



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

IRLAB, Q3 2023



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# Today's agenda

Q4 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

4



## Concluding words

5

## Q&A session

# Operational highlights in the third quarter

## Pirepemat

- In July, the Data Safety Monitoring Board (DSMB) **unanimously recommended continuing the ongoing Phase IIb** study of pirepemat per the approved study protocol following a planned review of the first 25 patients having completed the study.

# Operational highlights in the third quarter

## Mesdopetam

- The full ownership of the now Phase III-ready mesdopetam project was secured by IRLAB in August. Simultaneously, IRLAB confirmed its intention to continue with Phase III development of mesdopetam.
- An in-depth analysis of the Phase IIb study shows that mesdopetam has a dose-dependent anti-dyskinetic and anti-parkinsonian effect in combination with a tolerability and safety profile on par with placebo, giving mesdopetam a unique position. The results were presented at the end of August at the MDS Congress in Copenhagen.

# Operational highlights in the third quarter

## Business development and financing

- Business Development – increased activities in the evaluation of potential collaboration partners and licensees
- Investors – continued financing activities with participation in conferences as well as discussions with financial advisors and investors

# Operational events after end of period

## Mesdopetam

- In October, a collaboration commenced with the US regulatory advisors Clintrex, who leads IRLAB's US regulatory strategy, and ProPharma Group, who acts as IRLAB's regulatory agent in the US. Together with our advisors IRLAB is now preparing for an end-of-Phase 2 meeting with the FDA where the Phase III program for mesdopetam will be defined.

## Investors

- IRLAB held a capital markets day on October 17 where investors, analysts and financial media were updated on the company's drug development portfolio and growth strategy. Presentations were held by company representatives as well as an external opinion leader and a recording is available on IRLAB's website, [irlab.se/capital-markets-day-2023](https://irlab.se/capital-markets-day-2023).

# Financial summary of third quarter

All amounts in SEK	Q3 2023	Q3 2022
Net sales	-	16.5m
Operating profit	- 40.7m	- 23.9m
Earnings per share before and after dilution, SEK	- 0.74	-0.46
Cash and cash equivalents	118.8m	291.7
Cash flow from operating activities	- 36.7m	27.9
Average number of employees	31	28
Share price at the end of the period, SEK	7.38	34.50

*Figures in brackets = same period last year, unless otherwise stated*





# R&D update

# The most bothersome symptoms according to people with Parkinson's

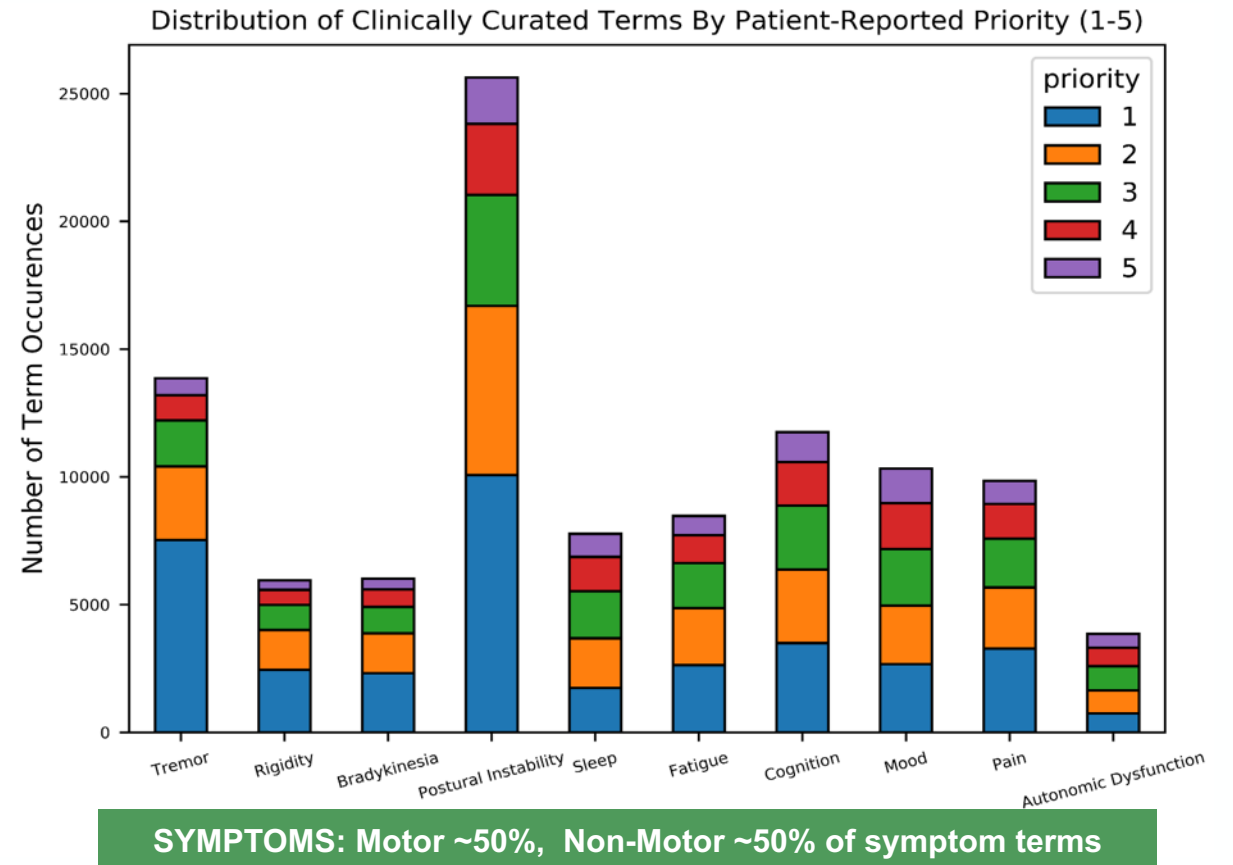
## Most frequent bothersome symptoms

- Balance/instability
- Hallmark symptoms
  - Tremor
  - Rigidity
  - Bradykinesia
- Cognition
- Mood

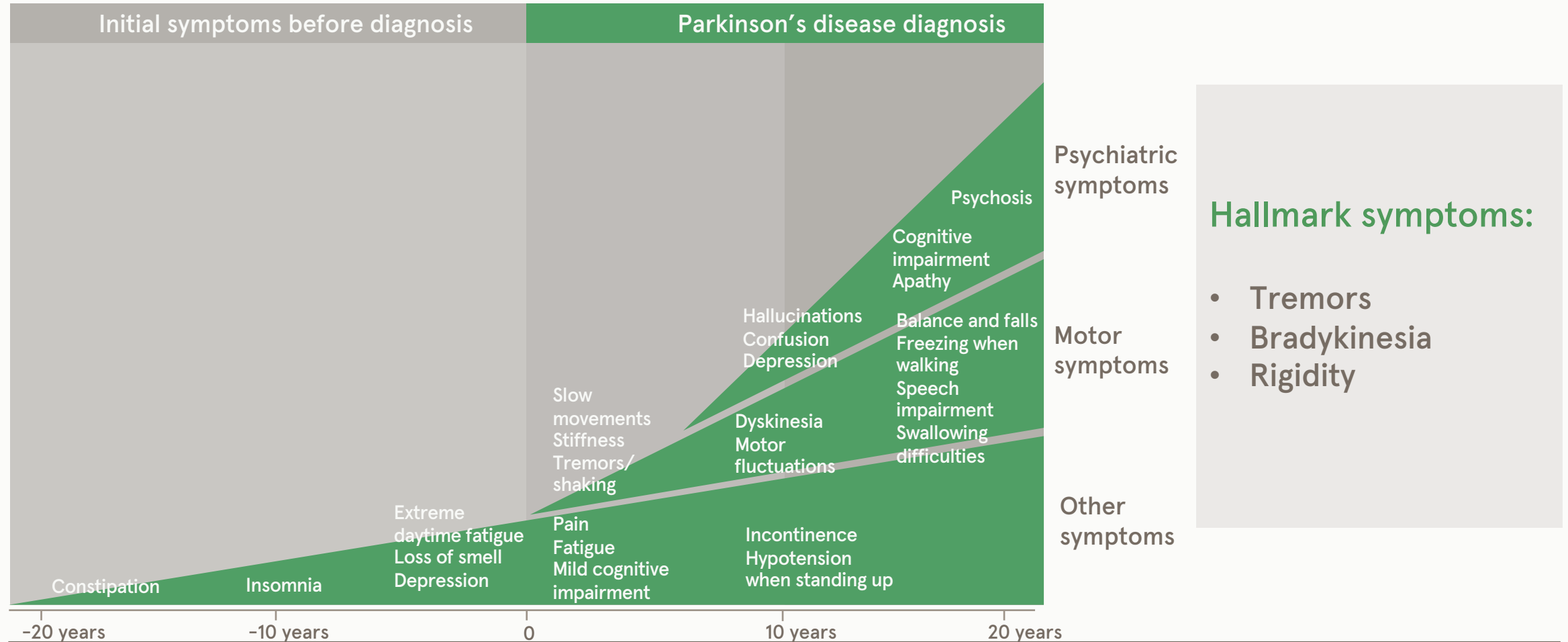
Align with areas addressed by IRLAB

## What bothers people with Parkinson's disease the most ?

Self-reported, n=25 000 (the Fox Insight project, Michael J. Fox Foundation)

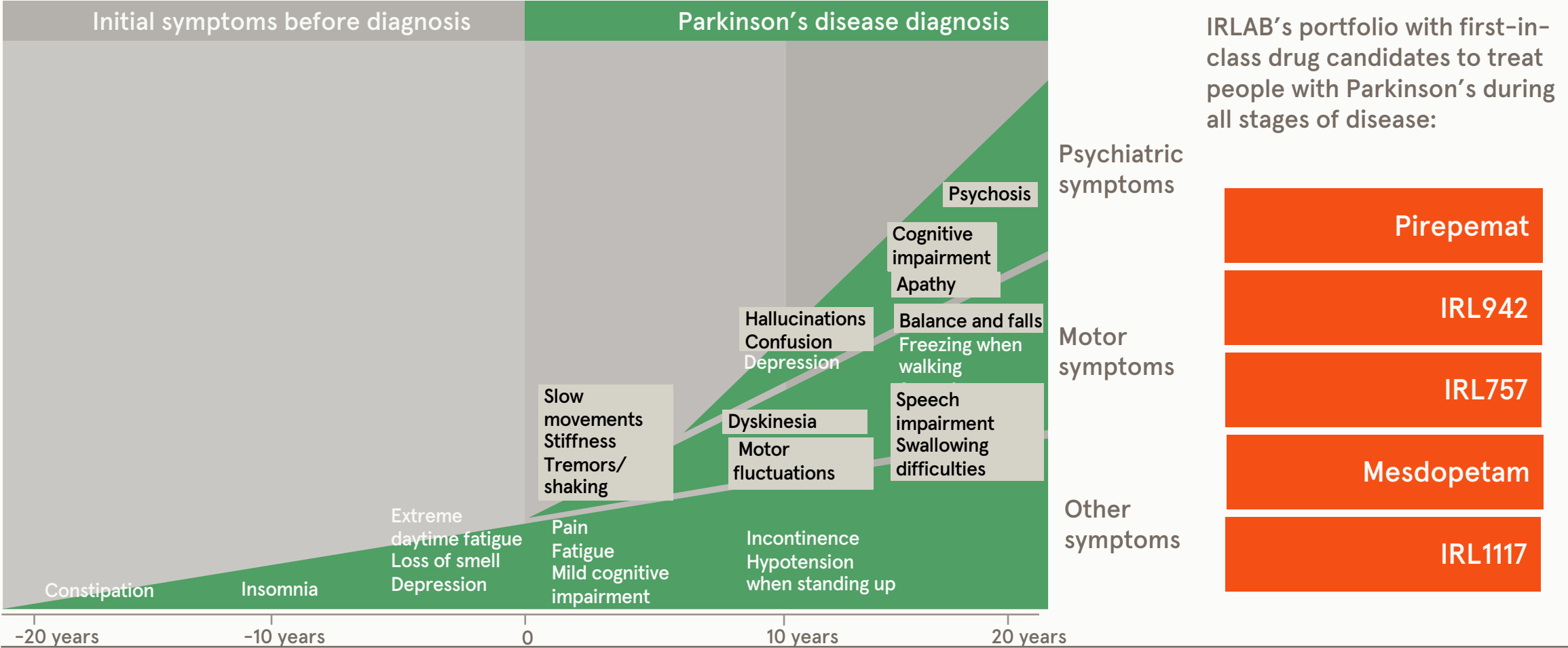


# Parkinson's disease progresses over time – symptoms and complications expand



# Parkinson's diagnosis is improving over time – treatments and indications expand

Parkinson's and  
IRLAB's portfolio



# Mesdopetam (IRL790)

*(mes\_dop\_e\_tam)*

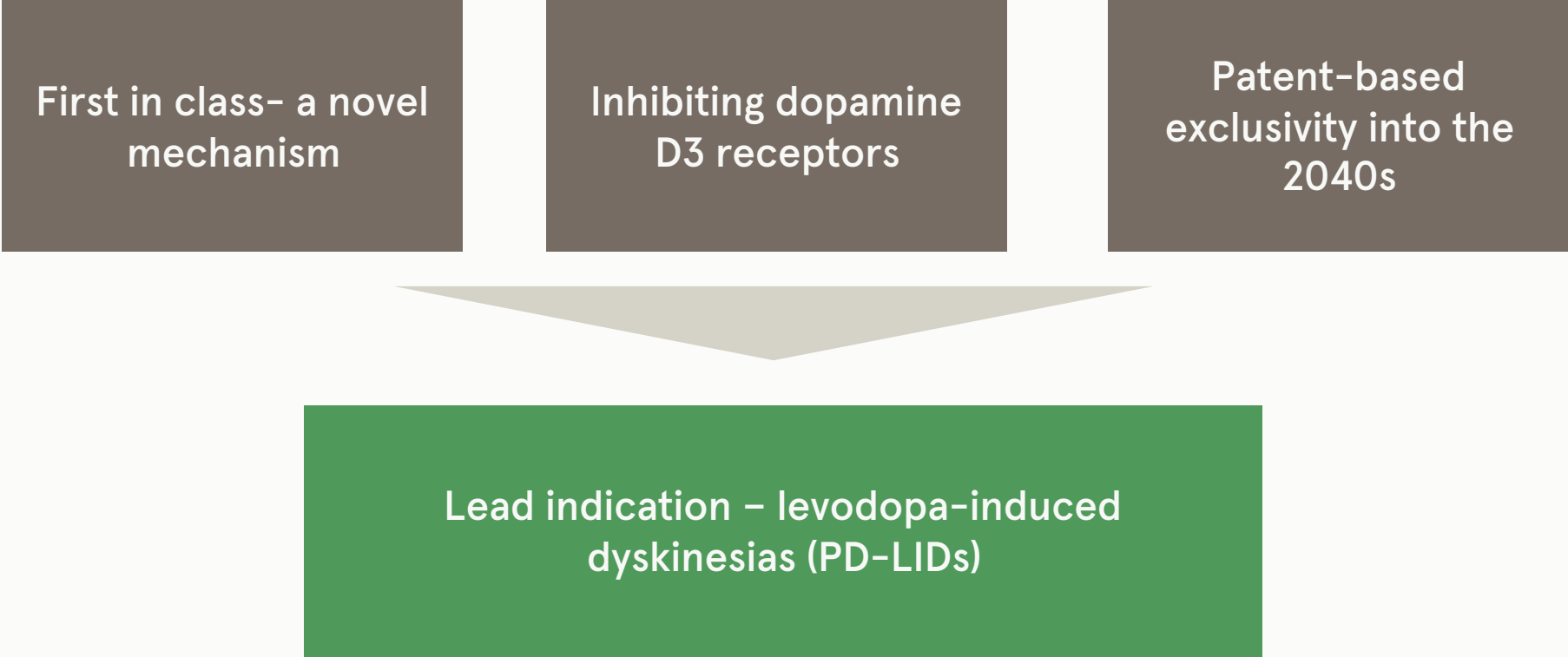
- Mesdopetam counteracts levodopa-induced dyskinesias (PD-LIDs) by a novel mechanism **inhibiting dopamine D3 receptors**

# Mesdopetam (IRL790)

First in class- a novel mechanism

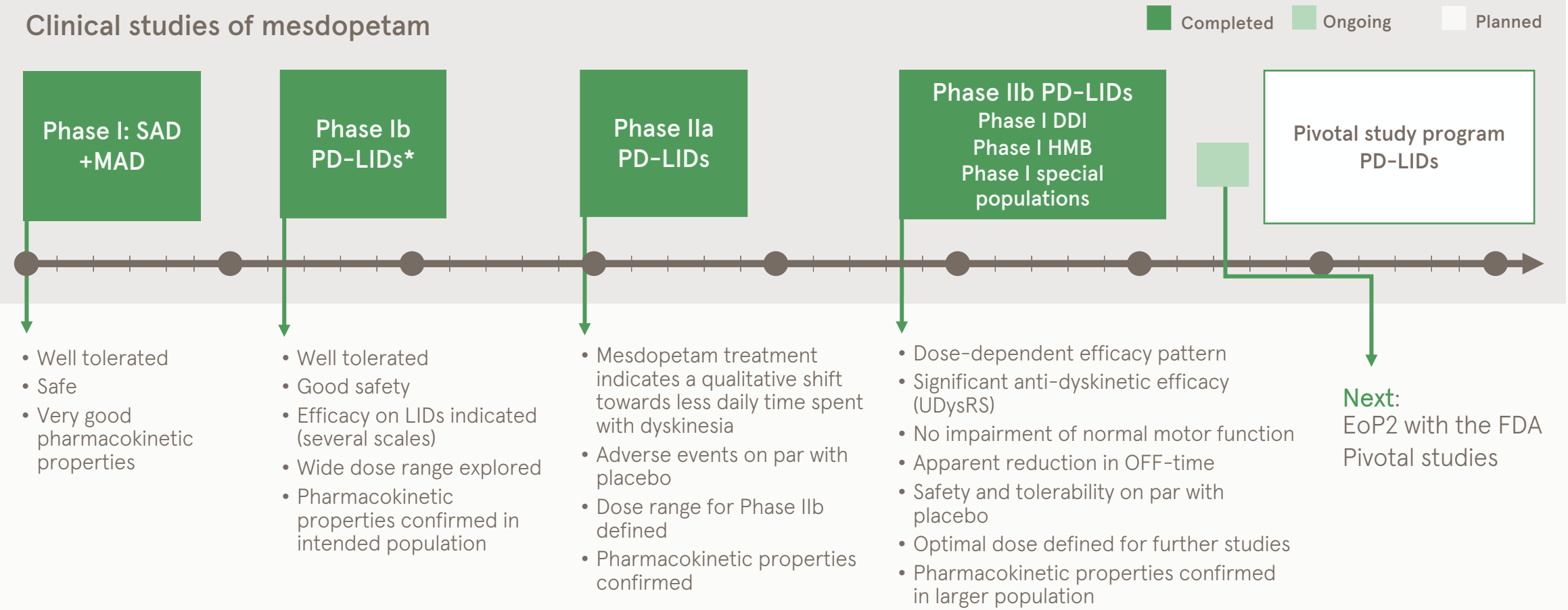
Inhibiting dopamine D3 receptors

Patent-based exclusivity into the 2040s



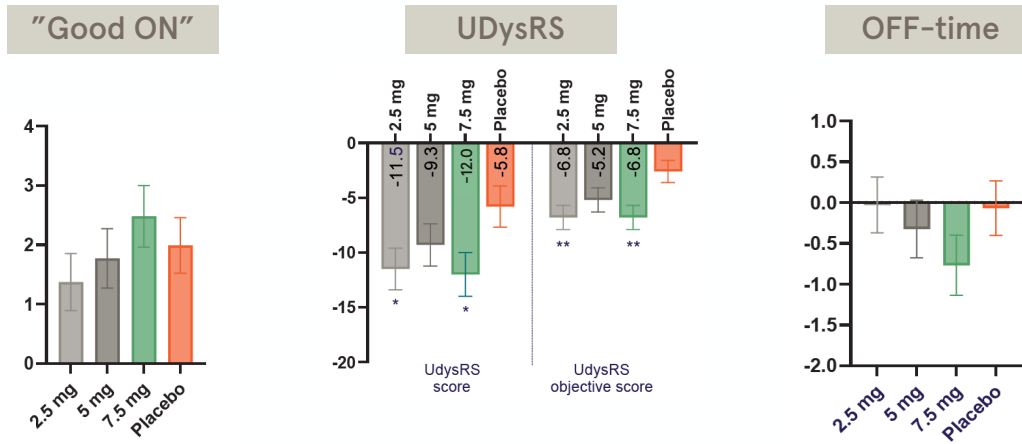
Lead indication – levodopa-induced dyskinesias (PD-LIDs)

# Growing body of clinical evidence supporting a novel treatment of dyskinesia in Parkinson's



# Mesdopetam – Phase IIb study conclusions

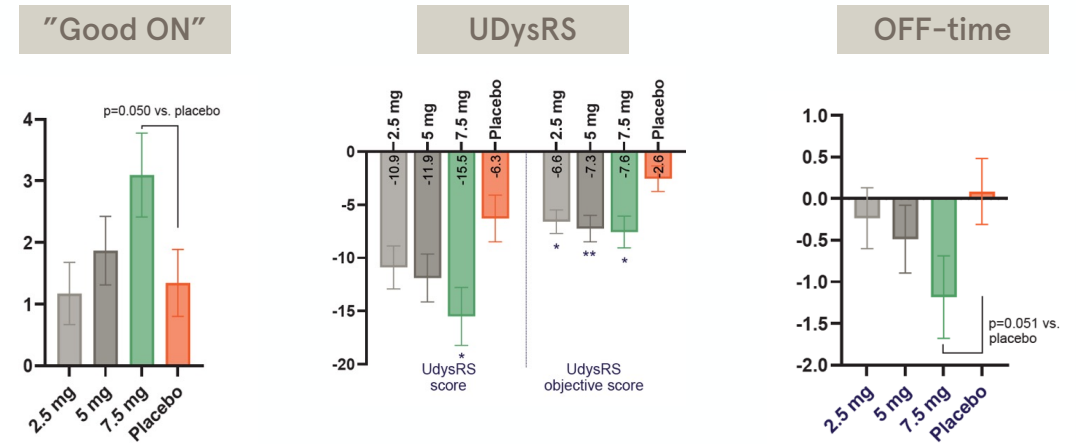
## FAS population



- Consistent dose-response **and clinically meaningful anti-dyskinetic efficacy**
  - Improvement in UDysRS
  - Improvement in "good ON"-time
- Consistent **dose-response pattern** in reduction in OFF-time, i.e., **anti-parkinsonian efficacy**

FAS = Full Analysis Set

## PS population



- No untoward effects on normal motor functions** or PD symptoms, i.e., no increase of Parkinsonism
- Safety and tolerability profile on par with placebo** at all doses
- Predictable plasma exposure – linear and dose-dependent
- Dose selection for Phase III achieved (7.5 mg b.i.d.)**

PS = Subjects compliant with the protocol



# Pirepemat (IRL752)

*(pir\_epe\_mat)*

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

# Pirepemat (IRL752)

First in class- a novel mechanism

Inhibiting alpha 2 and serotonin 7 receptors

Patent-based exclusivity into the 2040s



Objective – reduce falls in Parkinson's disease

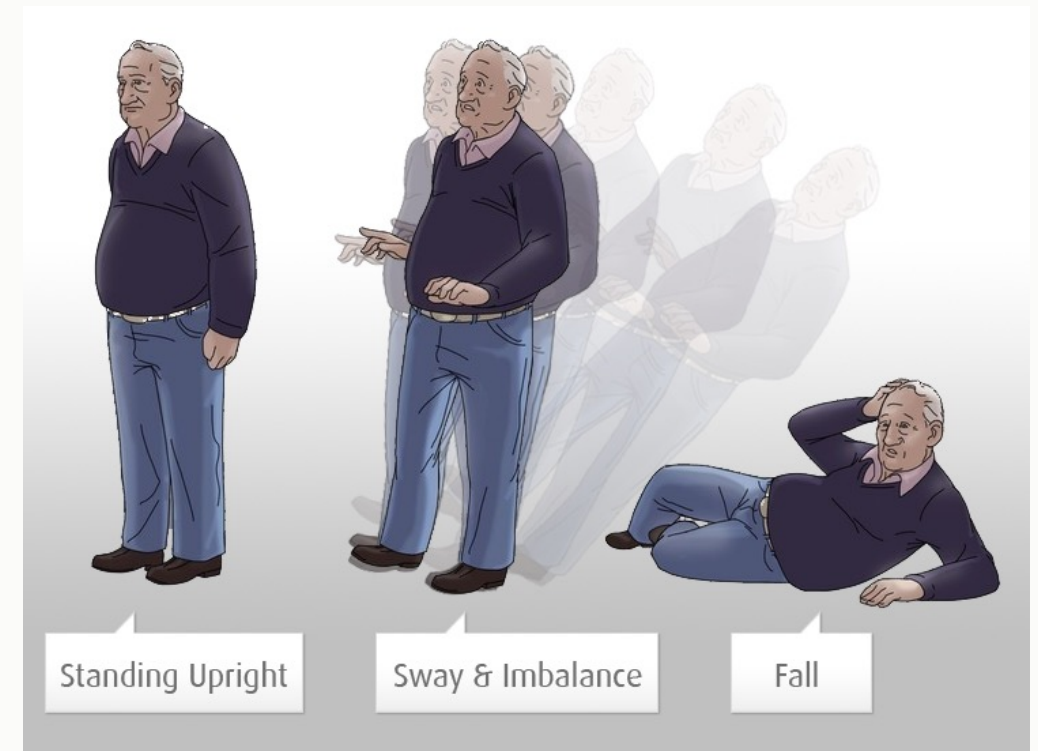
# Why preventing falls in Parkinson's?

Reducing falls is the greatest medical need and one of the worst aspects of Parkinson's.

- Prospective studies report that 70% of people with Parkinson's have at least one fall in a year and about 45% fall recurrently.
- Median survival in patients that have recurrent falls is 6 years.
- Reasons why people with Parkinson's fall<sup>1,2</sup>:

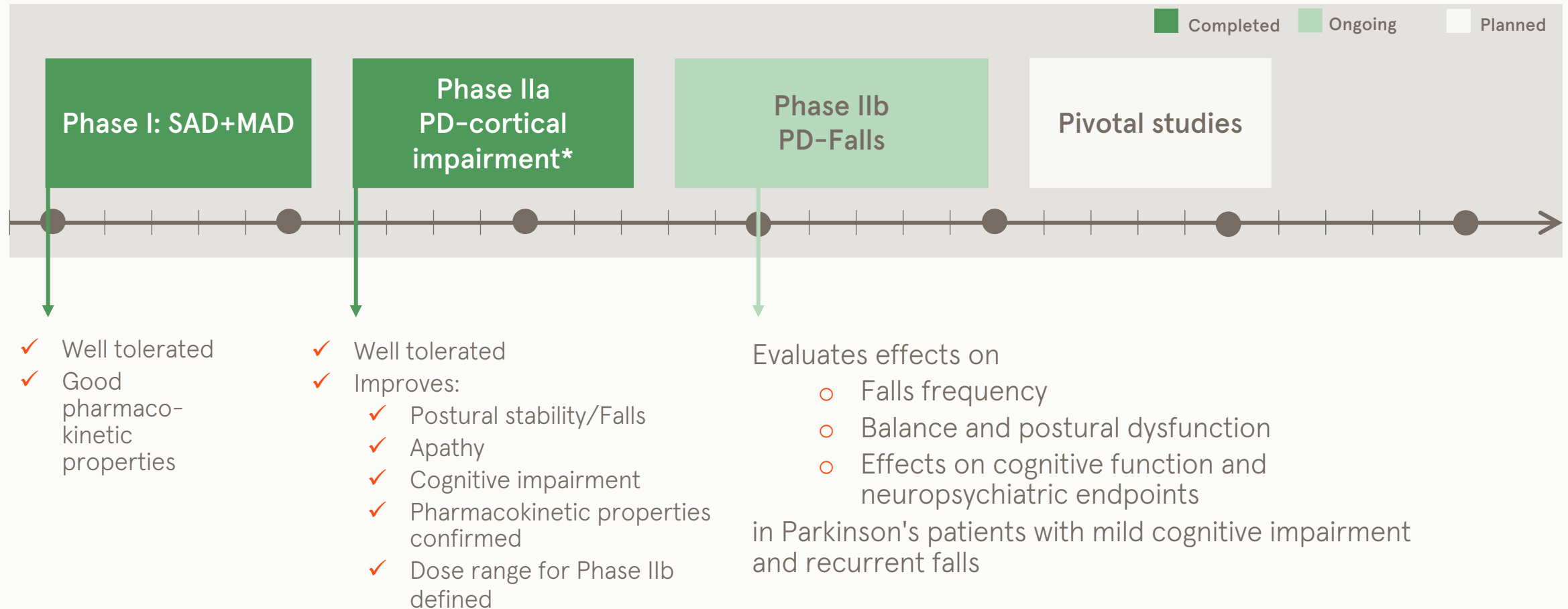
**Cognitive decline → Impaired balance → Falls → Injuries & costs**

- Consequences of falls include fractures and injury, fear of future falls, hospital admission, and increased caregiver burden, with falls cited as one of the worst aspects of the disease.



**Fall injuries are the dominant cause of hospitalization for people with Parkinson's**

# Clinical development path for pirepemat: Improvement of balance and falls



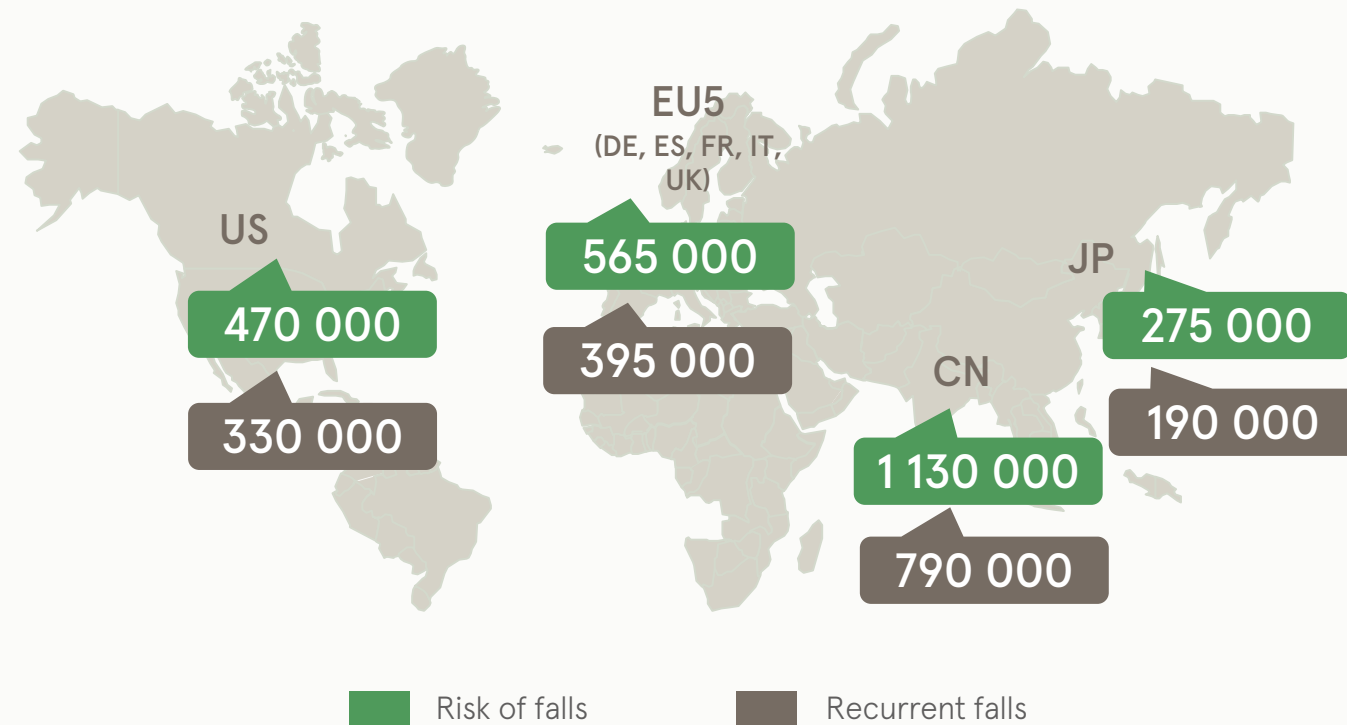
# Pirepemat – in development to improve balance and reduce falls in Parkinson's

- 45% of individuals with Parkinson's fall recurrently
- Cost of a fall injury approx. 30 000 USD in patients > 65 years
- There is no available treatment despite the large unmet need

## 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 continues into Q1 2024
- Aiming to report top-line results in H1 2024

## PD-Fall total patient population – 2.6 million<sup>1</sup> –



# Preclinical projects

IRL757	Clinical candidate	Treat apathy
IRL942	Clinical candidate	Improve cognitive function and brain health
IRL1117	Clinical candidate	Once-daily oral treatment of Parkinson's without troublesome complications

# Preclinical projects in development

Preclinical  
projects

## IRL757

Treatment for  
apathy

Loss of initiative, interest, and  
emotional expression/  
responsiveness

Addressable population:  
1.1–6.7 million people<sup>1</sup>

Status: IND-enabling studies;  
Phase I ready YE 2023

## IRL942

Improvement of cognitive  
function

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

Addressable population:  
1.5–3.0 million people<sup>1</sup>

Status: IND-enabling studies;  
Phase I ready H1 2024

## IRL1117

Once-daily treatment of  
Parkinson's (tremor, rigidity,  
bradykinesia) without treatment-  
related complications

➔ Next-generation Parkinson's  
treatment

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

Status: Preclinical  
development

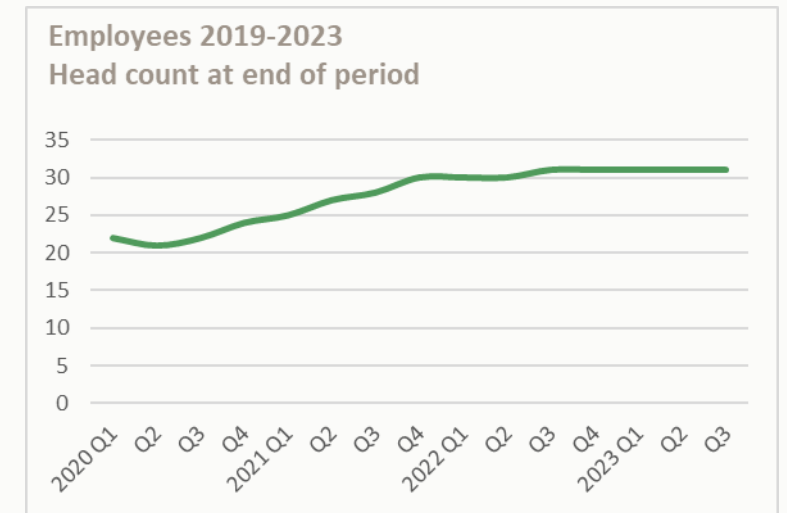
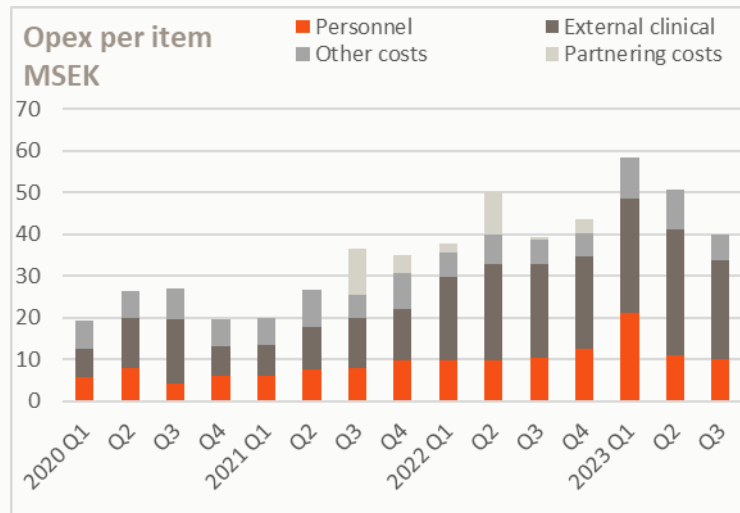
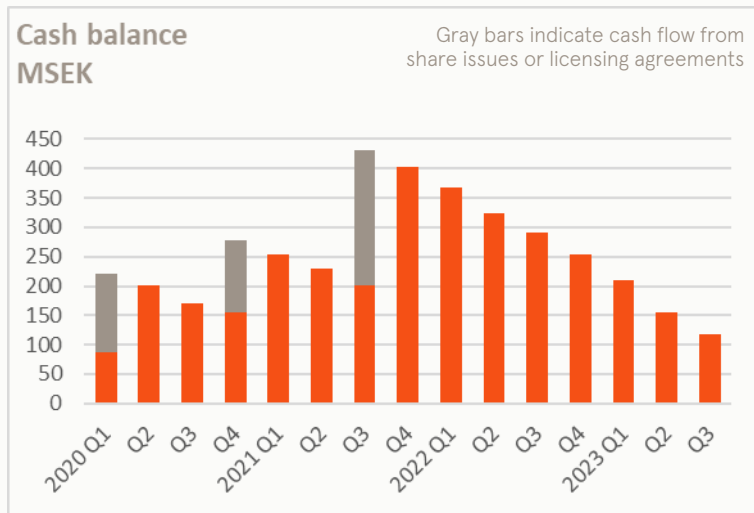
# Finance report Q3 2023

- Highlights and summary
- Analyst coverage



# Financial highlights of Q3 2023

- Cash position SEK 119 million
- Continued focus on cost control, prioritizing cost that will preserve or increase value in the projects
- Investing in the Phase IIb with pirepemat according to plan
- Maintaining investment in preclinical development, advancing IRL757 and IRL942 and IRL1117 towards clinical Phase I
- Headcount remain stable at around 30 employees



# Analyst coverage



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# Concluding words

# Our strategy

- Addressing all stages of Parkinson's disease and other CNS disorders
- Discovering novel candidate drugs (CDs) with our ISP platform
  - True innovation
  - Higher success rate
  - Strong IP position
- Developing CDs from discovery to Proof-of-Concept (PoC)
- Seeking partnering after PoC

# Key developments and growth of the project portfolio during 2023

- **Mesdopetam**
  - Phase IIb read out – Phase III readiness
  - Secured full ownership and rights to the product
- **Pirepemat**
  - Phase IIb study ongoing – all clinical sites opened
  - First pre-specified DSMB evaluation – continue according to plan
- **IRL1117**
  - CD selection and start of preclinical development
- **IRL757 & IRL942**
  - Preclinical development progress aiming for Phase I readiness by year-end 2023 and H1 2024
- **Project portfolio** – world-leading position in Parkinson's
- **Increased BD activity** – multiple opportunities evaluated

# Development portfolio transforming treatment of people living with Parkinson's

		Discovery	Preclinical	Phase I	Phase IIa	Phase IIb	Phase III	Next major event
<b>Mesdopetam (IRL790)</b>	Parkinson's disease levodopa-induced dyskinesia (PD-LIDs) D3 antagonist						Phase III ready	<ul style="list-style-type: none"> <li>End-of-Phase 2 meeting with FDA to define Phase III</li> </ul>
	Parkinson's disease Psychosis D3 antagonist						Phase I	
<b>Pirepemat (IRL752)</b>	Parkinson's disease impaired balance and falls PFC enhancer						Phase IIb	<b>H1 2024:</b> Top-line data Phase IIb study
	Parkinson's disease Dementia PFC enhancer						Phase IIa	
<b>IRL757*</b>	Apathy in neurology						Preclinical	<b>YE 2023:</b> Phase I ready
<b>IRL942*</b>	Cognitive impairment in neurology						Preclinical	<b>H1 2024:</b> Phase I ready
<b>IRL1117</b>	Parkinson's disease treatment						Preclinical	<b>2024:</b> Phase I ready

# Business development efforts

Awareness of IRLAB  
and the development  
pipeline is increasing

Continuous and  
frequent dialogue with  
potential partners

Partnering  
opportunities being  
evaluated across the  
portfolio

Near term focus on  
mesdopetam  
and IRL757/IRL942

# Our key priorities are focused on value-creating activities

## Clinical development

- End-of-Phase 2 meeting with the FDA to define the Phase III program for mesdopetam
- Complete recruitment for the Phase IIb study of pirepemat and present top-line results

## Preclinical development

- Drive the development of IRL757, IRL942 and IRL1117 toward clinical Phase I readiness

## Financing

- Increase capital base to enable further value creation – through BD activities and/or other financing opportunities.
  - Business Development – continue dialogue with potential collaboration partners and licensees
  - Continue dialogues with financial advisors and investors



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

## Mesdopetam

- End-of-Phase 2 meeting with the FDA
- BD activities for Phase III

## Pirepemat

- Top-line results from Phase IIb study in PD-Falls
- BD activities for Phase III

## Preclinical

- **IRL757 and IRL942**
  - Phase I ready
  - Start of Phase I
  - Development collaboration
- **IRL1117**
  - Phase I ready
  - Start of Phase I

# IRLAB – a world-leading portfolio to improve Parkinson's treatments



## 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 discovers and develops novel drugs for the treatment of Parkinson's disease and other disorders of the brain. The company's most advanced drug candidates, mesdopetam (IRL790) and pirepemat (IRL752), both of which are currently subject to Phase IIb studies, were designed to treat some of the most difficult symptoms associated with Parkinson's disease. In 2021, IRLAB entered into an exclusive global license agreement with Ipsen regarding the development and commercialization of mesdopetam. Through its proprietary research platform, ISP (Integrative Screening Process), IRLAB has discovered and developed all its projects and keeps discovering innovative drug candidates for the treatment of disorders of the central nervous system (CNS). In addition to IRLAB's strong clinical development portfolio, IRLAB runs several preclinical programs, with IRL942, IRL757 and IRL1117 in development for Phase I studies.

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