EDISON

IRLAB Therapeutics

Ipsen deal de-risks the strategy

Update to mesdopetam

Pharma & biotech

IRLAB Therapeutics has made substantial progress year to date with the mesdopetam (IRL790) global licensing deal with Ipsen. By partnering its lead asset mesdopetam, a D3 antagonist currently in a Phase IIb/III study in Parkinson's disease (PD) patients with levodopa-induced dyskinesias (PD-LIDs), IRLAB has de-risked its strategy. Importantly, IRLAB has the financial flexibility in the near term to focus on Phase II asset, pirepemat, (IRL752) and broadening its clinical portfolio through the development of its preclinical assets (including IRL942 and IRL1009) and its ISP platform technology. We value IRLAB at SEK5.1bn or SEK99.4/share.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/19	0.4	(95.1)	(2.34)	0.0	N/A	N/A
12/20	0.4	(91.4)	(1.92)	0.0	N/A	N/A
12/21e	237.7	129.7	2.51	0.0	N/A	24.1
12/22e	0.4	(137.8)	(2.66)	0.0	N/A	N/A

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

Ipsen a valuable partner with focus on neuroscience

Deal terms include a $28m upfront payment and up to $335m in development and sales milestones, plus double-digit royalties, which are commensurate with assets at this stage of development. Ipsen is a global, mid-sized pharmaceutical company, with a focus on neuroscience as one of its core competencies. It has historically been active in the research quest for PD treatments and will take over all future clinical development and global commercialisation of mesdopetam. Top-line data from the US/EU Phase IIb/III trial in PD-LIDs are expected in H122, and will define the pivotal trials required for approval. The Phase III trial could start in 2023.

Focus now on broadening proprietary pipeline

This deal provides external validation of IRLAB's Integrative Screening Process (ISP) research platform, which discovered mesdopetam and Phase II asset pirepemat. Pirepemat (IRL752) is a first-in-class oral small molecule currently in development for the treatment of postural dysfunction (impaired balance) and falls in PD (PD-Falls), both of which are untapped markets and represent a significant burden on healthcare systems. We expect IRLAB to continue to focus on its core competency of research and development utilising its ISP platform, potentially expanding its discovery efforts beyond PD to include discovery/preclinical compounds for a range of neurological and psychiatric conditions.

Valuation: SEK5.1bn or SEK99.4/share

Our revised valuation is SEK5.1bn or SEK99.4/share from SEK4.8bn or SEK93.3/share previously. We update for mesdopetam deal terms including the $28m upfront payment and assume a 20% royalty rate plus development and sales milestones (PD-LIDs and PD-Psychosis) versus our prior 30% blended royalty rate assumption. Our peak sales are unchanged. We do not include the early-stage portfolio (preclinical assets IRL942 and IRL1009), nor the proprietary ISP platform technology in our valuation. We include reported net cash of SEK253.9m at 31 March 2021 plus the $28m upfront payment from Ipsen.

12 August 2021

Price	**SEK60.6**
Market cap	**SEK3,136m**
	SEK8.47/US$
Net cash (SEKm) at 31 March 2021	253.9
Shares in issue	51.7m
Free float	56%
Code	IRLABA
Primary exchange	NASDAQ Stockholm
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	34.2	54.8	109.7
Rel (local)	27.2	36.3	46.5
52-week high/low	SEK70	SEK28	

Business description

IRLAB Therapeutics is a Scandinavia-based biotechnology company 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

Pirepemat Phase IIb trial initiation	H221
Top-line data from mesdopetam US/EU Phase IIb/III PD-LIDs trial	H122

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Edison profile page

Ipsen a valuable partner at this stage of development

Ipsen is a global pharmaceutical company (market cap: €7.6bn) which focuses on neuroscience as one of its three core drivers. In addition to in-licensing mesdopetam, Ipsen has been active in the neuroscience space for 25 years and has recently expanded its neurodegenerative pipeline further with an exclusive collaboration agreement with US-based Exicure to research, develop and commercialise novel Spherical Nucleic Acids (SNAs) for Huntington's disease and Angelman syndrome. Ipsen currently commercialises more than 20 products globally (FY20 sales of €2.6bn) and has a direct commercial presence in more than 30 countries. Importantly, it has experience in conducting late-stage clinical trials in neurodegenerative conditions, and we believe that mesdopetam could become a priority development candidate. Thus, in our view, this deal makes strategic sense for IRLAB.

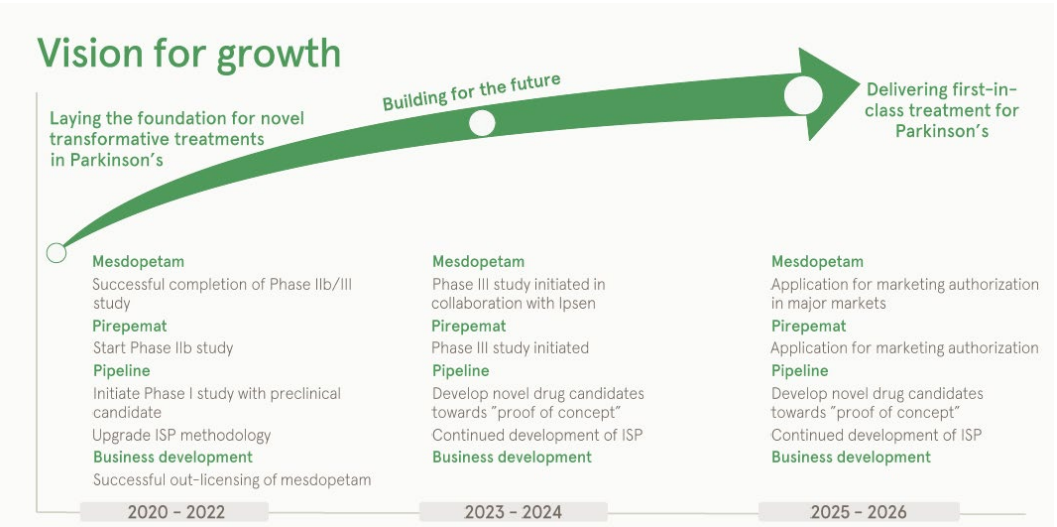
The mesdopetam global licensing agreement with Ipsen is worth up to $363m plus double-digit royalties. IRLAB will receive a $28m upfront payment and is eligible to receive up to $335m in potential development, regulatory and commercial milestones (spread across multiple indications) plus low double-digit tiered royalties on net sales. IRLAB will continue development until the end of the current Phase IIb/III trial in PD patients with PD-LIDs. Ipsen will take over for the Phase III clinical development in PD-LIDs and is responsible for all future clinical development and global commercialisation. Top-line data from the mesdopetam US/EU Phase IIb/III trial in PD-LIDs, expected in H122, will define the pivotal trials required for approval. Depending on the FDA/EMA, the Phase IIb/III study could be supportive of an NDA filing, which means that only one additional Phase III pivotal study would be required before regulatory filings. This means a potential pivotal Phase III study could start in 2023, leading to approval and launch in 2026.

Mesdopetam is also being developed for psychosis in Parkinson's disease (PD-Psychosis), a condition characterised by hallucinations and sometimes delusions. This is a significant unmet medical need that can be debilitating and cause patients to discontinue treatments that may have procognitive effects. IRLAB had planned to initiate a Phase II study in PD-Psychosis in 2022–23, and we now expect Ipsen to start this trial given that preclinical studies have highlighted mesdopetam's potential in psychosis and procognitive effects at the same therapeutic dose at which it is administered for LIDs.

ISP platform receives external validation

The mesdopetam deal with Ipsen validates the ISP technology, IRLAB's unique, proprietary research platform at the heart of its drug discovery engine, which enables the discovery of novel drugs for central nervous system (CNS) related diseases. Other compounds discovered by the ISP platform include pirepemat and preclinical assets IRL942 and IRL1009, which could be developed for psychiatric, cognitive and motor symptoms associated with neurodegenerative diseases and ageing. The platform contains a growing database of almost 1,400 CNS drug-like compounds developed over 25 years. With the development of mesdopetam in Ipsen's hands from the start of designing the Phase III programme, IRLAB can focus on the development of Phase II asset pirepemat, progressing preclinical compounds into clinical studies and the discovery of new molecular entities utilising ISP (Exhibit 1). We note that numerous other biotech and pharmaceutical companies have developed screening platforms, but the ISP platform is unique in combining measurements of both neurochemistry and behaviour through the use of AI-based analytics.

Exhibit 1: IRLAB milestones and catalysts 2020–26e



Source: IRLAB corporate presentation

Valuation

Our revised valuation of SEK5.1bn or SEK99.4/share versus SEK4.8bn or SEK93.3/share reflects the revisions made to our model with regards to mesdopetam. Our updated valuation includes net cash of SEK253.9m (at 31 March 2021) plus the $28m upfront payment from Ipsen, which provides funding in the medium term. It is based on a risk-adjusted NPV model for mesdopetam in PD-LIDs (SEK46.5/share), in PD-Psychosis (SEK14.2/share) and pirepemat in PD-Falls (SEK29.3/share). The breakdown of our NPV valuation, which uses a 12.5% discount rate, is shown in Exhibit 2. We do not include the early-stage portfolio (preclinical assets IRL942 and IRL1009), nor the proprietary ISP platform technology. We see uplift as assets move into clinical development.

Exhibit 2: IRLAB sum-of-the-parts valuation

Product	Indication	Launch	Peak sales ($m)	Value (SEKm)	Probability	rNPV (SEKm)	rNPV/share (SEK)
Mesdopetam	PD-LIDs	2026	1,207	4,657.7	50%	2,404.6	46.5
Mesdopetam	PD-Psychosis	2027	688	2,350.2	30%	734.0	14.2
Pirepemat	PD-Falls (postural dysfunction)	2027	1,036	5,190.8	30%	1,515.5	29.3
Net cash at 31 March 2021*				491.2	100%	491.2	9.5
Valuation				**12,690.0**		**5,145.2**	**99.4**

Source: Edison Investment Research. Note: *Plus $28m upfront payment from Ipsen.

For mesdopetam in PD-LIDs and PD-Psychosis in the US and EU5 only, we replace our blended tiered royalty rate of 30% with a flat 20% royalty on net sales, and include development and sales milestones totalling $290m relating to PD-LIDs and PD-Psychosis. We maintain our forecast R&D costs for completion of the Phase IIb/III study in PD-LIDs in 2021/22 and have removed all R&D costs associated with the potential start of a Phase II study in PD-Psychosis in 2022. We subsequently increase our unallocated R&D cost assumptions to reflect IRLAB's increased focus on its portfolio of preclinical assets and ISP platform. We forecast launch in 2026 and unchanged peak sales of $1.2bn in the US/EU5 in 2032 for PD-LIDs. We forecast launch in 2027 and unchanged peak sales of $688m in the US/EU5 in 2033 for PD-Psychosis.

Our pirepemat assumptions are unchanged. We model treatment of PD-Falls in the US and EU5 only and forecast peak sales of $1.0bn in 2033 assuming launch in 2027. We also assume an out-licensing deal post Phase IIb data and use a blended tiered royalty rate of 30%, which considers any potential milestone value.

Exhibit 3: Financial summary

Accounts: IFRS, year-end: 31 December, SEK'000s	2018	2019	2020	2021e	2022e
PROFIT & LOSS					
Total revenues	196	448	404	237,701	413
Cost of sales	0	0	0	0	0
Gross profit	196	448	404	237,701	413
Total operating expenses	(74,093)	(96,296)	(91,862)	(107,854)	(138,066)
Research and development expenses	(58,927)	(79,381)	(75,989)	(89,746)	(114,746)
EBITDA (reported)	(72,565)	(92,916)	(89,202)	133,195	(133,913)
Operating income (reported)	(73,897)	(95,848)	(91,458)	129,847	(137,653)
Operating margin %	N/A	N/A	N/A	N/A	N/A
Finance income/(expense)	(202)	(272)	(195)	(446)	(446)
Exceptionals and adjustments	0	0	0	0	0
Profit before tax (reported)	(74,099)	(96,120)	(91,653)	129,401	(138,099)
Profit before tax (normalised)	(73,359)	(95,121)	(91,394)	129,660	(137,840)
Income tax expense (includes exceptionals)	0	0	0	0	0
Net income (reported)	(74,099)	(96,120)	(91,653)	129,401	(138,099)
Net income (normalised)	(73,359)	(95,121)	(91,394)	129,660	(137,840)
Basic average number of shares, m	38.2	40.6	47.7	51.7	51.7
Basic EPS (SEK)	(1.94)	(2.37)	(1.92)	2.50	(2.67)
Adjusted EPS (SEK)	(1.92)	(2.34)	(1.92)	2.51	(2.66)
Dividend per share (SEK)	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET					
Tangible assets	1,197	5,919	4,317	10,282	10,295
Intangible assets	83,269	82,270	82,011	81,751	81,492
Other non-current assets	0	0	0	0	0
Total non-current assets	84,466	88,189	86,328	92,033	91,787
Cash and equivalents	134,442	110,527	277,009	407,316	270,689
Inventories	0	0	0	0	0
Trade and other receivables	6,028	9,351	6,732	6,732	6,732
Other current assets	0	0	0	0	0
Total current assets	140,470	119,878	283,741	414,048	277,421
Non-current loans and borrowings	0	0	0	0	0
Non-current lease liabilities	0	2,900	1,270	7,270	7,270
Other non-current liabilities	0	0	0	0	0
Total non-current liabilities	0	2,900	1,270	7,270	7,270
Accounts payable	5,997	8,438	3,683	4,295	5,520
Non-current loans and borrowings	0	0	0	0	0
Current lease liabilities	0	1,643	1,657	1,657	1,657
Other current liabilities	6,463	13,259	15,578	15,578	15,578
Total current liabilities	12,460	23,340	20,918	21,530	22,755
Equity attributable to company	212,476	181,826	347,879	477,280	339,181
CASH FLOW STATEMENT					
Operating income	(73,897)	(95,848)	(91,458)	129,847	(137,653)
Depreciation and amortisation	1,332	2,932	2,256	3,349	3,740
Share based payments	0	0	0	0	0
Other adjustments	(202)	(244)	(195)	(446)	(446)
Movements in working capital	1,977	1,959	183	612	1,225
Cash from operations (CFO)	(70,790)	(91,201)	(89,214)	133,362	(133,134)
Capex	(1,052)	(137)	(394)	(266)	(330)
Acquisitions & disposals net	0	0	0	0	0
Other investing activities	0	0	0	0	0
Cash used in investing activities (CFIA)	(1,052)	(137)	(394)	(266)	(330)
Net proceeds from issue of shares	131,575	68,970	257,706	0	0
Movements in debt	0	(1,547)	(1,616)	0	0
Other financing activities	0	0	0	(2,789)	(3,164)
Cash from financing activities (CFF)	131,575	67,423	256,090	(2,789)	(3,164)
Cash and equivalents at beginning of period	74,709	134,442	110,527	277,009	407,316
Increase/(decrease) in cash and equivalents	59,733	(23,915)	166,482	130,307	(136,627)
Effect of FX on cash and equivalents	0	0	0	0	0
Cash and equivalents at end of period	134,442	110,527	277,009	407,316	270,689
Net (debt)/cash	134,442	110,527	277,009	407,316	270,689

Source: Company accounts, Edison Investment Research

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