Herantis Pharma

FDA feedback clears HER-096 Phase IIa path

Herantis Pharma has announced positive FDA feedback and finalised the Phase IIa design for HER-096 in Parkinson's disease (PD). Following a pre-IND meeting, the FDA raised no concerns on the preclinical package, confirmed that current data would support activation of US clinical sites if an IND is submitted, and considered the Phase IIa design appropriate for this development stage. We view this as a positive step for Herantis, providing a clear path to the first efficacy study of HER-096 and strengthening the package for prospective partners. The randomised, double-blind, placebo-controlled study will enrol c 100 newly diagnosed PD patients not receiving symptomatic medication. Patients will be treated with twice-weekly subcutaneous dosing for six months, followed by a six-month open label extension. The primary endpoint will be a Digital Motor Score, supported by clinical assessments, imaging and biomarkers. More than 50% of the Phase II funding has now been secured or identified.

The finalised design builds on Herantis's May 2026 collaboration with Indivi, where Indivi's digital biomarker platform will be integrated into the Phase IIa study. The use of a Digital Motor Score as the primary endpoint is important, in our view, as it is intended to provide objective and continuous assessment of disease progression and treatment response, alongside conventional clinical measures. The enrolment of newly diagnosed PD patients who are not yet receiving symptomatic medication should also reduce confounding from background therapies and help assess whether HER-096 can show an early signal consistent with disease modification.

HER-096 is supported by a promising early clinical package. In the Phase Ib trial, repeated 200mg and 300mg doses were safe and well tolerated, with pharmacokinetics supporting twice-weekly dosing and blood brain barrier penetration confirmed in patients. The biomarker programme showed HER-096 exposure was linked to changes across PD relevant pathways. These biomarker data should not be read as evidence of efficacy, but they do provide proof of biology and a stronger basis for dose selection and endpoint refinement in Phase IIa.

The funding position has also improved. Herantis has the previously announced €8m Horizon Europe grant and potential further investment from the EIC Fund and now states that more than half of the required Phase II funding has been secured or identified. The company continues to evaluate strategic partnerships, equity financing and non-dilutive funding. We believe the latest update sharpens the investment case by aligning regulatory feedback, study design and trial execution plans. The next key milestones are likely to be confirmation of the remaining funding route, potential partnering progress and initiation of the Phase IIa study. On the associated webcast following this latest news, it was stated that the clinical trial application is due to be submitted in Q426, with acceptance expected in H127 and trial launch in the same period. The first data readout is anticipated from H129.

Historical financials

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
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
12/25	0.0	(6.6)	(0.28)	0.00	N/A	N/A

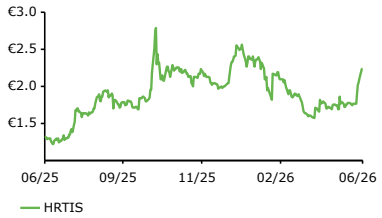
Source: Herantis Pharma

Healthcare

2 June 2026

Price	**€2.24**
Market cap	**€56m**

Share price performance



Share details

Code	HRTIS
Listing	HEL
Shares in issue	26.5m
Pro forma gross cash/ equivalents at 31 December 2025 (including the February 2026 directed share issue)	€6.8m

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 CDNF protein and has successfully completed Phase Ib for Parkinson's disease.

Bull points

- HER-096 has a novel mechanism 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 drug development.
- With its reliance on a single programme, Herantis is exposed to binary event risks.

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