EDISON

IRLAB Therapeutics

Phase I data supports IRL757's development

Clinical update

Healthcare

3 February 2025

IRLAB Therapeutics has reported positive top-line data from one of the two ongoing Phase I clinical trials evaluating its third clinical-stage asset, IRL757, as a potential treatment for apathy. This update corresponds to the study in healthy older adults (>65 years) being conducted in collaboration with the McQuade Center for Strategic Research and Development (MSRD), and the results demonstrate that the candidate can be sufficiently absorbed, providing good exposure in the body. Furthermore, all participants completed the study with no reports of serious adverse events, an encouraging indicator that IRL757 may proceed to the next stages of clinical development, in our view. The second Phase I trial, which is funded by the Michael J Fox Foundation (MJFF), is focused on younger healthy participants and is anticipated to conclude within H125.

Year end	Revenue (SEKm)	PBT (SEKm)	EPS (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/22	61.3	(113.1)	(2.18)	0.00	N/A	N/A
12/23	5.7	(177.8)	(3.43)	0.00	N/A	N/A
12/24e	104.0	(120.8)	(2.33)	0.00	N/A	N/A
12/25e	32.5	(169.9)	(3.27)	0.00	N/A	N/A

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

According to the announcement, the Phase I trial of IRL757 in healthy older adults has concluded, with the company reporting positive top-line results. This study, financed by the MSRD, assessed the pharmacokinetics, safety and tolerability of single ascending oral doses of IRL757 in adults over the age of 65. The results confirmed the interim findings of the other Phase I study in healthy younger adults, showing that IRL757 is well absorbed in the body, providing good systemic exposure, without any serious adverse events, highlighting the favourable safety profile of the candidate.

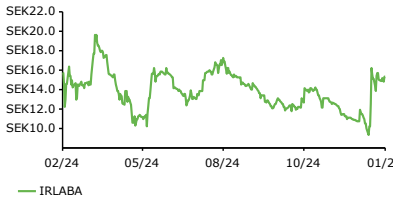
We note that the other Phase I study, funded by a US$2m grant from the MJFF, remains ongoing. This is assessing IRL757 in healthy younger participants with multiple ascending doses, and is due to readout in H125. Provided the results continue to be supportive, the MSRD will support further clinical development efforts through to proof of concept.

IRLAB is developing IRL757 to address apathy in patients with Parkinson's disease (PD) and Alzheimer's disease (AD). Apathy is a symptom characterised by indifference, resignation and a lack of responsiveness. While precise estimates of prevalence vary due to challenges in diagnosis (symptoms overlap with depression), apathy is estimated to affect 20–70% of PD patients and 20–90% of AD patients. We highlight that there are currently no approved drugs specifically targeting apathy and, hence, we believe there is a sizeable opportunity for IRLAB in this space.

IRLAB will present its FY24 results on 12 February 2025. The company has an active pipeline, mainly focused on PD, spanning all stages of clinical development. Key upcoming inflection points include the conclusion of the Phase IIb study for its second clinical asset, pirepemat, which has been designed to improve balance and reduce falls in PD patients; results are expected within Q125. Lead asset mesdopetam aims to address levodopa-induced dyskinesias in PD patients and, subject to securing a partnership agreement, management aims to launch a Phase III trial for the drug in 2025.

Price	**SEK14.75**
Market cap	**SEK774m**
Net cash at 30 September 2024 (including lease liabilities)	SEK30.1m
Shares in issue	51.9m
Code	IRLABA
Primary exchange	OMX
Secondary exchange	N/A

Share price performance



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).

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