EDISON

Herantis Pharma

Trading update

Trials on track as CDNF readout nears

Pharma & biotech

Patient recruitment in the Phase II Lymfactin trial (AdeLE) continues to progress well, aided by the addition (in March) of new treatment centres in Sweden. Initial efficacy and safety data are on track for the end of 2020. Near term, top-line data from Phase I/II asset CDNF in Parkinson's disease (PD) are expected by the year end; positive data from this trial could serve as validation of the research efforts and could also enable future partnering opportunities. H119 net loss was slightly above expectations as a result of higher than expected R&D, SG&A and financial costs. In March, Herantis raised gross €5.8m enabling a cash runway into late 2020. We value Herantis at €58.7m (€9.7/share) vs €47.9m (€9.7/share) previously.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/17	0.0	(2.2)	(0.5)	0.0	N/A	N/A
12/18	0.0	(4.2)	(0.8)	0.0	N/A	N/A
12/19e	0.0	(5.8)	(1.0)	0.0	N/A	N/A
12/20e	0.0	(4.2)	(0.7)	0.0	N/A	N/A

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

CDNF and Lymfactin inflection points approaching

Top-line efficacy and safety data from the ongoing Phase I/II trial testing CDNF in PD patients are expected by the year end. CDNF is a neuroprotective factor that Herantis hope could have a disease-modifying effect on patients with PD. Additionally, Herantis continues to progress its next generation, non-invasive CDNF and expects to select a lead molecule for development by the year end. Herantis's second clinical asset, Lymfactin, continues to enrol patients on schedule with new trial sites opened in Stockholm and Uppsala in March. Lymfactin is a gene therapy to stimulate lymph vessel growth as a therapy for breast cancer-related associated secondary lymphedema (BCAL). Phase I 12-month follow-up results announced in April 2019 demonstrated the treatment was safe with no serious adverse events reported. 12-month data from the Phase II AdeLE (adenovirus gene therapy for the treatment of lymphedema) trial in BCAL patients are expected by end 2020.

Financials: Cash runway into late 2020

R&D expenses increased to €1.4m (H118: €1.1m) in H119, reflecting the ongoing Lymfactin Phase II trial in BCAL and the Phase I/II CDNF trial in PD. The net loss grew substantially in H119 to €3.3m (H118: €1.8m) mainly as a result of minimal financial income (compared with €0.78m in H118) and increased financial expenses (H119: €0.41m vs H118: €0.03m) related to the capital raise. Herantis's cash and cash equivalents of €5.6m suggests it has a cash runway into late 2020.

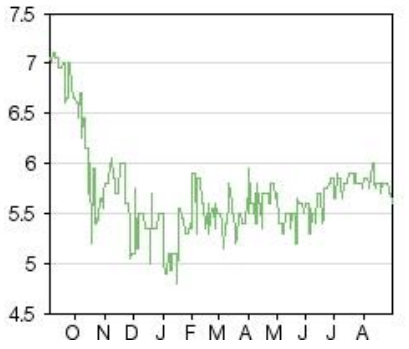
Valuation: €58.7m or €9.7/share

Our valuation of €58.7m (€9.7/share) vs €47.9m (€9.7/share) previously, includes net debt of €0.9m and is based on an rNPV of CDNF in PD (€3.9/share) and Lymfactin in BCAL (€6.0/share). We have rolled forward our model and updated for both FX and increased number of outstanding shares following the recent capital raise. For a detailed overview of our valuation please see our initiation note.

2 September 2019

Price	**€5.60**
Market cap	**€34m**
Net debt (€m) as at 30 June 2018	0.9
Shares in issue	6.1m
Free float	73.9%
Code	HRTIS
Primary exchange	NASDAQ OMX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(3.4)	1.8	(20.0)
Rel (local)	(1.7)	1.8	(8.3)
52-week high/low		€7.1	€4.8

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 data	H219
Lymfactin Phase II data	End 2020

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Edison profile page

Successful execution of clinical trials as readouts near

Herantis currently has two ongoing clinical trials; a Phase I/II trial testing its recombinant CDNF (cerebral dopamine neuroprotective factor) in patients with Parkinson's disease and a Phase II trial testing its Lymfactin gene therapy in patients with BCAL secondary lymphedema.

Neuro-trophic/protective 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 in a Phase I/II trial by Herantis for its potential neuroprotective and neurorestorative properties in PD. The trial is funded through an EU grant (Horizon 2020). CDNF is dosed intracranially once a month (a two- to three-hour infusion in the outpatient setting) using an implanted drug delivery device with portal access located behind the patient's ear. Top-line efficacy and safety data are expected by the year end. Herantis's CDNF is unable to cross the blood brain barrier (BBB) in its current formulation. Since Herantis in-licensed the global rights to a second generation of CDNF (from the University of Helsinki in July 2018), it has been actively developing a non-invasive way of delivering CDNF and expects to select a lead molecule for development by the year end.

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 Phase I 12-month follow-up results announced in April 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. If the Phase II AdeLE trial completes successfully, then a Phase III programme in BCAL could be initiated in 2021 either by Herantis or a potential development and commercialisation partner. New trial sites were opened in Stockholm and Uppsala in March 2019.

Financials: Funded through inflection points

In H119, Herantis issued 1.1m new shares (subscription price of €5.20) raising gross €5.8m, which we should enable a cash runway into late 2020. Herantis reported a net loss of €3.3m in H119 (€1.8m in H118). R&D expenses increased to €1.4m (H118: €1.1m), reflecting the advancement of the R&D pipeline. Financial expenses increased substantially to €411,733 (vs €28,817 in H118) due to the one-off costs associated with the capital raise in May. We note the majority of funding for the Phase I/II CDNF trial is through an EU grant. Cash burn amounted to €2.7m in H119 (H118: €1.8m). In the near term, Herantis will continue to be cash consumptive and operate as a non revenue-generating biotech. Cash and cash equivalents at 30 June 2019 were reported at €5.6m and debt was €6.5m (Business Finland loans). Due to higher than expected H119 costs we now forecast an FY19 net loss of €5.8m (vs €4.5m previously). We note that management is considering a secondary listing on the First North Stockholm marketplace. Herantis has previously been granted R&D loans from Business Finland, of which €0.6m remains to be drawn down; in H119 the company drew down €0.25m and we anticipate the remaining €0.6m will be drawn down by the year end. Additionally, the Phase I-II study (TreatER) of CDNF in PD is essentially funded by a grant (Horizon 2020) of €6.0m. We expect Herantis to raise additional capital (through either equity or debt) before late 2020 to fund ongoing operations.

Exhibit 1: Financial summary

Accounts: IFRS, Yr end: December, EUR:	2016	2017	2018	2019e	2020e
Income statement					
Total revenues	25	0	0	0	0
Cost of sales	0	0	0	0	0
Reported gross profit	25	0	0	0	0
SG&A (expenses)	(942)	(1,024)	(1,244)	(1,493)	(1,508)
R&D costs	(27)	0	0	(2,840)	(1,988)
Other (includes exceptionals)	(2,273)	(1,703)	(2,424)	232	235
Depreciation	(1,203)	(1,218)	(1,202)	(1,213)	(910)
Adjusted EBIT	(4,420)	(3,945)	(4,871)	(5,313)	(4,171)
Reported EBIT	(4,420)	(3,945)	(4,871)	(5,313)	(4,171)
Finance income/ (expense)	(4)	1,780	691	(485)	(68)
Other income (expense) (includes exceptionals)	0	0	0	0	0
Adjusted PBT	(4,425)	(2,165)	(4,180)	(5,799)	(4,239)
Reported PBT	(4,425)	(2,165)	(4,180)	(5,799)	(4,239)
Income tax expense	0	0	0	0	0
Adjusted net income	(4,425)	(2,165)	(4,180)	(5,799)	(4,239)
Reported net income	(4,425)	(2,165)	(4,180)	(5,799)	(4,239)
Earnings per share					
Basic EPS (€)	(1.1)	(0.5)	(0.8)	(1.0)	(0.7)
Diluted EPS (€)	(1.1)	(0.5)	(0.8)	(1.0)	(0.7)
Adjusted basic EPS (€)	(1.1)	(0.5)	(0.8)	(1.0)	(0.7)
Adjusted diluted EPS (€)	(1.1)	(0.5)	(0.8)	(1.0)	(0.7)
Average number of shares - basic (m)	4.1	4.2	4.9	5.5	6.1
Average number of shares - diluted (m)	4.1	4.9	5.5	6.1	6.1
Balance sheet					
Property, plant and equipment	9	7	5	4	3
Goodwill	0	0	0	0	0
Intangible assets	6,590	5,663	4,735	3,524	2,616
Other non-current assets	712	392	118	117	116
Total non-current assets	7,311	6,061	4,857	3,644	2,734
Cash and equivalents	2,829	5,402	2,186	4,233	904
Inventories	0	0	0	0	0
Trade and other receivables	65	109	105	105	105
Other current assets	0	0	0	0	0
Assets classified for sale	0	0	0	0	0
Total current assets	2,895	5,511	2,290	4,338	1,009
Non-current loans and borrowings	8,018	6,022	5,878	6,729	6,729
Trade and other payables	0	0	0	0	0
Other non-current liabilities	0	0	0	0	0
Total non-current liabilities	8,018	6,022	5,878	6,729	6,729
Trade and other payables	186	278	200	200	200
Current loans and borrowings	103	547	507	507	507
Other current liabilities	324	634	651	651	651
Liabilities of assets held for sale	0	0	0	0	0
Total current liabilities	613	1,460	1,358	1,358	1,358
Equity attributable to company	1,575	4,090	(89)	(106)	(4,345)
Non-controlling interest	0	0	0	0	0
Cashflow statement					
Profit before tax	(4,425)	(2,165)	(4,180)	(5,799)	(4,239)
Depreciation of tangible assets	1,203	1,218	1,202	1,213	910
Amortisation of intangible assets	0	0	0	0	0
Share based payments	(0)	(2,021)	(3)	0	0
Other adjustments	5	240	(688)	485	68
Movements in working capital	166	372	(79)	0	0
Net cash from operating activities (pre-tax)	(3,052)	(2,355)	(3,747)	(4,100)	(3,261)
Interest paid / received	16	(244)	15	(485)	(68)
Income taxes paid	0	0	0	0	0
Cash from operations (CFO)	(3,036)	(2,599)	(3,732)	(4,586)	(3,329)
Capex (includes acquisitions)	(10)	0	0	0	0
Other investing activities	(61)	(0)	7	0	0
Cash used in investing activities (CFIA)	(71)	(0)	7	0	0
Proceeds from issue of shares	0	4,680	0	5,782	0
Movements in debt	0	0	509	851	0
Other financing activities	396	492	0	0	0
Cash from financing activities (CFF)	396	5,172	509	6,633	0
Currency translation differences and other	0	0	0	0	0
Increase/(decrease) in cash and equivalents	(2,711)	2,573	(3,216)	2,047	(3,329)
Cash and equivalents at beginning of period	5,541	2,829	5,402	2,186	4,233
Cash and equivalents at end of period	2,829	5,402	2,186	4,233	904

Source: Edison Investment Research, Herantis accounts

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