

# World leader - developing new treatments for Parkinson's disease

IRLAB, Q2 2025



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## Today's agenda





News in the period Kristina Torfgård, CEO





R&D update
Nicholas Waters, EVP Head of R&D



Financials
Viktor Siewertz, CFO





Concluding words



**Q&A** session



## Key highlights in and after Q2 2025

New patent granted for mesdopetam – expands patent protection in the US and expires in the mid 2040s

Positive Phase I results on IRL757 support ongoing development

Data presented at AD/PD support treatment strategies for PD with "cortical enhancers" - pirepemat, IRL757 and IRL942

A rights issue provided the company SEK 115.7 million before issue costs and set-off of loans

Strengthening the value of mesdoptam

IRL757 progresses according to plan – fully funded through clinical PoC

Groundbreaking data – potential for a new class of CNS drugs

Strengthened financial position – opportunities for value creation





# 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 patentbased exclusivity towards mid 2040s

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

## "Pipeline-in-a-Pill" - life cycle management opportunities

- Parkinson disease psychosis
- Prevention of levodopa-induced dyskinesia
- Optimization of levodopa treatment without driving dyskinesia
- Tardive dyskinesia



### Regulatory validation and value creation Q1 & Q2

#### Regulatory guidance and payor input on mesdopetam phase III program achieved

Scientific advice with EMA and local EU regulatory agencies in line with FDA advice on design of Phase III program

#### Important value creating information & patents granted in the US

- Market research/Health provider activities guiding value proposition and positioning of mesdopetam provides input to the design of the Phase III program
- An additional composition of matter patent has been granted in the US
- The patent is previously granted in Europe
- This patent family provides exclusive market protection for mesdopetam but also protect the process for its production
- The granted patents expand the already strong patent protection for mesdopetam.
- There is therefore potential for market exclusivity towards the mid 2040s in large and important markets



# Mesdopetam fills the gap between current levodopa based and invasive treatments

#### PD Disease severity Pharmacological Invasive Levodopa adjustments + other Produodopa Duodopa DBS concomitant treatments (31 kGBP/yr) (28 kGBP/yr) (65 kUSD) payor position (ref: NICE) Advanced levodopa-responsive Mesdopetam Parkinson's disease with severe motor Fills the gap and fluctuations and hyperkinesia or can delay invasive dyskinesia when available combinations of Parkinson medicinal treatments products have not given satisfactory results





# Pirepemat

**IRL752** 

- A treatment reduce falls in Parkinson's (PD-Falls)
- Full program from preclin through a randomized, placebocontrolled dose-finding Phase IIb clinical trial completed

#### Pirepemat (IRL752)

First in class - a novel mechanism

Inhibiting alpha 2 and serotonin 7 receptors

Potential for patentbased exclusivity towards mid-2040s

Objective – reduce falls in Parkinson's disease

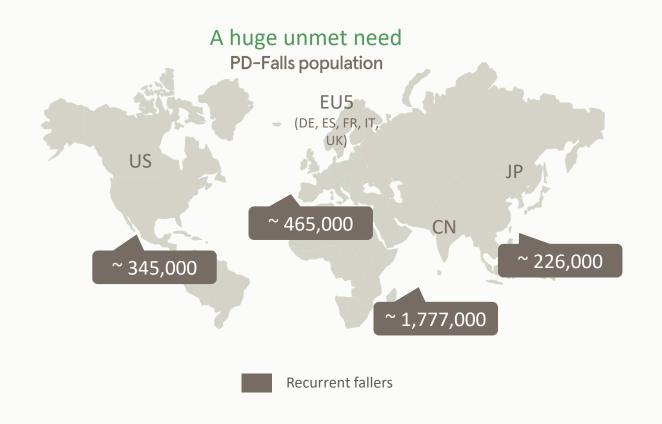


# Pirepemat - in development to reduce falls in Parkinson's



#### Reducing falls is the greatest medical need and one of the most complicating aspects of Parkinson's

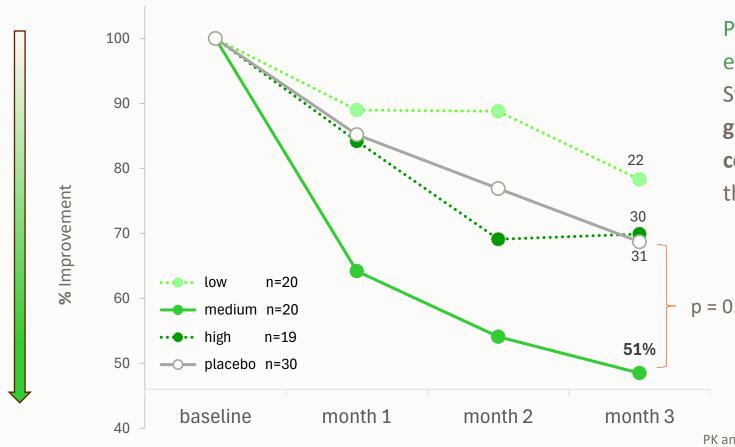
- 45% of individuals with Parkinson's fall recurrently
- Cost of a fall injury approx. 30 000 USD in patients > 65 years (CDC)
- About USD 80 billion was spent in the US (2020) for non-fatal falls in older adults





# Reduction in relative fall rate vs. pirepemat plasma concentration [exposure]: PK-PD





Prespecified assessment of exposure vs.
efficacy - therapeutic window
Study participants were assigned to three
groups of same size based on plasma
concentration [exposure] and compared to
the 30 participants receiving placebo

p = 0.037 over study period

PK analysis set, P-value based on negative binomial regression model



## Developments during Q2

#### **Status and ongoing activities**

- Based on the dose finding phase IIb data a strengthened development plan in place
- Preparing for a decision on the next step in the development of pirepemat including;
  - Preparation for a clinical study with the aim to optimize the titration of individual dosages so that all treated individuals remain within the therapeutic window
  - These results will be crucial for designing a future Phase III program
- Notice of allowance was granted for the new composition of matter patent for pirepemat in Canada
- The new patent has previously been granted in the US, Europe, Japan and China
- The exclusivity in the US and Canada is extended towards mid-2040s
- A pan-European expert group is preparing a publication of the Phase IIb study results





# IRL757 – treatment of apathy

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



# IRL757 is aimed at the huge untreated problem with apathy

#### Huge unmet medical need

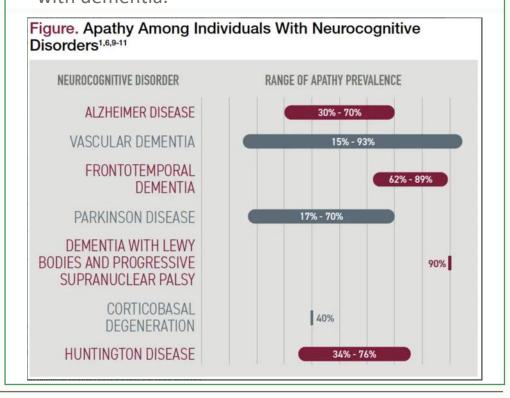
- Several million US and EU citizens may be affected by apathy
- Apathy occurs in 20-70% in people with PD and in 20-90% of people with AD and other CNS disorders

#### 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.





## 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

- 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 a large signal finding study

#### **Status**

- Preclinical and clinical phase I studies successfully completed
- The regulatory application for the clinical trial in individuals with Parkinson's disease and apathy is ready for submission to the European Medicines Agency (EMA)





# Preclinical projects

IRL942 Clinical candidate

**IRL1117** Clinical candidate

- Improve cognitive function

 Once-daily oral treatment of Parkinson's without troublesome complications



## Innovative preclinical pipeline with first-in-class NCEs

#### **IRL942**

Improvement of cognitive function

Memory, perception, attention, reasoning, problem-solving and decision-making

Addressable population: 5.8 million people<sup>1</sup>

Status: Preclinical Development

#### IRL1117

Next generation Parkinson's treatment

Once-daily

Parkinson's hallmark symptoms (tremor, rigidity, bradykinesia)

Without treatment-related complications

Addressable population: 5.7 million people<sup>1</sup>

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

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

Potential for both symptomatic relief and disease modification

#### 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 project progress in Q2

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

#### **Status**

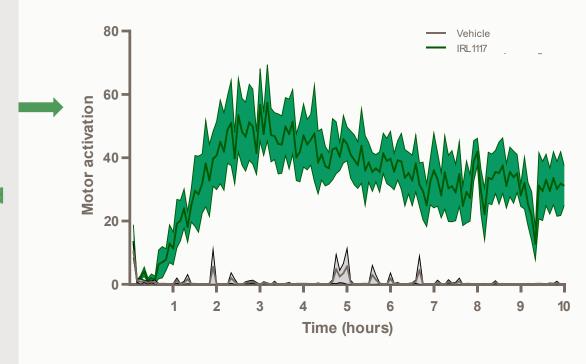
- GMP manufacturing of the drug substance and development of the method for drug product production is soon completed
- Due to priorities in the pipeline, we do not expect to initiate preparatory studies allowing for Phase I until H2 2026, at the earliest



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

#### **Status**

- *IRL1117* is a potent dopamine D1 and D2 receptor agonist
- The preclinical results from long-term treatment show that IRL1117 has full anti-Parkinson effect with clear differentiation vs. levodopa
- Long-term studies show that IRL1117 provides full
   anti-Parkinson's effect without activating genes linked
   to the well known motor fluctuations and thus,
   IRL1117 does not cause such motorcomplications
- Development of drug substance manufacturing on a larger scale (CMC work) ongoing
- Preparations for the preclinical regulatory studies that are necessary for the start of Phase I are underway





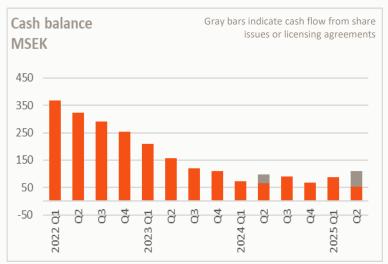


# Finance report Q2 2025

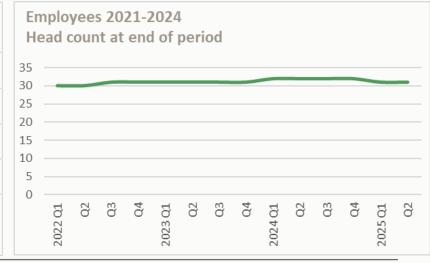
- Highlights and summary
- Analyst coverage

## Financial highlights

- Cash position SEK 54 million. Roughly 56 million (gray bar in left graph below) will be added from the rights issue that was announced in Q2 and concluded in Q3.
- External clinical cost continues to decrease. Most of the quarter's cost occurred during April.
- Partnering cost has increased and will remain quite high as the study with IRL757 advances.
- Increased focus on cost control which will be maintained in the coming quarters with a focus on the study with IRL757, retain competence in the organization but keep external cost low.
- Headcount remains stable at around 30 employees.









## Financial summary

	Q1-Q2 2025	Q1-Q2 2024
Net sales, SEK	23.9m	42.8
Operating profit, SEK	- 54.4m	- 42.7m
Earnings per share before and after dilution, SEK	- 1.28	- 0.89
Cash and cash equivalents, SEK	53.6m	98.3m
Cash flow from operating activities, SEK	- 36.3m	- 38.1m
Average number of employees	31	32
Share price at the end of the period, SEK	3.92	13.25



## Remarkable advances from 2013 until today

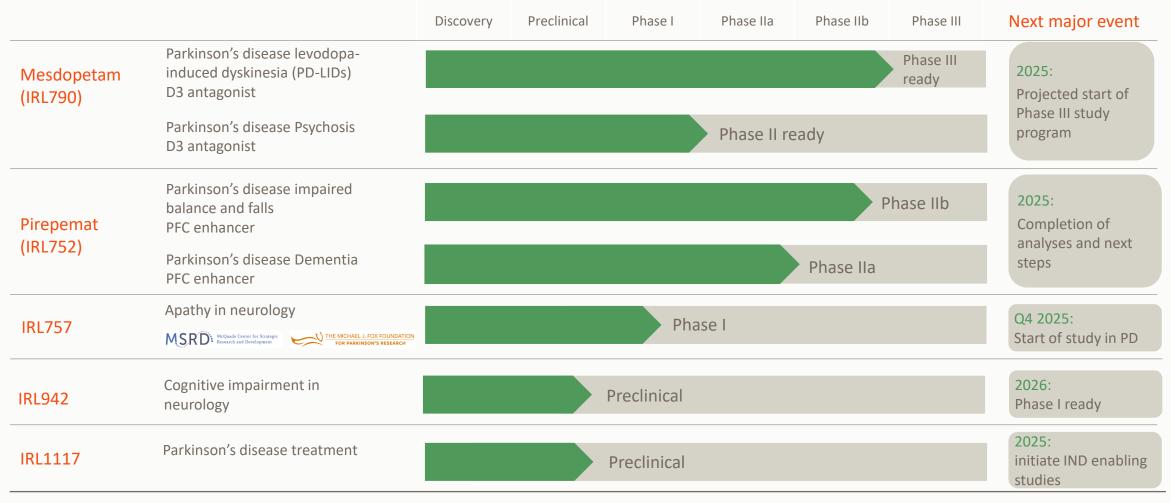
- The company started in 2013 with two preclinical projects and the development platform ISP
- Today we have **five projects, three of which are in clinical stage** and some even in late clinical stage
- Organizational momentum has been build going from a handful of part time employees to a team of roughly 30
  highly skilled professional in a wide array of competences
- 11 share issues, raising **SEK 900 million** 
  - Five share issues in private setting
  - Six in the public setting
- Roughly **SEK 700 million** acquired **from BD activities** to be used in the projects
  - The licensing of mesdopetam to Ipsen, including Ipsen's direct cost for mesdopetam
  - The research collaboration with MSRD regarding IRL757
  - Grants from The Michael J. Fox Foundation regarding IRL757
  - Grants from Vinnova/Horizon 2020





# Concluding words

# World leading portfolio of development programs for Parkinson's disease





# Value creation milestones over the next 12-18 months

Mesdopetam

BD activities

Initiation of the Phase III program

Pirepemat

Decision on next step – prepare for dose optimization study

BD activities

**IRL757** 

Start the study in PD-apathy (Phase Ib safety and efficacy signal finding)

Preclinical projects

IRL942: Phase I readiness

IRL1117: Phase I readiness, start of Phase I







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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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