EDISON

IRLAB Therapeutics

FY22 results

Don’t count mesdopetam out

Pharma and biotech

IRLAB Therapeutics has reported its full-year results for 2022, providing both a financial and an operational update of its active clinical and preclinical assets. The Phase IIb study of lead clinical asset, mesdopetam, in Parkinson’s disease levodopa-induced dyskinesias (PD-LIDs) has now concluded, with IRLAB’s licensing partner, Ipsen, assuming control of the drug’s development. IRLAB’s near-term catalysts for the company include the initiation of Phase I studies for IRL757 and IRL942 (Phase I ready in H223 and H124, respectively), and top-line readouts for pirepemat in the Phase IIb study in PD-Falls in H124. At end-Q422, IRLAB had net cash of SEK252.8m, which, at our estimated cash burn rates, we expect will fund operations into H224. Considering the recent results of the mesdopetam Phase IIb study, which failed to meet the primary endpoint, we have adjusted our valuation of IRLAB to SEK4.84bn or SEK93.3/share (previously SEK6.72bn or SEK129.8/share), although the valuation per share would reduce to SEK35.9 assuming our projected financing needs (SEK750m) are met via a share issuance at the current market price.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/21	207.9	91.1	1.76	0.0	N/A	N/A
12/22	61.3	(113.1)	(2.18)	0.0	N/A	N/A
12/23e	0.2	(160.0)	(3.08)	0.0	N/A	N/A
12/24e	0.2	(168.4)	(3.25)	0.0	N/A	N/A

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

Mesdopetam’s future lies with Ipsen

Following the conclusion of the Phase IIb PD-LIDs study, Ipsen is now responsible for all future clinical development of mesdopetam. With the trial failing to meet its primary objective, there remains uncertainty around Ipsen’s plans for mesdopetam. However, we note that the study did meet a key secondary efficacy endpoint, demonstrating significant dose dependent anti-dyskinetic effects, which, in our view, highlights the drug’s potential application in PD-LIDs.

Funding into FY24 past catalysts

IRLAB reported a net cash position of SEK252.8m at end-Q422, which we forecast will provide a cash runway for the company into H224. We estimate that IRLAB will need to raise SEK750m to fund operations to end-FY27 before reaching operating profitability in FY28. We estimate the company has sufficient cash past key readouts from the Phase IIb pirepemat study in PD-related falls (PD-Falls) in H124.

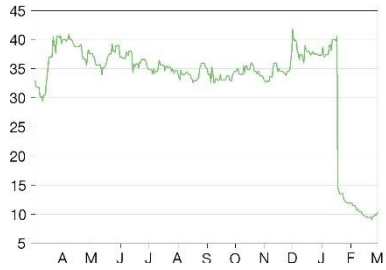
Valuation: SEK4.84bn or SEK93.3/share

We value IRLAB at SEK4.84bn or SEK93.3 per share (previously SEK6.72bn or SEK129.8 per share). Our valuation is adjusted as we reduce the probability of success for mesdopetam in PD-LIDs to 40%, from 50%. Furthermore, we have adjusted our timeline assumptions for mesdopetam and pirepemat following the announcement of slower patient enrolment in this drug’s PD-Falls study.

2 March 2023

Price	**SEK10.38**
Market cap	**SEK538m**
	US$/SEK10.41
Net cash (SEKm) at 31 December 2022 (ex-lease liabilities)	252.8
Shares in issue	51.9m
Free float	58%
Code	IRLABA
Primary exchange	Nasdaq Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(12.9)	(75.1)	(69.2)
Rel (local)	(12.6)	(76.2)	(69.0)
52-week high/low	SEK41.75	SEK9.05	

Business description

Based in Sweden, IRLAB Therapeutics is focused on developing novel drugs for the treatment of neurodegenerative diseases utilising its ISP technology platform. Its two lead assets are in late-stage clinical trials for the symptomatic treatment of Parkinson’s disease (PD): mesdopetam (D3 antagonist) and pirepemat (PFC enhancer).

Next events

IRL757 Phase I ready	H223
Top-line Phase IIb pirepemat data in PD-Falls	H124

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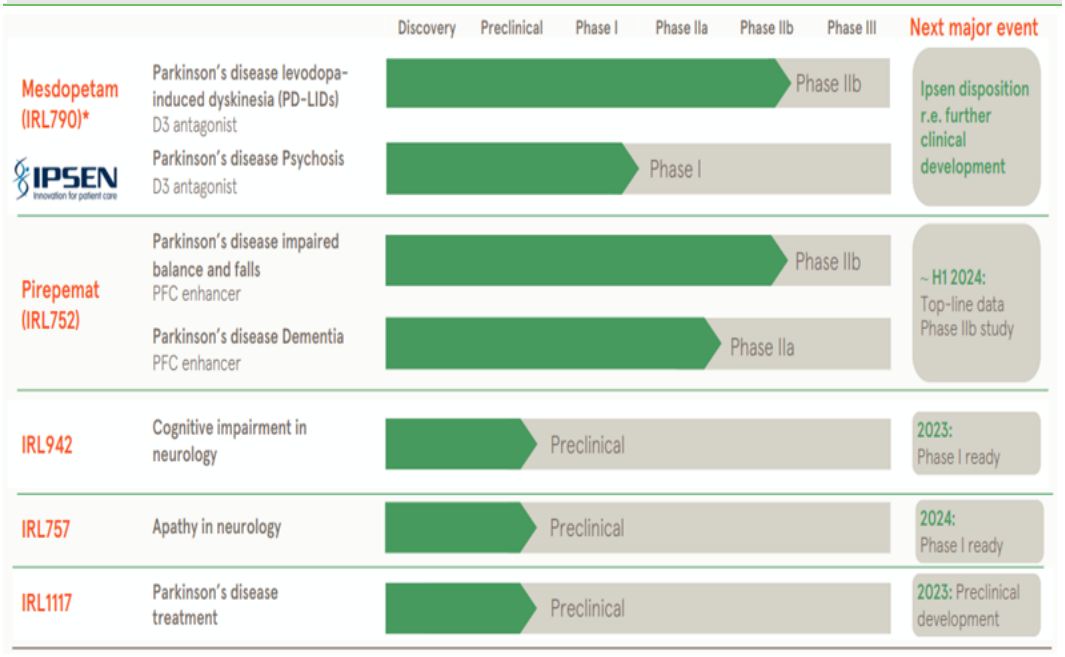
Edison profile page

An active pipeline with new assets on the horizon

Following the top-line results from the Phase IIb mesdopetam study in PD-LIDs, we await further communication of the full clinical data package from the trial before understanding Ipsen's future clinical development strategy for the drug. This may include Ipsen continuing to progress mesdopetam through clinical studies or potentially handing the drug back to IRLAB, which may internally develop mesdopetam or seek alternative partnering opportunities. Pirepemat now becomes IRLAB's most advanced candidate for internal development, as a potential treatment to improve balance and reduce falls in PD patients (PD-Falls). Following a recent update, top-line Phase IIb data are now expected in H124 (previously H223). IRLAB is also looking to re-stock its clinical pipeline and is preparing its preclinical assets, IRL757 in apathy and IRL942 in cognitive function, to be Phase I ready by end-2023 and in H124, respectively. The newly nominated candidate IRL1117 (for the hallmark symptoms of PD) will continue to progress through in-house R&D activities during 2023.

Exhibit 1: IRLAB Therapeutics' clinical pipeline



Source: IRLAB corporate presentation

Mesdopetam Phase IIb results

As a reminder, the Phase IIb study for mesdopetam in PD-LIDs was a randomised, double-blind, placebo-controlled study conducted at 46 trial sites across Europe, the United States and Israel that comprised 154 patients. The primary outcome from the study assessed the change in daily hours of good ON time without troublesome dyskinesia (uncontrolled involuntary movements) based on Hauser standardised 24-hour patient-reported diaries over 12 weeks. ON time represents the time that patients experience the benefits of levodopa to treat the symptoms of PD and is further characterised by good ON time (time without levodopa-induced dyskinesias) and bad ON time (time with levodopa-induced dyskinesias). While management reported that results from the Phase IIb trial confirmed the safety and tolerability of mesdopetam, the study failed to meet its primary objective of change in daily hours of good ON time compared to placebo.

However, the study did meet a secondary efficacy endpoint, demonstrating significant dose dependent anti-dyskinetic effects as measured by the Unified Dyskinesia Rating Scale (UDysRS), a clinically recognised scale for measuring dyskinesias versus placebo. Anti-dyskinetic effects were observed across the entire 12-week study period and may be interpreted as being of statistical significance (nominal p-value = 0.026 at 7.5mg bid at 12 weeks). Additionally, the secondary endpoint (MDS-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) part II), used to measure the motor aspects of experiences of daily living, was unchanged by mesdopetam treatment versus placebo, demonstrating that the drug does not impair normal motor function. Notably, a decrease in daily hours spent in OFF time was dose-dependent and a decrease compared to placebo was observed at the 7.5mg dose of mesdopetam. OFF time is when patients experience PD motor/non-motor symptoms between doses of levodopa treatment. OFF time may occur before the first daily dose of medication or during the day between treatment doses. The decrease in OFF time observed through mesdopetam treatment is therefore indicative of the drug's ability to alleviate the symptoms of parkinsonism. IRLAB intends to present further comprehensive data from the Phase IIb mesdopetam study during 2023.

Secondary endpoint highlights potential anti-dyskinetic effects

While the Phase IIb study failing to meet its primary endpoint may be seen as disappointing, we believe encouragement can be taken from the trial meeting the UDysRS secondary efficacy measure. As measured by the UDysRS, mesdopetam (7.5mg) displayed positive dose dependent anti-dyskinetic effects with onset of action after four weeks, at eight weeks and then continuing for the duration of the 12-week study. Importantly, the clear dose response pattern observed versus placebo from the study, in our view, further strengthens the argument that mesdopetam has an anti-dyskinetic effect during the ON phases for PD treatment. Notably, the approval for amantadine (Gocovri), currently the only FDA-approved treatment for PD-LIDs, was based on the results of two pivotal Phase III studies (EASE LID and EASE LID 3), both of which used the UDysRS measure as the primary efficacy endpoint. Additionally, unlike mesdopetam, amantadine is associated with severe side effects including peripheral edema, falls, suicidality and depression.

However, we caution against direct read-across between clinical trials and note that in IRLAB's previous Phase IIa trial of mesdopetam no improvement in PD-LIDs was observed using the UDysRS measurement as the primary outcome of the study. Management had attributed this to technical shortcomings of the Phase IIa study (many patients were not in the required ON state during UDysRS assessment), indicating that for the Phase IIb study sites had been carefully selected based on their experience in assessing subjects using the UDysRS scale. Additionally, as the results of the Phase IIb study were underpinned by patient reported outcomes, IRLAB had put additional effort into educating patients on the differences between impairments due to dyskinesias as opposed to impairments due to parkinsonism.

In our view, these latest results highlight the challenges associated in measuring endpoints to assess improvements in PD and LIDs in clinical trials. Patient- and clinician-completed rating scales such as UDysRS, MDS-UPDRS and patient diaries are somewhat subjective in comparison to more definitive clinical objective endpoints and can be less accurate and subject to recall bias. Furthermore, an actual reduction in the frequency of LIDs may not reflect a patient's perception of the severity of dyskinesia or their level of disability. However, the use of multiple clinical trial endpoints, such as those utilised in IRLAB's studies, may help mitigate some of the challenges associated with subjective measurements.

Ipsen assumes control of mesdopetam development

In July 2021, IRLAB licensed mesdopetam's global rights to Ipsen for an upfront payment of US$28m, up to US$335m in potential milestones and low double-digit royalties on sales. As part of

the agreement, IRLAB was to fund development of mesdopetam until the top-line results of the Phase IIb after which Ipsen would assume responsibility for all further clinical development and global commercialisation of mesdopetam in PD-LIDs. The latest results from the Phase IIb study will undoubtedly have an impact on Ipsen's development strategy for mesdopetam as well as the timing and receipt of potential milestone payments to IRLAB. Ipsen had begun preparatory Phase III activities with the initiation of pharmacological studies; however, we await further communication from the company as to its future plans for the drug.

Not all about primary endpoints in CNS

While we caution against read across between drug clinical outcomes, particularly across indications, a notable therapy in the CNS space that recently received FDA approval (using the accelerated approval pathway) was Biogen and Eisai's (originator BioArctic) anti-amyloid Alzheimer's disease (AD) therapy, lecanemab. The drug is being widely regarded as one of the most significant clinical breakthroughs in the AD treatment landscape. However, lecanemab had previously missed its primary efficacy endpoint measurement of 12-month clinical change on the Alzheimer's Disease Composite Score (ADCOMS) as part of a Phase IIb study. However, the trial did meet a key secondary endpoint as measured by the Clinical Dementia Rating-Sum-of-Boxes (CDR-SB) exhibiting cognitive and functional performance. The secondary CDR-SB measure was subsequently used as the primary endpoint in the pivotal Clarity AD study, which formed the basis of the FDA's approval for the drug.

Based upon the results of the Phase IIb mesdopetam study, in our view, mesdopetam is in a strong position to potentially progress into pivotal Phase III trials without additional clinical studies, having hit its key, clinically recognised secondary endpoint, a dose dependent anti-dyskinetic effect as measured by the UDysRS scale. Supporting this, mesdopetam has also demonstrated safety and tolerability throughout clinical studies, while also meeting an additional key secondary endpoint with an unchanged measurement in the MDS-UPDRS part II scale.

Next catalyst: Pirepemat in PD-related falls

Following the readout of the Phase IIb mesdopetam study, pirepemat becomes IRLAB's most advanced, active, internally developed clinical asset. Pirepemat is currently being investigated in clinical trials as the first potential treatment in a new drug class designed to improve balance and reduce falls in PD patients (PD-Falls). The Phase IIb study is a randomised, double-blind, placebo-controlled study that aims to recruit 165 patients across five European countries, and the trial is currently active at 28 of the planned 39 trial sites. The primary outcome measure is a change in the frequency of falls with pirepemat (assessing two different dose levels) when compared to placebo, assessed with the fall diary from the baseline period to the end of the planned 12 weeks of treatment.

As a reminder, pirepemat demonstrated early signs of efficacy in PD-Falls in the randomised, double-blind, placebo-controlled, multi-centre Phase IIa study (n=32) evaluating safety and tolerability as the primary endpoint. In addition to the trial meeting its primary outcome of safety, the study also demonstrated preliminary signs of efficacy with a 50% reduction in fall frequency of patients with PD and was well tolerated at clinically relevant doses (600mg). In a recent update on upcoming development milestones, IRLAB reported that patient enrolment for the Phase IIb pirepemat study has been slower than anticipated. The company now expects recruitment to be completed by end-2023, with top-line results in H124 (previously H223).

Re-stocking the clinical pipeline in 2023

In addition to its lead assets, IRLAB also intends to fill its clinical pipeline with the initiation of a further two Phase I studies. The candidates, IRL757 for the treatment of apathy and IRL942 for the improvement of cognitive function, are expected to be Phase I ready by end-2023 and in H124, respectively. Apathy is a common neuropsychiatric symptom in patients with degenerative neurological disorders that can affect up to 70% of patients with PD and up to 90% of patients with AD disease. There are currently no FDA-approved drugs for the treatment of apathy. Additionally, management has stated that IRL942 may potentially have both symptomatic and disease-modifying effects to improve cognitive function in neurological disorders. In our view, there remains a need for the development of novel disease-modifying therapies in central nervous system indications, and those drugs that can demonstrate such properties will offer significant differentiation in the market.

IRLAB also intends to progress development of its newly nominated clinical candidate IRL117 in 2023. The drug is being developed as a once-daily therapy for the hallmark symptoms of PD and intends to overcome side effects associated with levodopa, which include short duration of drug action and motor fluctuations. Preclinical studies have demonstrated that IRL117 induces a sustained response (10 hours) with no reported treatment-related complications. Such attributes would offer significant differentiation over existing levodopa treatment if replicated in human trials. Management has communicated that it expects Phase I studies to commence in 2024.

Fresh management to navigate the road ahead

In February 2023, IRLAB announced a change in management, with the company's CEO, Richard Godfrey, stepping down with immediate effect. Gunnar Olsson, who was chairman of the board for IRLAB, will act as interim CEO. Gunnar is a licenced physician who has acquired over 30 years of experience in senior leadership positions within the life sciences sector. IRLAB has communicated that it has started the recruitment process for a permanent CEO. We do not anticipate the changes to have an impact on any of IRLAB's clinical development timelines.

Valuation

Considering the latest data from the mesdopetam Phase IIb study, we have adjusted our valuation of IRLAB to SEK4.84bn or SEK93.3per share (previously SEK6.72bn or SEK129.8 per share). Our valuation is based on a risk-adjusted NPV calculation for the company's lead clinical assets mesdopetam and pirepemat (applying a 12.5% discount rate) and reflects a net cash position of SEK252.8m at end-December 2022. A breakdown of our rNPV valuation is shown in Exhibit 2.

Exhibit 2: IRLAB rNPV valuation

Product	Launch	Peak	Peak sales ($m)	Value (SEKm)	Probability	rNPV (SEKm)	rNPV/share (SEK)
Mesdopetam – PD-LIDs	2028	2034	1,268.5	5,146.8	40%	2,072.9	40.0
Mesdopetam – PD-Psychosis	2029	2035	493.7	2,258.9	30%	698.1	13.5
Pirepemat – PD-Falls (postural hypotension)	2028	2034	1,062.1	6,117.8	30%	1,815.4	35.0
Net cash at YE22				252.8.0	100%	252.8	4.9
Valuation				**13,776.3**		**4,839.2**	**93.3**

Source: Edison Investment Research

The company's value is reduced as we lower the probability of success for mesdopetam in PD-LIDs to 40% (previously 50%). We maintain the probability of success for mesdopetam in PD-Psychosis and pirepemat in PD-Falls at 30%; however, this is subject to change depending on clinical updates. Ipsen has yet to communicate its plans for mesdopetam's future development in PD-LIDs;

however, we anticipate that mesdopetam's existing data package could potentially mean the drug is a Phase III ready asset that has some measure of statistically significant efficacy, based on the Phase IIb study, and is likely suitable to progress into pivotal, registrational trials at this stage. Additionally, Ipsen has acquired the rights to mesdopetam in PD-Psychosis. However, there has been little commentary on Ipsen's clinical development strategy for mesdopetam in this indication, for which we had previously anticipated the initiation of Phase II studies in 2022 or 2023. Altogether, we have therefore delayed our estimated potential launch dates for mesdopetam in PD-LIDs to 2028 (previously 2026) and in PD-Psychosis to 2029 (previously 2027). These changes to our assumptions have also pushed out the potential receipt of developmental and commercial milestone payments attributed to the Ipsen deal, which are factored into our model.

Following IRLAB's announcement that patient enrolment in the Phase IIb pirepemat study in PD-Falls has been slower than anticipated, we have also delayed our estimated launch date for pirepemat to 2028 (previously 2027). We have not included IRL757, IRL942 or IRL117 in our model; however, once clinical studies have been initiated, this may provide additional value uplift.

Financials

In 2022 IRLAB reported operating losses of SEK113m, which contrasts with the operating profit the company reported in FY21 of SEK53m. This difference is attributed to IRLAB's licensing agreement with Ipsen in July 2021, which included an upfront payment of SEK239.6m. IRLAB recognised revenue of SEK61.2m in FY22, consisting of SEK42.6m of deferred income as part of the Ipsen deal and SEK18.6m in other services provided to Ipsen. The company's operating expenses for FY22 were SEK174.4m, a 12.2% increase from FY21's figure of SEK155.3m due to the increased clinical activities of the Phase IIb trials for mesdopetam and pirepemat. IRLAB's operational costs remained relatively stable between Q222 and Q422, at c SEK40m per quarter. Due to the winding down of the Phase IIb mesdopetam study, we expect R&D costs to reduce slightly in FY23, to SEK132m, while the Phase IIb pirepemat trial continues to enrol patients and the company invests in preclinical development and progressing IRL757, IRL942 and IRL117 towards clinical studies. We then estimate R&D costs to rise again in FY24, to SEK141m, with the anticipated initiation of the Phase I trials of IRL757 and IRL942.

Operating cash outflows for 2022 amounted to SEK142.6m and IRLAB ended 2022 with a net cash position of SEK252.8m, which we estimate should fund operations into H224. We estimate operating cash outflows of SEK155.9m in FY23, which will increase to SEK165.3m in FY24. We estimate that IRLAB will need to raise SEK750m before becoming self-sustainable in FY28 with the projected launches of mesdopetam and pirepemat. We account for this funding as illustrative debt in our model and have distributed the raise (SEK250m per year) across three consecutive years from FY24 to FY26. Alternatively, if funding is realised through an equity issue instead (assuming at the current trading price of SEK10.38/share), IRLAB would have to issue 82.9m shares, resulting in our per share valuation decreasing to SEK35.9 from SEK93.3 currently (shares outstanding would increase from 51.9m to 134.8m). As part of IRLAB's licensing agreement with Ipsen for mesdopetam, the company could potentially receive up to US$335m in development, regulatory and sales-based milestones, which would have an impact on such financing requirements. However, due to the Phase IIb mesdopetam study missing its primary endpoint, the timings of such payments are uncertain.

Exhibit 3: Financial summary

Accounts: IFRS; year end 31 December; SEK000s	2020	2021	2022	2023e	2024e
PROFIT & LOSS					
Total revenues	404	207,906	61,277	223	163
Cost of sales	0	0	0	0	0
Gross profit	404	207,906	61,277	223	163
Total operating expenses	(91,862)	(155,330)	(174,386)	(160,141)	(168,548)
Research and development expenses	(75,989)	(129,748)	(146,178)	(132,083)	(141,042)
EBITDA (reported)	(89,202)	56,050	(108,330)	(157,697)	(165,654)
Operating income (reported)	(91,458)	52,576	(113,109)	(159,918)	(168,385)
Operating margin %	N/A	N/A	N/A	N/A	N/A
Finance income/(expense)	(195)	(795)	(297)	(85)	(4)
Exceptionals and adjustments	0	0	0	0	0
Profit before tax (reported)	(91,653)	51,781	(113,406)	(160,003)	(168,389)
Profit before tax (normalised)	(91,394)	91,131	(113,147)	(160,003)	(168,389)
Income tax expense (includes exceptionals)	0	0	0	0	0
Net income (reported)	(91,653)	51,781	(113,406)	(160,003)	(168,389)
Net income (normalised)	(91,394)	91,131	(113,147)	(160,003)	(168,389)
Basic average number of shares, m	47.7	51.7	51.8	51.9	51.9
Basic EPS (SEK)	(1.92)	1.00	(2.19)	(3.08)	(3.25)
Adjusted EPS (SEK)	(1.92)	1.76	(2.18)	(3.08)	(3.25)
Dividend per share (SEK)	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET					
Tangible assets	4,317	8,348	8,009	5,789	3,057
Intangible assets	82,010	42,661	46,862	46,862	46,862
Other non-current assets	0	0	0	0	0
Total non-current assets	86,327	51,009	54,871	52,651	49,919
Cash and equivalents	277,009	401,897	252,776	96,848	431,515
Inventories	0	0	0	0	0
Trade and other receivables	6,732	19,543	15,908	15,908	15,908
Other current assets	0	0	0	0	0
Total current assets	283,741	421,440	268,684	112,756	447,423
Non-current loans and borrowings	0	0	0	0	500,000
Non-current lease liabilities	1,270	3,566	381	381	381
Other non-current liabilities	0	0	0	0	0
Total non-current liabilities	1,270	3,566	381	381	500,381
Accounts payable	3,683	4,634	4,634	6,490	6,814
Non-current loans and borrowings	0	0	0	0	0
Current lease liabilities	1,657	3,034	3,595	3,595	3,595
Deferred Income	0	42,576	0	0	0
Other current liabilities	15,578	19,158	24,114	24,114	24,114
Total current liabilities	20,918	69,402	32,343	34,199	34,523
Equity attributable to company	347,880	399,481	290,830	130,827	(37,562)
CASH FLOW STATEMENT					
Operating income	(91,458)	52,576	(113,109)	(159,918)	(168,385)
Depreciation and amortisation	2,256	3,474	4,779	2,220	2,731
Share based payments	0	0	0	0	0
Other adjustments	(195)	38,295	(297)	(85)	(4)
Movements in working capital	183	34,296	(33,985)	1,856	324
Cash from operations (CFO)	(89,214)	128,641	(142,612)	(155,927)	(165,333)
Capex	(394)	(708)	(2,876)	0	0
Acquisitions & disposals net	0	0	(500)	0	0
Other investing activities	0	0	0	0	0
Cash used in investing activities (CFIA)	(394)	(708)	(3,376)	0	0
Net proceeds from issue of shares	257,706	(180)	0	0	0
Movements in debt	(1,616)	(2,865)	(3,134)	0	500,000
Other financing activities	0	0	0	0	0
Cash from financing activities (CFF)	256,090	(3,045)	(3,134)	0	500,000
Cash and equivalents at beginning of period	110,527	277,009	401,897	252,775	96,848
Increase/(decrease) in cash and equivalents	166,482	124,888	(149,122)	(155,927)	334,667
Effect of FX on cash and equivalents	0	0	0	0	0
Cash and equivalents at end of period	277,009	401,897	252,775	96,848	431,515
Net (debt)/cash	277,009	401,897	252,776	96,848	(68,485)

Source: IRLAB company accounts, Edison Investment Research

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