



World-leader in drug development in Parkinson's: Reducing the burden and transforming lives

IRLAB, Q1 2024



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Today's agenda

Q1 business
update

1



News in the period

Gunnar Olsson, CEO

2



R&D update

Nicholas Waters, EVP Head of R&D

3



Financials

Viktor Siewertz, CFO

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Concluding words

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Q&A session

Key highlights

Collaboration with MSRD/Otsuka, funding IRL757 through clinical Proof-of-Concept

IRL757 program fully financed through PoC

Successful End-of-Phase 2-meeting with FDA for mesdopetam

Phase III study program confirmed

New insights from the Phase IIb study with pirepemat

Regulatory approvals for reduced sample size with retained power

Regulatory approval to start Phase I with IRL757

Phase I starts in May

IRL757 fully financed through Proof-of-Concept

Development collaboration with MSRD/Otsuka

- Financing of IRL757 now secured beyond the Phase I funded by The Michael J. Fox Foundation through clinical Proof-of-Concept

Phase I progression

- CRO contracted and study start expected in May 2024
- Regulatory approval to start Phase I study received

IRL757 development collaboration with MSRD/Otsuka signed

Scope of the collaboration

- Develop IRL757 through clinical Proof-of-Concept for the treatment of apathy in Parkinson's and Alzheimer's disease

Secures financing through clinical Proof-of-Concept

IRLAB

- Receives up-front payment and activity based milestone payments
- Executes the development activities
- Retains ownership of product and IP

MSRD

- Funds the development activities under the terms
- May extend the collaboration beyond Proof-of-Concept, subject to new negotiations
- In the event of no extension of the collaboration, MSRD/Otsuka receive low single digit royalty on future sales

Multiple positive aspects of the IRL757 agreement

- 1) Brings near term cash flow to IRLAB – up-front + milestones – 8.5 MUSD
- 2) Secures full financing of the Development activities through PoC in two populations; Parkinson's and Alzheimer's disease
- 3) Provides additional external validation of our R&D innovation and quality
- 4) Our assessment is that the deal provides conditions to run the business without additional capital injection, past a potential licensing deal with mesdopetam and past the topline data in the Phase IIb study with pirepemat

Benchmark – ca 25 MUSD is the average industry cost from Phase I initiation through Proof-of-Concept

Continued progress with mesdopetam

PD-LIDs – progress towards phase III

- Successful End-of-Phase 2 meeting with the FDA
 - Alignment on Phase III program
 - Alignment on the path forward towards NDA filing for market approval
- Continued high intensity BD activities

PD-P – progress in preclinical documentation of second indication

- Scientific article in the journal Neurotherapeutics reported anti-psychotic effect of mesdopetam in a preclinical model of Parkinson's disease psychosis (PD-P)

Pirepemat regulatory update

Clinical trial progress

- REACT-PD – a pioneering study in a new patient population
- Analyses of blinded data show
 - Stabilised patient recruitment rate
 - High and stable fall rates at base-line

Implications

- High probability to detect treatment effects with lower sample size
 - **Reassessment of sample size approved by regulatory authorities**
- Ability to use data driven estimates for more accurate study timelines
 - Anticipated completion of patient recruitment in Q3 2024

Operational highlights preclinical projects

IRL942

- CMC work to develop API route and DP manufacturing ongoing
- Anticipated Phase I ready during end of 2024 or in the beginning of 2025 depending on timeslots for toxicology studies at the CRO

IRL1117

- CMC work to develop manufacturing route ongoing
- Anticipated Phase I readiness end 2024 or early 2025

Participation and presentation at scientific meetings and financial conferences

- Two posters presented at 18th International Conference on Alzheimer's & Parkinson's Diseases in Lisbon March 5-9, 2024.
 - REACT-PD – A Randomized, Placebo-Controlled Phase IIb Trial Evaluating the Efficacy of pipermetat on Falls Frequency in Patients with Parkinson's Disease
 - Preclinical in vivo characterization of IRL1117; a novel dopamine D1/D2 agonist for the treatment of Parkinson's disease
- Statistical aspects of planning and evaluation of clinical trials at the scientific conference Bayes@Lund 2024, March 7.
- Presentation at Life-Science Day, Gothenburg - March
- "Fireside chat" with ABG - March
- Participated in Redeye Investor Forum – April



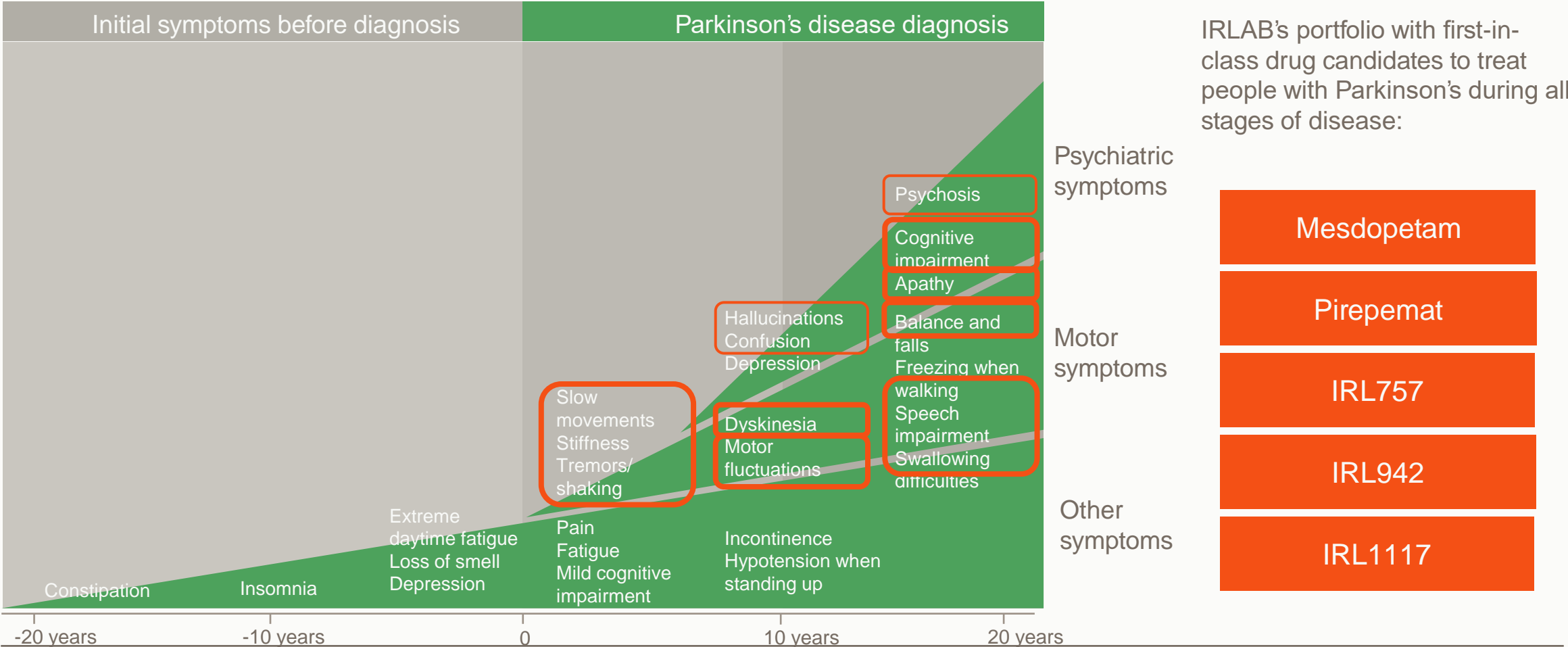
R&D update

Highly successful regulatory validation of R&D during the period

- End-of-Phase 2-meeting with FDA for mesdopetam
 - **Clear path to NDA**
- New insights from the Phase IIb study with pirepemat
 - **Approvals for refinement of study protocol, sample size and statistical considerations**
- Regulatory approval to start Phase I with IRL757
 - **Third (!) program to reach clinical phase**

World-leading portfolio to improve the treatment of Parkinson's

Parkinson's and IRLAB's portfolio





Mesdopetam

IRL790

Treating levodopa-induced dyskinesias (PD-LIDs)
through a novel mechanism

Mesdopetam (IRL790)

First in class- a novel mechanism

Inhibiting dopamine D3 receptors

Potential for patent-based exclusivity into the 2040s

Lead indication – levodopa-induced dyskinesias (PD-LIDs)

Mesdopetam - strong progress in Q1

LIDs

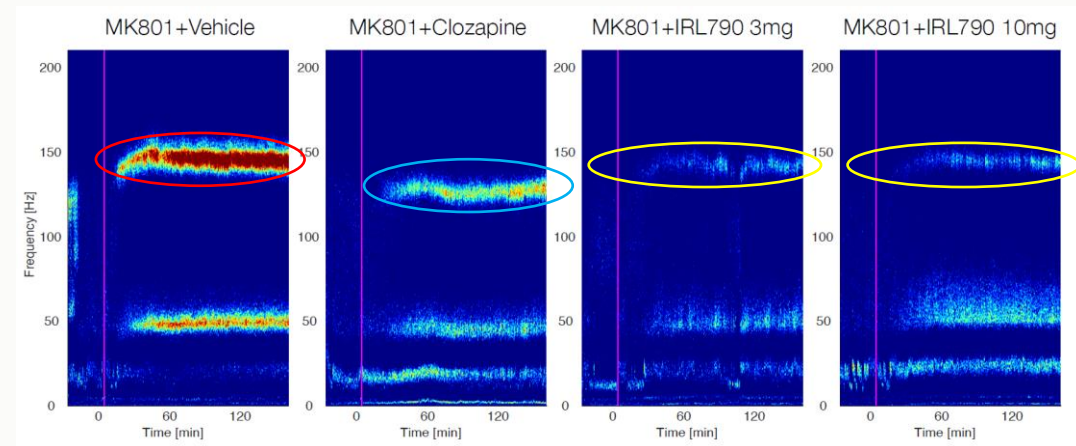
- FDA End-of-Phase 2 meeting written minutes
 - **Confirmed alignment between the agency and the company** with regards to Phase III program; and
 - Road map to NDA filing is clear
- Preparations for interactions with European Regulatory Agencies before Phase III start are ongoing
- Phase III study start possible by end of the year with current plans

Mesdopetam - progress in Q1

Q1 update

PD-P

- In March a scientific article in the journal Neurotherapeutics* reported on the anti-psychotic effect of mesdopetam in a preclinical model of Parkinson's disease psychosis (PD-P)



Mesdopetam

- **Suppresses abnormal signalling;** and
- Restores **signal complexity** across brain regions



Pirepemat

IRL752

- A treatment to improve balance and reduce falls in Parkinson's (PD-Falls)
- Ongoing randomized, placebo-controlled Phase IIb clinical trial

Pirepemat - in development to improve balance and reduce falls in Parkinson's

- Reducing falls is the greatest medical need and one of the worst aspects of Parkinson's
- 45% of individuals with Parkinson's fall recurrently
- Cost of a fall injury approx. 30 000 USD in patients > 65 years

Status

- Study start of Phase IIb - Q1 2022
- All clinical centers activated - May 2023
 - Centers in France, Poland, Spain, Sweden, Germany and the Netherlands
- Patient recruitment completion anticipated in Q3 2024
- Followed by 1 month baseline period, a 3-month treatment period, data management and database lock before top line results



Pirepemat (IRL752)

First in class- a novel mechanism

Inhibiting alpha 2 and serotonin 7 receptors

Potential for patent-based exclusivity into the 2040s

Objective – reduce falls in Parkinson's disease

Pirepemat project progress in Q1



Pirepemat has potential to be the first treatment in a new class of drugs designed to improve balance and reduce falls and fall injuries in people living with Parkinson's disease

REACT-PD - Phase IIb study run in France, Germany, the Netherlands, Poland, Spain and Sweden

- A pioneering study in a new patient population
- Blinded baseline data show
 - Higher fall rates
 - Stable base line fall frequency during the one-month study run-in
 - Withdrawal rates slightly lower than anticipated

Thus, a lower sample size than initially anticipated would give sufficient statistical power to detect treatment effects, **now approved by regulatory agencies across europe**

IRL757 – treatment of apathy

- A novel first-in-class treatment for apathy in neurological disorders
- Phase I SAD/MAD fully funded by Michael J Fox Foundation
- Funding through proof-of-concept secured through collaboration with MSRD/Otsuka
- Clinical Phase I dosing to start in Q2, 2024

Apathy: loss of initiative, interest, and emotional expression/responsiveness



Addressable population:
2-7 million people

IRL757 is aimed at the huge untreated problem with apathy

Huge unmet medical need

- Several million US and EU citizens may be affected by apathy
- Apathy occurs in 20-70% in people with PD and in 20-90% of people with AD and other CNS disorders

Pathophysiological background

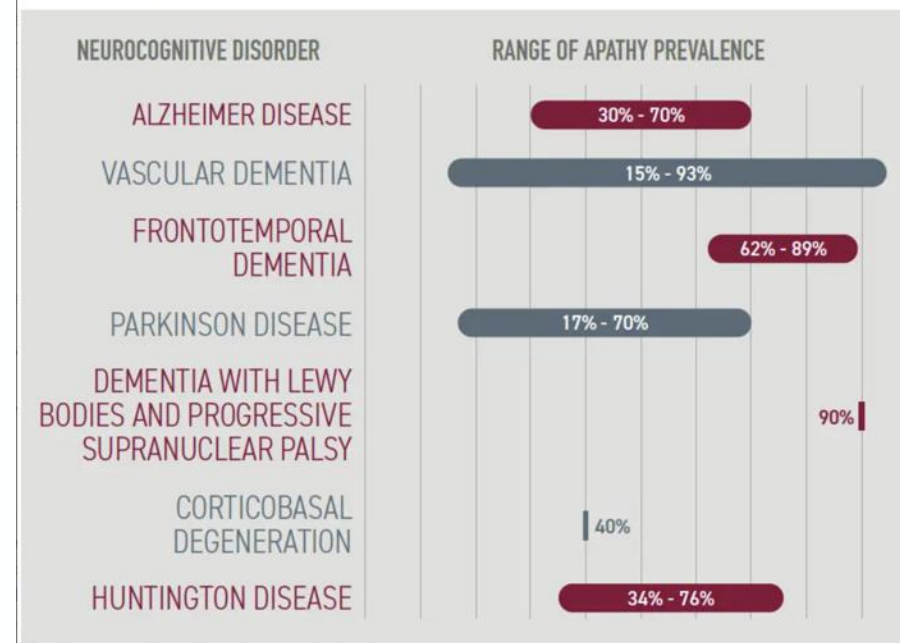
- Disruption of frontal-subcortical neurocircuits are implicated in apathy*

- IRL757 has a unique ability to **increase neuronal activity** in frontal-subcortical neurocircuits
- Potential for both symptomatic relief and disease modification

Apathy

Loss of initiative, interest and emotional expression/ responsiveness, often found in people with dementia.

Figure. Apathy Among Individuals With Neurocognitive Disorders^{1,6,9-11}



IRL757 project progress in Q1

IRL757 has the potential to be **the first drug in a new class** to treat apathy in Parkinson's and other neurological disorders

- Phase I ready after successfully completing the CMC development and regulatory preclinical studies
- Funding to conduct the Phase I study (including SAD, MAD and Food interaction) with IRL757 is secured in through The Michael J. Fox Foundation
- regulatory approval for Phase I study granted
- CRO to execute the Phase I study contracted
- Collaboration with MSRD/Otsuka funding IRL757 through proof-of-concept in **Parkinson's and Alzheimer's disease**

Preclinical projects

- IRL942 **Clinical candidate** - Improve cognitive function and brain health
- IRL1117 **Clinical candidate** - Once-daily oral treatment of Parkinson's without troublesome complications

Innovative preclinical pipeline with first-in-class NCEs

<u>IRL942</u>	<u>IRL1117</u>
Improvement of cognitive function	Next generation Parkinson's treatment
Memory, perception, attention, reasoning, problem-solving and decision-making	Once-daily Parkinson's hallmark symptoms (tremor, rigidity, bradykinesia) Without treatment-related complications
Addressable population: 5.8 million people ¹	Addressable population: 5.7 million people ¹
Status: IND-enabling studies; Phase I ready H2 2024/H1 2025	Status: Preclinical development

IRL942 to improve cognitive function in PD and other neurological indications

- Unmet need among a large population
- **12 %** of adults aged 65 years or more experience **cognitive decline** (CDC)
- Studies demonstrate a high cumulative risk of **dementia** in people with PD. Point prevalence is **25–30%**.
- Among PD patients without dementia, approximately **25–30%** have mild cognitive impairment (MCI), which is evident at the time of diagnosis in **10–20%** of patients

Cognition

Cognition encompasses all aspects of intellectual functions and processes such as **memory, perception, attention, reasoning, problem solving and decision-making.**

Impaired cognition is strongly associated to dementia.

IRL942 shows a unique ability to activate frontal circuits and **improve cognitive function in preclinical models**

Potential for both symptomatic relief and disease modification

IRL942 project progress in Q1

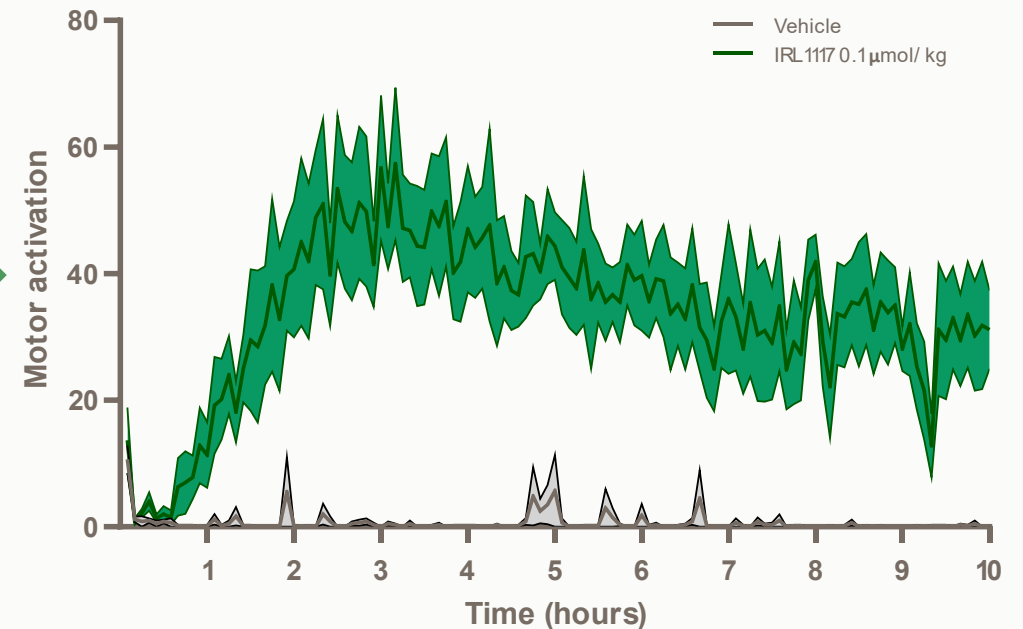
IRL942 has the potential to be the first drug in a new class to improve the cognitive function in people living with Parkinson's and other neurological disorders

- Development for preclinical studies as well as GMP manufacturing of API proceeds
- One-month toxicology and safety studies projected to start during 2024 depending on timeslots at CRO
- Development of drug product has been initiated and IRL942 is projected to be Phase I ready during H2 2024/H1 2025

IRL1117 – potential to be the first drug in a new class to treat Parkinson's

IRL1117 is a potent dopamine D1 and D2 receptor agonist with the **potential to be the first drug in a new class** for the treatment of the hallmark symptoms of Parkinson's.

- Once daily treatment that avoids the troublesome complications caused by today's mainstay levodopa-based treatments.
- In preclinical studies IRL1117 has demonstrated rapid onset and **more than 20 hours of sustained efficacy** without inducing motor complications.
- Currently activities related to substance manufacturing and planning for preclinical regulatory studies necessary for Phase I are ongoing



IRL1117 project progress in Q1:

Building a comprehensive preclinical efficacy, tolerability and DMPK package

Models of PD

- Single dose behavioral response >24h
- Improvement of motor deficits by IRL1117 over a period of 29 days (once-daily dosing) without signs of tolerance or motor complications
- Chronic treatment induces clear functional motor response without motor complications
- Switching to IRL1117 reverses existing L-DOPA-induced motor complications

DMPK

- High potency orally active compound
- Exposure @ relevant doses quantified over 24h in rodents and minipigs

CMC

- Development of API manufacturing ongoing

IPR

- Composition of matter: patent applications filed in 2022
- The estate potentially allows ultimate case exclusivity into 2040:ies



Finance report Q1 2024

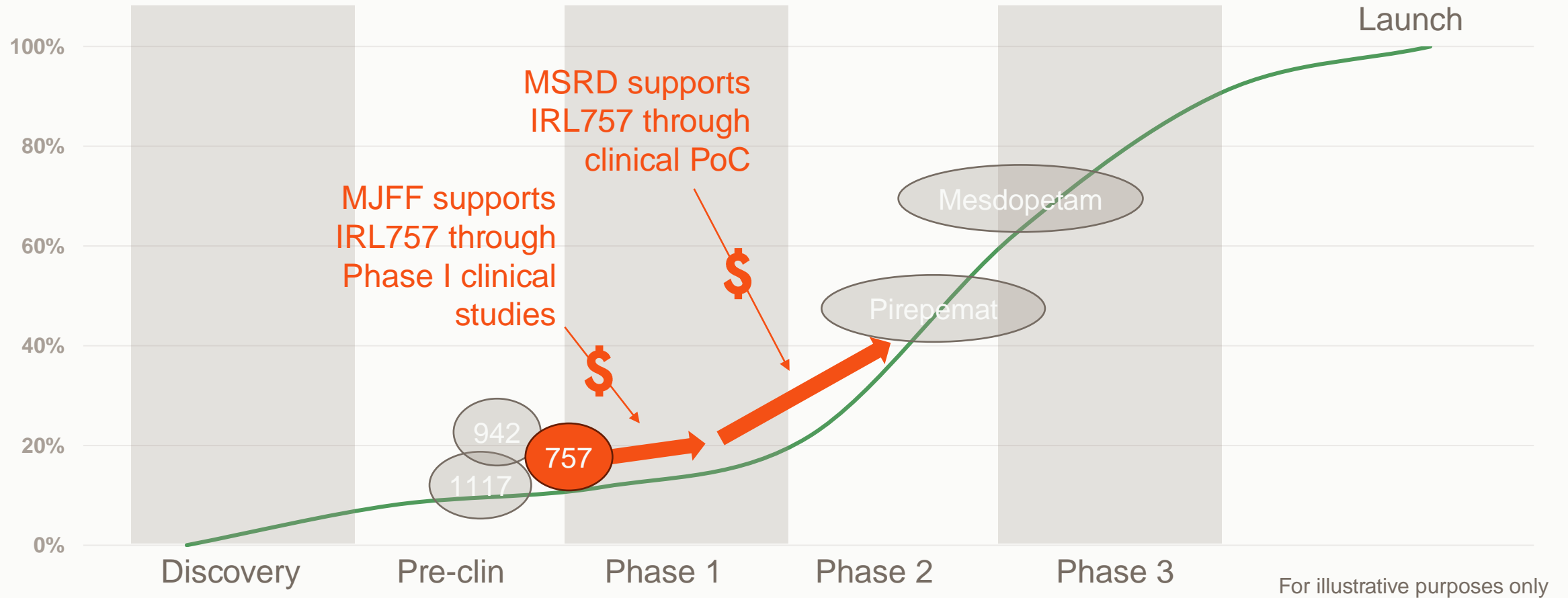
- Highlights and summary
- Analyst coverage

Multiple positive aspects of the IRL757 agreement

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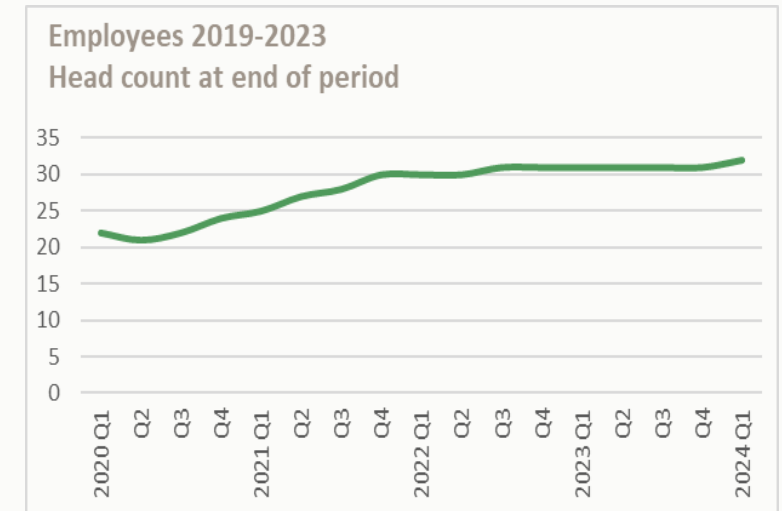
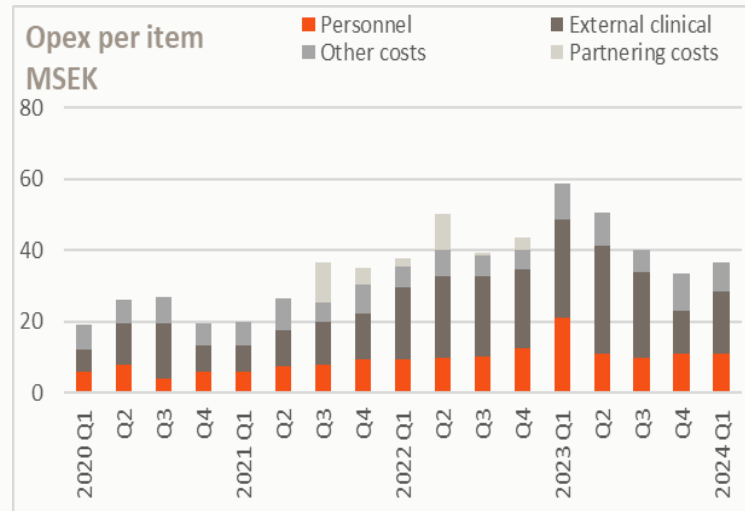
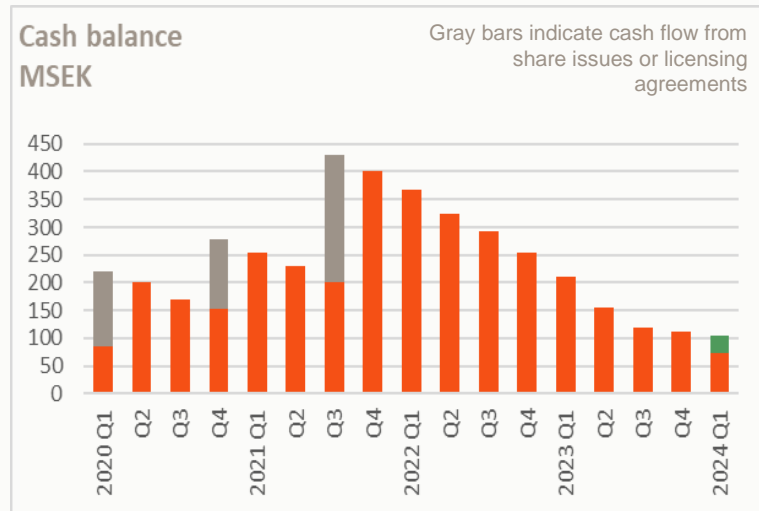
Benchmark – ca 25 MUSD is the average industry cost from Phase I initiation through Proof-of-Concept

MJFF and MSRD supports IRL757 through value creating activities



Financial highlights of Q1, 2024

- Cash position SEK 73 million (including MSRD cash is ca SEK106m)
- Investing in progressing mesdopetam towards Phase III
- Increase in cost compared to Q4 2023 is mainly due to cost according to plan relating to the Phase IIb study with pirepemat and investments in IRL757 to finalize preparations for clinical Phase I
- In preclinical development, advancing IRL942 and IRL1117 CMC development towards tox and Phase I
- Headcount remains stable at around 30 employees



Financial summary of Q1, 2024

	Q1 2024	Q1 2023
Net sales	-	-
Operating profit	- 37.6m	- 59.5m
Earnings per share before and after dilution, SEK	- 0.75	- 1.15
Cash and cash equivalents	73.1m	210.1m
Cash flow from operating activities	- 38.2m	- 41.5
Average number of employees	32	31
Share price at the end of the period, SEK	15.60	11.08

Figures in brackets = same period last year, unless otherwise stated. All amounts in SEK.

Analyst coverage



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Concluding words

World leading portfolio transforming treatment for people living with Parkinson's

Portfolio

		Discovery	Preclinical	Phase I	Phase IIa	Phase IIb	Phase III	Next major event
Mesdopetam (IRL790)	Parkinson's disease levodopa-induced dyskinesia (PD-LIDs) D3 antagonist	[Progress bar from Discovery to Phase IIb]					Phase III ready	Q4 2024: Projected start of Phase III study program
	Parkinson's disease Psychosis D3 antagonist	[Progress bar from Discovery to Phase I]				Phase II ready		
Pirepemat (IRL752)	Parkinson's disease impaired balance and falls PFC enhancer	[Progress bar from Discovery to Phase IIb]					Phase IIb	Q3 2024: Expected completion of recruitment
	Parkinson's disease Dementia PFC enhancer	[Progress bar from Discovery to Phase I]				Phase IIa		
IRL757	Apathy in neurology 	[Progress bar from Discovery to Phase I]				Phase I ready		Q2 2024: Phase I start
IRL942	Cognitive impairment in neurology	[Progress bar from Discovery to Preclinical]			Preclinical			H2 2024/H1 2025: Phase I ready
IRL1117	Parkinson's disease treatment	[Progress bar from Discovery to Preclinical]			Preclinical			H2 2024/H1 2025: Phase I ready

Key highlights

Collaboration with MSRD/Otsuka, funding IRL757 through clinical Proof-of-Concept

IRL757 program fully financed through PoC

Successful End-of-Phase 2-meeting with FDA for mesdopetam

Phase III study program confirmed

New insights from the Phase IIb study with pirepemat

Regulatory approvals for reduced sample size with retained power

Regulatory approval to start Phase I with IRL757

Phase I starts in May

Intensive Business Development efforts

Awareness of IRLAB and our development pipeline is increasing

Continuous and frequent dialogue with potential partners

Partnering opportunities being evaluated across the portfolio

Following the successful collaboration deal for IRL757, the focus is mesdopetam

IRLAB – a world-leading portfolio in Parkinson's



Pioneering biology & ISP

Deep profound understanding of Parkinson's. Team from Nobel laureate Prof. Arvid Carlsson's research group



Focused strategy

Discover and develop treatments for PD patients throughout their disease journey



Validated business model based on clinical proof-of-concept

From discovery through Phase I and Phase II to Phase III ready projects and dealmaking



Broad & Solid portfolio

Five unique drug candidates each with blockbuster potential generated by our disruptive ISP platform



Organization positioned for success

Experienced international organization. Listed Nasdaq Stockholm



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IRLAB is discovering and developing a portfolio of transformative therapies targeting all stages of Parkinson's disease. The company has its origin in Nobel Laureate Prof. Arvid Carlsson's research group and the discovery of a connection between the brain's neurotransmitters and CNS disorders. Mesdopetam (IRL790), in development for the treatment of levodopa-induced dyskinesias, has completed Phase IIb and is in preparation toward Phase III. Pirepemat (IRL752), is currently in Phase IIb, being evaluated for its effect on balance and fall frequency in Parkinson's disease. In addition, the company is also progressing the three preclinical programs IRL757 (financially supported by the Michael J. Fox Foundation), IRL942, and IRL1117 towards Phase I studies. IRLAB's pipeline is driven by the company's proprietary systems biology-based Integrative Screening Process (ISP) research platform. Headquartered in Sweden, IRLAB is listed on Nasdaq Stockholm (IRLAB A).

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