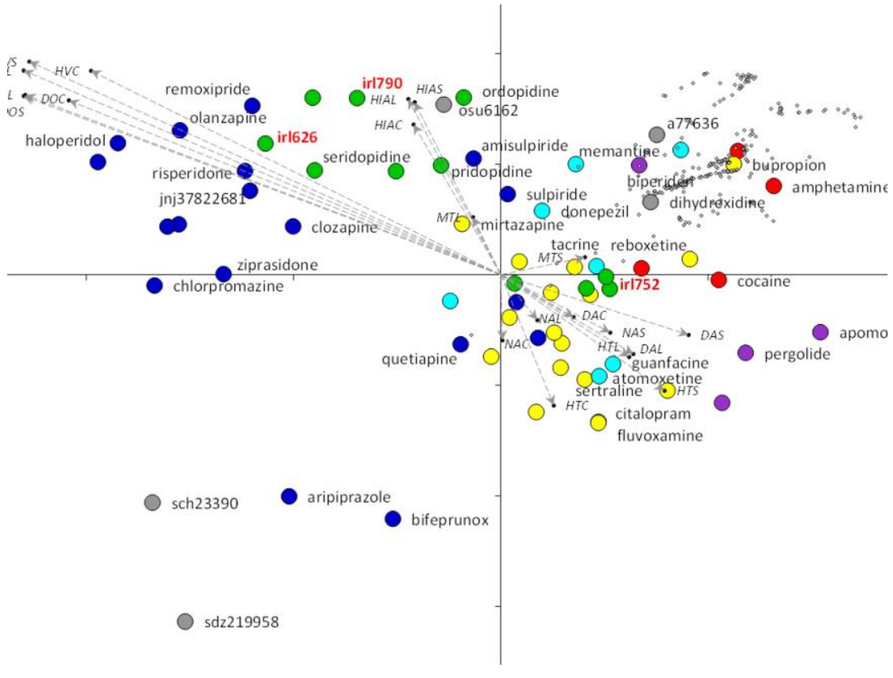
Integrative
Research
Laboratories

IRLAB Therapeutics



Börsveckans småbolagsdag Sept 5, 2018

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12.9 million patients by 2040

VIEWPOINT

E. Ray Dorsey, MD
Center for Health and Technology, Department of Neurology, University of Rochester Medical Center, Rochester, New York.

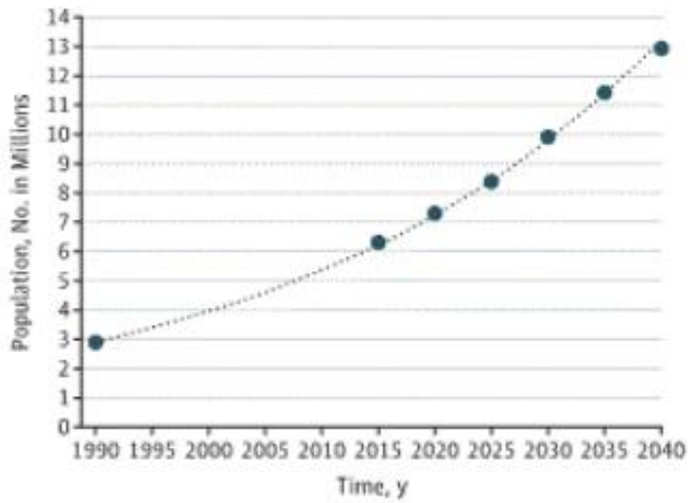
Bastiaan R. Bloem, MD, PhD
Radboud University Medical Center, Donders Institute for Brain, Cognition and Behavior, Department of Neurology, Nijmegen, the Netherlands.

The Parkinson Pandemic—A Call to Action

Pandemics are usually equated with infectious diseases such as Zika, influenza, and HIV. However, an imminent noninfectious pandemic, Parkinson disease (PD), requires immediate action.

Neurological disorders are now the leading cause of disability in the world.[1] Among these neurological disorders, the fastest growing is PD, whose growth is surpassing that of Alzheimer disease.[1] From 1990 to 2015, the prevalence of, and thus disability and deaths owing to, PD more than doubled.[1] The Global Burden of Disease Study estimates that 6.2 million individuals currently have PD. Because the incidence of PD increases sharply with age and because the world's population is aging, the number of individuals affected is poised for exponential growth (**Figure**). Conservatively applying worldwide prevalence data from a 2014 meta-analysis[2] to projections of the world's future population,[3] the number of people with PD will double from 6.9 million in 2015 to 14.2 million in 2040. Applying this same growth rate to the lower estimate by the Global Burden of Disease study (6.2 million in 2015) projects to a staggering 12.9 million affected by 2040.

Figure. Estimated and Projected Number of Individuals With Parkinson Disease, 1990-2040



Sources: Global Burden of Disease Study (1990 and 2015) and projections based on published[2] and public[3] sources.

PD do not see a neurologist, and those who do not are more likely to fall, be placed in a skilled nursing facility,

JAMA Neurol. Published online November 13, 2017. doi:10.1001/jamaneurol.2017.3299

IRLAB

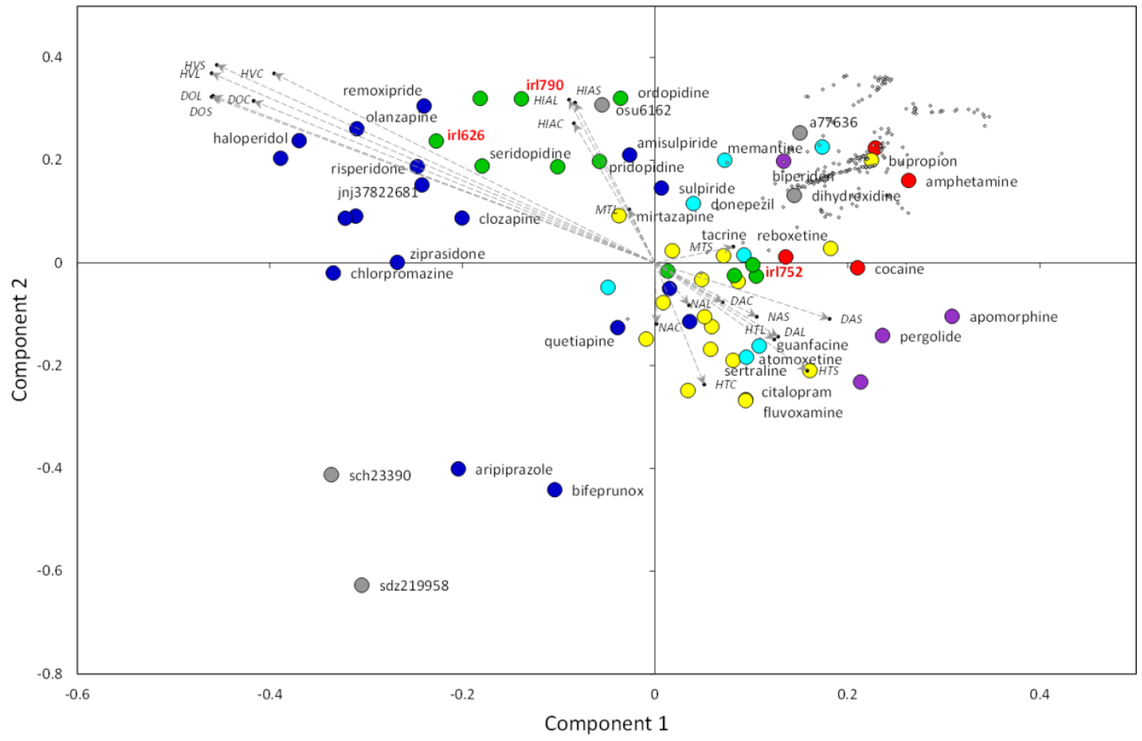
R&D company focused on treatments of CNS disorders

- Addressing unmet needs in Parkinson's disease
- Proprietary R&D technology platform: ISP
- Founded 2013, listed 2017 on NASDAQ OMX Stockholm First North Premier
- Laboratories in Gothenburg, Sweden, 20 employees
- Advisory & CRO network across Europe and the US
- www.irlab.se

Technology: ISP – it's all about data

The Integrative Screening Process (ISP)

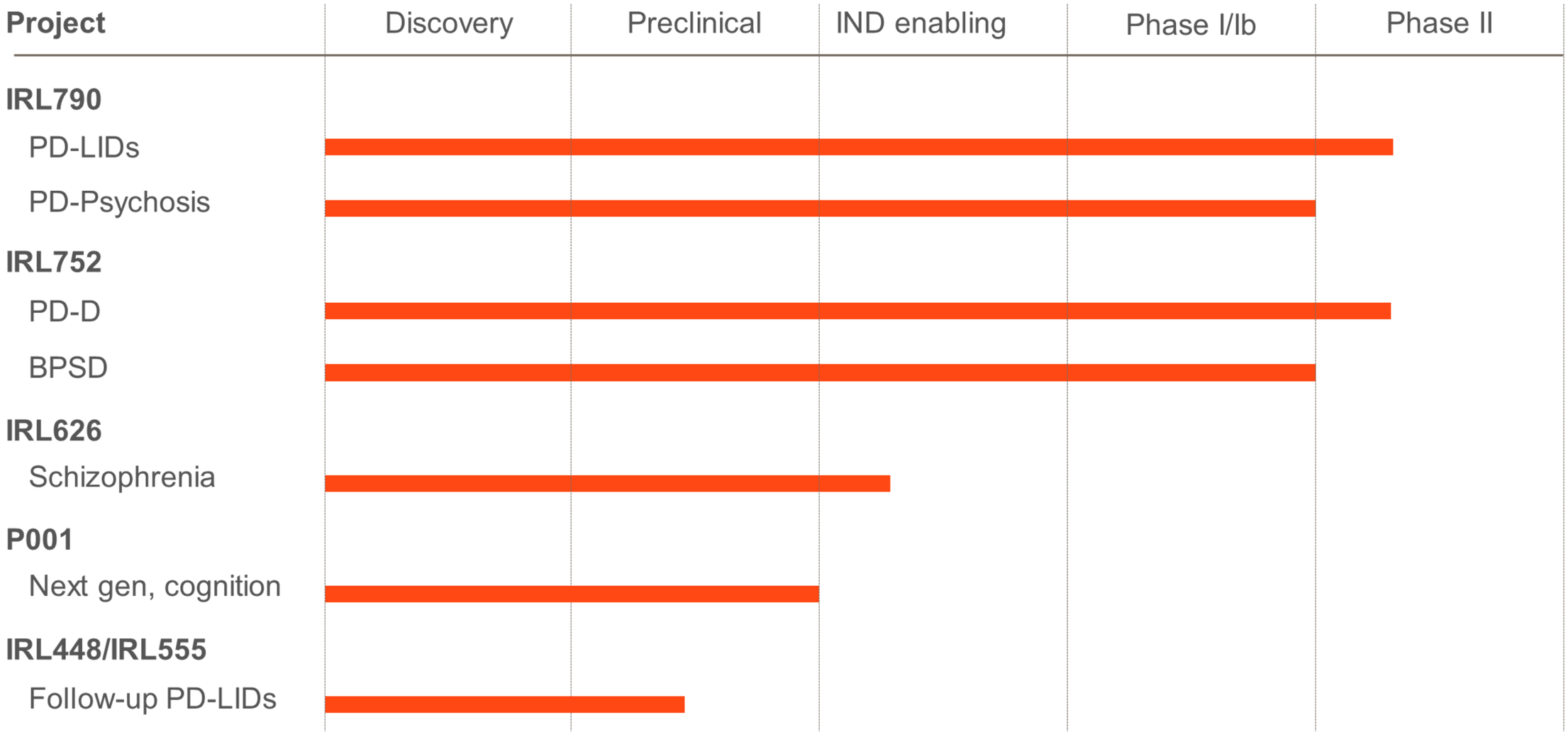
- **High content phenotypic screening**
- **Based on biomarker strategy**
  - Use wide array of "biological descriptors"
- **Response to treatment**
  Input - processing - output
  - Neurotransmitter activity
  - Synaptic gene expression; and
  - Objective behavioural measures
- **Filters and selects molecules suitable for development**



In Vivo Systems Response Profiling and Multivariate Classification of CNS Active Compounds: A Structured Tool for CNS Drug Discovery ACS Chemical Neuroscience (2017), 8(4), 785-97.

ISP Derived Pipeline

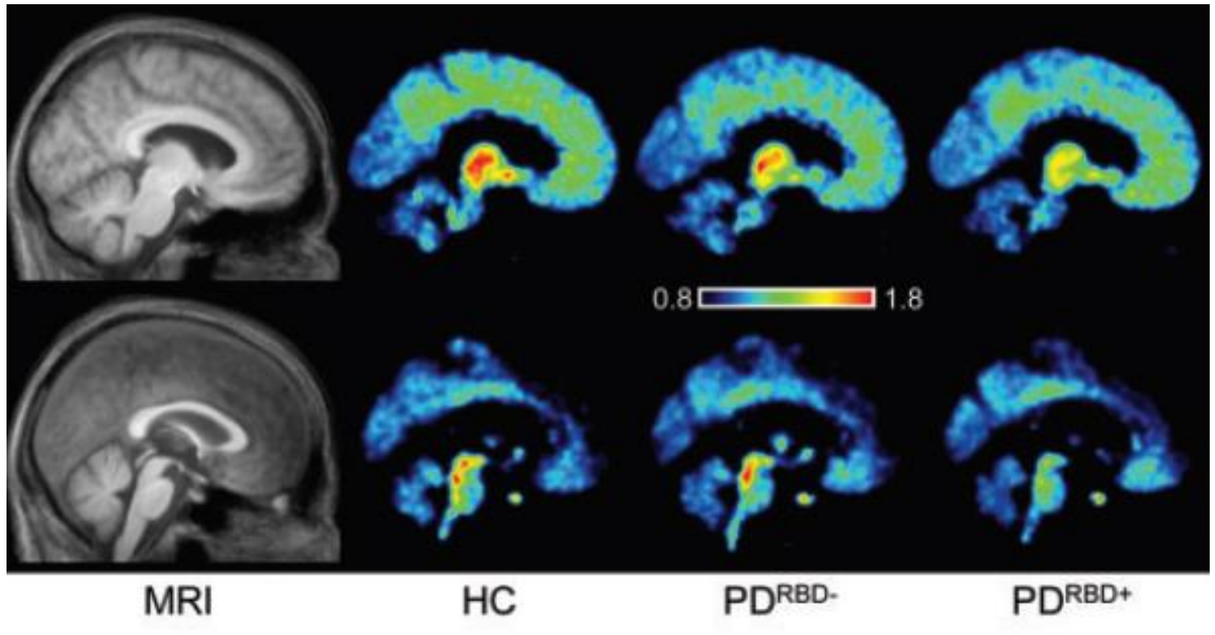
IRLAB is pursuing two comprehensive clinical development programmes and two follow-on programmes:



IRL752 – Background – Parkinson’s disease dementia

Parkinson’s disease dementia

- PD cause pronounced dopaminergic disturbance – the well described motor phenotype
- PD also affects the noradrenergic, serotoninergic and cholinergic systems, by degeneration of the locus coeruleus, dorsal raphe nuclei and cholinergic brainstem nuclei (Robbins and Cools: Movement Disorders, Vol. 29, No. 5, 2014).
- Axial motor symptoms and apathy strongly linked to executive functions and cognitive impairment in Parkinson’s disease *



Sommerauer et al. Evaluation of the noradrenergic system in Parkinson's disease: an 11C-MeNER PET and neuromelanin MRI study. Brain, 2017.

*** Literature**

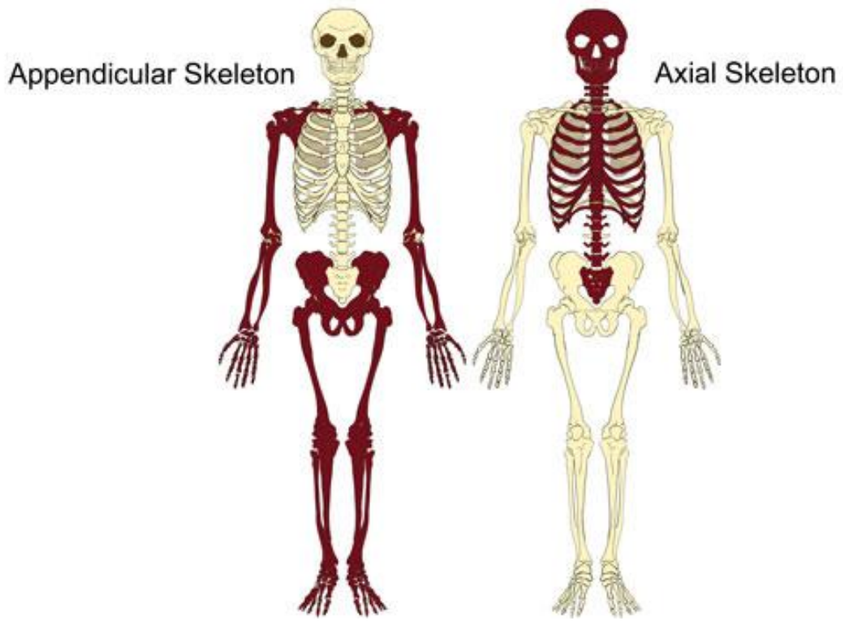
- Apathy, but Not Depression, Reflects Inefficient Cognitive Strategies in Parkinson’s Disease. Varanese S, Perfetti B, Ghilardi MF, Di Rocco A, PLoS ONE 6(3), 2011
- Apathy and noradrenaline: silent partners to mild cognitive impairment in Parkinson's disease? Loued-Khenissi, Preuschoff K., Curr Opin Neurol. 2015 Aug;28(4):344-50
- Managing Gait, Balance, and Posture in Parkinson’s Disease. Debu et al., Current Neurology and Neuroscience Reports (2018) 18:23
- Axial disability and deep brain stimulation in patients with Parkinson disease. Fasano, A. et al. Nat. Rev. Neurol. 11, 98–110 (2015)

Progression in Parkinson's Disease

Early Stage Parkinson's

- Tremor
- Rigidity
- Bradykinesia

Appendicular vs Axial motor symptoms

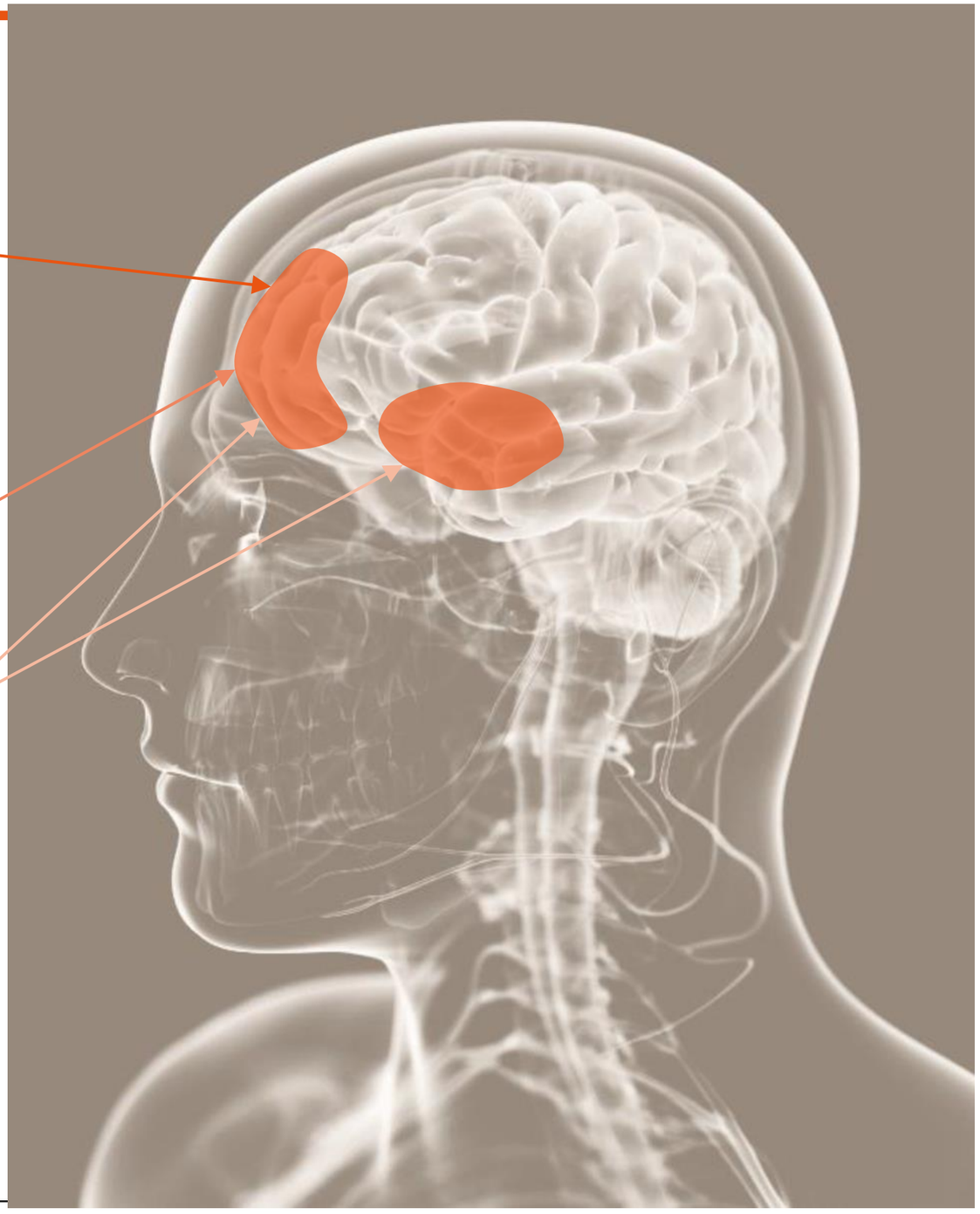


Later Stage Parkinson's

- Addition of Motor Features (Axial):
  - Postural dysfunction (Falls, Gait freezing)
  - Swallowing difficulties
  - Speech
- Addition of Non Motor Features
  - Cognitive deterioration
  - Orthostatic hypotension
  - Sleep/wakefulness problems
- Behavioural symptoms
  - Apathy
  - Hallucinations
  - Depression

IRL752 – Pharmacodynamics and efficacy profile

1. **Increased synaptic availability of dopamine (DA) and norepinephrine (NE) in the frontal cortex**
   - Executive function
   - Motor function
   - Cognition
   - Impulse control
   - Affect
2. **Acetylcholine mildly up (cortical regions)**
   - Improved memory/cognition
3. **Synaptic activation (cortico-striatal)**
   - Reverses reduced synaptic activity in Pfc and improves **cortico-striatal connectivity**



In preclinical studies IRL752 displays

- Improvement in motor function in DA/NE hypoactive state
- Functional effects in impaired cognitive states
- Functional effects in psychosis domain
- Antidepressant like effects

IRL752 – Phase IIa clinical trial (EudraCT # 2017-001673-17)

Phase IIa clinical trial in brief

IRL752: First in class to treat cortical NE and DA dependent dementias in PD

DESIGN and OBJECTIVES

- Objective: Safety and Tolerability in the intended patient population
- Conducted in 10 sites in Sweden and Finland. Enrolment started Q4 2017.
- Double blind, placebo controlled, 3:1 randomization. Four weeks treatment
- Forty-three (43) patients were screened and 32 were randomized to treatment, 25 with IRL752 and 7 with placebo.
- In the IRL752 treated group 23 of 25 completed the entire treatment period and 6 of 7 in the placebo group.

SECONDARY exploratory READ OUTS

- Motor
  - UPDRS
  - FOGQ
  - TUG
- Behavior
  - NPI-12
- Cognitive
  - CANTAB Test Battery
- Global
  - CBIC-Plus
- Biomarker
  - EEG

IRL752 – Safety and Tolerability Phase IIa study

Tolerability

- Well tolerated
- Average dose 594 mg/day (750 max allowed) (FAS population)

Safety

- One SAE in IRL752 group (not related to IRL752)
- One SAE in Placebo group
- AEs mainly CNS related
- Excellent cardiovascular safety
- Three cases of moderately increased liver enzyme levels

IRL752 – Efficacy – exploratory analysis

Significant improvements compared to baseline

- Axial motor symptoms
  - UPDRS II (speech, swallowing, gait freezing, falls)
  - UPDRS III, retropulsion pull test (balance)
- Apathy/Indifference (NPI)
  - Reduced apathy scores
  - Supported by reduced caregiver distress
- Cognition (CANTAB test battery)
  - Trend for improvement in executive function/strategic planning (OTS “Tower of London” test)

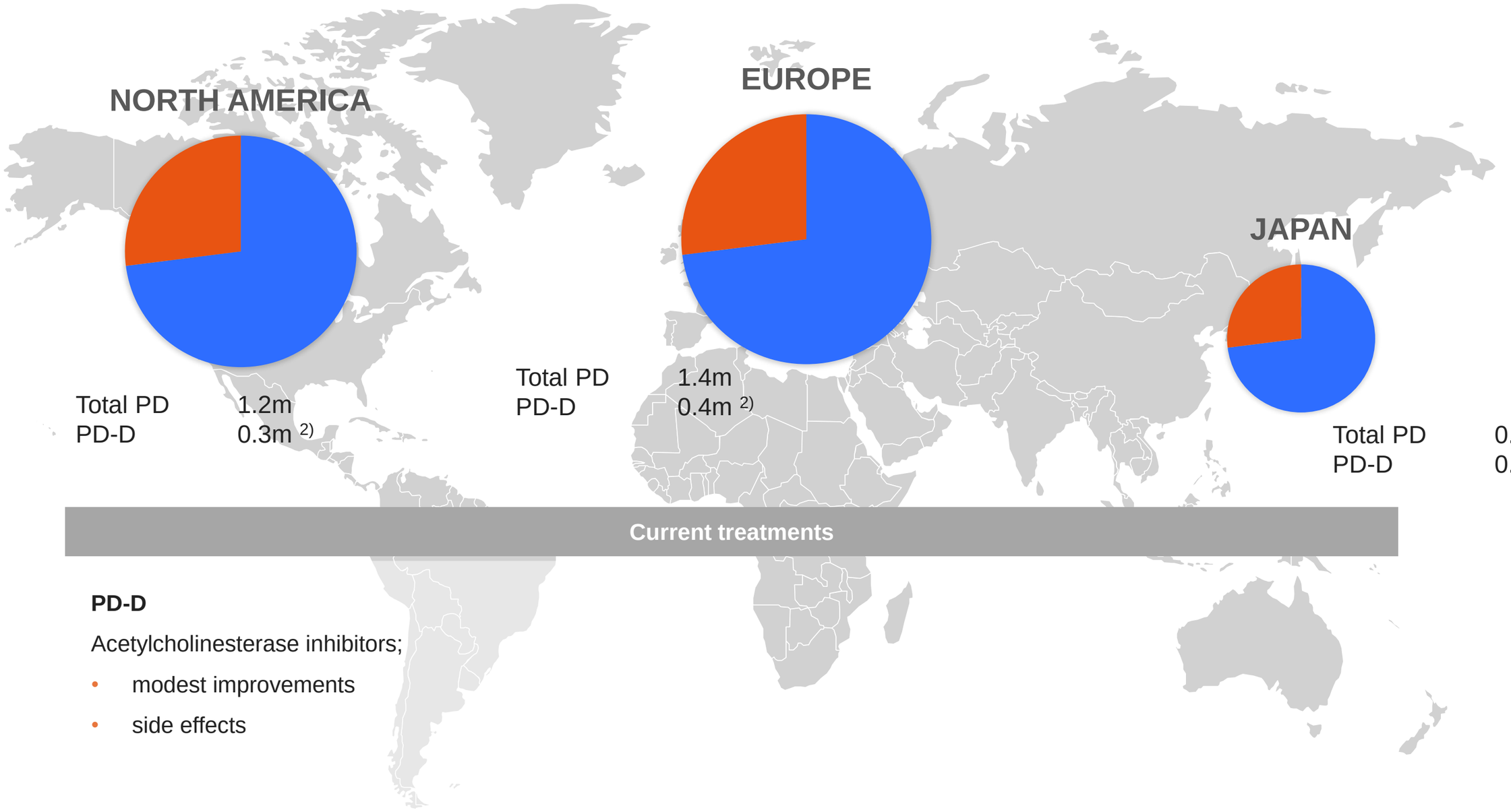
Note
- Efficacy assessments are all exploratory
- Study not designed or powered for efficacy

IRL752 – Phase IIa findings

- **Exploratory analysis indicate that IRL752 targets a previously well described symptom cluster which lacks sufficient treatment**
  - Axial motor symptoms
  - Apathy
  - Cognitive impairment*
  - Domains not treated by dopamine substitution (L-dopa, DA agonists, MAO-I, COMT-I)
- **The analysis indicates that IRL752 may have effects on these executive symptoms associated with dementia in PD**
- **Effects on axial motor symptoms and apathy suggest cortical mode of action of IRL752**
- **Results in line with predictions from preclinical studies**
- **Well tolerated – in line with Phase I results**
- **Data support continued development in a PD-D efficacy study**

***** Trend towards improvement

IRL752 – Market Opportunity



Total PD	1.2m	Total PD	1.4m
PD-D	0.3m [2]	PD-D	0.4m [2]
		Total PD	0.3m
		PD-D	0.1m [2]

Current treatments

PD-D

Acetylcholinesterase inhibitors;

- modest improvements
- side effects

1) Aegis Capital Corp Research 2015, Credit Suisse Research 2014, ISCTM (The International Society for CNS Clinical Trials and Methodology) 2013
2) Cowen and Company Research 2014, Acadia Pharmaceuticals 2016

- **Prepare for Phase IIb with IRL752**
- **Conclude IRL790 Phase IIa**
- **Pipeline update**
- **Expansion of patent estate**
- **Move towards Nasdaq Main Market**