



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

IRLAB, Q3 2024



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Today's agenda

Q3 business
update

1



News in the period

Kristina Torfgård, CEO

2



R&D update

Nicholas Waters, EVP Head of R&D

3



Financials

Viktor Siewertz, CFO

4

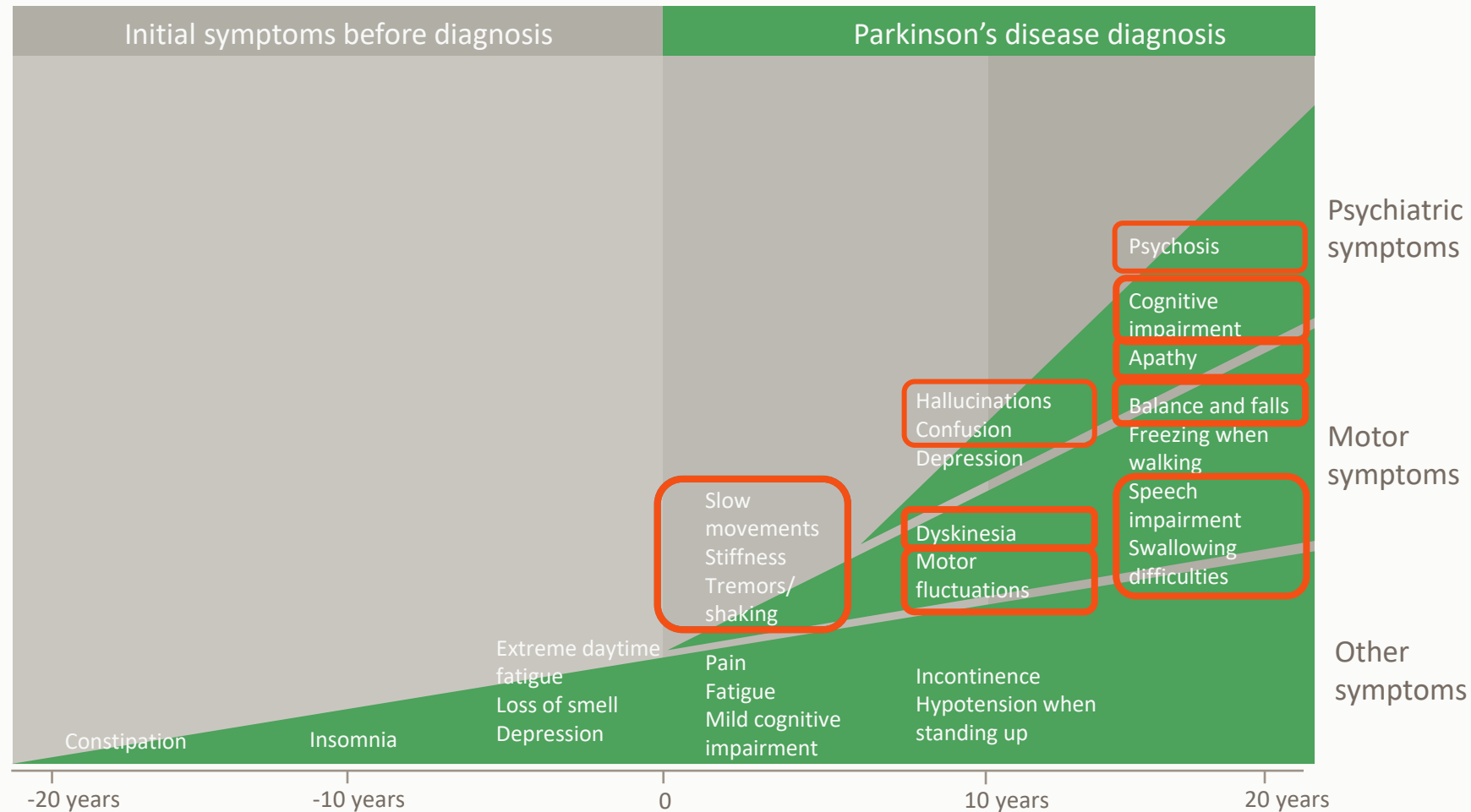


Concluding words

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Q&A session

First-in-class drug candidates to treat Parkinson's during all stages of the disease



IRLAB's portfolio with first-in-class drug candidates to **treat people with Parkinson's during all stages of disease:**

Mesdopetam

Pirepemat

IRL757

IRL942

IRL1117

Important events in and after Q3 2024

Mesdopetam

- A new patent was granted for mesdopetam, expanding the patent protection in Europe
- Data from a meta-analysis of two studies evaluating the efficacy of mesdopetam was presented at the International Congress of Parkinson's Disease and Movement Disorders (MDS), in Philadelphia, US

Pirepemat

- The Phase IIb study of pirepemat, React-PD, proceeds as planned after positive opinion from external safety committee (DSMB).
- Last patient in the Phase IIb study with pirepemat is enrolled. A reduction in the number of falls has been observed in the full patient population participating in the study.
- A new patent was granted for pirepemat, expanding the patent protection in the US



Important events in and after Q3 2024

IRL757

- Positive data reported in the first part (SAD) of the Phase I study with the drug candidate IRL757
- IRLAB to receive a milestone payment of USD 2.5 million in conjunction with first dosing in a Phase I study with IRL757 in healthy older adults



Presentations and interviews in and after Q3 2024

- IRLAB **presented at investor events** during the period and after to communicate updates of the company's strategy and pipeline
 - BioStock Investing in Life Science – September
 - Pareto Securities Health Care Conference – September
 - Redeye Neurology Theme Event - October
- In addition, **CEO interviews** have also been held
- Public recordings are available on the **website, irlab.se**.

Summary – project progresses in Q3 2024

Mesdopetam

- Preparation for Phase III - regulatory processes & health provider data

Pirepemat

- DSMB recommendation to drive Phase IIb study to completion without changes
- Completion of patient enrollment in the Phase IIb study

IRL757

- Phase I studies (SAD/MAD, food interaction & healthy adult >65) ongoing in collaboration with Michael J Fox Foundation and MSRD/Otsuka

IRL942

- Preclinical studies, CMC & documentation for Phase I readiness

IRL1117

- Preclinical studies, CMC & documentation for Phase I readiness





R&D update



Mesdopetam

IRL790

Treating levodopa-induced dyskinesias (PD-LIDs) through a novel mechanism – Dopamine D3 receptor antagonism

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)

Continued progress with mesdopetam

PD-LIDs –phase III program progress

- Scientific advice with European regulatory agencies in preparation for Phase III
- Market research/Health provider activities for positioning of mesdopetam and input to the design of the Phase III program

External validation in publication of an independent academia driven mesdopetam preclinical study*

- Confirms the MoA and anti-dyskinetic efficacy described in company lead studies
 - Potential for disease modifying properties by mesdopetam based on re-establishment of lost neuronal connections following treatment



Pirepemat

IRL752

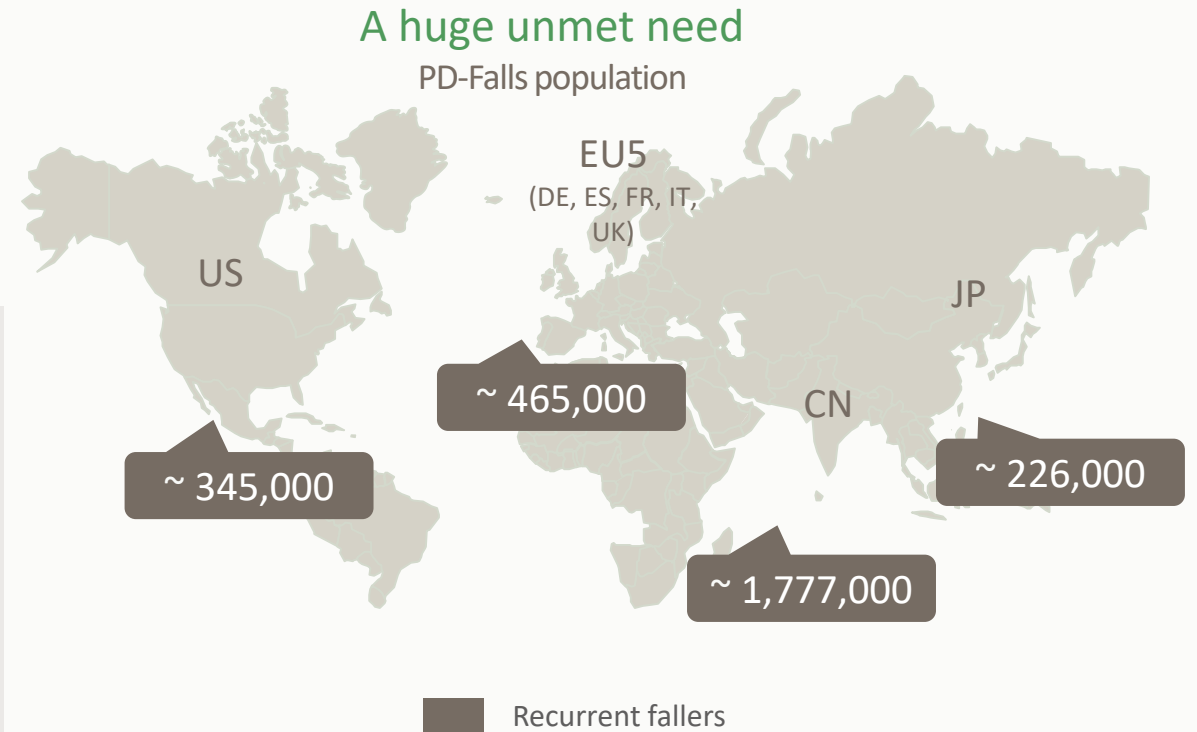
- A treatment to improve balance and reduce falls in Parkinson's (PD-Falls)
- Ongoing randomized, placebo-controlled Phase IIb clinical trial

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

- **Reducing falls is the greatest medical need and one of the most complicating 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

- Centers in France, Poland, Spain, Sweden, Germany and the Netherlands
- Patient recruitment completed in Q3 2024
- This is 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 update



REACT-PD – a pioneering study in recurrent fallers

Clinical trial progress

- DSMB for REACT-PD executed the last pre-specified review of the data integrity and safety in late June & recommends the company to continue the study according to plan
- High and stable fall rates through 1 month baseline period
- Last subject enrolled end of September

Implications

- Anticipated to top line data end of Q1 2025

IRL757 – treatment of apathy

- A novel first-in-class treatment for apathy in neurological disorders

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

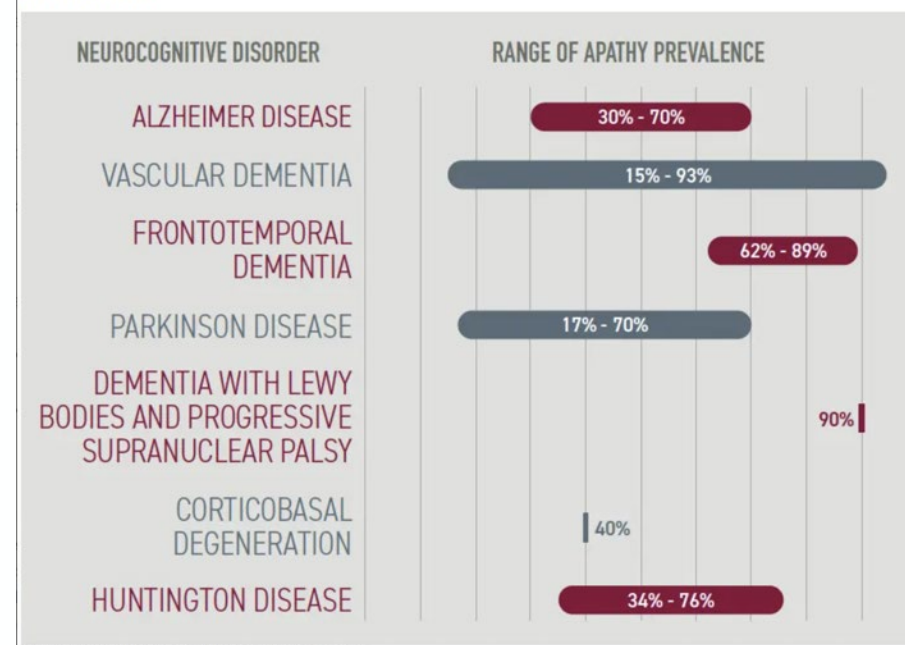
- Disruption of frontal-subcortical neurocircuits are implicated in apathy*

- 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 Q3

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

- Funding to conduct the Phase I (SAD & MAD) study with IRL757 is secured in through The Michael J. Fox Foundation
- Collaboration with MSRD/Otsuka funding IRL757 through proof-of-concept in **Parkinson's and Alzheimer's disease**

Current status

- **Successful completion** of Single Ascending Doses (SAD) part of the Phase I study program
- Multiple Ascending Dose, MAD part, **ongoing**
- An additional Phase I study **ongoing** in a group of adult healthy subjects aged 65 years and older

Preclinical projects

IRL942	Clinical candidate	- Improve cognitive function
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: Preclinical Development, Phase I ready in 2025	Status: Preclinical Development, Phase I ready in 2025

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 Q3

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

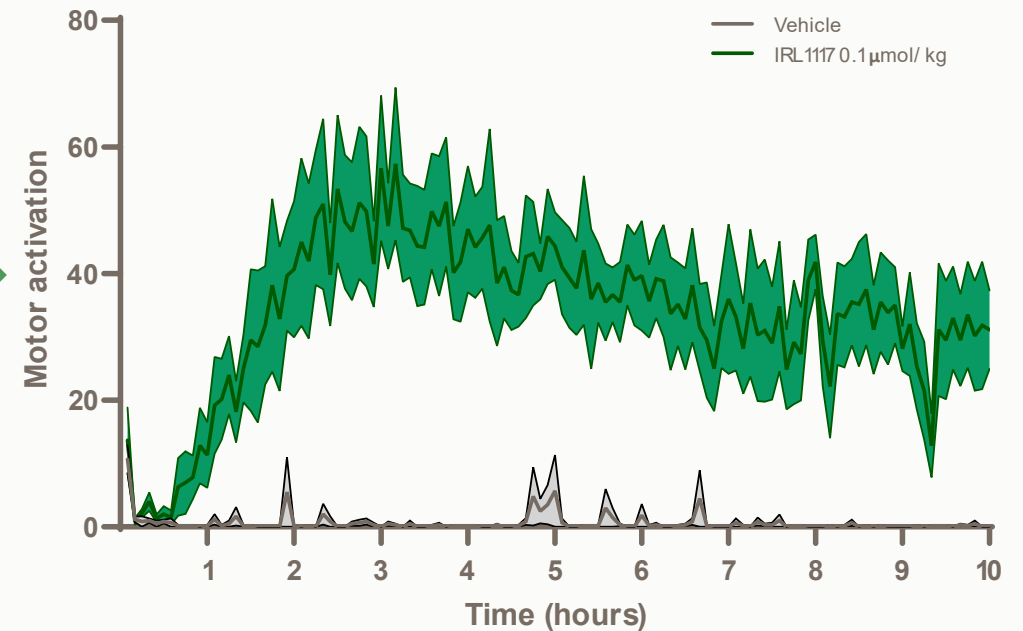
Current status

- Development in preclinical studies
- GMP manufacturing of **drug substance** ongoing (CMC)
- Development of **drug product** initiated and IRL942 is projected to be Phase I ready during 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 24 hours of sustained efficacy without** inducing motor **complications**.
- Currently activities related to substance manufacturing (CMC) and planning for preclinical regulatory studies necessary for Phase I are ongoing



IRL1117 project

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

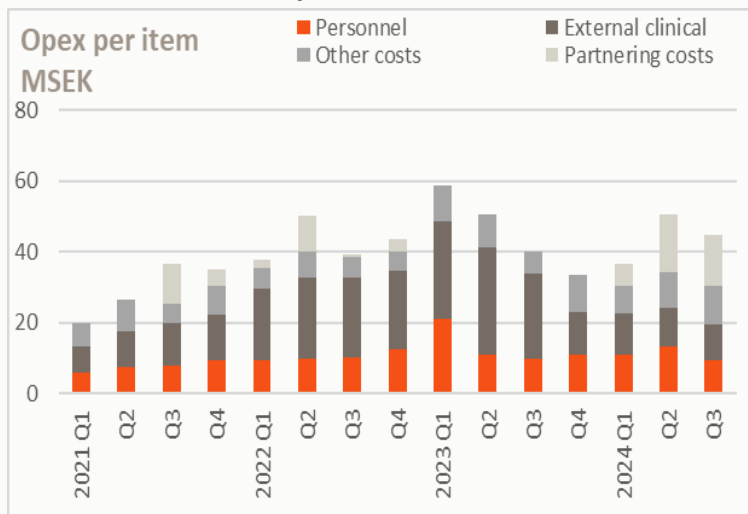
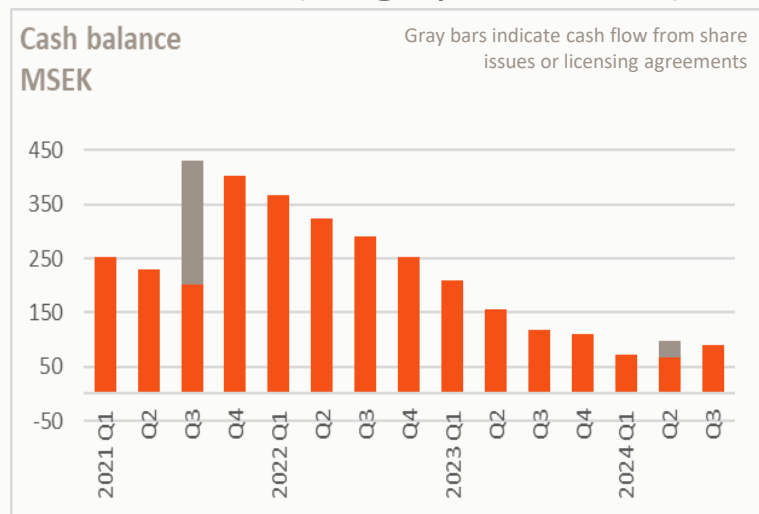
- Composition of matter: patent applications filed in 2022
- The estate potentially allows ultimate case exclusivity into 2040:ies

Finance report Q3 2024

- Highlights and summary
- Analyst coverage

Financial highlights of Q3, 2024

- Cash position SEK 90 million, whereof roughly SEK 34 million is prepayment for cost that will be covered by MJFF and MSRD/Otsuka
- Sustained high activity, and thus cost, related to IRL757, which are fully financed by MJFF and MSRD/Otsuka
- IRLAB's own cost remains stable at around SEK 30 million, whereof around SEK 10 million is external clinical cost
 - External clinical cost is predominantly cost for pirepemat Phase IIb study
- Headcount remains stable at around 30 employees
- USD 2.5m (roughly SEK 26.6m) milestone will be reported in Q4 2024.



Financial summary of Q3, 2024

	Q1-Q3 2024	Q1-Q3 2023
Net sales, SEK	51.8m	6.9m
Operating profit, SEK	- 72.1m	- 145.1m
Earnings per share before and after dilution, SEK	- 1.5	- 2.75
Cash and cash equivalents	90.4	118.8m
Cash flow from operating activities	- 43.0m	- 131.0m
Average number of employees	32	31
Share price at the end of the period, SEK	12.7	7.38

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

Analyst coverage



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Concluding words

Key highlights in and after Q3 2024

The Phase IIb study with pirepemat, REACT-PD, is being completed after a positive opinion from the external safety committee

The last patient in the Phase IIb study with pirepemat enrolled: A reduction in the number of falls has been observed in the overall patient population

New patents granted for mesdopetam and pirepemat – expands patent protection in Europe and the US

The company receive USD 2.5 million in connection with the first dosing in a Phase I study with IRL757 in healthy older adults





progresses towards finalization and read out as planned

Strengthens commercial value of mesdopetam and pirepemat

IRL757 fully funded through clinical PoC

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

Q3 update

		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						Phase III ready	2025: Projected start of Phase III study program
	Parkinson's disease Psychosis D3 antagonist				Phase II ready			
Pirepemat (IRL752)	Parkinson's disease impaired balance and falls PFC enhancer						Phase IIb	Q1 2025: Top-line results Recruitment completed in Sept
	Parkinson's disease Dementia PFC enhancer					Phase IIa		
IRL757	Apathy in neurology <div><div> McQuade Center for Strategic Research and Development</div><div> THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH</div></div>				Phase I			Q1 2025: Top-line results
IRL942	Cognitive impairment in neurology				Preclinical			2025: Phase I ready
IRL1117	Parkinson's disease treatment				Preclinical			2025: Phase I ready

Multiple possibilities for high value creation in the project portfolio during the next 12-18 months

Mesdopetam

- BD activities
- Initiation of the Phase III program

Pirepemat

- Top-line data Phase IIb study in PD-Falls
- BD activities

IRL757

- Completion of Phase I studies (SAD/MAD, food interaction & healthy older adult)
- Initiation of Proof-of-Concept study (efficacy and safety signal finding)

Preclinical projects

- IRL942: Phase I readiness, start Phase I
- IRL1117: Phase I readiness, start Phase I

IRLAB – a world-leading portfolio in Parkinson's



Pioneering biology & ISP

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



Focused strategy

Discover and develop treatments for PD patients throughout their disease journey



Validated business model

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 discovers and develops a portfolio of transformative treatments for all stages of Parkinson's disease. The company originates from Nobel Laureate Prof Arvid Carlsson's research group and the discovery of a link between brain neurotransmitter disorders and brain diseases. Mesdopetam (IRL790), under development for treating levodopa-induced dyskinesias, has completed Phase IIb and is in preparation for Phase III. Pirepemat (IRL752), currently in Phase IIb, is being evaluated for its effect on balance and fall frequency in Parkinson's disease. IRL757, a compound being developed for the treatment of apathy in neurodegenerative disorders, is in Phase I. In addition, the company is also developing two preclinical programs, IRL942 and IRL1117, towards Phase I studies. IRLAB's pipeline has been generated by the company's proprietary systems biology-based research platform Integrative Screening Process (ISP). Headquartered in Sweden, IRLAB is listed on Nasdaq Stockholm (IRLAB A).

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