

IRLAB Therapeutics

Q123 results

Positive signs for mesdopetam in Q1 update

Pharma and biotech

IRLAB Therapeutics has reported Q123 results, providing a financial update and highlighting its near-term strategic priorities. The company intends to present further comprehensive data from the Phase IIb mesdopetam study in FY23, while discussions with Ipsen continue regarding the next clinical steps for the drug. Patient recruitment in the PD-Falls Phase IIb pirepemat study continues as planned, with patient enrolment expected by end FY23. We see this as a positive indicator that IRLAB is on track to deliver top-line results in H124. In light of the quarterly results, we have made adjustments to our forecasts and estimate that IRLAB's net cash position of SEK210.1m at end March is sufficient to fund operations to the end of Q124. The company's lower net cash position has been offset slightly by rolling our model forward. Our valuation is virtually unchanged at SEK4.90bn or SEK94.7/share (previously SEK4.84bn or SEK93.3/share)

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/21	207.9	91.1	1.76	0.0	N/A	N/A
12/22	61.3	(113.1)	(2.18)	0.0	N/A	N/A
12/23e	0.2	(208.4)	(4.02)	0.0	N/A	N/A
12/24e	0.2	(190.2)	(3.67)	0.0	N/A	N/A

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

Collaboration with Ipsen continues

In its Q123 report, IRLAB highlighted that it remains in discussions with Ipsen (the licensee for mesdopetam) about the future, potentially registrational, clinical path for mesdopetam. However, Ipsen has still not been confirmed whether it intends to progress the drug into later studies. We note that Ipsen is currently conducting preparatory work including pharmacokinetic studies and upscale manufacturing, which, together with mesdopetam's clinical results to date, IRLAB believes marks the drug as a Phase III-ready asset.

Cash runway to end Q124

In the light of IRLAB's quarterly results, we have adjusted our forecasts. We now estimate FY23 R&D expenses of SEK169m (previously SEK132m) and operating losses of SEK208m (previously SEK160m). We attribute the increase in R&D expenses to ongoing patient recruitment in the Phase IIb pirepemat study, as well as development activities associated with preparing IRL757 and IRL942 for Phase I studies. We estimate that IRLAB's net cash position of SEK210.1m at end Q123 provides an operating cash runway to end Q124.

Valuation: SEK4.90bn or SEK94.7share

We value IRLAB at SEK4.90bn or SEK94.7/share (previously SEK4.84bn or SEK93.3/share). Our valuation is largely unchanged, but is affected by the lower net cash position, which has been slightly offset by rolling our model forward by three months.

15 May 2023

Price SEK9.78

Market cap SEK507m

SEK10.41/US\$

Net cash (SEKm) at 31 March 2023 210.1

(ex-lease liabilities)

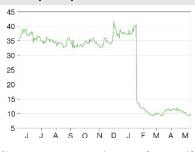
Shares in issue 51.8m Free float 68%

Code **IRLABA**

Primary exchange Nasdag Stockholm

Secondary exchange N/A

Share price performance



1m 12m Abs (17.8)(6.0)(71.2)Rel (local) (17.7)(5.4)(72.9)52-week high/low SEK41.8 SEK9.0

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 latestage clinical trials for the symptomatic treatment of Parkinson's disease (PD): mesdopetam (D3 antagonist) and pirepemat (PFC enhancer).

Next events

IRL757 Phase I ready H223 Top-line Phase IIb pirepemat data in H124 PD-Falls

Analysts

Soo Romanoff +44 (0)20 3077 5700 Dr Adam McCarter +44 (0)20 3077 5700

healthcare@edisongroup.com

Edison profile page

IRLAB Therapeutics is a research client of Edison Investment Research Limited



Financials and valuation

Following IRLAB's Q123 report, we have updated our financial estimates and forecast FY23 operating losses of SEK208m (previously SEK160m), with net cash outflows from operating activities of SEK200m (previously SEK156m). The increase in operating expenses has been attributed to costs associated with the ongoing Phase IIb pirepemat study, as well as preparatory Phase I activities for IRL757 and IRL942. We expect operating losses to reduce slightly in FY24 to SEK190m due to winding down the Phase IIb mesdopetam trial by end FY23 and forecast operating cash outflows of SEK187m. As such, we estimate that IRLAB's net cash position of SEK210.1m at end March 2023 is sufficient to fund operations to end Q124.

We estimate that IRLAB will need to raise SEK750m before becoming self-sustainable in FY28 with the projected launches of mesdopetam and pirepemat. We account for this funding as illustrative debt in our model and have distributed the raise (SEK250m per year) across three consecutive years (FY24–26). Alternatively, if funding is realised through an equity issue instead (assuming at the current trading price of SEK9.78/share), IRLAB would need to issue 76.7m shares, resulting in our per-share valuation decreasing to SEK38.1 from SEK94.7 currently (the number of shares outstanding would increase from 51.8m to 128.6m). As part of IRLAB's licensing agreement with Ipsen for mesdopetam, it could potentially receive up to US\$335m in development, regulatory and sales-based milestones, which would have an impact on its financing requirements. However, as a result of the Phase IIb mesdopetam study missing its primary endpoint, the timings of such payments are uncertain.

Our valuation of IRLAB remains largely unchanged at SEK4.90bn or SEK94.7/share (previously SEK4.84bn or SEK93.3/share). Our valuation is based on a risk-adjusted NPV calculation for the company's lead clinical assets, mesdopetam and pirepemat (applying a 12.5% discount rate), and reflects a net cash position of SEK210.1m at end December 2022. A breakdown of our rNPV valuation is shown in Exhibit 1.

Product	Launch	Peak	Peak sales (\$m)	Value (SEKm)	Probability	rNPV (SEKm)	rNPV/share (SEK)
Mesdopetam – PD-LIDs	2028	2034	1,268.5	5,276.8	40%	2,125.3	41.0
Mesdopetam – PD-Psychosis	2029	2035	493.7	2,316.0	30%	715.8	13.8
Pirepemat – PD-Falls (postural hypotension)	2028	2034	1,062.1	6,260.5	30%	1,853.7	35.8
Net cash at end-March 2023				210.1	100%	210.1	4.1
Valuation				14,063.4		4,904.8	94.7



Accounts: IFRS, year-end: 31 December, SEK000s	2020	2021	2022	2023e	2024
PROFIT & LOSS	10.1	207.000	04.077	200	40
Total revenues	404	207,906	61,277	223	163
Cost of sales	0 404	207.006	61 277	0 223	16.
Gross profit Total operating expenses	(91,862)	207,906 (155,330)	61,277 (174,386)	(208.427)	16: (190,325
Research and development expenses	(75,989)	(129,748)	(146,178)	(168,579)	(156,053
EBITDA (reported)	(89,202)	56,050	(146,176)	(205,063)	(187,004
Operating income (reported)	(91,458)	52,576	(113,109)	(208,204)	(190,162
Operating margin %	N/A	N/A	N/A	N/A	(130,102 N/A
Finance income/(expense)	(195)	(795)	(297)	(230)	(6
Exceptionals and adjustments	(130)	0	0	0	(0
Profit before tax (reported)	(91,653)	51,781	(113,406)	(208,434)	(190,168
Profit before tax (normalised)	(91,394)	91,131	(113,147)	(208,434)	(190,168
Income tax expense (includes exceptionals)	0	0 1,101	0	0	(100,100
Net income (reported)	(91,653)	51,781	(113,406)	(208,434)	(190,168
Net income (normalised)	(91,394)	91,131	(113,147)	(208,434)	(190,168
Basic average number of shares, m	47.7	51.7	51.8	51.8	51.8
Basic EPS (SEK)	(1.92)	1.00	(2.19)	(4.02)	(3.67
Adjusted EPS (SEK)	(1.92)	1.76	(2.18)	(4.02)	(3.67
Dividend per share (SEK)	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET					
Tangible assets	4,317	8,348	8,009	5,161	2,29
Intangible assets	82,010	42,661	46,862	46,862	46,862
Other non-current assets	0	0	0	0	(
Total non-current assets	86,327	51,009	54,871	52,023	49,158
Cash and equivalents	277,009	401,897	252,776	51,550	114,248
Inventories	0	0	0	0	
Trade and other receivables	6,732	19,543	15,908	13,522	13,52
Other current assets	0	0	0	0	(
Total current assets	283,741	421,440	268,684	65,072	127,769
Non-current loans and borrowings	0	0	0	0	250,000
Non-current lease liabilities	1,270	3,566	381	315	31
Other non-current liabilities	0	0	0	0	050.04
Total non-current liabilities	1,270	3,566	381	315	250,31
Accounts payable	3,683	4,634	0	0	(
Non-current loans and borrowings	0	0	0	0 700	0.70
Current lease liabilities Deferred Income	1,657 0	3,034 42,576	3,595 0	2,762	2,762
Other current liabilities	15,578	19,158	28,748	31,623	31,62
Total current liabilities	20,918	69,402	32,343	34,385	34,38
Equity attributable to company	347,880	399,481	290,830	82,396	(107,772
CASH FLOW STATEMENT	347,000	333,401	230,030	02,030	(101,112
Operating income	(91,458)	52.576	(113,109)	(208,204)	(190,162
Depreciation and amortisation	2,256	3,474	4,779	3,141	3,158
Share based payments	0	0,414	0	0,141	0,100
Other adjustments	(195)	38,295	(297)	(230)	(6
Movements in working capital	183	34,296	(33,985)	5,195	
Cash from operations (CFO)	(89,214)	128,641	(142,612)	(200,099)	(187,010
Capex	(394)	(708)	(2,876)	(293)	(293
Acquisitions & disposals net	Ó	Ó	(500)	Ó	, (
Other investing activities	0	0	0	0	(
Cash used in investing activities (CFIA)	(394)	(708)	(3,376)	(293)	(293
Net proceeds from issue of shares	257,706	(180)	0	0	
Movements in debt	(1,616)	(2,865)	(3,134)	(833)	250,00
Other financing activities	0	0	0	0	
Cash from financing activities (CFF)	256,090	(3,045)	(3,134)	(833)	250,00
Cash and equivalents at beginning of period	110,527	277,009	401,897	252,775	51,55
Increase/(decrease) in cash and equivalents	166,482	124,888	(149,122)	(201,225)	62,69
Effect of FX on cash and equivalents	0	0	0	0	
Cash and equivalents at end of period	277,009	401,897	252,775	51,550	114,24
Net (debt)/cash	277,009	401,897	252,776	51,550	(135,752



General disclaimer and copyright

This report has been commissioned by IRLAB Therapeutics and prepared and issued by Edison, in consideration of a fee payable by IRLAB Therapeutics. Edison Investment Research standard fees are £60,000 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Copyright: Copyright 2023 Edison Investment Research Limited (Edison)

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.