EDISON

Herantis Pharma

Results update

CDNF early data show biological promise

Pharma & biotech

Herantis has announced top-line data from the first part of the Phase I/II clinical trial on novel asset CDNF in Parkinson's disease (PD). Data reported for the first six months are preliminary in this first-in-human clinical study for this novel MOA drug class. Safety and tolerability have been confirmed but, interestingly, the early biological efficacy signals (seen on PET imaging) serve as validation of the scientific hypothesis for CDNF's potential neuroprotective and neurorestorative effects. Herantis expects data from the six-month extension study in Q320. It raised gross cash of €10m through two equity issues in 2019, which has extended the cash runway to key value inflection points. We increase our valuation to €66.9m (€10.0/share).

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 data, early efficacy signals encouraging

CDNF is a neuroprotective factor that is believed to promote neuronal survival and could potentially slow down disease progression in PD. Slowing down disease progression is an unmet need and the holy grail for an ideal PD treatment. Early-stage data are impressive in small patient numbers and we await the six-month follow-up data to see whether the early biological activity has been sustained before the start of the Phase II study. Herantis's second clinical asset, Lymfactin, has completed enrolment of the Phase II trial for the treatment of breast cancer-associated lymphedema (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 2021 – either by Herantis or a potential development and commercialisation partner.

Financials: Cash runway into 2021

R&D expenses increased to €4.0m in FY19 (FY18: €2.1m), reflecting the ongoing progress in the CDNF and Lymfactin clinical trials plus the preclinical work on targets for non-invasive CDNF. The FY19 net loss was €8.0m (FY18: €4.2m). In the near term, Herantis will continue to be cash consumptive and operate as a non-revenue generating biotech. We note that most of the funding for the Phase I/II CDNF trial comes from an EU grant. Herantis raised €5.8m in March and €4.2m in December through equity issues. Cash burn amounted to €6.0m in FY19, implying a cash runway to 2021.

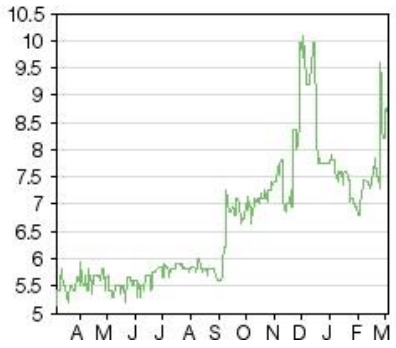
Valuation: €66.9m or €10.0 share

Our valuation is €66.9m (€10.0/share) versus €60.8m (€9.1/share) previously. It includes reported net debt of €0.2m at 31 December 2019, and is based on an rNPV of CDNF in PD (€3.9/share) and Lymfactin in BCAL (€6.1/share). Our product forecasts are unchanged, and we have rolled our model forward and updated FX.

5 March 2020

Price	**€8.7**
Market cap	**€58m**
	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	21.7	(10.8)	61.1
Rel (local)	29.2	(12.7)	62.9
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 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

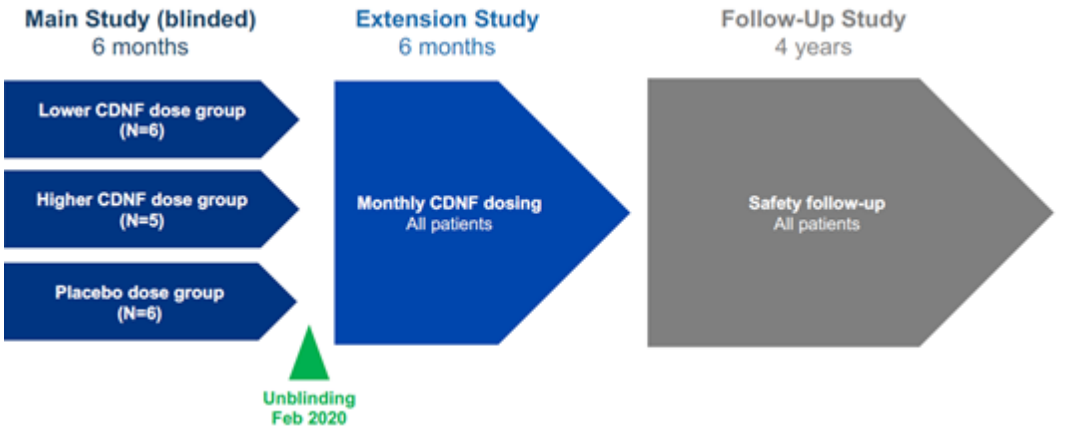
Herantis currently has two ongoing clinical trials: a Phase I/II trial testing its recombinant CDNF (cerebral dopamine neurotrophic factor) in patients with PD and a Phase II trial testing its Lymfactin gene therapy in patients with BCAL secondary lymphedema.

Herantis recently reported preliminary data from a first-in-human Phase I/II study with CDNF in patients with advanced PD. This study has a long follow-up period of four years after the data from the main and extension studies complete. The main study read out at six months and met its primary endpoint on safety and tolerability of CDNF, with all patients volunteering to continue in an extension study, in which they will receive either lower or higher CDNF doses for another six months (Exhibit 1). Similar safety profiles to the placebo group were confirmed in the two CDNF dosing groups. However, two patients discontinued from the study due to infections that were probably related to the drug delivery device.

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 (-6 to -21% decrease) 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 based on small patient numbers in a trial powered for safety and not for efficacy.

However, this is an encouraging observation at this early stage, as the patients are at an advanced disease stage and therefore less susceptible to the potential neuroprotective properties of CDNF. This suggests that dosing CDNF in patients with earlier signs of PD could be beneficial given that more dopaminergic neurons are available to potentially protect.

Exhibit 1: CDNF study design: three groups, three parts



Source: Herantis corporate presentation

Top-line results from the extension study are expected in Q320 and, if positive, will suggest that CDNF's activity is sustained for a year after the first dose. If positive, Herantis plans to start a Phase II trial that will assess the efficacy of CDNF in earlier-stage, well characterised PD patients. This study will use a longer treatment period and recruit a larger number of patients. Patient enrolment is expected in 2021.

Neurotrophic/neuroprotective factors (such as CDNF, MANF and GDNF) are endogenous secretory proteins that have been shown to have neuroprotective and neurorestorative effects, presenting the opportunity for their use in the treatment of PD. CDNF-based therapy is being evaluated for its

potential neuroprotective and neurorestorative properties in PD. 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. The novel drug delivery system (DDS) being used in the study has been developed by Renishaw, a global metrology company headquartered in the UK.

Herantis has in-licensed the global rights to a second generation of CDNF (from the University of Helsinki in July 2018). It has been developing a non-invasive way of delivering CDNF (such as subcutaneous) and has identified a number of candidates that will enter into the lead optimisation phase of preclinical development in 2020.

Lymfactin Phase II AdeLE data expected at the end of 2020

Herantis is developing its Phase II asset, Lymfactin gene therapy, as a potential therapy for BCAL, administered as a single-dose injection in combination with lymph node transfer surgery. The 12-month Phase I follow-up results announced in April 2019 demonstrated that the treatment was safe, with no serious adverse events reported. The study enrolled 15 patients from three universities in Finland (Helsinki, Tampere and Turku). 12-month data from the Phase II AdeLE (adenovirus gene therapy for the treatment of lymphedema) trial in BCAL patients is expected by the end of 2020 (enrolment has completed). If the data readout is positive, a Phase III registrational trial in BCAL could be initiated in 2021 – either by Herantis or a potential development and commercialisation partner. Furthermore, positive safety and efficacy data in BCAL would provide validation of the therapy for investigation in lymphedema from other secondary causes.

Financials: Cash runway extended

Herantis reported an FY19 net loss of €8.0m (€4.2m in FY18). R&D expenses increased to €4.0m (FY18: €2.1m), reflecting the advancement of the R&D pipeline including the start of the preclinical work associated with in-licensed asset, non-invasive CDNF (xCDNF). We note that the majority of the funding for the Phase I/II study (TreatER) of CDNF in PD is essentially from a (Horizon 2020) grant of €6.0m. In the near term, Herantis will continue to be cash consumptive and operate as a non-revenue generating biotech. Cash and cash equivalents at 31 December 2019 were reported at €7.0.m and debt at €7.2m (Business Finland loans).

In FY19, Herantis completed two financing rounds through share issues raising €5.8m in March and €4.2m in December. The latter issued 0.6m new shares (subscription price of 71 SEK), which should enable a cash runway into late 2021. Cash burn amounted to €6.0m in FY19 (FY18: €3.7m).

Valuation: €66.9m or €10.0/share

We value Herantis at €66.9m or €10/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 rolled forward our model and updated for net cash, but kept our operating assumptions unchanged. The breakdown of our NPV valuation, which uses a 12.5% discount rate, is shown in Exhibit 2. As detailed in our Herantis initiation note, we have applied a top-down analysis of the PD and BCAL markets, which form the basis of our sales projections.

Exhibit 2: Valuation breakdown

Product	Indication	Phase	Probability of success	rNPV (€m)	Per share (€)
CDNF	Parkinson's disease	I/II	5%	26.4	3.9
Lymfactin	BCAL	II	10%	40.7	6.1
Net debt at 31 December 2018				(0.2)	0.0
Valuation				**66.9**	**10.0**

Source: Edison Investment Research

Exhibit 3: 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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