



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

IRLAB, Q4 2023



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Today's agenda

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News in the period

Gunnar Olsson, CEO

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Nicholas Waters, EVP Head of R&D

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Financials

Viktor Siewertz, CFO

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Q&A session

Operational highlights in Q4, 2023

Mesdopetam

- In October initiation of a collaboration with Clintrex (US regulatory/clinical strategy advisors) and with ProPharma Group (US regulatory agent) to prepare for End-of-Phase II meeting with the FDA
- In mid-December submission of application for an End-of-Phase II meeting with the FDA
- Application granted and meeting date set to February 20, 2024

Operational highlights in Q4, 2023

Pirepemat

- IRLAB is granted additional patent of the drug used in the ongoing clinical development program. The patent is predicted to expire in 2038, and with the potential grant of supplementary protection certificates (SPCs) or patent term extension (PTE), exclusivity can potentially reach into the early 2040s

Operational highlights in Q4, 2023

IRL757

- Completion of preclinical development work and initiation of compilation of data to seek regulatory approval (CTA) to initiate clinical phase I studies
- IRLAB was selected to receive a grant of 2 million USD from **The Michael J. Fox Foundation** to support development of IRL757 for the treatment of apathy
- A CRO contracted to run the phase I study following Regulatory approval of the CTA

Operational highlights in Q4, 2023

Business development and financing

- Capital Markets Day in October in Stockholm – presentation of portfolio development and growth strategy
- Participation in BioEurope in Nov. Follow-up discussions are ongoing.
- Investors meetings – continued financing activities with company presentations at 5 conferences as well as discussions with financial advisors and investors
- IRLAB increased liquidity with a loan facility of up to SEK 55 million in December to extend financial runway and increase business opportunities

Operational highlights in Q4, 2023

Management

- IRLAB extended CEO appointment in December

Operations

- Fredrik Hansson, Director of Clinical Science & Biometrics, joins the company on Jan 1

Operational events after end of period

Pirepemat

- New insights generated in the phase IIb study, React-PD
 - One-month baseline - fall rates higher and more stable than anticipated
 - Steady recruitment rate following opening of all centers (from May 2023)
 - Patient feed-back positive and repeated requests to continue medication after end of study period
 - Ability to use data driven estimates for more accurate study timelines
- Outcome of the data driven estimations
 - Patient recruitment into Q3 2024
 - Higher probability to detect treatment effects

Operational events after end of period

Science

- Two abstracts accepted for presentation at 18th International Conference on Alzheimer's & Parkinson's Diseases in Lisbon March 5-9, 2024.
 - REACT-PD – A Randomized, Placebo-Controlled Phase IIb Trial Evaluating the Efficacy of piperemate on Falls Frequency in Patients with Parkinson's Disease
 - Preclinical in vivo characterization of IRL1117; a novel dopamine D1/D2 agonist for the treatment of Parkinson's disease



R&D update

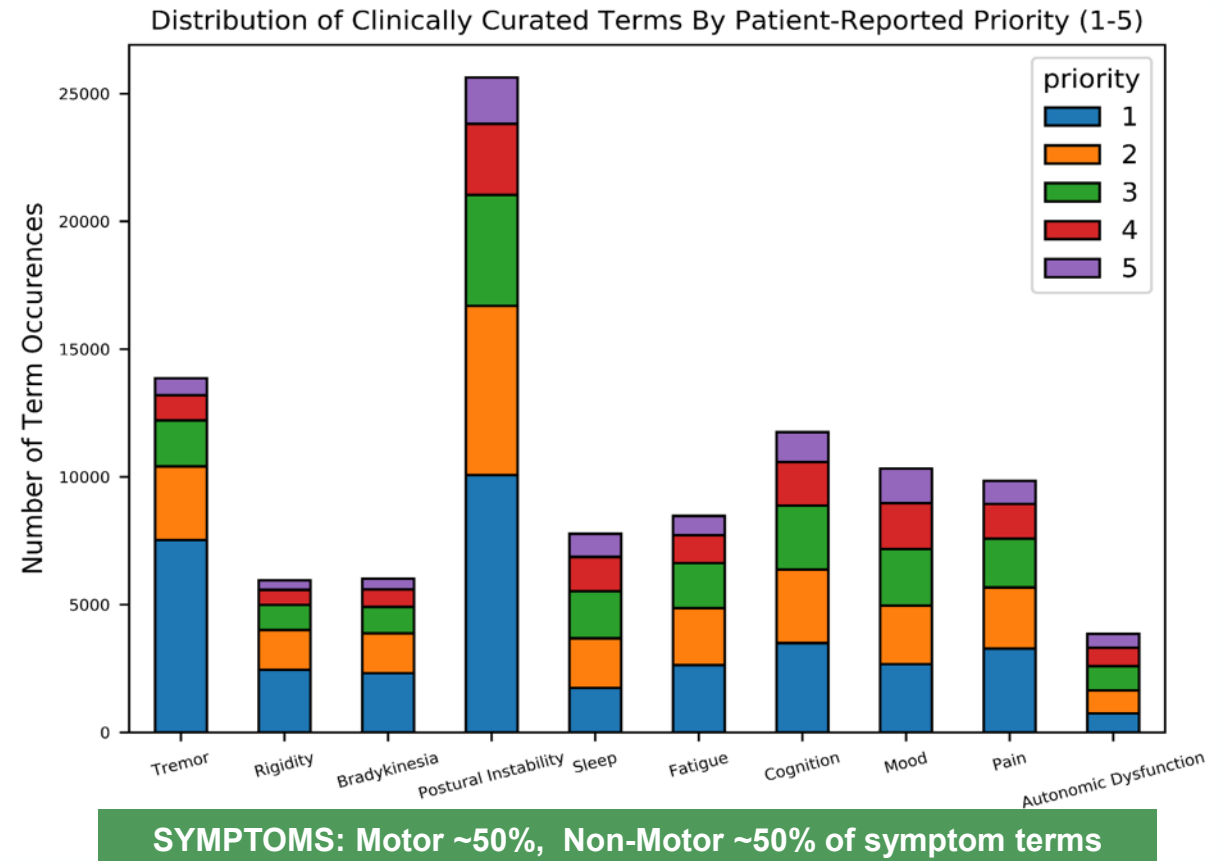
The most bothersome symptoms according to people with Parkinson's

Most frequent bothersome symptoms

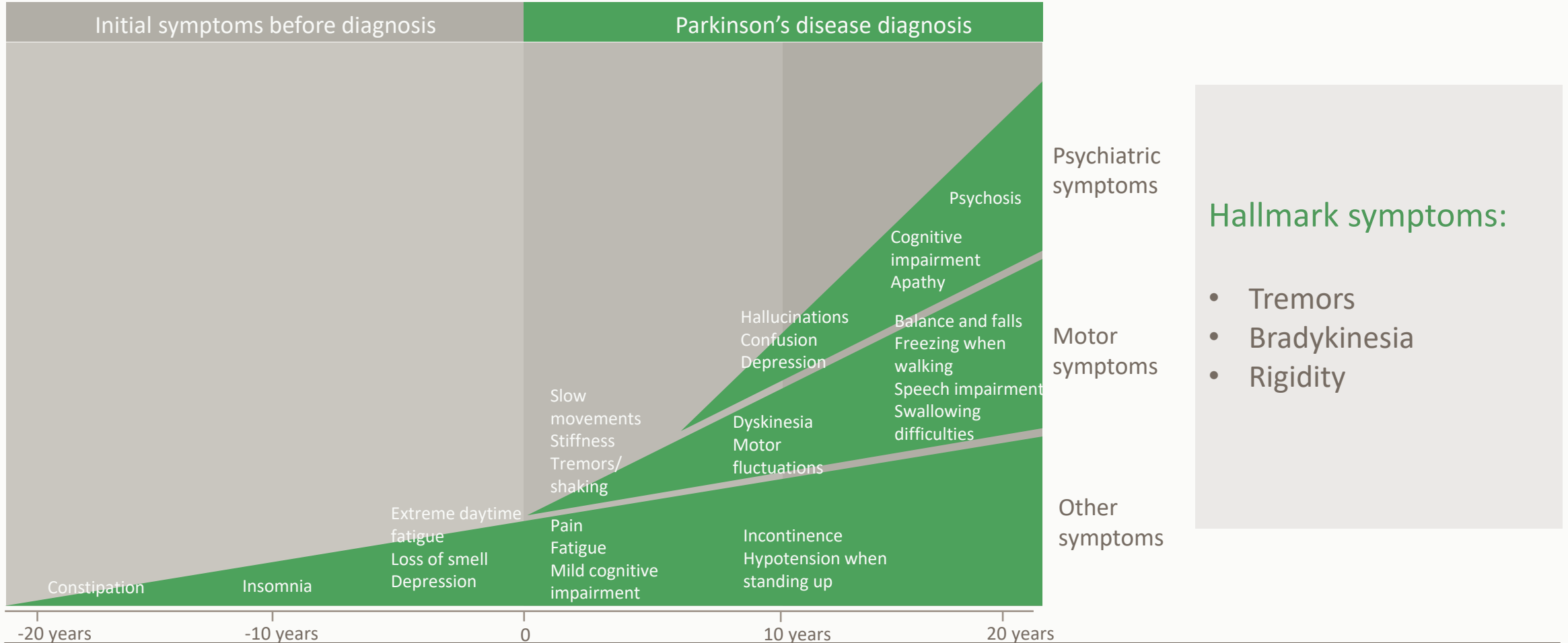
- Balance/instability
 - Tremor
 - Rigidity
 - Bradykinesia
- Cognition
- Mood

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)

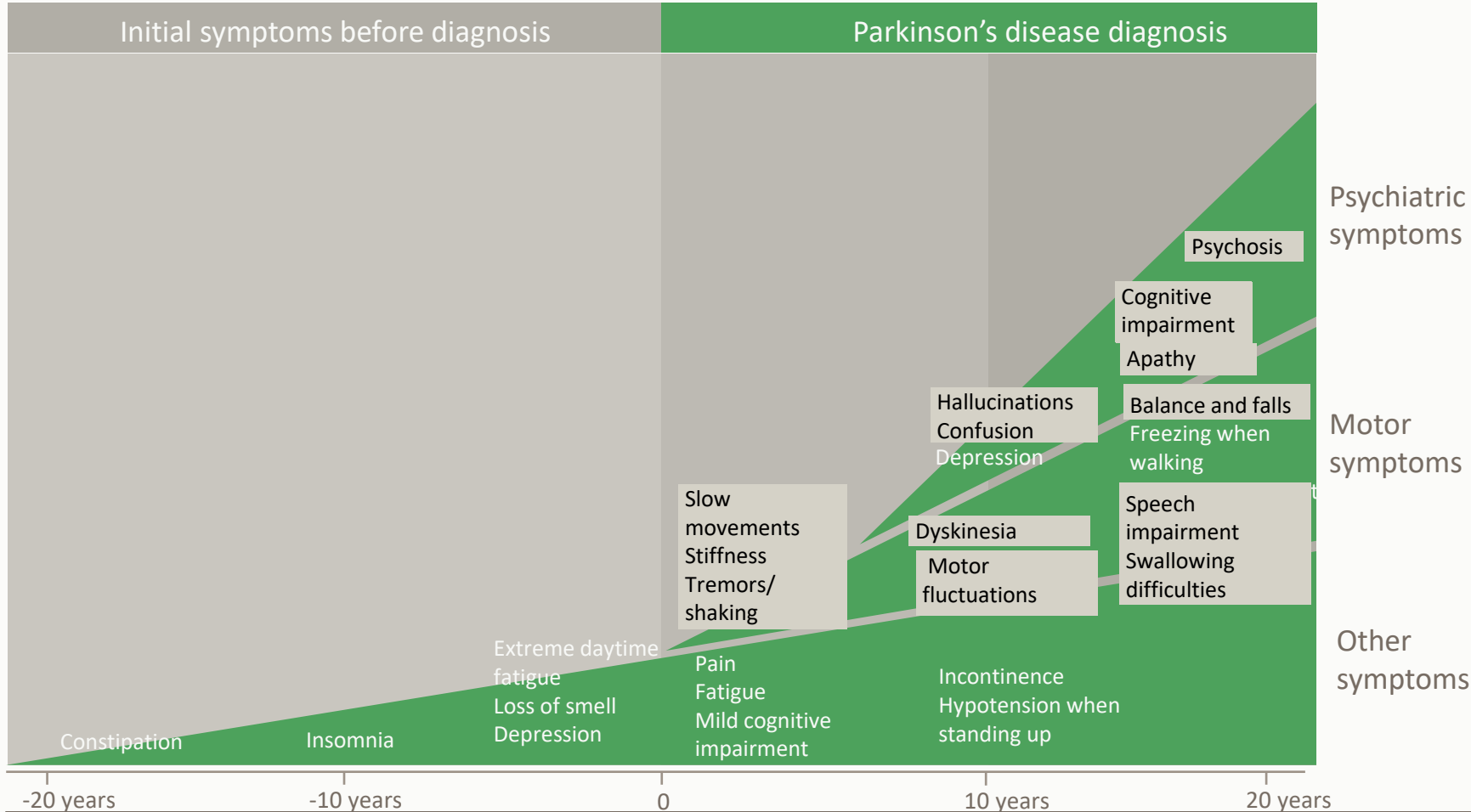


Parkinson's disease progresses over time – symptoms and complications expand



World-leading portfolio to improve the treatment of Parkinson's

Parkinson's and IRLAB's portfolio



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

- Pirepemat
- IRL942
- IRL757
- Mesdopetam
- IRL1117

Mesdopetam (IRL790)

- Mesdopetam: to treat levodopa-induced dyskinesias (PD-LIDs) through a novel mechanism

Mesdopetam (IRL790)

First in class- a novel mechanism

Inhibiting dopamine D3 receptors

Patent-based exclusivity into the 2040s

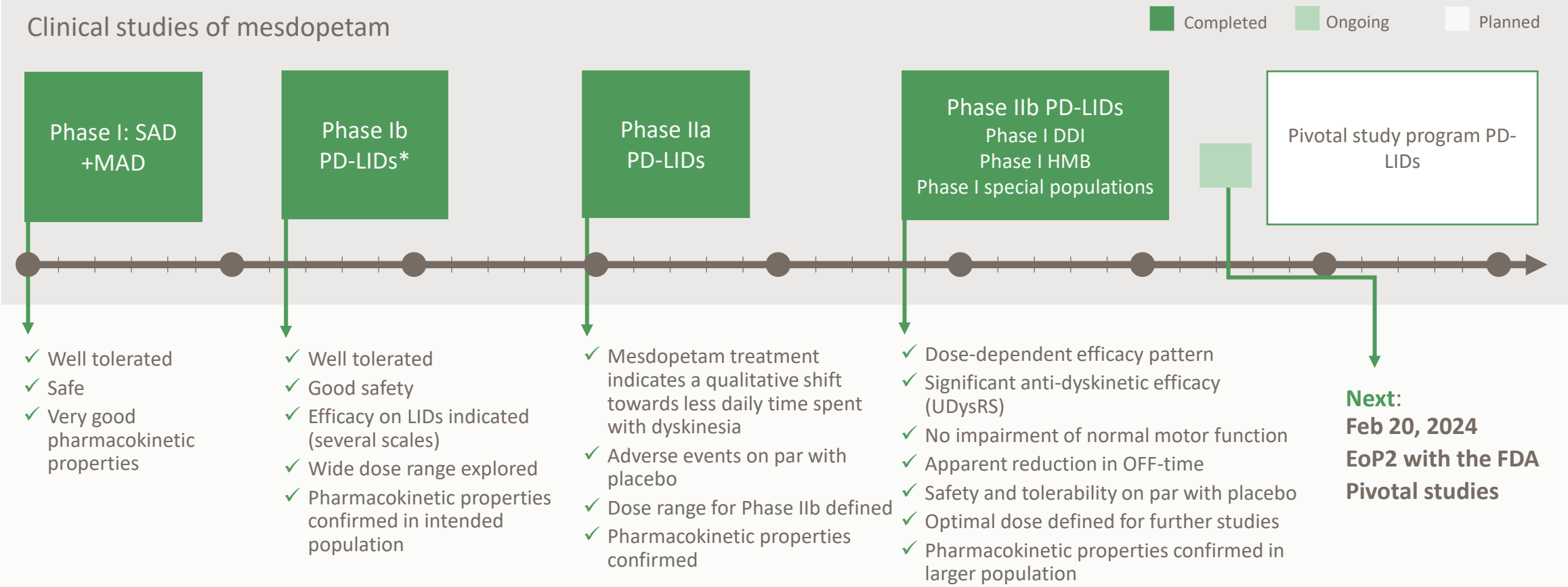
Lead indication – levodopa-induced dyskinesias (PD-LIDs)

Mesdopetam project progress in Q4

Mesdopetam has potential to be the first treatment in a new class of drugs designed to treat levodopa induced dyskinesias (PD-LIDs)

- End-of-Phase 2 meeting with the FDA on Feb 20,2024
- In collaboration with clinical and regulatory experts, IRLAB is preparing for the meeting
- Objective of the meeting is to define mesdopetam's Phase III program in PD-LIDs
- Feedback from the FDA could be received up to 30 days after the meeting

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



Pirepemat (IRL752)

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

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 (IRL752)

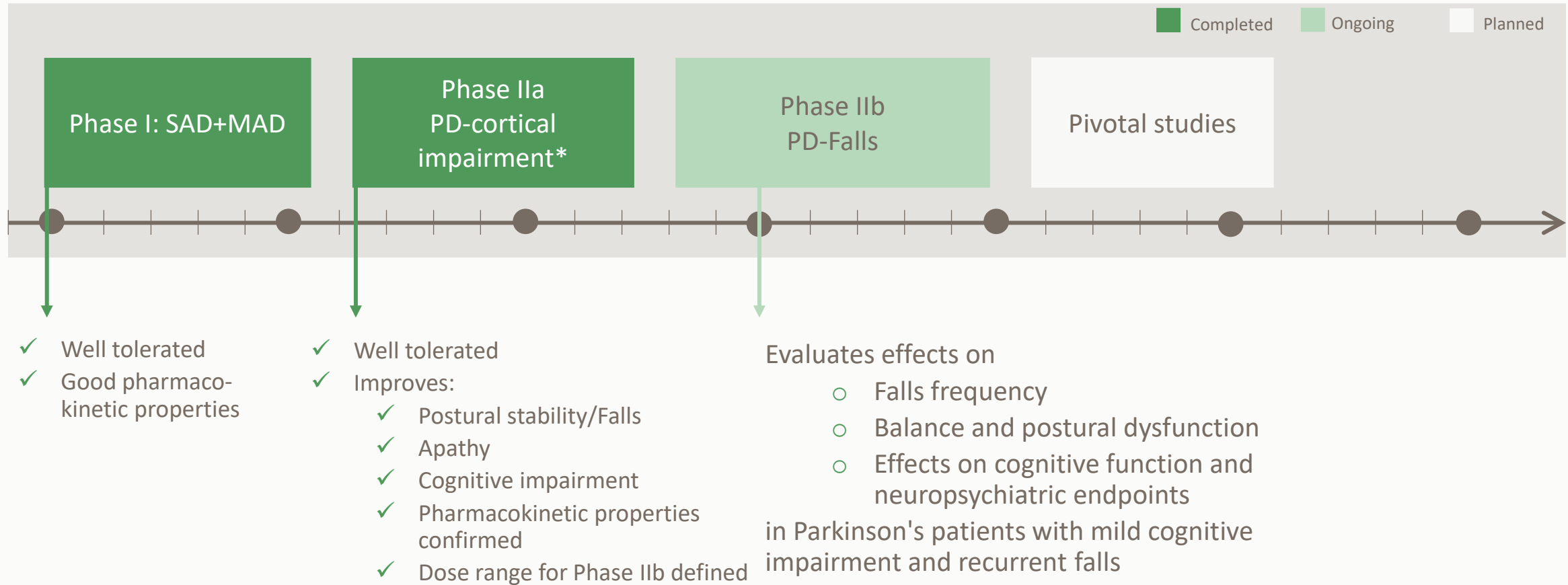
First in class- a novel mechanism

Inhibiting alpha 2 and serotonin 7 receptors

Patent-based exclusivity into the 2040s

Objective – reduce falls in Parkinson's disease

Clinical development path for pirepemat: Improvement of balance and falls



Pirepemat project progress in Q4



Pirepemat has potential to be the first treatment in a new class of drugs designed to improve balance and reduce falls and fall injuries in people living with Parkinson's disease

- The ongoing Phase IIb study is recruiting, in France, Germany, the Netherlands, Poland, Spain and Sweden, now at a steady pace since Q3 2023

New information providing insights regarding the specific patient population participating in the study has been collected

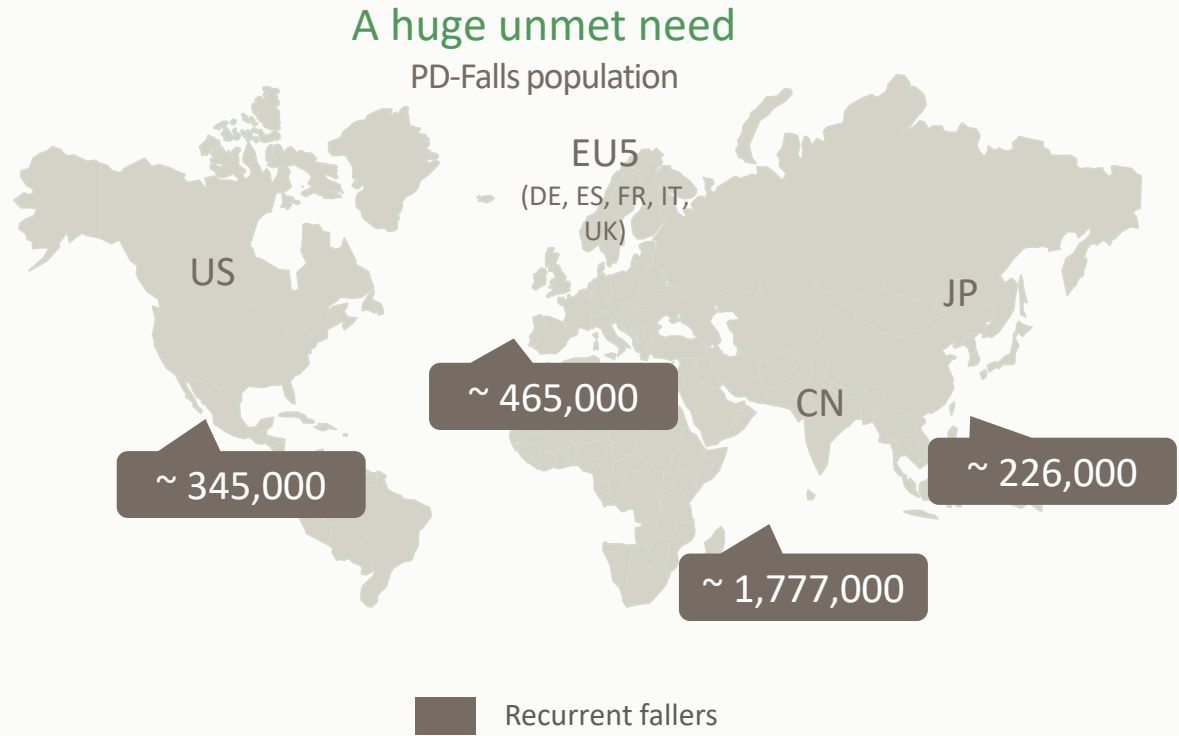
- Baseline fall rates show that subjects enrolled in the study **fall 2-3 times more** than previously anticipated, providing a higher probability to observe treatment dependent effects
- The company's assessment is that patient recruitment to the study will be completed during the third quarter of 2024
- Followed by a one-month baseline period, a three-month treatment period, data management and database lock before top-line results

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 Q3 2024
- Followed by 1 month baseline period, a 3-month treatment period, data management and database lock before top line results



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 people¹

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 people¹

Status: IND-enabling studies; Phase I ready 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 people¹

Status: Preclinical development

IRL757 & IRL942* project progress in Q4

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

- Now Phase I ready after successfully completing the preclinical studies and CMC development required
- Funding to conduct the Phase I study with IRL757 was also secured in December 2023 from The Michael J. Fox Foundation

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

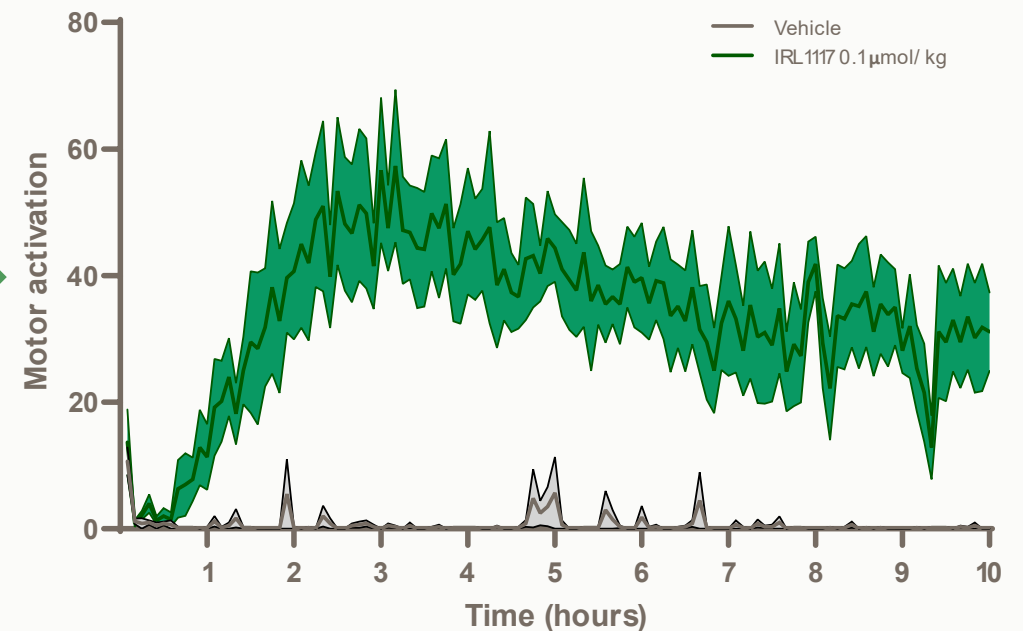
- Development proceeds according to the plan for preclinical development, toxicology and safety studies as well as GMP manufacturing of API.
- Development of drug product has been initiated and IRL942 is projected to be Phase I ready during 2024

*IRLAB and MSRD, a part of the Otsuka family of companies, are evaluating the possibility to collaborate in the further clinical and preclinical development of the drug candidates

IRL1117 project progress in Q4

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.

- The drug should be taken once daily and avoids the troublesome complications caused by today's mainstay levodopa-based treatments.
- In preclinical studies IRL1117 has demonstrated rapid onset and **more than 10 hours of sustained efficacy** without inducing motor complications.
- Currently activities related to substance manufacturing and planning for preclinical regulatory studies necessary for Phase I are ongoing



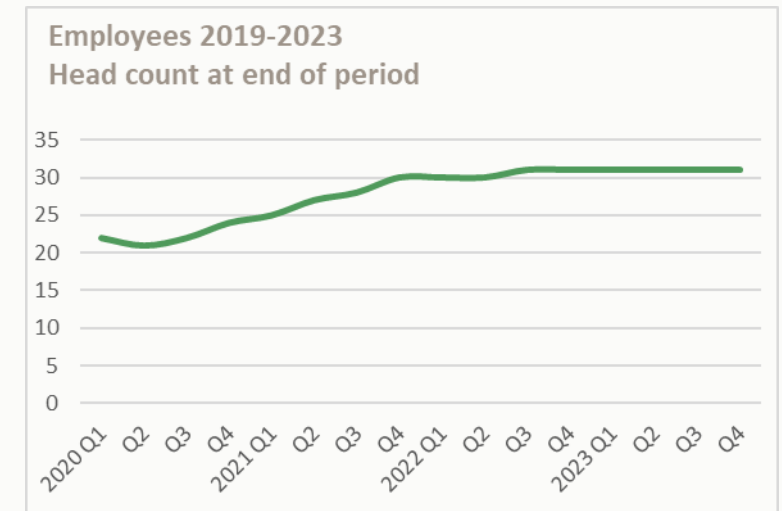
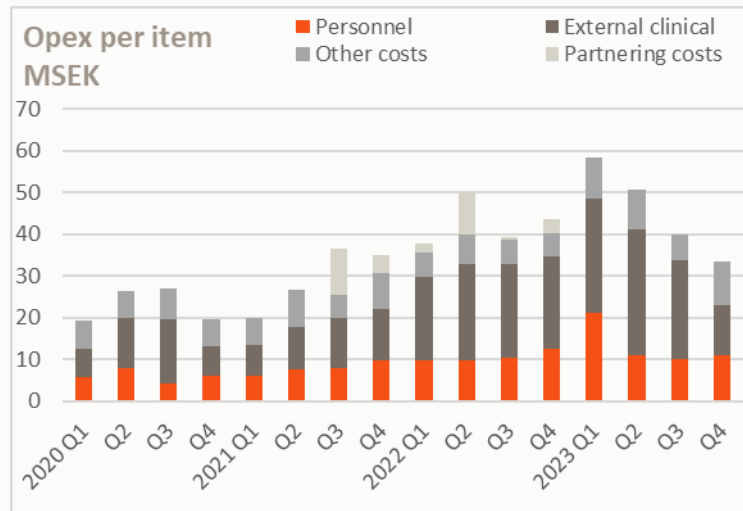
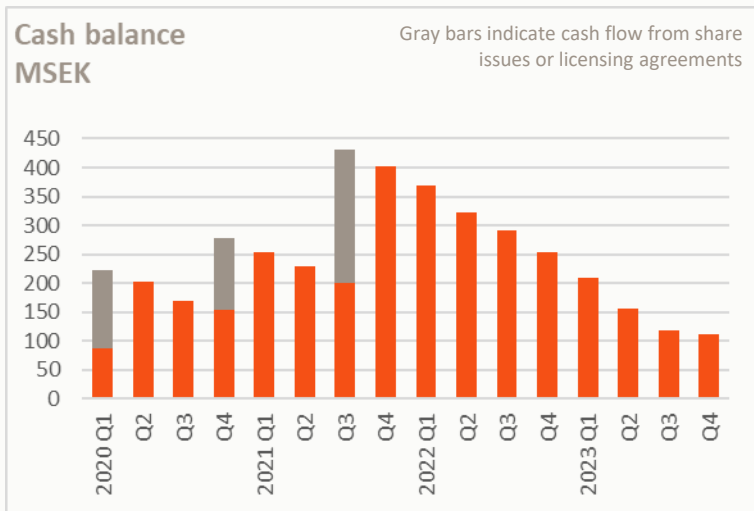


Finance report Q4 2023

- Highlights and summary
- Analyst coverage

Financial highlights of Q3 2023

- Cash position SEK 111 million
- Investing in progressing mesdopetam towards Phase III
- Investing in the Phase IIb with pirepemat according to plan - lower cost in Q4 than in Q3
- Maintaining investment in preclinical development, advancing IRL757 and IRL942 and IRL1117 towards clinical Phase I
- Headcount remain stable at around 30 employees



Financial summary of fourth quarter

	Q4 2023	Q4 2022
Net sales	- 1.2	12.2m
Operating profit	- 35.6m	- 33.1m
Earnings per share before and after dilution, SEK	- 0.67	- 0.64
Cash and cash equivalents	111.3m	252.8
Cash flow from operating activities	- 33.9m	- 37.9
Average number of employees	31	30
Share price at the end of the period, SEK	7.50	38.30

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

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
 - Secured full ownership and rights to the product
 - Phase III readiness
 - End-of-Phase 2 meeting with the FDA on Feb 20, 2024
- **Pirepemat**
 - Phase IIb study ongoing - all clinical sites opened
 - First pre-specified DSMB evaluation
 - New patents resulting in potential to extend market exclusivity into early 2040s
- **IRL757**
 - Completed preclinical development program
 - 2 million USD grant from **Michael J. Fox Foundation** to finance first-in-Human SAD/MAD/food interaction study in man
 - Phase I study in Start of Phase I Q2, 2024
- **IRL1117**
 - CD selection and initiation of preclinical development
- **IRL942**
 - Preclinical development in progress
- **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
Mesdopetam (IRL790)	Parkinson's disease levodopa-induced dyskinesia (PD-LIDs) D3 antagonist	[Progress bar from Discovery to Phase IIb]					Phase III ready	Feb 20, 2024: End-of-Phase 2 meeting with FDA to define Phase III
	Parkinson's disease Psychosis D3 antagonist	[Progress bar from Discovery to Phase I]				Phase II ready		
Pirepemat (IRL752)	Parkinson's disease impaired balance and falls PFC enhancer	[Progress bar from Discovery to Phase IIb]					Phase IIb	Q3 2024: Study enrollment completed
	Parkinson's disease Dementia PFC enhancer	[Progress bar from Discovery to Phase I]				Phase IIa		
IRL757*	Apathy in neurology	[Progress bar from Discovery to Preclinical]			Phase I ready			Q2 2024: Phase I start
IRL942	Cognitive impairment in neurology	[Progress bar from Discovery to Preclinical]		Preclinical				H1 2024: Phase I ready
IRL1117	Parkinson's disease treatment	[Progress bar from Discovery to Preclinical]		Preclinical				2024: 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

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 drive for completion of the study
- Initiate Phase I study with IRL757

Preclinical development

- Drive the development of 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

- Completion of the Phase IIb study in PD-Falls
- BD activities for Phase III

IRL757

- Completion of First in Human Phase I study (SAD/MAD & food interaction)
- BD activities to establish development collaborations

Preclinical

• IRL942

- Phase I ready
- Start of Phase I
- Development collaboration

IRL1117

- Phase I ready
- Start of Phase I

IRLAB – a world-leading portfolio in Parkinson’s to reduce the burden and transforming lives



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 is discovering and developing a portfolio of transformative therapies targeting all stages of Parkinson's disease. The company has its origin in Nobel Laureate Prof. Arvid Carlsson's research group and the discovery of a connection between the brain's neurotransmitters and CNS disorders. Mesdopetam (IRL790), in development for the treatment of levodopa-induced dyskinesias, has completed Phase IIb and is in preparation toward Phase III. Pirepemat (IRL752), is currently in Phase IIb, being evaluated for its effect on balance and fall frequency in Parkinson's disease. In addition, the company is also progressing the three preclinical programs IRL757 (financially supported by the Michael J. Fox Foundation), IRL942, and IRL1117 towards Phase I studies. IRLAB's pipeline is driven by the company's proprietary systems biology-based Integrative Screening Process (ISP) research platform. Headquartered in Sweden, IRLAB is listed on Nasdaq Stockholm (IRLAB A).

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