EDISON

IRLAB Therapeutics

Pirepemat stumbles in Phase IIb study

Clinical update

Healthcare

6 March 2025

IRLAB has announced top-line results for its Phase IIb trial assessing pirepemat's potential to improve balance and reduce falls in Parkinson's disease (PD-Falls). The primary endpoint was the change in patients' fall rates, and while the high-dose 600mg group showed a 42% reduction, the effect was not statistically significant compared to placebo. A meaningful improvement in cognitive impairment was also observed in the 600mg group, although this did not achieve statistical significance either. IRLAB will conduct a detailed review of the study data before making a decision on next steps for the programme. Reflecting the increased uncertainty, and pending release of the full data set, we have reduced our probability of success (PoS) for pirepemat to 10% (from 30% previously) and pushed out the expected launch timeline by a year, to 2030. Our valuation resets to SEK3.3bn or SEK63.3/share (from SEK5.0bn or SEK97.1/share previously).

Year end	Revenue (SEKm)	PBT (SEKm)	EPS (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/23	5.7	(177.8)	(3.43)	0.00	N/A	N/A
12/24	114.1	(83.1)	(1.60)	0.00	N/A	N/A
12/25e	20.9	(145.0)	(2.80)	0.00	N/A	N/A
12/26e	32.6	(144.0)	(2.78)	0.00	N/A	N/A

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

Setback for the pirepemat programme

While a 42% reduction in falls for the 600mg group may be interpreted as somewhat meaningful, we believe that a notably strong placebo effect prevented it from being classed as statistically significant and warrants further investigation. The pirepemat treatment was associated with an improvement in cognitive functions, which may provide opportunities for subsequent development efforts. However, the programme's prospects will be contingent on IRLAB's analysis of the full data. We await full disclosure of the detailed results, which will be published in abstracts at future scientific congresses and publications in scientific journals.

Shift of focus to other clinical programmes

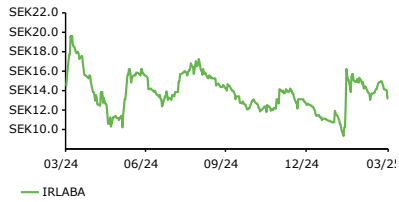
The pirepemat results are likely to bring heightened scrutiny of IRLAB's remaining clinical programmes, mesdopetam (PD-LIDs) and IRL757 (apathy). We also expect the company to focus on accelerating development work on its preclinical programmes, IRL1117 (a once-daily PD treatment) and IRL942 (for cognitive impairment) and perhaps aim to expand its collaboration on the Phase I candidate, IRL757, which has reported encouraging early safety data. The recent financing has secured the runway likely into Q425, although the short maturity and high servicing costs mean that securing a partnership for mesdopetam ahead of pivotal Phase III studies (planned within 2025) will take on increased importance.

Valuation: SEK3.3bn or SEK63.3 per share

Given the top-line Phase IIb data from the REACT-PD study, and pending the release of the full dataset, we reduce our PoS for pirepemat to 10%, from 30% previously, and extend the launch timeline to 2030 (from 2029 previously). Our valuation resets to SEK3.3bn or SEK63.3/share (from SEK5.0bn or SEK97.1/share).

Price	**SEK4.55**
Market cap	**SEK236m**
	SEK10.20/US$
Net cash at 31 December 2024 (including lease liabilities)	SEK6.5m
Shares in issue	51.8m
Free float	61.5%
Code	IRLABA
Primary exchange	OMX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(11.4)	4.8	(10.5)
52-week high/low		SEK20.2	SEK8.7

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: mesdopetam (D3 antagonist) and pirepemat (PFC enhancer).

Next events

IRL757: Phase I results	Q125
Mesdopetam: Phase III launch (projected)	2025

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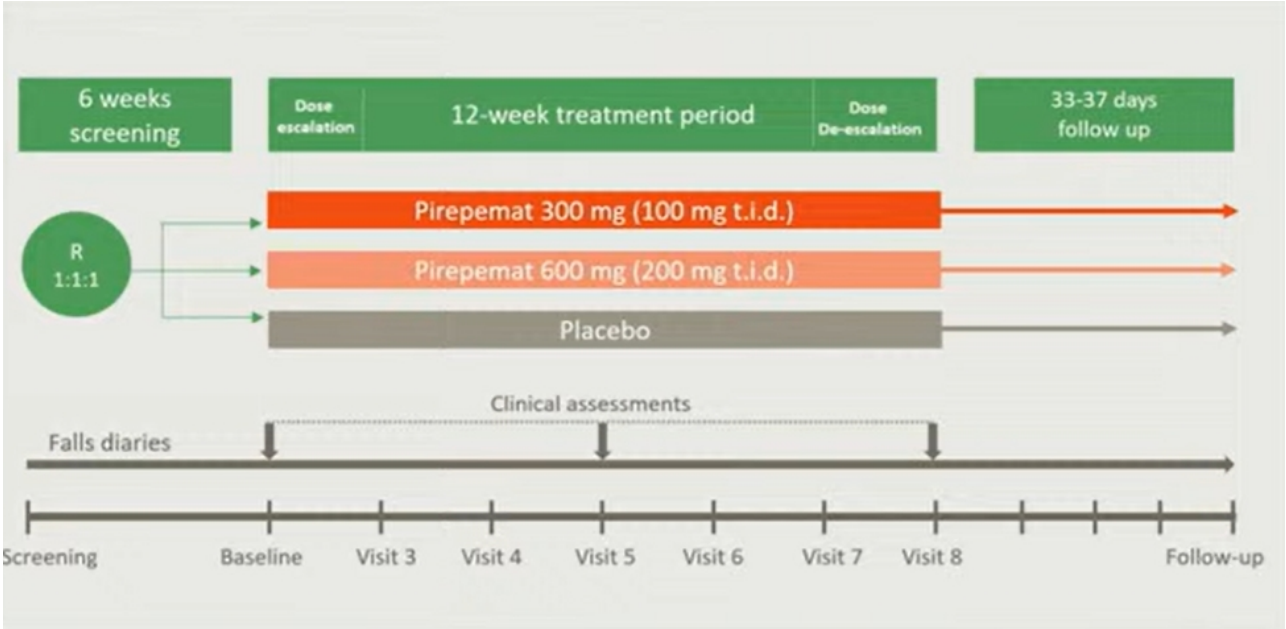
Valuation

The Phase IIb REACT-PD study randomised 104 patients (146 patients screened) across three arms (pirepemat 600mg, pirepemat 300mg and placebo), of which 90 patients completed the 12-week study (Exhibit 1). The company has reported that, while the 600mg arm showed a 42% reduction in falls, the results were not statistically significant. For the secondary endpoint (improvement in cognitive impairment), while the high-dose arm saw a meaningful improvement on the Montreal Cognitive Assessment scale, the results again were not statistically significant. 70% of the patients witnessed adverse events, although these were similar across the three arms and were mostly related to headaches and dizziness.

Exhibit 1: REACT-PD study design



Source: IRLAB corporate presentation

We are somewhat surprised with the conclusions from the Phase IIb REACT-PD study for pirepemat, as a 42% reduction in fall rate (as seen in the high-dose 600mg arm) would typically be considered meaningful. IRLAB has communicated this to be due to the strong placebo effect, which was materially higher than what has been seen in past studies. We believe further analysis and investigation of the data is warranted given these observations and management expects to present the full data analysis in the next couple of months. Given that the study was also unable to show statistical significance in the secondary endpoint, we foresee a challenging path ahead for the company's second-most clinically advanced asset.

While we do not rule out the possibility of further commercial opportunities for pirepemat, pending disclosure of the complete data set, we make material adjustments to our PoS for the drug, reducing it to 10%, from 30% previously. Moreover, given the additional time required for analysing the Phase IIb data, we have extended the anticipated launch timeline by one year, to 2030, from 2029 previously. Following these changes, our valuation for IRLAB adjusts to SEK3.3bn or SEK63.3/share (from SEK5.0bn or SEK97.1/share previously). If we were to assume no further development work on the asset, the valuation would reset to SEK2.7bn or SEK52.4/share. Our revised valuation for IRLAB is presented in Exhibit 2.

Exhibit 2: IRLAB Therapeutics rNPV valuation

Product	Indication	Launch	Peak	Peak sales ($m)	Value (SEKm)	Probability	rNPV (SEKm)	rNPV/share (SEK)
Mesdopetam	PD-LIDs	2028	2034	1,268.5	5,395.4	40%	2,158.2	41.6
Mesdopetam	PD-Psychosis	2032	2038	726.5	1,271.0	20%	225.3	4.3
Pirepemat	PD-Falls (postural hypotension)	2030	2035	1,078.3	5,640.4	10%	564.0	10.9
IRL757	Apathy (PD & AD)	2031	2037	2,305.7	4,385.2	7.5%	328.9	6.3
Net cash at 31 December 2024					6.5	100%	6.5	0.1
Valuation					**16,698.5**		**3,282.9**	**63.3**

Source: Edison Investment Research

We note that IRLAB recently raised SEK22.4m in shareholder loans and renegotiated its repayment terms with Fenja Capital, pushing out the SEK55m loan maturity from May 2025 to 31 December 2025 (with the possibility of extending it to 30 June 2026). According to our calculation, this has allowed the company to extend its cash runway into Q325, from Q125 previously. The new terms with Fenja include an option to secure another SEK20m in loans, contingent on certain predefined conditions being met. This would allow the company to secure another three months of runway, although it is unclear whether the latest pirepemat data would affect this clause. Given the funding situation, we believe that securing a partnering agreement for mesdopetam in the new few months is of crucial importance to IRLAB.

For a more detailed discussion of IRLAB's ongoing activities, we direct readers to our prior update note, published following the company's FY24 results.

Exhibit 3: Financial summary

Accounts: IFRS, Yr end: December 31, SEK000s	2022	2023	2024	2025e	2026e
PROFIT & LOSS					
Total revenues	61,277	5,720	114,083	20,945	32,640
Cost of sales	0	0	0	0	0
Gross profit	61,277	5,720	114,083	20,945	32,640
Total operating expenses	(174,386)	(186,486)	(189,194)	(162,294)	(168,377)
Research and development expenses	(146,178)	(151,312)	(163,669)	(120,000)	(130,000)
EBITDA (reported)	(108,330)	(176,450)	(70,528)	(137,225)	(132,025)
Operating income (reported)	(113,109)	(180,766)	(75,111)	(141,349)	(135,737)
Operating margin %	N/A	N/A	N/A	N/A	N/A
Finance income/(expense)	(297)	2,927	(8,018)	(3,636)	(8,288)
Exceptionals and adjustments	0	0	0	0	0
Profit before tax (reported)	(113,406)	(177,839)	(83,129)	(144,986)	(144,025)
Profit before tax (normalised)	(113,147)	(177,839)	(83,129)	(144,986)	(144,025)
Net income (reported)	(113,406)	(177,839)	(83,129)	(144,986)	(144,025)
Net income (normalised)	(113,147)	(177,839)	(83,129)	(144,986)	(144,025)
Basic average number of shares, m	51.8	51.9	51.9	51.9	51.9
Basic EPS (SEK)	(2.19)	(3.43)	(1.60)	(2.80)	(2.78)
Adjusted EPS (SEK)	(2.18)	(3.43)	(1.60)	(2.80)	(2.78)
Dividend per share (SEK)	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET					
Tangible assets	8,009	6,671	9,793	5,968	2,556
Intangible assets	46,862	46,862	46,862	46,862	46,862
Total non-current assets	54,871	53,533	56,655	52,830	49,418
Cash and equivalents	252,776	111,309	66,917	26,854	36,241
Trade and other receivables	15,908	12,278	12,641	2,641	2,641
Total current assets	268,684	123,587	79,558	29,495	38,882
Non-current loans and borrowings	0	24,511	0	148,466	298,466
Non-current lease liabilities	381	115	3,536	3,053	3,053
Total non-current liabilities	381	24,626	3,536	151,519	301,519
Current loans and borrowings	0	0	53,466	0	0
Current lease liabilities	3,595	2,940	3,419	0	0
Other current liabilities	28,748	33,792	43,156	43,156	43,156
Total current liabilities	32,343	36,732	100,041	43,156	43,156
Equity attributable to company	290,830	115,764	32,634	(112,352)	(256,377)
CASH FLOW STATEMENT					
Operating income	(113,109)	(180,766)	(75,111)	(141,349)	(135,737)
Depreciation and amortisation	4,779	4,316	4,583	4,125	3,712
Other adjustments	(297)	2,927	(4,063)	(3,636)	(8,288)
Movements in working capital	(33,985)	8,673	9,001	10,000	0
Cash from operations (CFO)	(142,612)	(164,850)	(65,590)	(130,861)	(140,313)
Capex	(2,876)	(293)	(199)	(300)	(300)
Acquisitions & disposals net	(500)	0	0	0	0
Cash used in investing activities (CFIA)	(3,376)	(293)	(199)	(300)	(300)
Movements in debt	(3,134)	20,905	21,396	91,098	150,000
Other financing activities	0	2,771	0	0	0
Cash from financing activities (CFF)	(3,134)	23,676	21,396	91,098	150,000
Cash and equivalents at beginning of period	401,897	252,776	111,309	66,917	26,854
Increase/(decrease) in cash and equivalents	(149,122)	(141,467)	(44,393)	(40,063)	9,387
Effect of FX on cash and equivalents	1	0	1	0	0
Cash and equivalents at end of period	252,776	111,309	66,917	26,854	36,241
Net (debt)/cash	248,800	83,743	6,496	(124,665)	(265,278)

Source: Edison Investment Research

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