

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

IRLAB, Q2 2024



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# Today's agenda





News in the period Gunnar Olsson, CEO





R&D update
Nicholas Waters, EVP Head of R&D





Financials
Viktor Siewertz, CFO





Concluding words



**Q&A** session



### Key highlights in Q2 2024

Clinical Phase I study with IRL757 started - funded by The Michael J Fox Foundation

IRL757 is our third clinical project

Collaboration with MSRD//Otsuka initiated – Takes IRL757 through clinical Proof-of-Concept in apathy in Parkinson's and Alzheimer's

IRL757 fully funded through clinical P-o-C

The REACT-PD Phase IIb study with pirepemat passes second and final DSMB review

REACT-PD continues towards finalization as planned

Kristina Torfgård is appointed CEO

Starts on August 1st, 2024



## IRL757 development collaboration with MSRD/Otsuka

#### Scope of the collaboration

 Develop IRL757 through clinical Proof-of-Concept for the treatment of apathy in Parkinson's and Alzheimer's disease

Secures financing through clinical Proof-of-Concept

#### **IRLAB**

- Receives up-front payment and activity based milestone payments
- Executes the development activities
- Retains ownership of product and IP

#### **MSRD**

- Funds the development activities under the terms
- May extend the collaboration beyond Proof-of-Concept, subjuct to new negotiations
- In the event of no extension of the collaboration, MSRD/Otsuka receive low single digit royalty on future sales



# Multiple positive aspects of the MSRD/Otsuka agreement

- 1) Brings near term cash flow to IRLAB upfront + milestones – 8.5 MUSD
- 2) Secures full financing of the Development activities through PoC in two populations; Parkinson's and Alzheimer's disease
- Provides additional external validation of our R&D innovation and quality, and in particular the potential of IRL757

#### Benchmark

Ca 25 MUSD is the average industry cost from Phase I initiation through Proof-of-Concept



## Summary – project progresses in Q2 2024

#### Mesdopetam

Preparation for Phase III and support to BD activities

#### **Pirepemat**

• DSMB recommendation to drive Phase IIb study to completion without changes

#### **IRL757**

Phase I ongoing and collaboration with MSRD/Otsuka initiated

#### IRL942

Preclinical documetation continues according to plan

#### IRL1117

Preclinical documetation continues according to plan



## Financing aspects in Q2 2024

- Up-front payment from MSRD/Otsuka 3 million USD
- 25 million SEK drawn from the loan facility provided by Fenja Capital
- Full financing of project cost relating to IRL757 development

#### Present financing takes the company through key value driving milestones

- Mesdopetam partnering for Phase III
- Pirepemat Phase IIb top line result presentation



# Participation and presentation at investor meetings in Q2

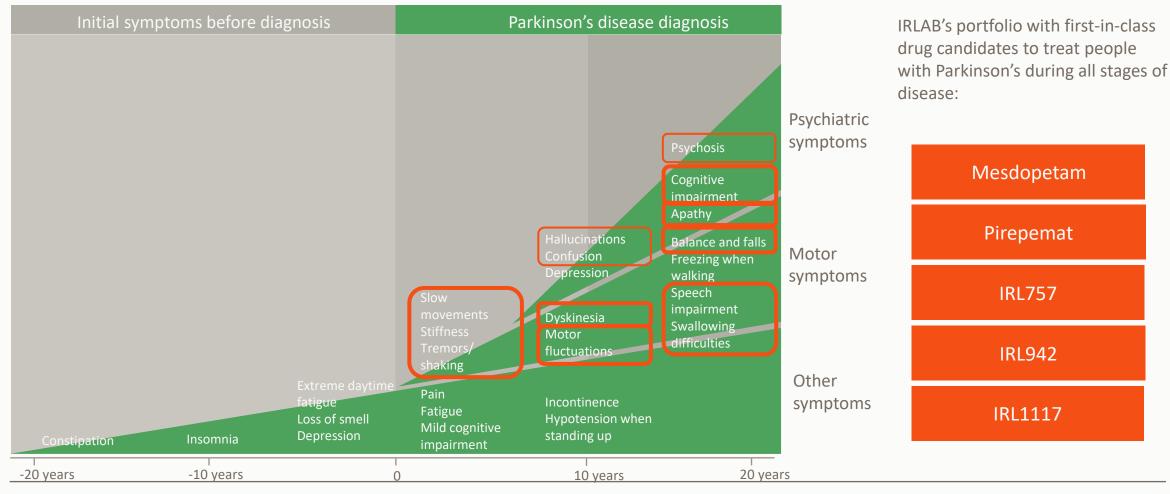
- Redeye Investor Forum April
- ABGSC Investor Days May
- Redeye Growth Day May
- Aktiespararna Stora Aktiedagarna in June





# R&D update

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







# Mesdopetam

IRL790

Treating levodopa-induced dyskinesias (PD-LIDs) through a novel mechanism – Dopamine D3 receptor antagonist

### Mesdopetam (IRL790)

First in class- a novel mechanism

Inhibiting dopamine D3 receptors

Potential for patentbased exclusivity into the 2040s

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



## Continued progress with mesdopetam

#### PD-LIDs –phase III program progress

- Preparation for interactions with European regulatory agencies ahead of Phase III start
- Market research activities for positioning and input to the Phase III program
- Current plans allows start of Phase III study start possible by end of the year/early-25

# External validation in publication of an independent academia driven mesdopetam preclinical study\*

- Confirms the anti-dyskinetic efficacy described in company lead studies
- Suggest a disease modifying potential of mesdopetam treatment based on re-establishment of lost neuronal connections following treatment





# Pirepemat

**IRL752** 

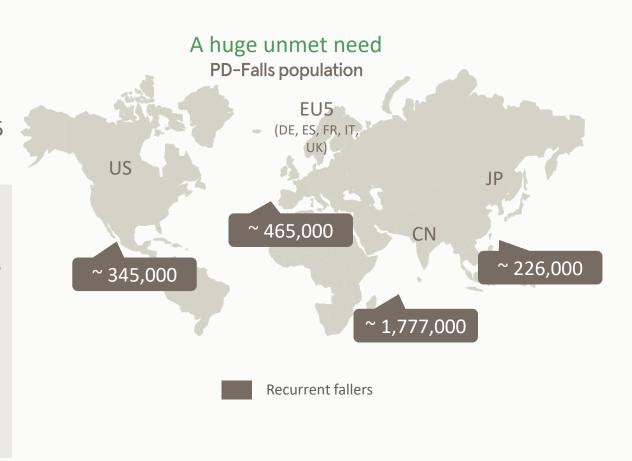
- A treatment to improve balance and reduce falls in Parkinson's (PD-Falls)
- Ongoing randomized, placebo-controlled Phase IIb clinical trial

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

- Reducing falls is the greatest medical need and one of the worst 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

#### Status

- Centers in France, Poland, Spain, Sweden, Germany and the Netherlands
- Patient recruitment completion anticipated in Q3 2024
- Followed by 1 month baseline period, a 3-month treatment period, data management and database lock before top line results





### Pirepemat (IRL752)

First in class- a novel mechanism

Inhibiting alpha 2 and serotonin 7 receptors

Potential for patentbased exclusivity into the 2040s

Objective – reduce falls in Parkinson's disease



## Pirepemat update



#### Clinical trial progress

- REACT-PD a pioneering study in a new patient population
- DSMB for REACT-PD executed the last prespecified review of the data integrity and safety in late June
- DSMB unanimously recommends the company to continue the study according to plan

#### **Implications**

- Anticipated completion of patient recruitment in Q3 2024
- Leading to top line data in the end of Q1 2025





# IRL757 – treatment of apathy

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



# IRL757 is aimed at the huge untreated problem with apathy

#### Huge unmet medical need

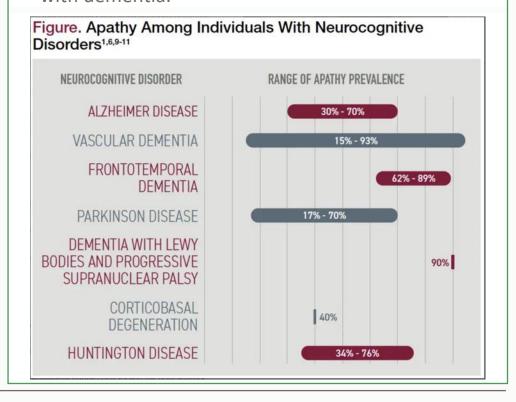
- Several million US and EU citizens may be affected by apathy
- Apathy occurs in 20-70% in people with PD and in 20-90% of people with AD and other CNS disorders

#### 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.





### IRL757 project progress in Q2

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

- Regulatory approval granted
- Phase I study started
- Funding to conduct the Phase I study with IRL757 is secured in through The Michael J. Fox Foundation
- Collaboration started with MSRD/Otsuka funding IRL757 through proof-of-concept in Parkinson's and Alzheimer's disease
  - Joint Steering Committee (JSC) in place and operative





# Preclinical projects

IRL942 Clinical candidate

**IRL1117** Clinical candidate

- Improve cognitive function and brain health

Once-daily oral treatment of Parkinson's without troublesome complications



### Innovative preclinical pipeline with first-in-class NCEs

#### IRL942

Improvement of cognitive function

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

Addressable population: 5.8 million people<sup>1</sup>

Status: IND-enabling studies; Phase I ready H2 2024/H1 2025

#### IRL1117

Next generation Parkinson's treatment

Once-daily

Parkinson's hallmark symptoms (tremor, rigidity, bradykinesia)

Without treatment-related complications

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

Status: Preclinical development



Source: 1. Datamonitor

# 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 Q2

IRL942 has the potential to be the <u>first drug in a new class</u> to improve the cognitive function in people living with Parkinson's and other neurological disorders

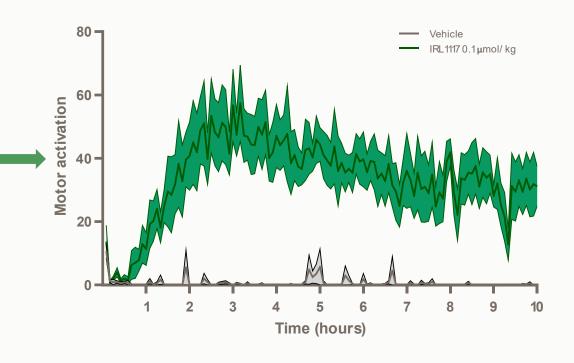
- Development in preclinical studies
- GMP manufacturing of API proceeds
- Development of drug product has been initiated and IRL942 is projected to be Phase I ready during H2 2024/H1 2025



# 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 levodopabased treatments.
- In preclinical studies IRL1117 has demonstrated rapid onset and more than 20 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





## IRL1117 project progress in Q2:

Building a comprehensive preclinical efficacy, tolerability and DMPK package - Phase I ready end 2024/H1 2025

**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

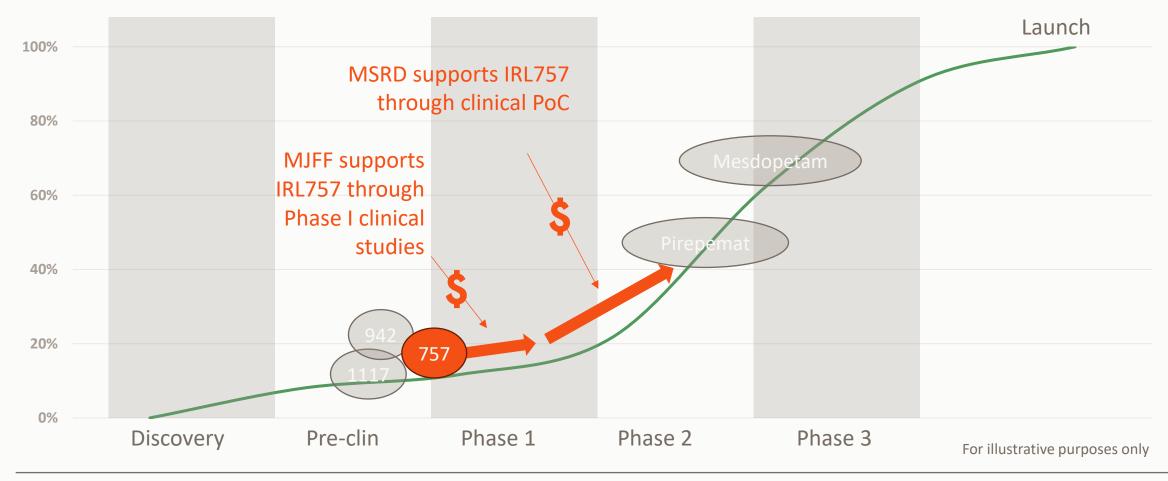




# Finance report Q2 2024

- Highlights and summary
- Analyst coverage

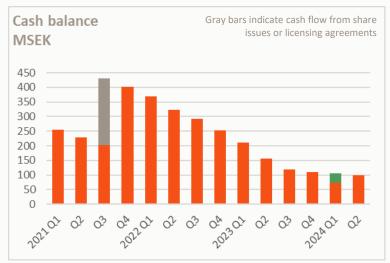
# MJFF and MSRD supports IRL757 through value creating activites

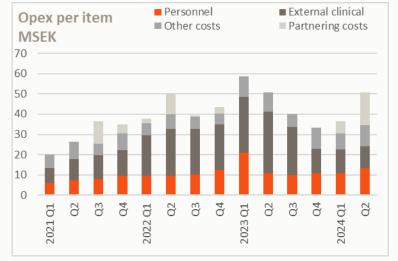


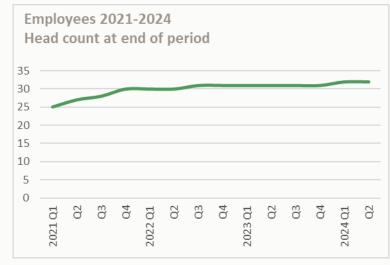


## Financial highlights of Q2, 2024

- Cash position SEK 98 million
- Investing in progressing mesdopetam towards Phase III
- Increase in cost compared to Q1 2024 is mainly due to cost related to IRL757, which are financed by MJFF and MSRD/Otsuka
- In preclinical development, advancing IRL942 and IRL1117 CMC development towards tox and Phase I
- Headcount remains stable at around 30 employees









# Financial summary of Q2, 2024

	H1 2024	H1 2023
Net sales, SEK	42.8m	6.9m
Operating profit, SEK	- 42.7m	- 104.4m
Earnings per share before and after dilution, SEK	- 0.89	- 2.01
Cash and cash equivalents	98.3m	156.4m
Cash flow from operating activities	- 38.1m	- 94.3m
Average number of employees	32	31
Share price at the end of the period, SEK	13.25	8.66

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



## Analyst coverage



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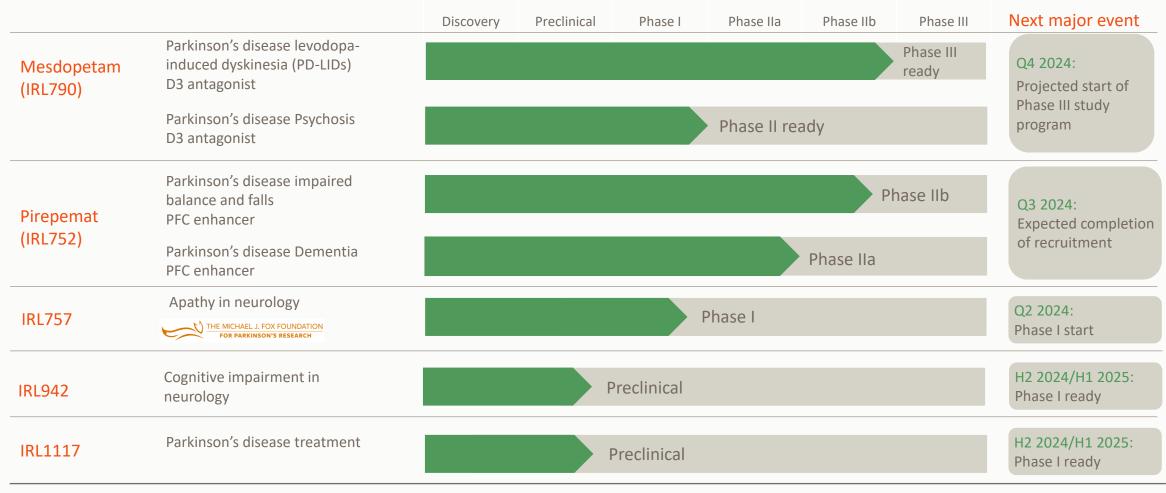




# Concluding words

# World leading portfolio transforming treatment for people living with Parkinson's

Portfolio





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### Intense Business Development activities

Awareness of IRLAB and our development pipeline is increasing

Continuous and frequent dialogue with potential partners

Partnering opportunities being evaluated across the portfolio

Present focus is mesdopetam



# Multiple possibilities for high value creation in the project portfolio during the next 12-18 months

BD activities for Phase III
 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)
 Start of first patient study for efficacy and safety signal finding
 IRL942
 IRL1117
 Start of Phase I
 Start of Phase I



## IRLAB – a world-leading portfolio in Parkinson's



Pioneering biology & ISP

Deep profound understanding of Parkinson's. Team from Nobel laurate Prof. Arvid 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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