

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

Capital Markets Day

October 17, 2023



Today's speakers



Karl Kieburtz Prof. in Neurology; President, cofounder Clintrex



Gunnar Olsson CEO, IRLAB



Joakim Tedroff Neurologist, CMO, IRLAB



Peter Wallich Commercial Director, IRLAB



Nicholas Waters EVP, Head of R&D, IRLAB



Today's program

Time	Торіс	Speaker
14.30	Welcome & introduction	Mats Thoren, Moderator
14.35	Transforming life for people living with Parkinson's disease	Gunnar Olsson, MD, CEO, IRLAB
14.45	Understanding Parkinson's and its burden on patients, families, and society	Joakim Tedroff, MD, CMO, IRLAB
14.55	Market opportunities in Parkinson's and CNS	Peter Wallich, Commercial Director, IRLAB
15.05	Mesdopetam: treating levodopa-induced dyskinesias in Parkinson's (PD-LIDs)	Nicholas Waters, PhD, EVP and Head of R&D, IRLAB Karl Kieburtz, MD, MPH, Professor in Neurology, President and co-founder of Clintrex
15.35	Pirepemat: Reducing risk of falls in Parkinson's	Joakim Tedroff, MD
15.50	Preclinical projects and proprietary research platform	Nicholas Waters, PhD
16.00	Panel discussion with a focus on regulatory strategy and	Moderated by moderator
	business development opportunities	All speakers
16.20	Questions from audience	Moderator
16.30	Key take aways	Moderator





Transforming life for people living with Parkinson's disease

Gunnar Olsson

CEO, IRLAB



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IRLAB's...

What?

 IRLAB strives to improve the life of people living with Parkinson's and other CNS diseases by developing new and better medicines Why?

- 10.9 million people with Parkinson's in 2022¹ – doubling in the next 15–20 years
- Serious lifelong disease with many complications
- Lack of effective drugs for many of the complications of the disease

How;

- Cutting-edge expertise in Parkinson's
- Unique discovery platform (ISP)
- Higher likelihood of successful phase transition vs. industry standard
- Reduced costs to develop molecules to late clinical phase

Our strategy

- Addressing all stages of Parkinson's disease and other CNS diseases
- Discovering novel candidate drugs (CDs) with our ISP platform
 - True innovation
 - Higher success rate
 - Strong IP position
- Developing CDs from discovery to Proof-of-Concept (PoC)
- Seeking partnering after PoC

Key developments and growth of the project portfolio during 2023

- Mesdopetam
 - Phase IIb read out Phase III readiness
 - Secured full ownership and rights to the product
- Pirepemat
 - Phase IIb study ongoing all clinical sites opened
 - First pre-specified DSMB evaluation continue according to plan
- IRL1117
 - CD selection and start of preclinical development
- IRL757 & IRL942
 - Preclinical development progress aiming for Phase I readiness by year-end 2023 and H1 2024
- Project portfolio world-leading position in Parkinson's
- Increased BD activity multiple opportunities evaluated



Development portfolio transforming treatment of people living with Parkinson's

		Discovery	Preclinical	Phase I	Phase IIa	Phase IIb	Phase III	Next major event
Mesdopetam (IRL790)	Parkinson's disease levodopa- induced dyskinesia (PD-LIDs) D3 antagonist						Phase III ready	• End-of-Phase 2 meeting with FDA
	Parkinson's disease Psychosis D3 antagonist			to define Phase III				
Pirepemat	Parkinson's disease impaired balance and falls PFC enhancer					P	hase IIb	H1 2024: Top-line data
(IRL752)	Parkinson's disease Dementia PFC enhancer					Phase IIa		Phase IIb study
IRL757*	Apathy in neurology		F	Preclinical				YE 2023: Phase I ready
IRL942*	Cognitive impairment in neurology		P	Preclinical				H1 2024: Phase I ready
IRL1117	Parkinson's disease treatment		F	Preclinical				2024: Phase I ready
	* Under evaluation by MSRD, an Otsu	ka company.						9

Portfolio

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

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Parkinson's and IRLAB's portfolio

Ranklich-slæna'di digs postef pliogtæinsteparovert biene tyænaptræmt afi Barokin polin ations expand

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Understanding Parkinson's and its burden on patients, families, and society

Joakim Tedroff, MD, PhD

Consultant Neurologist, Associate Professor of Neurology and Chief Medical Officer at IRLAB

Parkinson's disease

What is Parkinson's disease?



Parkinson's disease is chronic and progressive. It is lifelong and worsens over time.



The average patient is diagnosed at the age of 60

- The average age of onset is approximately 60 years, after which the risk of disease increases significantly.
- As global demographic shifts continue to increase the relative proportion of elderly populations, the social and economic burden associated with Parkinson's disease is likely to increase considerably.



The Emerging Evidence of the Parkinson's Disease Pandemic

Dorsey et al 2018

Pandemics are usually equated with infectious diseases like Zika, influenza, and HIV," said Dorsey.

"But neurological disorders are now the leading cause of disability in the world and the fastest growing is Parkinson's disease."





survive for a long period of time¹



Parkinson's disease progresses over time

Hoehn-Yahr **Early stage Complicated stage** Late stage (H-Y) staging HY 3-4 HY 0-2.5 HY 5 system Stage 2 Stage 3 Stage 4 Stage 5 Stage 0 Stage 1 **Prevalence** 13% 17% 7% 29% 34%

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Adapted from Claesson I, Better Balance with Somatosensory Exercises-a Parkinson Perspective Thesis · January 2018 Prevalence: Enders et al, 2017

Parkinson's disease progression - Quality of Life



Evans et al, 2011

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



Patient journey for Parkinson's patients

Patients present at Primary care, then quickly referred to specialist.

RLAR



Strengths and limitations of gold standard anti-Parkinson treatment levodopa



Sources: 1. Nutt & Fellman. Clin Neuropharmacol 1984;7(1):35–49; 2. Chapuis et al. Mov Disord 2005;20:224–230; 3. Freitas et al. Semin Neurol 2017;37(2):147–157; 4. Hametner et al. J Neurol 2010;257(Suppl 2):S268–S275; 5. Ferreira et al. Eur J Neurol 2013;20(1):5–15; 6. Sethi. Neurologist 2010;16(2):76–83

Top priorities in Parkinson's disease

- Systematic survey of PD patients, care giver, care professionals about crucial issues in day-to-day life.
- Deane et al, 2014

- Priority # 1: Falls
- Priority # 2: Stress and Anxiety
- Priority # 3: Dyskinesia



The Voice of the Patient

A series of reports from the U.S. Food and Drug Administration's (FDA's) Patient-Focused Drug Development Initiative

- Parkinson's disease impacts all aspects of their lives, limiting ability to work, care for themselves and others, and to maintain relationships.
- When asked to identify up to three symptoms with the greatest impact on daily life, the highest number of responses related to core motor symptoms of slowed movement and tremor, followed by impaired balance and coordination, then by cognitive impairment, and disturbed sleep.
- Impaired balance and co-ordination were regarded as a major challenge, leading to falls and fear of falling.
- Fatigue and constipation were also highlighted as problems.



Market opportunities in Parkinson's and CNS

Peter Wallich

Commercial Director, IRLAB



Targeting a large and growing market in Parkinson's disease

Most common neurodegenerative disorder after Alzheimer's disease



Aging populations fuel the number of Parkinson's patients requiring treatment.

- Parkinson's **market set for expansion** with approvals of pipeline drugs and improved diagnosis
- Reimbursement issues common barrier to uptake
 - New formulations/repurposing often required to be 2nd or 3rd line by insurance companies/payers
 - **Differentiated niche treatments** can command higher prices

Treatment of Parkinson's is heterogeneous with a no one-size-fits-all approach

Treatment of Parkinson's

- Highly personalized approach
- Complex
- Several concomitant medications, particularly in advanced disease stages
- Newer adjunctive treatments often also incur additional adverse events and drug interactions.





Parkinson's disease is a dynamic and evolving market

- Mainly mature brands as Standard of Care with **increasing genericization**
- Treatment of late-stage Parkinson's offers greater opportunities due to the emergence of motor and non-motor symptoms
- High level of pipeline activity
 - Slow progress and lack of agents transitioning from Phase II to Phase III
 - Phase I (34%), Phase II (50%) Phase III (14%)
 - Repurposed drugs and reformulations dominate the pipeline
 - The number of symptomatic treatment trials in Phase III has decreased from 25 to 14
- Potential impact to market with several late-stage readouts 2023/2024 and potential NDA approvals in disease modification and symptomatic treatment
- Need to balance benefit and tolerability with new treatments with risk of other adverse effects and drug interactions

Parkinson's disease pipeline target areas

Patient population



Parkinson's disease pipeline target areas





IRLAB focusing on differentiated medicines in niche segments with the greatest unmet needs

Patient population





IRLAB focusing on differentiated medicines in niche segments with the greatest unmet needs

Patient population





IRLAB's mid to late-stage programs aiming for differentiated medicines in segment areas with large unmet needs

Mesdop	etam – Phase III rea		Pirepemat – Phase IIb ongoing				
Dyskinesia is recognized as one of the key unmet needs	Anti-dyskinetic effect and Anti-parkinsonism	Good tolerability and safety profile comparable to placebo (Ph I-II)		Good tolerability and safety profile comparable to placebo (Ph I–II)		Falls represent a major unmet need with high-cost & injury impact	Low number of competitors in pipeline
Low potential for drug interactions & contraindications	Low number of competitors in pipeline	Strong potential as first to market with indication ex-US		Studies demonstrate a good tolerability and safety profile	Strong potential as first to market to reducing falls frequency		





IRLAB's commercial opportunity

IRLAB assets targeting large market opportunity with high unmet need in Parkinson's disease

	Parkinson's disease		PD LIDs	PD-Falls	PD- Apathy	Improvement of Cognitive Function	Alternativ e to levodopa
Diagnosed patients	7.2 million	IRLAB's asset	MESDOPETAM	PIREPEMAT	IRL757	IRL942	IRL1117
in 8 major markets*		Prevalence of treated	25-40%	45%	20%-70%	27%	100%
(78–92% depending	5.7 million	Eligible	1.4 – 2.3	2.6	1.1 – 4.0	1.5	5.7
on ooding y		population	million	million	million	million	million

*8 Major Markets (China, France, Germany, Italy, Japan, Spain, UK and the US)

Global Data; Datamonitor; Falls in Parkinson's Disease Subtypes: Risk Factors, Locations and Circumstances Paulo H. S. Pelicioni et al. Int J Environ Res Public Health. 2019 Jun; 16(12): 2216.Parkinson disease-associated cognitive impairment, Dag Aarsland Nature Reviews Disease Primers volume 7, Article number: 47 (2021); Apathy as a Treatment Target in Alzheimer's Disease: Implications for Clinical Trials Moyra E. Mortby et al, The American Journal of Geriatric Psychiatry Volume 30, Issue 2, February 2022, Pages 119-147

IRLAB assets targeting large market opportunity with high unmet need in Alzheimer's disease

	Alzheimer's disease		Apathy	Improvement of Cognitive Function
		IRLAB's asset	IRL757	IRL942
Diagnosed patients in 10 major markets*	11.2 million	Prevalence	54%, 59% and 43% (mild, moderate, and severe dementia)	27%
		Eligible population	4.9 – 6.7 million	3.0 million

*10 Major Markets (Canada, China, France, Germany, Italy, Japan, South Korea, Spain, UK and the US)

Global Data; Datamonitor; Falls in Parkinson's Disease Subtypes: Risk Factors, Locations and Circumstances Paulo H. S. Pelicioni et al. Int J Environ Res Public Health. 2019 Jun; 16(12): 2216.Parkinson disease-associated cognitive impairment, Dag Aarsland Nature Reviews Disease Primers volume 7, Article number: 47 (2021); Apathy as a Treatment Target in Alzheimer's Disease: Implications for Clinical Trials Moyra E. Mortby et al, The American Journal of Geriatric Psychiatry Volume 30, Issue 2, February 2022, Pages 119-147

Further opportunities for mesdopetam and pirepemat will access broader populations

RLAB's pipeline candidate

IRLAB's pipeline candidates	Life-cycle opportunities	Pipeline-in-a-Pill opportunities
Mesdopetam Lead indication: PD-LIDs	 Prevention of dyskinesia Psychosis in Parkinson's 	 Tardive dyskinesia (~ 2.3 million patients) Psychosis in other populations
Pirepemat Lead indication: Reduce risk of falls by improving balance	 Prevention of balance disturbance Neuropsychiatric symptoms 	



IRL757's potential to address broader populations

RLAB's pipeline candidate

IRLAB's	pipeline	candidates
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IRL757 Lead indication: Treatment of apathy

Life-cycle opportunities	Pipeline-in-a-Pill opportunities
Prevention of apathy	Frontotemporal dementia (1.2 to 1.8 million worldwide with prevalence of Apathy 62%-89%)



Commercialization strategy

Offering differentiated new chemical entities

- Addressing areas of high unmet need
- From early to mid-late stage development

Targeting

- Parkinson's disease
- CNS
- Specialists

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- Parkinson's disease
- Neurologists

Partnering approach

- Focus on Parkinson's disease and/or CNS
- Mid to large size pharma
- Specialty pharma looking for markets with unmet needs

Business development

- Awareness of IRLAB and the development pipeline is increasing
- Continuous and frequent dialogue with potential partners
- Partnering opportunities being evaluated across the portfolio
- Near term focus on mesdopetam and IRL757/IRL942



Mesdopetam: treating levodopa-induced dyskinesias in Parkinson's (PD-LIDs)

Nicholas Waters, MD EVP and Head of R&D, IRLAB



Mesdopetam (IRL790)

First in class- a novel mechanism

Inhibiting dopamine D3 receptors Patent-based exclusivity into the 2040s

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



Mesdopetam

Growing body of clinical evidence supporting a novel treatment of dyskinesia in PD

Clinical studies of mesdopetam

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Mesdopetam

Mesdopetam - Phase IIb study conclusions



- Consistent dose-response and clinically meaningful antidyskinetic efficacy
 - Improvement in UDysRS
 - Improvement in "good ON"-time
- Consistent **dose-response pattern** in reduction in OFF-time, i.e., **anti-parkinsonian efficacy**

FAS = Full Analysis Set

ΓΡΙΑΒ



- No untoward effects on normal motor functions or PD symptoms, i.e., no increase of Parkinsonism
- Safety and tolerability profile on par with placebo at all doses
- Predictable plasma exposure linear and dose-dependent
- Dose selection for Phase III achieved (7.5 mg b.i.d.)
- PS = Subjects compliant with the protocol

Mesdopetam

Mesdopetam's Phase IIb study results align with the endpoint structure in the amantadine ER file

• Phase IIb study results on 7.5 mg b.i.d. dose

 ✓ = aligns with the FDA amantadine approval

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Key efficacy endpoints important to the FDA	FAS population	Nominal P-value	PS population	Nominal P-value
Primary endpoint*				
UDysRS part 1, 3 and 4	-6.2 🗸	0.026	-9.2 🗸	0.011
Key secondary endpoint				
UDysRS part 1b and 4	-3.5	0.062	-5.5 🗸	0.019
Safety endpoints				
OFF-time	-0.7 h 🗸	0.16	-1.27 h 🗸	0.051
MDS-UPDRS part 2	0 🗸	0.98	-0.5 🗸	0.63
"Bad ON"-time	-0.14 🗸	0.89	-0.93 🗸	0.3
Optional secondary endpoint				
"Good ON"-time	0.49 h	n.s.	1.75 h 🗸	0.049



Mesdopetam as a solution with great potential

Karl Kieburtz, MD, MPH

- Professor in Neurology; President and co-founder of Clintrex
- Former chairman of the Peripheral and Central Nervous System US FDA Advisory Committee
- Former Chairman of the Scientific Evaluation Committee for the Cooperative Studies Program, Veterans Administration
- Advisor to the Michael J. Fox Foundation



Planning for a Phase III – 1/2

- Critical steps with US FDA in Drug development;
 - Type B meetings pre-IND, End-of-Phase 2, pre-NDA
- Type B meetings are live interactions with FDA staff since they occur at critical junctures
- End-of-Phase 2 (EOP2) meetings are essential to reach consensus with the review Division of FDA about all the aspects of product development: clinical, non-clinical tox, CMC, clinical pharmacology
- IRLAB has a strong position on the clinical impact of mesdopetam, especially on dyskinesias, but also on parkinsonian severity. An EOP2 meeting provides the opportunity to discuss these data and get feedback on the planned pivotal study, as well as whether a single study is sufficient in the context of the current data package



Planning for a Phase III – 2/2

- After a EOP2, it is also possible to have a Special Protocol Assessment (SPA) to get definitive agreement about the pivotal study protocol design and analysis plan.
- Having a clear consensus at an EOP2, potentially with a SPA agreement, substantially decreases the likelihood of difficulties or disagreements at the time of pre-NDA meetings or at NDA submission, because it sets FDA expectations about what data they will have available for review at those events.
- An EOP2 meeting cannot be requested until the meeting package is in hand, formatted in a series of questions to the FDA, because the time from having a meeting granted to data submission is very short.



A pivotal study in Parkinson's

- Unlike many clinical trials in CNS conditions, a pivotal trial in PD-LIDs is intended to demonstrate clinical benefit in a short time frame, in this case 12-13 weeks. Many CNS trials attempt to show slowing of clinical decline (eg most AD studies) which require up to 10 times as many participants followed 18 months or longer, in contrast to the shorter time frame for trials demonstrating benefit
- Despite the shorter trial duration, there is no restriction on the duration of treatment. The opicapone FDA approval for motor fluctuations had such studies in their approval package
- A pivotal trial to demonstrate improvement in dyskinesias as well as improvement in OFF-time will require less than 100 participants per arm
- It is acceptable to study a single dosage in a pivotal study, although the FDA may ask for dosage ranging. IRLAB has sufficient clinical data to argue for a single dosage 7.5 mg bid.
- The FDA has already expressed acceptance of the UDysRS as the primary outcome measure
- Details about entry criteria, outcome measures, study duration and analytic approaches will be discussed at the EOP2, and may be definitively agreed to in a SPA



Possible evidence needed for approval

- In general, the FDA requires 'substantial evidence of efficacy' for approval, most commonly achieved 2 pivotal studies. However, there is a strong movement within the FDA Office of Neuroscience to utilize other pathways. Although accelerated approval based on biomarkers (as in Duchenne dystrophy, and hereditary ALS and AD) is not applicable here, a single study with 'confirmatory evidence' is applicable (as was utilized in the approval of the Amylyx ALS drug Relyvrio).
- The **Phase IIb mesdopetam study showed benefit on the UDysRS scale** (even if not the primary endpoint) in the primary analysis population. Such data from a randomized placebo-controlled study may meet the recently described criteria in the September FDA guidance on single studies with confirmatory evidence
- Other trial designs can be considered if an additional pivotal study is required, or a duplicative study could be launched.
- Long-term safety data in PD-LIDs, typically requires 100 individuals at the maximum dosage for at least one year



Mesdopetam's clinical utility and potential

- A treatment that both reduces dyskinesias and improves PD disability (as measured by OFF-time) is exceedingly rare.
- Only Gocovri has FDA approval for this unusual combination of features
- Most drugs can produce one or the other effect, usually mildly worsening the other. For instance, most of the drugs available to reduce off time (e.g., dopamine agonists, COMT inhibitors, MAOB inhibitors, etc) describe dyskinesias as an adverse effect
- Most drugs intended to treat dyskinesias have been abandoned because they concomitantly worsened PD severity
- While Gocovri is approved (in the US) for this dual effect, it is associated with serious safety limitations due to confusion, hallucinations and skin reactions, which limit the use in any populations. In addition, the PK is affected by renal dysfunction.
- A safe and well tolerated drug to provide both anti-dyskinetic effects and to improve PD disability would have tremendous clinical appeal to clinicians, patients and families





Pirepemat: Reducing falls in Parkinson's

Joakim Tedroff, MD, PhD

Consultant Neurologist, Associate Professor and Chief Medical Officer at IRLAB



Pirepemat

Falls in Parkinson's disease

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.



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



Clinical development path for pirepemat: Improvement of balance and falls



Pirepemat

Pirepemat (IRL752) Phase IIa in Parkinson's – postural function

Pirepemat improves 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)



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.



Pirepemat (IRL752) Phase IIa in Parkinson's – executive function

- Pirepemat significantly improve executive function

One Touch Stockings of Cambridge							
		Med	ian	Mean (SD)			
Parameter		baseline	End of Ttrt	baseline	End of Ttrt		
First choice accuracy	Higher better	3	4.5	3.9 (4.0)	4.9 (3.0)		
Latency to correct	Lower better	3.92	2.48	4.7 (3.5)	4.3 (3.9)* *p<0.05		

FABLE 4. Descriptive statistics of Cambridge Neuropsychological Test Automated Battery cognitive assessments at BSL and EOT for the Spatial Working Memory Test and the One Touch Stockings of Cambridge Test

		IRL752				Placebo			
		Me	dian	Mea	n (SD)	Me	dian	Mean (SD)	
Parameter		BSL	EOT	BSL	EOT	BSL	EOT	BSL	EOT
Test	Sense	Spatial V	Vorking Mem	ory					
Total errors	Lower better	27	26	28.3 (8.2)	27.7 (9.3)	27	28.5	28 (4.4)	30.8 (10.1
Within errors	Lower better	1	1	4.3 (6.7)	3.9 (8.8)	2	4	3.7 (3.6)	5.5 (5.8)
Between errors	Lower better	27	25.5	27.1 (7.2)	26.7 (7.2)	25	28.5	27.3 (4.4)	29.7 (8.9)
Strategy	Lower better	10	10	9.4 (1.5)	9.6 (1.5)	10	9.5	10.3 (1.1)	9.8 (1.0)
		One Tou	ch Stockings	of Cambridge					
First choice accuracy	Higher better	3	4.5	3.9 (4.0)	4.9 (3.0)	3	3	3.0 (1.1)	3.2 (1.1)
Latency to correct	Lower better	3.92	2.48	4.7 (3.5)	4.3 (3.9) ^a	2.54	2.58	5.8 (6.4)	6.0 (5.9)

 $^{8}P < 0.05$ versus placebo, analysis of covariance test with baseline as covariate.

Note. Full analysis set population. Abbreviations: BSL, baseline: EOT, end of treatment: SD, standard deviation.

A randomised, placebo-controlled, multi-centre Phase IIb study evaluating the efficacy of **pirepemat** on **falls frequency** in patients with Parkinson's disease



IRL752C003 / REACT-PD A randomised, placebo-controlled, multi-centre Phase IIb study evaluating the efficacy of pirepemat on falls frequency in patients with Parkinson's disease



Status

- Study start of Phase IIb Q1 2022
- All clinical centers activated May 2023
 - 38 centers in France, Poland, Spain, Sweden, Germany and the Netherlands
- Completion of patient recruitment aimed for end 2023
- Top-line results estimated in H1 2024





Preclinical projects and generating a pipeline with ISP

Nicholas Waters

EVP, Head of R&D at IRLAB



Preclinical projects in development

IRI 757*	IRI 0/12*	IRI 1117
Treatment for apathy	Improvement of cognitive function	Once-daily treatment of Parkinson's (tremor, rigidity, bradykinesia) without treatment- related complications
Loss of initiative, interest, and emotional expression/ responsiveness	Memory, perception, attention, reasoning, problem–solving and decision–making	Next-generation Parkinson's treatment
Addressable population: 2.1-7.4 million people ¹	Addressable population: 5.8 million people ¹	Addressable population: 5.7 million people ¹
Status: IND-enabling studies; Phase I ready YE 2023	Status: IND-enabling studies; Phase I ready H1 2024	Status: Preclinical development

IRLAB

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)

ISP gives an advantage through increased probability of development success





Research platform

ISP



Panel discussion with a focus on regulatory strategy and business development opportunities

Biogen and Alectos announce license and collaboration agreement in Parkinson's Disease

Biogen + Alectos

Transaction	 Exclusive global license Collaboration on preclinical activities. Biogen assumes sole responsibility for clinical development, regulatory, manufacturing and commercial activities and costs
Target molecule/s	 AL01811 - a selective GBA2 inhibitor with first-in-class potential as an oral disease modifying treatment for Parkinson's Disease (+ unnamed back-up molecules) In preclinical development
Financial terms	 Up-front: USD 15m Development milestones: Up to USD 77.5m Commercial milestones: Up to USD 630m Royalties: Tiered royalties in the high-single-digits to mid-teens



Deal Value: Up to USD 722.5m

Takeda and Ovid Therapeutics announce license agreement with respect to Seizure Control in DS and LGS

Takeda

Transaction	 Exclusive global license Takeda assumes sole responsibility for clinical development, regulatory and commercial activities and costs
Target molecule/s	 Soticlestat - a selective, first-in-class inhibitor of the enzyme cholesterol 24-hydroxylase with the potential to improve seizure control in patients with Dravet Syndrome and Lennox-Gastaut Syndrome Demonstrated proof-of-concept in a Phase II trial
Financial terms	 Up-front: USD 196m Development and commercial milestones: Up to USD 660m (split not disclosed) Royalties: Tiered royalties beginning in the low double-digits and up to 20%



Deal Value: Up to USD 856m

Jazz Pharmaceuticals announces acquisition of Cavion with activities in Movement Disorders

	Jazz Pharmaceuticals + Cavion = Deal Value: Up to USD 312.5m
Transaction	 Acquisition (global rights) Privately held target company
Target molecule/s	 CX8998 – a modulator of T-type calcium channels as a potential treatment of Essential Tremor (+ two molecules in Phase I) Demonstrated proof-of-concept in a Phase II trial
Financial terms	 Up-front: USD 52.5m Development milestones: Up to USD 75m Commercial milestones: Up to USD 185m Royalties: No royalties



Supernus announces acquisition of Adamas with activities in e.g. Parkinson's Disease LIDs



Transaction	 Acquisition (global rights) Listed target company
Target molecule/s	 GOCOVRI – extended release capsules of amantadine as a treatment for PD LIDs and PD OFF Epsiodes (+ Osmolex ER (amantadine) for the treatment of PD) Marketed (GOCOVRI net sales USD 71.2m)
Financial terms	 Up-front: USD 400m Contingent Value Rights: Up to USD 50m (based on sales milestones for GOCOVRI) Acquisition premium: ≈75%





Questions from the audience





Contact:

Gunnar Olsson, CEO, gunnar.olsson@irlab.se

General enquiries: ir@irlab.se

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

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