Mendus

Q123 results

Planning the route forward for vididencel in AML

Pharma and biotech

Mendus's Q123 report provided an insight into the strategic next steps for its lead cancer vaccine, vididencel (DCOne), as the company pursues a clinical path in the acute myeloid leukaemia (AML) maintenance setting. Following the positive results from the Phase II ADVANCE II study, Mendus intends to initiate a follow-on Phase II study in H223, investigating the combination of vididencel with oral azacitidine (current standard of care, SoC) as an AML maintenance treatment regime. It had previously been reported that Mendus may look to explore vididencel as a maintenance treatment in patients post-hematopoietic stem cell transplantation (HSCT). However, with no maintenance therapy indicated in post-HSCT, to date, and the potential for synergistic efficacy enhancements with SoC oral azacitidine, we view Mendus's prioritisation of the combination study as a sensible strategic decision. We have adjusted our forecasts, but our valuation of Mendus remains largely unchanged at SEK1.8bn or SEK9.19/share (previously SEK1.8bn or SEK9.07/share).

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/21	0.0	(133.4)	(0.73)	0.0	N/A	N/A
12/22	3.4	(138.8)	(0.70)	0.0	N/A	N/A
12/23e	0.0	(133.6)	(0.67)	0.0	N/A	N/A
12/24e	0.0	(145.3)	(0.72)	0.0	N/A	N/A

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

Combination study next on the AML horizon

Mendus is looking to make further inroads in AML maintenance with the initiation of a Phase II combination study. The company has communicated that the planned study may have potential to expand into a pivotal (registrational) trial. We note that there are limited competitive technologies in the AML maintenance pipeline with ongoing studies primarily focused on repositioning more recently approved AML treatments (venetoclax, azacitidine, gilteritinib), representing an opportunity for vididencel to offer market differentiation, in our view.

Financing on hand provides runway to Q224

Mendus has secured financing commitments worth up to a total of SEK210.0m. The facility consists of a remaining SEK15.0m shareholder loan from Van Herk Investments and SEK195.0m of convertible debt from Negma Group available for drawdown at the discretion of Mendus. With a gross cash position of SEK37.5m at end-Q123 and quarterly operating cash burn of SEK33.5m, the company will likely have to access the debt facility in Q223 to continue to fund its operations. If Mendus fully exercises the committed financing available, we believe it should provide an operating cash runway to Q224, based on our projected burn rates.

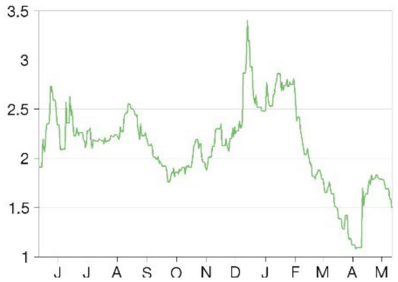
Valuation: SEK1.8bn or SEK9.19 per share

Our valuation of Mendus remains relatively unchanged at SEK1.8bn or SEK9.19/share, including net debt of SEK46.0m at end-Q123. The increased net debt position has been offset slightly by rolling our valuation model forward.

15 May 2023

Price	**SEK1.42**
Market cap	**SEK285m**
	SEK10.4/US$
Net debt (SEKm) at 31 March 2023 (excluding lease liabilities)	46.0
Shares in issue	201.3m
Free float	37%
Code	IMMU
Primary exchange	Nasdaq Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(6.8)	(30.4)	(26.0)
Rel (local)	(6.7)	(29.9)	(30.5)
52-week high/low		SEK3.40	SEK1.08

Business description

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

Next events

Vididencel Phase II combination study initiation	H223
Vididencel mRFS data in ADVANCE II	Q423

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Financials

Following the Q123 report, we have updated our financial estimates for Mendus and forecast FY23 operating losses of SEK132m (previously SEK149m), with net cash outflows from operating activities of SEK130m (previously SEK148m). The decrease in operating expenses has been attributed to slightly muted clinical development activities associated with vididencel and ilixadencel, reducing FY23 R&D spend forecast to SEK82.3m, from SEK99.1m. However, we estimate that Mendus's current quarterly costs are likely to increase in H223 as the company prepares for the initiation of the follow-on Phase II study for vididencel. We therefore expect operating losses to increase in FY24 to SEK136m (previously SEK67.4m), primarily driven by increased R&D expenses to SEK84.4m (previously SEK15.0m) associated with the commencement of the Phase II trial, and forecast operating cash outflows of SEK142m. Changes to our key estimates are summarised in Exhibit 1.

Exhibit 1: Key changes to forecasts

	FY23e			FY24e		
SEKm	**Old**	**New**	**Change (%)**	**Old**	**New**	**Change (%)**
Operating Expenses	**(149.3)**	**(131.6)**	***11.9%***	**(67.4)**	**(135.8)**	***-100.3%***
-- R&D	*(99.1)*	*(82.3)*	*17.0%*	*(15.0)*	*(84.4)*	*-462.7%*
-- G&A	*(46.1)*	*(45.2)*	*2.0%*	*(47.5)*	*(46.5)*	*2.0%*
- D&A	*(4.1)*	*(4.1)*	*0%*	*(4.9)*	*(4.9)*	*0%*
EBIT	**(149.3)**	**(131.6)**	***11.9%***	**(67.4)**	**(135.8)**	***-100.3%***
Operating cash outflow	**(148.0)**	**(130.3)**	***12.0%***	**(73.4)**	**(141.8)**	**-93.2%**

Source: Edison Investment Research

As such, if the company fully exercises the committed financing available, we believe it should provide sufficient funds to support its clinical programmes and working capital requirements into Q224. If the entire SEK195.0m of convertible debt is used by Mendus, the ensuing stock conversion, assuming a price of SEK1.50/share, would result in the issue of 130.0m shares, diluting existing shareholders by c 65%. We do not expect Mendus to be fully revenue generating and self-sustaining until 2027, following the launch of vididencel, and we estimate the company will need to raise an additional SEK425.0m in funding, which we account for as illustrative debt in our model. If this is realised through an equity issue at the current market price, it would result in the issuance of 283.3m shares. If we assume full drawdown of the Negma debt facility (SEK195.0m) and our estimated additional funding requirements (SEK425.0m), Mendus would have to issue c 413.3m shares, resulting in our per share valuation decreasing from SEK9.19/share to SEK3.01/share.

Exhibit 2: Financial summary

Accounts: IFRS, Yr end: December, SEK: Thousands	2020	2021	2022	2023e	2024e
Income statement					
Total revenue	0	31	3,375	0	0
Cost of sales	0	0	0	0	0
Gross profit	0	31	3,375	0	0
SG&A (expenses)	(37,193)	(42,498)	(44,737)	(45,184)	(46,540)
R&D costs	(47,883)	(85,796)	(87,049)	(82,270)	(84,373)
Other income/(expense)	(65)	(845)	(1,134)	0	0
Exceptionals and adjustments	0	0	0	0	0
Reported EBITDA	(85,141)	(129,108)	(129,545)	(127,455)	(130,913)
Depreciation and amortisation	(887)	(992)	(4,139)	(4,131)	(4,939)
Reported Operating Profit/(loss)	(86,028)	(130,100)	(133,684)	(131,586)	(135,851)
Finance income/(expense)	(3,220)	(3,310)	(5,101)	(2,026)	(9,440)
Other income/(expense)	0	0	0	0	0
Exceptionals and adjustments	0	0	0	0	0
Reported PBT	(89,248)	(133,410)	(138,785)	(133,611)	(145,292)
Adjusted PBT	(89,248)	(133,410)	(138,785)	(133,611)	(145,292)
Income tax expense	0	0	0	0	0
Reported net income	(89,248)	(133,410)	(138,785)	(133,611)	(145,292)
Basic average number of shares, m	76.2	184.0	198.3	200.4	201.3
Basic EPS (SEK)	(1.17)	(0.73)	(0.70)	(0.67)	(0.72)
Diluted EPS (SEK)	(1.17)	(0.73)	(0.70)	(0.67)	(0.72)
Balance sheet					
Property, plant and equipment	1,705	2,109	13,899	14,588	15,191
Intangible assets	532,441	532,441	532,441	532,441	532,441
Right of use assets	1,204	361	26,216	26,216	26,216
Other non-current assets	677	843	618	618	618
Total non-current assets	536,027	535,754	573,174	573,863	574,466
Cash and equivalents	167,643	155,313	41,851	48,128	97,233
Prepaid expenses and accrued income	4,760	10,214	1,919	1,919	1,919
Other current assets	20,230	19,702	3,442	3,442	3,442
Total current assets	192,633	185,229	47,212	53,489	102,594
Non-current loans and borrowings*	18,982	36,666	22,844	187,844	382,844
Non-current lease liabilities	303	0	23,706	23,706	23,706
Total non-current liabilities	19,285	36,666	46,550	211,550	406,550
Trade and other payables	10,365	11,610	7,411	7,411	7,411
Current loans and borrowings	14,879	0	29,198	0	0
Short-term lease liabilities	880	309	2,413	2,413	2,413
Other current liabilities	22,157	15,657	20,375	20,375	20,375
Total current liabilities	48,281	27,576	59,397	30,199	30,199
Equity attributable to company	661,094	656,743	514,440	385,604	240,312
Cashflow statement					
Operating Profit/(loss)	(86,028)	(130,100)	(133,684)	(131,586)	(135,851)
Depreciation and amortisation	1,774	1,851	4,139	3,311	3,477
Other adjustments	0	0	0	0	0
Movements in working capital	27,731	(10,089)	27,030	0	0
Interest paid / received	(103)	(140)	(1,135)	(2,026)	(9,440)
Income taxes paid	0	0	0	0	0
Cash from operations (CFO)	(56,626)	(138,031)	(109,331)	(130,300)	(141,815)
Capex	(464)	(1,361)	(12,324)	(4,000)	(4,080)
Acquisitions & disposals net	0	0	0	0	0
Other investing activities	0	0	0	0	0
Cash used in investing activities (CFIA)	157,298	(1,361)	(12,324)	(4,000)	(4,080)
Net proceeds from issue of shares	51,629	128,949	0	4,775	0
Movements in debt	(725)	(1,922)	10,925	165,000	195,000
Other financing activities	0	0	(2,731)	(29,198)	0
Cash flow from financing activities	50,904	127,027	8,194	140,577	195,000
Increase/(decrease) in cash and equivalents	153,611	(12,330)	(113,462)	6,277	49,105
Cash and equivalents at beginning of period	14,032	167,643	155,313	41,851	48,128
Cash and equivalents at end of period	167,643	155,313	41,851	48,128	97,233
Net (debt) cash	133,782	118,647	(10,191)	(139,716)	(285,611)

Source: Mendus company accounts, Edison Investment Research. Note: *Includes the Van Herk Investments shareholder loan and the Negma Group convertible debt facility which we assume will both be fully drawn down.

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