Herantis Pharma Plc

Company release August 25, 2016 at 9:00am

Development of Lymfactin® and CDNF proceeds as planned Herantis Pharma Plc's Half year financial report January 1-June 30, 2016 (unaudited)

Highlights in January-June 2016 (compared with January-June 2015):

- Patient recruitment was started in May in a clinical study with the company's drug candidate Lymfactin® in breast cancer associated lymphedema
- In March, European Medicines Agency EMA granted orphan designation for the company's drug candidate CDNF for the treatment of Amyotrophic Lateral Sclerosis (ALS). After the end of the review period, also the US Food and Drug Administration FDA granted orphan designation for CDNF
- In January, the company expanded on the outlook of its development programs
- Revenue was €25.3 (€1.2) thousand
- Cash flow from operations was € -2.1 (-5.3) million

Key figures

€ thousands	1-6/2016	1-6/2015	1-12/2015
	Consolidated	Consolidated	Consolidated
Revenue	25.3	1.2	0.2
Personnel expenses	544.9	766.0	1,332.1
Depreciation and amortization	599.0	8,593.2	9,421.1
Other expenses for business operations	1,427.2	4,372.5	5,415.0
Profit for the period	-2,597.5	-13,585.2	-16,044.7
Cash flow from operations	-2,113.0	-5,335.8	-7,397.7

€ thousands	Jun 30, 2016	Jun 30, 2015	Dec 31, 2015
	Consolidated	Consolidated	Consolidated
Cash and cash equivalents	3,732.3	6,635.8	5,540.6
Equity	3,401.9	8,135.8	5,999.4
Balance sheet total	11,582.3	15,899.9	14,088.6

	1-6/2016	1-6/2015	1-12/2015
	Consolidated	Consolidated	Consolidated
Equity ratio %	29.4	51.2	42.6



Earnings per share €	-0.63	-3.34	-3.94
Number of shares at end of period	4,118,305	4,067,794	4,085,994
Average number of shares	4,116,341	4,063,201	4,070,468

Formulae used in calculating key figures

Equity ratio = Equity / balance sheet total

Earnings per share = Profit for period / average number of shares

Average number of shares = Weighted average number of shares. The number of shares is weighted by the number of days each share has been outstanding during the review period

Guidance for 2016

In pharmaceutical development, the speed of research defines the expenses incurred. The faster the research, the more quickly expenses are created. The company does not expect essential revenue in 2016. The financial position is expected to be positive at the end of the period.

Outlook for 2016

Herantis has focused on the clinical development of its three most important drug candidates. Herantis' long-term goal is to significantly increase its business through commercialization agreements for its drugs and investing the received income in the development of new drug candidates.

Thus far, no commercialization agreements exist. Instead, Herantis' operations focus on the clinical development of its drugs. The objective has been set to enter a commercialization agreement for at least one of the drug candidates with a Finnish or international pharmaceutical company by the end of 2017.

In 2016, Herantis started patient recruitment in the first clinical study with Lymfactin® in breast cancer associated lymphedema. The company intends to start patient recruitment also in the first clinical study with its drug candidate CDNF in Parkinson's disease by the end of 2016. These drug candidates are based on leading academic science by the research groups of academy professor Kari Alitalo and professor Mart Saarma and they intend to provide novel treatments in serious diseases with significant unmet clinical needs.

The company continues partnering discussions related to its Cis-UCA Eye Drops. No essential further funding will be allocated to their development at present.

Pekka Simula, CEO:

"Development of our drug candidates CDNF and Lymfactin® has proceeded as planned in the review period. Patient recruitment in the first clinical study with Lymfactin® was started in May in Finland. At the same time the preparations for the first clinical study with CDNF have continued as intended and I remain confident that patient recruitment in our Parkinson's disease study will also start by the end of the year. Both of these drug candidates are based on leading academic science in their fields. I am grateful to academy professor Kari Alitalo, professor Mart Saarma, and the University of Helsinki for the excellent collaboration. I am also proud for the expertise we have in Finland for the conduct of such challenging clinical



studies, which may lead to significant benefits for patients with Parkinson's disease and lymphedema all over the world.

A significant achievement in the review period was obtaining orphan designation from the European Medicines Agency EMA for CDNF for the treatment of ALS. ALS, or amyotrophic lateral sclerosis, is an aggressive and fatal motor neuron disease for which there are no efficacious treatments. More than 100,000 patients die every year of ALS.

In addition to the EMA orphan designation also the Food and Drug Administration of the USA (FDA) granted us orphan designation after the end of the review period. There are only about half a dozen drug candidates being developed for the treatment of ALS with orphan designations from both the FDA and the EMA; and CDNF has a completely novel mechanism of action compared to other development programs. Encouraged by our initial results we are working hard to launch a formal development program on CDNF also for the treatment of ALS."

Herantis' drug development

The development of novel, innovative drug candidates aiming at medical breakthroughs requires long-term research and development of many years. Herantis' drug candidates are based on internationally renowned academic research.

Herantis intends to establish the safety and a signal of efficacy of its prioritized drug candidates in clinical studies over the next years. If the studies proceed as planned the company aims to negotiate commercialization agreements with larger pharmaceutical companies covering the late stage development and marketing of the drugs. The goal of Herantis is to enter at least one commercialization agreement by the end of 2017.

Lymfactin® for the treatment of breast cancer associated lymphedema

Approximately 20% of breast cancer patients who undergo axillary lymph node dissection develop secondary lymphedema, a chronic, progressive, disabling, and disfiguring condition that severely affects quality of life. Symptoms include a chronic swelling of an upper limb, thickening and hardening of skin, loss of mobility and flexibility, pain, and susceptibility to secondary infections. Secondary lymphedema is currently treated with compression garments, special massage, and exercises. While these therapies may relief the symptoms in some patients they do not cure lymphedema, which is caused by damage to the lymphatic system. There are currently no approved medicines for the treatment of this condition.

Lymfactin® is a gene therapy expressing the growth factor VEGF-C specific to the development of lymphatic vessels. Based on preclinical studies it is expected to trigger the growth of new functional lymphatic vasculature in the damaged area and thus repair the underlying cause of lymphedema. Lymfactin® is based on the internationally renowned scientific research of academy professor Kari Alitalo and his research group at the University of Helsinki.

As stated in a company release May 18, 2016 the company has started patient recruitment in a Phase 1 clinical study. The primary endpoint of the study is establishing safety and tolerability of Lymfactin®. Signals of efficacy of Lymfactin® will also be analyzed. The clinical study is being conducted in Finland and it aims to recruit up to 18 patients by the end of 2017.

CDNF neuroprotective factor for the treatment of Parkinson's disease



Herantis is developing its drug candidate CDNF for the treatment of Parkinson's disease (PD). Parkinson's disease is a slowly progressing incurable neurodegenerative disease affecting estimated 7 million people worldwide. The known treatments of PD alleviate its motor symptoms but cannot slow disease progression; their efficacy is typically lost with years of disease progression. Herantis intends to significantly improve the treatment of PD with CDNF.

CDNF is an endogenous protein first identified in the long-term academic research lead by professor Mart Saarma. In preclinical disease models of PD it has alleviated both motor and non-motor symptoms associated with the disease and also slowed disease progression. Herantis has completed the preclinical toxicology studies required by the authorities and intends to start patient recruitment in the first clinical study in the end of 2016. This clinical study aims to investigate the safety and initial efficacy of CDNF in 18 patients with Parkinson's disease in Finland and Sweden.

CDNF neuroprotective factor for the treatment of ALS

ALS (Amyotrophic Lateral Sclerosis) is a fatal motoneuron disease. With disease progression the patient loses ability to control muscles causing difficulty in moving, speaking, swallowing and breathing. Average lifetime expectation from diagnosis is between two and five years. ALS cannot be cured and available treatments are essentially symptomatic. Estimated 140,000 new cases are diagnosed annually.

In the spring 2016 the European Medicines Agency EMA granted Herantis CDNF an orphan designation for the treatment of ALS, based on the scientific results provided by the company justifying the assumption that CDNF will be of significant benefit to ALS patients. Herantis is investigating the possibilities of launching a formal development program of CDNF for the treatment of ALS. At the present any decisions have not been made on such development program and the company does not have funding for it.

Cis-UCA eye drops for the treatment of Dry Eye

Dry eye (Keratoconjunctivitis sicca) is the most common cause for eye irritation. Its typical symptoms include dryness of the eye, a burning feeling, pain, redness and a sensation of a foreign object in the eye. Severe or prolonged dry eye may damage the surface of the eye and deteriorate eyesight.

As stated in a company release June 6, 2015 the company completed its randomized Phase 2 clinical study with Cis-UCA Eye Drops in 2015. The study did not establish the superiority of Cis-UCA efficacy in primary endpoints of the study. Herantis nevertheless continues negotiations in 2016 aiming at a co-development agreement on the drug candidate.

Financial review

Income from business operations, R&D expenses

Herantis had no essential revenue during the review period or in the corresponding period in the previous year.

The review period's R&D expenses were € 1.2 (4.1) million, recorded in the profit and loss statement as expense for the period. The R&D expenses mainly comprised expenses for preparations of the clinical studies of CDNF in Parkinson's disease and of Lymfactin® for the treatment of breast cancer associated lymphedema.



The profit for the review period was € -2.6 (-13.6) million.

Financing and capital expenditure

The company's cash and cash equivalents on June 30, 2016 amounted to € 3.7 million (6.6 million). In addition the company has R&D loans granted by Tekes, the Finnish Funding Agency for Innovation, totaling approximately €2.1 million that it has not yet raised.

The group's cash flow from operations in the review period was € -2.1 (-5.3) million.

Acquisitions and directed share issues

As stated in a company release January 14, 2016 the Board of Directors of Herantis decided on a directed share issue to Broadview Ventures I, LLC based on authorization by the company's annual meeting of shareholders and according to a subscription agreement between the parties. Broadview Ventures I, LLC fully subscribed to this share issue, total of 32,311 new shares in Herantis Pharma Plc for a subscription price of €10.00 per share. The new shares were registered in the Trade Register on January 12, 2016, as of which date the new shares have established shareholder rights.

The share capital was not increased with subscriptions. The entire subscription price of €323,110.00 was entered in the invested unrestricted equity reserve of the company. As a result of the share subscriptions, the number of shares of Herantis Pharma Plc increased to 4,118,305 shares. The new shares have been traded on the Nasdaq Helsinki Ltd's First North marketplace together with the old shares as of January 14, 2016.

Balance sheet

The consolidated balance sheet on June 30, 2016 stood at approximately € 11.6 (15.9) million.

At the end of the review period on June 30, 2016 the consolidated balance sheet totaled \in 0.5 (0.9) million in short term loans, \in 7.6 (6.8) million in long term loans from credit institutions, and \in 0.1 (0.1) million in capital loans. Financial income was \in 0.0 (0.1) million.

No R&D expenses were capitalized during the review period.

Equity

Consolidated equity on June 30, 2016 was €3.4 (8.1) million.

Personnel, management and administration

At the end of the review period, Herantis Pharma employed 7 (7) persons.

In the review period, the members of the board of directors of the company were Pekka Mattila (chairman), Jim Phillips, Aki Prihti, Timo Veromaa, and Frans Wuite.

The management team of the company consisted of CEO Pekka Simula and Chief Medical Officer Burkhard Blank.

Annual General Meeting of Shareholders 2016

The Annual General Meeting of Shareholders ("AGM") was held in Helsinki on Monday April 11, 2016.



The AGM adopted the consolidated financial statements and the parent company's financial statements for the financial year 2015 and discharged the members of the Board of Directors and the CEO from liability. The AGM decided that, as proposed by the Board of Directors, no dividend be paid for the financial year January 1 - December 31, 2015 and that the loss for the financial year shall be entered in the compilation of loss.

The AGM resolved that the remuneration payable to the members of the Board of Directors shall be € 1,000 per month except for the Chairman of the Board who shall be paid € 2,000 monthly. It was further resolved that the board members shall also be eligible to subscribe to stock options of option program 2014 I, according to the rules of which the board members can be given stock options for each full 12 month period as a Board member.

The AGM decided that the auditor will be paid a reasonable remuneration in accordance with the invoice approved by the company.

The firm of authorised public accountants PricewaterhouseCoopers Oy was appointed as Herantis Pharma Plc's Auditor for the term ending at the end of the next Annual General Meeting of Shareholders, with APA Martin Grandell as the responsible auditor.

Stock option programs

Herantis has five stock option programs: Stock option program 2010, Stock option program 2014 II, Stock option program 2014 II, and Stock option program 2016 I, whereby stock options have been offered to senior employees of the company to increase their commitment toward long-term contribution to growing shareholder value. The essential details of the stock option programs are listed in the table below. More detailed information is provided on the company's web site at www.herantis.com.

Stock option program	Number of shares at most ¹	Share subscription price	Decision on the stock option program made by
2010	37,600	€ 0.00005	General Meeting 26.8.2010
2014 I	50,800	€ 0.00005	General Meeting 20.3.2014
2014 II A	24,027	€ 7.32	General Meeting 29.4.2014
2014 II B	0	€ 20.73	General Meeting 29.4.2014
2014 II C	0	€ 0.02	General Meeting 29.4.2014
2014 II D	22,349	€ 8.78	General Meeting 29.4.2014
2014 II E	16,342	€ 10.00	General Meeting 29.4.2014
2014 II F	10,253	€ 10.00	General Meeting 29.4.2014
2014 III G	10,232	€ 10.00	General Meeting 29.4.2014
2014 III H	10,232	€ 10.00	General Meeting 29.4.2014
2016 I	70,000	€ 2.92	General Meeting 9.4.2015, Board Meeting 19.5.2016
TOTAL	251,835	-	-

¹ The maximum number of shares to be subscribed by stock options



Risks and uncertainties

The most significant risks and uncertainties in Herantis' business operations are detailed in the IPO prospectus dated May 12, 2014 (available in Finnish).

The clinical risk of cis-UCA Eye Drops have partially materialized as based on the Phase 2 clinical study its efficacy was weaker than expected based on preclinical research.

The company announced on February 25, 2016 that the arbitration proceedings initiated by Finvector Vision Therapies Ltd against a subsidiary of Herantis, Laurantis Pharma Ltd, and a number of its former shareholders (company release March 9, 2015) had been concluded. The arbitral tribunal held that there had been no alleged breach of shareholders' agreement and thus Finvector was not entitled to claim damages. Finvector's claim was dismissed in full and Finvector was obligated to pay to Laurantis and its former shareholders as compensation for the legal costs approximately €200,000. The compensation to Laurantis was approximately €50,000. The decision did not impact Herantis' outlook or guidance for 2016.

Shares and shareholders

Herantis' market capitalization at the end of the review period was €3.4 million. The closing price of the share on June 30, 2016 was €0.84, with the highest price during the review period being €2.10, lowest €0.80, and average €0.99; and total trading volume being 9.1% of the shares in the company.

According to Herantis' shareholder register on June 30, 2016 the company had 537 registered shareholders.

At the end of the review period on June 30, 2016 the members of Herantis' Board of Directors and the CEO held a total of 49,866 (43,486) shares, including shares held through controlled companies, equaling 1.2% (1.1%) of the company's total stock.

Essential updates after the review period

Herantis informed on 11 July 2016 that also the Food and Drug Administration of the USA (FDA) had granted CDNF an orphan designation for the treatment of ALS.

Herantis informed on 8 Aug 2016 that an EU funding application coordinated by the company has passed evaluation and has been invited to start grant preparation. The application concerns an approximately €6 million grant for the planned first clinical study of CDNF in Parkinson's disease.

Accounting principles for the half-year report

This half-year interim report is prepared in accordance with good accounting practices, local legislation and the rules of the First North Finland marketplace. The figures in this report are not audited. The figures are independently rounded.

Financial reporting in 2016

Financial reports for the period Jan 1, 2016 - Dec 31, 2016 will be published on Tuesday February 28, 2017.

This report is published in Finnish and in English. In case of any discrepancies between the language versions, the Finnish version shall prevail.



In Helsinki on 25 August 2016 Herantis Pharma Plc Board of Directors

APPENDICES

Profit & loss statement and balance sheet January 1-June 30, 2016 Cash flow statement January 1-June 30, 2016 Changes in equity

Distribution: Nasdaq Helsinki Main media www.herantis.com

For more information, please contact:

Pekka Simula, CEO, telephone: +358 40 730 0445

Company web site: www.herantis.com

Certified Advisor: UB Securities Oy, telephone +358 9 2538 0254

Herantis Pharma in brief:

Herantis Pharma Plc is a drug development company focused on early clinical development of innovative drugs in unmet clinical needs. Our special emphasis is in regenerative medicine where the company has two first-in-class assets based on globally leading science in their fields: CDNF for neurodegenerative diseases, primarily Parkinson's and ALS; and Lymfactin® for breast cancer associated lymphedema, with potential also in primary lymphedema. The shares of Herantis are listed on the First North Finland marketplace run by Nasdaq Helsinki stock exchange.



CONSOLIDATED INCOME STATEMENT

Currency EUR	1.1.2016 30.6.2016	1.1.2015 30.6.2015	1.1.2015 31.12.2015
NET TURNOVER	25 291,91	1 155,00	1 955,00
Other operating income Staff expenses	0,00	16,47	16,47
Wages and salaries Social security expenses	-436 738,20	-656 211,79	-1 121 083,87
Pension expenses	-74 861,29	-82 825,93	-155 779,86
Other social security expenses	-33 319,77	-26 975,24	-55 244,93
	-544 919,26	-766 012,96	-1 332 108,66
Depreciation and reduction in value			
Depreciation according to plan	-494 572,68	-8 488 862,11	-9 212 362,07
Depreciation from consolidation difference	-104 381,99	-104 381,99	-208 763,98
	-598 954,67	-8 593 244,10	-9 421 126,05
Other operating charges	-1 427 198,01	-4 372 491,54	-5 414 990,10
OPERATING PROFIT (LOSS)	-2 572 868,67	-13 730 577,13	-16 166 253,34
Financial income and expenses Other interest and financial income From others Interest and other financial expenses	32 958,24	199 455,92	205 814,03
For others	-57 572,90	-54 077,90	-84 244,08
	-24 614,66	145 378,02	121 569,95
PROFIT (LOSS) BEFORE EXTRAORDINARY ITEMS	-2 597 483,33	-13 585 199,11	-16 044 683,39
PROFIT (LOSS) BEFORE APPROPRIATIONS AND TAXES	-2 597 483,33	-13 585 199,11	-16 044 683,39
PROFIT (LOSS) FOR THE FINANCIAL YEAR	-2 597 483,33	-13 585 199,11	-16 044 683,39
CONSOLIDATED PROFIT (LOSS)	-2 597 483,33	-13 585 199,11	-16 044 683,39

CONSOLIDATED BALANCE SHEET

Currency EUR	30.6.2016	30.6.2015	31.12.2015
ASSETS			
NON-CURRENT ASSETS			
Intangible assets			
Development expenses	7 054 082,65	8 211 411,16	7 517 935,15
Intangible rights	196 391,24	249 792,70	226 126,96
Consolidation difference	591 497,24	800 261,93	695 879,23
	7 841 971,13	9 261 465,79	8 439 941,34
Tangible assets	•	•	,
Machinery and equipment	6 891,21	1 493,76	1 287,06
	6 891,21	1 493,76	1 287,06
Investments			
Participating interests	1 162,50	1 162,50	1 162,50
	1 162,50	1 162,50	1 162,50
	7 850 024,84	9 264 122,05	8 442 390,90
CURRENT ASSETS			
Debtors			
Short-term			
Other debtors	88 309,52	47 312,34	87 203,63
Prepayments and accrued income	10 067,48	5 432,47	18 473,94
	98 377,00	52 744,81	105 677,57
Securities	3 004 913,40	5 000 000,00	5 000 000,00
Cash in hand and at banks	628 989,24	1 583 052,66	540 558,76
	3 732 279,64	6 635 797,47	5 646 236,33
	11 582 304,48	15 899 919,52	14 088 627,23

CONSOLIDATED BALANCE SHEET

Currency EUR	30.6.2016	30.6.2015	31.12.2015
ASSETS TOTAL			
LIABILITIES			
CAPITAL AND RESERVES			
Subscribed capital			
Subscribed capital	80 000,00	80 000,00	80 000,00
	80 000,00	80 000,00	80 000,00
Other reserves			
Free invested equity reserve	32 976 176,82	32 653 065,91	32 976 176,82
Retained earnings (loss)	-27 056 772,27	-11 012 088,17	-11 012 088,87
Profit (loss) for the financial year	-2 597 483,33	-13 585 199,11	-16 044 683,39
	3 401 921,22	8 135 778,63	5 999 404,55
CREDITORS			
Long-term			
Capital loans	98 300,00	98 300,00	98 300,00
Loans from credit institutions	7 626 229,65	6 755 329,65	7 413 259,65
	7 724 529,65	6 853 629,65	7 511 559,65
Short-term		0 000 020,00	7 017 000,00
Loans from credit institutions			212 970,00
Trade creditors	280 464,63	618 273,46	188 759,88
Other creditors	44 223,69	113 405,42	29 824,10
Accruals and deferred income	131 165,29	178 832,36	146 109,04
	455 853,61	910 511,24	577 663,02
	8 180 383,26	7 764 140,89	8 089 222,67
LIABILITIES TOTAL	11 582 304,48	15 899 919,52	14 088 627,23

FUNDS STATEMENT

Currency EUR	30.6.2016	30.6.2015	31.12.2015
Cash flow from operating activities			
Profit (loss) before extraordinary items	-2 597 483,33	-13 585 199,11	-16 044 683,39
Corrections:	-2 031 400,00	-13 303 199,11	-10 044 005,59
Depreciation According to plan and amortization	494 572,68	8 488 862,11	9 212 362,07
Depreciation from consolidation difference	104 381,99	104 381,99	208 763,98
Unrealized exchange rate profits and losses	1 321,31	30 167,91	-167 891,92
Other financial income and expences	23 293,35	0,00	289 461,87
Cash flow before change in working capital	-1 975 235,31	-4 961 787,10	-6 334 095,47
	. 0. 0 2.00,0 ,	. 001 /01,10	0 004 000,47
Change in working capital:			
Increase(-)/decr.(+) in short-term interest-free receivables	7 867,39	168 451,51	62 011,11
Increase(+)/decr.(-) in short-term interest-free liabilities	-122 376,24	-512 309,61	-1 079 308,57
Cash flow from operations before financial items and taxes	-2 089 744,16	-5 305 645,20	-7 351 392,93
Interest paid and pmts for other financ. exp. from operat.	-53 681,26	-54 077,90	-71 054,32
Financial income received from operations	30 387,91	23 909,99	24 732,35
Cash flow before extraordinary items	-2 113 037,51	-5 335 813,11	-7 397 714,90
Cash flow from operating activities (A)	-2 113 037,51	-5 335 813,11	-7 397 714,90
Cash flow from investments:			
Investments in tangible and intangible assets	-6 588,61	0,00	-6 151,51
Capital expenditure on other investments	0,00	0,00	0,00
Cash flow from investments (B)	-6 588,61	0,00	-6 151,51
Cook flow from firm in			
Cash flow from financing:	2.22	440	
Share issue	0,00	11,85	323 122,76
Long-term loans	212 970,00	334 000,00	1 204 900,00
Cash flow from financing (C)	212 970,00	334 011,85	1 528 022,76
Change in cash and cash equivalents(A+B+C) incr.(+)/decr.(-)	-1 906 656,12	-5 001 801,26	-5 875 843,65
Cash and cash equivalents at beginning of period	5 540 558,76	11 637 598,73	11 416 402,41
Cash and cash equivalents at end of period	3 633 902,64	6 635 797,47	5 540 558,76
•	•	•	, -

STATEMENT OF CHANGES IN EQUITY

€

	Share capital	Other funds	Retained	Equity total
			earnings	
Equity on Dec 31, 2015	80 000	32 976 177	-22 397 094	10 659 083
Profit/loss for the period			-1 714 156	
Issue of shares for cash		0		
Equity on Jun 30, 2016	80 000	32 976 177	-24 111 250	8 944 927

	Share capital	Other funds	Retained	Equity total
			earnings	
Equity on Dec 31, 2014	80 000	32 653 054	-6 910 570	25 822 484
Profit/loss for the period			-1 779 093	
Issue of shares for cash		12		
Equity on Jun 30, 2015	80 000	32 653 066	-8 689 663	24 043 403

	Share capital	Other funds	Retained	Equity total
			earnings	
Equity on Dec 31, 2014	80 000	32 653 054	-6 910 570	25 822 484
Profit/loss for the period			-15 486 524	
Issue of shares for cash		323 123		
Equity on Dec 31, 2015	80 000	32 976 177	-22 397 094	10 659 083