

Herantis Pharma

Sector: Biotech

Soon again a (stronger) clinical company

Redeye revisits its view of Herantis in the wake of the company's shifted strategy toward HER-096 – an engineered derivative of its previous lead drug CDNF that allows for non-invasive administration. We slightly raise our base case to SEK 24 per share (22) and expect Herantis to take the important step back into the clinic now in H1 2023.

Research at the forefront

An investment in Herantis, we argue, is a bet on the company's strong scientific foundation which – if successful – could revolutionize the field of Parkinson's disease and yield blockbuster peak sales. We argue that the company has made significant progress in the last year – most notably its pivot towards HER-096.

Clear path towards the clinic

Since our last review of the case, Herantis has made further pipeline progress, especially with HER-096 and its upcoming phase I trial. We argue that Herantis approach to Parkinson's has become increasingly compelling and that the pre-clinical data with HER-096 indicates that it has solved the key challenges we saw in our initiation report.

We make some minor adjustments

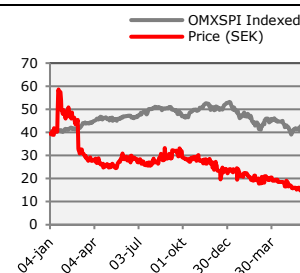
We make some minor changes to our valuation, mainly relating to the increased commercial potential of HER-096 but also slightly different risk profile and deal structure. We also raise our discount rate due to the higher risk-free rate and adjust our Fx assumptions. We land at a base case of SEK 24 per share (SEK 22 per share).

Key Financials (EURm)	2019	2020	2021	2022E	2023E
Revenues	0	0	0	0	0
Revenue growth	NA	NA	NA	NA	NA
EBITDA	-7	-7	-10	-9	-6
EBIT	-7	-8	-12	-9	-6
EBIT Margin (%)	NA	NA	NA	NA	NA
Net Income	-8	-9	-13	-9	-6

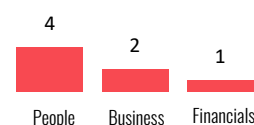
FAIR VALUE RANGE

BEAR	BASE	BULL
4	24	55

Herantis VERSUS OMXSPI



REDEYE RATING



KEY STATS

Ticker	HRNTS
Market	First North
Share Price (SEK)	22
Market Cap (SEKm)	371
Free Float (%)	55%

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Investment Thesis

Case: Soon again a (stronger) clinical company

Herantis Pharma is a Finnish biotech company developing a drug candidate in the difficult area of Parkinson's disease, an area with great potential to improve the standard of care. The case hinges on blockbuster potential in this expanding market, supported by experienced management, institutional ownership, and a prospective licensing deal. We see an upside of today but argue that the longer-term upside is more compelling – especially if Herantis takes the important step back into the clinic and de-risks the compound further.

Evidence: Research in the Forefront

No disease-modifying drugs have yet been approved for Parkinson's disease. The current treatment regime, while initially effective in relieving symptoms, becomes less effective over time. Payers and doctors emphasize the need for a disease-modifying treatment that can stop and reverse this chronic neurodegenerative disease's progression, preventing the high costs and low quality of life associated with late-stage Parkinson's. While the Parkinson's market is relatively modest in size in view of the disease's economic burden (USD 4.5bn across the US, EU5, and Japan), we expect it to grow rapidly as new treatments emerge. We estimate the peak sales for Herantis alone at more than USD 3bn.

Supportive analysis:

We find the scientific foundation of Herantis' lead candidate CDNF compelling, despite its early stage. This is reinforced by the high interest from the science community, including several publications in leading journals such as Nature and early interest from significant investors. The case is based on the science of HER-096s multimodal mode of action, which differentiates it from other Parkinson's candidates. Furthermore, the candidate's broad mode of action makes it less dependent on a full understanding of the underlying pathological features. This adds to its attractions, given the current scientific knowledge gap and lack of established biomarkers.

Challenge: Dependent on partnering or additional funding

Herantis is a pre-clinical biotech company with an expensive clinical program going forward. Herantis will likely need additional funding in the upcoming 12-18 months, in our view. The best strategy would likely be a licensing deal with a non-dilutive upfront payment after phase I, but an alternative would be to take HER-096 into phase II on its own, which would require additional cash.

Challenge: Risky Inflection Points Remain

Herantis develops HER-096 in-house in the early clinical stage, and risky inflection points (most notably phase II readouts) remain in the company.

Valuation: Compelling long-term potential

Our base case for Herantis is SEK 24 per share, indicating a small upside from today's (very volatile) levels. We see an even more compelling investment case over time as Herantis takes the important step back to clinic with HER-096.

Catalysts

Further pre-clinical progress/initiation of phase I trial

We expect the phase I trial with HER-096 to start in H1 2023 and then top-line data by H2 the same year. Positive results (as we expect) would further de-risk the compound both in terms of safety and in ensuring successful blood/brain barrier delivery in humans.

Licensing deal for clinical candidate

Herantis business model revolves around out licensing the asset to a larger pharmaceutical company. We note that licensing agreements for Parkinson's candidates can occur as early as in the pre-clinical stage, but also note that there is a lot of variability. We assume a licensing deal after the first evidence of efficacy to stay conservative at this stage, but note that HER-096 could be outlicensed sooner.

Counter-Thesis

High development risks

In most early-stage biotech companies, development risks are high, and Herantis is no exception.

Failure to attract enough capital

We estimate that Herantis requires additional funding in 2024.

Loss of key personnel

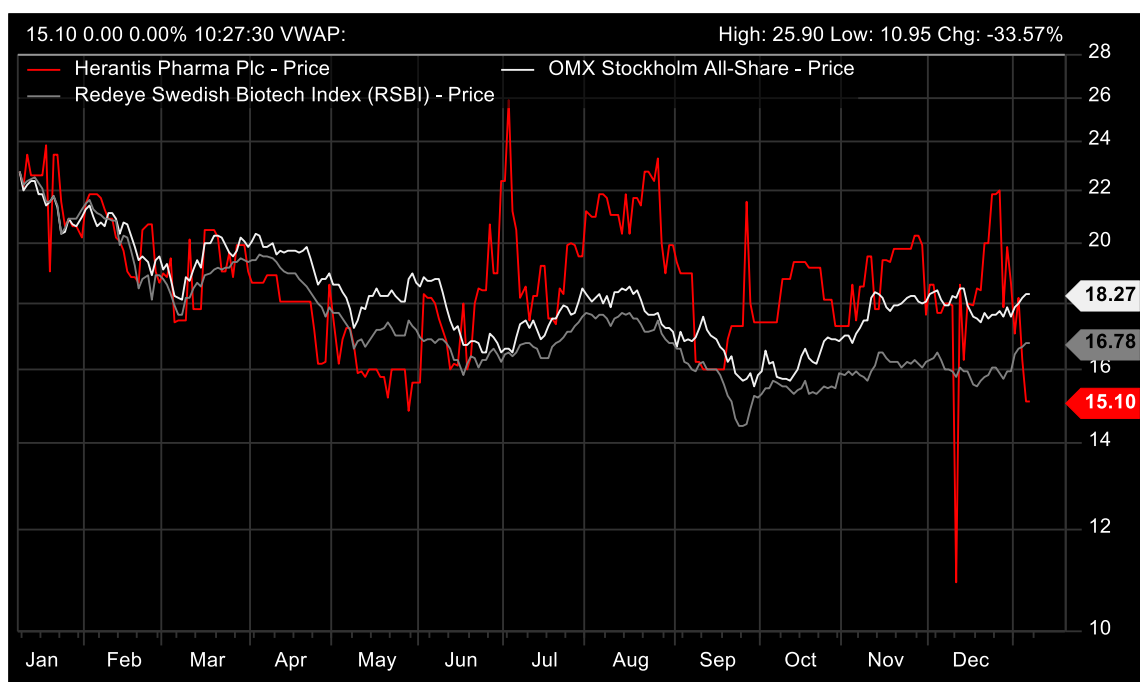
As with all small biotech companies, loss of key personnel, including R&D, would be a setback for the company.

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Share Price Development (1 Year)



Over the past year, Herantis stock has traded in a relatively volatile manner but has largely followed our Swedish Biotech Index (RSBI)¹ during the period. In December, it was announced that the stock will be delisted on the Swedish exchange and only be traded on First North Helsinki, partly due to low liquidity.

Ownership Structure

#	Holders	Herantis	Capital	Votes
1	Kyösti Kakkonen	1750559	10,35%	10,35%
2	Swedbank Robur Fonder	1506029	8,90%	8,90%
3	Nanoform Finland Oyj	1165404	6,89%	6,89%
4	Sp-Fund Management	1136691	6,72%	6,72%
5	Fjärde AP-fonden	966539	5,72%	5,72%
6	Veritas Pension Insurance Company	596522	3,53%	3,53%
7	University of Helsinki Funds	572678	3,39%	3,39%
8	OP Asset Management	554497	3,28%	3,28%
9	Nordea Fonder	331786	1,96%	1,96%
10	Inveni Capital	237013	1,96%	1,96%

Source: Holdings/Modular Finance: Redeye Research

We argue that Herantis has a very strong ownership list, including several institutions and industrial partner Nanoform, noteworthy for an early-stage biotech company.² This, we judge, is a key reason for the relatively stable valuation and continued efficient capital injections.

¹ RSBI consists of roughly 90 Swedish Biotech Companies

Background

Herantis Pharma Plc was founded in Helsinki, Finland, in 2008 by four neuroscientists from the University of Helsinki. The company was initially called Hermo Pharma Ltd. In 2014, it acquired Finnish drug development company Laurantis Pharma Ltd and changed its name to Herantis Pharma Plc. The company's headquarters are in Finland, it was publicly listed on Nasdaq First North Helsinki in 2014 and Stockholm in 2019, and had 11 employees in 2022.

The company's lead asset is HER-096, a disease-modifying compound that targets Parkinson's disease. It is an engineered peptide based on active fragments of CDNF, a human protein that previously was Herantis lead candidate. HER-096 is administered via simple skin injection and is able to cross the blood-brain barrier non-invasively. CDNF, the predecessor to HER-096, has been tested in a phase Ib/IIa trial, where CDNF was administered directly to the brain of late-stage patients by surgical means. HER-096 has a unique mode of action and acts through the maintenance and restoration of proteostasis, a process that can, if interrupted, in Parkinson's lead to neuronal cell death and the accumulation of protein aggregates – the two key pathological features of the disease.











At present, there are no disease-modifying drugs approved for Parkinson's and the current treatment paradigm is based on Levodopa, a symptom-relief treatment with tapering efficacy over time. The demand for approved disease-modifying therapies is high, and while the market size is relatively modest compared to the incidence, due to generics and limited treatment options (USD 4.5bn in US, EU5 and Japan), the willingness to pay is high to reverse this chronic degenerative disorder. We expect the market to grow rapidly as new treatments emerge.

Herantis Pharma: Clinical Projects Under Development

Project	Indication	Research	Pre-clinical	Phase I	Phase II	Phase III	NDA	Market
HER-096	Parkinson's Disease							
	Completed development phase							
	Potential external development							
	Ongoing phase							

Major Events and Financing Rounds – Herantis Pharma

Year	Event
2008	- Herantis Pharma founded by professors from University of Helsinki; focused on a CDNF portfolio
2010	- Received grant from Michael J Fox Foundation for CDNF Research
2014	- Acquired Laurantis Pharma. Herantis Pharma is established with the original CDNF assets plus new lymphedema assets - IPO on Nasdaq First North Finland; raised EUR 14.5m
2015	- Announced negative phase II (n=161) results in dry eye disease - Business Finland granted Herantis almost EUR 3m as an R&D loan for the development of CDNF
2016	- Started Lymfactin phase I trial - EUR 6m grant for CDNF development from EU Horizon 2020
2017	- Directed share issue of EUR 4.7m - Started CDNF clinical phase I-IIa trial
2018	- Started Lymfactin phase II trial - xCDNF program started
2019	- Directed share issue of EUR 5.8m - IPO on Nasdaq First North Stockholm and directed share issue of EUR 4.2m
2020	- Directed share issue of EUR 15m - Craig Cook appointed CEO and Tone Kvåle CFO - Positive outcome of CDNF phase I-IIa - Strategic shift away from invasive intracranial administration; changed clinical development plan
2021	- Strategic partnership with Nanoform on novel CDNF formulation method - Lymfactin phase II results announced - Strategic direction shifted fully to neurodegenerative diseases with CDNF and xCDNF - Directed share issue of EUR 4m
2022	- Craig Cook leaves role of CEO and Herantis shifts its focus to HER-096 (xCDNF) - Raises in total EUR 9 million in directed issue and rights issue - Antti Vuolanto Appointed role as CEO - Submits CTA application

Name	Position
 Antti Vuolanto Doctor of Science in Technology at Aalto University. Vast experience in research, development and manufacturing of biological drugs. Antti has worked in various senior management positions in early stage biotech companies. Prior to his work as CEO of Herantis, Antti served as the COO of Veb Therapeutics, Executive Vice President at Targovax, and COO and co-founder of Oncos Therapeutics Ltd which merged with Targovax.	CEO
 Tone Kvåle CFO Tone Kvåle joined Herantis in October 2020 and she has more than 25 years of experience from the biotech and life sciences industry. She held CFO roles at Nordic Nanovector (publicly listed company), NorDiag (publicly listed company), Kavi Holding, Dynal Biotech, as well as senior management positions at Invitrogen/Life Technologies, in US, now part of Thermo Fisher. In these roles, she helped raise over EUR 200m in financing, was involved in IPOs and M&A's and was responsible for financial reporting under various reporting standards including US GAAP and IFRS. She is member of board and audit committee president of MedinCell (MEDCL), France and has been board member and chair of the audit committee of Bonesupport AB (BONEX), Sweden from December 2016 until May 2022. Tone has a diploma in finance and administration from UiT, The Arctic University of Norway, Hørsfjord. She has completed the prescribed course of study and the examination for Advanced Programme in Corporate Finance at The Norwegian School of Economics, NHH.	Chief Financial Officer
 Henri Huttunen PhD in biochemistry from the University of Helsinki. Vast experience of research in neuroscience. Henri has led an academic research group focusing on molecular mechanisms of neurodegenerative diseases at the Neuroscience Center, University of Helsinki. Other previous assignments includes research positions at the University of Helsinki, Orion Pharma and Massachusetts General Hospital.	Chief Scientific Officer
 Charlotte Videbæk Board-certified neurologist with a track record from international pharmaceutical companies developing therapies for neurodegenerative diseases, including Parkinson's disease. Prior to her work at Herantis, Charlotte worked at Novartis, Roche and Lundbeck where she held various positions including VP Corporate Project Management R&D.	Vice President Clinical Development
Source: Redeye Research	
Name	Position
 Timo Veromaa PhD in immunology from the University of Turku and Special Competence in Pharmaceutical Medicine from the Finnish Medical Association. Vast experience in leading positions within biotech and life sciences industry. Prior experience includes chairman of Domainex Ltd, CFO of Biotie Therapies Corp. Other current assignments includes Chairman of Finnish BioBanks FINBB.	Chairman of the board
 Frans Wuite MBA, Business Administration from Tilburg University. Long international career with a track records of successfully commercializing and growing pharmaceutical and biotech businesses. Previous assignments includes CEO of Acesion Pharma ApS, Oncos Therapeutics Oy, COO of Warren Pharmaceuticals Inc, Co-founder and Board Member of Araim Pharmaceuticals. Frans is also a current board member of Healthcap VII GP SA and Nukute Oy.	Director
 Jim Phillips Current CEO of PAIGON AG a commercial stage pharmaceutical company. Previous assignments includes CEO of Imevax GmbH, CEO for Midatech Pharma PLC, President of EUSA Pharma Europé, and CEO & Founder in Talisker Pharma.	Director
 Aki Prihti Current CEO of Aplagon Oy, CFO and board member of MedTentia International Ltd Oy. Aki is one of the founding partners of the venture fund management company Inveni Capital and currently serves as a board member in Dassiet Oy and Rokote Laboratories Finland Oy.	Director
 Mats Thorén Current CEO of Vixco Capital. Mats is one of the founding partners of Catella Healthcare which is an investment firm in the Healthcare business. Mats has also been a first ranked equity research analyst in Sweden with SEB and the Head of Swedish Healthcare with SHB Markets Corporate Finance. Current assignments includes board member of Arcoma AB, Xbrane Biopharma AB and FluoGuide AS.	Director
 Hilde Furberg Hilde Furberg was elected to the Herantis Pharma board in 2021. Hilde Furberg has worked in companies such as Genzyme and Baxter, she was most recently SVP and General Manager / European Head of Rare Diseases at Sanofi Genzyme. Since 2005, Hilde has also worked as non-executive director and Board member of Probi, Pronova, Clavis, Bergenbio and Algeta. She holds a Master of Science from the University of Oslo.	Director
Source: Redeye Research	

Recap – Market for Parkinson's Treatments

Parkinson's disease is the second most common neurodegenerative disease and affects 0.1-0.2% of the world population. Parkinson's is positively correlated with age and roughly 1% of the population aged over 60 get the disease. In total, roughly 2 million in EU5, the US, and Japan have Parkinson's and receive some form of treatment. 1.3 million of these patients are in the early stages, defined as 1-3 on the Hoehn-Yahr scale, which we define as the primary market for CDNF in its new administration form. The prevalence of Parkinson's is expected to grow in the upcoming decades, mostly due to an aging population.

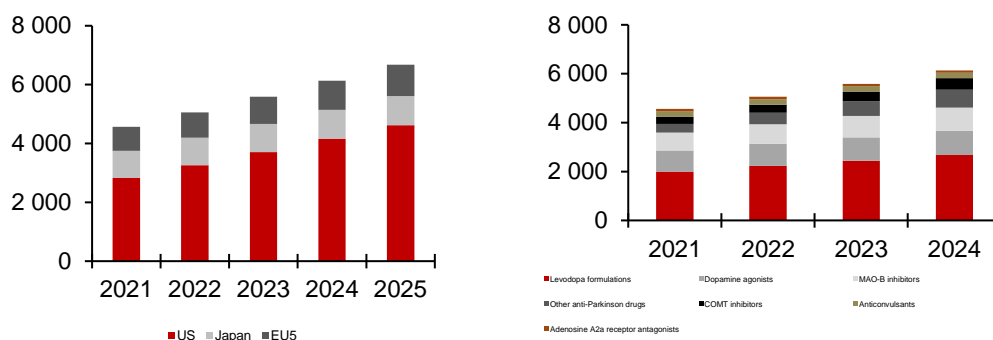
The current Parkinson's market is relatively modest in size (USD 2-4bn) due to the current drugs mainly being generics with limited efficacy and problematic side effects. Given the high and increasing disease burden and the innovative treatments in the pipeline, we expect the market to grow rapidly in the upcoming decade.

The Parkinson's drug market in the EU5, Japan, and the US is worth roughly USD 4.5bn today and largely consists of mainstay drug classes and combination therapies. As we can see in the graph above to the right, Levodopa formulations are the highest-selling class, followed by dopamine agonists. Due to innovation and an aging population, growth is expected to remain high in the coming years and decades. The high rate of Parkinson's generics means the pharmaceutical cost per patient is relatively low today in comparison to other neurological diseases – although niche products, such as Duopa and Nuplazid, are costly treatments. However, the direct and indirect costs to society of Parkinson's patients is high; health economic studies have shown annual costs exceeding USD 20bn in the US alone. As innovative and disease-modifying drugs reach the market, we expect costs to increase in relation to the increased benefits.

Unmet Need and the Pipeline of Parkinson's Therapies

While many of today's treatments are cost-efficient and clinically effective, there is an ongoing need for therapies that prevent disease progression, of which HER-096 is one. Patients today still see accumulating symptoms over time and experience a reduced quality of life, including non-motor symptoms. Non-motor symptoms are under-reported and are not effectively targeted with today's treatment regime. According to Datamonitor, disease modifying therapies are by far the most desired progress preferred amongst clinicians. Furthermore, payers' interest is high owing to the health economic benefits – late-stage Parkinson's in particular is associated with morbidity and a high economic burden to society.

Estimated market (USDm) US, EU5 and Japan – Parkinson's Disease



Source: Biomedtracker

Today's Standard of Care

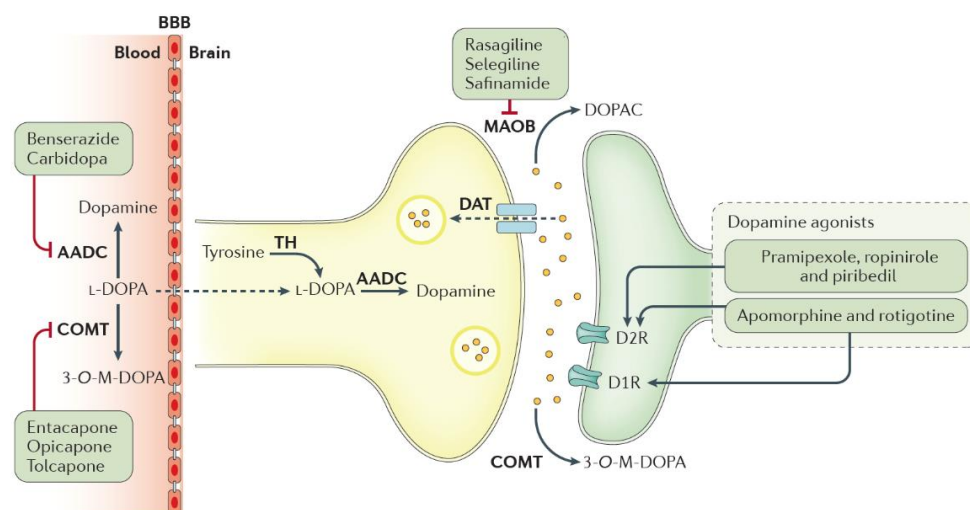
Levodopa

Today, the current treatment regime is based on symptom relief and has primarily been based on the same dopaminergic therapy paradigm since the 1970s, when the FDA approved Levodopa. Researchers discovered that Levodopa (or L-Dopa), a precursor amino acid of dopamine, can pass through the blood-brain barrier, unlike dopamine itself. Once in the central nervous system, it can convert into dopamine. The treatment rationale is to substitute the dopamine loss with systemic administration of Levodopa. The blood-brain barrier is a significant obstacle for most CNS therapies, prohibiting large molecules and most small-molecule drugs from entering the central nervous system.

While Levodopa remains a mainstay as a first-in-line drug and is the most potent treatment of motor symptoms, its use is also muddled by motor complications and tapering efficacy. Motor response fluctuations and on/off periods of symptom control are common, especially in the later stages of Parkinson's. The drug effect wears off before the next dose kicks in (the "on" period). This is partly due to the short half-life of Levodopa but also because of the level of gastrointestinal absorption and blood-brain barrier transport, as only about 10% breaches the blood-brain barrier. Long-term use of Levodopa can also induce side effects, including involuntary movements (dyskinesia), leading some patients to postpone Levodopa treatment in the early stages.

Since the development of Levodopa, there have been advances in the scientific understanding of the regulation of nigrostriatal dopaminergic transmission, increasing the role and strategy of dopaminergic therapies.

Dopaminergic Therapy Modalities



Source: Poewe et al 2017

Levodopa is typically combined with Carbidopa, an AADC-inhibitor, to increase bioavailability and prevent dopamine metabolism outside of the central nervous system, leading to reduced side effects and lower required doses of Levodopa. Another addition is COMT-inhibitors such as Entacapone, which further enhance bioavailability and the half-life of Levodopa. This combination is currently the first-in-line for patients experiencing motor fluctuations (i.e. with on-off periods). Moreover, MAOB inhibitors are a class of enzymes used to reduce off time from Levodopa and as an alternative treatment in early-stage Parkinson's. In severe Parkinson's, a medical device can be inserted that delivers Levodopa by continuous intestinal administration (Duodopa intestinal gel from AbbVie). Duodopa is one of the most lucrative drugs on the Parkinson's market and several studies have shown that it reduces motor fluctuations and dyskinesia versus oral Levodopa. However, Duodopa requires an invasive installation and is also expensive. Due to its efficacy, it is deemed cost-efficient amongst payers, and sales are expected to remain high.

Finally, dopamine agonists are another class of drugs used to stimulate dopamine production. Unlike Levodopa, dopamine agonists do not convert to dopamine, but instead mimic its effects. While they have a longer half-life than Levodopa and a lower risk of leading to motor complications, their treatment effect is less and they may cause drowsiness and impulse dyscontrol.

Deep Brain Stimulation

Deep brain stimulation (DBS) is a treatment option where electrodes are implanted in specific targets in the patient's brain. Due to the invasive nature of the procedure, it has mostly been reserved for patients in advanced stages of Parkinson's but has become more accepted for early-stage patients in recent years. DBS is a complicated procedure and requires a high level of multidisciplinary expertise. Adverse events are uncommon but include intracranial bleeding and, in the worst case, death (less than 1% of cases).

DBS was initially approved by the FDA for Parkinson's in 1997 and is today also used in other indications such as obsessive-compulsive disorder, epilepsy, and major depression disorder. The treatment effect of DBS correlates with the treatment response to Levodopa, meaning

that the DBS is best used for patients who respond well to Levodopa but who have motor complication due to long-term use. Several studies have shown a significant increase in quality of life and reduced motor symptoms (up to 60-70%) with DBS.

Key Events – Parkinson’s Disease

Since our initiation report, we note that there have been relatively few significant breakthroughs in the clinic regarding disease-modifying treatments for Parkinson’s disease, and that most noteworthy events have been related to deals – and we note a continued high interest for assets in all development stages.

Irlab Licensing Agreement

In the summer of 2021, the Swedish Parkinson’s company IRLAB Therapeutics out-licensed the global rights to one of its lead assets, Mesdopetam, with a total deal value of USD 363 million and an upfront payment of USD 28 million. Although Mesdopetam targets levodopa-induced dyskinesia, i.e. more of a symptomatic approach to Parkinson’s disease, we are encouraged to see a significant licensing deal within the Nordic neurology sector – also before its phase IIb readout. We think that this licensing agreement is a good reference deal for Herantis.

Bioarctic regains rights to alpha-synuclein antibodies

In April, AbbVie announced that it terminated its collaboration with BioArctic on the alpha-synuclein antibodies targeting Parkinson’s disease. We see this as an internal business decision and a strategic re-orientation related to AbbVie’s existing Parkinson’s portfolio, rather than an indication of the clinical results from the phase I study. Although there have been a few setbacks with a-synuclein antibodies, we note that alpha-synuclein still remains an attractive target.

Biogen and Novartis buys into small-molecules targeting alpha-synuclein

We note that big pharma companies have continued to buy rights to disease modifying drug candidates – lately also small molecule approaches to alpha-synuclein reduction. This summer, Biogen paid USD 15 million upfront (and total deal value of USD 700 million) for the rights to AL01811 from Alectos Therapeutics, a small molecule drug candidate in the pre-clinical stage that selectively inhibits GBA2, hoped to correct lysosomal dysfunction. Lysosomal dysfunction has been linked to a-synuclein accumulation. In 2021, Novartis paid USD 150 million in upfront (and a total deal value of USD 1.5 billion) for UCB0599, a small molecule treatment in phase II targeting misfolded a-synuclein.

“Frontrunner” Prasinezumab set to present phase IIb data in 2024

We note that most advanced candidate among a-synuclein-targeted therapies remains to be Prasinezumab, inlicensed by Roche from Proteina in 2013. In 2020, data was released from the randomized placebo-controlled PASADENA phase II study, with mixed (at best) results. Roche now has a phase IIb study ongoing called PADOVA (n=575) and guides at clinicaltrials.gov that topline data will be released by 2024. Compared to the PASADENA trial, the PADOVA trial has a stronger focus on motor-related symptoms, which was also the area where the PASADENA trial indicated a treatment effect).

Focused Strategy on xCDNF/HER-096

In connection with the CEO transition in January 2022, it was also announced that the board of directors had decided to focus the development efforts to HER-096 (also known as xCDNF), a peptidomimetic compound that retains the therapeutics characteristics of CDFN while it is designed to breach the blood-brain-barrier non-invasively through subcutaneous injection. HER-096 has crossed the blood-brain-barrier successfully in pre-clinical models of both small animals and larger animals – a major milestone, we judge.

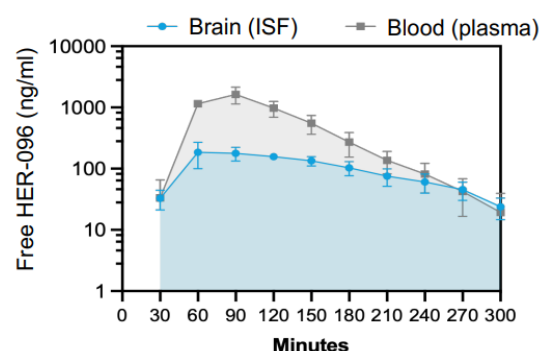
Blood-brain-barrier penetration – Small Animals

Small animals

Following a single subcutaneous injection, the concentration of free HER-096 in the brain is

>20%

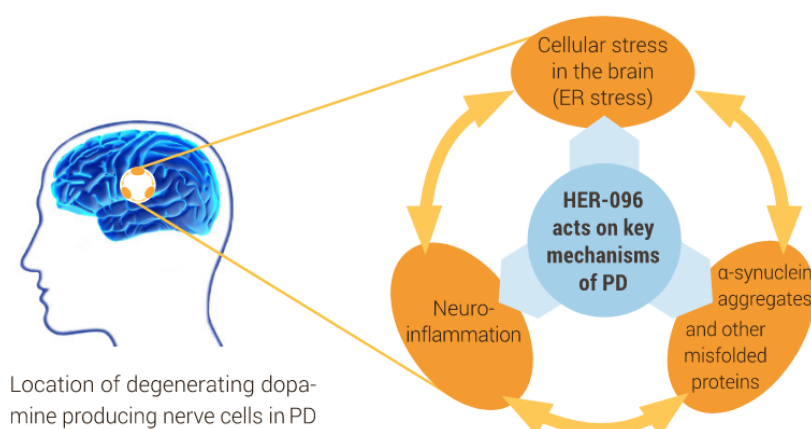
of the concentration in blood clearly exceeding the required therapeutic concentration in healthy rats



Source: Herantis Pharma

So far in pre-clinical models, Herantis has also shown that HER-096 retains the known multimodal properties of CDFN, including protecting neurons, reducing neuroinflammation and reducing α -synuclein aggregation – key biological hallmarks of the disease. Previously, Herantis developed rhCDFN and xCDFN in tandem, and the aim was to develop an intranasal injection for CDFN. Our impression is that the move to xCDFN/HER-096 was a combination of quick advancements with HER-096, a clear preference from KOLs and potential partners for easy administration and also some challenges involved with intranasal formulation of the biologic compound (rhCDFN).

Mode of Action – HER-096



Source: Herantis

Overall, we are positive to the pivot as easy administration in combination with blood-brain-barrier penetration are two key obstacles in CNS diseases that HER-096 appears to have a solution to. Furthermore, CMC and production costs are significantly lower with HER-096 compared to the recombinant protein CDNF while the patent life is significantly better. We do acknowledge that we know less about how HER-096 acts in humans however, and we make some adjustments in our valuation as a result relating to risk-adjustment.

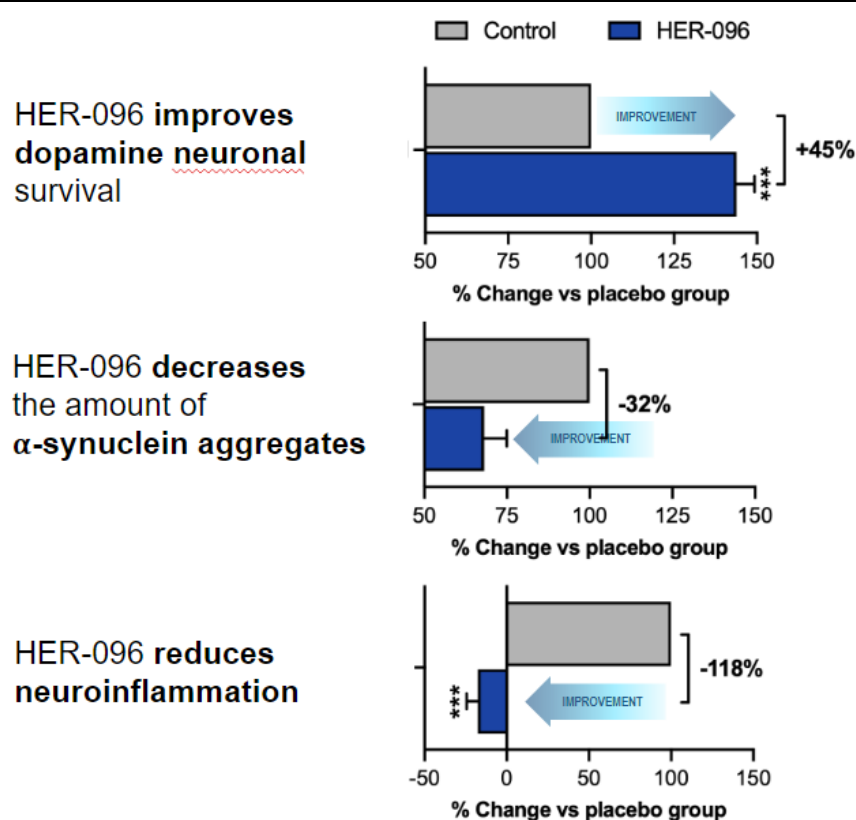
Timeline

	2022		2023	
	H2		H1	H2
HER-096	Pre-clinical safety data and clinical trial application		First human dose phase I	Phase I Data on blood-brain barrier penetration and safety

Source: Redeye Research

In terms of timeline, we expect Herantis to start the phase Ia trial in H1 of 2023 and top-line data already in H2. The next step will then likely be a dose escalation study (phase Ib), either separately or in combination with exploratory endpoints on clinical efficacy (Ib/Ila).

Pre-clinical data – HER-096



Source: Herantis Pharma

Financials

Herantis business model revolves around early development in-house with the goal to out-license its lead asset HER-096 to larger pharmaceutical companies for further clinical development.

Key figures from the H1 2022 report:

- The result for the period amounted to EUR -5.6m (-7.9m)
- Cash flow from operating activities amounted to EUR -5.6m (-5.5m)
- Cash and cash equivalents at the end of the quarter amounted to EUR 9.5m (6.9m)

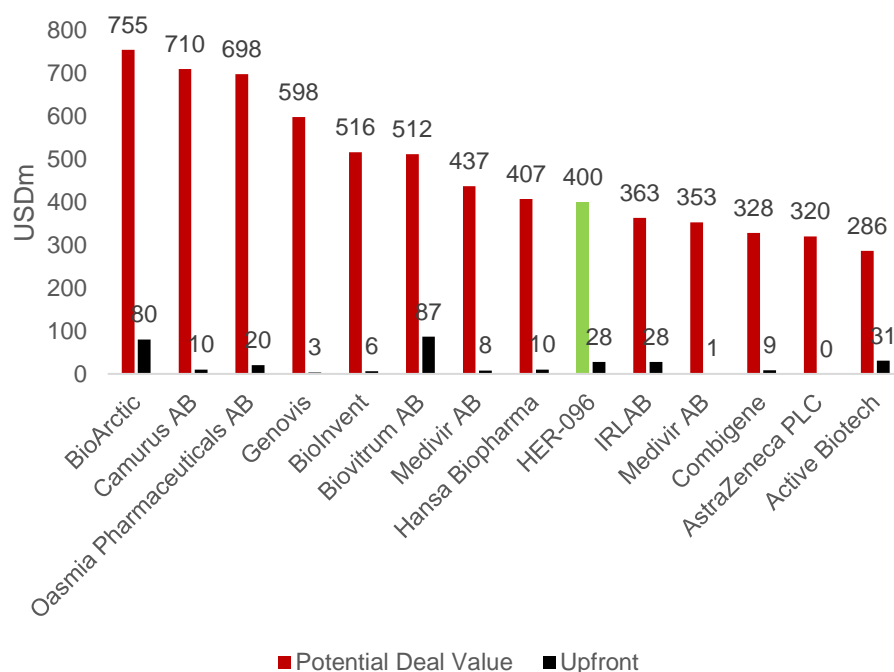
(The numbers in parenthesis refer to the corresponding quarter of last year)

Herantis raised EUR 1.5m in a directed issue (April) and EUR 7.25m in a rights issue (May), an impressive result given the turbulent markets, that especially hit a lot of early-stage biotech companies. A key factor, we believe, is the strong ownership structure.

We assess that Herantis cash runway extends into 2024 and thus beyond the phase Ia readout, as we assume lower costs in H2 2022 and 2023 following a slimmer organization, focused approach on HER-096 and completed IND- and CMC-related work.

Valuation and Assumptions

Nordic Peer Deals (Largest deals in Sweden between 2001-2022)



Source: Redeye Research; Biomedtracker

We have done further due diligence on Nordic licensing agreements and make some adjustments to our model. We note that the Irlab deal serves as a good reference deal and assume that Herantis can land a slightly larger deal (total deal value of USD 400 million) if it can show a disease modifying treatment effect in an initial efficacy trial (phase IIa). We note that Herantis goal is to out license HER-096 after phase Ia. In our base case, we choose to stay a bit more conservative and assume that efficacy data is needed to land a significant deal on par with the peer deals above, but note that licensing agreements within Parkinson's disease also can be finalized at earlier stages (as seen below). We include an earlier licensing agreement in our bull scenario. We also note that a smaller deal after phase Ia is a possibility, but we have fewer Nordic peer deals for this type of transaction.

Global Reference Deals – Parkinson's Disease

Originator	Sponsor	Candidate	Phase during Licensing	Upfront	Total (m USD)
Prothena	Roche	Prasinezumab	Pre-clinical	45	600
Neurimmune	Biogen	Cinpanemab	Pre-clinical	32.5	395
BioArctic	Abbvie	ABBV0805	Pre-clinical	50	755
Astra Zeneca	Takeda	MEDI1341	Pre-clinical	400	400+
Alectos	Biogen	AL01811	Pre-clinical	15	700
UCB	Novartis	UCB0599	II	150	1500

Source: Redeye Research; Biomedtracker

Sales Model – HER-096 in Parkinson's Disease

HER-096	2022e	2023e	2024e	2025e	2026e	2027e	2028e	2029e	2030e	2031e	2032e	2033e	2034e	2035e	2036e	2037e	2038e	2039e	2040e	2041e	2042e
	Total Milestones																				
Licensing deal milestones	400																				
Phase	Precinical	I	II	II	II	III	III	III	NDA	Market	Market	Market	Market	Market	Market	Market	Market	Market	Market	Market	Market
	95%	95%	57%	57%	57%	14%	14%	14%	14%	10%	9%	9%	9%	9%	9%	9%	9%	9%	9%	9%	9%
US																					
Total patients	878 352	902 796	927 848	953 571	978 600	1 003 630	1 028 604	1 053 402	1 077 942	1 099 804	1 120 809	1 141 154	1 160 998	1 180 507	1 196 644	#####	1 250 159	1 272 850	1 272 850	1 272 850	1 272 850
Receiving Treatment	92%	807 341	829 809	852 835	876 479	899 485	922 491	945 446	968 239	990 795	1 010 890	1 030 197	1 048 896	1 067 137	1 085 068	1 099 901	#####	1 149 089	1 169 946	1 169 946	1 169 946
Early Stage	63%	508 625	522 780	537 286	552 182	566 675	581 169	595 631	609 990	624 201	636 861	649 024	660 805	672 296	683 593	692 938	701 732	723 926	737 066	737 066	737 066
Market share		0%	0%	0%	0%	0%	0%	0%	0%	0%	1%	4%	6%	8%	9%	10%	10%	10%	10%	10%	10%
Compliant	70%	356 038	365 946	376 100	386 527	396 673	406 818	416 941	426 993	436 941	445 803	454 317	462 563	470 607	478 515	485 056	491 213	506 748	515 946	515 946	515 946
Treated Patients		-	-	-	-	-	-	-	-	-	4 543	18 503	29 178	38 281	43 655	46 665	50 675	51 595	51 595	51 595	51 595
List price	35000	35 000	35 000	35 000	35 000	35 000	35 000	35 000	35 000	35 000	35 875	36 772	37 691	38 633	39 599	40 589	41 604	42 644	43 710	44 803	45 923
Sales \$mm		-	-	-	-	-	-	-	-	-	167	697	1 127	1 516	1 772	1 941	2 161	2 255	2 312	2 369	2 429
EU5																					
Total patients	798 314	813 208	827 899	842 445	858 080	872 894	887 396	902 144	917 601	934 464	950 791	966 894	983 216	1 000 284	1 017 317	#####	1 033 768	1 033 768	1 033 768	1 033 768	1 033 768
Receiving Treatment	92%	693 008	705 938	718 691	731 318	744 891	757 751	770 340	783 143	796 560	811 199	825 373	839 352	853 520	868 337	883 123	897 404	897 404	897 404	897 404	897 404
Early Stage	63%	408 875	416 503	424 028	431 478	439 486	447 073	454 501	462 054	469 971	478 608	486 970	495 218	503 577	512 319	521 042	529 469	529 469	529 469	529 469	529 469
Market share		0%	0%	0%	0%	0%	0%	0%	0%	0%	1%	4%	6%	8%	9%	10%	10%	10%	10%	10%	10%
Compliant	70%	265 769	270 727	275 618	280 461	285 666	290 597	295 425	300 335	305 481	311 095	316 530	321 891	327 325	333 007	338 678	344 155	344 155	344 155	344 155	344 155
Treated Patients		-	-	-	-	-	-	-	-	-	2 691	10 944	17 250	22 644	25 909	27 790	29 253	29 253	29 253	29 253	29 253
List price	17500	17 500	17 500	17 500	17 500	17 500	17 500	17 500	17 500	17 500	17 500	17 500	17 500	17 500	17 500	17 500	17 500	17 500	17 500	17 500	17 500
Sales \$mm		-	-	-	-	-	-	-	-	-	60	251	406	546	641	704	760	779	798	818	889
JP																					
Total patients	175 509	178 339	180 845	182 935	184 191	184 934	185 370	185 777	186 345	186 535	186 713	186 938	187 258	187 736	187 861	188 008	188 008	188 008	188 008	188 008	188 008
Receiving Treatment	92%	175 509	178 339	180 845	182 935	184 191	184 934	185 370	185 777	186 345	186 535	186 713	186 938	187 258	187 736	187 861	188 008	188 008	188 008	188 008	188 008
Early Stage	63%	108 815	110 570	112 124	113 420	114 199	114 659	114 929	115 181	115 534	115 652	115 762	115 901	116 100	116 396	116 474	116 565	116 565	116 565	116 565	116 565
Market share		0%	0%	0%	0%	0%	0%	0%	0%	0%	1%	3%	5%	6%	7%	8%	8%	8%	8%	8%	8%
Compliant	70%	70 730	71 871	72 881	73 723	74 229	74 529	74 704	74 868	75 097	75 173	75 245	75 336	75 465	75 658	75 708	75 767	75 767	75 767	75 767	75 767
Treated Patients		-	-	-	-	-	-	-	-	-	602	2 411	3 743	4 842	5 451	5 758	6 061	6 061	6 061	6 061	6 061
List price	17500	17 500	17 938	18 386	18 846	19 317	19 800	20 295	20 802	21 322	21 855	22 401	22 962	23 536	24 124	24 727	25 345	25 979	26 628	27 294	27 976
Sales \$mm		-	-	-	-	-	-	-	-	-	13	55	88	117	135	146	157	161	165	170	174
Total sales (USDm)		-	-	-	-	-	-	-	-	-	241	1 004	1 621	2 179	2 547	2 792	3 078	3 196	3 275	3 357	3 441
Risk-adj. Royalties & Sales (USDm)	15%	-	-	-	-	-	-	-	-	-	36	149	241	325	379	416	459	476	488	500	513
Risk-adj. Royalties & Sales (EURm)		-	-	-	-	-	-	-	-	-	3	14	22	30	35	38	42	43	44	46	47
Risk-adj. Milestones (USDm)		-	-	-	16	-	-	2	-	11	7	1	5	2	-	-	6	-	2	-	2
Risk-adj. Milestones (EURm)		-	-	-	16	-	-	2	-	11	7	1	5	2	-	-	6	-	2	-	2

Source: Redeye Research

Our Sales Assumptions

- Market launch in 2032
- Market penetration of 10% in the US/EU and 8% in Japan
- Net pricing of USD 35000 and USD 17500 in the US and EU5/Japan, respectively
- Royalty rate of 15% in all markets
- Deal size of USD400m
- Likelihood of approval of 9%

With these assumptions, we arrive at global peak sales of USD +3 billion in Parkinsons.

Sum-of-the-parts: Herantis Pharma

Asset	Indication	LoA	Royalties	Peak sales (USDm)	Est. launch	Deal size (EURm)	rNPV (EURm)
HER-096	Parkinson's	9%	15%	3 275	2032	400	63
Project value (EURm)							63
Net cash							5,5
Shared costs incl. tax (EURm)							-32,2
Fair value (EURm)							36,4
Shares outstanding (2023)							16,9
Value per share (EUR)							2,2
Value per share (SEK)							24

Source: Redeye Research

We make some minor changes to our valuation, that leads to a slightly higher base case at EUR 2.2 (SEK 24 per share compared to SEK 22 per share).

Summary of changes:

- Raise USD/EUR exchange rate to 0.95 and EUR/SEK exchange rate to 10.9
- Increase risk-free rate to 2,5% (1%) per our policy to account for higher market rates, but also lower our risk premium following improved score in our Redeye Rating. Net effect is a WACC increase to 13.5% (13%)
- We assume a slightly higher addressable market due to the improved administration method, and now assume peak sales of +USD 3 billion
- We assume a slightly lower total deal USD 28/400 following a peer-comparison, but now assume a licensing agreement after initial efficacy data in 2025
- Push the launch to 2032 (2031) due to the prolonged time in pre-clinic
- We keep our likelihood of approval at 9%, but see lower risk in the pre-clinical stage and slightly higher risk in phase I following the change of compound

Bear Case SEK 3

- The pre-clinical development of HER-096 is prolonged and goes back into clinic in 2024 with mixed data on blood-brain-barrier penetration.
- LoA: 3%
- Cash position

Base Case SEK 24

As detailed above

Bull Case SEK 48

- We assume a successful phase I study, including safety and blood-brain-barrier penetration in humans
- We assume a deal in early 2024 (upfront payment not risk-adjusted)

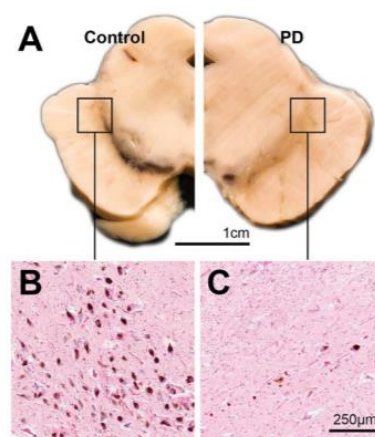
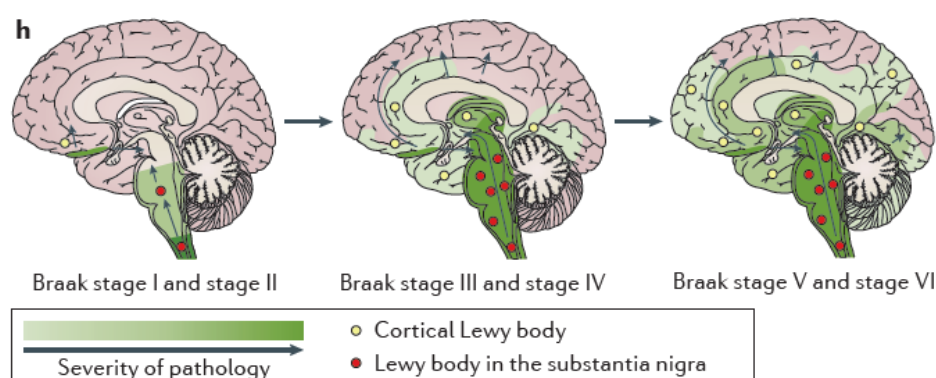
Appendix: Overview of Parkinson's Disease

Parkinson's is a chronic degenerative disorder of the central nervous system (CNS) that has mainly been linked to movement deterioration and disorders. At more advanced stages of the disease, serious non-motor symptoms are also common, such as dementia, depression, and autonomic dysfunction. There is no cure or disease-altering treatment on the market and the devastating illness is associated with morbidity and worsened quality of life. Parkinson's is the second most common neurodegenerative disease after Alzheimer's and poses a significant cost to society. Parkinson's is typically split into two types: genetic and sporadic. Genetic Parkinson's accounts for roughly 5-10% of all reported cases. However, all forms of Parkinson's are believed to be a consequence of a complex interplay between environment and genetic predispositions.

Parkinson's is caused by the degeneration of dopamine-producing neurons in the brain, specifically in the substantia nigra region, and the accumulation of intracellular protein (alpha-synuclein). In early-stage patients, the loss of dopaminergic neurons is relatively concentrated but becomes more widespread at later stages, as shown in the diagram below to the left. The early loss of neurons suggests that the degeneration starts before motor symptoms are apparent. When dopamine neurotransmission is reduced due to the loss of dopamine-generating neurons, the muscles lose control and motor symptoms arise. Most of today's symptom-focused therapies target dopamine. The underlying mechanisms for the start of the degeneration and non-motor symptoms have not been fully established.

The aggregation of the alpha-synuclein protein in certain neurons is the other hallmark of sporadic Parkinson's; these are called Lewy bodies. These structures have been found to be increasingly complex and also constitute many other molecules. Lewy pathologies are known to occur in elderly people with other diseases, Alzheimer's being the most common diagnosis. As we will discuss later, many disease-modifying therapies for Parkinson's focus on alpha-synuclein accumulation.

A-Synuclein accumulation (left) and dopamine loss (right)

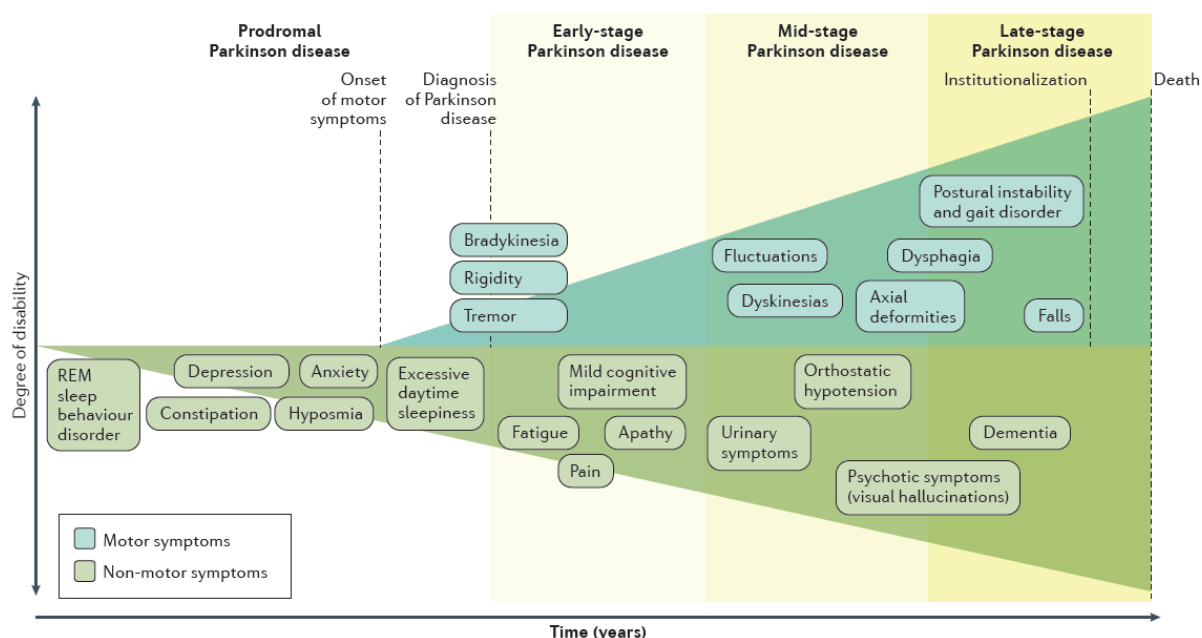


Source Poewe et al 2017; Obeso et al 2017

Diagnosis

Parkinson's is an underdiagnosed disease at present due to the lack of definite biomarkers and tests. It is mainly diagnosed through symptoms and by excluding other potential causes of them. However, there has been significant progress in research on new biomarkers, which could lead to earlier identification of Parkinson's in the future.

Symptoms and disease stages



Source Poewe et al 2017

As shown above, the symptoms of Parkinson's evolve over time. In the prodromal stage, symptoms have started to show but are typically non-motor symptoms and are insufficient to diagnose a patient with Parkinson's. The neurodegeneration starts even earlier in the pre-clinical stage of Parkinson's. A patient can be in the prodromal stage for several years or even decades. Patients are usually diagnosed when the first motor symptoms show, typically when they are in their late fifties. Both motor and non-motor symptoms progress over time, making Parkinson's a more severe and disabling disease, even with the current treatment regime, as we will describe further below.

A common way to follow the progression of Parkinson's is to use disease scales. The Hoehn and Yahr scale, from 1 to 5, is one of the most widely applied owing to its simplicity. 1-3 is defined as early stage and 4-5 as late-stage Parkinson's. The scale was created in 1967 and focuses on motor symptoms. The scientific understanding of symptoms has since progressed and scales that also measure non-motor symptoms, such as the Unified Parkinson's Disease Rating Scale (UPDRS), are now widely used, especially in clinical trials

and research. The UPDRS scale consists of four parts and provides a comprehensive view of a patient's condition.

Summary Redeye Rating

People: 4

Business: 2

Financials: 1

	2021	2022E	2023E	2024E
INCOME STATEMENT				
Revenues	0	0	0	0
Cost of Revenues	0	0	0	0
Gross Profit	0	0	0	0
Operating Expenses	10	9	6	5
EBITDA	-10	-9	-6	-5
Depreciation & Amortization	3	0	0	0
EBIT	-12	-9	-6	-5
Net Financial Items	0	0	0	0
EBT	-13	-9	-6	-5
Income Tax Expenses	0	0	0	0
Non-Controlling Interest	0	0	0	0
Net Income	-13	-9	-6	-5
BALANCE SHEET				
Assets				
Current assets				
Cash & Equivalents	7	5	5	7
Inventories	0	0	0	0
Accounts Receivable	0	0	0	0
Other Current Assets	0	0	0	0
Total Current Assets	8	5	5	7
Non-current assets				
Property, Plant & Equipment, Net	0	0	0	0
Goodwill	0	0	0	0
Intangible Assets	0	0	0	0
Right-of-Use Assets	0	0	0	0
Shares in Associates	0	0	0	0
Other Long-Term Assets	0	0	0	0
Total Non-Current Assets	0	0	0	0
Total Assets	8	5	5	7
Liabilities				
Current liabilities				
Short-Term Debt	1	1	1	1
Short-Term Lease Liabilities	0	0	0	0
Accounts Payable	0	0	0	0
Other Current Liabilities	2	0	0	0
Total Current Liabilities	3	1	1	1
Non-current liabilities				
Long-Term Debt	6	6	6	6
Long-Term Lease Liabilities	0	0	0	0
Other Long-Term Liabilities	0	0	0	0
Total Non-current Liabilities	6	6	6	6
Non-Controlling Interest	0	0	0	0
Shareholder's Equity	-1	-2	-2	-1
Total Liabilities & Equity	8	5	5	7
CASH FLOW				
NOPAT	-12	-9	-6	-5
Change in Working Capital	1	-1	0	0
Operating Cash Flow	-10	-11	-6	-5
Capital Expenditures	0	0	0	0
Investment in Intangible Assets	0	0	0	0
Investing Cash Flow	0	0	0	0
Financing Cash Flow	4	9	5	7
Free Cash Flow	-9,9	-10,85	-5,65	-5,138

Redeye Rating and Background Definitions

Company Quality

Company Quality is based on a set of quality checks across three categories; PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive long-term earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of people behind a business is a significant part of understanding the long-term drive of the company. It all comes down to doing business with people you trust, or at least avoiding dealing with people of questionable character.

The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

Business

If you don't understand the competitive environment and don't have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won't succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.

The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company's financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.

The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

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Disclaimer

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Redeye Rating (2023-01-13)

Rating	People	Business	Financials
5p	32	16	4
3p - 4p	130	115	42
0p - 2p	5	36	121
Total	167	167	167

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Fredrik Thor owns shares in the company : No

Kevin Sule owns shares in the company : No

Redeye performs/have performed services for the Company and receives/have received compensation from the Company in connection with this.