EDISON

Herantis Pharma

Capital markets day

Funded to key data inflection points

Pharma & biotech

Herantis Pharma is focused on the development of innovative regenerative medicines targeting unmet needs. The recent virtual capital markets day highlighted the progress of its two innovative assets: cerebral dopamine neurotrophic factor (CDNF), a potential disease-modifying treatment for Parkinson's disease (PD); and Lymfactin, the only gene therapy in development for breast cancer-associated lymphedema (BCAL). Top-line data from the first part of the Phase I/II CDNF trial confirmed its safety in PD and encouragingly, early biological efficacy signals (PET imaging) of its neurorestorative effects. Lymfactin (AdeLE) data are expected in Q121. Herantis is funded into 2021 key inflection points and expects little impact from COVID-19 in the near term. We value Herantis at €87.2m.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/18	0.0	(4.2)	(0.8)	0.0	N/A	N/A
12/19	0.0	(8.0)	(1.4)	0.0	N/A	N/A
12/20e	0.0	(5.3)	(0.8)	0.0	N/A	N/A
12/21e	0.0	(5.6)	(0.8)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

CDNF neuroprotection in PD the holy grail

PD is the second most common neurodegenerative disease in the world (c 7–10 million patients) and no treatments as yet slow disease progression. This is an unmet need and the holy grail for an ideal PD treatment. CDNF is a neuroprotective factor and early data (six months) from the Phase I/II study are impressive (albeit in small patient numbers). DAT PET imaging shows improved DAT binding potential and the data serves as early validation for CDNF's potential neuroprotective and neurorestorative effects. We await the six-month follow-up data to see whether the early biological activity has been sustained at 12 months.

Lymfactin moving towards Phase III start in 2021

Herantis's second clinical asset, Lymfactin, has completed enrolment of the Phase II trial for the treatment of BCAL; 12-month proof-of-concept safety and efficacy data are expected in Q121. If the Phase II trial completes successfully, a Phase III programme in BCAL could initiate in 2022; depending on size, either by Herantis or a potential development and commercialisation partner.

Financials: Cash runway into 2021

In 2019, Herantis raised €5.8m in March and €4.2m in December in equity issues. Cash burn amounted to €6.0m in FY19 and net debt was €0.2m at end 2019; with funding for the CDNF trial from an EU grant, this implies a cash runway to 2021.

Valuation: €87.2m or €13.0/share

Our revised risk-adjusted valuation is €87.2m or €13.0/share from €66.9m or €10.0/share. We have revisited our assumptions and pushed out EU Lymfactin launch to 2025 vs the previous 2022 launch (we had expected filing Phase II data, and now await completion of the Phase III trial). We have increased the probability of CDNF success to 10% from 5%.

20 April 2020

Price	**€7.50**
Market cap	**€50m**
	SEK:€0.095
Net debt (€m) at 31 December 2019	0.2
Shares in issue	6.7m
Free float	73.8%
Code	HRTIS
Primary exchange	Nasdaq OMX
Secondary exchange	Nasdaq First North Growth Market

Share price performance

%	1m	3m	12m
Abs	15.4	(1.3)	31.6
Rel (local)	0.2	25.4	58.0
52-week high/low		€10.1	€5.2

Business description

Herantis Pharma is a Finnish innovative biopharmaceutical company focusing on regenerative medicines for unmet needs. Key assets include CDNF for Parkinson's disease and Lymfactin for breast cancer-associated lymphedema.

Next events

CDNF PD Phase I/II extension (12-month) study data	Q320
Lymfactin BCAL Phase II data	Q121

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Edison profile page

CDNF: Phase II top-line data early, but encouraging

Herantis is developing its innovative recombinant factor CDNF for the treatment of a range of neurodegenerative conditions. This protein-based therapy is being evaluated for its potential neuroprotective and neurorestorative properties in PD. Herantis believes this is the only scalable, recombinant factor CDNF in development globally.

Herantis recently reported preliminary data for the first six months from a first-in-human Phase I/II placebo-controlled study with CDNF in patients with advanced PD. Similar safety profiles to the placebo group were confirmed in the two CDNF dosing groups. The secondary and exploratory endpoints of the study evaluated initial signs of efficacy. Promising signals were observed in some patients by dopamine transporter (DAT) PET imaging, which is an indirect measure of the dopaminergic function. Specifically, there was a marked difference between DAT binding potential in the putamen area of the brain between placebo and one CDNF group (decrease of -6% to -21%) and the other CDNF group (increase of 17%). Two patients in the CDNF group showed a 37–51% increase in DAT binding potential in the putamen. We highlight that these data are preliminary and are based on small patient numbers in a trial powered for safety and not for efficacy. We note further data analyses ongoing include six-month alpha-synuclein results; given one of CDNF's modes of action is its potential to inhibit alpha-synuclein oligomerisation and subsequent neuronal toxicity, positive signals on this metric would be additional validation of its potential disease-modifying effects.

This study has a long follow-up period of four years after the data from the main and extension studies complete. Following the main study readout at six months, all patients (n=17) have volunteered to continue in an extension study, in which they will receive either lower or higher CDNF doses for another six months. Data from the six-month extension study is expected in Q320 and, if positive, this will suggest that CDNF's activity is sustained for 12 months after the first dose.

Although early stage, the data so far are encouraging. Herantis has started planning a Phase II trial that will assess the efficacy of CDNF in earlier-stage, well characterised PD patients; the hypothesis is that these patients should be even more responsive to its neuroprotective properties given the higher percentage of dopaminergic neurons present to preserve/protect. Patient enrolment is expected in 2021, after the 12-month data readout of the Phase I/II extension study.

xCDNF: Positioned for lead optimisation

CDNF is a recombinant factor, large molecule-based treatment that is unable to cross the blood-brain barrier in its current formulation; it therefore needs to be administered into the exact region of the brain (the putamen) where it can target its effect. CDNF is dosed intracranially once a month (two- to three-hour infusion in the outpatient setting) using an implanted drug delivery device with portal access located behind the patient's ear.

Herantis has licensed the global rights from the University of Helsinki for the therapeutic application of a non-invasive CDNF approach for potential utility in several indications beyond PD (eg Alzheimer's, amyotrophic lateral sclerosis, stroke). While in the early stages of development, this is of importance for the longevity of the franchise and could provide patients with a non-invasive drug treatment option in the very long term. Herantis is currently progressing its three xCDNF candidates through the lead optimisation stage of preclinical development. xCDNF is a biologically active peptide fragment of the CDNF protein that can penetrate the blood-brain barrier. This should allow xCDNF to be administered using peripheral non-invasive dosing methods much like how insulin is administered.

Herantis has shown in preclinical in vitro models that xCDNF engages the same target and operates via the same mechanism as the parent CDNF protein. This de-risks its development as the encouraging clinical data on CDNF validates its mechanism of action. Furthermore, preclinical dosing in rat models has shown that xCDNF reaches pharmacologically active levels in the brain within 30 minutes of peripheral dosing and exhibits a half-life of approximately 90 minutes.

PD: The commercial opportunity

For Herantis, we forecast a partnering deal on CDNF after positive proof-of-concept data are achieved on the modification of disease progression in PD. We assume a partnering deal y to take CDNF through mid- to late-stage clinical trials and for commercialisation. Given the patient population size and the unmet need in PD, we estimate a price per year of $80k for the drug treatment alone. We note that non-drug treatment options such as deep brain stimulation (DBS) surgery can cost between $35,000 and $50,000 and upwards of $70,000 to $100,000 for bilateral procedures; these estimates include the cost of the surgery, devices, anaesthesia, hospital fees and physician fees.

For modelling CDNF we consider the total PD prevalence in the context of the DBS patient population. Special consideration has been given to the intracranial method of administration, as patients will need to be fit and healthy (despite the PD diagnosis) to be eligible for the therapy. We forecast an eligible peak patient population of c 74,000 in the US and c 66,000 in EU5. We forecast that peak penetration rates of 30% of this defined population are achievable in 2035 in the EU and 2039 in the US, eight years after launch. We model a slower uptake trajectory than small molecule drugs reflecting the need for patient acceptance of the drug delivery method and requirement for a permanent device to be in place.

Lymfactin: A novel gene therapy for lymphedema

Herantis is developing Phase II asset Lymfactin gene therapy as a potential therapy for BCAL secondary lymphedema administered as a single-dose injection in combination with lymph node transfer surgery. Lymphedema is one of the unfortunate outcomes of breast cancer treatment and is an unavoidable consequence of having surgical treatment (lumpectomy/mastectomy plus auxiliary lymph node dissection), radiotherapy or chemotherapy that prolongs patients' survival.

Lymfactin is a recombinant replication deficient Adenovirus 5 gene transfer vector that delivers VEGF-C growth factor to stimulate lymphangiogenesis (formation of new lymphatic vessels). Delivery of Lymfactin in combination with surgical lymph node transfer leads to VEGF-C production localised to the targeted area of damage; expression of the gene is limited to a couple of weeks. Adenovirus is the optimal viral vector, given the need for small amounts, relative low cost of production and requirement for the expression to be transient (long-term expression of VEGF-C could be oncogenic). However, we note that treatment with adenovirus will probably be limited to one or two attempts per patient as the immune system will likely build a response to the treatment.

Breast cancer accounts for 23% of all diagnosed cancers in women, with ~1.67m women globally diagnosed in 2012. Advancements in the treatment of breast cancer mean the five-year survival rate for breast cancer is 90% and at present there are 2.9 million breast cancer survivors in the US alone. While chemotherapy, targeted therapies and hormone therapies are critical in the management of breast cancer, surgical removal (lumpectomy, mastectomy) plus/or axillary lymph node removal plus radiotherapy remains the cornerstone alongside medical management (depending on the subtype of breast cancer). Removal of the corresponding auxiliary lymph nodes leads to the complication of secondary lymphedema in up to 40% of patients due to damage to the lymphatic vessels and absence of lymph nodes. It is estimated that up to 60% of breast cancer

survivors develop symptoms of lymphedema. Herantis estimates that in the US and Europe there are 30,000 diagnosed cases per year.

Phase II AdeLE trial readout expected in Q121

Following encouraging Phase I data that evaluated 15 patients with BCAL, a randomised, placebo-controlled efficacy, safety and tolerability Phase II trial AdeLE (adenoviral gene therapy for the treatment of LE) was initiated in H118 (n=39). The AdeLE trial has fully recruited and all treatments have concluded. The 12-month proof-of-concept safety and efficacy data are expected in Q121 (the study is in the blinded 12-month follow up stage until December 2020). We had originally expected Herantis to file the Lymfactin NDA in Europe on the basis of the Phase II data. We note the plans for a Phase III trial, which we now believe will form the basis of regulatory submissions in Europe and the US. We have therefore pushed back EU launch to 2025 and maintain our original forecast for US launch in 2026.

Phase III registration trial could start in 2022

Herantis is currently planning a pivotal Phase III study for Lymfactin (single dose Lymfactin administered as an adjunct to lymph node transplantation) with registrational intent. This study will have a clear US focus, with clinical sites also located in several European countries. The target indication will be the same as the ongoing Phase II AdeLE study and, following a positive readout from this trial in Q121, could treat the first patients at the start of 2022. Herantis expects to enrol 200–300 patients in the Phase III study and therefore is capable of managing it independently. However, we note that the trial size will depend on the results from the Phase II AdeLE study and subsequent regulatory discussions and could be significantly larger. Over the next 12 months Herantis will continue to develop the Phase III protocol and finalise the commercial scale manufacturing process for Lymfactin. Once approved as an adjunct to surgery, long-term value creation could come from establishing Lymfactin as a monotherapy for the treatment of lymphedema. Herantis has already engaged in early discussions with key opinion leaders and clinicians.

Lymfactin: The opportunity

We forecast peak sales of $1.2bn for Lymfactin in the BCAL setting in the US and €600m in Europe. We model an initial pricing of $50k for a single dose of Lymfactin and take into consideration 30% of breast cancer patients as the eligible patient pool. We assume 80% of breast cancer patients receive surgical treatment and removal of their lymph nodes, 95% of these patients will survive five years and 40% of these patients will develop lymphedema. In these patients we assume a peak penetration of 20% for Lymfactin.

While we assume Herantis will partner the asset post the Phase II trial, the company could potentially further develop Lymfactin in BCAL for commercialisation itself as the lymph node surgery is only performed by specialists, so only a small salesforce would be required to target specialist hospitals in each country. However, for other more sizeable opportunities in secondary lymphedema and primary lymphedema, we would anticipate development by a future partner given the need for larger clinical trials in these conditions and thus the requirement for much higher associated R&D and regulatory and commercialisation expenses.

COVID-19: Minimal impact so far

With the global pandemic in effect, hospitals globally have come under strain due to the mass influx of COVID-19 patients. This has led to resources being redirected and a restriction on unrelated hospital visits, which may impact on clinical trials.

Our current observations of Herantis's position are:

- In terms of clinical trials, Herantis has already completed almost all clinical treatments from its two ongoing trials. All treatments in the Phase II AdeLE study were completed in December 2019. Top-line data are expected in Q121 with little or no impact expected from the COVID-19 pandemic. In the Phase I/II study of CDNF in PD, all patients have completed the first six months of treatment and only two patients are still to complete the second six months of treatment. However, the PET centre of the Karolinska Institute will now focus on critical patients only. As a result, any patient follow-up PET imaging studies in the next few months will have to be rescheduled. Herantis does not expect this to have a material effect on the clinical study as it only represents a small number of data points (other outcome measurements include alpha-synuclein levels).
- Herantis extended its cash runway into late 2021 via two financing rounds in 2019 (share issues raising €5.8m in March and €4.2m in December), which should enable a cash runway into late 2021. This should take Herantis to the key inflection points of the Phase I/II extension study data of CDNF in PD expected Q320 and the Phase II top-line data of Lymfactin in BCAL expected in Q121. We note cash burn amounted to €6.0m in FY19 (FY18: €3.7m) and is expected to decrease significantly due to the completion of almost all clinical treatments. Herantis reported cash and cash equivalents at 31 December 2019 of €7.0m and debt of €7.2m (Business Finland loans). We also highlight that most of the funding for the Phase I/II study (TreatER) of CDNF in PD comes from a (Horizon 2020) grant of €6.0m in total, part of which will be received during 2020.
- Herantis already operates as a virtual biotech with employees working remotely and therefore the global pandemic has had minimal impact on its daily operations. The company continues to discuss collaboration opportunities with potential partners for its drug development programmes and does not expect COVID-19 to have a material impact or effect on its outlook and guidance for next year.

Valuation: €87.2m or €13.0/share

Our increased valuation is €87.2m or €13.0/share from €66.9m or €10.0/share based on a risk-adjusted NPV analysis, which includes €0.2m net debt at the end of December 2019 and risk-adjusted contributions for CDNF in PD and Lymfactin in BCAL. We have pushed out timelines for the EU Lymfactin launch which we now forecast for 2025 vs our previous assumption of a 2022 launch). Our forecast for a US launch in 2026 remains unchanged. We have increased the probability of CDNF success to 10% from 5% reflecting the encouraging top-line data from the Phase I/II study. The breakdown of our NPV valuation, which uses a 12.5% discount rate, is shown in Exhibit 1. As detailed above, we have applied a top-down analysis of the PD and BCAL markets, which form the basis of our sales projections. Our forecasts are unchanged from our last note dated 5 March 2020.

Exhibit 1: Valuation breakdown

Product	Indication	Phase	Probability of success	rNPV (€m)	Per share (€)
CDNF	Parkinson's disease	I/II	10%	52.7	7.9
Lymfactin	BCAL	II	10%	34.7	5.2
Net debt at 31 December 2019				(0.2)	0.0
Valuation				**87.2**	**13.0**

Source: Edison Investment Research

Exhibit 2: Financial summary

Accounts: IFRS, year-end: December, €000s	2017	2018	2019	2020e	2021e
INCOME STATEMENT					
Total revenues	0	0	0	0	0
Cost of sales	0	0	0	0	0
Reported gross profit	0	0	0	0	0
SG&A (expenses)	(1,024)	(1,244)	(1,403)	(1,417)	(1,431)
R&D costs	(1,400)	(2,100)	(4,000)	(2,800)	(2,828)
Other (includes exceptionals)	(303)	(324)	(705)	225	225
Depreciation	(1,218)	(1,202)	(1,047)	(762)	(610)
Adjusted EBIT	(3,945)	(4,871)	(7,155)	(4,754)	(4,644)
Reported EBIT	(3,945)	(4,871)	(7,155)	(4,754)	(4,644)
Finance income/(expense)	1,780	691	(849)	(565)	(965)
Other income (expense) (includes exceptionals)	0	0	0	0	0
Adjusted PBT	(2,165)	(4,180)	(8,005)	(5,319)	(5,609)
Reported PBT	(2,165)	(4,180)	(8,005)	(5,319)	(5,609)
Income tax expense	0	0	0	0	0
Adjusted net income	(2,165)	(4,180)	(8,005)	(5,319)	(5,609)
Reported net income	(2,165)	(4,180)	(8,005)	(5,319)	(5,609)
Earnings per share					
Basic EPS (€)	(0.5)	(0.8)	(1.4)	(0.8)	(0.8)
Diluted EPS (€)	(0.5)	(0.8)	(1.4)	(0.8)	(0.8)
Adjusted basic EPS (€)	(0.5)	(0.8)	(1.4)	(0.8)	(0.8)
Adjusted diluted EPS (€)	(0.5)	(0.8)	(1.4)	(0.8)	(0.8)
Average number of shares - basic (m)	4.2	4.9	5.5	6.7	6.7
Average number of shares - diluted (m)	4.9	5.5	6.7	6.7	6.7
BALANCE SHEET					
Property, plant and equipment	7	5	4	3	2
Goodwill	0	0	0	0	0
Intangible assets	5,663	4,735	3,807	3,046	2,437
Other non-current assets	392	118	0	0	0
Total non-current assets	6,061	4,857	3,811	3,049	2,439
Cash and equivalents	5,402	2,186	6,998	2,441	2,443
Inventories	0	0	0	0	0
Trade and other receivables	109	105	262	262	262
Other current assets	0	0	0	0	0
Assets classified for sale	0	0	0	0	0
Total current assets	5,511	2,290	7,260	2,703	2,704
Non-current loans and borrowings	6,022	5,878	7,206	7,206	12,206
Trade and other payables	0	0	0	0	0
Other non-current liabilities	0	0	0	0	0
Total non-current liabilities	6,022	5,878	7,206	7,206	12,206
Trade and other payables	278	200	1,625	1,625	1,625
Current loans and borrowings	547	507	6	6	6
Other current liabilities	634	651	383	383	383
Liabilities of assets held for sale	0	0	0	0	0
Total current liabilities	1,460	1,358	2,014	2,014	2,014
Equity attributable to company	4,090	(89)	1,851	(3,468)	(9,076)
Non-controlling interest	0	0	0	0	0
CASH FLOW STATEMENT					
Profit before tax	(2,165)	(4,180)	(8,005)	(5,319)	(5,609)
Depreciation of tangible assets	1,218	1,202	1,047	762	610
Amortisation of intangible assets	0	0	0	0	0
Share based payments	(2,021)	(3)	0	0	0
Other adjustments	240	(688)	849	565	965
Movements in working capital	372	(79)	1,000	0	0
Net cash from operating activities (pre-tax)	(2,355)	(3,747)	(5,109)	(3,992)	(4,034)
Interest paid/received	(244)	15	(849)	(565)	(965)
Income taxes paid	0	0	0	0	0
Cash from operations (CFO)	(2,599)	(3,732)	(5,958)	(4,557)	(4,999)
Capex (includes acquisitions)	0	0	0	0	0
Other investing activities	(0)	7	0	0	0
Cash used in investing activities (CFIA)	(0)	7	0	0	0
Net proceeds from issue of shares	4,680	0	9,945	0	0
Movements in debt	0	509	826	0	5,000
Other financing activities	492	0	0	0	0
Cash from financing activities (CFF)	5,172	509	10,771	0	5,000
Currency translation differences and other	0	0	0	0	0
Increase/(decrease) in cash and equivalents	2,573	(3,216)	4,812	(4,557)	1
Cash and equivalents at beginning of period	2,829	5,402	2,186	6,998	2,441
Cash and equivalents at end of period	5,402	2,186	6,998	2,441	2,443
Net (debt)/cash	(1,168)	(4,200)	(214)	(4,770)	(9,769)
Movement in net (debt)/cash over period	4,123	(3,033)	3,987	(4,557)	(4,999)

Source: Company accounts, Edison Investment Research

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