

Transforming life for people living with Parkinson's

Q3 business update - Nov 9, 2022

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Today's agenda



- Agenda for Quarterly
 presentation
- News in the quarter
- IRLAB overview



R&D update

- Mesdopetam
- Pirepemat
- Preclinical programs



- Pipeline
- Newsflow
- Outlook



Financials

- Financial highlights
- Analyst coverage



Q&A session

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Operational highlights in the third quarter

- Solid progress in clinical, preclinical and research projects, according to plan
- Phase IIb study of mesdopetam in patients with Parkinson's levodopa-induced dyskinesias (PD-LIDs)
 - July: Study expanded to include 154 patients.
 - September: Patient **recruitment** to the study was **completed**
 - Around year-end: **Top-line data** is anticipated.
- Ipsen sponsored clinical trials with mesdopetam
 - September: Ipsen initiated three clinical pharmacokinetic studies, expect completion by Q1 2023.
 - Provides a standard set of data typically required for late-stage clinical trials.
- **Presentations** at several investor healthcare events: Pareto Securities, ABG Sundal Collier and ProHearings. Public recordings are available on the website, irlab.se.
- Registration of share issue of 120,000 Class A shares
 - Relating to the acquisition of know-how related to the P003 discovery project.
 - After the registration, the total number of registered shares is 51,868,406 (51,748,406).



Financial highlights in the third quarter

- Net sales recorded in Q3 SEK 16.5m (SEK 195.6m)
- Total operating expenses during the quarter SEK 40.4 (SEK 74.1m)
- The operational result for the quarter **SEK -23.9m** (SEK 121.7m)
- Cash flow from operations **SEK-27.9m** (SEK 202.8m)
- Cash and cash equivalents amounted to **SEK 291.7m** (SEK 431.2m)
- Average number of employees: **31** (22), of which in R&D: **27** (20)
- Total number of registered shares on September 30, 2022: **51,868,406** (51,748,406)

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



IRLAB – at a glance

		PSEN Innovation for patient care		
Pioneering biology & ISP	Focused strategy	Validated proof- of-concept	Four shots on goal	Organization positioned for success
Deep profound understanding of Parkinson's based on research by Nobel laurate Prof. Arvid Carlsson	Treating PD patients throughout disease journey, has blockbuster potential as a pharma business	One clinical program already licensed to pharma \$363m + royalties	Four unique drug candidates each with blockbuster potential generated by our disruptive ISP platform	Experienced international organization, Strong Balance sheet, Listed Nasdaq Stockholm

Parkinson's disease is a chronic and progressive Parkinson's disease neurodegenerative disease, with no cure



Caused by loss of brain cells that produce dopamine, which has central role in how the brain regulates and controls movement¹



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1) Parkinson's disease is characterized by the loss of cells (neurons) in many areas of the brain and elsewhere in the body. In addition to the loss of neurons at one critical site near the base of the brain (midbrain) in a structure called the 'substantia nigra,' (shown in blue) neurons are also lost in other locations, including areas of the brainstem (shown in black) as well as in the olfactory bulb (shown in green) and the cortex (shown in gray). Cells outside of the brain can also be affected, including those in the gut (not shown).

Parkinson's disease

Loss of >50% cells in the brain that produce dopamine

Dopamine is one of the most important signaling substances in the brain. Controlling emotions, thoughts and movements (motor functions)

Why does it happen?

Why is that important?

What happens?

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, COMTinhibitors and MAO-B inhibitors)
Bradykinesia	Slowness of moving	Levodopa (in combination with agonists, COMTinhibitors and MAO-B inhibitors)
Rigidity	Stiffness	Levodopa (in combination with agonists, COMTinhibitors and MAO-B inhibitors)
Postural instability	\rangle 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.



Long-term challenges: Changes in levodopa response



30-40% of patients experience dyskinesias within 5 years on levodopa treatment¹

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Parkinson's and IRLAB's solutions

IRLAB to address top priorities for management of Parkinson's

2040

12.9

million

diagnosed

Parkinson's is one of the fastest growing disorders

2015 6.2 million diagnosed

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



Living with Parkinson's: IRLAB transforms the treatment algorithm

IRLAB's solution Parkinson's diagnosis Objective **Prior to diagnosis** Early-stage Advanced/late-stage Balance/falls Speech/swallowing **Pirepemat** No more falls Freezing of difficulties gait Apathy Cognitive **Promoting cognitive** Confusion IRL942 & IRL757 impairment function Depression Dementia **Optimal treatment with Dyskinesia Psychosis** Mesdopetam* levodopa without LIDs or 8 IPSEN Motor fluctuations psychosis Once daily -Bradykinesia P003 project normal motor function Rigidity without complications Tremor Total symptom load Extreme daytime Pain fatigue ---Fatigue Incontinence Loss of smell Mild cognitive Hypotension when Depression impairment standing up Insomnia Constipation -20 yrs -10 yrs 20 yrs 0 yr 10 yrs Approximate onset of symptoms

IRLAB References: Based on Kalia, LV. and Lang, AE. Lancet 2015;386-912.

* Currently in development with partner Ipsen who holds an exclusive global 11 license to develop and commercialize mesdopetam

Parkinson's and IRLAB's solutions

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)





Mesdopetam (IRL790) (mes_dop_e_tam)

- Mesdopetam counteracts levodopa-induced dyskinesias (PD-LIDs) by 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

Currently in development with partner Ipsen who holds an exclusive global license to develop and commercialize mesdopetam (<u>https://www.irlab.se/press-releases/ipsen-and-irlab-enter-exclusive-worldwide-licensing-agreement-aimed-to-improve-the-lives-of-people-livingwith-parkinsons-disease//</u>)

Mesdopetam is designed to reduce levodopa-induced dyskinesia



- Levodopa alleviates the stiffness and slowness of movement associated with Parkinson's and it is necessary to take levodopa several times a day to maintain mobility, patients are then 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 aims at limiting the occurrence of "bad ON" and allows the ON to be "good ON" during more hours of the day, improving quality of life

Pharmacology and efficacy profile

Activity dependent psychomotor stabilization

- Reduces effects of excessive DA following L-dopa at dopamine D3 receptors: reduces LIDs

2 DA/NE/Ach (cortex)

- Increases synaptic availability of DA, NE, and acetylcholine in cortex
 - Cognition
 - Motor control

3 Synaptic activation (cortico-striatal)

- Reverses reduced synaptic activity in prefrontal cortex and improves cortico-striatal connectivity and mechanisms involved in the control of motor and mental functions.
- Can potentially activate neuroprotective pathways

4 The specific pharmacological profile is attributed to:

- Dopamine D3 receptor antagonism

5 In preclinical studies, mesdopetam displays

- Antidyskinetic effects
- Antipsychotic effects
- Pro-cognitive effects

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Mesdopetam's clinical development plan

Study	Study Population	Treatment duration	Design	# subjects	Primary objectives	Status	Result
Ph I: SAD+ MAD	Healthy male volunteers	SAD+MAD 10 days	DB placebo controlled cross- over	16 (SAD) 24 (MAD)	PK, safety, tolerability	Finalized	Tolerable, good safety, linear PK, up to 120 mg/day in the SAD part and up to 80mg/day in the MAD part
Ph Ib (patients)	PD-LIDs (dyskinesia)	4 weeks	DB placebo controlled	15 (3:1 allocation)	Tolerability, PK, safety, UDysRS, PKG (actigraph), UPDRS	Finalized	Mesdopetam can be safely administered to patients with advanced PD. Assessments for motor function showed a numeric reduction in dyskinesia across assessments
Ph IIa	PD-LIDs (dyskinesia)	4 weeks	DB placebo controlled	74	UDysRS, CGI, MDS- UPDRS, Hauser diary	Finalized	Mesdopetam is tolerable and displays good safety. AEs were predominantly central nervous system related, mild, and predominantly reported during the first 2 weeks of treatment Aggregated doses of mesdopetam 2.5, 5, 7.5 mg (b.i.d) improved "good ON"-time by ~2.8 hours (p=0.002)
Ph IIb	PD-LIDs (dyskinesia)	12 weeks	DB placebo controlled	154	Primary EP: Change in average daily hours of ON-time without troublesome dyskinesia	Fully recruited. Top-line data YE	Study power is 80% to detect 2 hours and 90% to detect approximately 3 hours increase of "good ON"-time through reduction of "bad ON"-time
Phase III*	- PD-LIDs (dyskinesia) - PD-P	Post Phase II.	b data, Ipsen is res _l	ponsible for the fu	rther decisions regarding a	levelopment and	d commercialization



Phase IIa completed: Increases "good ON"-time Mesdopetam and reduces "bad ON"-time



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Key interpretations

- Support for dose dependent efficacy
- Peak efficacy appears at 7.5 mg b.i.d
- Above 7.5 mg b.i.d no added benefit
- Aggregated doses 2.5, 5, 7.5 mg (b.i.d) improved "good ON"-time by ~2.8 hours (p=0.002)
- <u>Dose-range defined</u> for Phase IIb/III studies

Adverse event	IRL790 dose Titration (N=39)	IRL790 Stable dose phase (N=39)	Placebo (N=36)
Parkinsonism	7 (18%)	2 (7%)	3 (8%)
Fatigue	2 (5%)	0	9 (25%)
Nausea	0	0	4 (11%)
Freezing	1 (3%)	0	4 (11%)

• Adverse event (AE) profile on par with placebo at stable dosing

• Table showing AEs with largest difference vs placebo

Phase IIb: Randomized, placebo-controlled study evaluating efficacy on daily ON-time without troublesome dyskinesia in Parkinson's patients

Primary endpoint

- Increase in daily "good ON"time through reduction of "bad ON" as assessed with patient diaries.
- Efficacy is assessed by means • of Hauser patient diaries (a PRO), the UPDRS scale and UDysRS scale.



Mesdopetam

Guidance: Phase IIb top-line data around the year-end

Anticipated top-line results	 Chang placeb Signific Full ac 	e in daily hours of good ON-time without o cance and clinical relevance count of the study to be presented at a m	troublesome dyskinesia compared to nedical congress in H1 2023
		/ 1	
 Phase IIb study objectives a endpoints Primary objective To evaluate the effectiveness of a treatment with mesdopetam dose 5 mg or 7.5 mg b.i.d. compared to patients with PD exhibiting trouble phase dyskinesia 	adjunctive ed at 2.5 mg, placebo in esome ON	 Secondary objectives To establish the dose response relationship with 3 dose levels of mesdopetam To evaluate the effects of mesdopetam on severity of ON phase dyskinesia and motor symptoms of PD To evaluate the effects of mesdopetam on the daily hours spent in different motor states To evaluate safety and tolerability of mesdopetam 	 Placebo for the following measures: ON-phase dyskinesia assessed by MDS-UPDRS part 4, Q 4.2 (Functional impact of dyskinesias) Modified UDysRS parts 1b and 4 of the UDysRS Motor symptoms of PD assessed with MDS-UPDRS total score of part 2 (M-EDL) Daily OFF-time
 Primary endpoint Change in average daily hours of ON-time without troublesome dyskinesia with mesdopetam compared to Placebo as 		 given twice daily during 84 consecutive days To evaluate trough and 2-hour post dose plasma concentrations of mesdopetam and its two main metabolites 	 Change from baseline in average daily hours of ON-time without troublesome dyskinesia for each individual dose level (2.5 mg, 5 mg, 7.5 mg b.i.d.), as well as all active doses grouped compared to Placebo

assessed with 24-hour patient home diaries from baseline to end of study (EOT/EW) (visit

5, week 12)

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• Change from baseline in mean score or average daily hours with mesdopetam compared to

19

Competitors do not target "bad ON"time (PD-LIDs)

МОА	Drug	Increase in "good ON"	Efficacy Mechanism	Side effect profile
MAO inhibitor	Safinamine Rasagiline	1.66 h 1.95 h	Reduced Off time	Dyskinesia , Fall Weight loss, Anorexia, Vomiting
COMT inhibitor	Opicapone	0.97 h	Reduced Off time	Dyskinesia, Constipation, Dry mouth
DA agonist	Ropinirole	1.5 h	Reduced Off time	Dyskinesia , Sleep attacks, Compulsive behavior
Adenosine antagonist	lstradefylline	0.69 h	Reduced Off time	Dyskinesia
Levodopa reformulations	IPX-203* (oral) Duodopa (I/D infusion) FosDopa* (S/C infusion)	0.53 h 1.86 h 1.75 h	Reduced Off time	infusion site AEs, dyskinesia , "On" and "Off" phenomenon, fall, hallucinations and psychosis
NMDA antagonist etc	Amantadine (Gocovri)	2.5 h	Reduced bad ON & reduced Off time	Hallucinations (24%), Peripheral edema Dizziness Dry mouth, Constipation, Fall, Anxiety, Livedo reticularis





Illustration of a day for a person with Parkinson's on standard anti-Parkinson's medication (levodopa) and mesdopetam.

Mesdopetam vs. amantadine in rodent dyskinesia models



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Reference: 1. Waters, N., **Carta, M**., J., Tedroff, Sonesson, C., Kullingsjö. J., Svensson, P., Waters, S. (2016, September). Pharmacology of IRL790, a psychomotor stabilizer for the treatment of L-dopa induced dyskinesias and psychosis in Parkinson's disease. Poster (We-66C) presented at Dopamine 2016, Vienna, Austria; 2. E. Tronci, c. Fidalgo, e. Zianni, m. Collu, r. Stancampiano, m. Morelli, f.Gardoni and **m. Carta**. Neuroscience 265 (2014) 245–252 http://dx.Doi.Org/10.1016/j.Neuroscience.2014.01.042

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
 - **\$335 million** in potential development, regulatory and salesbased milestones, and;
 - Tiered low double-digit royalties on worldwide net sales



Туре	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







- Improve balance and reduce falls in Parkinson's (PD-Falls)
- Ongoing randomized, placebo-controlled Phase IIb clinical trial
- Wholly-owned unencumbered asset



Pirepemat

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

Pirepemat can 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.

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 enhance synaptic activity in the cerebral cortex

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 a-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



Pirepemat

ISSN 1521-010

OGY ntal Therapeutics

SERT

a20

a2A

A first-in-class treatment for impaired balance and falls

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Mechanism of Action	Combines antagonism at 5HT7 and alpha-2 receptors leading to highly specific activation of frontal cortex NA and DA	Velume 374 Number 3 September 2020 ISSN 152
Tolerability	Well tolerated in clinical studiesDose range defined	The Journal of PHARMACOLOG And Experimental Therapy
Efficacy	• Pirepemat shows promising improvements of balance and has potential to reduce falls in Parkinson's by 50%	Chemical structure and <i>in vitro</i> profile of IRL752 30 µM 25 µM 20 µM 15 µM 02 02 5-HTZA 5-HTZA 5-HTZA 5-HTZA 5-HTZA 5-G2 5-BC
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 IND. These studies are expected to be finalized Q4 2022 	SIM MOR MOR ADD SHTZA S-HTZA S-HTZC
Potential	 About 50% of patients with Parkinson's fall (Hoehn&Yahr stage ≥ 3) Health economic data show cost of falls are very high 	A Publication of the American Society for Pharmacology and Experimental Therapeutics
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

Pirepemat's clinical development plan

Study	Study Population	Treatment duration	Design	# subjects	Primary objectives	Status	Result
Ph I: SAD+ MAD	Healthy male volunteers	SAD+MAD 10 days	DB placebo controlled alternate panel design	16 (SAD) 24 (MAD)	PK, safety, tolerability	Finalized	Single and multiple doses of pirepemat were generally well tolerated. The safety, tolerability, and PK profiles in this study support 3-times-daily dosing and further clinical development.
Ph I new PK tablet formulation	Elderly male and female healthy volunteers Average 72 years	MAD 14 days	Open label	9	Pharmacokinetics Tablet formulation	Finalized	The half-life of pirepemat may be longer, and plasma exposures somewhat higher, in elderly subjects as compared to younger subjects. No SAEs occurred in the study and there were no clinically significant abnormal findings in any of the clinical safety parameters. Elevated plasma liver enzymes levels following discontinuation of study treatment were seen in some individuals.
Ph Ila	Patients with Parkinson's disease and dementia	4 weeks	DB placebo controlled	32 (3:1 active vs. placebo)	Falls frequency as compared to placebo Cognitive function MDS-UPDRS, NPI, CGI Balance tests	Finalized	Pirepemat appears to be safe and well tolerated during 4-week treatment in study population. Adverse events were predominantly central nervous system related, mild, and predominantly reported during the first 2 weeks of treatment. Elevated liver enzymes observed in three pts following discontinuation. The interpretation is that this is part of a rebound effect following an abrupt termination of treatment with pirepemat.
Ph IIb	Parkinson's patients at H&Y stage >2,5. with MoCA<26 At least 2 falls 1 mo prior to randomization	12 weeks	DB placebo controlled	165	Reduction in falls frequency MoCA, UPDRS II+III, CGI-S	Ongoing	Recruiting in France, Germany, Poland Spain & Sweden.



Pirepemat

Phase IIa clinical proof-of-concept¹

Pirepemat affects Parkinson's symptoms not treated by levodopa



Mean absolute from baseline (with 95% conf. Intervals) in the four cardinal PD motor domains in pirepemat treated subjects. 1) Postural dysfunction construct: UPDRS part 2: Falling (unrelated to freezing) (13), Freezing when walking (14) UPDRS part 3: Postural stability (30)

Adverse events

AEs were predominantly central nervous system related, mild, and mostly reported during the first 2 weeks of treatment. No events related to the cardiovascular system were noted. Hepatic enzymes increased (n = 3) and cognitive disorder (n = 2). Most of the events were assessed as mild. Pirepemat has potential to improve the postural dysfunction associated with Parkinson's not treated by levodopa

-60



70% reduction in Apathy



53% reduction in falls



Falls, absolute change with 95% conf. intervals for UPDRS q13 (Falling unrelated to freezing) in fallers. Fallers are defined as a score of ≥ 1 at baseline.



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Publication: Svenningsson, P. et al. (2020) A Phase 2a Trial Investigating the Safety and Tolerability of the Novel Cortical Enhancer IRL752 in Parkinson's Disease Dementia. Mov Disord. doi:10.1002/mds.28020 1: Assessments are exploratory. Study not designed or powered for efficacy

Clinical Phase IIb: Improve balance and reduce 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

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

Data expected YE 2023

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Protocol considerations: Dose de-escalation and specific exclusion criteria are applied in the protocol to limit the impact of rebound effect on liver enzymes after abrupt discontinuation of study medication



Preclinical & Research projects

- **IRL942:** Clinical candidate: to improve cognitive function and brain health
- **IRL757: Clinical candidate:** to treat apathy
- **P003:** Lead optimization stage: Once-daily treatment of Parkinson's without the troublesome complications



Ongoing preclinical development programs on track

IRL942 Restore cognitive function	IRL757 Treat apathy in neurology	P003 Once-daily treatment of Parkinson's
Improvement of cognitive function: memory, perception, attention, reasoning, problem solving and decision-making	Treatment for apathy loss of initiative, interest and emotional expression/ responsiveness	Once-daily treatment of Parkinson's without the troublesome complications -> Next generation Parkinson's treatment
Status: Phase I to initiate in 2023	Status: Phase I to initiate in 2023	Status: Nominate candidate in 2022

Scientific rationale of IRL942 & IRL757

Problem

Disruption of frontal neurotransmission is implicated in the pathogenesis of cognitive decline and neuro-psychiatric symptoms in PD and other neurological disorders

No current treatments directly address these specific cortical deficiencies

IRLAB's solution

IRL942 and IRL757 show a unique ability to activate frontal neurotransmission, synaptic gene expression, and associated circuits, improving cognitive function across modalities

Potential for both symptomatic relief **and** disease modification

Potential clinical indications:

- Parkinson's disease: dementia, apathy, depression, attention/vigilance
- Besides PD dementia, data support potential in additional indications with unmet needs:
- Other dementias

Cortical synaptic dysfunction a hallmark in multiple dementia types

- Lewy body dementia, Alzheimer's disease, Vascular dementia, Frontotemporal dementia, Age related cognitive decline/MCI
- Apathy & Depression
 - Apathy: Cortex crucial in control of motivation, mood, cognition, and social behavior
 - Depression: Disruption of PFC signaling implicated in the pathogenesis
- ADHD
 - Cortical weakness in NA/DA transmission no cortically targeted treatments available today
- Schizophrenia
 - Difficult-to-treat pathology converges on cortical dysfunction negative and cognitive symptoms



P003 – First orally active, full efficacy, long-acting Parkinson's treatments

- 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
 - D_1/D_2 agonist high efficacy but poor PK and not orally bioavailable
 - Available as acute rescue during 'off'-periods or chronically implanted pump







Finance report Q3 2022

- Highlights and summary
- Analyst coverage

Financial highlights of Q3 2022

- Geopolitical events and global economics induce sustained focus on cost control
- Investing in two clinical Phase IIb programs according to plan
- Increasing investment in preclinical development, advancing IRL757 and IRL942 towards clinical Ph I
- Stable cost development at circa SEK 40m per quarter
- Strong cash position SEK 292m



Partnering cost are cost for entering licensing agreements and costs which are covered by a corresponding revenue from partners.

Financial summary of Q3 2022

Highlights

- Strong cash position: SEK 292m
- Cash flow increasing due to increased R&D activity
- Net sales
 - SEK 13m realized cost for Phase IIb study with mesdopetam
 - SEK 3m for services to lpsen

	Jul-Sept 2022	Jul-Sept 2021	Jan-Sept 2022	Jan-Sept 2021	Jan-Dec 2021
Net sales	16 503	195 641	48 955	195 641	207 782
Operating profits/loss	-23 894	121 665	-79 998	75 177	52 576
Profit/loss for the period	-23 957	121 567	-80 241	74 897	51 781
Earnings per share before and after dilution	-0.46	2,35	-1,55	1.45	1.00
Cash and cash equivalents	291,749	431 168	291749	431 168	401 897
Cash flow from operating activities	-27 932	202 829	-104 725	157 029	128 641
Equity per share at end of period, SEK	6.25	8.17	6.25	8.17	7.72
Equity ratio at end of period, %	87	85	87	85	85
Average number of employees	31	22	28	21	22
- of which in R&D	27	20	25	18	20
Number of registered shares end of period	51 868 406	51748406	51 748 406	51 748 406	51 748 406
Share price at the end of period, SEK	34.50	46.75	34.50	46.75	44.00

Analyst coverage



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Increasing visibility and company reach



Outlook

Pipeline transforming treatment of people living with Parkinson's

IRLAB

		Discovery Preclinical Phase I Phase Ila Phase Ilb	Phase III Next major event
Mesdopetam (IRL790)*	Parkinson's disease levodopa- induced dyskinesia (PD-LIDs) D3 antagonist	Pha	ase IIb ~ year-end: Top-line data
FIPSEN Innovation for patient care	Parkinson's disease Psychosis D3 antagonist	Phase I	Phase IIb study
Pirepemat	Parkinson's disease impaired balance and falls PFC enhancer	Pha	ase IIb ~ YE 2023: Top-line data
(IRL752)	Parkinson's disease Dementia PFC enhancer	Phase IIa	Phase IIb study
IRL942	Cognitive impairment in neurology	Preclinical	2023: Initiation Phase I
IRL757	Apathy in neurology	Preclinical	studies
P003	Parkinson's disease treatment	Discovery	2022: CD selection

Anticipated newsflow the next 18 months

	Q3 '22	Q4 '22	H1 2023	H2 2023
Milestones	 Mesdopetam Phase IIb recruitment closed Mesdopetam Phase IIb last patient randomized 	 P003 CD nomination Mesdopetam Phase IIb last patient last visit Mesdopetam Phase IIb top-line results 	 Capital Markets Day IRL757 preparation for Phase I study IRL942 preparation for Phase I study Mesdopetam clinical development 	 Pirepemat Phase IIb top-line results IRL757 Phase I study initiation IRL942 Phase I study initiation P003 Phase I study preparation
Events	 ✓ 8 Sep: Pareto Securities Annual HC Conference, Sthlm ✓ 13 Sep: ABGSC Investor Day, Sthlm 	 ✓ 12 Oct: Redeye Neurology Seminar, Sthlm ✓ 24-26 Oct: Bio-Europe 2022, Germany o 14 Nov: LSX Investival Showcase, London o 23 Nov: SEB Healthcare Seminar, Sthlm o 24 Nov: Redeye Life Science Summit, Sthlm o 15 Dec: DNB event, Oslo 	 Participation at medical congresses 31 Mar: AD/PD congress, Gothenburg 	 Mesdopetam clinical development Participation at medical congresses
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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)

IRLAB

IRLAB at a glance

		PSEN Innovation for patient care		
Pioneering biology & ISP	Focused strategy	Validated proof- of-concept	Four shots on goal	Organization positioned for success
Deep profound understanding of Parkinson's based on research by Nobel laurate Prof. Arvid Carlsson	Treating PD patients throughout disease journey, has blockbuster potential as a pharma business	One clinical program already licensed to pharma \$363m + royalties	Four unique drug candidates each with blockbuster potential generated by our disruptive ISP platform	Experienced international organization, Strong Balance sheet, Listed Nasdaq Stockholm



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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 and IRL747 in development for Phase I studies.

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