

IRLAB Therapeutics

Q321 results

Platform validated, pipeline momentum building

The [Ipsen deal](#) for mesdopetam (IRL790) during Q321 was a significant achievement for IRLAB Therapeutics. It has provided strong external validation for IRLAB's ISP discovery platform and the \$28m upfront payment has bolstered its cash runway. Moreover, with Ipsen now responsible for mesdopetam's Phase III development, additional resource has been freed up for IRLAB to kick on with its other programmes and further enrich its pipeline. Next up on the agenda is pirepemat (IRL752), which is due to start a Phase IIb trial for treatment of postural dysfunction and falls in Parkinson's disease (PD) by end-2021. IRLAB continues to make progress across its preclinical pipeline, with IRL942 potentially entering clinical development during 2022 for cognitive disorders. We value IRLAB at SEK5.2bn or SEK101/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	205.6	97.6	1.89	0.0	N/A	N/A
12/22e	39.7	(98.6)	(1.90)	0.0	N/A	N/A

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

Pirepemat Phase IIb trial initiation before year end

Pirepemat is a first-in-class oral small molecule being developed for the treatment of postural dysfunction (impaired balance) and falls in PD (PD-Falls). These are largely untapped markets and represent a significant burden on healthcare systems. Subject to clearance from regulators, a Phase IIb study in PD-Falls is expected to start before end-2021. The trial will enrol c 150 patients and investigate pirepemat as an add-on therapy. We expect top-line data could be available by end-2022, after which IRLAB will look at partnering options.

ISP discovery platform will continue to beat

At the heart of IRLAB is its Integrative Screening Process (ISP) platform, which enabled the discovery of mesdopetam and pirepemat. With resources freed up following the Ipsen deal, IRLAB can continue to focus on its core competency of research and development utilising this [ISP platform](#), potentially expanding its discovery efforts beyond PD into a range of other neurological and psychiatric conditions. The most advanced preclinical asset, IRL942, is being developed for cognitive dysfunction and is currently undergoing the requisite regulatory studies for Phase I development, which could potentially start in 2022. We do not currently include the early-stage, preclinical portfolio or the ISP platform technology in our valuation, but highlight these could provide additional upside to our base-case.

Valuation: SEK5.2bn or SEK101/share

Our valuation is virtually unchanged at SEK5.2bn or SEK101/share (SEK5.1bn or SEK99/share previously). We have updated for reported net cash, FX and rolled forward our model in time. Mesdopetam remains the largest value contributor at c SEK62/share for its potential use in PD-LIDs and PD-Psychosis; pirepemat's potential use in PD-Falls contributes c SEK31/share.

Pharma & biotech

22 November 2021

Price **SEK50.8**
Market cap **SEK2,626m**

SEK8.47/US\$

Net cash (SEKm) at 30 Sep 2021 431.2

Shares in issue 51.7m

Free float 59%

Code IRLABA

 Primary exchange NASDAQ
Stockholm

Secondary exchange N/A

Share price performance



%	1m	3m	12m
Abs	13.4	(13.5)	9.6
Rel (local)	6.0	(18.2)	(20.3)

52-week high/low SEK70 SEK35

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), which has been out licensed to Ipsen; and pirepemat (PFC enhancer).

Next events

Pirepemat Phase IIb trial initiation H221

Mesdopetam Phase IIb/III top-line data H122

Progression of preclinical programmes 2022

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Valuation and financials

Our risk-adjusted net present value (NPV) model is virtually unchanged and we value IRLAB at SEK5.2bn or SEK101/share (SEK5.1bn or SEK99/share previously). We have rolled forward our model, and updated for FX and reported net cash. We forecast c \$1.9bn peak sales for mesdopetam for its potential use in PD-LIDs and PD-Psychosis, contributing SEK46.5/share and SEK15.1/share respectively. We forecast c \$1bn peak sales for pirepemat in PD-Falls for SEK31.3/share. We do not currently include preclinical assets (IRL942 and IRL1009), early-stage programmes (P003) or its proprietary ISP platform technology but see potential for uplift as assets move into clinical development.

Exhibit 1: 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	4,775.4	50%	2,407.0	46.5
Mesdopetam	PD-Psychosis	2027	688	2,508.7	30%	783.5	15.1
Pirepemat	PD-Falls	2027	1,036	5,540.8	30%	1,617.6	31.3
Net cash at 30 Sep 2021				431.2	100%	431.2	8.3
Valuation				13,256.0		5,239.3	101.2

Source: Edison Investment Research

The SEK240m (\$28m) upfront payment from Ipsen has bolstered IRLAB's balance sheet and provided it with a strong cash runway. SEK185m was fully recognised on receipt, with the remaining SEK55m deferred to reflect IRLAB's responsibility to complete the ongoing Phase IIb/III, due to finish in 2022. In Q321, IRLAB's reported revenues were SEK195.6m, comprised of the initial amount recognised from the upfront payment, SEK5.4m of deferred revenue and SEK5.0m relating to other services performed for Ipsen. We expect the remaining c SEK50m of deferred revenue will be recognised by end-2022 on a straight-line basis and have updated our forecasts to reflect this.

Reported cash and cash equivalents were SEK431.2m at 30 September 2021, and the company remains debt free. Operating expenses were artificially higher in Q321 at SEK74.1m (Q221: SEK26.5m) due to a one-off, non-cash cost of SEK39.1m resulting from the reversal of the booked value for mesdopetam and reflecting the technology transfer to Ipsen. R&D costs associated with mesdopetam's development will begin winding up over the near term with completion of the ongoing Phase IIb/III in 2022, but we expect these will largely be offset by the planned Phase IIb trial for pirepemat and progression of preclinical assets into the clinic. Based on foreseeable R&D plans, we forecast a cash runway until at least 2024 and highlight subsequent milestone payments from Ipsen (up to \$335m due) could potentially alleviate additional financing needs.

Exhibit 2: Financial summary

Accounts: IFRS; year-end 31 December; SEK'000s	2018	2019	2020	2021e	2022e
PROFIT & LOSS					
Total revenues	196	448	404	205,620	39,701
Cost of sales	0	0	0	0	0
Gross profit	196	448	404	205,620	39,701
Total operating expenses	(74,093)	(96,296)	(91,862)	(146,945)	(138,066)
Research and development expenses	(58,927)	(79,381)	(75,989)	(89,746)	(114,746)
EBITDA (reported)	(72,565)	(92,916)	(89,202)	62,023	(94,625)
Operating income (reported)	(73,897)	(95,848)	(91,458)	58,674	(98,365)
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)	58,229	(98,811)
Profit before tax (normalised)	(73,359)	(95,121)	(91,394)	97,579	(98,552)
Income tax expense (includes exceptionals)	0	0	0	0	0
Net income (reported)	(74,099)	(96,120)	(91,653)	58,229	(98,811)
Net income (normalised)	(73,359)	(95,121)	(91,394)	97,579	(98,552)
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)	1.13	(1.91)
Adjusted EPS (SEK)	(1.92)	(2.34)	(1.92)	1.89	(1.90)
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	42,660	42,401
Other non-current assets	0	0	0	0	0
Total non-current assets	84,466	88,189	86,328	52,942	52,696
Cash and equivalents	134,442	110,527	277,009	414,549	277,895
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	421,281	284,627
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	406,108	307,297
CASH FLOW STATEMENT					
Operating income	(73,897)	(95,848)	(91,458)	58,674	(98,365)
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)	38,645	(446)
Movements in working capital	1,977	1,959	183	39,926	(38,089)
Cash from operations (CFO)	(70,790)	(91,201)	(89,214)	140,594	(133,160)
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	414,549
Increase/(decrease) in cash and equivalents	59,733	(23,915)	166,482	137,540	(136,654)
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	414,549	277,895
Net (debt)/cash	134,442	110,527	277,009	414,549	277,895

Source: Company accounts, Edison Investment Research

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