



Transforming life for people living with Parkinson's

Q1 2023

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Today's agenda

Q4 business
update

1



News in the period

2



R&D update

3



Financials

4



Concluding words

5

Q&A session

Operational highlights in the first quarter

- 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
- **IRL1117 was nominated development candidate 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 fluctuations and complications** caused by today's mainstay anti-Parkinson's levodopa-based treatments

Operational highlights in the first quarter

- **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.
- While the study did not reach statistical significance in the primary endpoint, it **achieved its purpose of confirming dose-dependent effects and the selection of best dose for further clinical studies.**
- Mesdopetam demonstrated **clear anti-dyskinetic effects during the full 12-week treatment period** with an adverse event and tolerability profile at the same level as placebo.
- The anti-dyskinetic **effects were achieved without reducing normal motor function** and are further **strengthened by a clear reduction of OFF-time**. Detailed analyses of the full data set from the study are ongoing in collaboration with our partner Ipsen.

Operational highlights in the first quarter

- In mid-February, the company announced an update to the portfolio development milestones following an assessment of the operational priorities for 2023
- On February 20, Dr **Gunnar Olsson, M.D., Ph.D** was appointed as interim CEO following Richard Godfrey's termination. **Carola Lemne, former Vice Chair, took over the role as Chairperson of the Board** from Gunnar Olsson, and An van Es-Johansson elected to leave her assignment as a Board member on February 21. As the new Chairperson of IRLAB, Carola Lemne took over the membership in the nomination committee after Gunnar Olsson's resignation as Chairperson of the Board.

Operational highlights in the first quarter

- At the end of March, IRLAB **presented new data related to the preclinical drug candidates IRL942 , IRL757 and the ISP platform** in an oral presentation and in three poster presentations at the International Conference on Alzheimer's and Parkinson's Diseases and Related Neurological Disorders, AD/PD TM 2023.
- The **industry symposium** at the scientific congress AD/PD TM 2023 **was organized by IRLAB** on Friday, March 31, 2023. A recording of the symposium titled "The management dilemma of Parkinson's disease progression and emerging treatment approaches" can be found on IRLAB's website, www.irlab.se.

Operational events after end of period

- On May 3, IRLAB was made aware that Ipsen's 2022 Universal Registration Document (URD), published on April 6, 2023, contains the incorrect information that the development and commercialization rights for mesdopetam have been transferred back to IRLAB.
- This is incorrect. Ipsen corrected the URD on May 4, 2023. Following contact from Ipsen on May 1, 2023, a discussion was initiated with IRLAB to mutually agree on the best way forward to secure that the mesdopetam program gets the best possible prospects to reach registration and to ensure that mesdopetam can be made available to the benefit of all people living with Parkinson's disease.

Financial highlights in the first quarter

- Net sales recorded: SEK 0 (SEK 9.0m)
- Total operating expenses: SEK 59.5m (SEK 38.2m)
- The operating result: SEK -59.5m (SEK -29.1m)
- Cash flow from operations: SEK -41.5m (SEK -28.4m)
- Cash and cash equivalents at the end of the period: SEK 210.1m (SEK 368.0m)
- 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. Team from Nobel laureate Prof. Arvid Carlsson's research group



Focused strategy

Discover and develop treatments for PD patients throughout their disease journey



Validated proof-of-concept

From discovery through Phase II
First program out-licensed to major pharma company



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.

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.

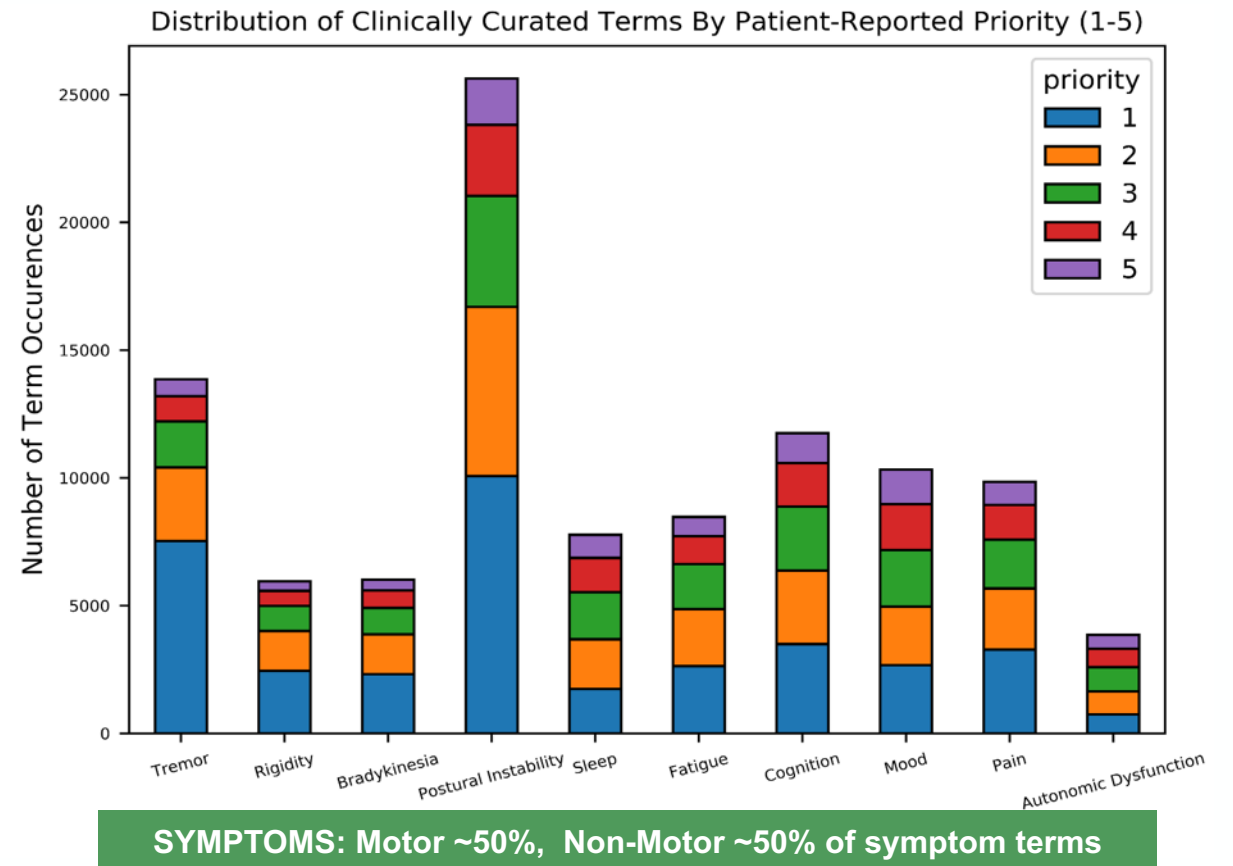
The most bothersome symptoms according to people with Parkinson's

25 000 people with Parkinson's reported about their illness through the instrument PROP, part of the Fox Insight project led by the Michael J. Fox Foundation.

Number 1 most bothersome symptoms of Parkinson's is related to **gait and balance** (postural dysfunction).

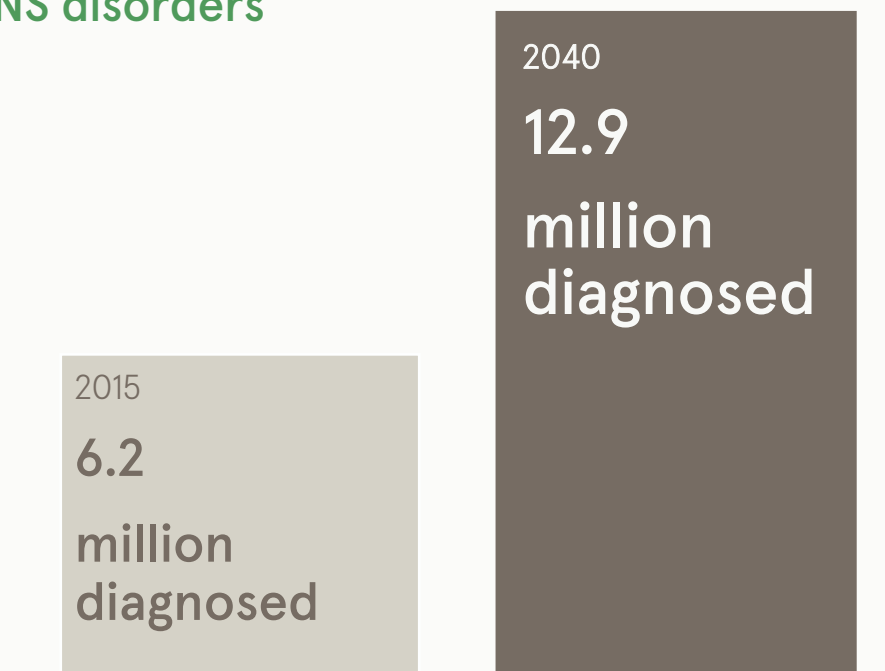
Hallmark symptoms, cognition and mood were also frequently rated as the absolute most troublesome symptom.

What bothers people the most with Parkinson's disease?
Self-reported, n=25 000



IRLAB to address top priorities for management of Parkinson's

Parkinson's is one of the fastest growing CNS disorders



The burden of society from PD in the US alone translates to \$51,800 per year per patient with Parkinson¹

IRLAB's drug candidates are aimed to address the full disease progression

Identified treatment priorities²

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

IRLAB's portfolio

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

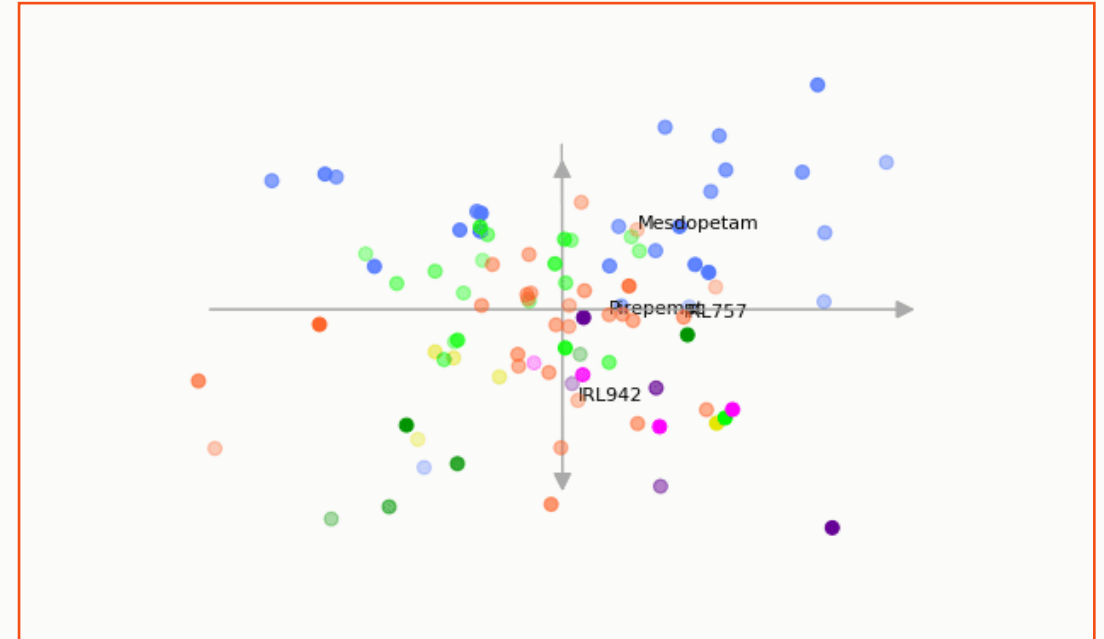
Pipeline generated with our unique proprietary drug discovery platform – ISP

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

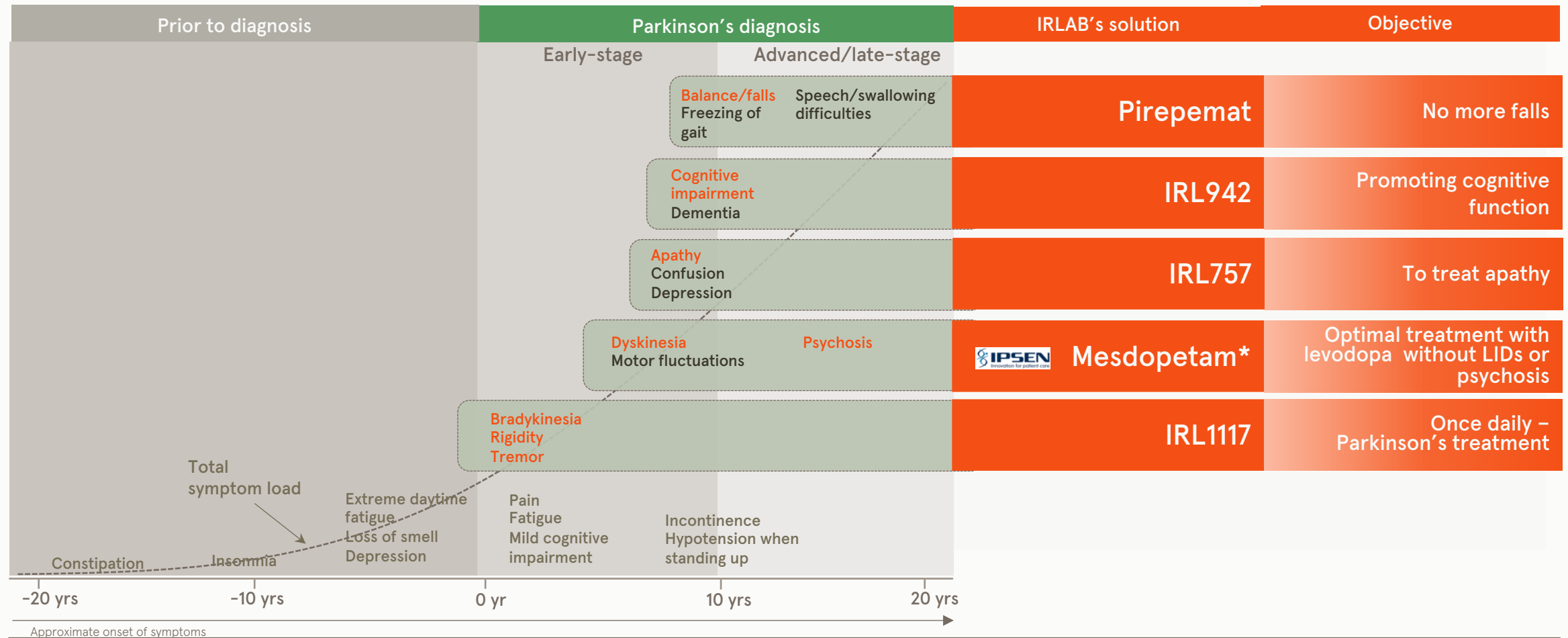
- Discovery of truly novel **first-in-class** compounds
- Strong IPR
- Improvement in probability of drug discovery success and clinical phase transitions, compared with industry standard



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

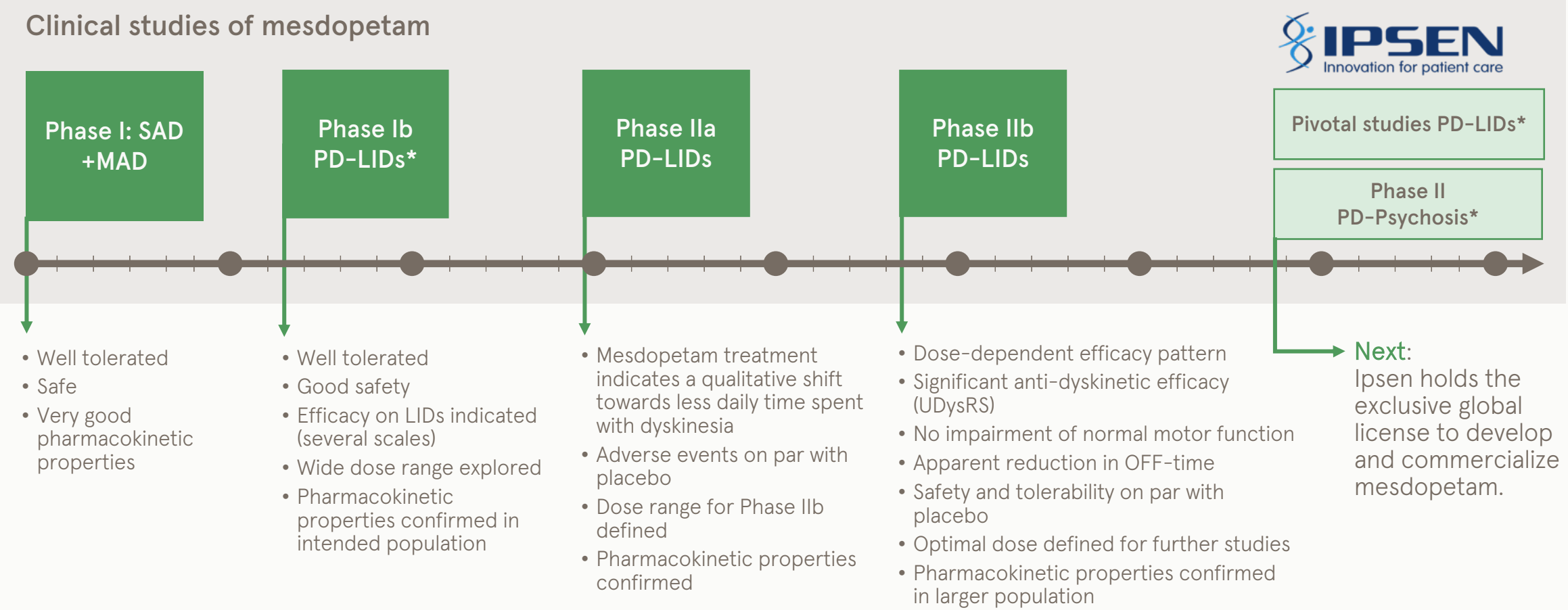


Mesdopetam (IRL790)

(*mes_dop_e_tam*)

- Mesdopetam counteracts levodopa-induced dyskinesias (PD-LIDs) by a novel mechanism **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

Growing body of clinical evidence supporting a novel 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

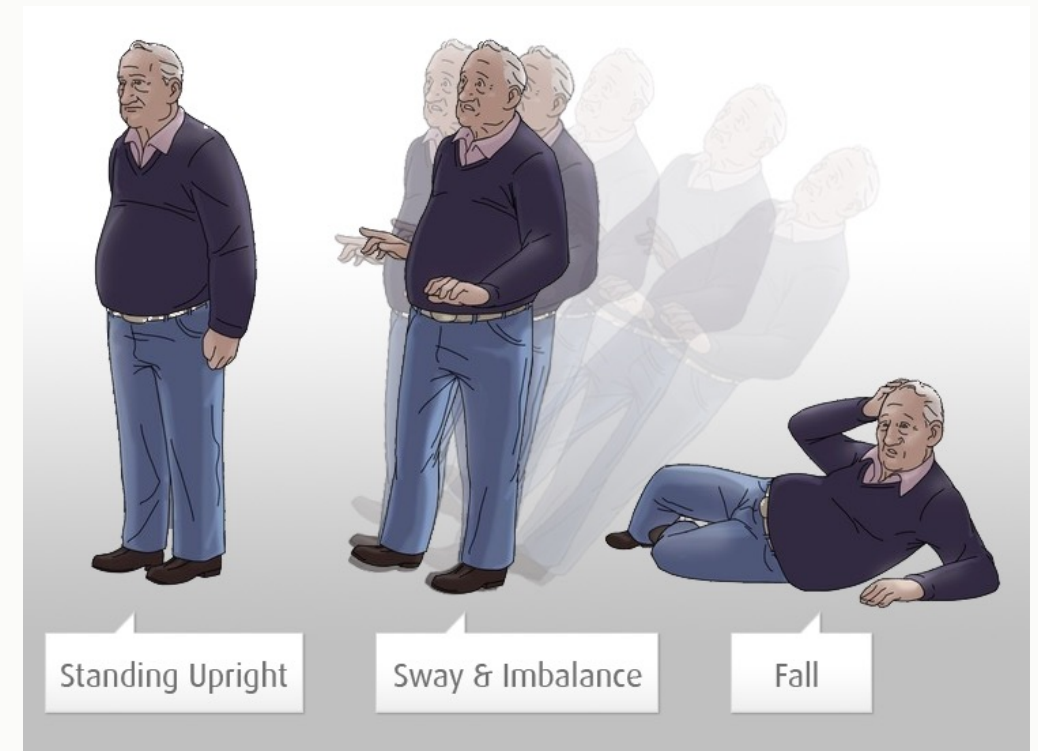
Why preventing falls in Parkinson's?

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^{1,2}:

Cognitive decline → Impaired balance → Falls → Injuries & costs

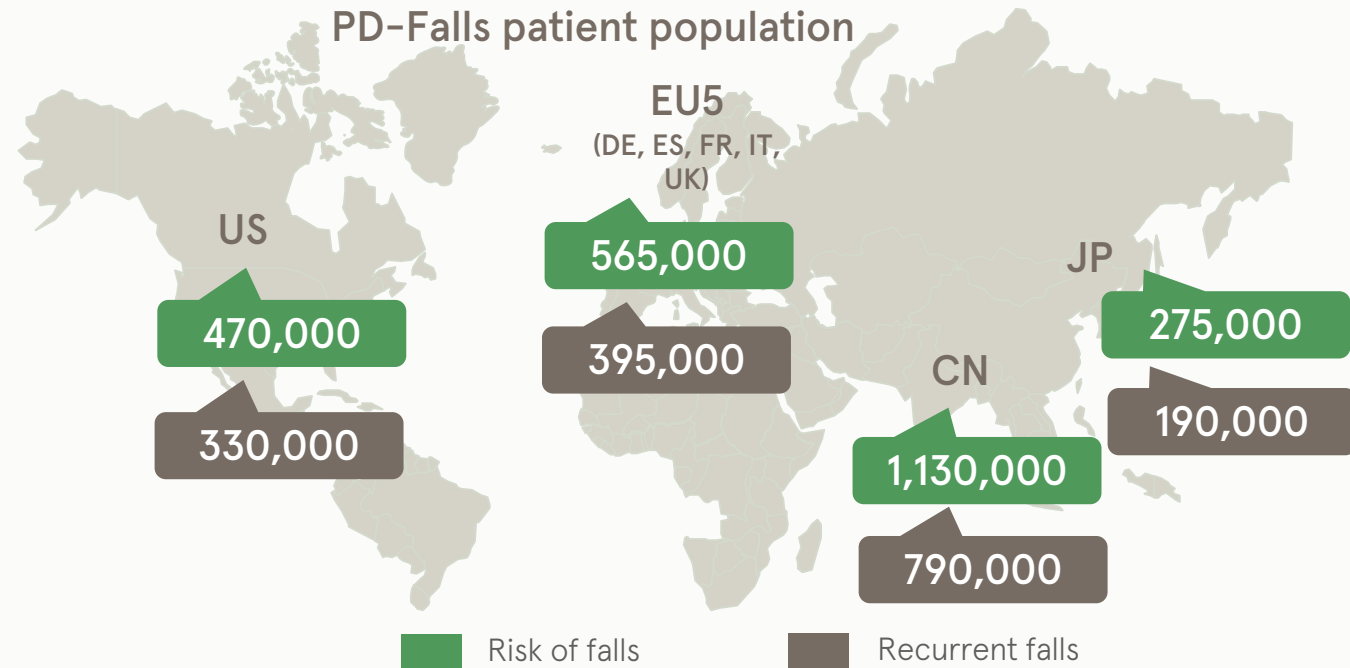
- Consequences of falls include fractures and injury, fear of future falls, hospital admission, and increased caregiver burden, with falls cited as one of the worst aspects of the disease.



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

Pirepemat in development 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

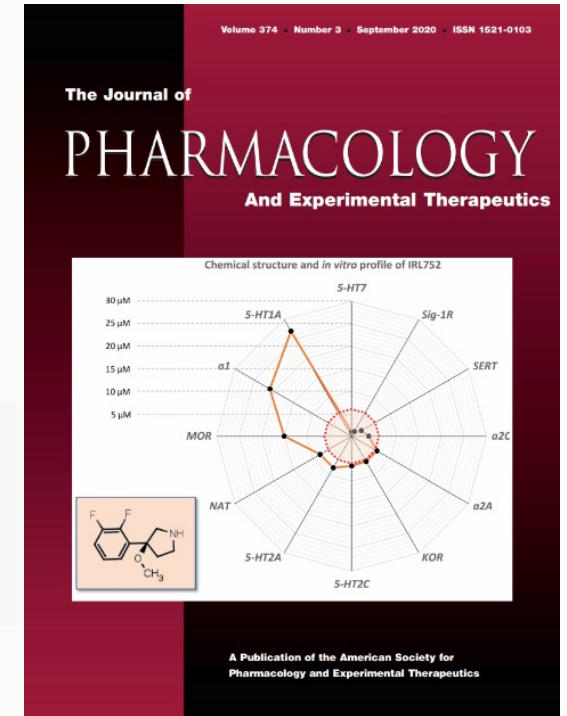
- Ongoing Phase IIb program developed with regulatory agencies, scientific advisors and regulatory experts
- EU regulatory agencies: Study and ethical approvals granted; study ongoing.
- FDA advice to conduct additional DMPK and in vitro mechanism studies, prior to US IND. These studies are expected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

Potential

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

Validation

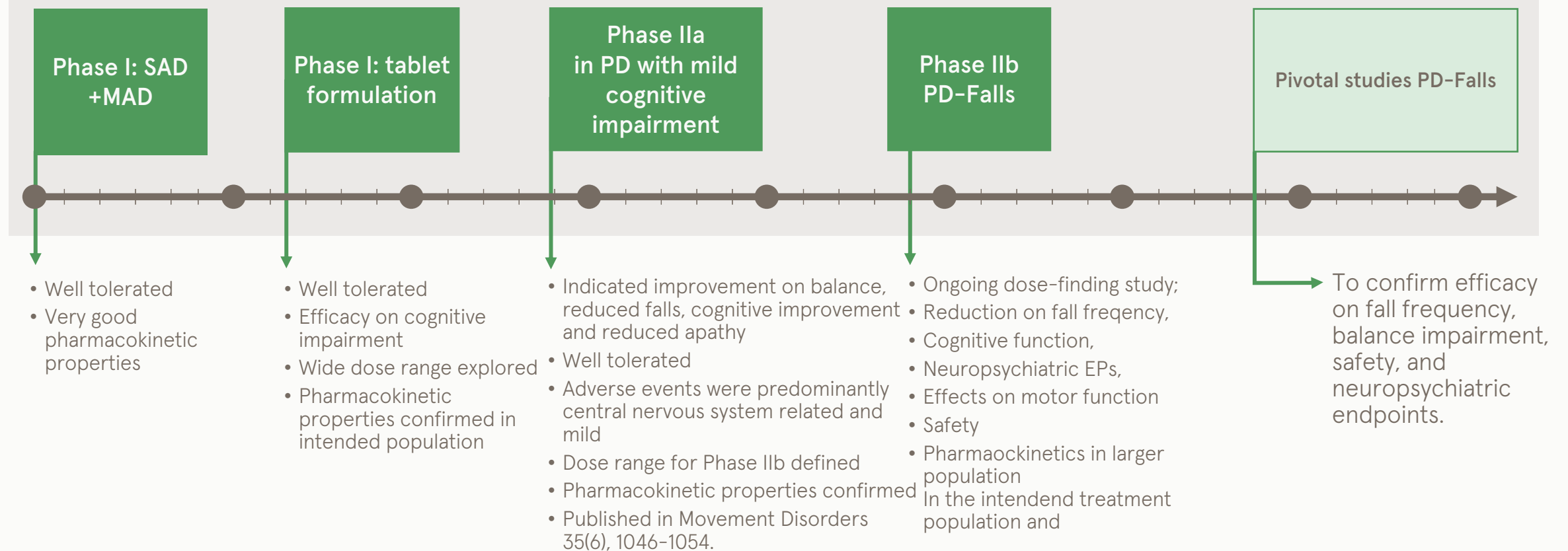
- **WHO-INN** proposes new INN, pirepemat (generic name) representing a new CNS compound class = first-in-class
- **Studies published** in highly ranked scientific journals



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

Growing body of clinical evidence supporting potential as treatment of falls in Parkinson's

Clinical studies of pirepemat



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

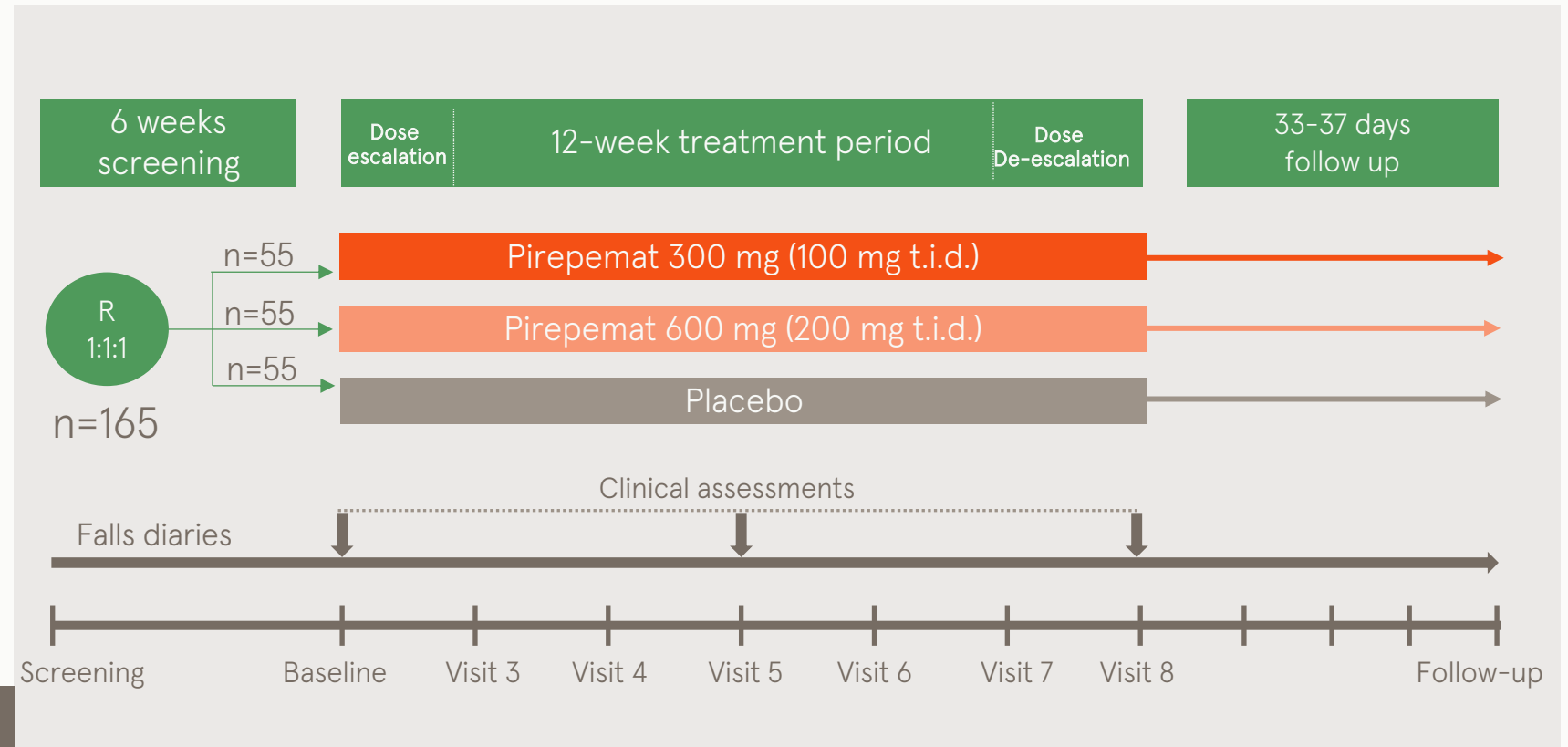
Inclusion criteria

- 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

Objectives

- Evaluate the effects of pirepemat on falls frequency, cognitive functions, neuropsychiatric EPs and motor function
- Efficacy assessed by Falls diaries, motor function, Cognitive and balance assessments as well as a CGIS

Top-line data expected H1-24



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

Ongoing preclinical development programs on track

IRL757

Treat apathy in neurology

Treatment for apathy

Loss of initiative, interest and emotional expression/
responsiveness

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

IRL942

Restore cognitive function

Improvement of cognitive
function

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

Status: IND-enabling studies;
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

IRL757 is aimed at the huge untreated problem with apathy

Huge unmet medical need

- **Over 10 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

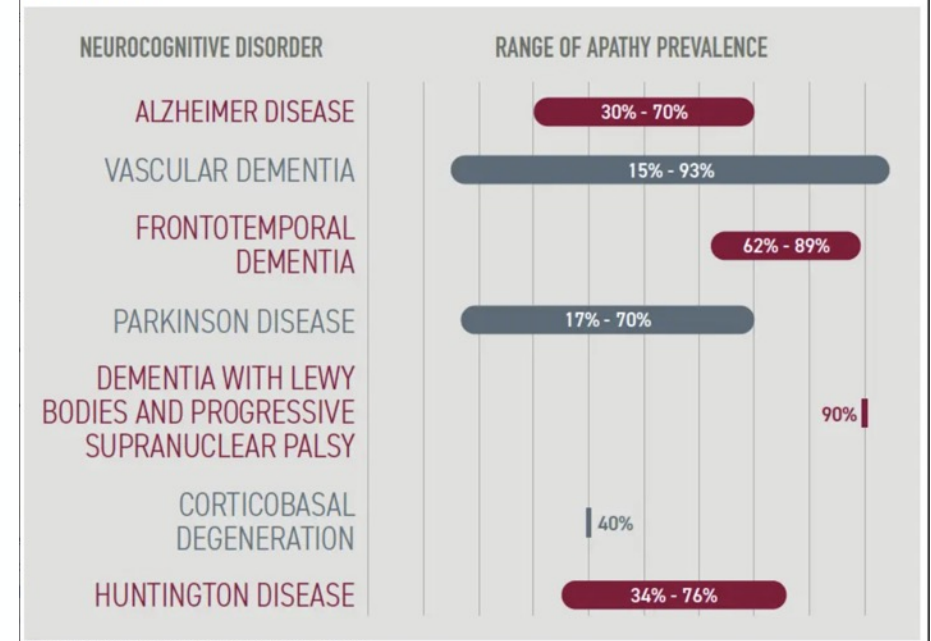
- **Disruption of frontal-subcortical neurocircuits** are implicated in apathy*

- 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}



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

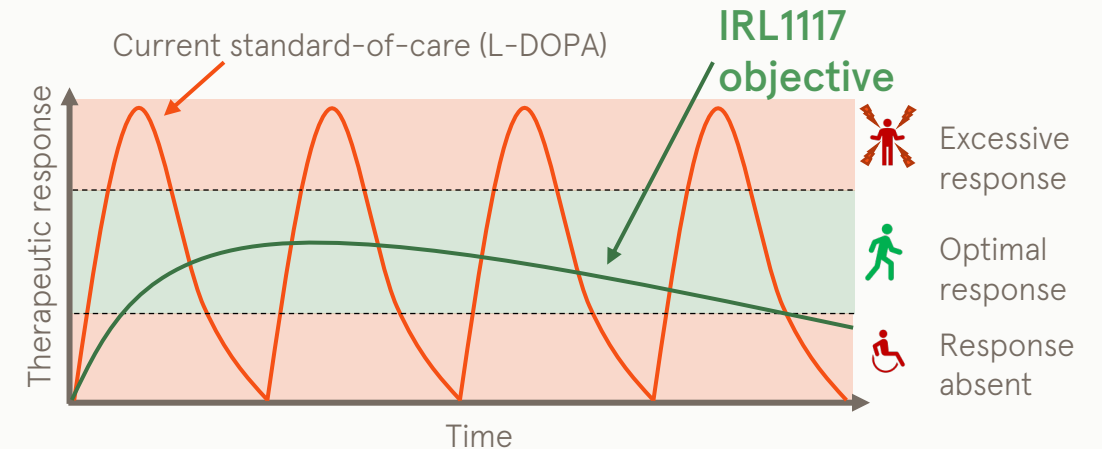
Cognition

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.

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 D₂ agonists
 - Long duration of action but inferior efficacy
 - Enzyme inhibitors
 - Provides minor extension of levodopa duration of action
 - Apomorphine
 - D₁/D₂ agonist – high efficacy but poor PK and not orally bioavailable
 - Available as acute rescue during 'off'-periods or chronically implanted pump



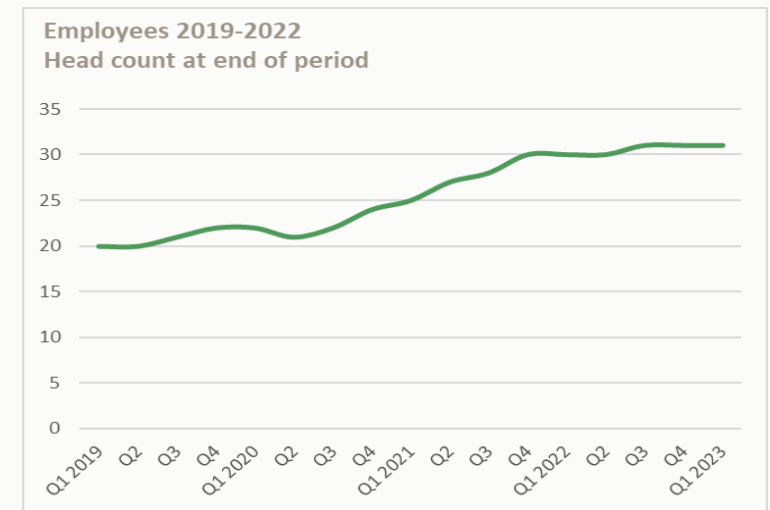
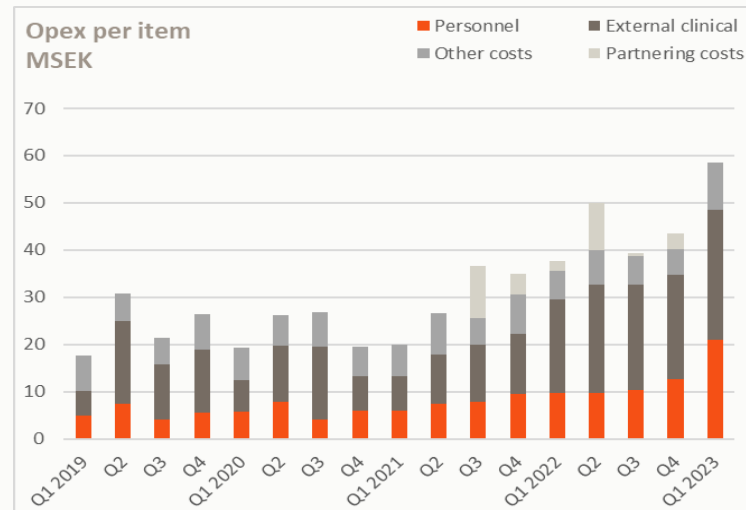
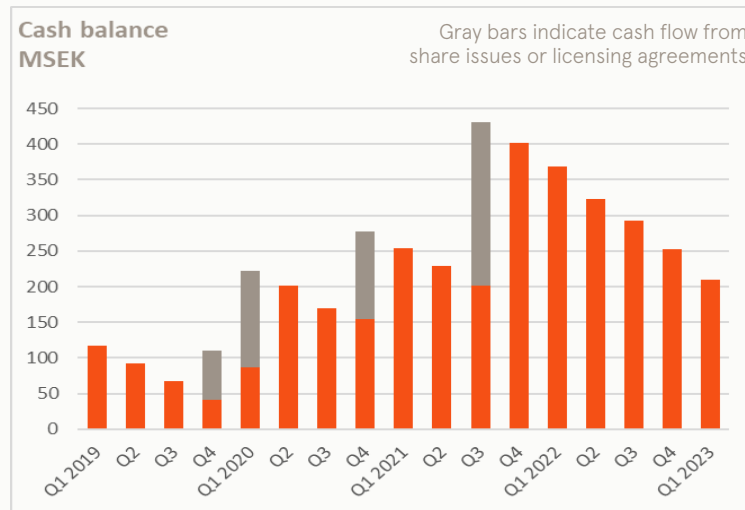
Finance report Q1 2023

- Highlights and summary
- Analyst coverage

Financial highlights of Q1 2023

Financial report

- Increased focus on cost control
- Investing in the Phase lib with pirepemat according to plan
- Maintaining investment in preclinical development, advancing IRL757 and IRL942 and IRL1117 towards clinical Phase I, leading to higher cost for “external clinical”, though under cost control limitations
- One time cost of SEK 10.6 million for termination of CEO effects the personnel cost during the quarter
- Cash position SEK 210 million



Analyst coverage



- Fredrik Thor and Kevin Sule

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- Dr Gonzalo Artiach Castañón

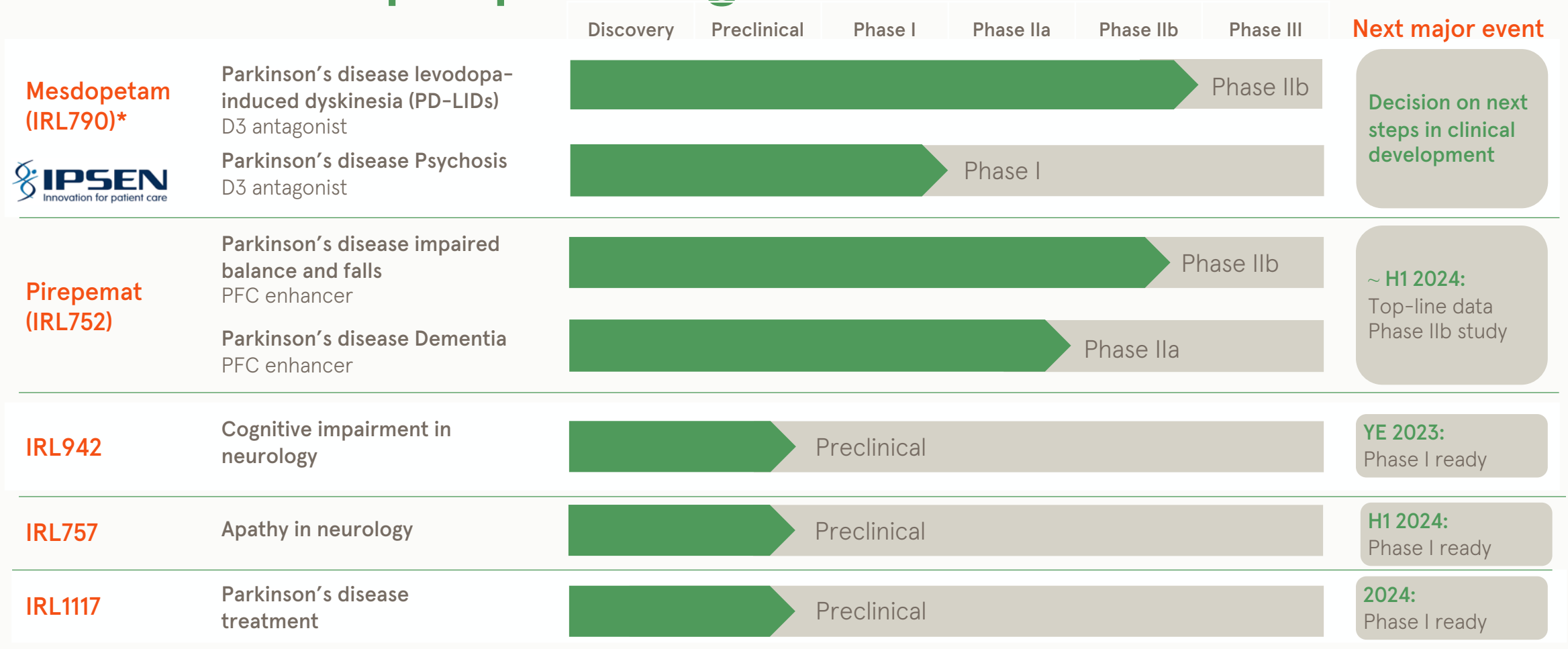
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Development portfolio transforming treatment of people living with Parkinson's



Anticipated key development milestones the next 18 months

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

IRLAB – at a glance



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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



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Broad & Solid portfolio

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



Organization positioned for success

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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 | Follow us on [LinkedIn](#) >

