



# Transforming life for people living with Parkinson's

2022 Q4 and Year-end summary

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Nicholas Waters, EVP and Head of R&D



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# Today's agenda

Q4 business  
update

1



- Opening words
- News in the period

2



- R&D update**
- Mesdopetam
  - Pirepemat
  - Preclinical programs

3



- Financials**
- Financial highlights
  - Analyst coverage

4



- Portfolio
- Newsflow & events

5

Q&A session

# Opening words

- **Organizational changes**

- Management
- Board

- **Way forward**

- Working closely with management team
- Focus on strategic priorities
- Partnering and business development

## Our 2023 strategic priorities

1. Fully describe the potential of mesdopetam to be an effective treatment for people in Parkinson's disease.
2. Publish and present the comprehensive results of the Phase IIb trial of mesdopetam in Parkinson's disease at scientific congresses and in scientific journals during 2023.
3. Pursue the timely completion of the Phase IIb study of pirepemat in PD-Falls.
4. Progress IRL942, IRL757 and IRL1117 towards Phase I clinical studies.

# Operational highlights in the fourth quarter

- **Solid progress** in clinical, preclinical and research projects, according to plan
- **Phase IIb study of mesdopetam** in people with Parkinson's levodopa-induced dyskinesias (PD-LIDs)
  - Fully recruited
  - Database lock year-end 2022
  - Top-line results reported in mid January 2023
- New preclinical data was published providing insight into the mechanisms underlying **antipsychotic and antidyskinetic efficacy** of drug candidate mesdopetam (IRL790) in PD-Psychosis and PD-LIDs by an independent academic research group led by Prof. Per Petersson at Lund and Umeå University and presented at the premier congress Neuroscience 2022.
- Presentations at **several national and international investor events**: DNB Nordics Healthcare Conference, LSX Inve\$tival Showcase, Redeye Life Science Day and SEB Annual Healthcare Summit. Public recordings are available on the website, [irlab.se](https://irlab.se).

# Operational highlights after end of period

- IRLAB **participated at the 6th Neuroscience Innovation Forum** hosted by Sachs Associates in early January, held in connection to the Annual J.P. Morgan Healthcare Conference, in San Francisco, US.
- **Drug candidate IRL1117 was nominated from the P003 research project** in early January. IRL1117 will be developed as a once-daily oral treatment for the hallmark symptoms of Parkinson's without inducing the troublesome complications caused by today's mainstay anti-Parkinson's levodopa treatments.
- The **top-line results from the Phase IIb study of mesdopetam** in people with Parkinson's disease levodopa-induced dyskinesias (PD-LIDs) were announced in mid-January. Mesdopetam demonstrated dose-dependent anti-dyskinetic effects in several dyskinetic assessment scales with an adverse event and tolerability profile similar to placebo, even though the study did not statistically meet the primary efficacy endpoint of "good ON"-time. Additional analysis of the full data is currently ongoing.
- In mid-February, the company **announced an update to the portfolio development milestones** following an assessment of the operational priorities for 2023.

# Objectives at different stages of clinical development

## Phase I

- Pharmacokinetics
- Safety and tolerability

## Phase IIa

- Exploration of efficacy signals
- Safety and tolerability

## Phase IIb

- Establish dose response and dose selection
- Safety and tolerability

## Phase III

- Document efficacy in larger patient population
- Safety and tolerability

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- In mid-February, the company **announced an update to the portfolio development milestones** following an assessment of the operational priorities for 2023.



# Financial highlights in the fourth quarter

- Net sales recorded: SEK 12.2m (SEK 12.1m)
- Total operating expenses: SEK 45.8m (SEK 35.0m)
- The operating result: SEK -33.1m (SEK -23.1m)
- Cash flow from operations: SEK -37.9m (SEK -28.4m)
- Cash and cash equivalents at the end of the period: SEK 252.8m (SEK 401.897m)
- The total number of registered shares: 51,868,406 (51,748,406)

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

# IRLAB – at a glance



## Pioneering biology & ISP

Deep profound understanding of Parkinson's based on research by Nobel laureate Prof. Arvid Carlsson



## Focused strategy

Treating PD patients throughout disease journey, has blockbuster potential as a pharma business



## Validated proof-of-concept

One clinical program already licensed to pharma  
\$363m + royalties



## Broad & Solid portfolio

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



## Organization positioned for success

Experienced international organization, Strong Balance sheet, Listed Nasdaq Stockholm

# Parkinson's disease

## What happens?

Loss of >50% cells in the brain that produce **dopamine**

## Why is that important?

Dopamine is one of the most important signaling substances in the brain. Controlling emotions, thoughts and movements (motor functions)

## Why does it happen?

**Age is the most important factor.** Environmental and genetic factors involved.

## Cardinal symptoms

### How do you tell?

### Current treatment

Tremor

"Shaking"

**Levodopa** (in combination with agonists, COMT inhibitors and MAO-B inhibitors)

Bradykinesia

Slowness of moving

**Levodopa** (in combination with agonists, COMT inhibitors and MAO-B inhibitors)

Rigidity

Stiffness

**Levodopa** (in combination with agonists, COMT inhibitors and MAO-B inhibitors)

Postural instability

Trouble with balance and falls

**No available treatment**

## Other symptoms

**Motor:** Facial masking, dystonia, drooling etc.

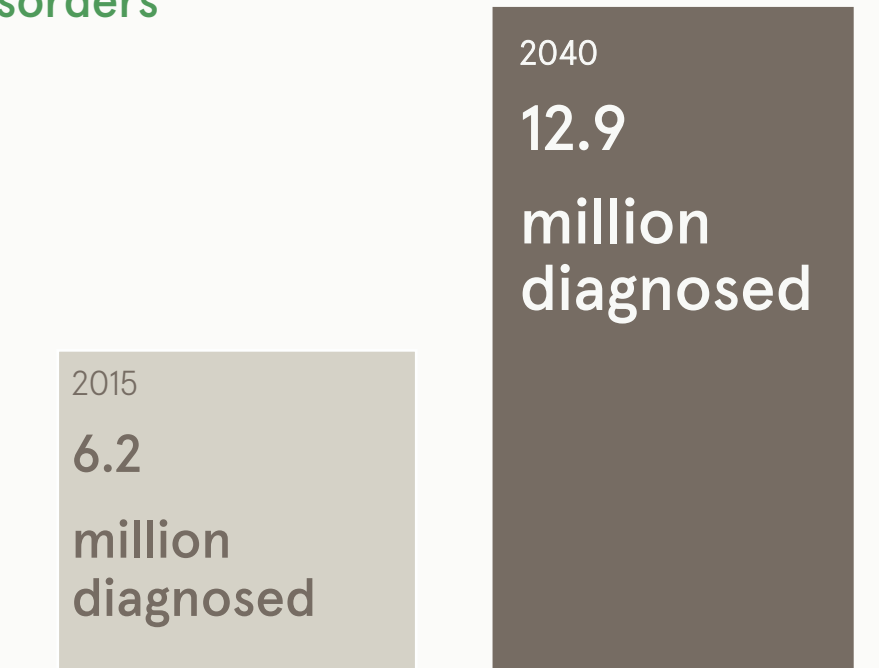
**Non-motor:** Hallucinations, apathy, dementia, problems with speech and swallowing

**Parkinson's disease is chronic and progressive. It is lifelong and worsens over time.**

# IRLAB to address top priorities for management of Parkinson's

Parkinson's and  
IRLAB's solutions

Parkinson's is one of the fastest growing disorders



The burden of society from PD in the US alone translates to \$51,800 per year per patient with Parkinson<sup>1</sup>

## Identified treatment priorities

- Impaired balance and falls
- Cognitive decline
- Motor complications: levodopa-induced dyskinesias (LIDs)
- Non-motor symptoms, e.g. psychosis, anxiety

## IRLAB's solution

- **Pirepemat**
- **Pirepemat, IRL942, IRL757**
- **Mesdopetam**
- **Mesdopetam**



Priority setting partnership to identify the top 10 research priorities for the management of Parkinson's disease

Deane KHO, et al. BMJ Open 2014;4:e006434. doi:10.1136/bmjopen-2014-006434

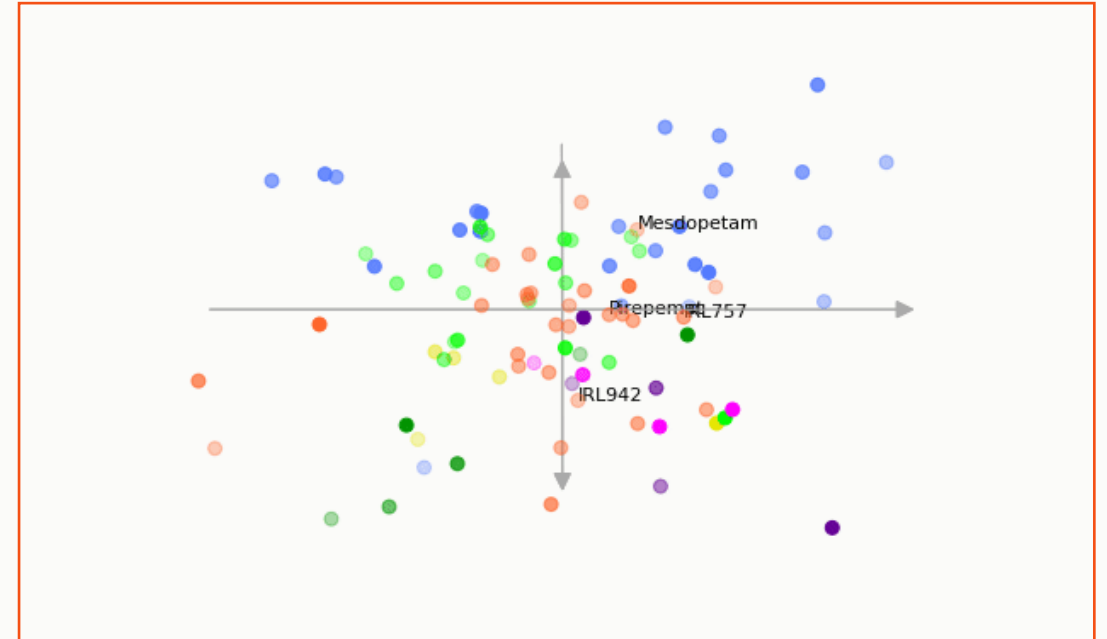
# Pipeline generated with our unique proprietary drug discovery platform – ISP

## Integrative Screening Process (ISP)

- Advanced systems biology approach
- Drug design informed by machine learning techniques
- ISP predicts drug candidates with greatest benefit potential and lowest toxicity risk, based on best biological fit.

## Proven advantages

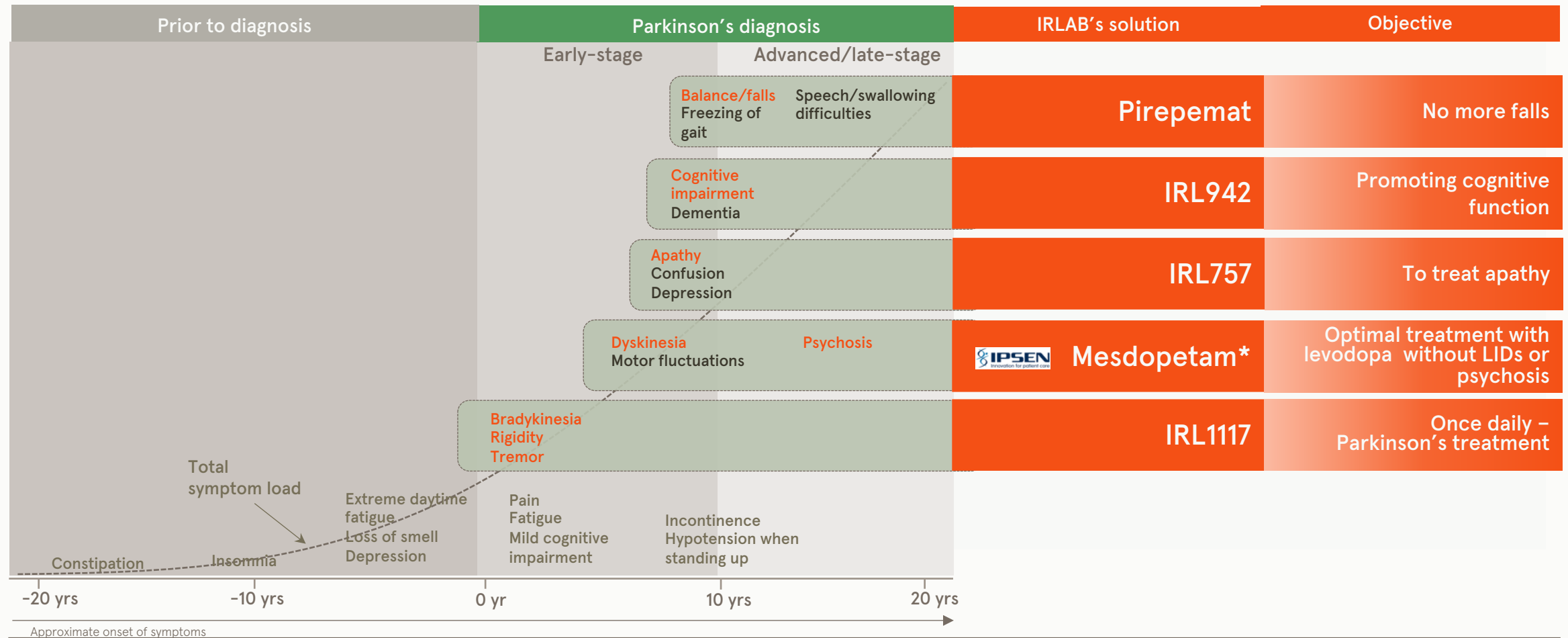
- Discovery of truly novel **first-in-class** compounds
- Strong IPR
- Improvement in probability of drug discovery success and clinical phase transitions, compared with industry standard



**ISP predictions:** Based on dose response data for each compound **24** neurotransmission related biomarkers, **40** gene expression biomarkers and **308** behavioral descriptors (ca **1400** drugs, other reference compounds & IRLAB compounds from **ISP database**)

# Living with Parkinson's: IRLAB transforms the treatment algorithm

Parkinson's and  
IRLAB's solutions



# Mesdopetam (IRL790)

(*mes\_dop\_e\_tam*)

- Mesdopetam counteracts levodopa-induced dyskinesias (PD-LIDs) by **inhibiting dopamine D3 receptors**
- Potential treatment and prevention of psychosis in Parkinson's (PD-P)
- Ipsen licensed the exclusive global rights to develop and commercialize mesdopetam

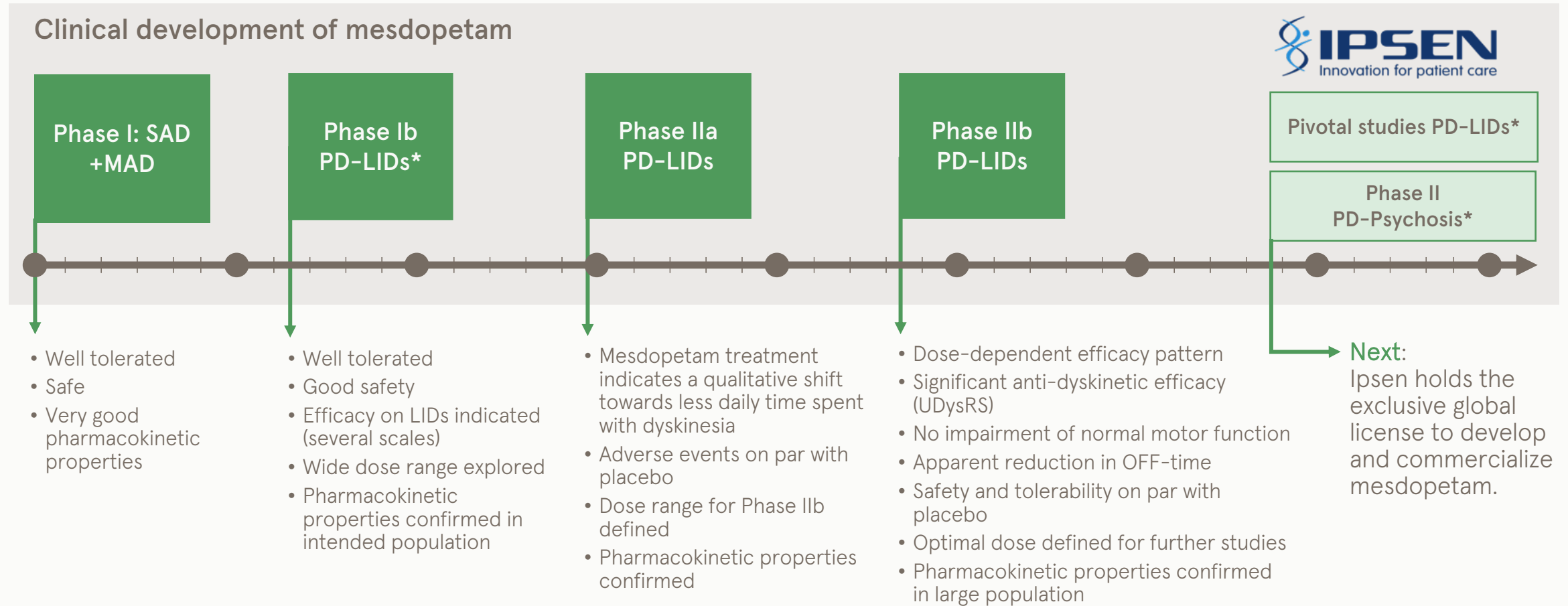
# Mesdopetam's clinical development plan

Mesdopetam

Study	Study Population	Treatment duration	Design	# subjects	Primary objectives	Status	Result
Ph I: SAD+ MAD	Healthy male volunteers	SAD+MAD 10 days	DB placebo controlled cross-over	16 (SAD) 24 (MAD)	PK, safety, tolerability	Finalized	Tolerable, good safety, linear PK, up to 120 mg/day in the SAD part and up to 80mg/day in the MAD part
Ph Ib (patients)	PD-LIDs (dyskinesia)	4 weeks	DB placebo controlled	15 (3:1 allocation)	Tolerability, PK, safety, UDysRS, PKG (actigraph), UPDRS	Finalized	Mesdopetam can be safely administered to patients with advanced PD. Assessments for motor function showed a numeric reduction in dyskinesia across assessments
Ph IIa	PD-LIDs (dyskinesia)	4 weeks	DB placebo controlled	74	UDysRS, CGI, MDS-UPDRS, Hauser diary	Finalized	Mesdopetam is tolerable and displays good safety. AEs were predominantly central nervous system related, mild, and predominantly reported during the first 2 weeks of treatment. Aggregated doses of mesdopetam 2.5, 5, 7.5 mg (b.i.d) improved "good ON" -time by ~2.8 hours (p=0.002)
Ph IIb	PD-LIDs (dyskinesia)	12 weeks	DB placebo controlled	154	Primary EP: Change in average daily hours of ON-time without troublesome dyskinesia	Fully recruited. Top-line data YE	Dose finding successful. Preferred dose 7.5 mg b.i.d. Did not meet significance on primary endpoint. Objective UDysRS showed consistent and statistically significant effects. Improvement in UPDRS scale measuring disability associated with dyskinesia. Dose dependent reduction in OFF. No impairment of normal motor function. AE profile like placebo.
Phase III*	- PD-LIDs (dyskinesia) - PD-P	Post Phase IIb data, Ipsen is responsible for the further decisions regarding development and commercialization					



# Growing body of clinical evidence supporting potential as treatment of dyskinesia in PD



# Pirepemat (IRL752)

(*pir\_epe\_mat*)

- Improve balance and reduce falls in Parkinson's (PD-Falls)
- Ongoing randomized, placebo-controlled Phase IIb clinical trial
- Wholly-owned unencumbered asset

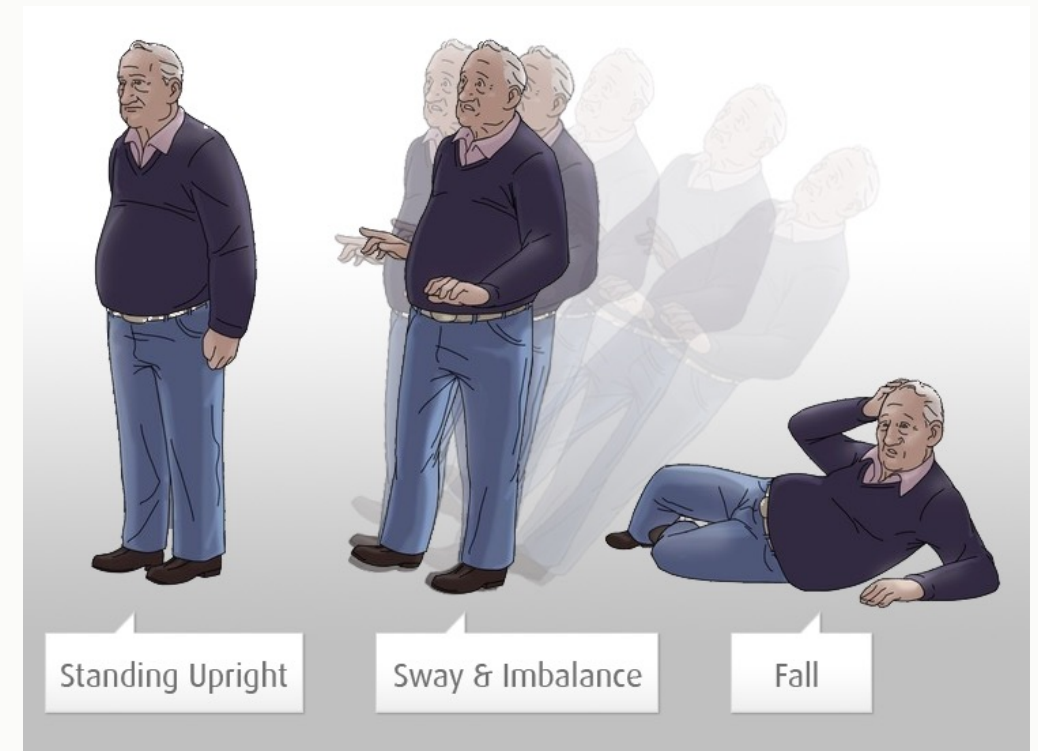
# Why preventing falls in Parkinson's?

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.

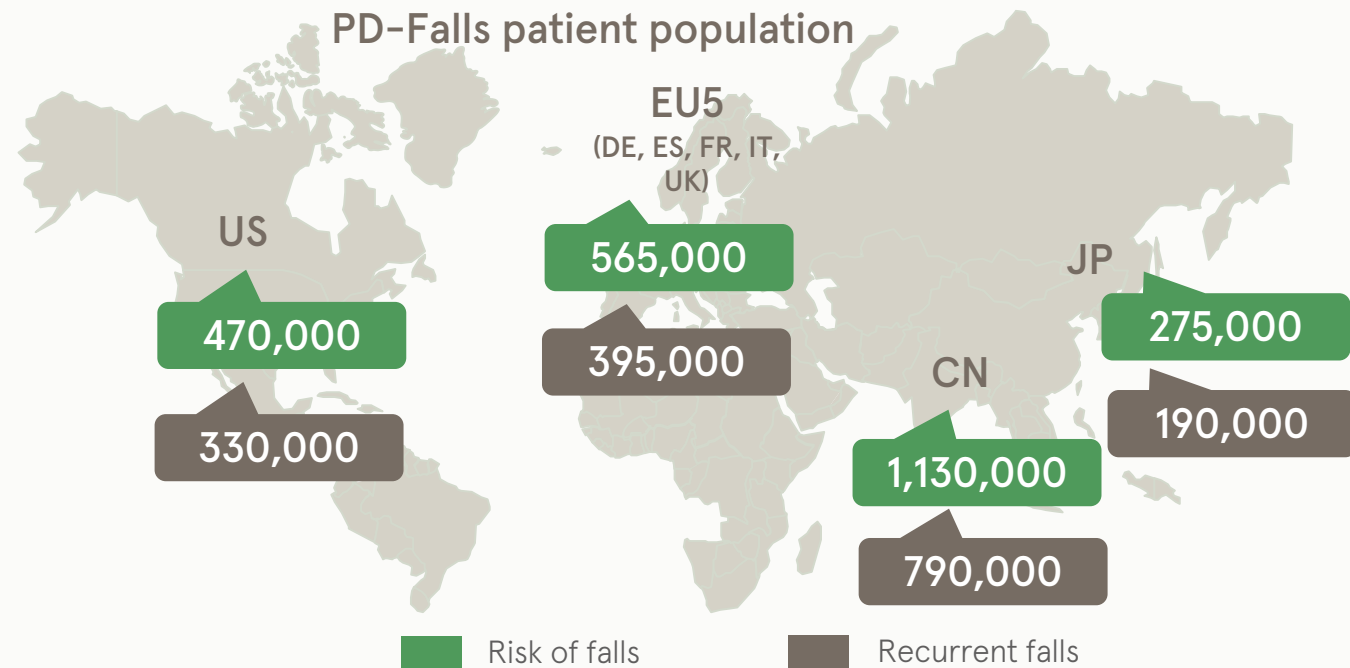


**Fall injuries are the dominant cause of hospitalization for people with Parkinson's**

# Pirepemat can improve balance and reduce falls in Parkinson's

– A large unmet need

- **45% of all people with Parkinson's fall recurrently**
- Impaired balance and a fear of falling significantly impair the daily lives of many with Parkinson's
- **Pirepemat is designed to improve balance and reduce falls** by strengthening nerve cell signalling in the cortex via action at 5HT7 and alpha-2 receptors
- The **cost of treatment for a fall** injury is estimated to about **30,000 USD** in people over age 65



## IRLAB addresses a new, untapped market

Impaired balance leading to falls in Parkinson's have high prevalence and represent a great unmet medical need. There are currently no approved drugs.

# A first-in-class treatment for impaired balance and reduction of falls

## Mechanism of Action

- Combines antagonism at 5HT7 and alpha-2 receptors leading to highly specific activation of frontal cortex NA and DA

## Tolerability

- Well tolerated in clinical studies
- Dose range defined

## Efficacy

- Pirepemat shows promising improvements of balance and has potential to reduce falls in Parkinson's by 50%

## Regulatory

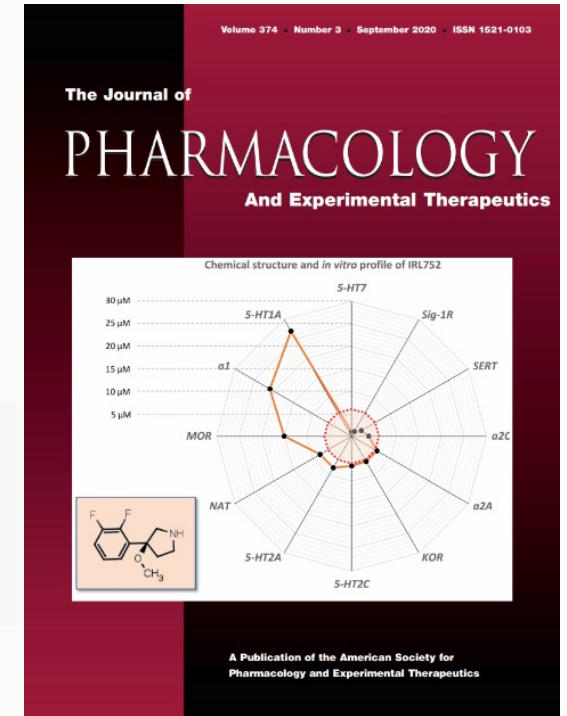
- Ongoing Phase IIb program developed with regulatory agencies, scientific advisors and regulatory experts
- EU regulatory agencies: Study and ethical approvals granted; study ongoing.
- FDA advice to conduct additional DMPK and in vitro mechanism studies, prior to US IND. These studies are expected to be finalized Q2 2023

## Potential

- About 50% of patients with Parkinson's fall (Hoehn&Yahr stage  $\geq 3$ )
- Health economic data show cost of falls are very high

## Validation

- WHO-INN proposes new INN, pirepemat (generic name) representing a new CNS compound class = first-in-class
- Studies published in highly ranked scientific journals



About the cover: Pirepemat featured on the cover of the Sep 2020 issue of JPET

# Pirepemat's clinical development plan

Pirepemat

Study	Study Population	Treatment duration	Design	# subjects	Primary objectives	Status	Result
Ph I: SAD+ MAD	Healthy male volunteers	SAD+MAD 10 days	DB placebo controlled alternate panel design	16 (SAD) 24 (MAD)	PK, safety, tolerability	Finalized	Single and multiple doses of pirepemat were generally well tolerated. The safety, tolerability, and PK profiles in this study support 3-times-daily dosing and further clinical development.
Ph I new PK tablet formulation	Elderly male and female healthy volunteers Average 72 years	MAD 14 days	Open label	9	Pharmacokinetics Tablet formulation	Finalized	The half-life of pirepemat may be longer, and plasma exposures somewhat higher, in elderly subjects as compared to younger subjects. No SAEs occurred in the study and there were no clinically significant abnormal findings in any of the clinical safety parameters. Elevated plasma liver enzymes levels following discontinuation of study treatment were seen in some individuals.
Ph IIa	Patients with Parkinson's disease and dementia	4 weeks	DB placebo controlled	32 (3:1 active vs. placebo)	Falls frequency as compared to placebo Cognitive function MDS-UPDRS, NPI, CGI Balance tests	Finalized	Pirepemat appears to be safe and well tolerated during 4-week treatment in study population. Adverse events were predominantly central nervous system related, mild, and predominantly reported during the first 2 weeks of treatment. Elevated liver enzymes observed in three pts following discontinuation. The interpretation is that this is part of a rebound effect following an abrupt termination of treatment with pirepemat.
Ph IIb	Parkinson's patients at H&Y stage >2.5. with MoCA<26 At least 2 falls 1 mo prior to randomization	12 weeks	DB placebo controlled	165	Reduction in falls frequency MoCA, UPDRS II+III, CGI-S	Ongoing	Recruiting in France, Germany, Poland Spain & Sweden.

# Clinical Phase IIb: Improve balance and reduction of falls

“A Phase IIb to evaluate the effects of pirepemat on falls frequency as compared to placebo.”

## Study IRL752C003

### Primary objective

- To evaluate the effects of pirepemat on **falls frequency** as compared to placebo.

### Secondary & other objectives

- To evaluate the effects of pirepemat on **cognitive functions** assessed with Montreal Cognitive Assessment (MoCA), as compared to placebo.
- To evaluate the effects of pirepemat on **Parkinson's disease symptoms** assessed with Unified Parkinson's Disease Rating Scale (MDS-UPDRS) as compared to placebo.
- To evaluate the effects of pirepemat on **postural dysfunction**, tandem walking and single leg stance test compared to placebo.
- To evaluate the effects of pirepemat on **global function** assessed with Clinicians Global Impression of Severity (CGIS), as compared to placebo.
- To examine the relationship between dose and plasma concentration of pirepemat and pharmacodynamic effects.

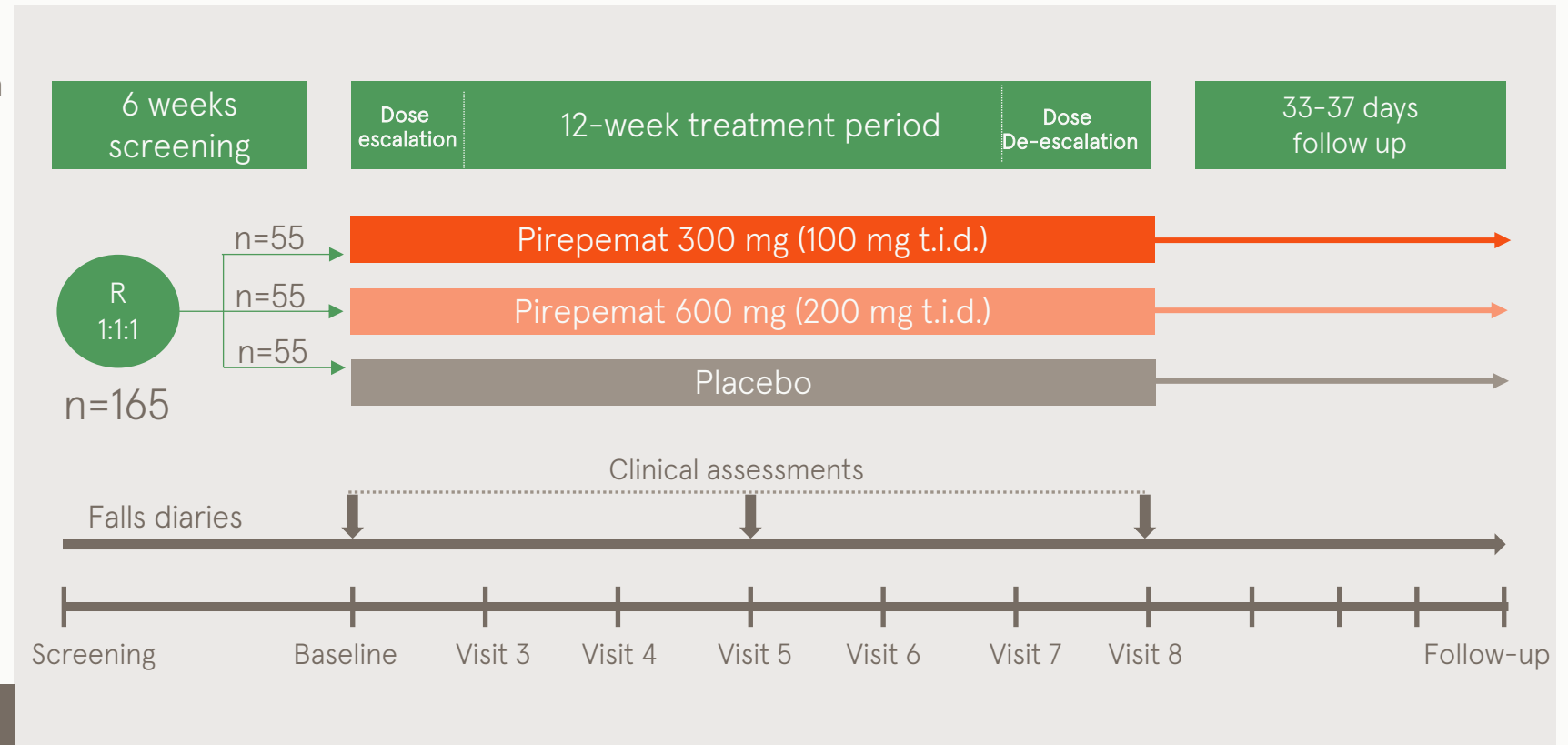
# Ongoing Phase IIb study evaluating efficacy of pirepemat on falls frequency in Parkinson's patients

## Inclusion criteria

- Parkinson's patients (55-85 yrs) with mild cognitive impairment
- Recurrent falls during the past 3 months and at least 2 falls during the past 4 weeks before baseline

## Primary endpoint

- Evaluate the effects of pirepemat on falls frequency as compared to placebo
- Efficacy assessed by Falls diaries, motor function, Cognitive and balance assessments as well as a CGIS





# Preclinical & Research 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

# Ongoing preclinical development programs on track

## IRL757

Treat apathy in neurology

Treatment for apathy:

Loss of initiative, interest and emotional expression/  
responsiveness

Status: Phase I YE 2023

## IRL942

Restore cognitive function

Improvement of cognitive function:

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

Status: Phase I ready H1 2024

## IRL1117

Once-daily treatment of Parkinson's

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

-> Next generation Parkinson's treatment

Status: Preclinical development

# Scientific rationale of IRL942 & IRL757

## Problem

Disruption of frontal neurotransmission is implicated in the pathogenesis of cognitive decline and neuro-psychiatric symptoms in PD and other neurological disorders

No current treatments directly address these specific cortical deficiencies

## IRLAB's solution

**IRL942 and IRL757** show a unique ability to activate frontal neurotransmission, synaptic gene expression, and associated circuits, improving cognitive function across modalities

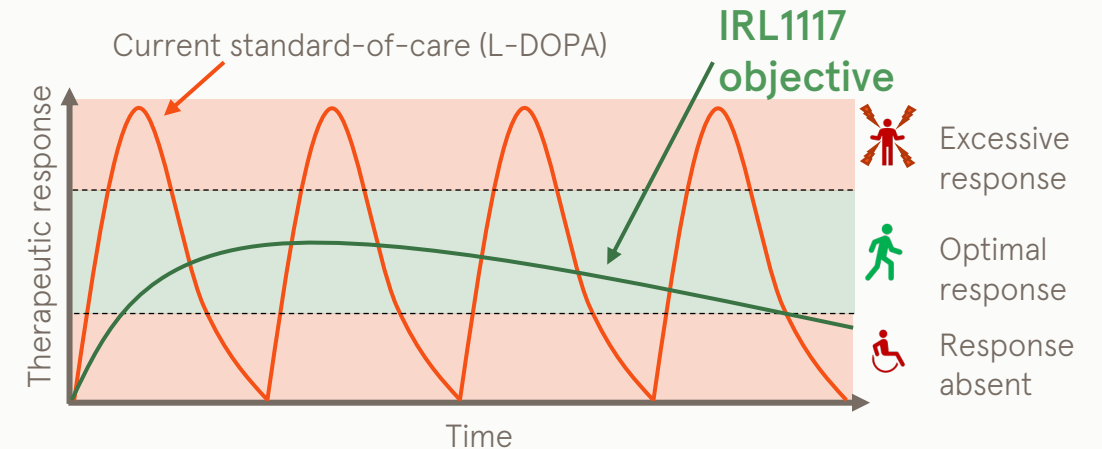
Potential for both symptomatic relief **and** disease modification

## Potential clinical indications:

- Parkinson's disease: dementia, apathy, depression, attention/vigilance
- Besides PD dementia, data support potential in additional indications with unmet needs:
- Other dementias
  - Cortical synaptic dysfunction a hallmark in multiple dementia types
    - Lewy body dementia, Alzheimer's disease, Vascular dementia, Frontotemporal dementia, Age related cognitive decline/MCI
- Apathy & Depression
  - Apathy: Cortex crucial in control of motivation, mood, cognition, and social behavior
  - Depression: Disruption of PFC signaling implicated in the pathogenesis
- ADHD
  - Cortical weakness in NA/DA transmission - no cortically targeted treatments available today
- Schizophrenia
  - Difficult-to-treat pathology converges on cortical dysfunction - negative and cognitive symptoms

# IRL1117 – First orally active, full efficacy, long-acting Parkinson's treatment

- Current treatment of Parkinson's is based on levodopa
- Limitations of levodopa
  - Short duration of action warrants multiple daily administrations leading to complications
    - Excessive stimulation and involuntary movements
    - 'On-off'-fluctuations (periods of absent effect)
- Levodopa supplemented by add-on medications:
  - Dopamine D<sub>2</sub> agonists
    - Long duration of action but inferior efficacy
  - Enzyme inhibitors
    - Provides minor extension of levodopa duration of action
  - Apomorphine
    - D<sub>1</sub>/D<sub>2</sub> agonist – high efficacy but poor PK and not orally bioavailable
    - Available as acute rescue during 'off'-periods or chronically implanted pump

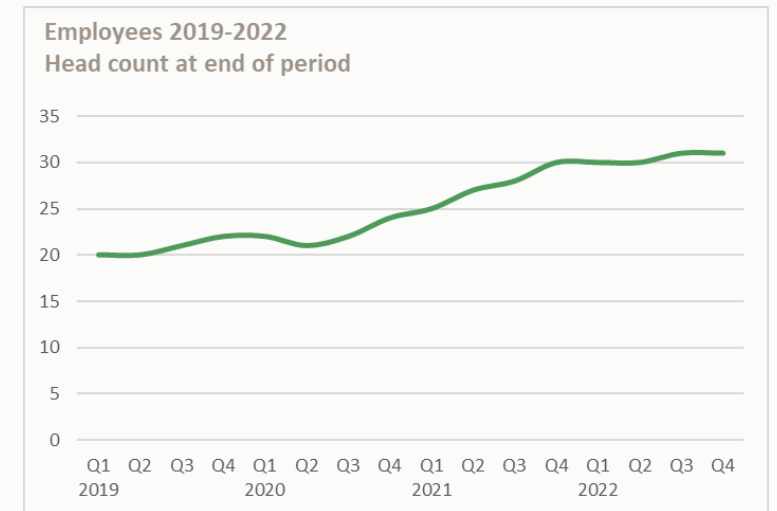
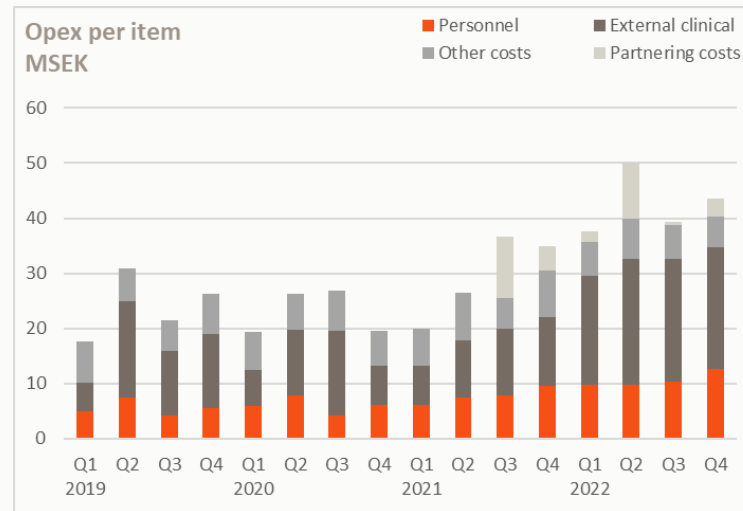
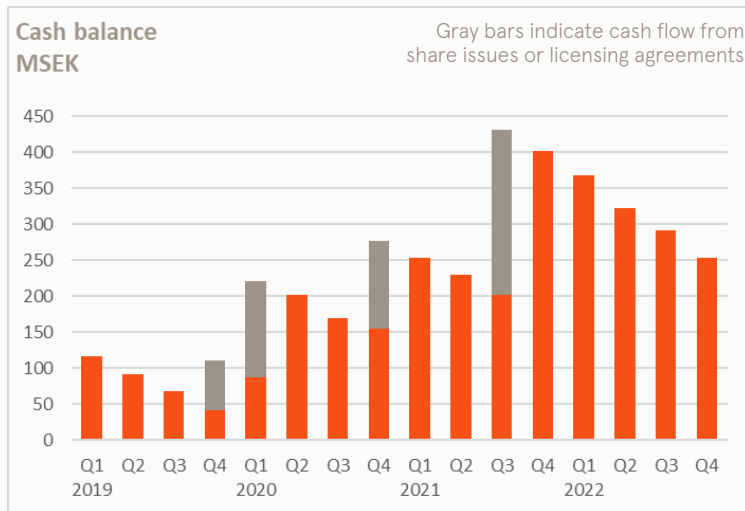


# Finance report Q4 2022

- Highlights and summary
- Analyst coverage

# Financial highlights of Q4 2022

- Sustained focus on cost control
- Investing in pirepemat clinical Phase IIb according to plan
- Maintaining investment in preclinical development, advancing IRL757 and IRL942 and IRL1117 towards clinical Phase I
- Stable cost base (Q2 2022 through Q4 2022) at about SEK 40 million per quarter
- Cash position SEK 253 million



# Analyst coverage



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# 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 IIb		<b>Ipsen disposition</b> r.e. further clinical development
	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>IRL942</b>	Cognitive impairment in neurology				Preclinical			<b>2023:</b> Phase I ready
<b>IRL757</b>	Apathy in neurology				Preclinical			<b>2024:</b> Phase I ready
<b>IRL1117</b>	Parkinson's disease treatment				Preclinical			<b>2023:</b> Preclinical development



# Anticipated newsflow and events the next 18 months

	Q1 '23	Q2 '23	H2 '23	H1 '24
Milestones	<ul style="list-style-type: none"> <li>○ IRL1117 CD nomination</li> <li>○ Mesdopetam Phase IIb top-line results</li> </ul>	<ul style="list-style-type: none"> <li>○ Mesdopetam additional Phase IIb study results</li> </ul>	<ul style="list-style-type: none"> <li>○ IRL757 Phase I ready</li> <li>○ Pirepemat Phase IIb completes recruitment</li> <li>○ IRL942 Phase I study preparation</li> </ul>	<ul style="list-style-type: none"> <li>○ Pirepemat Phase IIb top-line results</li> <li>○ IRL942 Phase I ready</li> <li>○ IRL1117 Phase I study preparation</li> </ul>
Events	<ul style="list-style-type: none"> <li>○ 8 March: ABGSC Investor Day, Sthlm</li> <li>○ 28 March–1 April: AD/PD 2023 congress, Gothenburg</li> </ul>	<ul style="list-style-type: none"> <li>○ 22–28 April: AAN congress, Boston</li> <li>○ Participation at investor events</li> </ul>	<ul style="list-style-type: none"> <li>○ Capital Markets Day</li> <li>○ Participation at medical congresses</li> <li>○ Participation at investor events</li> </ul>	<ul style="list-style-type: none"> <li>○ Participation at medical congresses and investor events</li> </ul>

# IRLAB – at a glance



## Pioneering biology & ISP

Deep profound understanding of Parkinson's based on research by Nobel laureate Prof. Arvid Carlsson



## Focused strategy

Treating PD patients throughout disease journey, has blockbuster potential as a pharma business



## Validated proof-of-concept

One clinical program already licensed to pharma  
\$363m + royalties



## Broad & Solid portfolio

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



## Organization positioned for success

Experienced international organization, Strong Balance sheet, 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.

Website: [irlab.se](http://irlab.se) | Follow us on [LinkedIn](#) >

