

Herantis Pharma

HER-096 clears Phase Ib, eyes Phase II

Herantis Pharma **reported** positive top-line results from the second part of its Phase Ib trial, evaluating lead candidate HER-096 in Parkinson's disease (PD) patients, meeting both the primary and secondary endpoints. Both 200mg and 300mg twice-weekly doses (administered for four weeks) were shown to be safe, well tolerated and achieved the predicted cerebrospinal fluid (CSF) exposure, confirming effective blood-brain barrier (BBB) penetration. We look forward to the full dataset and biomarker data to be released before end FY25 and believe that these top-line results provide pharmacological rationale for HER-096 to advance to Phase II efficacy studies. The 300mg twice-weekly dose has been deemed suitable for the Phase II trial in early-stage PD patients, expected to commence in 2026, potentially under a partnering agreement.

After demonstrating a favourable safety and pharmacological profile in **part one** of the Phase Ib study (in elderly, healthy volunteers; n=8; 300mg single dose), part two was designed to test HER-096 in PD patients with repeated subcutaneous doses. This was a randomised, double-blind part of the study designed to assess safety and biomarkers with multiple doses of HER-096 in PD patients (12 each at 200mg and 300mg twice weekly, randomised 2:1 between the treatment and placebo arms).

The study met both its primary endpoints (safety and tolerability) and secondary objectives (pharmacokinetics), reporting mostly mild adverse events (AEs) in the treatment arms (one serious AE reported in the placebo cohort) and pharmacologically active drug concentration in CSF, confirming strong BBB penetration. By targeting the deregulated unfolded protein response pathway signalling, HER-096 is designed to address key mechanisms underlying PD progression (rather than just symptom control), offering disease-modifying potential, a significant unmet need in PD. We believe that initial confirmation of effective brain penetration by the compound, a historical hurdle with its predecessor cerebral dopamine neurotrophic factor (CDNF), represents a meaningful milestone supporting its translational potential.

The Phase Ib trial was not designed or sufficiently powered to test efficacy (stable motor scores were reported across both treatment and placebo arms, indicative of the small patient population and short treatment duration) and we look forward to the biomarker data (to be reported before end FY25) for any initial symptoms of biological activity. We expect the company to use this data to refine the Phase II design prior to trial initiation in FY26. In terms of dosing, 300mg twice weekly has been deemed suitable for the Phase II trial by management. While this Phase Ib trial was funded by the Michael J Fox Foundation and Parkinson's UK, we expect Herantis to seek a partnering agreement for the upcoming Phase II study. Herantis had a gross cash balance of €4.6m at end H125, with a runway into Q226, as per management guidance.

Historical financials

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/22	0.0	(9.3)	(0.64)	0.00	N/A	N/A
12/23	0.0	0.3	0.02	0.00	N/A	N/A
12/24	0.0	(4.9)	(0.24)	0.00	N/A	N/A

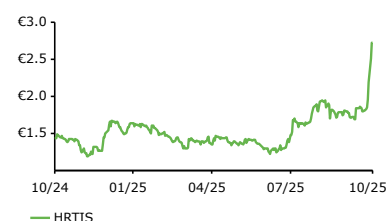
Source: LSEG Data & Analytics

Healthcare

8 October 2025

Price €2.72
Market cap €60m

Share price performance



Share details

Code	HRTIS
Listing	HEL
Shares in issue	24.1m
Gross cash/equivalents at 30 June 2025	€4.6m

Business description

Herantis Pharma is a clinical-stage biotechnology company based in Finland. It is focused on developing disease-modifying therapies to stop or reverse the progression of neurodegenerative diseases. Lead candidate HER-096 is a peptide mimic of CDFN protein, and has successfully completed Phase Ib for Parkinson's disease.

Bull points

- Lead candidate has a novel mechanism of action and has shown promising early pharmacokinetics data in humans.
- Sizeable commercial opportunity for an effective PD treatment with disease-modifying properties.
- External validation received via funding from recognised organisations, including the European Innovation Council, the MJFF and Parkinson's UK.

Bear points

- Extended time to market and reliant on external funding to progress the development of HER-096.
- Typical regulatory, development and funding risks associated with the early stages of drug development.
- With its reliance on a single programme, Herantis is exposed to binary event risks.

Analysts

Jyoti Prakash, CFA	+44 (0)20 3077 5700
Arron Aatkar, PhD	+44 (0)20 3077 5700

healthcare@edisongroup.com

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