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# IRLAB Therapeutics

Clinical study update

## Ipsen confirms commitment with clinical studies

Pharma and biotech

**IRLAB Therapeutics announced that Ipsen, the out-licensing partner for its lead asset, mesdopetam, has commenced standard clinical studies for the drug. These preparatory studies are necessary to progress into Phase III and confirm the arrangement is progressing as planned. The three studies to be conducted on healthy volunteers include a pharmacokinetic, a drug-to-drug interaction and a mass balance study, and will be run in parallel with the ongoing Phase IIb study conducted by IRLAB. As top-line data from Phase IIb are expected around the end of CY22, the data from the Ipsen studies will support the late-stage development of the drug. We maintain our estimates and valuation of IRLAB at SEK6.40bn or SEK123.7 per share.**

| Year end | Revenue (SEKm) | PBT* (SEKm) | EPS* (SEK) | DPS (SEK) | P/E (x) | Yield (%) |
|---|---|---|---|---|---|---|
| 12/20 | 0.4 | (91.4) | (1.92) | 0.0 | N/A | N/A |
| 12/21 | 207.9 | 91.1 | 1.76 | 0.0 | 18.5 | N/A |
| 12/22e | 62.1 | (112.9) | (2.18) | 0.0 | N/A | N/A |
| 12/23e | 0.3 | (122.7) | (2.37) | 0.0 | N/A | N/A |

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

As part of the mesdopetam drug development plan, Ipsen intends to initiate three standard pharmacology studies, including a pharmacokinetic, a drug-to-drug interaction and a mass balance study in healthy participants. These studies will run simultaneously with the in-progress Phase IIb clinical trial, which is managed by IRLAB, and top-line data are expected around the end of CY22. The standard data from these studies are usually required for late-stage drug development and confirm Ipsen's commitment to further studies. The studies are likely to be completed during Q322 and Q123.

As a reminder, mesdopetam is a D3 receptor antagonist being investigated in an ongoing Phase IIb trial for Parkinson's disease (PD-LIDs). 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 will fund the development of mesdopetam until top-line results from the currently ongoing Phase IIb trial are reported.

We note that top-line Phase IIb results will be important in defining Ipsen's Phase III development strategy. These pharmacokinetic studies are part of Ipsen's Phase III preparatory activities for mesdopetam, as announced in the initial licensing agreement. If the data from the Phase IIb study are positive, Ipsen will assume full responsibility for any further development, registration and commercialisation. For IRLAB, the top-line data are the most important near-term event, followed by the top-line readout from the Phase IIb study of pirepemat in the treatment of PD-related falls, which we expect in H223.

**8 September 2022**

| | |
|---|---|
| **Price** | **SEK32.6** |
| **Market cap** | **SEK1820m** |
| | SEK10.73/US$ |
| Net cash (SEKm) at 30 June 2022 (ex-lease liabilities) | 322.6 |
| Shares in issue | 51.7m |
| Free float | 58% |
| Code | IRLABA |
| Primary exchange | Nasdaq Stockholm |
| 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, mesdopetam (D3 antagonist) and pirepemat (PFC enhancer), are in late-stage clinical trials for the symptomatic treatment of Parkinson's disease.

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