same time, the large players have the need and the funds to supplement their pipelines with new drug candidates and treatments. We therefore expect the current M&A slowdown to be transitory. We review recent partnering deals and M&As in more detail In the Valuation section.

**EBIT margin of global biotech companies**




Source: Bloomberg Global Mature Biotech / Inderes

# Business model 4/5 – Risk profile




Strict regulation in the industry makes drug development slow. On the other hand, when the company reaches the commercialization phase, the defensive nature of the industry provides stability.

As a clinical stage (Phase II) biotech company without marketing authorization, Mendus' risk level is very high.

The target market is very defensive. However, due to the company's development stage, it does not yet benefit from this defensiveness.

The company does not have any revenue yet. If commercialization is successful, revenue will be stable and diversified.

Administrative expenses are fixed and R&D costs are highly flexible. In the commercialization stage scalability would be excellent.

Administrative costs are low relative to the business potential. Frontloading costs keeps profitability weak for the time being.

Drug development requires a significant up-front capital investments. The targeted commercial phase can be very capital-light.

The company's cash assets are sufficient until at least Q3'25. The financing needs of the research program in the coming years are significant and will likely require new equity issues.

Source: Inderes

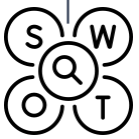
# Business model 5/5 – SWOT

## Strengths

- Rather unique mode of action with few direct competitors
- Technology is difficult to copy and/or reproduce
- Benign safety profile of the lead products
- Clear differentiation strategy in the crowded AML space
- Vididencel manufacturing is highly scalable and ilixadencel relatively scalable compared to products using patients own cells (such as Sipuleucel-T)

## Weaknesses

- Mendus' capability to accelerate both vididencel and ilixadencel programs simultaneously is limited because of resources.
- Small team requires extreme focus with little room for maneuver.




## Opportunities

- Clear need for better maintenance therapies and high achievable prices especially in the US market
- Expansion of indications in the long-term
- Cell-based therapies have become more mainstream for possible big pharma partners following successes of CAR T therapies

## Threats

- Clinical trials can show lack of safety and/or efficacy leading to permanent loss of capital
- Lack of a licensing deal or one with disappointing value
- New treatments entering the market and raising barrier to market for Mendus' products
- Recent funding environment has been difficult for biotech companies
- Share count and price diluted by repeated new share issues

Source: Inderes

# Investment profile Mendus

1. **Cellular immunotherapy company focused on cancer maintenance therapies**
2. **Urgent need for new treatments and strong growth outlook for the industry creates high market potential**
3. **Lead asset vididencel in combination with standard-of-care for AML holds the greatest potential currently**
4. **Potential for high returns, but also risk for permanent loss of capital**
5. **Possible market entry is still many years in the future**

## Potential

- Urgent need for new cancer treatments
- Target market is estimated to grow to 9.5 BNUSD by 2030 (CAGR >8%)
- Very defensive sector with potential for high profitability
- Potential for globally sold products with annual revenue potential estimated in several billions SEK per indication.
- Potential can also materialize through a partnering agreement or an M&A deal.

## Risks

- Therapy development requires substantial upfront investment
- Failed development is likely to result in permanent loss of invested capital
- Success depends on the safety and efficacy of the therapy candidates, which may prove to be insufficient in clinical trials
- Even if market entry is successful, the market share, sales price and royalties involve significant uncertainties

Source: Inderes

# Industry and competitive landscape 1/3

### Market is driven by strong megatrends, with US leading geographically

The cancer drug therapy markets are driven by familiar trends: aging populations and increasing numbers of cancer cases. Importantly, the improvements in available treatments will increase patient survival, resulting in more people who live with cancer. This creates a further need for maintenance therapies, which will support Mendus' markets in the long term.

The United States is by far the most important region in the cancer drug market followed by Europe. This US market represents almost half of the total market and is driven by the highest prices in the world, adoption of new treatments, and rising number of cancer patients (Allied Market Research). We expect Mendus to prioritize the US market due to the rapid uptake of new therapies and the high prices achievable for treatments.

### Mendus operates in the immuno-oncology space

In a broad sense, Mendus is targeting the immuno-oncology market. According to GlobalData, this market will be valued at USD 48 billion in 2022 and is expected to grow at a compound annual growth rate (CAGR) of 21% to reach approximately USD 150 billion by 2028. The immuno-oncology market has grown significantly over the past decade, driven by the commercialization of so-called checkpoint inhibitors (CPIs), which typically disinhibit cytotoxic T-cells and cause them to attack and destroy cancer cells. The CPI market was valued at USD 30 billion in 2022, making it by far the largest contributor to the overall immuno-oncology market.

After entering the market in 2011, CPIs have significantly changed cancer therapeutics and provided further evidence to support the concept of cancer treatment by activating the immune system. CPIs are also a commercially valuable group of drugs and the leading drug Keytruda (pembrolizumab) sold nearly USD 21 billion in 2022 (Statista). CPI drugs are very expensive, with the cost of treating a patient in the US estimated at 0.1-0.15 MUSD. This creates a certain framework for the pricing of other immunotherapies, including those of Mendus. To date, attempts to use CPIs against blood cancers have been largely unsuccessful. We note in particular the setbacks with CD47 inhibitors.

With many of the leading checkpoint inhibitors losing patent protection by the end of the decade, manufacturers are looking for potential combination therapies to extend sales of their CPIs. The large and growing market has attracted a large number of new immuno-oncology drug candidates in the development pipeline, both as monotherapy and in combination with existing CPIs. As a result, the market is crowded with pipeline drug candidates, creating a need for differentiation.

In addition to CPIs, immuno-oncology also includes cell and gene therapies. Currently, the majority of cell therapies that have been commercialized are called CAR T therapies. In a nutshell, T-cells are harvested from the cancer patient.

### Market trends and growth drivers

Number of cancers are estimated to raise by 47 % by 2040 (WHO)

Market entry of new and better drug and new indications for existing drugs grow the overall market

Aging of the population increases cancer incidence.

People live longer with cancer because of better treatments.

Source: Allied Market Research, Inderes

# Industry and competitive landscape 2/3

The cells are then activated *ex vivo* or outside the body in the laboratory. Finally, these activated cells are injected back into the patient where they attack the cancer. CAR-T therapies have shown benefit, and their use has expanded in recent years. However, these therapies are very expensive, ranging from USD hundreds of thousands to even million. As a result, we see limited applicability for widespread use at the population level.

There are currently two FDA-approved CAR T-cell therapies for acute lymphoblastic leukemia ALL. Brexucabtagene autoleucel (Tecartus™): a CD19-targeting CAR T-cell immunotherapy was approved for a subset of patients with ALL, tisagenlecleucel (Kymriah®): a CD19-targeting CAR T-cell immunotherapy was approved for subsets of children and young adults with ALL. To our knowledge, there are no approved CAR T therapies for AML.

### Acute myeoloid leukemia AML market

The AML treatment market has been estimated to be worth 2,000 MUSD in 2023 and to grow at a CAGR of over 8% to reach 3,900 MUSD by 2031 (iHealthCareAnalyst). In the US, AML affects about 20,000 people annually and leads to some 11,000 deaths (National Cancer Institute). The overall 5-year survival rate for MRD-negative patients is 68 %. However, for MRD-positive patients (Mendus' primary target population) survival drops down to 34 % (Short, et al.). MRD positivity is also associated with higher relapse rate.

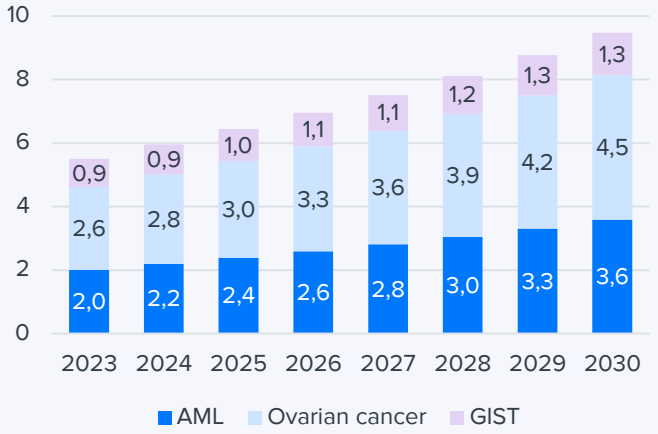
After AML diagnosis, the patient is typically treated with initial chemotherapy and consolidation chemotherapy, resulting in complete remission in about 2 out of 3 cases. Until recently, the therapeutic options for patients in remission after initial chemotherapy were extremely limited. Progress was made in 2020 when oral azacitidine (Onureg), a type of chemotherapy, was approved by the Food and Drug Administration (FDA) for the US market specifically for AML maintenance therapy. European Medicines Agency EMA approval for the EU market followed in 2021.

As the only approved drug for the maintenance treatment of AML, oral azacitidine, marketed under the brand name Onureg® by Bristol Myers Squibb has achieved significant sales. Sales for the last 12 months (Q4'23) were 168 MUSD based on BMS' reports. The cost of Onureg is approximately USD 20,000 per 28-day treatment cycle. As the median relapse-free survival in the QUAZAR AML trial was about 10 months, we estimate the cost of treatment would be roughly USD 200,000 per patient giving some indication of the potential future pricing of vididencel and ilixadencel.

### Ovarian cancer market

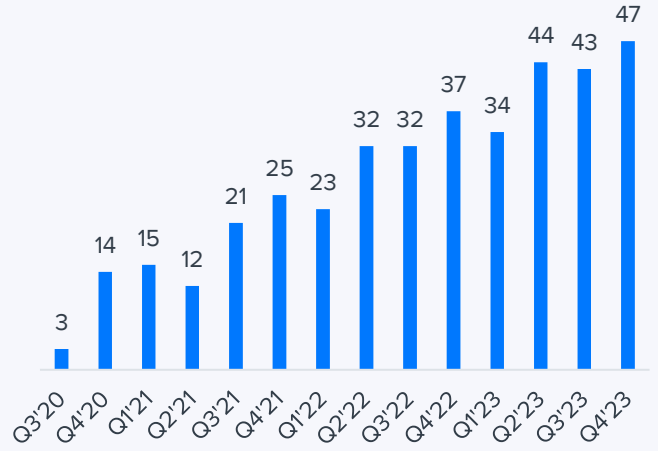
The market size for ovarian cancer treatments is estimated to be 2,600 MUSD in 2023 and to grow at a CAGR of over 8 % to reach 5,350 MUSD by 2032 (Emergen Research). Ovarian cancer is typically first treated with platinum-based chemotherapy.

**Size of key markets**, BUSD




Source: iHealthCareAnalyst, Emergen Researc, Future Market Insights

**Onureg sales**, MUSD




Source: Bristol Myers Squibb

# Industry and competitive landscape 3/3

For those patients who respond to the initial chemotherapy two options exist for maintenance therapy: PARP inhibitors and bevacizumab. PARP inhibitors are recommended as first-line maintenance therapy, while the anti-VEGF drug bevacizumab has been recommended to be spared as a second-line maintenance option. The efficacy of bevacizumab is rather modest as overall survival has improved from 3 to 5 months in different trials. Thus, the is a clear need for better therapies and an opportunity for vididencel to achieve better outcomes.

### Gastrointestinal stromal tumor market

Gastrointestinal stromal tumors (GIST) are soft-tissue sarcomas of the gastrointestinal tract. At this point it is unclear if GIST will be the prioritized ilixadencel indication for Mendus. However, as GIST has been on the Company's roadmap earlier, we review this market briefly and use GIST in modelling ilixadencel estimates.

The market size for GIST therapies has been estimated at 890 MUSD in 2023. The market is estimated to grow at a CAGR of 6% to reach 1,600 MUSD by 2033 (Future Market Insights). The standard of care for GIST is surgery for non-metastatic disease. GIST is also associated with a high probability of recurrence and a poor prognosis for patients who relapse.

The tyrosine kinase inhibitor imatinib is recommended by guidelines as a first-line option to reduce the risk of relapse. However, resistance to this drug often develops. Therefore, sunitinib is typically used as a second-line option and regorafenib, another tyrosine kinase inhibitor, as a third-line treatment option. Beyond these therapies, treatment options are limited. To our knowledge combination therapies are not currently approved or frequently used although some combinations are currently in clinical trials. Other approaches to treating GIST that have been or are currently being investigated include novel tyrosine kinase inhibitors, antibody-drug conjugates, and immunotherapies. The combination of TKIs and CPIs has shown some promising results in Phase I and II clinical trials. However, with the frequent development of resistance to TKIs, there appears to be a clear need for combination therapies that would improve the efficacy of TKI monotherapies.

**Mendus' competitive factors**

- \+ Off-the-shelf products
- \+ Simple administration
- \+ Benign safety profile
- \+ Promising Phase II clinical data
- \+ Technology is difficult to copy
- \+ Clear differentiation strategy in AML
- \+ Vididencel is a highly scalable cellular product and ilixadencel semi-scalable
- – Mendus' capability to initiate multiple clinical trials simultaneously is limited because of resources
- – Small team requires extreme focusing with little room for maneuvering

Source: Inderes, Mendus

# Strategy and financial objectives

## Vision and mission

Mendus develops treatments that activate the immune system to attack cancer. The Company's vision is to become a major player in the treatment of cancer. By this, Mendus means both providing clinical benefit to patients and building a solid foundation for the Company's long-term financial and operational success.

Mendus' mission is to change the way cancer is treated. In the current cancer treatment environment, more and more patients benefit from treatments in the short term, but later experience tumor recurrence, which is responsible for the majority of tumor deaths. Mendus' goal is to activate the immune system to control residual disease and achieve deeper and longer-lasting clinical remissions. Ultimately, this may lead to a cure for at least some of the cancer cases.

## Strategic focus on cancer maintenance therapy

Over the past decade, the immuno-oncology market has grown tremendously and is now worth approximately 50 BUSD. The market is led by checkpoint inhibitors such as Merck's Keytruda (pembrolizumab). With many of the leading checkpoint inhibitors losing patent protection by the end of the decade, manufacturers are looking for potential combination therapies to extend sales of their CPIs. The large and growing market has attracted a large number of new immuno-oncology drug candidates in the development pipeline, both as monotherapy and in combination with existing CPIs. As a result, the market is crowded with pipeline drug candidates, creating a need for differentiation.

Mendus' approach is to differentiate in this crowded space by focusing on maintenance therapy. Immuno-oncology holds the promise of achieving durable responses and is therefore well suited as a maintenance therapy. Another advantage for Mendus is the benign safety profile of vididencel and ilixadencel, with the only side effects seen so far being related to mild injection site reactions. For example, AML patients have typically undergone strenuous chemotherapy that is associated with high toxicity. These patients may not be fit enough to withstand aggressive treatments with severe side effects. From this perspective, Mendus' drug candidates are well suited for patients weakened by harsh chemotherapy.

The leading indication for Mendus is currently AML, which is characterized by rapid relapse and a clear medical need for maintenance therapy. The currently ongoing ADVANCE II study has shown promising preliminary efficacy in AML as monotherapy. However, since the start of the trial, azacytidine has been approved as a maintenance therapy for AML, creating an opportunity to develop vididencel as a combination therapy with azacitidine to improve efficacy. Mendus is currently launching a combination therapy trial with standard-of-care azacitidine via the CADENCE trial.

The company's resources are obviously limited and Mendus will have to prioritize which trials to pursue. We think the company is very data-driven and flexible. We believe that Mendus will allocate its resources to the projects that are most supported by scientific evidence. However, this reduces visibility into the future, as the company's development may take somewhat directions that are difficult to predict.

## Partnering is probable but difficult to forecast

Financing Mendus' clinical pipeline solely through the issuance of new shares may not be optimal for shareholder value. According to the company, the option of partnering with a large pharmaceutical company remains an open option to accelerate and broaden the pipeline. A partnership would typically involve an upfront payment, milestone payments based on clinical and commercial progress, and royalties based on eventual sales. We see a partnering deal as an increasingly likely path for Mendus as it approaches the largest and most expensive pivotal trial stage. That said, the optimal time for such a deal may not yet be at hand as Mendus now focuses on the Phase II trial CADENCE.

# Financial position 1/2

### Historical earnings development

Mendus has been loss-making throughout its existence due to its business model and up-front investments in clinical trials. The company has been funded via new share issues.

The most recent share issue of 317 MSEK was organized in Summer 2023. The financing round included a directed issue of 90 MSEK to Flerie Invest AB and a rights issue of 227 MSEK. Flerie is a new investor in Mendus. The subscription price was SEK 0.48 per share. The primary purpose of the round was to advance the preclinical and clinical programs, to develop the manufacturing of vididencel and ilixadencel, and to establish a manufacturing alliance with NorthX. We note that the rights issue was fully underwritten by existing investors, signaling strong support from the current owners. Flerie Invest is an investor in NorthX and as we understand the investment is related to the strategic alliance between Mendus and NorthX on manufacturing vididencel. The financing rounds organized since 2017 are presented in the table on right.

Of note, Mendus has already paid production costs of some 90 MSEK to NorthX. These payments cover costs of the technology transfer phase as well as vididencel production for the planned pivotal trial.

Following the share issue and exercise of TO3 warrant, the cash runway is until Q3'25. This includes finalizing the futility analysis of the CADENCE trial, a first step towards the pivotal trial design, and the primary analysis of the ilixadencel proof-of-concept trial.

### Cost structure

Mendus reports expenses for administration, R&D and other expenses. Since the merger of Immunicum and DCPrime in 2020, administration costs have been in the range of 37 to 49 MSEK per year. During the last twelve months these expenses have decreased likely due to lower number of employees (2023: 27 vs. 2022: 33). The other major category, R&D expenses, has been in the range of 48 to 93 MSEK annually. R&D costs are highly dependent on the number and phase of ongoing clinical trials. Therefore, we expect R&D costs to be more volatile depending on the status of the research program. Mendus does not capitalize R&D costs, which are fully expensed in the income statement. In addition, the company's depreciation of property, plant and equipment is low and Mendus has not amortized intangible assets at a meaningful level. As a result, reported expenses are largely in line with and representative of cash flows.

### Cash flows

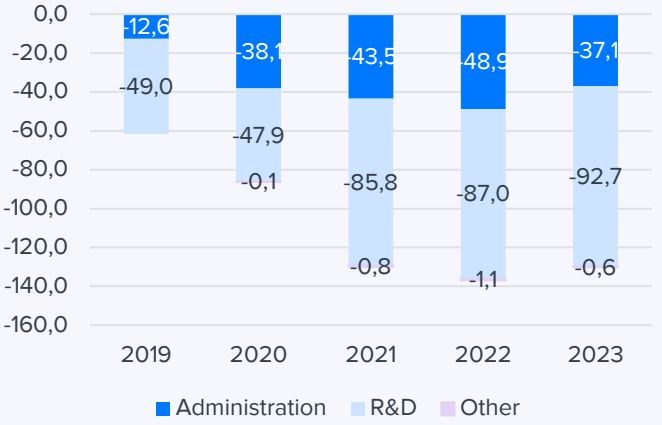
Mendus' operating cash flow in 2023 was -101 MSEK before changes in working capital. Working capital increased significantly and accounting for that the operating cash flow was -166 MEUR. To our understanding the the increase in working capital is transitory.

## Recent share issues

| Year | Total shares, millions | New shares added, millions | Change, % |
|---|---|---|---|
| 2023 | 675.6 | 476.2 | 239 % |
| 2021 | 199.4 | 33.2 | 20 % |
| 2020 | 166.2 | 73.9 | 80 % |
| 2018 | 92.3 | 41.3 | 84 % |
| 2017 | 50.1 | 25 | 100 % |

Source: Mendus

**Expenses**, MSEK




Source: Inderes

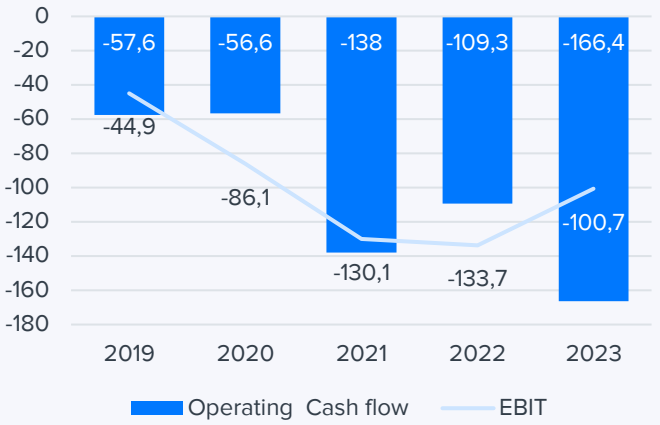
# Financial position 2/2

## Balance sheet

Following the new share issue in June 2023, cash and cash equivalents at the end of 2023 were 121 MSEK. Mendus expects a cash runway until Q4'24, which we consider feasible in view of the projected cash flows (see Estimates section. Upon full exercise of the warrants of series TO3, Mendus will receive approximately up to an additional 91 MSEK. According to Mendus, this would extend the cash runway till Q3'25. Other tangible assets amounted to 80 MSEK. Prepaid expenses were 64 MSEK, which we expect to normalize to historical levels (2022: 2 MSEK). Equipment was 11 MSEK. Intangible assets totaled 556 MSEK, of which the acquisition of Ilixadencel represents 424 MSEK. Goodwill was 108 MSEK and right-of-use assets (i.e. real estate) were 23 MSEK.

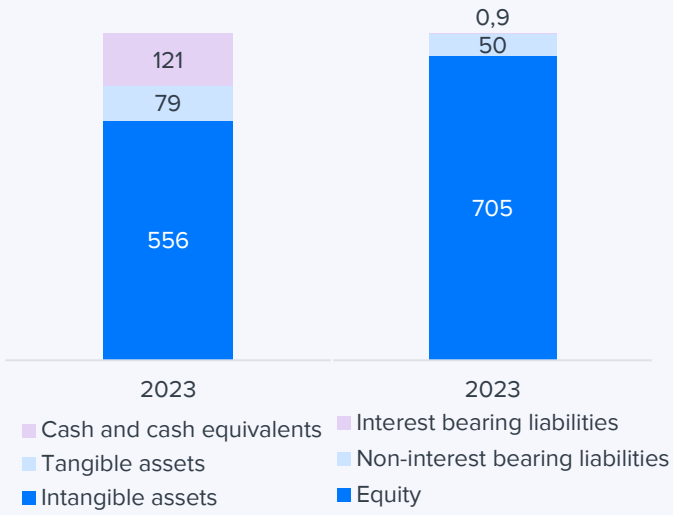
Equity amounted to 705 MSEK. Mendus' liabilities are low and mostly non-interest bearing. Lease liabilities (21 MSEK) was the main item. Interest-bearing liabilities amounted to only 0.9 MSEK.

**Operating cash flow & EBIT**, MSEK




Source: Inderes

**Balance sheet 2023,** MSEK




Source: Inderes

# Estimates 1/3

### Mendus estimates focus on the future of vididencel

The main driver of our estimates is the commercialization of vididencel for maintenance AML as this indication is currently prioritized by Mendus. Vididencel for ovarian cancer and ilixadencel for soft-tissue sarcomas (STS) support the estimates and value creation. Mendus has currently not decided the specific indication for ilixadencel development in STS. However, we model our ilixadencel based on gastrointestinal stromal tumor GIST indication because of the Company's previous plans for GIST as a possible STS indication. We do not estimate the potential future revenues of the preclinical pipeline as these projects are far from commercialization and the future indications and applications are not clear at this time. The detailed estimates are presented on the table on page 28.

### Probability of success of the clinical development

The uncertainties and risks associated with Mendus' estimates can be divided into two categories: 1) the R&D risk of the success of the drug development; and 2) the business risk associated with post-approval commercialization.

The R&D risk associated with drug development is binary in nature as the clinical program will or will not continue based on the clinical data. We assess the R&D probability of success by reflecting the characteristics of the company's assets and their stage of development to the research literature[1,2] describing average success rates in drug development. For oncology drug candidates, the average probability of passing Phase I has historically been approximately 50%, Phase II 25%, Phase III 50%, and final regulatory approval 90%. In addition to these numbers, the probabilities are affected by many variables[2]. These include the indication, whether the drug is biologic or small molecule, and whether biomarkers are available for patient selection etc. We have further refined Mendus' probabilities based on the information available. We believe that the positive safety data and ADVANCE II efficacy data increases the likelihood that the company will be able to proceed with the next clinical phases of the clinical pipeline.

We emphasize that vididencel and ilixadencel are not drugs per se, but Advanced Therapy Medicinal Products (ATMP). We believe that historical drug development data is not entirely applicable to these cell-based products. However, in the absence of high-quality historical data on ATMPs, we rely on drug development data in our analysis.

In addition to the binary R&D risk, we believe the Company is exposed to regular business risks. This uncertainty relates to the achievement of market share and realized sales prices. In addition, the terms of any licensing agreements, such as the amount of royalties, vary widely. On the other hand, the high defensiveness of the industry and the strong cash flows generated by a successful market entry reduce the uncertainty related to the business.

### Assessing revenue

We estimate Mendus' revenues by evaluating numbers of patients, drug sales prices, achievable market share, and royalty rates. We estimate the start of sales based on the clinical phase of the research program. The revenue estimates are then multiplied by the estimated probability of success of the clinical

## Probabilities of success

| | Ph1 | Ph2 | Ph3 | Regulatory | Total |
|---|---|---|---|---|---|
| **Vididencel** | | | | | |
| AML | 100 % | 35 % | 50 % | 92 % | 16 % |
| Ovarian cancer | 70 % | 30 % | 50 % | 92 % | 10 % |
| **Ilixadencel** | | | | | |
| GIST | 100 % | 30 % | 50 % | 92 % | 14 % |

Source: Inderes, Statista, David, Robeu, Matthews. Biotech forecasting & valuation, 2016.

## Summary of estimates

| Product | Indication | Eligible patients | Launch | Peak sales | Peak sales, RA |
|---|---|---|---|---|---|
| **Vididencel** | AML | 20800 | 2029 | 2477 | 399 |
| | Ovarian cancer | 19710 | 2031 | 1760 | 170 |
| **Ilixadencel** | GIST | 5000 | 2030 | 521 | 72 |

Source: Inderes, sales in MSEK
RA = risk-adjusted

1) https://www.statista.com/statistics/597819/drug-development-phases-probability-of-success-oncology-nononcology-drugs/
2) David, Robeu, Matthews. Biotech forecasting & valuation, 2016.

# Estimates 2/3

program. The reported estimates are risk-adjusted for R&D risk. We model revenues based primarily on US sales and assume that sales in the rest of the world reach 50% of US sales. We evaluate the numbers of eligible patients based on incidence of a given cancer and on our estimate of the share of high-risk patients eligible for maintenance therapy.

Regarding sales prices, our estimates are based on pricing of competing drugs and therapies. Sales prices of immuno-oncology drugs are typically very high. In the case of Mendus, it is difficult to assess the ultimate pricing of vididencel and ilixadencel, as pricing is likely to depend on many unknowns. In our modeling, we use pricing consistent with existing therapies such as Onureg® and checkpoint inhibitors. CAR T-cell therapies are more expensive, but they are also much more labor and resource intensive treatments.

In our estimates, Mendus' revenues will be realized through royalties, which we estimate to be typical to the industry at 20% of sales. This assumes the completion of a licensing deal, which would typically include upfront and milestone payments in addition to licensing fees. We assume upfront payments to cover the cost of pivotal Phase III trials of the key indications from 2027 onwards but we do not model in milestone payments. We remind readers that the value and timing of such a deal is inherently unpredictable. However, we consider an eventual deal the most likely scenario for Mendus.

It typically takes about 6 years for a new drug to reach its full sales potential. We have used these six years as the basis for our estimates of full market penetration and have revised the penetration speed, e.g. based on the competitive situation and our evaluation.

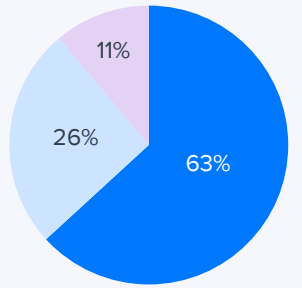
Our understanding is that the IPR of Mendus will largely expire in the early 2030s. Normally, this would lead to a significant drop in estimated sales. However, we believe that vididencel, and to some extent Ilixadencel, have significant moats that may protect them from competition beyond patent expiry. These moats include undisclosed details of the manufacturing process that make it very difficult to replicate vididencel and ilixadencel (see page 12 for more details). We therefore model peak sales at 2038 and moderately declining sales after that.

### Revenue will start to accumulate from 2029

For the vididencel indications, we estimate that sales from AML will start in 2029 and from ovarian cancer in 2031. For the ilixadencel indications, we expect sales to start in 2030. In our estimates, the Group's revenue reaches it's peak of approximately 4800 MSEK in 2038. When adjusted with R&D risk (i.e. probability of market entry), we estimate peak revenue of approximately 641 MSEK. In terms of EBIT, we expect the company to be deep in the red until the end of the decade. We expect the company to be profitable by 2032.

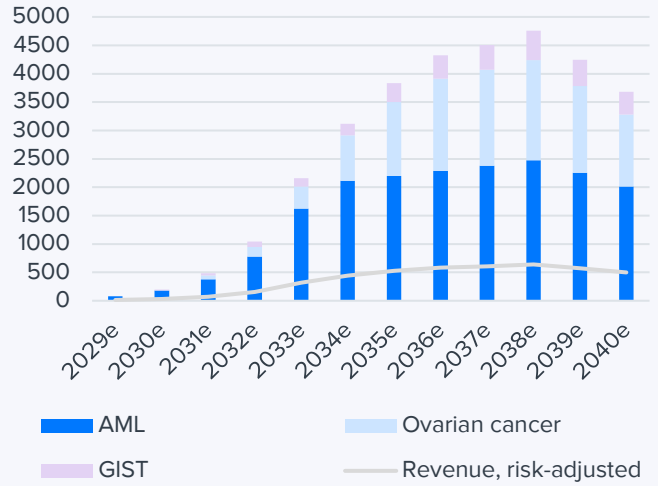
The company will likely finance the period through licensing deals, equity issuance, and possibly debt. We model a licensing deal from 2026 onwards covering expenses of expected pivotal Phase III trials.

**Percent of peak sales**




Source: Inderes

**Revenue**, MSEK




Source: Inderes

# Estimates 3/3

| | 2029 | 2030 | 2031 | 2032 | 2033 | 2034 | 2035 | 2036 | 2037 | 2038 | 2039 | 2040 | 2041 | 2042 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **VIDIDENCEL** | | | | | | | | | | | | | | |
| AML new cases in the US | 22965 | 23424 | 23893 | 24371 | 24858 | 25355 | 25862 | 26379 | 26907 | 27445 | 27994 | 28554 | 29125 | 29708 |
| Eligible patients % | 45 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % |
| Potential addressable patients | 10334 | 11712 | 11946 | 12185 | 12429 | 12678 | 12931 | 13190 | 13454 | 13723 | 13997 | 14277 | 14563 | 14563 |
| Matket penetration rate | 2,0 % | 4,0 % | 8,0 % | 16,0 % | 32,0 % | 40,0 % | 40,0 % | 40,0 % | 40,0 % | 40,0 % | 35,0 % | 30,0 % | 25,0 % | 25,0 % |
| Discontinuation rate | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % |
| Cost of treatment, MSEK | 1,3 | 1,4 | 1,4 | 1,4 | 1,4 | 1,5 | 1,5 | 1,5 | 1,6 | 1,6 | 1,6 | 1,6 | 1,7 | 1,7 |
| License fee | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % |
| **US revenue, MSEK** | **52** | **120** | **250** | **521** | **1084** | **1409** | **1466** | **1526** | **1587** | **1651** | **1503** | **1341** | **1162** | **1162** |
| **Rest of world, (50 % of US)** | **26** | **60** | **125** | **260** | **542** | **705** | **733** | **763** | **794** | **826** | **752** | **670** | **581** | **581** |
| Probability of success to market | 16 % | 16 % | 16 % | 16 % | 16 % | 16 % | 16 % | 16 % | 16 % | 16 % | 16 % | 16 % | 16 % | 16 % |
| **Revenue, risk adjusted, US** | **8** | **19** | **40** | **84** | **174** | **227** | **236** | **246** | **256** | **266** | **242** | **216** | **187** | **187** |
| **Rest of world, (50 % of US)** | **4** | **10** | **20** | **42** | **87** | **113** | **118** | **123** | **128** | **133** | **121** | **108** | **94** | **94** |
| **Global revenue, risk adjusted** | **13** | **29** | **60** | **126** | **262** | **340** | **354** | **368** | **383** | **399** | **363** | **324** | **281** | **281** |
| **VIDIDENCEL** | | | | | | | | | | | | | | |
| Ovarian cancer, new cases in the US | 21761 | 22197 | 22641 | 23093 | 23555 | 24026 | 24507 | 24997 | 25497 | 26007 | 26527 | 27058 | 27599 | 28151 |
| Eligible patients % | 30 % | 35 % | 40 % | 45 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % |
| Potential addressable patients | 6528 | 7769 | 9056 | 10392 | 11778 | 12013 | 12253 | 12499 | 12748 | 13003 | 13264 | 13529 | 13799 | 13799 |
| Matket penetration rate | 0,0 % | 0,0 % | 2,0 % | 4,0 % | 8,0 % | 16,0 % | 25,0 % | 30,0 % | 30,0 % | 30,0 % | 25,0 % | 20,0 % | 15,0 % | 15,0 % |
| Discontinuation rate | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % |
| Cost of treatment, MSEK | 1,3 | 1,4 | 1,4 | 1,4 | 1,4 | 1,5 | 1,5 | 1,5 | 1,6 | 1,6 | 1,6 | 1,6 | 1,7 | 1,7 |
| License fee | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % |
| **US revenue, MSEK** | **0** | **0** | **47** | **111** | **257** | **534** | **868** | **1084** | **1128** | **1174** | **1018** | **847** | **661** | **661** |
| **Rest of world, (50 % of US)** | **0** | **0** | **24** | **56** | **128** | **267** | **434** | **542** | **564** | **587** | **509** | **423** | **330** | **330** |
| Probability of success to market | 10 % | 10 % | 10 % | 10 % | 10 % | 10 % | 10 % | 10 % | 10 % | 10 % | 10 % | 10 % | 10 % | 10 % |
| **Revenue, risk adjusted, US** | **0** | **0** | **5** | **11** | **25** | **52** | **84** | **105** | **109** | **113** | **98** | **82** | **64** | **64** |
| **Rest of world, (50 % of US)** | **0** | **0** | **2** | **5** | **12** | **26** | **42** | **52** | **54** | **57** | **49** | **41** | **32** | **32** |
| **Global revenue, risk adjusted** | **0** | **0** | **7** | **16** | **37** | **77** | **126** | **157** | **163** | **170** | **147** | **123** | **96** | **96** |
| | | | | | | | | | | | | | | |
| **ILIXADENCEL** | | | | | | | | | | | | | | |
| GIST | 5520 | 5631 | 5743 | 5858 | 5975 | 6095 | 6217 | 6341 | 6468 | 6597 | 6729 | 6864 | 7001 | 7141 |
| Eligible patients % | 0 % | 40 % | 45 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % | 50 % |
| Potential addressable patients | 0 | 2252 | 2585 | 2929 | 2988 | 3047 | 3108 | 3171 | 3234 | 3299 | 3365 | 3432 | 3501 | 3501 |
| Matket penetration rate | 0,0 % | 2,0 % | 4,0 % | 8,0 % | 12,0 % | 16,0 % | 25,0 % | 30,0 % | 30,0 % | 35,0 % | 30,0 % | 25,0 % | 20,0 % | 20,0 % |
| Discontinuation rate | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % | 5,0 % |
| Cost of treatment, MSEK | 1,3 | 1,4 | 1,4 | 1,4 | 1,4 | 1,5 | 1,5 | 1,5 | 1,6 | 1,6 | 1,6 | 1,6 | 1,7 | 1,7 |
| License fee | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % | 20 % |
| **US revenue, MSEK** | **0** | **12** | **27** | **63** | **98** | **136** | **220** | **275** | **286** | **347** | **310** | **269** | **224** | **224** |
| **Rest of world, (50 % of US)** | **0** | **6** | **14** | **31** | **49** | **68** | **110** | **138** | **143** | **174** | **155** | **134** | **112** | **112** |
| Probability of success to market | 14 % | 14 % | 14 % | 14 % | 14 % | 14 % | 14 % | 14 % | 14 % | 14 % | 14 % | 14 % | 14 % | 14 % |
| **Revenue, risk adjusted, US** | **0** | **2** | **4** | **9** | **13** | **19** | **30** | **38** | **39** | **48** | **43** | **37** | **31** | **31** |
| **Rest of world, (50 % of US)** | **0** | **1** | **2** | **4** | **7** | **9** | **15** | **19** | **20** | **24** | **21** | **19** | **15** | **15** |
| **Global revenue, risk adjusted** | **0** | **0** | **6** | **13** | **20** | **28** | **46** | **57** | **59** | **72** | **64** | **56** | **46** | **46** |

# Income statement

| Income statement | 2021 | 2022 | 2023 | Q1'24e | Q2'24e | Q3'24e | Q4'24e | 2024e | Q1'25e | Q2'25e | Q3'25e | Q4'25e | 2025e | 2026e | 2027e |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Revenue** | **0,0** | **0,0** | **0,0** | **0,0** | **0,0** | **0,0** | **0,0** | **0,0** | **0,0** | **0,0** | **0,0** | **0,0** | **0,0** | **0,0** | **0,0** |
| **EBITDA** | **-132,0** | **-138,5** | **-133,2** | **-28,6** | **-31,0** | **-32,0** | **-32,3** | **-123,8** | **-31,1** | **-29,6** | **-30,9** | **-31,4** | **-123,0** | **-93,0** | **-95,3** |
| Depreciation | 1,9 | 4,8 | 7,3 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| **EBIT (excl. NRI)** | **-130,1** | **-133,7** | **-125,9** | **-28,6** | **-31,0** | **-32,0** | **-32,3** | **-123,8** | **-31,1** | **-29,6** | **-30,9** | **-31,4** | **-123,0** | **-93,0** | **-95,3** |
| **EBIT** | **-130,1** | **-133,7** | **-125,9** | **-28,6** | **-31,0** | **-32,0** | **-32,3** | **-123,8** | **-31,1** | **-29,6** | **-30,9** | **-31,4** | **-123,0** | **-93,0** | **-95,3** |
| Net financial items | -3,3 | -5,1 | -1,0 | -0,6 | -0,6 | -0,6 | -0,6 | -2,4 | 0,0 | 0,0 | 0,0 | 0,0 | -3,0 | -3,0 | -3,0 |
| **PTP** | **-133,4** | **-138,8** | **-126,9** | **-29,2** | **-31,6** | **-32,6** | **-32,9** | **-126,2** | **-31,1** | **-29,6** | **-30,9** | **-31,4** | **-126,0** | **-96,0** | **-98,3** |
| Taxes | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| **Net earnings** | **-133,4** | **-138,8** | **-126,9** | **-29,2** | **-31,6** | **-32,6** | **-32,9** | **-126,2** | **-31,1** | **-29,6** | **-30,9** | **-31,4** | **-126,0** | **-96,0** | **-98,3** |
| **EPS (adj.)** | **-0,67** | **-0,70** | **-0,15** | **-0,03** | **-0,03** | **-0,03** | **-0,03** | **-0,13** | **-0,03** | **-0,03** | **-0,03** | **-0,03** | **-0,13** | **-0,10** | **-0,10** |
| **EPS (rep.)** | **-0,67** | **-0,70** | **-0,15** | **-0,03** | **-0,03** | **-0,03** | **-0,03** | **-0,13** | **-0,03** | **-0,03** | **-0,03** | **-0,03** | **-0,13** | **-0,10** | **-0,10** |

Source: Inderes

# Balance sheet

| Assets | 2021 | 2022 | 2023e | 2024e | 2025e |
|---|---|---|---|---|---|
| **Non-current assets** | **536** | **573** | **580** | **580** | **580** |
| Goodwill | 108 | 108 | 108 | 108 | 108 |
| Intangible assets | 424 | 450 | 450 | 450 | 450 |
| Tangible assets | 2,1 | 13,9 | 21,2 | 21,2 | 21,2 |
| Associated companies | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| Other investments | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| Other non-current assets | 0,8 | 0,6 | 0,6 | 0,6 | 0,6 |
| Deferred tax assets | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| **Current assets** | **185** | **47,2** | **161** | **241** | **114** |
| Inventories | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| Other current assets | 10,2 | 1,9 | 1,9 | 1,9 | 1,9 |
| Receivables | 19,7 | 3,4 | 0,0 | 0,0 | 0,0 |
| Cash and equivalents | 155 | 41,9 | 159 | 239 | 112 |
| **Balance sheet total** | **721** | **620** | **742** | **821** | **694** |

Source: Inderes

| Liabilities & equity | 2021 | 2022 | 2023e | 2024e | 2025e |
|---|---|---|---|---|---|
| **Equity** | **657** | **514** | **665** | **745** | **618** |
| Share capital | 10,0 | 10,0 | 10,0 | 10,0 | 10,0 |
| Retained earnings | -487,2 | -626,0 | -740,9 | -861,4 | -988,3 |
| Hybrid bonds | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| Revaluation reserve | 3,6 | -0,2 | 0,0 | 0,0 | 0,0 |
| Other equity | 1130 | 1131 | 1396 | 1596 | 1596 |
| Minorities | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| **Non-current liabilities** | **36,7** | **46,5** | **46,5** | **46,5** | **46,5** |
| Deferred tax liabilities | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| Provisions | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| Interest bearing debt | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| Convertibles | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| Other long term liabilities | 36,7 | 46,5 | 46,5 | 46,5 | 46,5 |
| **Current liabilities** | **27,6** | **59,4** | **30,2** | **30,2** | **30,2** |
| Interest bearing debt | 0,0 | 29,2 | 0,0 | 0,0 | 0,0 |
| Payables | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| Other current liabilities | 27,6 | 30,2 | 30,2 | 30,2 | 30,2 |
| **Balance sheet total** | **721** | **620** | **742** | **821** | **694** |

# Valuation and recommendation 1/3

### The risk-reward ratio is reasonable

We initiate the coverage of Mendus with an Accumulate recommendation and a target price of SEK 0.7. Our risk-adjusted valuation is primarily based on the DCF model. We also reflect Mendus' valuation relative to Nordic peers. In addition to the free cash flow generated by product sales, Mendus' value can also be realized through a partnering or acquisition deal. As the timing and value of such deals are virtually impossible to predict, we have not included such scenarios in our valuation model with the exception of a partner covering Phase III R&D costs from 2026. We view such a partnering deal or becoming an acquisition target as positive options for Mendus investors.

Our R&D risk-adjusted estimates, and thus our valuation, are based on weighing probabilities between two rather extreme scenarios. In our optimistic scenario, therapy development is successful in all major indications, resulting in high cash flows in the 2030s. Discounted to the present, these cash flows would justify share prices several times higher than current levels. On the other hand, in our pessimistic scenario, clinical trial data would fail to support continued development of the therapies, leading to abandonment of the current indications and possibly pivoting to new indications and/or products. In our view, this scenario would lead to a permanent loss of capital, dilutive financing rounds and a share value approaching zero. Thus, the long-term value creation and share price performance of Mendus will depend on the success of the clinical program and eventual commercialization success, including potential licensing deals. In the short to medium term, we believe that the share price will be driven by the news flow of clinical data. We also expect market sentiment to have a strong impact on the share price. The company's ability to find financing solutions favorable to shareholders remains an important theme for future share price performance.

We note that due to the nature of the industry and Mendus' business model, our estimates and the valuation based on these estimates are subject to a very high degree of uncertainty. This uncertainty stems, for example, from the many assumptions made about the markets as well as the R&D and commercial successes achieved by Mendus. Therefore, our target price, which is expressed as a specific number, should be interpreted with a wide range. As a result of these uncertainties, which are typical for most biotech companies, we expect the share price to be highly volatile and to correlate with market sentiment.

Despite these uncertainties and caveats, we believe that the current share price represents a favorable risk/reward ratio that supports a positive recommendation. Due to the binary risk associated with the stock, we believe that for most investors, a limited allocation to drug/therapy development companies is warranted to limit risks.

### Valuation scenarios

| | Optimistic[1] | Estimates[2] | Pessimistic[3] |
|---|---|---|---|
| **Success of clinical development** | Success in all 3 indications | According to estimates | Failed development |
| **Probability of scenario** | Low | ~10-16 % depending on indication | Considerable |
| **EBIT 2035e** Risk-adjusted | ~4800 MSEK | ~530 MSEK | Neg. |
| **DCF value,** SEK per share | ~4.5 | ~0.7 | ~0 |

1) Commercialization is successful in all key indications. Expanding to further indications is possible in the long-term.
2) Commercialization successful as described in Estimates section considering the R&D probabilities of success.
3) Clinical data does not support further developing the pipeline.

Source: Inderes

# Valuation and recommendation 2/3

### Risk-adjusted DCF model indicates upside

Our discounted cash flow (DCF) model yields a net present value of SEK 0.7 per share, indicating strong upside potential for the stock. We expect a new funding round to take place in mid 2025 in line with Mendus' cash runway. In case of a new share issue, the increase in the number of shares may limit the upside by diluting the per share metrics. However, we see a possibility for a partnering deal that may potentially be highly value-creating for shareholders.

We model increasing revenues that peak in 2038, after which we expect revenues to decline as new competing innovations are likely to enter the market. Our modeling extends to 2042, after which we assume terminal growth of 2%, supported by an aging population and increasing incidence of cancer. Cash flows are strongly negative during the clinical research phase 2024-2028. The vast majority of cash flows are generated during the growth phase from 2029-2038, while the period thereafter still generates cash flows relevant for the current valuation.

The projected cash flows are discounted using a weighted average cost of capital (WACC) of 12%. This is in line with industry standards of about 11 %. We use a slightly higher WACC for Mendus to reflect the risk of developing a rather novel therapy based on living cells. To date, there is limited data on the feasibility of such an approach. In general, our estimated WACC reflects the business risk of bringing a new therapy to market. It reflects risks related to, for example, unknown pricing levels of the therapies, market penetration, etc. R&D risk has been factored into our estimates prior to discounting. If the R&D risk has not been included in the estimates, the WACC should be above 20% in line with the industry.

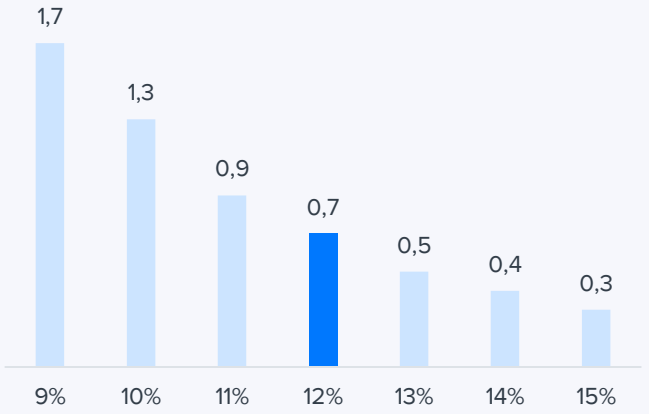
We reiterate that there are significant uncertainties regarding the realization of the cash flows. Therefore, the DCF model is inherently sensitive to the assumptions used. In other words, a change in the assumptions has a significant impact on the output value of the model.

### Valuation is in line with Nordic Peers

To complement our DCF-based valuation, we compare the valuation of Mendus to its Nordic peers. As a peer group, we use clinical Phase II companies that are developing new cancer immunotherapies or drugs. Our peer group consists of 13 companies: Active Biotechnology, Alligator Bioscience, Bavarian Nordic, BerGenBio, BioInvent International, Cantargia, Circio Holdings, Faron Pharmaceuticals, Isofol Medical, Lytix Biopharma, Medivir, Oncopeptides and Ultimovacs.

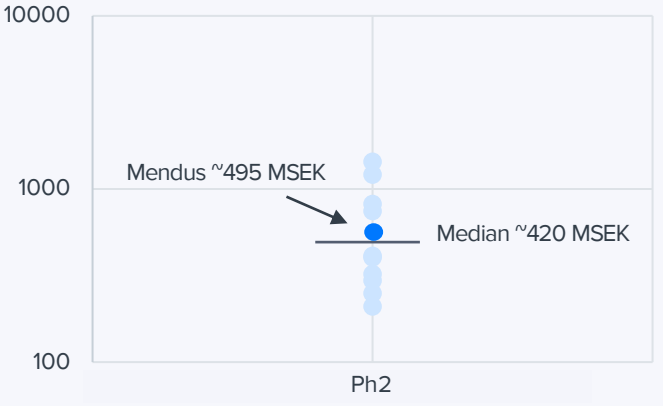
We note that these peers differ significantly in terms of target indications and other factors. The indications affect the addressable market and sales potential, and thus have an impact on market capitalization. Nevertheless, we believe that the peers as a group provide a reasonable framework for the relative valuation of Mendus. In this comparison, we consider Mendus to be a Phase II clinical stage company based on the upcoming Phase II CADENCE trial.

**Sensitivity of DCF to WACC-%,** SEK/share




Source: Inderes

**Market cap of Ph2 immuno-oncology companies**, MSEK




Source: Millistream, Inderes

# Valuation and recommendation 3/3

The Nordic immuno-oncology peers in clinical Phase II have a median market capitalization of approx. 420 MSEK compared to Mendus' ~490 MSEK. This puts Mendus' valuation slightly above the peer group. The highest market cap is ~1,500 MSEK for Faron, a company in Phase II clinical trial in blood cancers and ambitions to expand the lead asset indications into solid tumors. At the lower end of the spectrum, four companies are valued in the range of 200-300 MSEK, highlighting the significant spread in valuations within the sector. In summary, we believe that Mendus is valued in line with its Nordic peers.

### Partnering deals for Phase II immuno-oncology companies

We expect that Mendus will at some point enter into a partnering deal to fund the expensive pivotal trials. Such a deal could be accretive, although this is highly dependent on the value of the deal. We note that since the timing and value of a potential deal is virtually impossible to predict, we don't include such a deal in our valuation model. However, we see such a deal as a positive option for Mendus investors.

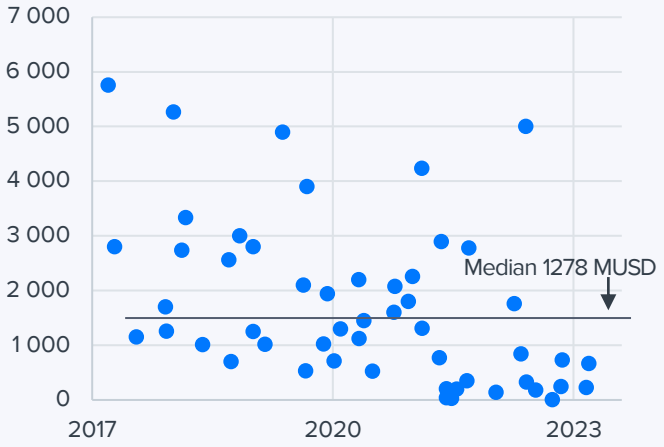
The graph on the right shows the total value of partnering deals for immuno-oncology Phase II clinical stage companies, with the goal of providing a reference for Mendus' potential future deal. We note a slightly declining trend in deal values, and the majority of deals in the last 18 months have been in the hundreds of millions, rather than the frequent multi-billion deals announced in 2018-2021. In our view, recent immuno-oncology deals, regardless of clinical phase, seem to have emphasized CAR T therapies and antibody-drug conjugates.

The median deal value is significant compared to Mendus' market capitalization. We advise caution in interpreting these values, as deals in general, and high value deals in particular, are only landed by those therapies and pipelines that are considered by the industry to have the most potential. Thus, there is a good chance that no partnering deal will be struck, or that the value will be disappointing.

### Becoming a acquisition target is an additional opportunity to realize value

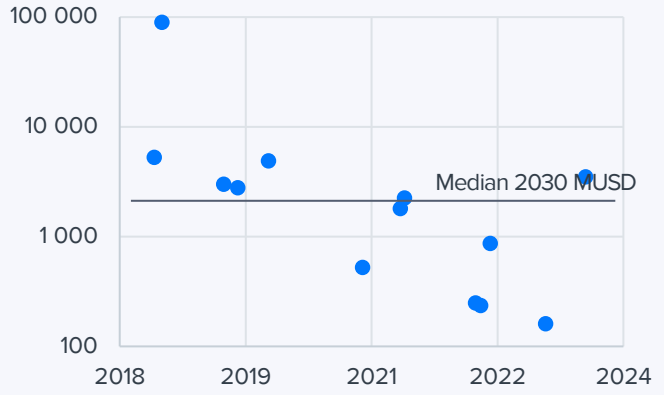
Similar to partnering deals, being the target of an acquisition is not part of our valuation model. The immuno-oncology M&A deals shown on the right have historically been highly valued, although the trend has declined somewhat. In our view, Mendus' pipeline could be a good complement to a larger biotech's pipeline if the two companies' technologies and indications match. Again, we don't speculate on the timing and value of a potential acquisition offer for Mendus. However, an acquisition is a potential near-term value creation avenue for Mendus investors.

**Immuno-oncology clinical Ph2 partnering deals,** MUSD




Source: GlobalData, Inderes

**Immuno-oncology clinical Ph2 mergers and acquisitions,** MUSD




Source: GlobalData, Inderes

# DCF calculation

| DCF model | 2023 | 2024e | 2025e | 2026e | 2027e | 2028e | 2029e | 2030e | 2031e | 2032e | 2033e | 2034e | 2035e |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Revenue growth-% | 0,0 % | 0,0 % | 0,0 % | 0,0 % | 0,0 % | 0,0 % | NA | 131,3 % | 150,9 % | 112,3 % | 106,1 % | 39,7 % | 17,9 % |
| EBIT-% | | | | | | | -716,4 % | -272,9 % | 30,0 % | 35,0 % | 35,0 % | 35,0 % | 35,0 % |
| **EBIT (operating profit)** | **-125,9** | **-123,8** | **-123,0** | **-93,0** | **-95,3** | **-97,6** | **-90,0** | **-79,3** | **21,9** | **54,2** | **112** | **156** | **184** |
| + Depreciation | -7,3 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| - Paid taxes | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| - Tax, financial expenses | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| + Tax, financial income | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| - Change in working capital | -63,2 | 4,2 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| **Operating cash flow** | **-196,5** | **-119,5** | **-123,0** | **-93,0** | **-95,3** | **-97,6** | **-90,0** | **-79,3** | **21,9** | **54,2** | **112** | **156** | **184** |
| + Change in other long-term liabilities | -24,6 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| - Gross CAPEX | 12,9 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| **Free operating cash flow** | **-208,1** | **-119,5** | **-123,0** | **-93,0** | **-95,3** | **-97,6** | **-90,0** | **-79,3** | **21,9** | **54,2** | **112** | **156** | **184** |
| +/- Other | 0,0 | 69,1 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 | 0,0 |
| FCFF | -208,1 | -50,4 | -123,0 | -93,0 | -95,3 | -97,6 | -90,0 | -79,3 | 21,9 | 54,2 | 112 | 156 | 184 |
| **Discounted FCFF** | | **-46,5** | **-101,2** | **-68,3** | **-62,6** | **-57,3** | **-47,1** | **-37,1** | **9,1** | **20,2** | **37,2** | **46,5** | **48,9** |
| Sum of FCFF present value | | 615 | 661 | 762 | 831 | 893 | 950 | 998 | 1035 | 1026 | 1005 | 968 | 922 |
| **Enterprise value DCF** | | **615** | | | | | | | | | | | |
| - Interest bearing debt | | 0,0 | | | | | | | | | | | |
| + Cash and cash equivalents | | 121 | | | | | | | | | | | |
| -Minorities | | 0,0 | | | | | | | | | | | |
| -Dividend/capital return | | 0,0 | | | | | | | | | | | |
| **Equity value DCF** | | **735** | | | | | | | | | | | |
| **Equity value DCF per share** | | **0,7** | | | | | | | | | | | |

| WACC | |
|---|---|
| Tax-% (WACC) | 20,6 % |
| Target debt ratio (D/(D+E) | 0,0 % |
| Cost of debt | 10,0 % |
| Equity Beta | 1,78 |
| Market risk premium | 4,75 % |
| Liquidity premium | 1,00 % |
| Risk free interest rate | 2,5 % |
| **Cost of equity** | **12,0 %** |
| **Weighted average cost of capital (WACC)** | **12,0 %** |

Source: Inderes

# Summary

| Income statement | 2021 | 2022 | 2023 | 2024e | 2025e |
|---|---|---|---|---|---|
| Revenue | 0,0 | 0,0 | 0,0 | **0,0** | **0,0** |
| EBITDA | -132,0 | -138,5 | -133,2 | **-123,8** | **-123,0** |
| EBIT | -130,1 | -133,7 | -125,9 | **-123,8** | **-123,0** |
| PTP | -133,4 | -138,8 | -126,9 | **-126,2** | **-126,0** |
| Net Income | -133,4 | -138,8 | -126,9 | **-126,2** | **-126,0** |
| Extraordinary items | 0,0 | 0,0 | 0,0 | **0,0** | **0,0** |

| Balance sheet | 2021 | 2022 | 2023 | 2024e | 2025e |
|---|---|---|---|---|---|
| Balance sheet total | 721,0 | 620,4 | 756,0 | **711,9** | **641,9** |
| Equity capital | 656,7 | 514,4 | 704,7 | **654,5** | **528,5** |
| Goodwill | 108,4 | 108,4 | 108,4 | **108,4** | **108,4** |
| Net debt | -155,3 | -12,7 | -120,8 | **-74,8** | **51,2** |

| Cash flow | 2021 | 2022 | 2023 | 2024e | 2025e |
|---|---|---|---|---|---|
| EBITDA | -132,0 | -138,5 | -133,2 | **-123,8** | **-123,0** |
| Change in working capital | -2,4 | 27,1 | -63,2 | **4,2** | **0,0** |
| Operating cash flow | -134,4 | -111,4 | -196,5 | **-119,5** | **-123,0** |
| CAPEX | 2,1 | -32,6 | 12,9 | **0,0** | **0,0** |
| Free cash flow | -114,9 | -134,1 | -208,1 | **-50,4** | **-123,0** |

| Valuation multiples | 2021 | 2022 | 2023 | 2024e | 2025e |
|---|---|---|---|---|---|
| EV/S | neg. | neg. | neg. | **neg.** | **>100** |
| EV/EBITDA (adj.) | 1,2 | 0,1 | 0,9 | **0,6** | **neg.** |
| EV/EBIT (adj.) | 1,2 | 0,1 | 1,0 | **0,6** | **neg.** |
| P/E (adj.) | 0,0 | 0,0 | 0,0 | **0,0** | **0,0** |
| P/B | 0,0 | 0,0 | 0,0 | **0,0** | **0,0** |
| Dividend-% | | | | | |

Source: Inderes

| Per share data | 2021 | 2022 | 2023 | 2024e | 2025e |
|---|---|---|---|---|---|
| EPS (reported) | -0,67 | -0,70 | -0,15 | **-0,13** | **-0,13** |
| EPS (adj.) | -0,67 | -0,70 | -0,15 | **-0,13** | **-0,13** |
| OCF / share | -0,67 | -0,56 | -0,23 | **-0,12** | **-0,12** |
| FCF / share | -0,58 | -0,67 | -0,25 | **-0,05** | **-0,12** |
| Book value / share | 3,29 | 2,58 | 0,84 | **0,65** | **0,52** |
| Dividend / share | 0,00 | 0,00 | 0,00 | **0,00** | **0,00** |

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| | |
|---|---|
| Buy | The 12-month risk-adjusted expected shareholder return of the share is very attractive |
| Accumulate | The 12-month risk-adjusted expected shareholder return of the share is attractive |
| Reduce | The 12-month risk-adjusted expected shareholder return of the share is weak |
| Sell | The 12-month risk-adjusted expected shareholder return of the share is very weak |

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## Recommendation history (>12 mo)

| Date | Recommendation | Target | Share price |
|---|---|---|---|
| 10.4.2024 | Accumulate | 0,70 € | 0,49 € |

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