



World leader in developing new treatments for Parkinson's disease

IRLAB, Q1 2025



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Today's agenda

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News in the period

Kristina Torfgård, CEO

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R&D update

Nicholas Waters, EVP Head of R&D

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Financials

Viktor Siewertz, CFO

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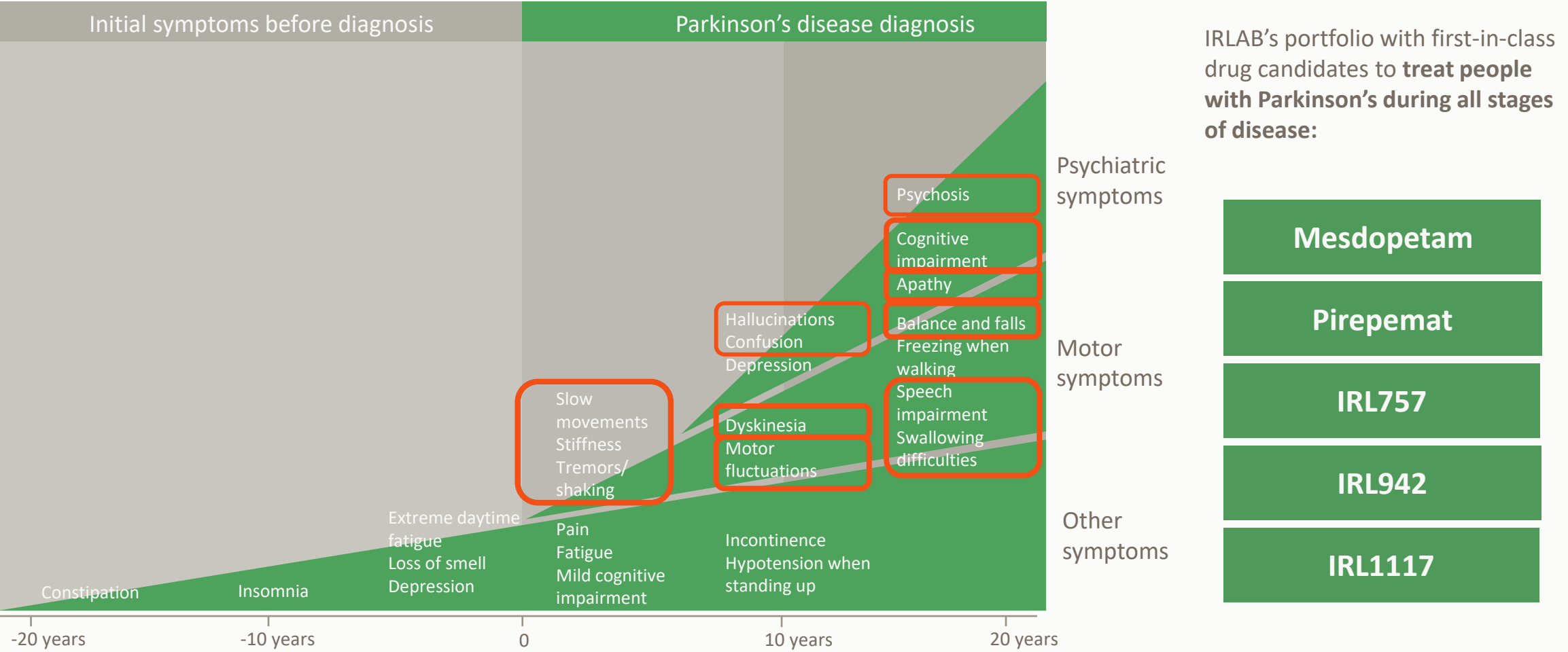


Concluding words

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Q&A session

First-in-class drug candidates to treat Parkinson's during all stages of the disease



Key highlights in Q1 2025

Positive feedback from the EMA – confirms alignment with the FDA on Phase III for mesdopetam

Strengthening the potential and value of mesdoptam

Positive Phase I results support continued development of IRL757

IRL757 progress according to plan – fully funded through clinical PoC

IRL757 study in Parkinson's decision taken to initiate, funded by development partner MSRD/Otsuka



Phase IIb study with pirepemat indicates a significant and clinically meaningful reduction in fall frequency

Guides design of future clinical trials with pirepemat and next steps

Important events in Q1 2025

Mesdopetam

- A waiver was received from the EMA regarding pediatric studies with mesdopetam in Parkinson's Disease
- Positive feedback was received from the EMA, confirming the alignment with the FDA regarding the Phase III program for mesdopetam
- Preclinical data for mesdopetam were published in the *European Journal of Neuroscience* – new insights into the antidyskinetic mechanism of mesdopetam and suggest potential additional benefits in the treatment of Parkinson's related psychosis



Important events in Q1 2025

Pirepemat

- The last patient completed the full treatment period in the Phase IIb study with pirepemat, **REACT-PD**
- Topline results from the Phase IIb study with pirepemat were reported, followed by additional positive efficacy data from the same study. In-depth analysis indicates a significant and clinically meaningful reduction in fall frequency

IRL757

- Positive topline results reported from Phase I study with IRL757 in healthy older adults – support the continued development of IRL757
- Decision to run a study with IRL757 in Parkinson's, funded by development partner MSRD



Presentations in and after Q1 2025

- IRLAB **presented at investor events** during the period and after to communicate updates of the company's strategy and pipeline
 - Insight Direkt Dagen – January
 - Redeye Investor Forum – February
 - Aktiespararna's Stora Aktiedagarna – March
 - Redeye Theme: Alzheimer's & Parkinson's – April
 - Redeye Investor Forum – April
- Public recordings are available on the **website, irlab.se**.



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 patent-based exclusivity into the 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 on Phase III program

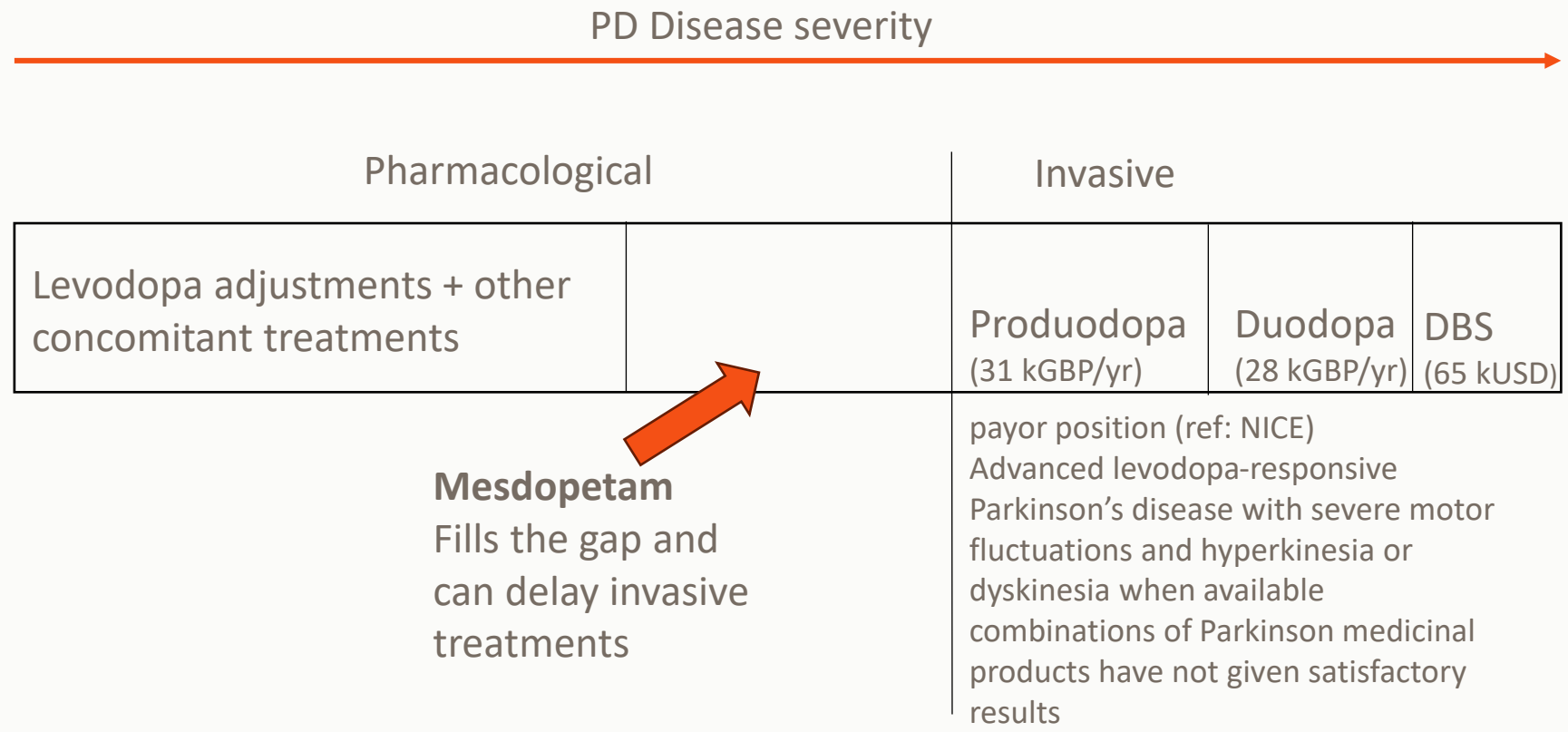
Regulatory guidance and payor input on mesdopetam phase III program achieved

- Scientific advice with EMA and local EU regulatory agencies in line with FDA advice
- Market research/Health provider activities guiding positioning of mesdopetam and also provides input to the design of the Phase III program

Key components of the Phase III

- Two parallel Phase III studies double-blind treatment with mesdopetam or placebo in 250-270 patients over 3 months divided into of approx. 130 patients/study
- Participants offered continued treatment with mesdopetam in an Open Label Extension (OLE)
- Primary endpoint – UDysRS, sum of parts 1+3+4
- Dose - 7.5 mg twice daily
- In parallel with the efficacy and OLE studies, a separate safety study of 6-12 months will run

Mesdopetam fills the gap between current levodopa based and invasive treatments





Pirepemat

IRL752

- A treatment 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

Potential for patent-
based exclusivity into
the 2040s



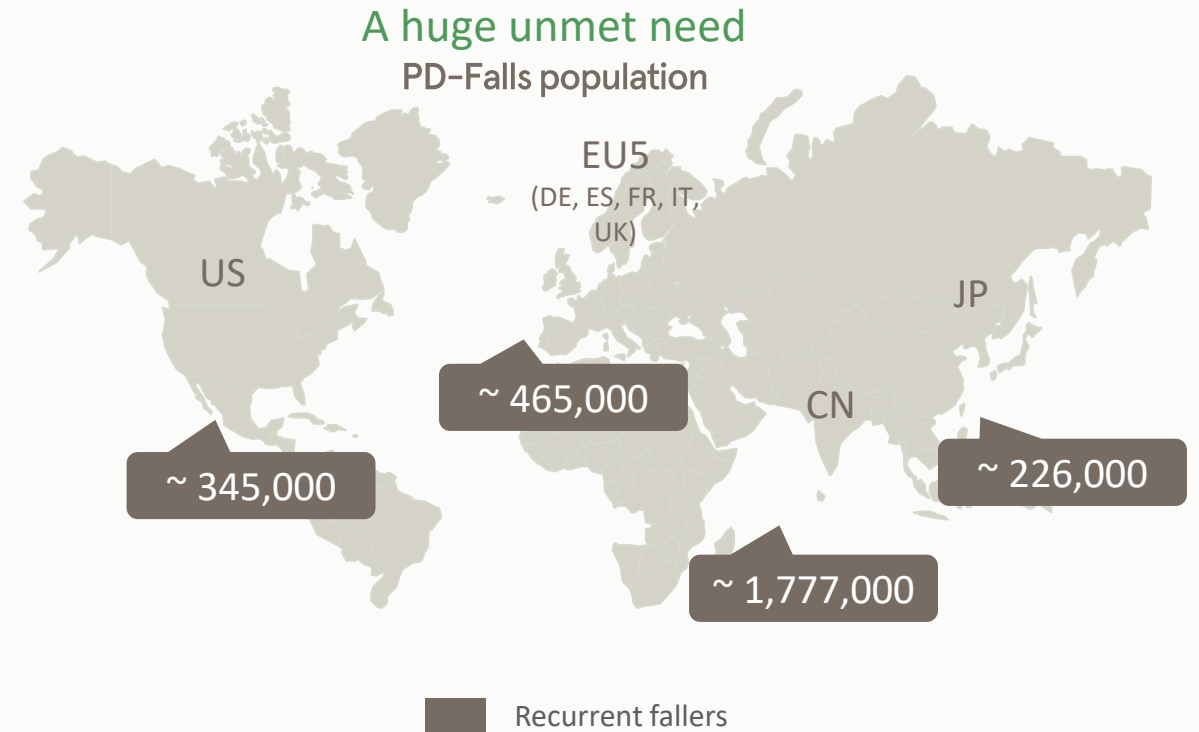
Objective – reduce falls in Parkinson's disease

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

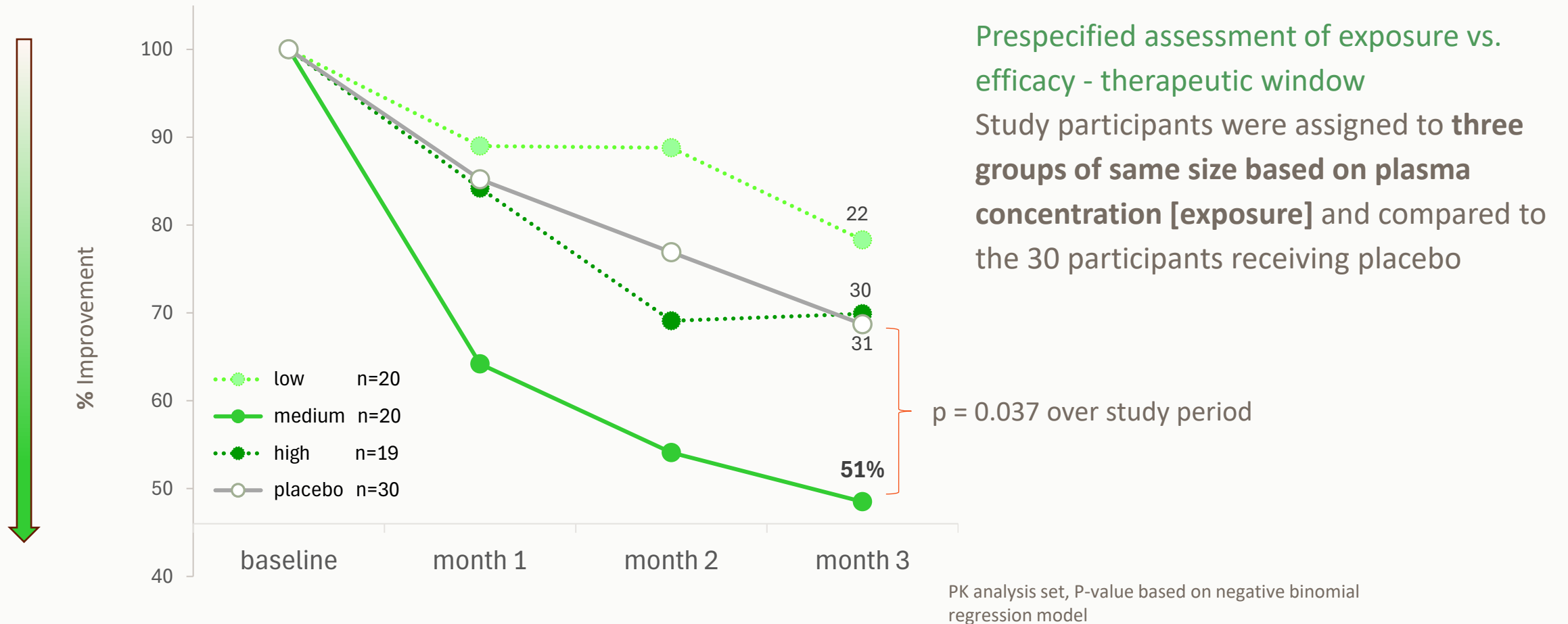


Topline results of Phase IIb study:

Study topline results:

- The **fall rate decreased by 42%** for those treated with pirepemat at a daily dose of 600 mg, but the effect was not statistically significant compared to placebo
- The results on the cognitive scale (MoCA) **indicated a meaningful improvement in cognitive impairment** for patients treated with pirepemat (600 mg daily), but did not achieve statistical significance
- The **adverse event (AE) profile was consistent with previously reported clinical trial results** for pirepemat
- Adverse events were reported by approximately 70% of study participants, evenly distributed among the three treatment groups

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



IRL757 – treatment of apathy

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

Apathy: loss of initiative, interest, and emotional expression/responsiveness



Addressable population:
2-7 million people

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

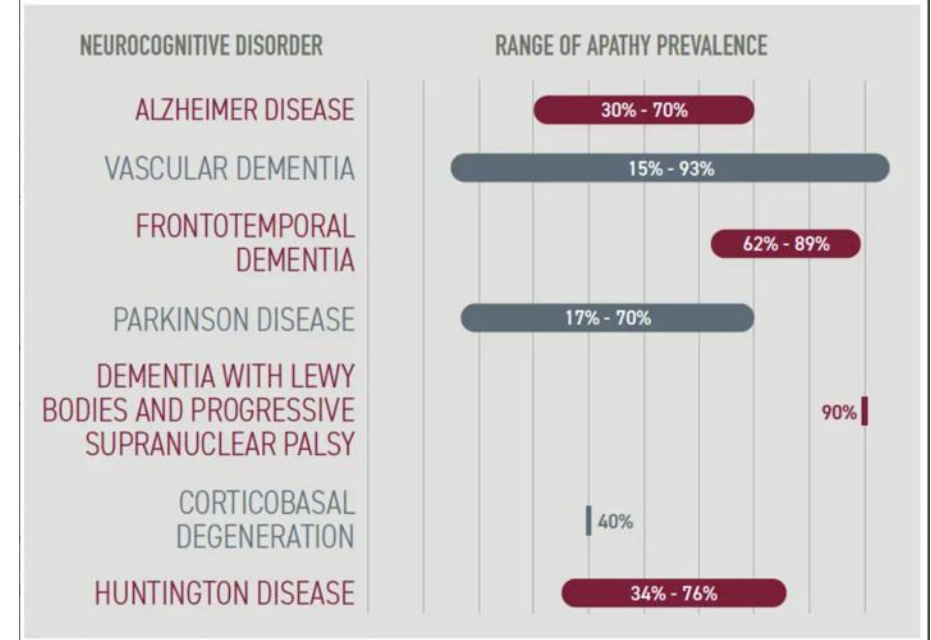
- Disruption of frontal-subcortical neurocircuits are implicated in apathy*

- 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.

Figure. Apathy Among Individuals With Neurocognitive Disorders^{1,6,9-11}



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 proof-of-concept

Status

- **Successful completion** of Single Ascending Doses (SAD) part and Multiple Ascending Dose, MAD part of the **Phase I study program**
- **An additional Phase I study** in a group of adult healthy subjects aged 65 years and older **successfully completed**
- Preclinical and clinical phase I data supportive of continued development
- A **decision to initiate a clinical trial in patients** with Parkinson's disease and apathy has been taken

Preclinical projects

IRL942	Clinical candidate	- Improve cognitive function
IRL1117	Clinical candidate	- Once-daily oral treatment of Parkinson's without troublesome complications

Innovative preclinical pipeline with first-in-class NCEs

<u>IRL942</u>	<u>IRL1117</u>
Improvement of cognitive function	Next generation Parkinson's treatment
Memory, perception, attention, reasoning, problem-solving and decision-making	Once-daily Parkinson's hallmark symptoms (tremor, rigidity, bradykinesia) Without treatment-related complications
Addressable population: 5.8 million people ¹	Addressable population: 5.7 million people ¹
Status: Preclinical Development	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 Q1

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

Current status

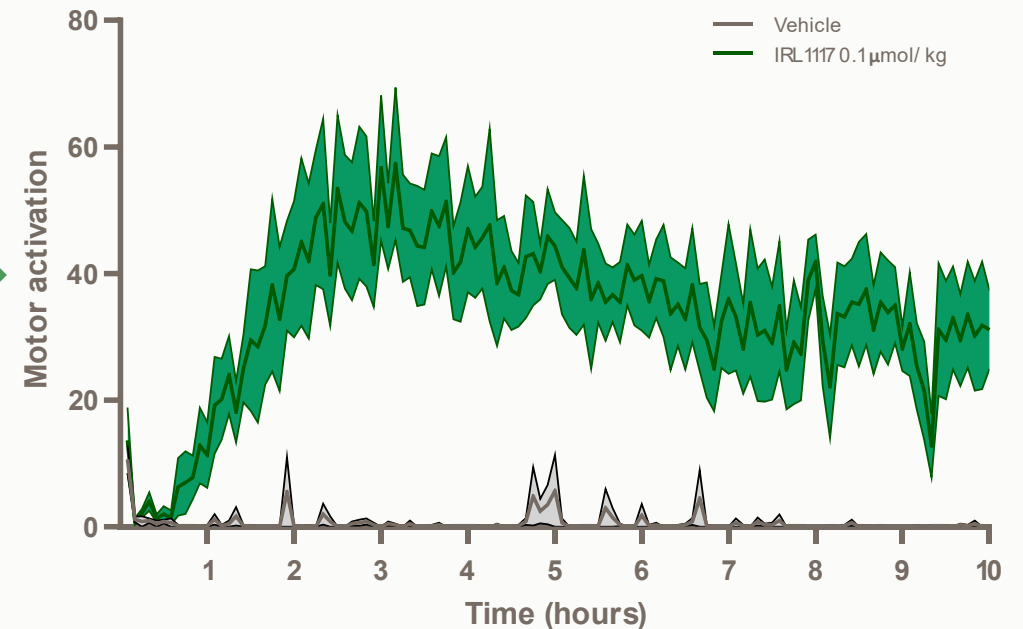
- Development in preclinical studies
- GMP manufacturing of **drug substance** ongoing (CMC)
- Development of **drug product** ongoing

For the benefit of other prioritized projects, we will **reduce the development pace of IRL942** and not proceed with toxicology studies during 2025, which means that we will not be ready for Phase I during 2025.

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

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.

- Once daily treatment that avoids the troublesome complications caused by today's mainstay levodopa-based treatments
- In preclinical studies IRL1117 has demonstrated rapid onset and **more than 24 hours of sustained efficacy without** inducing motor **complications**.
- Currently activities related to substance manufacturing (CMC) and planning for preclinical regulatory studies necessary for Phase I are ongoing



IRL1117 program

Building a comprehensive preclinical efficacy, tolerability and DMPK package

Models of PD

- Single dose behavioral response >24h
- Improvement of motor deficits by IRL1117 over a period of 29 days (once-daily dosing) without signs of tolerance or motor complications
- Chronic treatment induces clear functional motor response without motor complications
- Switching to IRL1117 reverses existing L-DOPA-induced motor complications

DMPK

- High potency orally active compound
- Exposure @ relevant doses quantified over 24h in rodents and minipigs

CMC

- Development of API manufacturing **ongoing**

IPR

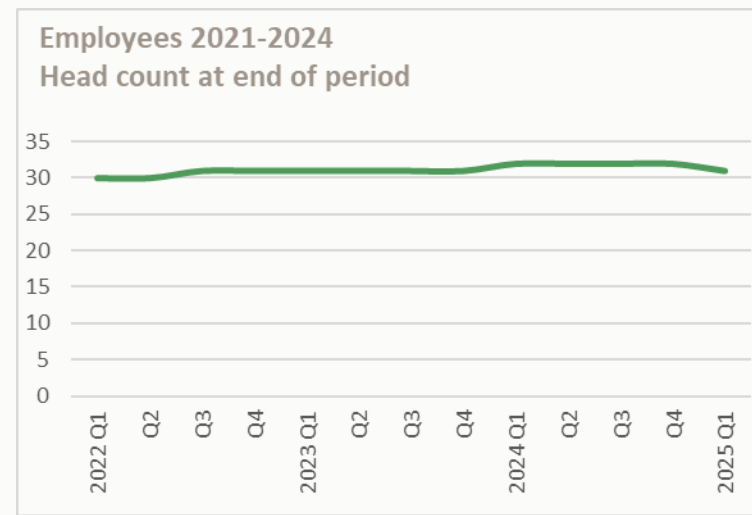
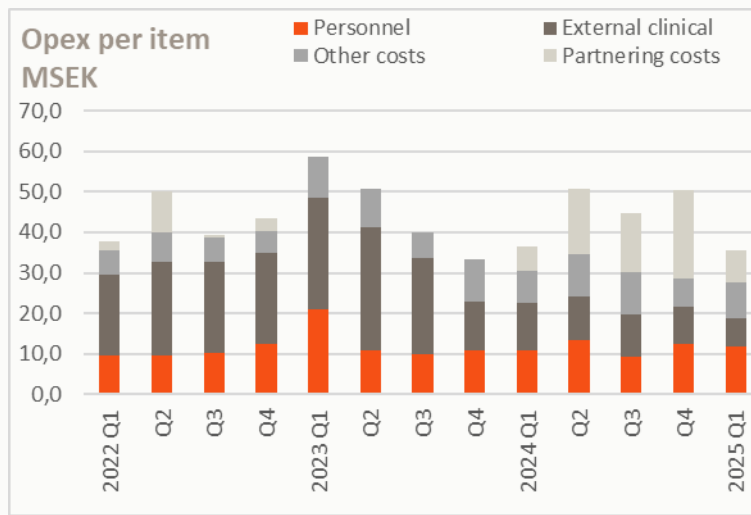
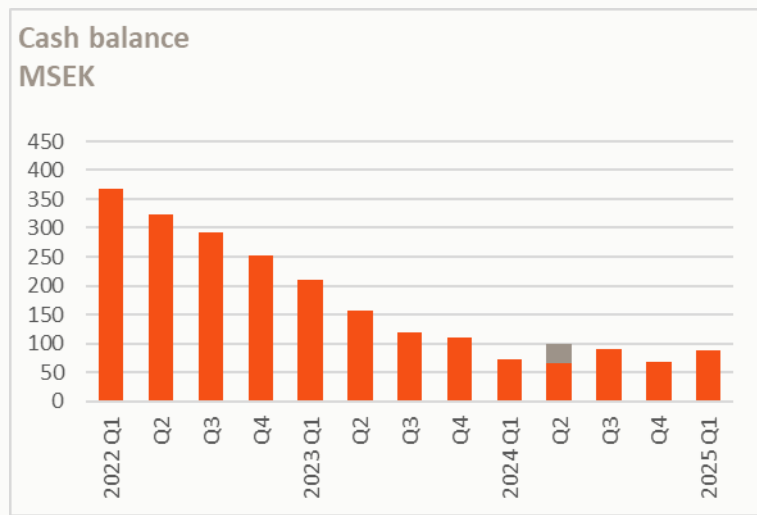
- Composition of matter: patent applications filed in 2022
- The estate potentially allows ultimate case exclusivity into 2040:ies

Finance report Q1 2025

- Highlights and summary
- Analyst coverage

Financial highlights

- Cash position SEK 89 million, whereof roughly SEK 58 million is prepayments from MJFF and MSRD/Otsuka
- As Phase I studies (SAD/MAD) with IRL757 has been finalized, cost related to IRL757, which are fully financed by MJFF and MSRD/Otsuka, has decreased slightly. Probable uptick going forward as the signal finding study has been initiated.
- Increased focus on cost control which will be further emphasized in the coming quarters. Still some cost relating to the finalization of the Phase IIb study with pirepemat (external clinical cost, mid grey bar)
- Headcount remains stable at around 30 employees





Financial summary

	Q1-Q4 2024	Q1-Q4 2023
Net sales, SEK	4.4m	-
Operating profit, SEK	- 28.6m	- 37.6m
Earnings per share before and after dilution, SEK	- 0.65	- 0.75
Cash and cash equivalents, SEK	88.6m	73.1m
Cash flow from operating activities, SEK	6.3m	- 38.2m
Average number of employees	31	32
Share price at the end of the period, SEK	7.94	15.6

Concluding words

World leading portfolio of development programs for Parkinson's disease

		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						Phase III ready	2025: Projected start of Phase III study program
	Parkinson's disease Psychosis D3 antagonist				Phase II ready			
Pirepemat (IRL752)	Parkinson's disease impaired balance and falls PFC enhancer						Phase IIb	2025: Completion of analyses and next steps
	Parkinson's disease Dementia PFC enhancer					Phase IIa		
IRL757	Apathy in neurology  <small>McQuade Center for Strategic Research and Development</small>  <small>THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH</small>				Phase I			H2 2025: Start of study in PD
IRL942	Cognitive impairment in neurology			Preclinical				2026: Phase I ready
IRL1117	Parkinson's disease treatment			Preclinical				2025: initiate IND enabling studies

Intensive Business Development efforts

Awareness of IRLAB and our development pipeline is increasing

Continuous and frequent dialogue with potential partners

Partnering opportunities being evaluated across the portfolio

Following the successful collaboration deal for IRL757, the focus is on mesdopetam and pirepemat

Value creation milestones over the next 12-18 months

Mesdopetam

- BD activities
- Initiation of the Phase III program

Pirepemat

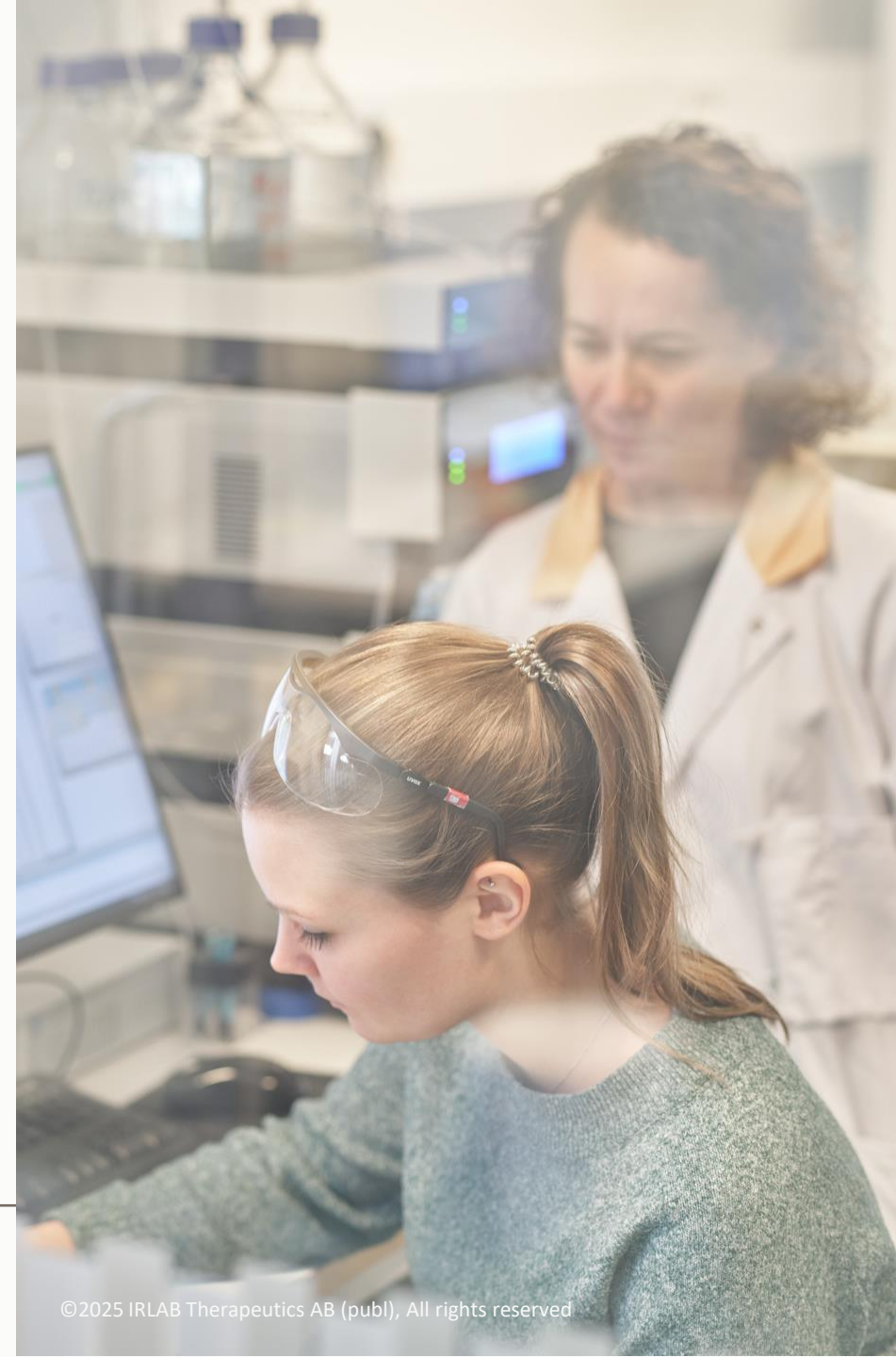
- Complete in-depth analyses of study data
- Defining strategy forward
- BD activities

IRL757

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

Preclinical projects

- IRL942: Phase I readiness
- IRL1117: Phase I readiness, start of Phase I



IRLAB – a world-leading portfolio in Parkinson's



Pioneering biology & ISP

Deep profound understanding of Parkinson's. Team from Nobel laureate Prof. A Carlsson's research group



Focused strategy

Discover and develop treatments for PD patients throughout their disease journey



Validated business model

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 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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