Herantis Pharma

Dedicated to disease modification for PD

Herantis is striving to develop disease-modifying treatments for central nervous system (CNS) conditions, with an initial focus on Parkinson's disease (PD). Lead asset HER-096 has a novel mechanism of action, and has shown encouraging results in preclinical and clinical studies to date. It is now being tested in a Phase Ib trial, the first test in PD patients. The results, due in September 2025, may be the next major catalyst for Herantis. It has been financially supported by the European Innovation Council (EIC), as well as the Michael J Fox Foundation (MJFF) and Parkinson's UK Virtual Biotech. Herantis is currently seeking a partnership for the further development and commercialisation of HER-096.

HER-096 programme is the current strategic priority

HER-096 is a peptide mimic of the preceding protein therapeutic candidate, cerebral dopamine neurotrophic factor (CDNF), but has been optimised to cross the blood-brain barrier. HER-096 showed a robust safety profile and efficient brain penetration in a Phase Ia study (single doses in healthy volunteers). It is now being assessed in Phase Ib, aiming to confirm safety with repeated dosing (subcutaneous injections) in PD patients, while studying pharmacokinetics (PK) and biological responses in preparation for Phase II. Through its unique, multi-pronged mechanism of action, HER-096 holds promise as a potential disease-modifier for PD, offering sizeable commercial potential, should future clinical results continue to be favourable.

The growing CNS space is a key opportunity

The CNS therapeutics market is seeing a major resurgence, and is projected to be worth c $216bn by 2032. Neurodegenerative diseases, particularly PD, have substantial unmet need with current options only targeting symptoms. This creates a compelling opportunity for potential disease modifiers, such as HER-096. This CNS renaissance is reflected in a growth in M&A in the past 18 months, with a recent notable transaction being J&J's $14.6bn acquisition of Intra-Cellular. This trend signals investor confidence in CNS innovation, despite broader market volatility.

Funded to mid-2026 based on historical cash burn

Herantis secured a €2.5m grant from the EIC and a €15m equity investment commitment from the EIC Fund (€3.2m invested to date). The Phase Ib trial for HER-096 is also supported by €3.6m in funding (repayable under certain conditions) from the MJFF and Parkinson's UK Virtual Biotech. At end-2024, Herantis had gross cash/equivalents of €2.1m, bolstered post-period by a €5.2m (gross) raise. Assuming that cash burn rates remain similar, these funds would be projected to provide a runway to mid-2026.

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	86.9	N/A
12/24	0.0	(4.9)	(0.24)	0.00	N/A	N/A

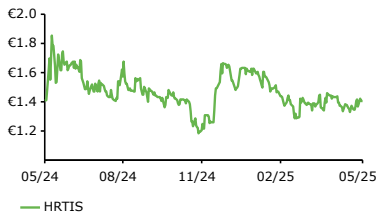
Source: LSEG Data & Analytics

Healthcare

22 May 2025

Price	**€1.42**
Market cap	**€34m**

Share price performance



Share details

Code	HRTIS
Listing	HEL
Shares in issue	24.1m
Pro forma gross cash/ equivalents at 31 December (including the February 2025 directed share issue)	€7.3m

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 is currently in a Phase Ib trial 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
Edison profile page

Herantis Pharma is a research client of Edison Investment Research Limited

Investment summary

Company description: A novel and innovative approach to CNS

Herantis is a Finnish-based clinical-stage biotechnology company, developing disease-modifying therapies with the aim to stop or reverse the progression of PD and other neurodegenerative diseases. Its current strategic priority is HER-096, a potential disease modifier for PD. Herantis's streamlined clinical pipeline stems from its prior efforts in PD, with the development of CDNF, a protein-based therapeutic that, despite having shown a clinical effect, did not cross the blood-brain barrier (BBB), and thus required intra-cranial administration. HER-096 was developed as a peptidomimetic (a biological molecule designed as a protein mimic) of CDNF, and, importantly, HER-096 has been shown to cross the BBB following administration via subcutaneous injection, paving the way for the company's current clinical development strategy, with potential to be a disruptor in the field of PD and CNS therapeutics. Following substantial preclinical research, HER-096 successfully completed a Phase Ia trial in late-2023; it demonstrated favourable safety and tolerability, as well as a desirable PK profile in healthy volunteers, confirming BBB penetration. It is now being evaluated in a Phase Ib trial, which commenced in Q424. The first part of this trial was completed swiftly, providing important PK data with extended sampling timepoints in eight elderly healthy volunteers. The second part of the study is underway, and is the first assessment of HER-096 in PD patients (expected n=24). An interim update was reported in January 2025, showing encouraging PK insights, and management confirmed in May 2025 that the study had progressed to dosing the final patient cohort (of the second part of the Phase Ib trial). The Phase Ib results are expected in September 2025, and could represent an important catalyst for investor attention. While management is already preparing for Phase II, it is also engaged in potential partnering discussions, seeking the best path forward for the subsequent development and commercialisation of HER-096 in PD.

Herantis is listed on the First North Growth Market in Helsinki, trading under the ticker HRTIS (ISIN: FI4000087861).

Financials: Financial position supported by recent fundraise

Herantis is yet to generate recurring revenue, and its activities are supported through a combination of equity issuances, grants and non-dilutive funding. Notably, a consortium of the MJFF and Parkinson's UK Virtual Biotech, contributing a combined €3.6m (€1.8m each), is providing funding (repayable under certain conditions) for the Phase Ib trial of HER-096 in PD, as well as an ongoing biomarker project. Similarly, Herantis has secured a €2.5m grant from the EIC for the EIC Accelerator project ReTreatPD, which aims to develop biomarkers for monitoring target engagement and treatment response to HER-096, supporting preparations for Phase II. Herantis is also eligible to receive up to €15m in direct equity investments from the EIC Fund, which may participate with up to one-third of the aggregate capital raised in future capital raises. As of February 2025, €3.2m of this had been invested by the EIC Fund (€1.7m from the directed share issue in February 2025, and €1.5m from the directed share issue in December 2023). We believe the strong commitment from the EIC Fund adds confidence in the company's ability to secure potential future funding to support its pipeline activities. Herantis published its FY24 annual report in March 2025. It finished the year with a net debt position of €51k (including €2.1m in gross cash and cash equivalents, and €2.2m in debt). Post-period, the company bolstered its cash position by raising €5.2m in gross proceeds (including €1.7m from the EIC Fund) through a direct share issue. If we assume that recent cash burn rates (cash outflow from operations of €6.5m in FY24) remain similar going forward, the company's current cash position would be projected to provide a runway to approximately mid-2026, past the conclusion of the Phase Ib HER-096 trial (guided by management for September 2025) as well as the biomarker project (by end-2025 according to management), and with additional operational headroom to secure a suitable partnership, and/or commence Phase II studies for HER-096 in PD (tentatively planned for H226, pending financing).

Sensitivities: Late-stage development depends on securing a partnership

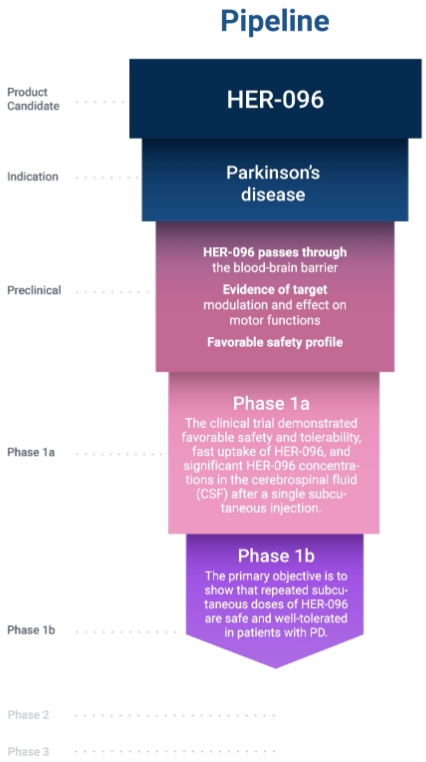
Herantis is exposed to typical biotech risks, such as potential clinical trial setbacks, regulatory uncertainties and funding challenges. Company-specific risks include binary event risks associated with its sole clinical candidate, though we note the potential to expand the application of HER-096 to other indications. For the ongoing Phase Ib trial, failure to confirm safety or show early signs of efficacy may impair the investment case. Furthermore, the company faces an extended time to market before creating a recurring revenue stream, meaning it is reliant on external financing, heightening execution, funding and dilution risks. We note that while management is seeking partnership opportunities for subsequent clinical development efforts and potential commercialisation, there remains an ongoing uncertainty on the timing of such a partnership.

A Parkinson's disease-focused clinical pipeline

Herantis's clinical development pipeline is currently focused exclusively on its lead candidate and programme, HER-096, a peptidomimetic of CDNF, as a potential disease-modifying treatment option for PD (Exhibit 1). The ongoing Phase Ib trial is the first test of the candidate in PD patients, and topline results are anticipated in September 2025, potentially a significant inflection point for the company. In parallel, the company is preparing for a Phase II trial of HER-096 in PD, including work towards developing biomarkers for monitoring target engagement and treatment response through the EIC Accelerator project (ReTreatPD). Management is also in discussions with potential pharma partners, to support its plans for the programme from Phase II and beyond.

Scientific literature references the potential of CDNF to have application in additional conditions (eg Alzheimer's disease, amyotrophic lateral sclerosis, Huntington's disease), which we believe could represent a longer-term opportunity for Herantis. However, further research and confirmation from the company would be required.

Exhibit 1: Herantis's clinical development pipeline



Source: Herantis website

PD remains a challenging indication

The second most common neurodegenerative condition

PD is a highly complex and debilitating neurodegenerative condition. It is characterised by a triad of cardinal motor symptoms (tremor, rigidity and bradykinesia), and postural instability also often presents as the disease progresses, though we note that non-motor symptoms (eg psychosis, dementia and cognitive impairment) are just as debilitating and remain undertreated. It is estimated that PD currently afflicts around one million people in the US, around 1.2 million in Europe, and over 10 million people worldwide. Furthermore, in the US alone, c 90,000 people are diagnosed with PD each year, reflecting a rising figure in line with an ageing population, with the global number of cases expected to double by 2040. Notably, the incidence of PD increases with age, with only 4% of patients diagnosed before the age of 50, and interestingly, men are 1.5 times more likely to develop PD than women, though the reasons for the bias are yet to be fully elucidated given that the underlying cause(s) of PD are still being researched. PD is the second most common

neurodegenerative condition, behind Alzheimer's disease/dementia, where it is estimated there are currently 55m cases around the globe.

Current standard of care relies on dopamine approach

Levodopa firmly remains the current standard of care as a first-line treatment option for PD, as a dopamine replacement agent (it is a prodrug, which is converted in the body to form dopamine). It is often combined with carbidopa (which inhibits enzymes in the body from metabolising levodopa before it reaches the brain). The cause of PD is thought to stem from the degeneration of nerve cells in the substantia nigra (part of the brain that controls movement), and when these nerve cells are impaired, they lose the ability to produce dopamine. Levodopa was developed in the 1960s to directly address this as a dopamine replacement agent, and was approved by the FDA in 1970. However, the drug only improves motor symptoms, is associated with a myriad of side effects and long-term use can lead to dyskinesia. Furthermore, despite substantial efforts to develop disease-modifying approaches for PD, symptomatic treatment remains the mainstay. It is our opinion that there is a widespread opportunity for innovative novel treatment options, such as Herantis's HER-096, to provide a more beneficial outcome for patients with PD.

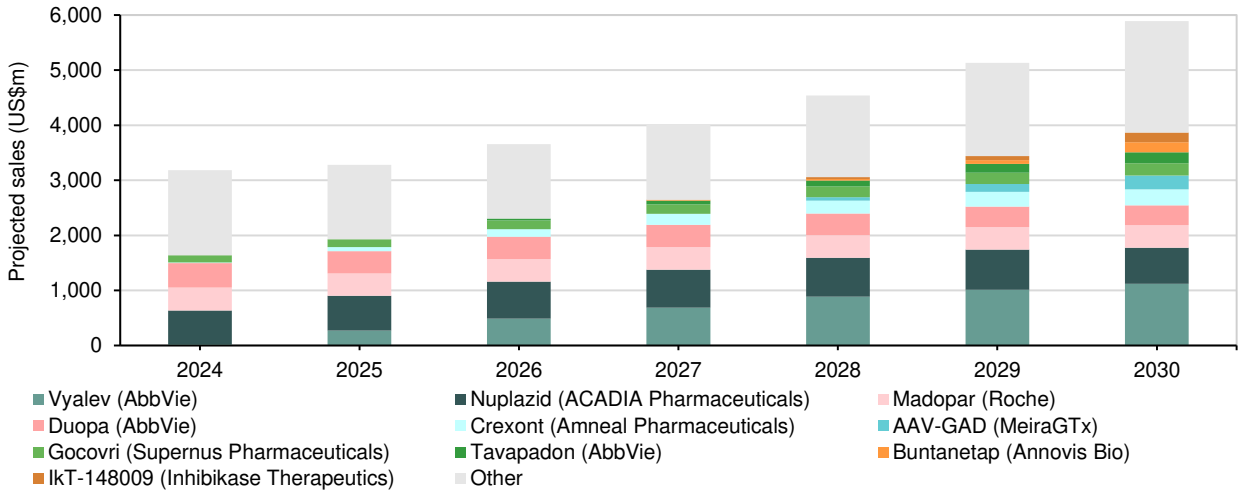
Competitive landscape includes both old and new technologies

We note that in recent years, the PD field has not seen as many advancements as other areas of the CNS, with only limited new treatment options approved for patients. The current treatment landscape for PD largely comprises treatments relying on the traditional dopamine approach, which serve as symptomatic treatments, though some new technologies are emerging (Exhibit 2 and Exhibit 3). For example, AbbVie's Vyalev is a continuous subcutaneous infusion of levodopa and carbidopa, administered through a pump as an alternative to orally dosed medications. Acadia's Nuplazid selectively targets serotonin 5-HT2A receptors and is used to address PD-psychosis. Roche's Madopar is an oral formulation of levodopa and benserazide to address restless leg syndrome in PD patients. Other treatments in the pipeline include AbbVie's Tavapadon (a selective partial agonist of dopamine D1 and D5 receptors, currently in Phase III) and Annovis Bio's Buntanetap (which inhibits the formation of neurotoxic proteins and is also being investigated for Alzheimer's disease, currently in Phase III for both PD and Alzheimer's).

Gene therapies have also emerged as potential candidates to treat PD. However, to date the array of results has been mixed, reflecting the challenge of this research area, exemplified by candidates that failed to progress beyond Phase III from Voyager Therapeutics and Oxford Biomedica. MeiraGTx's AAV-GAD recently showed promise in a clinical bridging study, and the company is preparing for Phase III. AAV-GAD is a gene therapy that encodes the glutamic acid decarboxylase (GAD) enzyme in the subthalamic nucleus, leading to an increase in the production of neurotransmitter gamma-aminobutyric acid (GABA), which helps regulate neuronal activity. The therapy aims to normalise motor circuits and reduce symptoms like tremors, rigidity and difficulty walking. Cell therapies are also emerging, with BlueRock Therapeutics (a subsidiary of Bayer) preparing bemdaneprocel for Phase III.

While encouraging, given that these new technologies would likely be associated with high price tags, in our view, they will need to demonstrate a highly superior effect on disease progression with minimal side effects to achieve notable uptake. We also acknowledge that should disease-modifying potential not be demonstrated with such gene therapies, or HER-096, this may point towards the potential to combine these therapies in an aim to maximise patient benefit, though we note that this would be contingent on safety and tolerability profiles.

Exhibit 2: Projected sales of the PD treatment market from 2024–30



Source: Edison Investment Research, Evaluate Pharma

Exhibit 3: Current and projected PD treatment landscape

Product	Company	Launch year (actual or projected)	Patent expiry	Mechanism of action	Technology	Estimated 2030 worldwide sales* (US$m)
Vyalev	AbbVie	2024	2030	DOPA decarboxylase inhibitor; Dopamine receptor agonist	Small molecule	1,122
Nuplazid	ACADIA Pharmaceuticals	2016	2030	5-HT2A (serotonin) receptor inverse agonist	Small molecule	655
Madopar	Roche	1973	-	DOPA decarboxylase inhibitor; Dopamine receptor agonist	Small molecule	409
Duopa	AbbVie	2004	2014	DOPA decarboxylase inhibitor; Dopamine receptor agonist	Small molecule	356
Crexont	Amneal Pharmaceuticals	2024	2034	DOPA decarboxylase inhibitor; Dopamine receptor agonist	Small molecule	295
AAV-GAD	MeiraGTx	2028	2032	Glutamic acid decarboxylase (GAD) gene transference	Gene therapy	249
Gocovri	Supernus Pharmaceuticals	2017	2035	Metabotropic glutamate receptor (mGluR) antagonist	Small molecule	220
Tavapadon	AbbVie	2026	2034	Dopamine D1 receptor partial agonist; Dopamine D5 receptor partial agonist	Small molecule	200
Buntanetap	Annovis Bio	2027	2033	Alpha-synuclein accumulation inhibitor; Amyloid precursor protein (APP) inhibitor; Huntington protein interaction inhibitor; Tau protein inhibitor	Small molecule	183
IkT-148009	Inhibikase Therapeutics	2027	2033	Dopamine receptor agonist	Small molecule	177

Source: Edison Investment Research, Evaluate Pharma. Note: *According to Evaluate Pharma.

While a disease-modifying treatment option for PD may be considered to be on the horizon at present, we highlight that the first disease-modifying therapy for the CNS condition multiple sclerosis was approved in 1993, when the FDA granted approval to interferon-β 1b. There are now over 20 approved disease-modifying therapies for multiple sclerosis, with the progress primarily driven by the growth in the understanding of specific biomarkers. For PD, research into biomarkers is increasing in pace. For example, aggregations of the protein α-synuclein are believed to be a cause of PD, and hence it may serve as a valid biomarker. This may pave the way for promising disease-modifying candidates, and Herantis is pursing this approach (discussed in further detail below).

Herantis's approach: From CDNF to HER-096

CDNF showed promise, but was hindered by intracranial administration

It is important to note that Herantis's current lead programme, HER-096, has its roots in CDNF, the company's prior clinical candidate for PD. CDNF is produced naturally in the body, but was being explored as a protein therapeutic. It is a neurotrophic factor, which, through a multi-pronged mechanism of action, is believed to protect dopaminergic neurones and restore function to degraded neurons, with potential to address both motor and non-motor symptoms of PD, while also slowing or stopping disease progression. Herantis has carried out substantial research to build a robust data package to support the hypothesis that CDNF could be an effective therapy in PD. In preclinical studies, CDNF was found to promote neurorestoration in a monkey model of PD, when administered via intracranial infusion to the putamen (the part of the brain involved in learning, movement and other cognitive functions). This led to notable improvements in motor function as well as in non-motor symptoms.

A Phase I study conducted by Herantis assessed CDNF in patients with advanced PD, though intracranial administration was required due to the inability of CDNF to cross the BBB. Accordingly, it was a regulatory requirement to only include participants with advanced disease, whereby patients would be implanted with a drug delivery device with portal access

located behind the ear. Encouragingly, the patients involved in the study exhibited signs of biological response and clinical improvements. However, Phase I was primarily focused on safety, and while the candidate was found to be safe and well tolerated, some concerns arose relating to the implanted drug delivery device.

In November 2020, Herantis concluded that the invasive route of administration would have significantly limited the eligible patient population. Management also communicated the anticipated risks associated with the drug-device combination and subsequent commercialisation of the product. Following on from this, in March 2021 the company confirmed its plans to prioritise a programme focused on the design of a synthetic peptide version of CDNF.

For a more detailed discussion of CDNF and its mechanism targeting the deregulated unfolded protein response (UPR) pathway signalling mechanism of PD, we direct readers to a paper published in *Nature Communications*; one of the authors is Dr Henri Huttunen, co-founder and current chief scientific officer of Herantis. This paper discusses the structural rationale for HER-096.

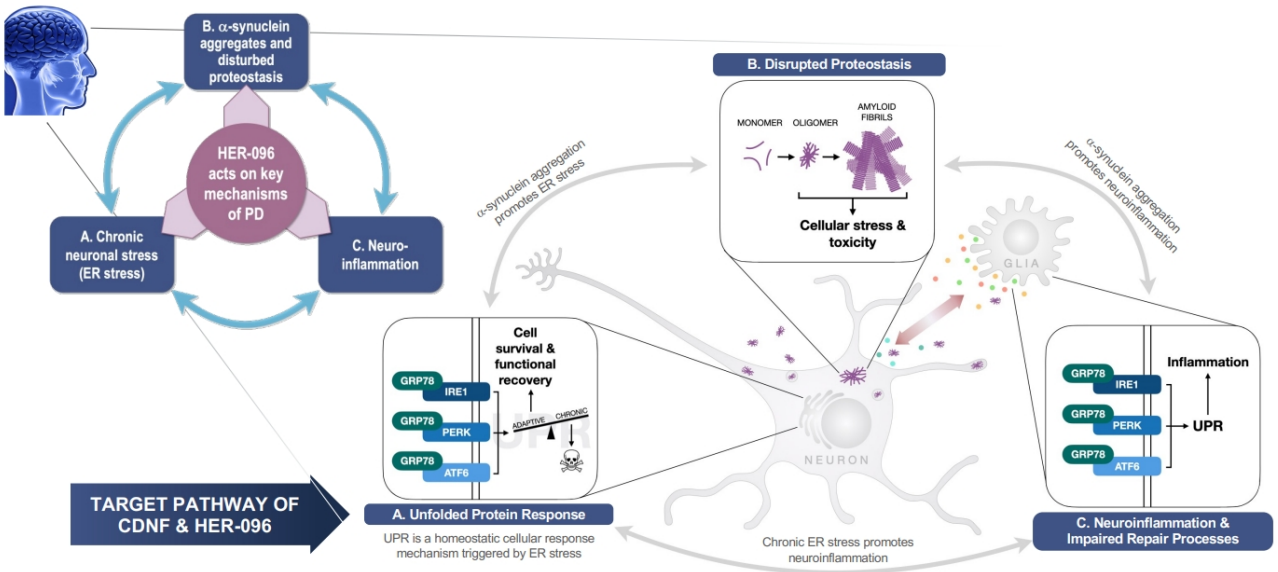
HER-096 developed as an effective solution

In May 2021, HER-096 was nominated as the the lead candidate. The decision was primarily based on preclinical research demonstrating that HER-096:

- effectively penetrates the BBB,
- potently protects neurons and restores their functional phenotype,
- reduces aggregation of the toxic protein α-synuclein and associated neuroinflammation, and
- restores proteostasis (ie targets the UPR pathway).

As with CDNF, HER-096 has been designed on the basis that the pathogenesis of PD stems from the UPR pathway, that is, the cellular signalling pathway triggered by endoplasmic reticulum (ER) stress that leads to the aggregation of misfolded α-synuclein in the substantia nigra of the brain, resulting in neuroinflammation and dopamine neuron loss. As such, HER-096's multi-pronged mechanism of action aims to modulate the UPR pathway (more specifically, it binds to GRP78, the protein responsible for regulating the UPR pathway) to restore homeostatic levels of this cell stress, and ultimately slow down or stop neurodegeneration. Therefore, rather than acting as a dopamine replacement agent, HER-096 is intended to be disease-modifying, anticipated to target the root cause of the disease (Exhibit 4).

Exhibit 4: HER-096's mechanism of action targets the root cause of PD

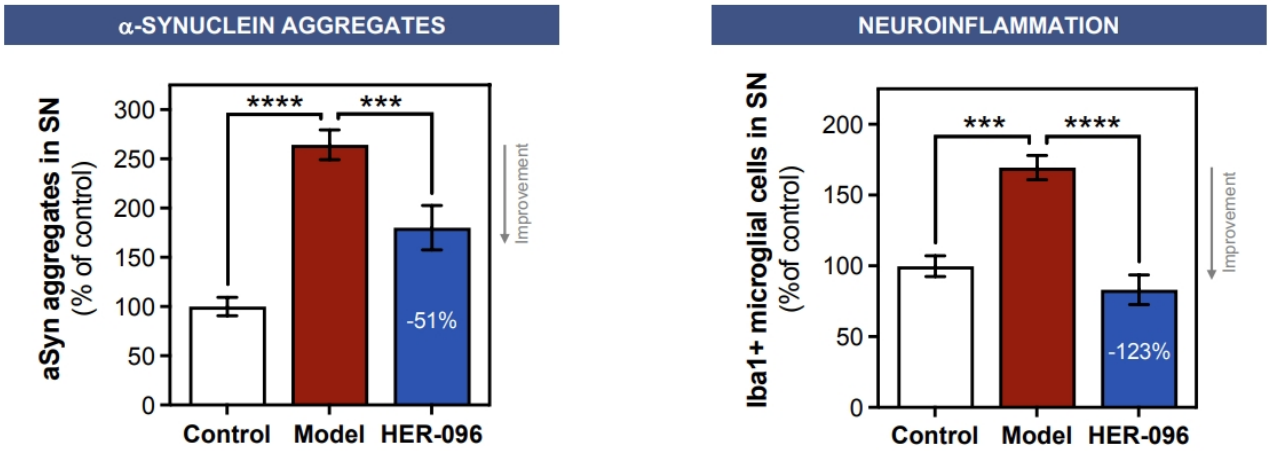


Source: Company resources

Preclinical studies for the programme focused on showing that HER-096 does indeed cross the BBB and has a sufficient half-life to be pharmacologically active. The research also confirmed desirable target engagement with GRP78, measured via the activation of IRE1 and ATF6 (proteins associated with UPR signalling as shown in Exhibit 4). Key indicators of the disease-modifying potential of HER-096 included studies demonstrating the candidate provides meaningful improvements in α-synuclein aggregation and associated neuroinflammation (Exhibit 5). In the exhibit, the

white bars refer to measured levels of α-synuclein aggregation and neuroinflammation in normal mice that received placebo (saline), the red bars refer to an aged mouse model of PD whereby mice did not receive treatment but received placebo (saline), while the blue bars refer to the aged mouse model of PD whereby mice were treated with HER-096. Similar studies also confirmed that HER-096 provided improvements in terms of: the protection of dopamine neurons, the restoration of dopamine neurons to a healthy level, and resultant improvements in motor symptoms.

Exhibit 5: Key indicators of HER-096's disease modifying potential in preclinical studies



Source: Company resources

Further details of these studies can be found in a paper published in *Cell Chemical Biology*. As part of this research, to exemplify the potential of HER-096 prior to entering the clinic, the video below was prepared, demonstrating the benefits HER-096 to motor function in mice. Collectively, this array of preclinical research provided a robust foundation as Herantis progressed HER-096 into Phase I studies.

Mouse model of PD showcases the benefit of HER-096 in improving motor function

Company resources

HER-096 Phase Ib result: A key upcoming inflection point

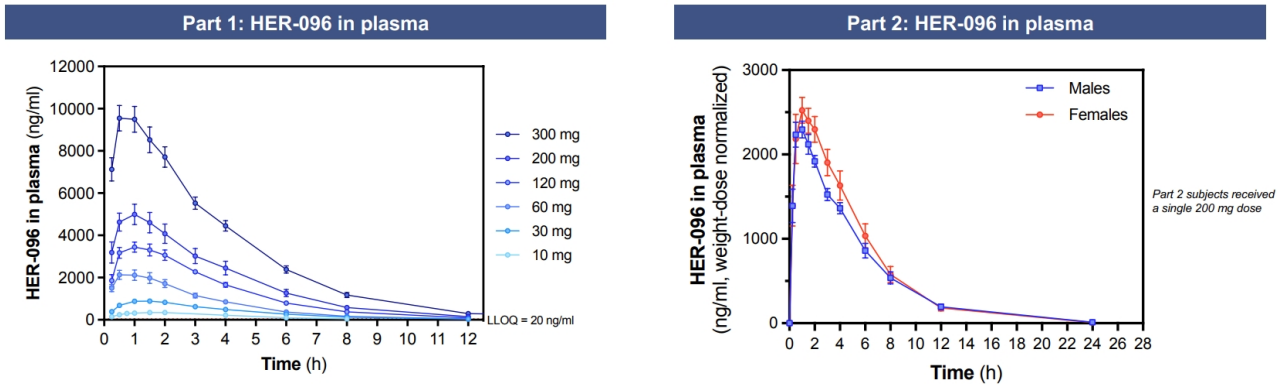
Encouraging start in Phase Ia

Herantis has made encouraging headway in the clinic, with the timely completion of HER-096's Phase Ia trial (NCT05915247). This was a double-blinded, placebo-controlled study, investigating the candidate in healthy volunteers. Primary objectives included safety and tolerability; secondary endpoints focused on PK (including BBB penetration); the study also included exploratory objectives based on a biomarker analysis. The trial included a total of 60 participants, 48 in Part 1 and 12 in Part 2. Part 1 tested single ascending doses of HER-096 (10mg up to 300mg) administered by subcutaneous injections in males aged 20–45. Part 2 tested a single dose of HER-096 (at 200mg) in males and females aged >50, and assessed the concentration of HER-096 in cerebrospinal fluid (CSF) as a measure of BBB penetration.

This Phase Ia trial concluded in October 2023, with positive results:

- The primary endpoint was met:
  - Single subcutaneous doses of HER-096 (10–300mg) were found to be safe and well tolerated.
- The secondary endpoints were met:
  - Single ascending doses of HER-096 showed a robust plasma PK profile in younger and elderly healthy volunteers, showing fast uptake of the candidate, and with no significant differences between males and females after weight normalisation (Exhibit 6).
  - CSF levels of HER-096 were in the pharmacologically active range and in alignment with the expected concentration range based on preclinical research, confirming BBB penetration in older participants.
- Exploratory endpoints laid the groundwork for subsequent studies:
  - Potential PK biomarkers were identified, providing initial insight into biological responses to treatment.

Exhibit 6: HER-096 Phase Ia PK outcomes

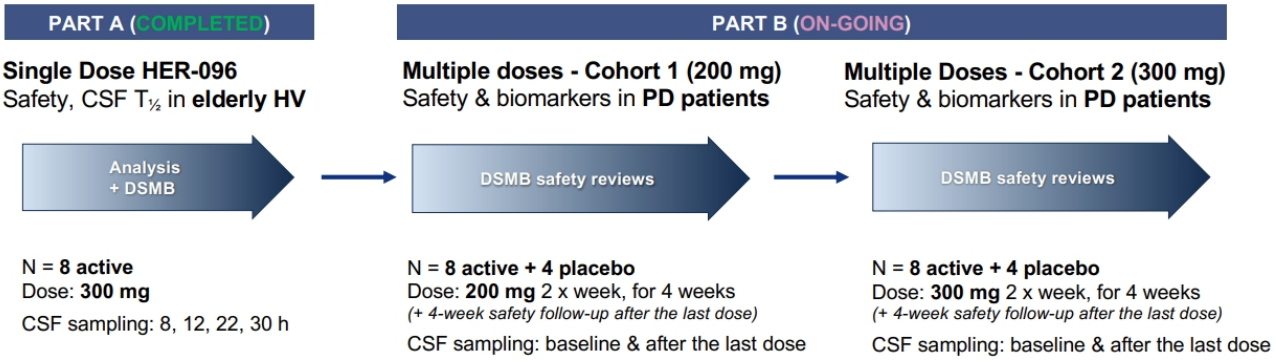


Source: Company resources

All eyes on the September 2025 readout for Phase Ib

The Phase Ib trial (NCT06659562) commenced in October 2024. The primary goal is to demonstrate that repeated subcutaneous doses of HER-096 are safe and well-tolerated in PD patients. The trial was designed to take place in two parts (Exhibit 7). Part 1, which was completed in November 2024, tested single doses of HER-096 in elderly healthy volunteers (n=8; dose: 300mg) and confirmed the safety and tolerability of the candidate, while completing the CSF PK profile with extended sampling timepoints in elderly healthy volunteers. Results from Part 1 also aligned with the PK data from the prior Phase Ia trial. Part 2 of the Phase Ib trial is currently ongoing, assessing safety and tolerability, as well as the PK profile, with repeated dosing. Exploratory biomarker analyses are also ongoing, aiming to evaluate biological responses to the treatment.

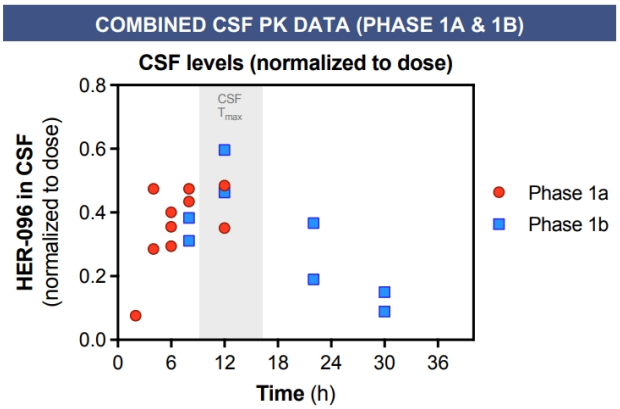
Exhibit 7: Design of the ongoing Phase Ib trial for HER-096 in PD patients



Source: Company resources

An interim update was presented in January 2025, confirming that the first patient had been dosed in Part 2 of the Phase Ib trial, while also showcasing the latest insights from the PK data, from Phase Ia and Part 1 of Phase Ib (Exhibit 8). The results to date show elimination of HER-096 from the CNS by c 48 hours, supporting a potential dosing regimen of every 2–3 days. The most recent update was in May 2025, which confirmed that the Phase Ib trial had progressed to dosing the second (and final) cohort of patients. Management has communicated that the Phase Ib trial results are on track to be reported in September 2025, and we believe this could be the most significant upcoming catalyst for Herantis.

Exhibit 8: Combined single-dose CSF PK data for HER-096



CSF concentration of HER-096 in Phase 1b	
Mean concentration (ng/ml)	95.7 (range: 26.7 – 179)

Note: Subjects received a single 300 mg dose s.c. and were sampled at different timepoints post-dosing at 8-30 h (a single lumbar puncture per subject). Phase 1b CSF data is QC'd but final report is pending completion of the whole study.

Source: Company resources

A key component of the clinical development of HER-096 is the exploration of novel biomarkers that demonstrate biological responses to treatment. This is being funded through a €2.5m grant from the EIC, and is referred to as Herantis's EIC Accelerator project, ReTreatPD. As part of this, Herantis received €1.4m in grant financing in 2023, and a €750k milestone payment in June 2024. The grant project was finalised in April 2025 and we understand that Herantis is now in the process of reporting the outcome, including project costs to EIC. Herantis is also being financially supported by a consortium of the MJFF and Parkinson's UK Virtual Biotech, each contributing €1.8m towards the Phase Ib trial, including the biomarker project. (Further details on the company's financials are discussed below.)

The biomarkers selected to be evaluated aim to explore:

- the biological definition of disease and/or disease subtype,
- fluid biomarkers (measured in plasma and CSF), and
- potential use as a digital biomarker, using the Parkinson's KinetiGraph (PKG) wearable actigraphy device (for continuous monitoring of bradykinesia and dyskinesia symptoms).

We understand that the outcomes of the biomarker project are likely to be shared in Q425, after topline results from the Phase Ib trial. This could support the company as it prepares for Phase II.

HER-096 has broad commercial potential

As stated earlier, there is currently no cure for PD, and current treatment options, while often effective in alleviating symptoms, do not slow or prevent disease progression. As a direct consequence, PD represents a major economic and societal burden, estimated (in 2017) at US$25.4bn for direct medical costs and US$26.5bn in indirect and non-medical costs in the US alone (the largest addressable market). We therefore highlight that there is a significant unmet medical need for disease-modifying treatment options. The global treatment market for PD therapeutics was estimated to be worth US$6.6bn in 2024 and is projected to reach US$13.3bn by 2034, corresponding to a compound annual growth rate (CAGR) of 7.3%. We believe this sizeable estimated CAGR largely stems from expected developments in disease-modifying options.

Although in the early stages of development, Herantis is positioning itself to target this commercial opportunity, which could be lucrative, even if only a modest portion of the market is captured. However, we note that Herantis will likely require a partnering deal to take HER-096 through to the subsequent stages of clinical development and potential commercialisation. While the company is currently in preparations for Phase II, we understand that management is seeking a global development partner, preferably before commencing Phase II studies (tentatively planned to start in H226, contingent on supportive results in Phase Ib and pending financing). The company is open to different partnering models, and believes that a suitable partnership may expand the opportunity for HER-096 beyond PD to additional indications, such as Alzheimer's disease, amyotrophic lateral sclerosis and/or Huntington's disease.

Indeed, we note that big pharma companies are showing a growing interest in the space. For example, GSK signed a US$650m biobuck deal in late-2024 with Vesalius for a PD programme. More generally, CNS is experiencing a resurgence, as reflected in four multi-billion-dollar acquisitions of biotech players within the last 18 months: Cerevel Therapeutics (by AbbVie at a 22% premium), Karuna Therapeutics (by Bristol Myers Squibb at a 53% premium), Longboard Pharmaceuticals (by Lundbeck at a 54% premium) and, most recently (announced during the J.P. Morgan Healthcare Conference in January 2025), Intra-Cellular Therapies (by Johnson & Johnson at a 39% premium). We highlight that, to our knowledge, HER-096 is the only clinical candidate in the PD therapeutic development pipeline targeting the UPR pathway, meaning its novel mechanism of action could give it a competitive edge. Furthermore, HER-096 may have applicability in other related CNS indications, which would broaden its commercial potential, though we await further news on this front.

Management team

CEO: Antti Vuolanto, DSc (Tech), started in his current role in July 2022. He joined Herantis Pharma in February 2018 as chief operating officer (COO). Antti has vast experience in financing, partnering, research, development and manufacturing of biological drugs. Previously he served as COO at Valo Therapeutics, executive vice president at Targovax and COO and co-founder at Oncos Therapeutics, which merged with Targovax in 2015. Dr Vuolanto graduated as a doctor in science and technology at Aalto University, Finland, in 2004 in bioprocess engineering.

See below for an Edison TV executive interview we recently conducted with Antti Vuolanto**.**

CFO: Tone Kvåle joined Herantis as CFO in October 2020. She has more than 25 years of experience from the biotech, medtech and life sciences industry. She has previously held CFO roles at Nordic Nanovector (a publicly listed company), NorDiag (a publicly listed company), Kavli Holding and Dynal Biotech, as well as senior management positions at Invitrogen/Life Technologies, in the US, now part of Thermo Fisher. She is board member and audit committee chair of Medincell (MEDCL), France, and LifeCare (LIFE), Norway. She has been a board member and chair of the audit committee of Bonesupport (BONEX), Sweden from December 2016 until May 2022. Tone has a diploma in finance and administration from UiT, The Arctic University of Norway, Harstad. She has completed the prescribed course of study and the examination for Advanced Programme in Corporate Finance at The Norwegian School of Economics, NHH.

CSO: Henri Huttunen co-founded Herantis Pharma in 2008 and served as the company's founding CEO for the first two years. Dr Huttunen is currently the CSO of Herantis. Dr Huttunen has previously held research positions at the University of Helsinki, Orion Pharma and Massachusetts General Hospital, Harvard Medical School (USA). Dr Huttunen has a PhD in biochemistry from the University of Helsinki and 25+ years of experience in neuroscience research. As an adjunct professor, Dr Huttunen previously led an academic research group focusing on molecular mechanisms of neurodegenerative diseases at the Neuroscience Center, University of Helsinki.

Herantis Pharma – Edison TV executive interview

Source: Edison Investment Research

Sensitivities

Herantis is subject to the typical risks associated with drug discovery and development. As a pure-play biotech, the company may be affected by delays or failures in ongoing or future clinical programmes, regulatory discussions and decisions, the successes of competitors in the space, potential partnering setbacks, as well as risks corresponding to financing and the potential commercialisation of its drug candidate.

More specifically for Herantis, the company is currently reliant on a single clinical development programme to drive its current value and future value proposition. This accentuates Herantis's exposure to binary risk events, mainly, the success or failure of its ongoing Phase Ib clinical trial for HER-096 in PD patients, with the September 2025 readout of utmost importance.

Access to financing is another key overriding sensitivity associated with all early clinical-stage biotechnology companies. Herantis has to date supported its preclinical and clinical activities through a combination of equity issuances, grants and sources of non-dilutive funding. The MJFF and Parkinson's UK Virtual Biotech, as well as the EIC, are supporting the Phase Ib HER-096 trial as well as the biomarker project. Following its most recent equity fundraise in February 2025, the company would be projected to have capital at hand to fund operations approximately to mid-2026, assuming that recent cash burn rates remain similar going forward. We note that Herantis also has an investment (equity) commitment in place from the EIC Fund (€3.2m out of €15m invested to date), adding some confidence in Herantis's ability to raise further capital (the EIC may participate with up to one third of the aggregate capital raised in future raises). However, with an extended time to market, the potential of dilution for current shareholders is an ongoing risk, should future funds be raised through equity issuances. Further, the timing for future development is also contingent on obtaining timely financing, which is not assured.

In terms of partnering, Herantis is currently seeking partnership opportunities with the goal of ensuring it has resources to see HER-096 through to potential commercialisation. Management has communicated that it is open to a range of partnering models, including: out-licensing to a global partner; strategic investment by a global partner through to a specific stage of development; research collaborations; and regional deals. Herantis's FY24 annual report stated that it has had discussions with dozens of pharmaceutical companies about partnerships, and that the company received positive feedback. While encouraging, we highlight that the timing and scope of such deals can be difficult to predict, which should be an important consideration for investors. The Phase Ib HER-096 trial readout could be a trigger to

accelerate these discussions and the launch of a potential partnership.

Financials

Herantis reported its FY24 results in March 2025. As an early-stage clinical development company, it is yet to generate a recurring revenue stream, though operations are supported by periodic equity issuances, as well as various grants and non-dilutive funding. In FY24, other operating income was reported as €1.6m, mainly related to the grant for the EIC Accelerator project, ReTreatPD, which is progressing as planned with the ultimate aim of monitoring target engagement and treatment response to HER-096 from Phase II and beyond. The grant, €2.5m in total to be paid in three instalments, was announced in April 2023, and Herantis received €1.4m in grant financing in 2023, a €750k milestone payment in June 2024, and the grant project was finalised in April 2025.

Also supporting the company's ongoing clinical activity is the €3.6m research funding, announced in July 2024, from the MJFF and Parkinson's UK Virtual Biotech (each contributing €1.8m). This funding is intended to finance the Phase Ib trial of HER-096 in PD as well as the ongoing biomarker project. It is paid in cash to Herantis over two years, in three tranches, based on completion of pre-agreed milestones. Repayment of this research funding is only required should Herantis enter into a licensing or sub-licensing agreement, if HER-096 generates product sales, or if there is a change of control of the company or intellectual property rights related to the drug candidate. Contingent on the commercial success of HER-096, no more than 10% of the cash or non-cash consideration the company receives will be repaid to MJFF and Parkinson's UK Virtual Biotech, until the maximum of four times the research funding is received. At end-FY24, Herantis had received €2.2m of this funding, however, this is not reflected as income in the company's financial statements; rather, it is reflected as long-term debt.

For FY24, Herantis's operating expenses amounted to €6.6m, up from €5.2m in FY23. Of this, R&D expenses were €3.6m, up from €2.7m in FY23, with the increase primarily related to conducting the Phase Ib clinical trial, chemistry, manufacturing and controls expenses, preparations for Phase Ib and Phase II, as well as the development of biomarkers for HER-096. The overall increase in operating expenses was somewhat offset by a slight decrease in payroll and related expenses, €1.5m in FY24 versus €1.7m in FY23, due to lower bonus payments to employees. Overall, Herantis reported a net loss of €4.9m for FY24, versus profit of €280k in FY23. The reason for this disparity is mainly driven by the decision from Business Finland in September 2023 to waive €4.5m of the principal amount of the loans granted by it to Herantis for the development of CDNF; this was recorded as other operating income in FY23.

At end-FY24, Herantis had a net debt position of €51k (including €2.1m in gross cash and cash equivalents, and €2.2m in long-term debt). The cash position was subsequently bolstered by a directed share issue in February 2025, raising €5.2m in gross proceeds through the issuance of 3.9m new shares at €1.32 per share (corresponding to a discount of c 12% to the closing price on 6 February 2025). We reiterate that in April 2023 (alongside the €2.5m grant from EIC), Herantis announced it was also eligible to receive up to €15m in direct equity investments from the EIC Fund, where the EIC Fund may participate with up to one third of the aggregate capital raised in future capital raises by Herantis. As of February 2025, €3.2m of this had been invested by the EIC Fund (€1.7m from the directed share issue in February 2025, and €1.5m from the directed share issue in December 2023).

Based on historical burn rates (cash outflow from operations of €6.5m in FY24, slightly higher than prior periods due to higher operating expenses related to the Phase Ib trial), if we conservatively assume the burn rate is similar going forward, the cash position would be projected to last approximately to mid-2026. This would be past the conclusion of the Phase Ib HER-096 trial (guided by management in September 2025) as well as the biomarker project (expected by end-2025, according to management), and potentially with additional operational headroom to secure a suitable partnership and/or commence Phase II studies for HER-096 in PD (tentatively planned for H226, contingent on supportive results in Phase Ib and pending financing).

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London | New York | Frankfurt
20 Red Lion Street
London, WC1R 4PS
United Kingdom