EDISON

Mendus

Q224 results

Broad progress across the pipeline

Pharma and biotech

Mendus's Q224 results reflect a period of steady progress across its clinical programmes. For vididencel, the Phase II CADENCE trial (for acute myeloid leukaemia, AML) is now ready to commence patient recruitment with the first sites opening in September. Latest data from the ADVANCE II monotherapy trial confirmed broad immune responses (updated survival data expected in Q424), bolstering sentiment in the build-up to the pivotal registrational study. Data from the Phase I ALISON trial highlighted vididencel's safety in ovarian cancer (OC) and we expect the next readout in Q424 to drive further development work. For ilixadencel, the highlight from Q2 was the collaboration with Institut Bergonié in soft tissue sarcomas (STS), where the first patient data are expected from H126. Increased spending on the NorthX collaboration saw the operating loss rising 37% q-o-q to SEK37.9m, although cash burn improved q-o-q (to SEK22.4m) given that a large portion of these expenses were prepaid to NorthX. The cash position remains strong (SEK130.2m) and provides a runway into Q325. Following adjustments to our estimates, our valuation is now SEK2.0bn (vs SEK2.1bn previously).

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/22	3.4	(138.8)	(13.9)	0.0	N/A	N/A
12/23	29.6	(101.6)	(4.4)	0.0	N/A	N/A
12/24e	4.2	(141.8)	(3.0)	0.0	N/A	N/A
12/25e	0.0	(124.0)	(2.5)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. EPS adjusted for 20:1 share consolidation.

Vididencel continues to lead the way

Q224 was an eventful quarter for vididencel, marked by positive data updates from ADVANCE II and ALISON, as well as the build-up to the launch of the CADENCE study (recruitment due to commence in September). For ALISON (OC), the primary goal of generating sufficient vaccine-induced responses was achieved in at least 10 patients. Detailed results from all treated patients are expected in Q424. Notably, supplementary data from ADVANCE II (AML) showcased the drug's potential in generating a broader immune response through both T-cell and B-cell activation (vs just T-cell action of antigen-targeting approaches), indicative of longer-term clinical benefit. We expect this to provide a competitive edge to vididencel, should the data be replicated in the planned registrational trial due to commence from H225.

Ilixadencel back in the reckoning

Following a strategic repositioning, we are encouraged by the collaboration with Institut Bergonié to generate proof-of-concept data for ilixadencel as a combination treatment in STS, an indication lacking durable treatment options. This is consistent with management's strategy and we believe participation in the basket trial will allow Mendus to assess ilixadencel's potential in a cost-efficient way. Preparatory activities will take place in H224 and first patient data are expected in H126.

Valuation: SEK2.0bn or SEK39.8 per share

We have adjusted our estimates to reflect the H124 performance, as well as the potential launch timelines for ilixadencel (from 2029 to 2031). Our valuation adjusts to SEK2.0bn or SEK39.8 per share (SEK2.1bn or SEK41.8/share previously).

27 August 2024

Price	**SEK8.15**
Market cap	**SEK411m**
	SEK10.2/US$
Net cash (SEKm) at 30 June 2024 (excluding lease liabilities)	130.2
Shares in issue (following 20:1 share consolidation in June 2024)	50.4m
Free float	37%
Code	IMMU
Primary exchange	Nasdaq Stockholm
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	0.0	(14.6)	24.2
Rel (local)	0.1	(14.0)	(0.9)
52-week high/low	SEK14.5	SEK6.05	

Business description

Mendus is a clinical-stage immuno-oncology company based in Sweden and the Netherlands. It specialises in allogeneic dendritic cell biology and currently has two lead cell-based, off-the-shelf therapies for haematological and solid tumours.

Next events

CADENCE trial patient enrolment	September 2024
ADVANCE II and ALISON updates	Q424
Ilixadencel REGOMUNE data (STS)	H126

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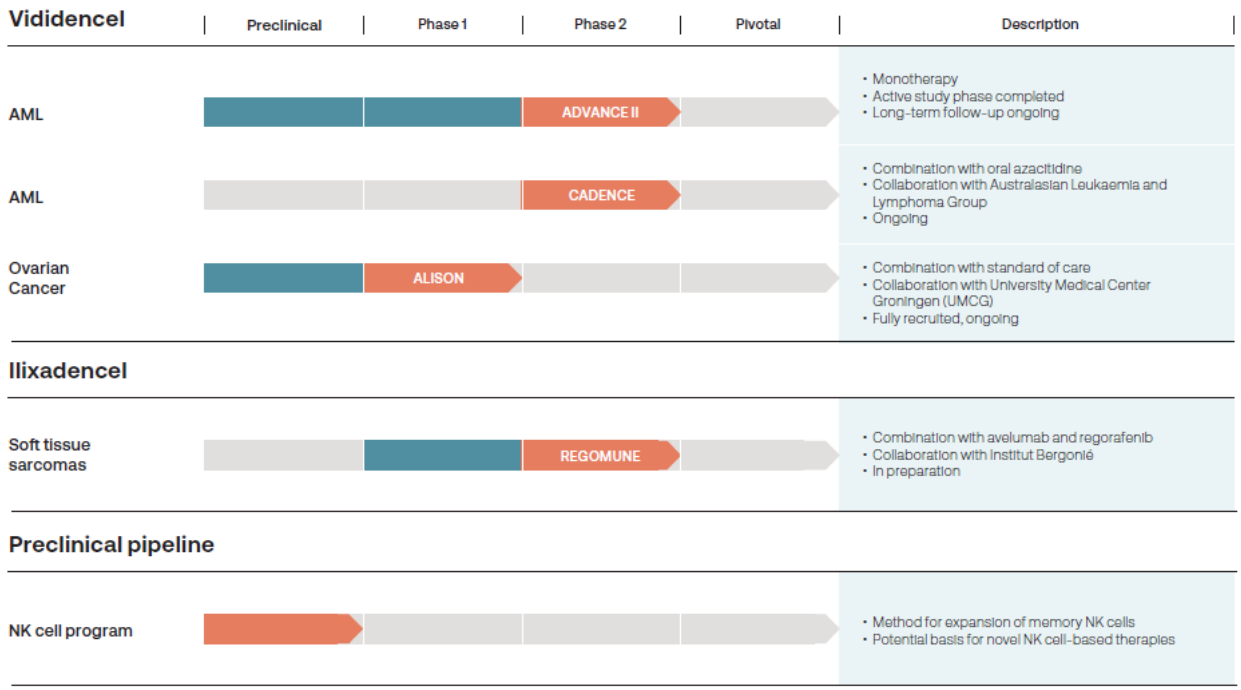
Edison profile page

Momentum continues across clinical pipeline

The past few months have seen Mendus taking tangible steps towards progressing its novel development pipeline, with both assets making headways in their clinical pathways (Exhibit 1). We discuss the company's key assets and programmes, as well as highlights from Q224 below.

Exhibit 1: Mendus's development pipeline



Source: Mendus Q224 report

Vididencel development stays on track in AML and OC

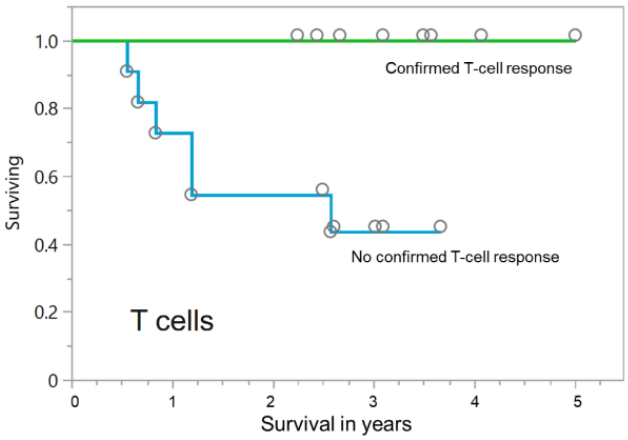
Vididencel, Mendus's lead asset, is being primarily developed as a maintenance treatment for AML, an indication where disease relapse represents a major barrier to long-term survival and one that has been underserved by immunotherapies, such as checkpoint inhibitors. With limited durable treatment options currently available, the five-year survival rate stands at c 30%. With the aim of addressing this ongoing medical need, vididencel generated compelling monotherapy data in the ADVANCE II trial (long-term follow-up ongoing) and will now be assessed in the Phase II CADENCE trial (following the regulatory green light in March 2024). CADENCE will test vididencel's efficacy in combination with oral azacitidine, the standard of care and only approved AML maintenance drug. The trial sponsor is the Australasian Leukaemia & Lymphoma Group (ALLG), a well-regarded non-profit blood cancer clinical trial research group in Australasia. The trial (expected n=140) will be a randomised, multi-centre study consisting of two stages and will involve AML patients in complete remission following high-intensity chemotherapy. The first stage (18–24 months) will assess the safety of the combination compared to oral azacitidine alone in 40 patients. The second stage (24–36 months) will assess efficacy in a further 100 patients. Management has indicated that site activation and patient recruitment for CADENCE will commence in September 2024. Since the trial is being run by the ALLG, Mendus will have limited control over its progress. However, we anticipate an interim safety readout from the first stage in H225. We continue to expect that this should align with Mendus's planned launch for a global registrational trial for vididencel in AML. Preparatory activities for the registrational study are expected to complete by H225 (including large-scale good manufacturing practice manufacturing in collaboration with NorthX

Biologics, a specialised Nordic contract development and manufacturing organisation). Management has communicated that the first large-scale runs have been completed and preparatory activities remain on track with expected timelines.

In June 2024, Mendus presented incremental data from ADVANCE II at the European Hematology Association (EHA) conference, confirming vididencel's ability to generate a broad and active immune response through both T-cell and B-cell activation (vs selected T-cell action seen in antigen and neo-antigen-based approaches), indicative of better clinical outcomes in AML maintenance. The poster presented at the EHA conference related to readings at the median follow-up of 31.6 months (as of November 2023), reaffirming the previously reported median relapse-free survival of 30.4 months, and that median overall survival (OS) had not yet been reached, with 14 of 20 patients still alive. Seven patients had a measurable residual disease (MRD) response, of which five had turned MRD negative and two saw a 10 times reduction in MRD levels. All MRD responders were alive and had significantly better OS rates. We believe that the key take-away from the EHA presentation was the breadth of immune response generated by vididencel, delivered via activation of both T-cell and antibody-producing B-cells (Exhibits 2 and 3). The data also indicated that observed immune responses were associated with durable clinical remissions. For example, all patients with confirmed T-cell responses (detailed below) against tumour antigens were alive in long-term follow-up at the time of readout.

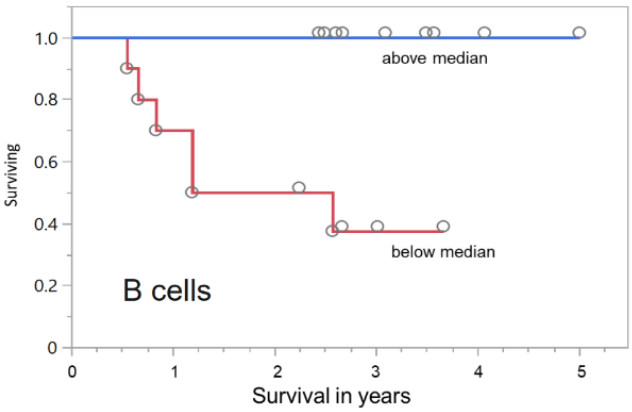
In our opinion, the combination of broad antigen targeting (full spectrum of tumour-associated antigens) and ability to generate an active immune response (stimulating the patients' immune system to build up immunity against residual cancer cells) differentiates the treatment (a whole cell-based vaccine comprising irradiated, leukemic-derived dendritic cells) from traditional antigen-based treatments, with selective T-cell targeting of antigens, providing proof-of-concept that vididencel acts as an active immunotherapy in AML.

Exhibit 2: ADVANCE II T-cell response data



Source: Mendus Q224 results presentation

Exhibit 3: ADVANCE II B-cell response data



Source: Mendus Q224 results presentation

The data highlighted that 85% of patients (17 of 20) showed at least one vaccine-induced T-cell response (VIR) against common tumour antigens (WT1, PRAME and RHAMM) after treatment with vididencel, and nine of 20 patients had at least two VIRs (confirmed T-cell responses), which led to notably improved OS rates. Moreover, vididencel treatment increased the B-cell levels across all responder subgroups, which was also associated with higher OS rates. We believe the drug's ability induce a broad immune response should correlate with longer-term clinical benefit in AML.

Beyond AML, vididencel is also being explored as a potential maintenance therapy for OC. The ongoing Phase I ALISON trial completed patient recruitment in December 2023 and management presented interim data at the European Society for Medical Oncology (ESMO) in June 2024. This update revealed that all 17 patients had completed their planned treatment regimens and 10 of the 15 evaluated patients had shown a VIR against typical OC-related tumour antigens, meeting the

primary objective for the trial. The ESMO update also confirmed the robust safety profile of vididencel, with the only product-related side effects being injection site responses. At week 22, 10 patients had stable disease. Long-term follow-up is ongoing and results from the primary analysis of the full population will be presented in Q424.

During Mendus's Q224 results presentation, management also communicated that market research had confirmed the attractiveness of the AML maintenance market for vididencel, with an estimated addressable market of c US$3.7bn. It was also stated that a potentially broader market opportunity may be accessible should additional AML maintenance settings be explored. We look forward to the next update from management on this.

Ilixadencel primed to re-enter the clinic following repositioning

Ilixadencel is an intratumoural immune primer, backed by preclinical and clinical data in solid tumours to support its safety and potential efficacy. In Mendus's Q224 results presentation, management noted the success of checkpoint inhibitors in solid tumours, making it challenging for other treatments to prove incremental efficacy benefits. This resulted in a strategy pivot for Mendus, to target indications poorly served by such immunotherapies, with STS as the prioritised indication.

In July 2024, management announced that it entered into a collaboration with Institut Bergonié, an established comprehensive cancer centre, to test the vaccine in STS patients as part of an ongoing Phase I/II basket trial called REGOMUNE. This is a multi-centre, prospective, open-label study assessing the combination of regorafenib and avelumab in multiple solid tumours. It is currently in the Phase I dose-escalation phase, based across seven hospitals in France, and will be followed by a Phase II portion involving 17 separate cohorts. As part of the collaboration, Mendus will provide ilixadencel for one of these cohorts (n=43), where it will be tested alongside the regorafenib and avelumab combination. First patient data are currently guided for H126. We believe this is a sensible strategy for ilixadencel, as a cost-efficient approach to gain proof-of-concept data, somewhat de-risking the programme.

Financials

Mendus reported operating expenses of SEK38.6m in Q224, up 39% y-o-y (Q223: SEK27.8m), but broadly in line with the Q124 figure of SEK38.1m. This can be attributed to a material increase in R&D expenses (SEK28.9m, compared to SEK19.2m in Q223), with the primary driver being costs related to the technology transfer of the vididencel manufacturing process to NorthX Biologics in preparation for the planned registrational trial from H225. We estimate these costs to be between SEK10m and SEK15m, with the remaining attributed to R&D investments in other vididencel and ilixadencel programmes and its DCOne platform. Mendus accounts for these incremental costs as prepaid expenses on its books and, therefore, the impact of the increased costs on cash flows is limited. General and administrative expenses increased marginally to SEK9.4m, up 11% y-o-y, and were mainly related to financing and investor relations functions, as well as general group management. Other operating income, which primarily consisted of patent transfer revenue and a research grant from Oncode-PACT, increased to SEK0.63m, from SEK0.01m in Q223. Overall, Mendus reported an operating loss of SEK37.9m, up 36.8% y-o-y, but broadly in line with the Q124 reported figure of SEK35.3m. The cash outflow from operating activities was reported as SEK22.4m, versus SEK7.3m in Q223 (which benefited from the receipt of SEK25.3m in interest income). On a quarter-on-quarter basis, cash outflow reduced during Q2 (SEK30.6m in Q124).

Based on the H124 performance and near-term visibility, we have made certain adjustments to our FY24 estimates. Reflecting the H124 run rate, we increase our estimate for other income to SEK4.2m (vs SEK3.1m previously). The primary change to our estimates comes from R&D expenses, which we have increased materially to SEK108.1m (SEK90.0m previously) in

anticipation of ongoing technology transfer to NorthX Biologics in H224. G&A expenses stay unchanged at SEK31.7m. Overall, we now expect the operating loss for the year to be SEK141.8m (from SEK124.8m previously). For FY25, our operating loss estimate is SEK124.0m (vs SEK125.7m previously).

Mendus ended Q224 with net cash reserves of SEK130.2m (excluding lease liabilities of SEK22.9m). This includes a contribution from the SEK69.1m raised in April 2024 from the exercise of series TO3 warrants. In June 2024, the company undertook a 20:1 share consolidation, resulting in the shares outstanding figure adjusting to 50.4m. Based on the current balance sheet position, we continue to see Mendus funded into Q325, by which time we expect significant progress in preparatory activities for the global registrational trial for vididencel.

Valuation

We continue to value Mendus using a risk-adjusted net present value (rNPV) approach for its various clinical programmes. While we keep our peak sales estimates unchanged for all three programmes (vididencel in AML and OC, and ilixadencel in STS), we conservatively push out our launch estimate for ilixadencel to 2031, from 2029 previously, reflecting the longer lead times due to the company's participation in the REGOMUNE basket trial. This is subject to revision as the study progresses and when we receive more clarity on its development path. Based on these changes, as well as rolling our model forward and updating the net cash position, our overall valuation changes to SEK2.0bn, from SEK2.11bn previously. The per share value adjusts to SEK39.8, reflecting the recent 20:1 share consolidation. Exhibit 4 presents a breakdown of our valuation assumptions across Mendus's clinical programmes.

Exhibit 4: Mendus rNPV valuation

Product	Indication	Launch	Peak sales ($m)	NPV (SEKm)	Probability of success	rNPV (SEKm)	NPV/share (SEK/share)
vididencel (DCP-001)	AML	2028	980	4,164	20%	909	18.05
vididencel (DCP-001)	OC	2031	760	2,462	15%	745	14.80
ilixadencel	GIST	2029	230	1,477	15%	221	4.40
Net cash at 30 June 2024				130.2	100%	130.2	2.58
Valuation				**8,233**		**2,006**	**39.84**

Source: Edison Investment Research

In line with our standard approach, we consider a diluted valuation of the company. We estimate that Mendus would need to raise SEK75m in H225, before signing a partnership deal for vididencel in FY26. For illustrative purposes, should the licensing deal not materialise, based on our modelling assumptions, the company would need to raise a combined SEK300m through FY26 and FY27. If it were to raise these funds (SEK375m) through an equity issue, it would have to issue c 46.0m shares (at the current share price of SEK8.15), which would lead to the total number of shares outstanding increasing to 96.4m, and our per share valuation would reduce to SEK24.7.

Exhibit 5: Financial summary

Accounts: IFRS; year-end: 31 December; SEK'000s	2022	2023	2024e	2025e
INCOME STATEMENT				
Total revenue	3,375	29,612	4,176	0
Cost of sales	0	0	0	0
Gross profit	3,375	29,612	4,176	0
SG&A (expenses)	(44,028)	(30,748)	(31,670)	(32,621)
R&D costs	(87,049)	(92,653)	(108,145)	(85,076)
Other income/(expense)	(1,134)	(559)	0	0
Exceptionals and adjustments	0	0	0	0
Reported EBITDA	(128,836)	(94,348)	(135,639)	(117,696)
Depreciation and amortisation	(4,848)	(6,303)	(6,184)	(6,289)
Reported Operating Profit/(loss)	(133,684)	(100,651)	(141,823)	(123,985)
Finance income/(expense)	(5,101)	(968)	72	21
Exceptionals and adjustments	0	0	0	0
Reported PBT	(138,785)	(101,619)	(141,751)	(123,964)
Adjusted PBT	(138,785)	(101,619)	(141,751)	(123,964)
Income tax expense	0	0	0	0
Reported net income	(138,785)	(101,619)	(141,751)	(123,964)
Basic average number of shares, m	10.0	23.1	46.8	50.4
Basic EPS* (SEK)	(13.92)	(4.40)	(3.03)	(2.46)
Diluted EPS* (SEK)	(13.92)	(4.40)	(3.03)	(2.46)
BALANCE SHEET				
Property, plant and equipment	13,899	11,197	9,197	6,897
Intangible assets	532,441	532,441	532,441	532,441
Right of use assets	26,216	23,247	20,922	18,830
Other non-current assets	618	624	624	624
Total non-current assets	573,174	567,509	563,184	558,792
Cash and equivalents	41,851	120,782	89,800	63,228
Prepaid expenses and accrued income	1,919	64,359	22,451	4,451
Other current assets	3,442	3,302	3,302	3,302
Total current assets	47,212	188,443	115,553	70,981
Non-current loans and borrowings	22,845	850	850	75,850
Non-current lease liabilities	23,706	21,115	21,115	21,115
Total non-current liabilities	46,551	21,965	21,965	96,965
Trade and other payables	7,411	8,129	8,129	8,129
Current loans and borrowings	29,198	0	0	0
Short-term lease liabilities	2,413	2,523	2,523	2,523
Other current liabilities	20,375	18,608	18,608	18,608
Total current liabilities	59,397	29,260	29,260	29,260
Equity attributable to company	514,438	704,727	627,512	503,548
CASH FLOW				
Operating profit/(loss)	(133,684)	(100,651)	(141,823)	(123,985)
Depreciation and amortisation	4,848	6,303	6,184	6,289
Other adjustments	(6,390)	(1,966)	0	0
Movements in working capital	27,030	(65,479)	41,908	18,000
Interest paid / received	(1,135)	(968)	72	21
Income taxes paid	0	0	0	0
Cash from operations	(109,331)	(162,761)	(93,659)	(99,675)
Capex	(12,324)	(1,823)	(1,859)	(1,897)
Acquisitions & disposals net	0	0	0	0
Other investing activities	0	1,380	0	0
Cash used in investing activities	(12,324)	(443)	(1,859)	(1,897)
Net proceeds from issue of shares	0	297,904	64,536	0
Movements in debt	8,194	(55,807)	0	75,000
Other financing activities	0	0	0	0
Cash flow from financing activities	8,194	242,097	64,536	75,000
Increase/(decrease) in cash and equivalents	(113,461)	78,893	(30,982)	(26,572)
Cash and equivalents at beginning of period	155,313	41,851	120,781	89,799
Cash and equivalents at end of period	41,851	120,781	89,799	63,227
Net (debt) cash	(10,192)	119,932	88,950	(12,622)

Source: Company reports, Edison Investment Research. Note: *EPS adjusted for 20:1 share consolidation.

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