



Transforming life for people living with Parkinson's

Q2 presentation – Aug 24, 2022

Richard Godfrey, CEO

Nicholas Waters, EVP and Head of R&D

Viktor Siewertz, CFO



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Strengthening the leadership of IRLAB

"I am grateful for the warm welcome I have received. Having spent the summer taking a deep dive into our science and pipeline, I am convinced that we have a robust pipeline that will both transform the quality of life for patients living with Parkinson's and deliver substantial shareholder value"

Richard Godfrey
CEO



"I am delighted to welcome Richard to IRLAB. He brings a wealth of international commercial and financial experience together with a valuable network and a plethora of fresh ideas."

Furthermore, with IRLAB's rich pipeline I can now focus on ensuring we deliver on our R&D promises."

Nicholas Waters

Co-founder, EVP and Head of R&D

IRLAB is poised for success

- After 8 years of research and development, **4 drugs candidates** are poised for significant high value inflection points in the near future
- **Leadership team strengthened** with a new CEO to allow executive focus on commercial priorities and R&D program delivery
- **Discovery platform ISP**, validated and highly productive having generated the promising pipeline:
 - Mesdopetam Phase IIb top-line data in PD-LIDs trial is around YE 2022
 - Two preclinical assets to initiate Phase I in 2023 focusing to treat cognitive impairment (IRL942) and apathy (IRL757)
 - Pirepemat Phase II top-line data in PD-Falls trial is anticipated at YE 2023
 - P003 nominate clinical candidate for once-daily treatment of Parkinson's without the troublesome complications

IRLAB develops new Parkinson's drugs with blockbuster potential

1. Proprietary drug discovery platform – ISP

- Rapid, efficient and successful in-house small molecule drug discovery process
- Systems biology: medicinal chemistry + phenotypic in-vivo screening + machine learning

2. Patient focused, blockbuster potential strategy

- Pipeline of first-in-class drug candidates to treat symptoms of Parkinson's throughout the patient journey
- Two Phase IIb candidates, one out-licensed
- Two preclinical programs and one discovery project

3. Clinical and Commercial proof-of-concept and traction

- Two compelling Phase IIa read outs from randomized placebo-controlled studies
- Ipsen global license to develop and commercialize mesdopetam (\$363m + royalties)

IRLAB has a highly experienced management and near-term inflection points

4. Experienced organization

- Founders are successful serial biotech entrepreneurs, with >30 years research experience in PD
- Founded on pioneering PD research by Prof. Arvid Carlsson, for which he was awarded the Nobel Prize in Physiology or Medicine in 2000
- HQ in Gothenburg, 40 staff and contractors
- Listed on Nasdaq Stockholm, IRLAB-A, Strong cash position (Q2'22: SEK 323m)

5. Near-term high value inflection points

- Phase IIb top-line data mesdopetam around YE 22
- Phase IIb top-line data pirepemat YE 23

Parkinson's continues to be common and debilitating disease

- 9 million patients, the second most common neurodegenerative disease after Alzheimer's
- It is a chronic and progressive disease with no cure
- Caused by loss of brain cells that produce dopamine
- Dopamine has central role in how the brain regulates and controls movement
- The standard treatment is a drug called levodopa
- Has to be taken 6-8 times a day and works well for a few years but has complications
 - ~30% PD patients experience LIDs¹
 - Levodopa-induced dyskinesias
 - ~45% PD patients FALL recurrently²⁻⁴

“ My 3-year-old granddaughter came up to me a few weeks ago and said “...why do you walk like a penguin?”
– Colin, Parkinson's patient via Parkinson's UK²

Parkinson's core symptoms:

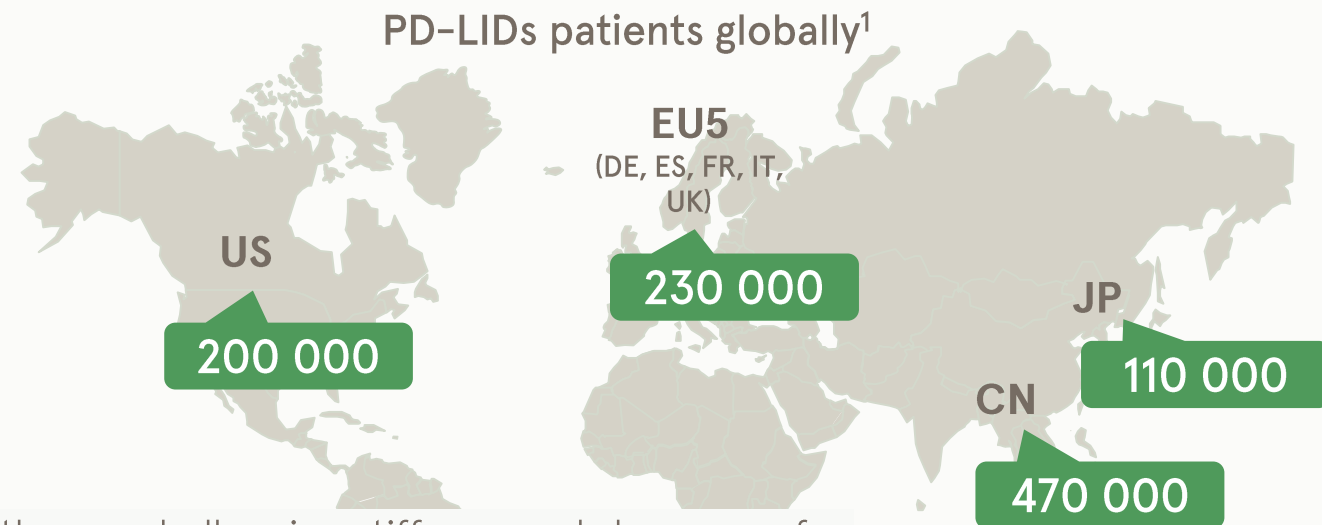
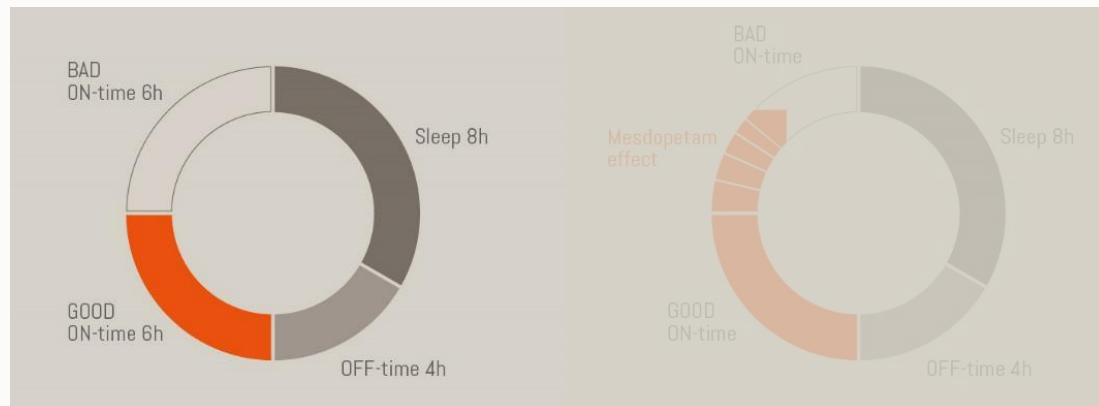
- Tremors in hands, arms and legs
- Muscle rigidity
- Slowness of movement (bradykinesia)
- Impaired balance (postural dysfunction)

With disease progression, other symptoms occur:

- Speech and swallowing difficulties
- Severe balance problems and falls
- Psychiatric symptoms, e.g. hallucinations
- Autonomous symptoms, e.g. fall in blood pressure and incontinence
- Cognitive difficulties – dementia
- Dyskinesia (after long-term use of levodopa)

Mesdopetam is designed to reduce levodopa-induced dyskinesia

Mesdopetam

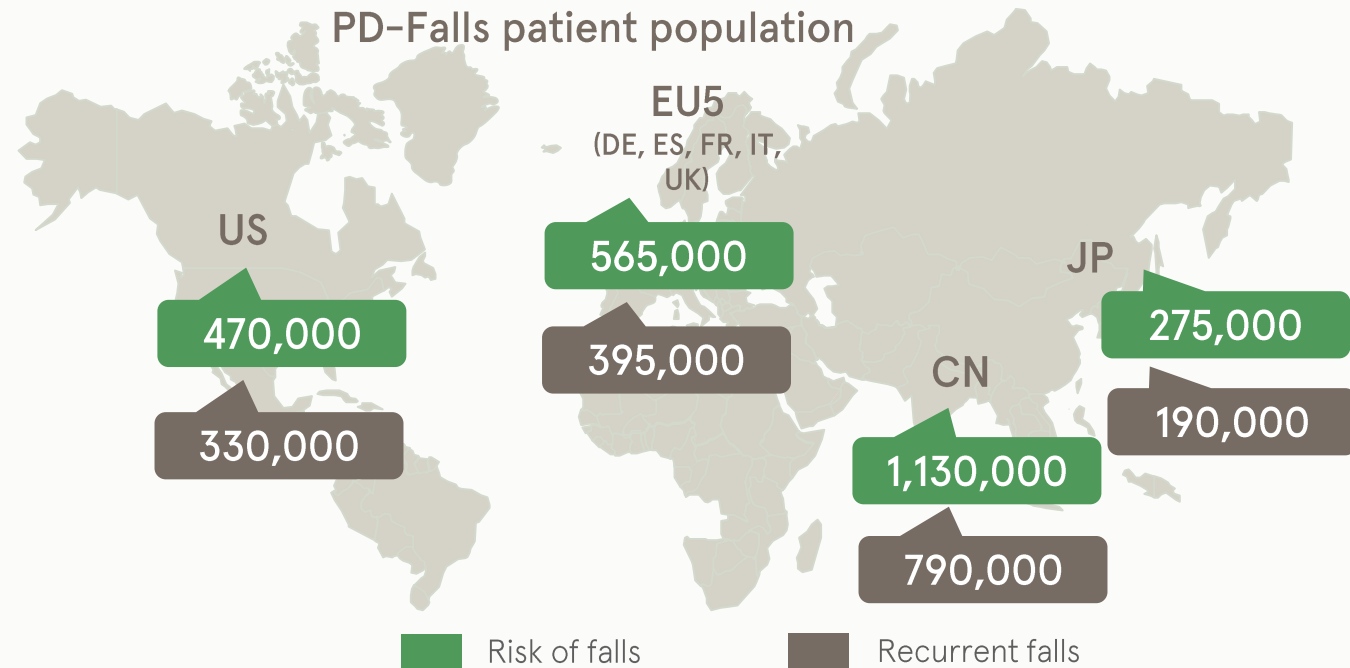


- In a typical day, people living with Parkinson's wake up with very challenging stiffness and slowness of movement – they are OFF
- Levodopa alleviates the OFF and is necessary to take 6-8 times a day to maintain patients in "ON"
- As the disease progresses, the ON is hampered by the occurrence of dyskinesia and involuntary movements, inducing what is called "bad ON"
- Mesdopetam limits the occurrence of bad ON and allows the ON to be "good ON" during more hours of the day improving quality of life

Pirepemat is designed to 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 living with Parkinson's
- The **cost of treatment for a fall injury** is estimated to about **30,000 USD** in elderly > age 65



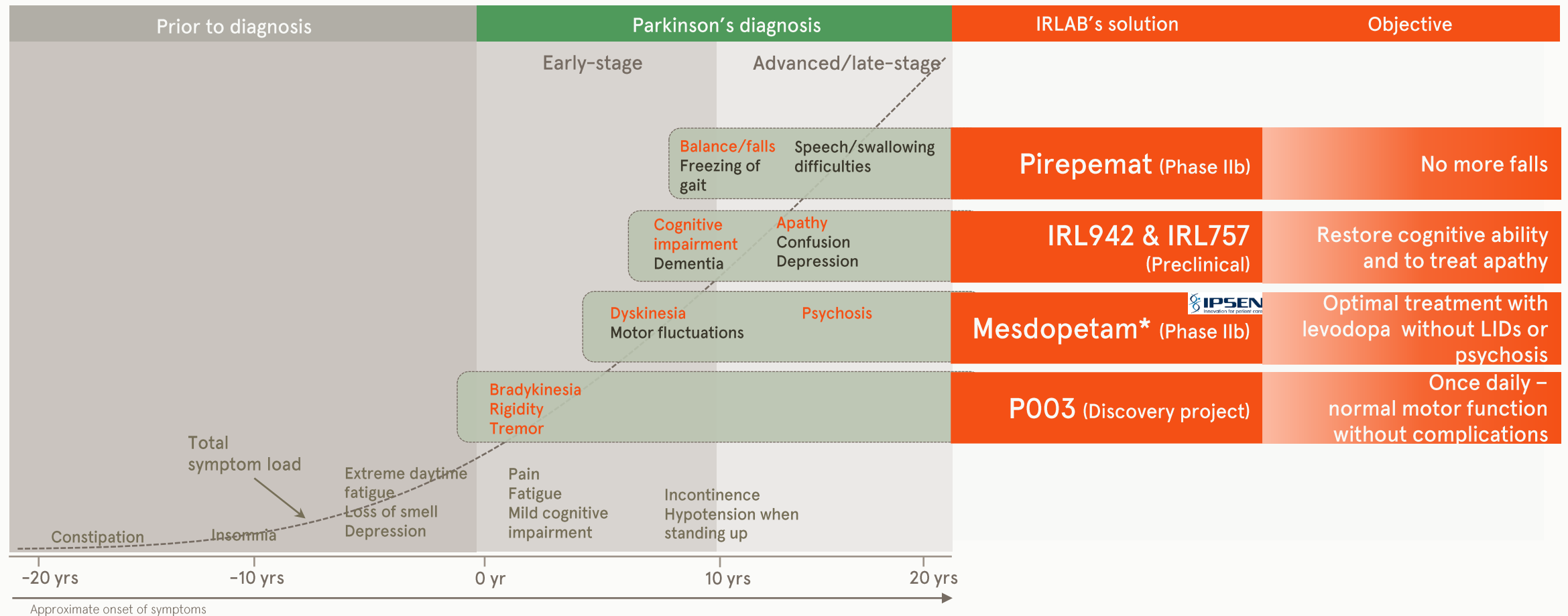
IRLAB addresses a new, untapped market

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

Patient journey, living with Parkinson's

IRLAB PD portfolio transforms the treatment algorithm

Parkinson's and
IRLAB's solutions




Q2 agenda

1



News in the quarter


2



R&D update

- Mesdoeptam
- Pirepemat
- Preclinical (IRL942, IRL757, P003)

3



Financials

- Financial highlights
- Analyst coverage

4



Outlook

- Pipeline
- Newsflow and outlook

5

Q&A session

Operational highlights in the second quarter (including post-period end)

- The management team strengthened by **appointing Richard Godfrey as new CEO and Nicholas Waters as Executive Vice President and Head of Research & Development**, effective July 1, 2022.
- **Know-how acquired to support a strong patent application** for chemical matter claims related to the P003 discovery project. The P003 project aims to provide a once-daily treatment of Parkinson's without the troublesome complications.
- IRLAB **presented at several investor events** during May and June to communicate updates of the company's strategy and pipeline. Public recordings are available on the website, irlab.se.
- **Viktor Siewertz CFO, was a guest speaker at the Expert session** at the BioStock Life Science Summit 2022, talking about the licensing agreement with Ipsen – one of the larger in the Swedish biotech sector in decades.
- **Phase IIb PD-LIDs study with mesdopetam** has been expanded to include 154 patients, top-line data is anticipated around year end.

Financial highlights in the second quarter

- Net sales recorded in Q2 **SEK 23.4m** (SEK0m)
- Total operating expenses during the quarter **SEK 50.6** (SEK 26.5m)
- The operational loss for the quarter **SEK 27.0m** (SEK 26.5m)
- Cash flow from operations **SEK-44.0m** (SEK-23.4m)
- Cash and cash equivalents amounted to **SEK 322.6m** (SEK 229.4m)
- Average number of employees: **28** (21), of which in R&D: **25** (19)
- The total number of registered shares on June 30, 2022, were **51,748,406** (51,748,406)

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

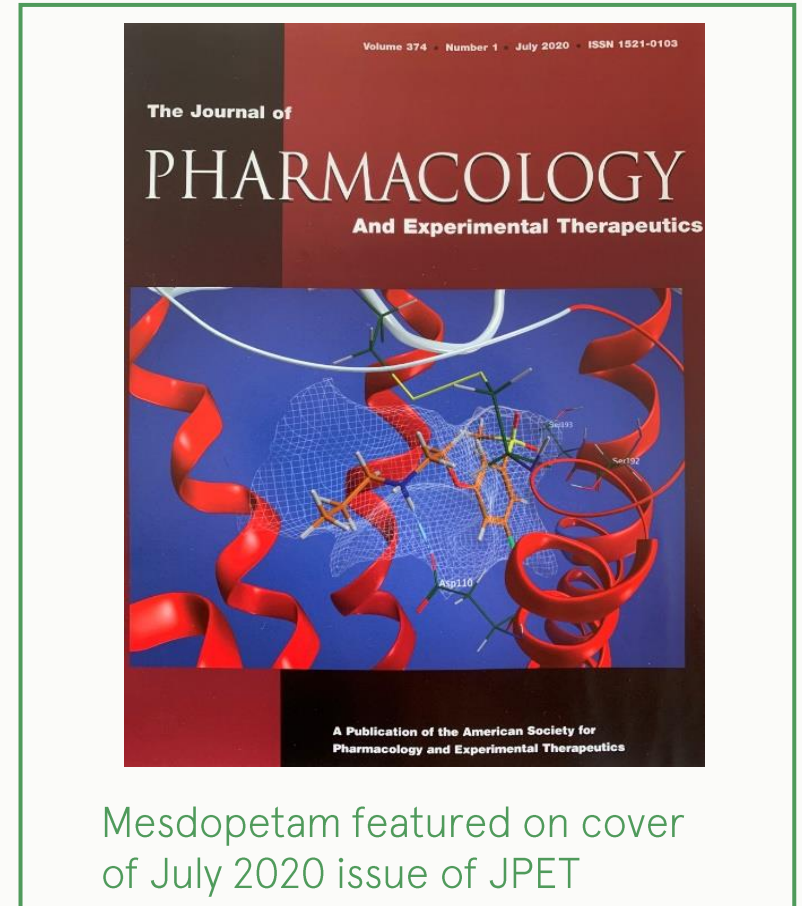
Mesdopetam (IRL790)

(*mes_dop_e_tam*)

- Ipsen acquired the exclusive global license to develop and commercialize mesdopetam
- Mesdopetam counteracts levodopa-induced dyskinesia (PD-LIDs) by **inhibiting dopamine D3 receptors**
- Treatment and prevention of psychosis in Parkinson's (PD-P)

Mechanism: Dopamine D3 receptor antagonist

- Dopamine receptors D1 and D2 in the striatum of the brain control movement
- In PD, the neurons that release dopamine are lost and the control of movement is weakened
- Levodopa is an effective drug to replace the loss of dopamine in Parkinson's and restores movement control
- With levodopa treatment the D3 receptors are upregulated in Parkinson's and dyskinesia (PD-LIDs) is developed
- **Mesdopetam inhibits dopamine D3 receptors and, thus, counteracts the levodopa-induced dyskinesias**
- Proof-of-concept has been demonstrated in preclinical – and clinical Phase Ib & IIa



Mesdopetam's efficacy in Phase Ib & IIa studies highly clinically relevant

- The patient reported outcomes (PROs) in the studies suggest that adding mesdopetam to their otherwise stable anti-parkinsonian treatment can improve the quality of daily motor function by reducing troublesome dyskinesias and increase "good ON"
- Clinically meaningful increase in "good ON" is 1 hour
- Standard of care (amantadine/Gocovri) increase "good ON" by ~1.5 hours through reduction of troublesome dyskinesias
- **In the Phase IIa study, mesdopetam at doses 5–7.5 mg (b.i.d) improved "good ON"-time by ~2.8 hours ($p=0.002$)**
- Well-tolerated and no significant side effects observed, approximately par with placebo



Joakim
Tedorff,
CMO at IRLAB

Efficacy and tolerability is studied in the ongoing Phase IIb study

Study design

- 154 patients at 46 sites in Europe, Israel and the US
- Four treatment arms
 - Three different doses (2.5, 5 and 7.5mg b.i.d)
 - and placebo group
- Three months treatment
- **The study is powered to detect ~3 hours increase of “good ON” through reduction of “bad ON”**

Primary objective

- Increase in daily “good ON”-time through reduction of ON time with troublesome dyskinesia, so called “bad ON”.
- Efficacy is assessed by means of Hauser diaries (a PRO), the UPDRS scale and UDysRS scale
- **Top-line data** expected around year end 2022

Study objective

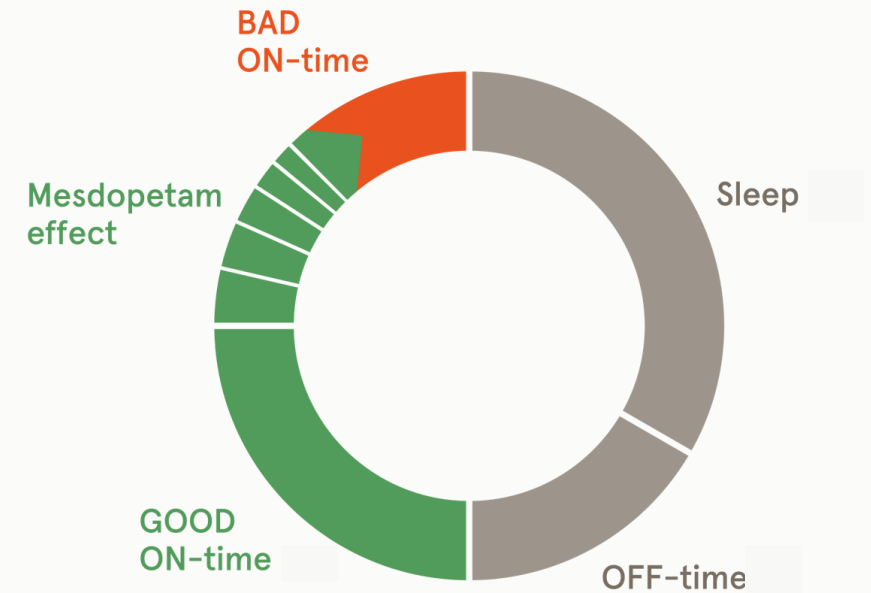


Illustration of a day for a person with Parkinson's on standard anti-Parkinson's medication (levodopa) and mesdopetam. The time is aggregated and grouped according to categories.

One of the largest licensing agreements in Swedish biotech

IRLAB is eligible to receive up to \$363 million plus royalties of worldwide sales:

- Ipsen is responsible for all remaining clinical development and worldwide commercialization
- Good strategic fit with their existing products and synergy with their commercial footprint in neuromuscular treatment clinics
- The terms
 - **\$28 million** upfront payment, eqv. to approx. SEK 240m, fully deployable towards current pipeline and/or new programs
 - **\$335 million** in potential development, regulatory and sales-based milestones, and;
 - Tiered low **double-digit royalties** on worldwide net sales



Type	Global, mid-sized biopharmaceutical company
Employees	approx. 5,700 worldwide
Offices	Paris-Saclay, France (hq); Oxford, UK; Cambridge, U.S.; Shanghai, China
Specialty	Transformative medicines in Oncology, Rare Disease and Neuroscience
Total sales (FY 2020)	over €2.5 billion
Sales operations	Sells more than 20 medicines in over 115 countries, with a direct commercial presence in more than 30 countries

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

Mechanism of action: pirepemat

- In Parkinson's, cognitive impairment, postural instability, and falls (balance impairment) occurs due to loss of NE & DA transmission in the cerebral cortex of the brain
- Levodopa does not restore neuronal function in the cerebral cortex
- Pirepemat designed to activate the synaptic activity in the cerebral cortex

1 Increased synaptic availability of dopamine (DA) and norepinephrine (NE) in the frontal cortex

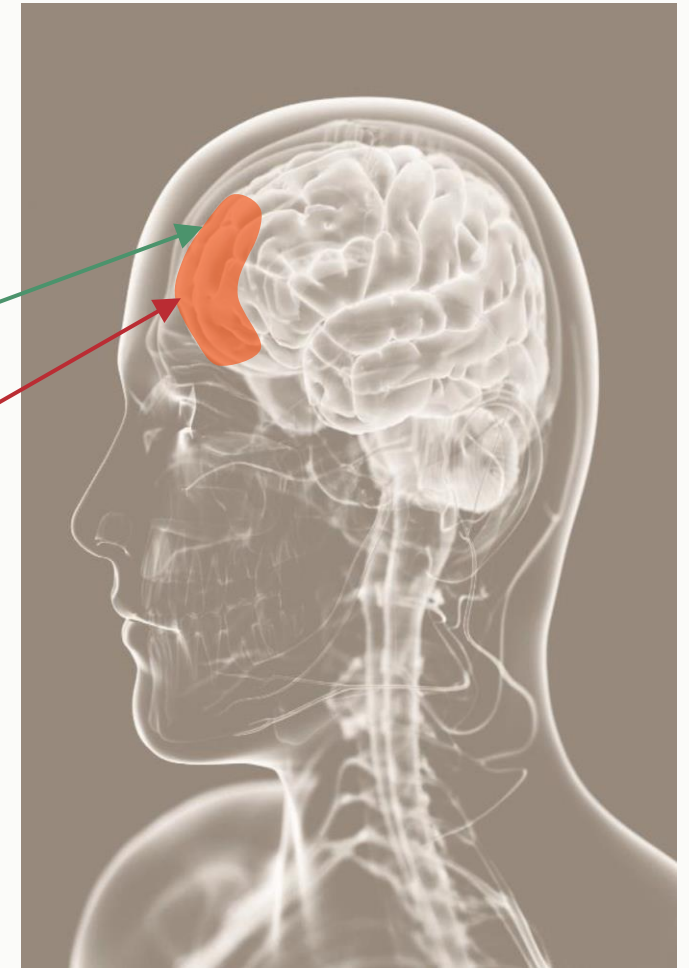
- Balance, motor function
- Cognitive function, Affect and impulse control

2 Specific pharmacological profile attributed to:

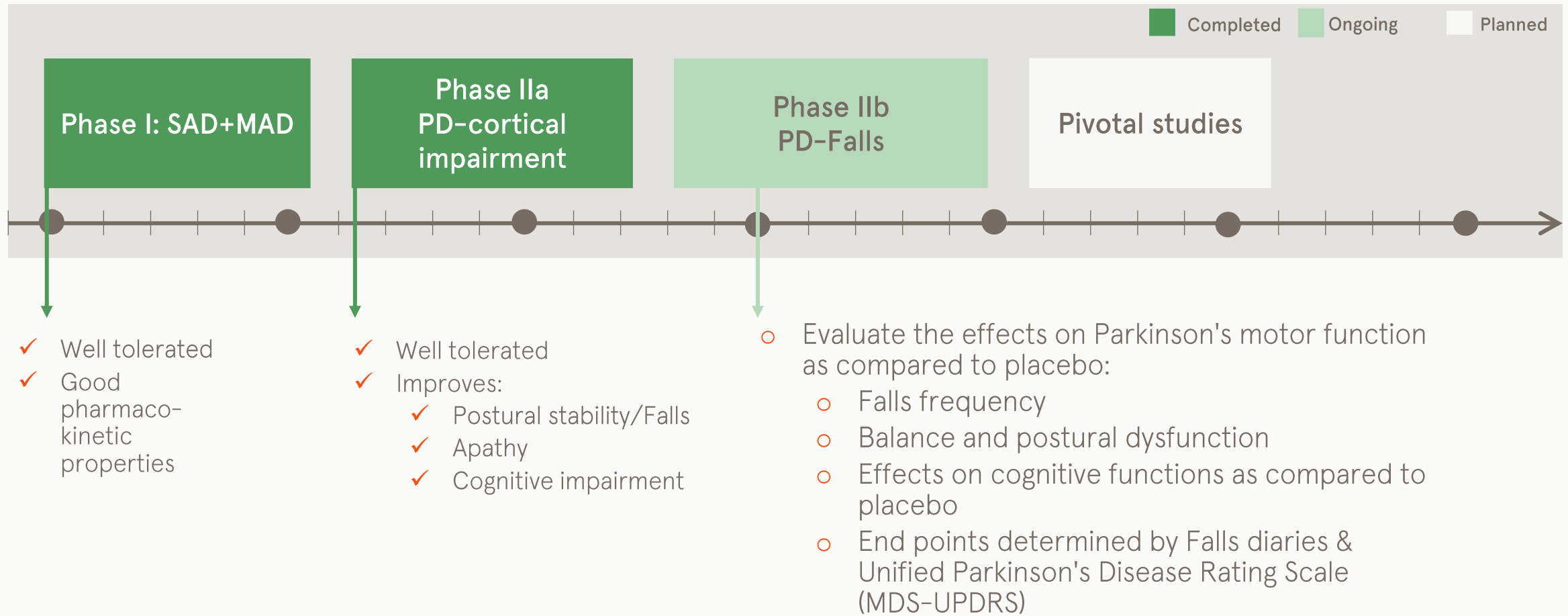
- Effects at 5HT7 receptors, cortical α -receptors (2c)

3 In preclinical studies evaluating effects on cortical function pirepemat displays

- Improvement in DA & NE transmission and gene expression related to synaptic activity
- Functional effects in impaired cognitive states
- Improvement in motor function in DA/NE hypoactive state



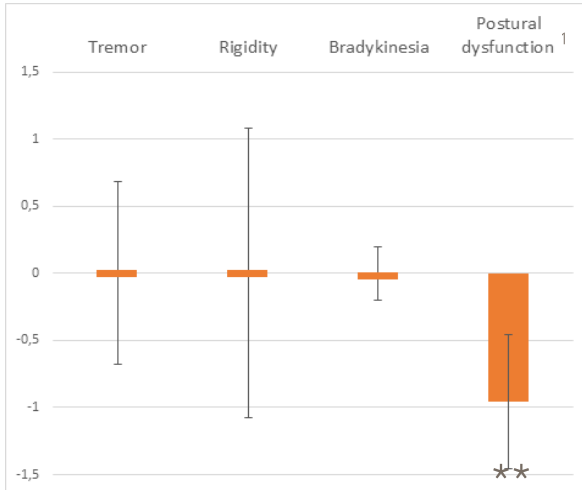
Clinical development path for pirepemat: Improvement of balance and falls



Phase IIa clinical proof-of-concept⁶

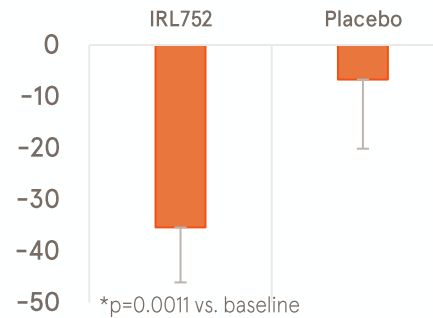
Pirepemat

Pirepemat affects the Parkinson's symptoms not treated by levodopa

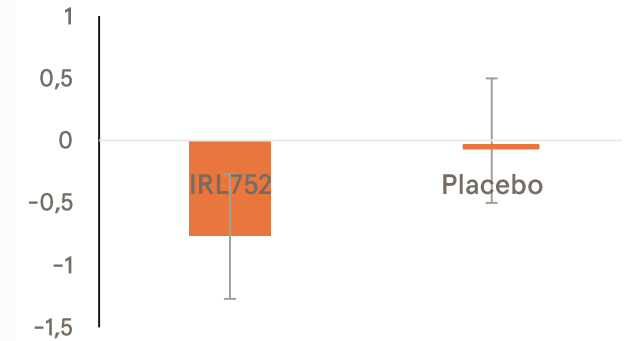


Pirepemat improves the executive functions associated with Parkinson's symptoms not treated by levodopa

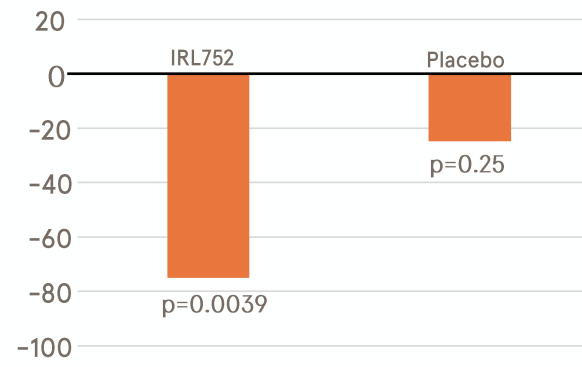
35% improvement in balance²



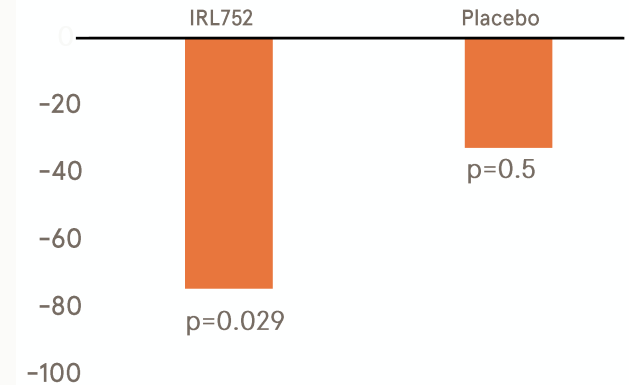
53% reduction in falls³



70% reduction in Apathy⁴



80% reduction in Caregiver distress⁵



Summary:

- Well tolerated in Parkinson's patients
- Shows promising improvements in executive function in Parkinson's:
 - Balance (Axial motor symptoms /Postural stability)
 - Reduced fall frequency
 - Apathy & Cognitive impairment
- Effects support cortical mode of action of pirepemat

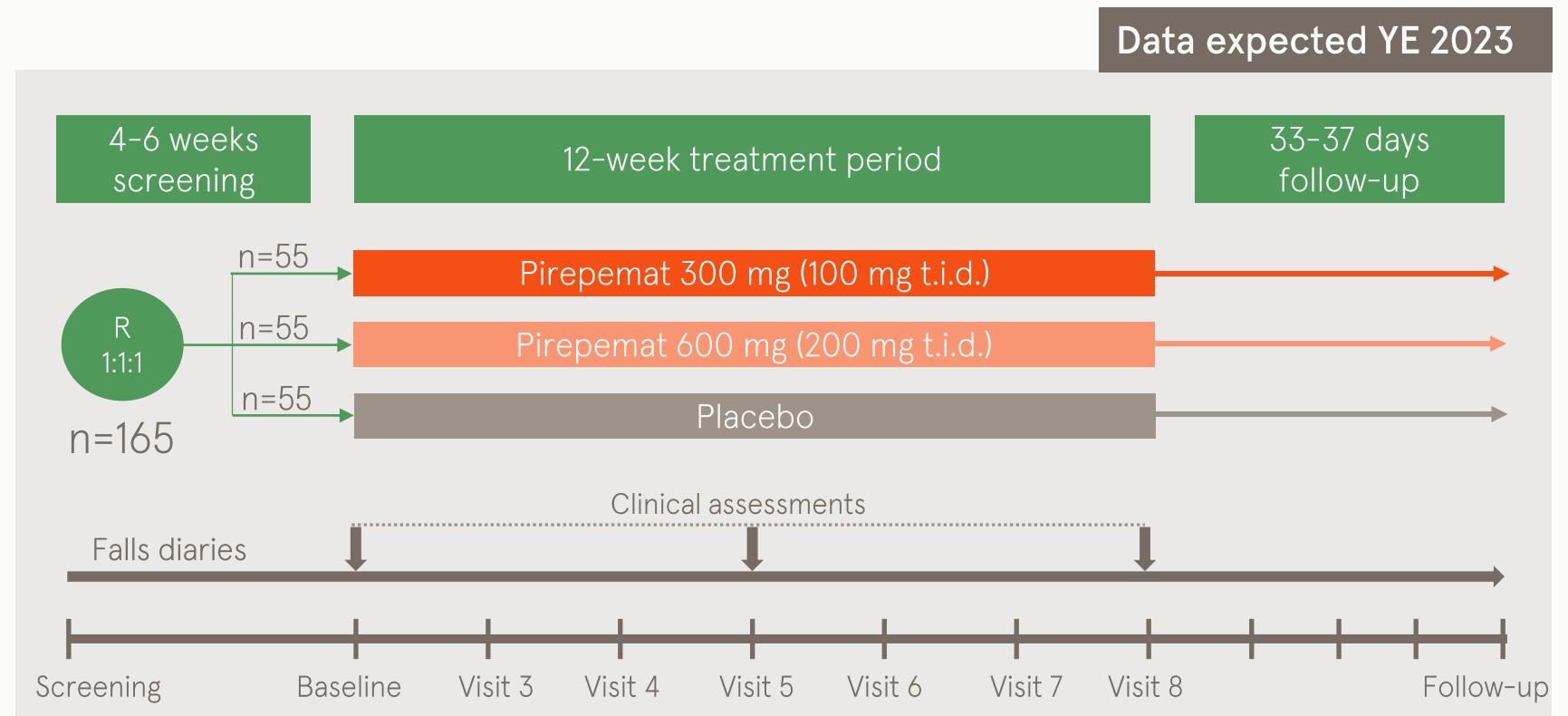
Phase IIb study evaluating efficacy of pirepemat on falls frequency in Parkinson's patients

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 development: IRL942, IRL757 and the P003 project

IRL942 Restore cognitive function

IRL757 Treat apathy in neurology
(Target populations: Parkinson's, dementias, schizophrenia, depression)

P003 Once-daily treatment of Parkinson's
Without the troublesome complications

IRL942 to improve cognitive function in neurological indications

IRL942 opportunity

- **12 %** of adults aged 65 years or more experience **cognitive decline** (CDC)

Problem

- **Disruption of frontal neurocircuits** are implicated in the pathogenesis of cognitive decline

IRLAB's solution

- IRL942 show a **unique ability** to activate frontal circuits and **broadly improve cognitive function**
- **Potential for both symptomatic relief and disease modification**

IRL942 status

- CMC campaign, regulatory tox/safety during 2022/23, Clinical Phase I planned for 2023

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.

IRL757 – to treat apathy in neurological indications

IRL757 opportunity

- Over 10 million US and EU citizens each may be affected by apathy
- Apathy occurs in 20–70% in people with Parkinson's and in 20–90% of people with Alzheimer's and other psychiatric and CNS and disorders

Pathophysiological background

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

IRLAB's solution

- IRL757 presents a unique ability to increase neuronal activity in frontal-subcortical circuits
- Potential for both symptomatic relief and disease modification

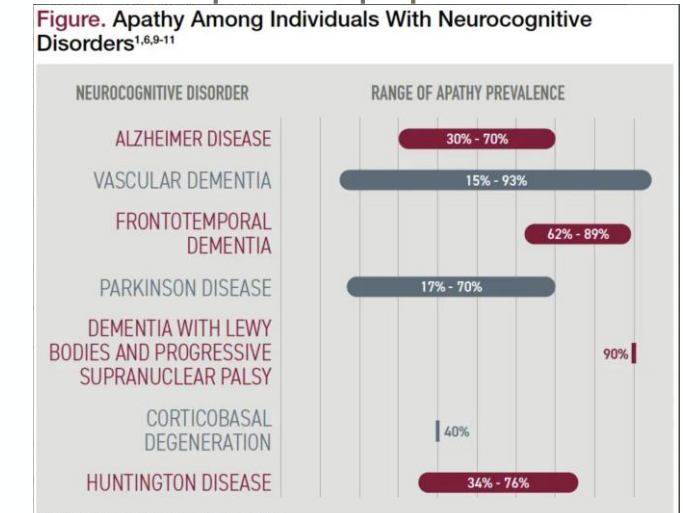
IRL757 status

- CMC campaign, regulatory tox/safety during 2022/23
- Clinical Phase I planned for 2023

Apathy

Loss of initiative, interest and emotional expression/responsiveness, often found in people with dementia.

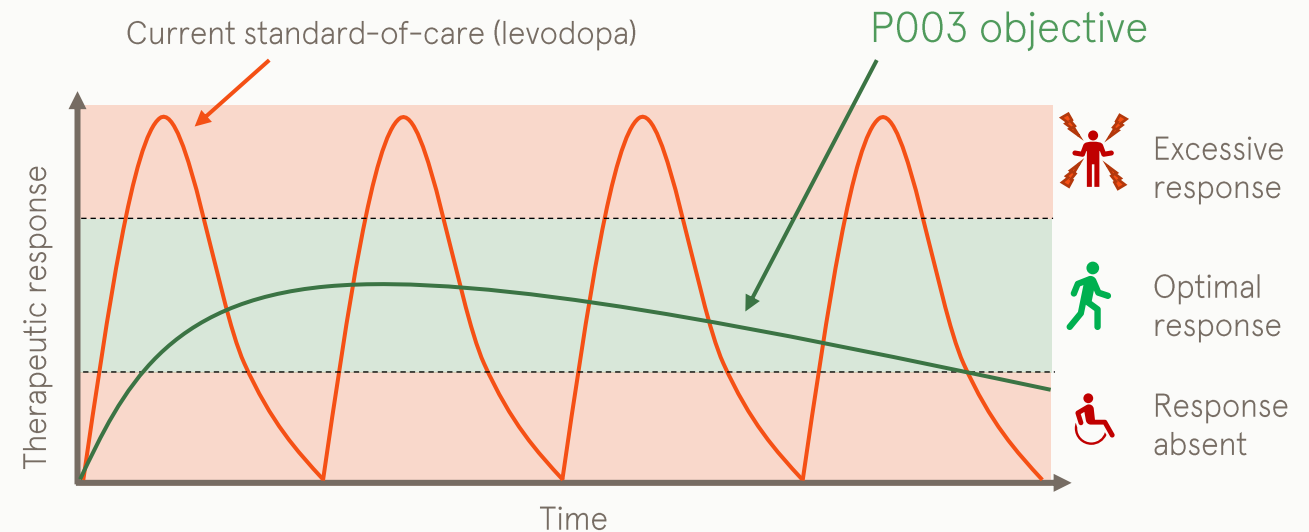
Potential patient population



P003 is the next generation Parkinson's treatment

Objective: once-daily, orally available, treatment of core motor symptoms of Parkinson's without the complications

- Total market (16 largest regions): 8.3 million people diagnosed with Parkinson's in 2022
- Mechanism: D1/D2 agonist with efficacy equivalent to levodopa / apomorphine
- Potential to provide optimal functional efficacy without limitations of current treatments



P003 status

- 1st generation: lead optimization ongoing
- 2nd generation: candidate identification through structural chemistry ongoing
- Nominating drug candidate 2022

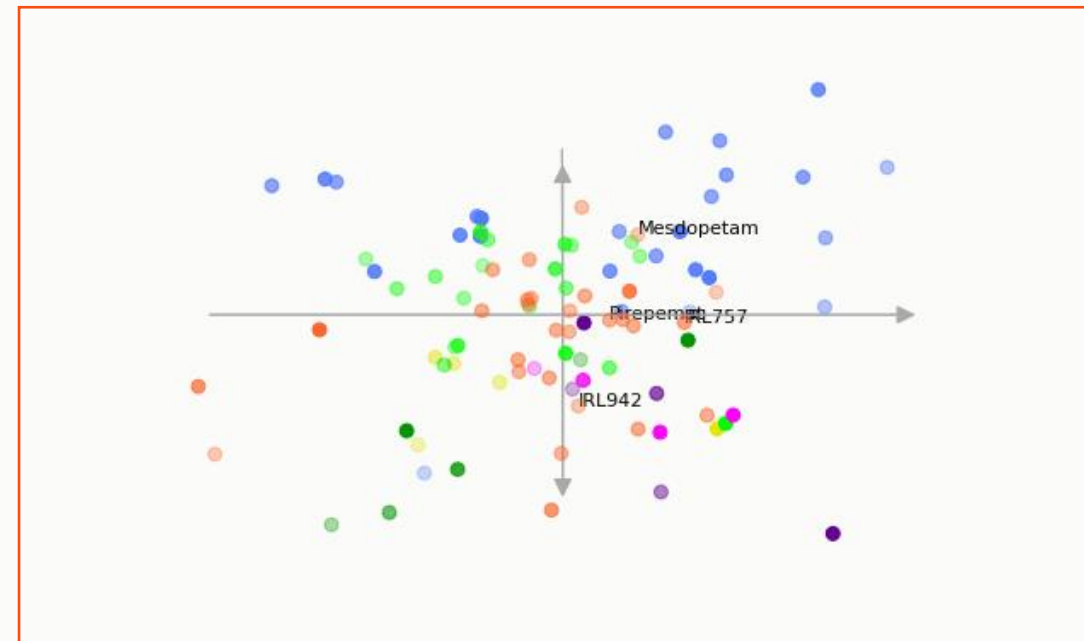
Pipeline generated with our unique proprietary drug discovery platform – ISP

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**)

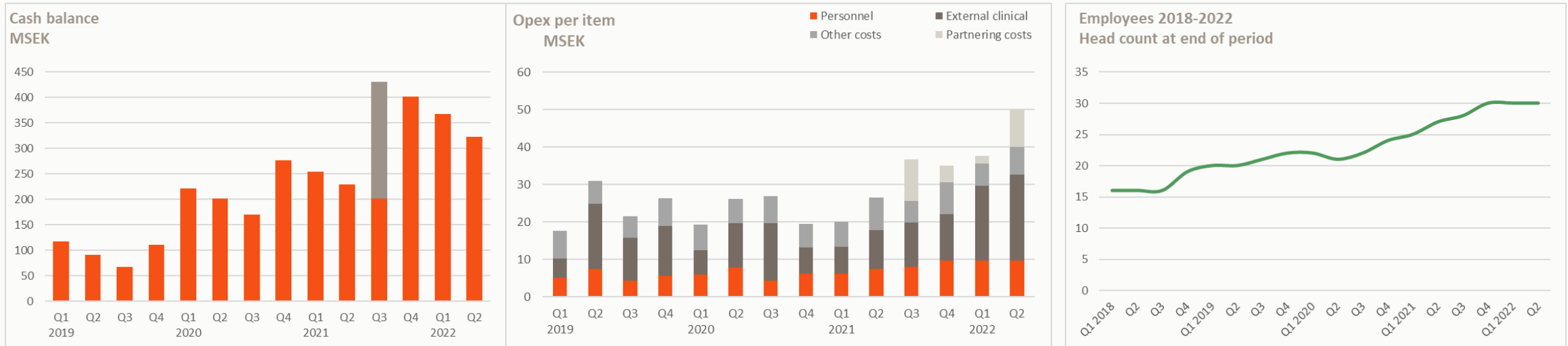
Finance report Q2 2022

- Highlights and summary
- Analyst coverage

Financial highlights of Q2 2022

Financial report

- Geopolitical events and global economics have increased our focus on cost control
- Investing in two clinical Phase IIb programs according to plan
- Investing in preclinical development, advancing IRL757 and IRL942 towards clinical Phase I
- Strong cash position SEK323m



Financial summary of Q2 2022

Financial report

Highlights

- Strong cash position: SEK 323m
- Cash flow increasing due to increased R&D activity
- Net sales – SEK 13m realized cost¹ for Phase IIb study with mesdopetam, and SEK 10m for services to Ipsen

	Apr-Jun 2022	Apr-Jun 2021	Jan-Jun 2022	Jan-Jun 2021	Jan-Dec 2021
Net sales	23,410	0	32,452	0	207,782
Operating profits/loss	-27,015	-26,520	-56,103	-46,487	52,576
Profit/loss for the period	-27,115	-26,520	-56,285	-46,670	51,781
Earnings per share before and after dilution	-0.52	-0.51	-1.09	-0.9	1.00
Cash and cash equivalents	322,615	229,383	322,615	229,383	401,897
Cash flow from operating activities	-44,010	-23,430	-76,793	-45,800	128,641
Equity per share at end of period, SEK	6.63	5.82	6.63	5.82	7.72
Equity ratio at end of period, %	87	92	87	92	85
Average number of employees	28	21	27	20	22
– of which in R&D	25	19	24	18	20
Number of registered shares end of period	51,748,406	51,748,406	51,748,406	51,748,406	51,748,406
Share price at the end of period, SEK	34.95	38.20	34.95	38.20	44.00

Analyst coverage



- Fredrik Thor and Kevin Sule

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- Dr Adam Karlsson and Dr Gonzalo Artiach

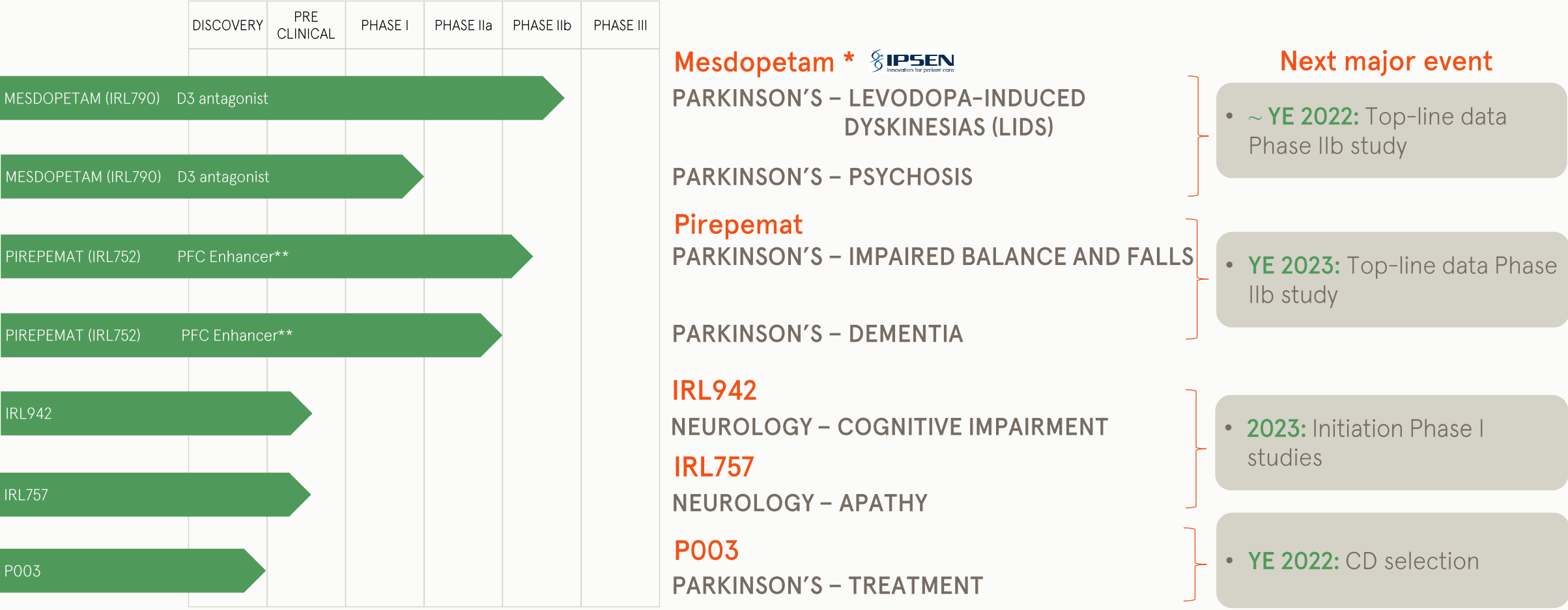
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Pipeline transforming treatment of people living with Parkinson's



* Currently in development with partner Ipsen who holds an exclusive global license to develop and commercialize mesdopetam
**PFC enhancer = noradrenaline and serotonin antagonists In the prefrontal cortex

Anticipated newsflow the next 18 months

Q3 '22	Q4 '22	H1 2023	H2 2023
<ul style="list-style-type: none"> ○ Pirepemat Phase IIb study update ○ Mesdopetam Phase IIb recruitment closed ○ Mesdopetam Phase IIb last patient randomized ○ 8 Sep: Pareto Securities Annual HC Conference, Stockholm ○ 13 Sep: ABGSC Investor Day, Stockholm 	<ul style="list-style-type: none"> ○ P003 CD nomination ○ Mesdopetam Phase IIb last patient last visit ○ Mesdopetam Phase IIb top-line results ○ 12 Oct: Redeye Neurology Seminar, Stockholm ○ 21-23 Nov: SEB Healthcare Seminar, Stockholm ○ 24 Nov: Redeye Life Science Summit, Stockholm ○ 8 Dec: Redeye Life Science Deal Makers (TBD) 	<ul style="list-style-type: none"> ○ Capital Markets Day ○ IRL757 preparation for Phase I study ○ IRL942 preparation for Phase I study ○ Mesdopetam clinical development ○ Participation at medical congresses (TBD) 	<ul style="list-style-type: none"> ○ Pirepemat Phase IIb top-line results ○ IRL757 Phase I study initiation ○ IRL942 Phase I study initiation ○ P003 Phase I study preparation ○ Mesdopetam clinical development ○ Participation at medical congresses (TBD)

Outlook

Outlook

Foundation for transformative treatments

2020 – 2023

Mesdopetam

Successful completion of Phase IIb study

Pirepemat

Successful completion of Phase IIb study

Pipeline

Initiate Phase I studies with IRL942 and IRL757

Initiate preclinical development of CD from P003

Continued ISP development

Business development

Active collaboration with Ipsen on the clinical development of mesdopetam

Building for the future

2023 – 2025

Mesdopetam

Phase III studies initiated*

Pirepemat

Initiating Phase III studies

Pipeline

Development of new drug candidates toward clinical PoC in Phase Ib and Phase II – IRL942, IRL757, CD from P003

Continued ISP development

Business development

Potential milestones from Ipsen.

Retain full strategic autonomy to develop and / or commercialize our unincumbered pipeline assets, alone or in partnership

Delivering first-in-class treatments

2025 – 2027

Mesdopetam

Finalizing Phase III and apply for marketing authorization*

Pirepemat

Finalizing Phase III and apply for marketing authorization

Pipeline

Development of new drug candidates: Phase II PoC and initiation of Phase III (IRL942, IRL757 and CD from P003)

Investment highlights



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



Four shots on goal

Four 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



Contact:

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Viktor Siewertz, CFO, viktor.siewertz@irlab.se

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 and IRL747 in development for Phase I studies.

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

