EDISON

Mendus

Clinical outlook

Sights on vididencel (in AML) combination study

Pharma and biotech

On the heels of Mendus's recent Q123 results, we take a deep dive into the company's lead cancer vaccine candidate, vididencel, and the acute myeloid leukaemia (AML) maintenance treatment landscape. On closer inspection of the current AML pipeline and standard of care (SoC), vididencel's clinical profile and the potential advantages associated with the vaccine's 'off-the-shelf' characteristics may enable more timely and wider access of treatment to patients compared to individualised therapy approaches. Additionally, we view the company's move to prioritise a combination study of vididencel with AML maintenance SoC Onureg (oral azacitidine) as a sensible strategic decision. Our valuation of Mendus remains unchanged at SEK1.8bn or SEK9.19 per 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.

The clinical road laid out in AML

Following the positive results of the ADVANCE II study, management intends to focus on maximising vididencel's potential value as an AML maintenance treatment. The company's planned Phase II combination study with Onureg will include the same patient population as the ADVANCE II trial, patients who have gone into complete disease remission following first-line induction chemotherapy, and, in our view, represents a logical next step in vididencel's clinical development. Additionally, we see combination treatment regimens as being critical for future clinical breakthroughs to disrupt SoC treatment protocols in oncology.

'Off-the-shelf' therapies the next generation

While we acknowledge the notable clinical advances that have been made in recent years with personalised (autologous) cell-based therapies, notably CAR-T in the treatment of haematological malignancies, these patient-specific treatments continue to suffer from significant logistical drawbacks. Notably, extended manufacturing lead times continue to be a major bottleneck for personalised treatments, which is a potentially serious issue for patients with highly aggressive cancers. As an 'off-the-shelf', non-patient-specific product, vididencel may be able to overcome such production constraints and offer a more advantageous COGS profile to facilitate broader access to patients.

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

Our valuation of Mendus remains unchanged at SEK1.8bn or SEK9.19/share, including net debt of SEK46.0m at end-Q123. We will revisit our valuation assumptions for vididencel once the full survival results of the ADVANCE-II study are reported.

23 May 2023

Price	**SEK1.29**
Market cap	**SEK260m**
	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	(27.9)	(29.7)	(45.1)
Rel (local)	(28.6)	(30.2)	(47.9)
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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AML maintenance remains an untapped opportunity

AML is an aggressive type of blood and bone marrow cancer that affects a patient's white blood cells. While the disease is among the most common leukaemia types in adults, AML is still a relatively rare cancer, with an estimated 20,380 new cases expected to be diagnosed in the United States in 2023. While chemotherapy may not be suitable for certain patient populations, particularly older individuals, the regimen continues to be widely used with c 75% of AML patients potentially eligible to receive this treatment. However, despite advances in AML therapies, c 50% of AML patients who have achieved complete remission will experience disease relapse. An emerging space in AML treatment paradigms is that of maintenance therapy, which involves the complete eradication of residual cancerous cells from the body, following a patient's complete response to induction therapy, to prolong remission duration, prevent relapse and improve overall survival (OS). An important concept in AML maintenance therapy is measurable residual disease (MRD), which refers to the presence of cancerous cells at levels conventional testing methods cannot detect but that more sensitive modern methods can. Therefore, a patient may be classified as in complete remission while still being MRD positive. Importantly, as a prognostic biomarker, MRD status is recognised as an important relapse risk factor in AML, and MRD negativity is associated with superior long-term survival.

Maintenance therapies are designed to combat MRD after remission, as the safety and toxicity of continuing certain chemotherapy regimens is unsatisfactory (venetoclax + azacitidine, 3+7 regimens). However, there are only two approved maintenance treatments indicated in AML patients following complete remission after 3+7 chemotherapy (three days of an anthracycline antibiotic and seven days of cytarabine chemotherapy):

- **Oral azacitidine** (Onureg, CC-486, Bristol Myers Squibb) monotherapy is currently the only approved AML maintenance drug and current SoC for patients ineligible for allo-HSCT. We note that azacitidine is considered a chemotherapy but possesses a safer profile, making it more suitable for longer-term use.
- **Allogeneic hematopoietic stem cell transplantation** (allo-HSCT) continues to be one of the most effective post-remission therapies for AML patients who have first undergone induction chemotherapy. However, certain patient groups (particularly older patients) may not be eligible for treatment due to potential toxicity issues and many patients are likely to relapse. To date, no maintenance therapy is indicated post-HSCT.

As the number of AML patients in complete remission is likely to increase as new, effective therapies are approved and patients survive longer, the requirement for safe and effective AML maintenance therapies that do not affect patient quality of life will represent a considerable area of medical need, in our opinion.

Scope to differentiate vididencel in a quieter pipeline

Onureg is the only approved AML maintenance drug that has been indicated in patients who are in complete remission following induction chemotherapy. Onureg was approved by the FDA as an AML maintenance therapy in 2020, based on data from the randomised, placebo-controlled, double-blind Phase III QUAZAR AML-001 (NCT01757535) study, where the drug demonstrated a median overall survival (mOS) of 14.6 months (vs 10.4 months in placebo group) and median relapse-free survival (mRFS) of 7.1 months (vs 2.7 months in placebo group) in baseline MRD+ patients. With currently limited treatment options, there remains significant scope for new AML maintenance treatments that can demonstrate more durable clinical responses to offer market differentiation, in our view.

The AML maintenance pipeline may appear quite competitive on first inspection; however, on closer analysis, the setting that Mendus is strategically prioritising with vididencel (patients in first complete remission, CR1, after induction chemotherapy) appears to have relatively limited emerging technologies, Exhibit 1.

Exhibit 1: Active AML post-remission maintenance therapy studies

Drug	Company	Phase	Maintenance setting	Technology	Description	Notes
Galinpepimut-S (Zeltherva)	Sellas Life Sciences	Phase III	Following second complete remission (CR2) after chemotherapy	Cancer vaccine	A Wilms tumour-1 (WT1) peptide cancer vaccine. WT1 is a protein highly overexpressed in AML, making it a potential target for tumour selective cancer vaccines	Results from a Phase II study in CR1 AML patients reported mOS of >67.6 months while a Phase I/II trial in CR2 AML patients reported a mOS of 21.0 months. The ongoing Phase III trial is focused on the CR2 setting.
Oral azacitidine (Onureg) + Venetoclax	AbbVie/Roche	Phase III	Following CR1 after chemotherapy	Small molecule/s	Onureg is a hypomethylating agent with anticipated improved drug properties over injectable azacitidine. Venetoclax is a selective BCL-2 inhibitor	Phase III VIALE-M study combines venetoclax with existing SoC maintenance AML treatment (Onureg). Randomised, double-blind, placebo-controlled trial with primary endpoint of relapse-free survival.
Venetoclax + azacitidine injectable	AbbVie	Phase III	Post-HSCT	Small molecule/s	See above in table	Phase III randomised and open-label VIALE-T study investigating venetoclax + azacitidine injectable, current SoC first-line therapy in chemo-unfit AML patients, as maintenance post HSCT.
Gilteritinib (Xospata)	Astellas	Phase III	Post-HSCT	Small molecule	Targeted FMS-like tyrosine kinase (FLT3) inhibitor that competitively binds with ATP	Phase III randomised, double-blind, placebo-controlled study investigating Gilteritinib, current SoC in relapsed/refractory FLT3+ AML patients, as maintenance post HSCT in FLT3-ITD+ patients.
Gilteritinib (Xospata)	Astellas	Phase II	Following CR1 after chemotherapy	Small molecule	See above in table	Phase II randomised, double-blind, placebo-controlled study assessing Gilteritinib maintenance in FLT3-ITD+ patients following CR1 after chemotherapy.
Siremadlin (HDM-201)	Novartis	Phase I/II	Post-HSCT	Small molecule	MDM2 specific inhibitor, restoring p53 activity and promoting tumour cell apoptosis	Previous Phase I study demonstrated safety and preliminary response data with overall response rate (ORR) of 22% observed in one dosing protocol consisting of various AML patient populations.
Sabatolimab with/without azacitidine	Novartis	Phase I/II	Post-HSCT	Monoclonal antibody	TIM-3 inhibitor, novel target expressed on leukaemic and immune cells, enhancing anti-tumour immune response	Previous Phase I study in first-line AML patients demonstrated safety and response to treatment with ORR of 40%.
TSC-100 + TSC-101	TScan Therapeutics	Phase I	Post-HSCT	Autologous T-cell	Personalised cell therapy targeting minor histocompatibility antigens (MiHA) HA-1 and HA-2	First patient dosed in Phase I study in March 2023 with dose escalation following initially observed safety.
Mana 312	Mana Therapeutics	Phase I	Post-HSCT	Allogenic T-cell	Allogenic (donor derived) T-cell therapy targeting multiple tumour associated antigens (TAA)	Being investigated in a Phase I open-label, non-randomised, single- and multiple-dose escalation study. Little detail on trial status or expected readouts.
MT-401	Marker Therapeutics	Phase II	Post-HSCT	Allogenic T-cell (donor matched)	Allogenic multiple TAA T-cell therapy requiring a matched unrelated donor with at least six or eight human leukocyte antigen (HLA) markers	Phase II open-label, single-arm study looking to recruit up to 180 patients. Preliminary safety profile has been demonstrated in the Phase II study
MT-401-OTS	Marker Therapeutics	Phase I	Post-HSCT	Allogenic T-cell	Allogenic multiple TAA T-cell therapy that does not require a matched donor. Could be considered a true 'off the shelf' therapy	No previous clinical data, with first patient dosing expected in 2023. Phase I open-label, single-arm study expected to recruit up to 44 patients.

Source: Clinicaltrials.gov, EvaluatePharma, Edison Investment Research

To our knowledge, the only late-stage therapeutic vaccine technology currently under development in AML maintenance is Sellas Life Sciences' Wilms tumour-1 targeting peptide cancer vaccine, Galinpepimut-S. However, the treatment currently does not appear to directly compete with

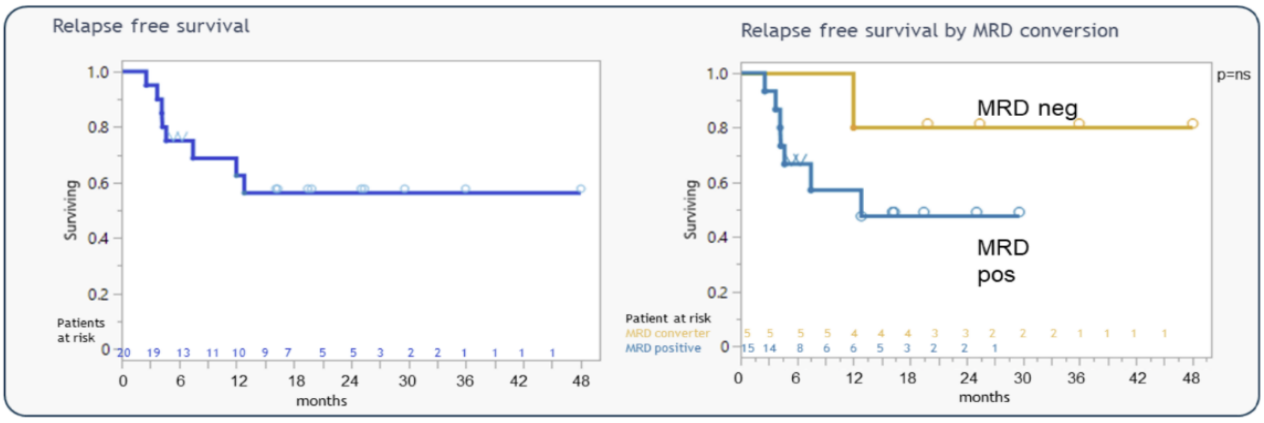
vididencel as it is being investigated as a maintenance therapy in patients who have undergone complete remission following second-line salvage therapy (CR2), not following first-line chemotherapy. While Sellas has selected the CR2 setting to secure an initial FDA label for Galinpepimut-S, the company has communicated its Phase I and II clinical data in CR1 patients could potentially support future label expansion into the CR1 maintenance line.

We note that the Phase III VIALE-M study (AbbVie/Roche) investigating the combination of Onureg (alternatively called CC-486) plus venetoclax is the most direct competition to vididencel. Venetoclax in combination with injectable azacitidine has previously received FDA approval as a first-line therapy in chemo-unfit patients (over the age of 75) and the VIALE-M trial is looking to expand venetoclax into the AML maintenance setting. Should the results from the combination VIALE-M study show clinically meaningful improvements in mRFS compared to Onureg alone, it could potentially disrupt the existing SoC in AML maintenance and may have an impact on Mendus's future clinical strategy for vididencel. Astellas is also conducting a Phase II AML maintenance study in CR1 patients with Gilteritinib (FDA approved in relapsed/refractory line FLT3+ AML patients). However, the scope of this trial is focused on patients who possess an FLT3 mutation (FLT3+), representing c 30% of the AML population.

... backed up by a supportive clinical profile, to date

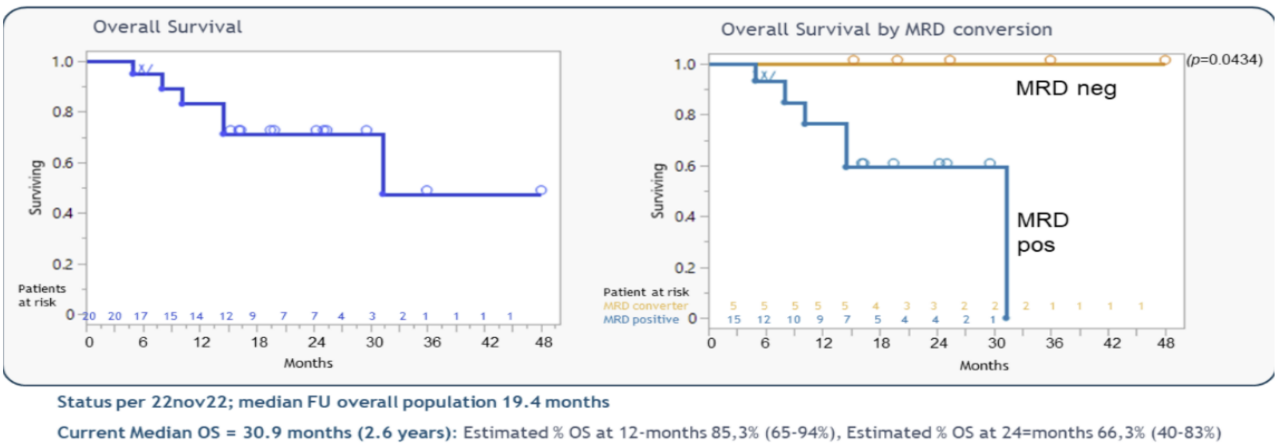
The most recent clinical data reported for vididencel are from the Phase II ADVANCE II trial where at a median follow-up period of 19.4 months, mRFS for the study patient population (n=20) was not yet reached (but 12-month RFS was estimated at 64%) and mOS stood at 30.9 months, Exhibits 1 and 2.

Exhibit 2: ADVANCE-II RFS data



Source: Mendus corporate presentation

Exhibit 3: ADVANCE-II OS data



Status per 22nov22; median FU overall population 19.4 months

Current Median OS = 30.9 months (2.6 years): Estimated % OS at 12-months 85,3% (65-94%), Estimated % OS at 24=months 66,3% (40-83%)

Source: Mendus corporate presentation

Patients who were still in complete remission (12 out of 20 patients) had been so for 16 to 47 months after start of treatment and those who had converted to MRD-negative displayed a significantly prolonged RFS and OS, with neither mRFS nor mOS being reached in this sub-group. Additionally, vididencel continued to display a good safety profile, with no serious or severe adverse events reported (the main adverse events continued to be injection site reactions occurring within 48 hours of treatment). While we caution against direct comparison between the results of differently designed clinical studies (the QUAZAR AML-001 trial is randomised, placebo controlled and double blind), the fact that ADVANCE II had not reached RFS at a median follow-up period of 19.4 months suggests significantly improved relapse rates with vididencel treatment (mRFS in QUAZAR AML-001: 7.1 months). This is further supported by the mOS data from the ADVANCE trial (30.9 months), which, in our view, compares very favourably with the QUAZAR AML-001 data for Onureg (14.6 months). We acknowledge that the results of the ADVANCE II study are based on a smaller patient population (n=20) and that larger studies will need to be conducted to strengthen the evidence of vididencel's clinical utility.

... and the potential advantages of an 'off-the-shelf' treatment

One of the major limitations of individualised cell therapy approaches continues to be constraints around manufacturing and patient access. Large-cap pharma companies, such as Bristol Myers Squibb and Johnson & Johnson, have reported ongoing issues around supply chain bottlenecks associated with their personalised multiple myeloma (MM) CAR-T treatments, Abecma and Carvykti. As a result, MM patient waiting times can be over six months and, once patients are referred, the turnaround time from patient biopsy to CAR-T infusion ('vein-to-vein' time) can be three to six weeks on average. Our view remains that the operational infrastructure to support the effective commercialisation and mass production of personalised treatments is not yet in place and may not be for quite some time. As such, we believe more universal cell therapy approaches looking to provide more timely, upfront access to treatment for patients offer significant potential to differentiate in the market.

With vididencel, Mendus is developing an 'off-the-shelf', multiple tumour-associated antigens (TAA) expressing, dendritic cell vaccine produced from the company's proprietary AML cell line, DCOne. This cell-line based approach aims to circumvent the existing challenges encountered by patient-derived treatments by allowing for scalable, centralised manufacturing that may facilitate more timely and wider patient access. As vididencel is a non-individualised therapy, it could potentially benefit from shorter production and 'vein-to-vein' times compared to those currently observed for personalised cell therapies. Mendus has now engaged with Minaris, a global contract manufacturing organisation specialising in cell-therapy scale up, to support the clinical and

commercial-scale production of vididencel. With these potential logistical advantages, and provided vididencel can continue to demonstrate a durable clinical and safety profile, we believe there is significant potential for Mendus's lead asset to differentiate itself in the AML maintenance treatment market.

Further positive results may heighten interest

The re-emergence of cancer vaccine technology has seen the signing of notable licensing deals in recent years, Exhibit 4. In our view, a comparable deal of note is the worldwide licensing agreement signed in 2020 between Roche and Nykode worth up to $715m in upfront and milestone payments for the Scandinavian biotech's personalised cancer vaccine, VB10.NEO. At the time of the agreement, VB10.NEO was in the Phase I portion of a Phase I/II basket trial that included patients with advanced or metastatic melanoma, non-small cell lung carcinoma, clear renal cell carcinoma urothelial cancer or squamous cell carcinoma of the head and neck. The study is ongoing, and Roche will assume full development responsibilities after the conclusion of the Phase I arm of the trial. However, we acknowledge the upfront payment of $200m received by Nykode is at the upper end of the industry average.

In our view, should vididencel continue to demonstrate positive results in the clinic it may significantly enhance the asset's value and potential deal value that could be commanded from future licensing opportunities. Additionally, vididencel is being investigated in ovarian cancer and the broader application may add further value to the asset in the eyes of potential licensing partners.

Exhibit 4: Comparison oncology vaccine and immunotherapy licensing deals

Phase	Date	Licensee/partner	Licensor	Product	Upfront milestone payments ($m)	Total potential deal value ($m)
Phase I	20/10/2022	Roche	Hookipa	HB-700	40	970
Phase III**	07/12/2020	3D Medicines	Sellas Life Sciences	Zeltherva	8	202
Phase I	01/10/2020	Roche	Nykode	VB10.NEO	200	715
Phase II	18/11/2019	Fosun	Mimivax	SurVaxM	10	148
Preclinical	02/08/2016	Amgen	Advaxis	ADXS-NEO	40	540
Phase II*	10/08/2015	AstraZeneca	Inovio Pharmaceuticals	INO-3112	28	728
Phase III*	03/04/2015	Bristol Myers Squibb	Bavarian Nordic	Prostvac	60	975
Median					40	715

Source: EvaluatePharma, Edison Investment Research. Note: *Deal subsequently terminated. **Deal includes Greater China only.

Financials and valuation

As we had previously anticipated, in May 2023 Mendus drew down the remaining SEK15.0m shareholder loan (6% interest) from Van Herk Investments, meaning the company has now utilised the full SEK50m financing facility. As part of the new loan agreement, the end dates of the previous loans, the initial SEK10.0m two-year loan and subsequent SEK25.0m one-year loan, have been amended and the entirety of the SEK50m loan is now due by end-FY23. While refinancing of the loan could be a potential option, in the absence of additional funding opportunities, Mendus may need to further access the SEK195.0m convertible debt facility from Negma Group to pay off the outstanding current debt. This may provide an immediate source of financing for the company; however, we note that the convertible debt facility has the potential to be highly dilutive for shareholders. Mendus had previously accessed the Negma facility for an amount of SEK13.7m; however, subsequent conversions between 27 January 2023 and 4 April 2023 saw the company's stock price fall by c 60% over this period.

Our forecasts and valuation, described in our prior note, are unchanged.

Exhibit 5: Financial summary

Accounts: IFRS; Year end 31 December; SEK000s	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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