Herantis Pharma Plc

Company release August 29, 2017 at 9:00am

Drug development progresses towards randomized trials

Herantis Pharma Plc's half year financial report January 1 - June 30, 2017 (unaudited)

Highlights in January-June 2017 (compared with January-June 2016):

- Herantis Pharma's ("Herantis") Phase 1 clinical study with Lymfactin® advanced in March to the highest dose and in June to the last patient cohort. The company announced in June that it had started planning a Phase 2 clinical study.
- The Swedish drug and device authority MPA approved in March the first clinical study with Herantis' investigational drug CDNF for the treatment of Parkinson's disease. The same study was approved in June by Finland's drug authority Fimea.
- United States' patent authority USPTO granted Herantis a patent on the therapeutic use of MANF in May.
- Revenue was €0.0 (25.3) thousand
- Cash flow from operations was €-0.9 (-2.1) million
- Earnings per share were €-0.49 (-0.63)
- Cash and cash equivalents on June 30, 2017 amounted to €2.2 (3.7) million
- The company's financial position in the last half-year period are as expected and there have not been any exceptional events.

Key figures

€ thousands	1-6/2017	1-6/2016	1-12/2016
Revenue	0.0	25.3	25.3
Personnel expenses	575.1	544.9	942.1
Depreciation and amortization	611.2	599.0	1,202.9
Other expenses for business operations	891.1	1,427.2	2,273.3
Profit for the period	-2,027.9	-2,597.5	-4,424.5
Cash flow from operations	-949.5	-2,113.0	-3,035.7

	1-6/2017	1-6/2016	1-12/2016
Equity ratio %	-5.1	29.4	15.4
Earnings per share €	-0.49	-0.63	-1.07
Number of shares at the end of period	4,118,305	4,118,305	4,118,305
Average number of shares	4,118,305	4,116,341	4,117,331

€ thousands	30 Jun 2017	30 Jun 2016	31 Dec 2016
Cash and cash equivalents	2,218.8	3,732.3	2,829.5
Equity	-453.0	3,401.9	1,574.9
Balance sheet total	8,918.3	11,582.3	10,205.5

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 2017

The company does not expect essential revenues in 2017. The company continues to invest in its ongoing development programs in Secondary Lymphedema and Parkinson's disease, and expects to be cash positive at the end of the year.

Outlook for 2017

Herantis' long-term goal is to significantly increase its business through commercialization agreements for its drug candidates. The company continues discussing collaboration possibilities with potential development partners for its development programs. Thanks to the significant grant awarded by the European Union's the company can continue its drug development further than previously estimated before signing any collaboration agreements to optimize shareholder value in Herantis.

The main objectives for 2017 are recruiting and safely treating patients in the clinical trials with Lymfactin® and CDNF. Both of these drug candidates aim at a breakthrough in unmet clinical needs and are based on leading science in their fields.

Pekka Simula, CEO:

The company's development programs in the treatment of lymphedema and Parkinson's disease progressed favorably during the review period. For both the company and patients it is most important that our drug candidate Lymfactin® has initially proven safe in patient treatments, and independent experts recommended continuing treatments with the highest dose. The highest dose translates into the greatest chance of benefit for the patients.

Another important achievement for the company was clinical trial approvals in both Sweden and Finland for our drug candidate CDNF in Parkinson's disease. This ensures we can fully exploit the about €6 million grant awarded by the European Union for the clinical study.

The EU funding was directed for clinical development based on leading science and having the highest potential to advance clinical practice. This is an appropriate description of all our work. Our development programs are based on internationally renowned long-term scientific research and aim at clinical breakthroughs in diseases with unmet clinical needs.

From Herantis' viewpoint it is also interesting that the investors in our field are in general increasingly looking at novel biological drug candidates based on scientific breakthrough even if their risks are considered greater as compared to conventional drugs. Societies and insurance companies, i.e. the payers of ever more expensive therapeutics, are becoming more sensitive to costs and demand better therapies in return for the high prices. Our societies cannot afford paying ten times more for a new drug, which is only slightly more efficacious than the older and economical medicine. New drugs need to be significantly better than the old ones.

In case of Herantis' Lymfactin® this makes an easy equation. There are no approved medicines for the treatment of lymphedema. Lymfactin® aims at repairing the damages that cause lymphedema. We aim at curing lymphedema instead of just alleviating its symptoms.

For Parkinson's disease a clinical breakthrough could mean a treatment that stops progression of the disease. This is exactly our aim with our CDNF; known treatments can only provide relief in some of the symptoms of the disease. According to a study at the University of Pennsylvania a treatment to stop the progression of Parkinson's disease would save $400,000 per patient in the United States. With 60,000 new patients diagnosed each year such treatment would reduce the economical burden associated with Parkinson's by estimated $24 billion a year.

Drug developers like to remind of the human suffering they are trying to reduce. For the investors it is also important that the drugs-in-development make sense from the health-economic viewpoint.

REVIEW OF OPERATIONS JANUARY 1–JUNE 30, 2017

Herantis' drug development

Herantis develops innovative drugs based on leading scientific research in their fields that aim at breakthrough in unmet clinical needs. The company's objective is to establish the safety of its drug candidates in early-stage clinical studies, show signals of their efficacy, and then negotiate commercialization agreements with large pharmaceutical companies.

Lymfactin® for breast cancer associated lymphedema

Surgery or trauma can damage lymph nodes, which may lead into secondary lymphedema (LE). Its common symptoms are permanent swelling of the affected limb, thickening and hardening of skin, limited limb mobility, pain, and increased sensitivity to inflammations. Secondary lymphedema is a chronic, progressive disease that severely decreases the patient's quality of life. Current treatments such as compression garments, special massage, and exercise may relieve symptoms but do not cure the damages of the lymphatic system that cause the disease.

Herantis' Lymfactin® is an investigational gene therapy drug that produces a growth factor called VEGF-C, which is highly selective to the growth of lymphatic vessels. Based on preclinical results Lymfactin® promotes the regeneration of lymphatic vessels and thus repairs damages of the lymphatic system. Lymfactin® is based on research at an Academy of Finland Centre of Excellence led by Professor Kari Alitalo at the University of Helsinki.

Lymfactin® is currently in a Phase 1 clinical study in patients with breast cancer associated LE. The company announced in the first half of 2017 that the study had advanced favorably and estimated that patient recruitment would be completed by the end of 2017. The company also announced having started planning a Phase 2 clinical study. Herantis believes that if Lymfactin® is shown efficacious it may also be suitable for the treatment of other types of secondary lymphedema.

CDNF neuroprotective factor for Parkinson's disease

Herantis develops its drug candidate CDNF for the treatment of Parkinson's disease (PD). Parkinson's disease is a slowly progressing neurodegenerative disease that cannot be cured. Estimated 7 million people worldwide have Parkinson's disease. Known treatments only alleviate the motor symptoms of the disease but have no effect on its progress, which is caused by the death of dopaminergic neurons in the brain.

CDNF is a protein naturally present in humans. It was discovered in the long-term academic research led by Professor Mart Saarma and shown to protect dopaminergic neurons. In preclinical disease models CDNF has broadly alleviated the symptoms of Parkinson's disease and protected and recovered dopaminergic neurons. Herantis aims at developing CDNF into a drug that addresses both motor and non-motor symptoms of PD and also stops disease

progression.

Thanks to the promising scientific results and development work the European Union granted an approximately €6 million grant for the Phase 1-2 clinical study of CDNF for the treatment of PD. The grant became effective 1 Jan 2017 and the clinical study intends at starting patient recruitment in Q3/2017. The clinical study will assess the safety and signals of efficacy in 18 patients with Parkinson's disease at three university hospitals in Finland and Sweden.

CDNF neuroprotective factor for ALS

ALS (Amyotrophic Lateral Sclerosis) is a fatal motor neuron disease. As the disease progresses the patient loses control of her muscles, which leads to difficulties in motion, speech, swallowing, and breathing. The estimated average survival from symptom onset is from two to five years. There is no known cure; present treatments can only alleviate the symptoms of ALS. An estimated 140,000 people contract ALS annually. The European Medicines Agency EMA and the US Food and Drug Administration FDA have both granted an Orphan Designation for Herantis' CDNF for the treatment of ALS based on the preliminary preclinical results on its possible efficacy. The company is exploring possibilities to start a clinical development program in ALS. Decisions on starting such a program have not been made and no funding is allocated.

MANF neuroprotective factor

MANF is the only known neuroprotective factor similar to Herantis' patented CDNF. CDNF and MANF for instance protect cells from endoplasmic reticulum stress, a condition linked to several neurodegenerative and other chronic diseases. Herantis has been a patent in the USA for the use of MANF for the treatment of neurological diseases including Parkinson's disease, epilepsy, and ischemic brain injury. Herantis will inform separately if it launches formal drug development of MANF.

Cis-UCA eye drops for dry eye

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

Herantis' Phase 2 randomized clinical study of the cis-UCA eye drop for the treatment of dry eye was completed in 2015. The study did not show statistically significant improvements in the primary endpoints in comparison with placebo and the company has fully written off the related development investments in its balance sheet. Herantis will continue partnering discussions in 2017 for product development collaboration.

FINANCIAL REVIEW JANUARY 1–JUNE 30, 2017

Income from business operations, R&D expenses

Herantis Group did not have essential revenues in the review period or in the corresponding period in the previous year.

The R&D expenses for the review period were €0.7 million, recorded in the profit and loss statement as an expense for the period. The R&D expenses for the review period mainly comprised for the clinical study with Lymfactin® for the treatment of breast cancer associated lymphedema and for preparations for the clinical study with CDNF for the treatment of Parkinson's disease. The group's R&D expenses for the corresponding period in the previous year, €1.2 million, were recorded as the review period's expenses in the profit and loss statement.

The profit for the review period was €-2.0 (-2.6) million.

Financing and capital expenditure

The company's cash and cash equivalents on June 30, 2017 amounted to €2.2 (3.7) million.

In addition the company has R&D loans previously granted by the Finnish Funding Agency for Innovation, Tekes, to be drawn in the amount of €1.6 million. During the review period Herantis drew €0.3 million in Tekes loans.

In addition the European Union has awarded a grant of €6.0 million for the project TreatER. The TreatER project is essentially the Phase 1-2 clinical study of Herantis' CDNF for the treatment of Parkinson's disease. During the review period the company received an advance payment of €0.7 million related to the project. Advance payments have also been paid to the other EU project participants such as the hospitals where the patients will be treated.

The company estimates that its current funding will suffice approximately to the end of 2018. However the EU funding granted for the TreatER project is estimated to suffice until project completion at the end of 2019.

The consolidated cash flow from operations in the review period was €-0.9 (-2.1) million.

Acquisitions and directed share issues

There have been no acquisitions or directed share issues during the review period.

Balance sheet

The consolidated balance sheet on June 30, 2017 stood at €8.9 (11.6) million.

At the end of the review period on June 30, 2017 the consolidated balance sheet included short-term debt in the amount of €1.4 (0.5) million, long-term loans in the amount of €7.9 (7.6) million, and capital loans in the amount of €0.1 (0.1) million. Financing earnings and expenses totaled €0.0 (0.0) million.

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

Equity

Consolidated equity on June 30, 2017 was €-0.5 (3.4) million. The change is a result of the consolidated loss of the review period.

Personnel, management, and administration

The number of personnel at the end of the review period on June 30, 2017 was 7 (7) persons.

During the review period, the company's Board of Directors comprised Pekka Mattila (Chairman), Jim Phillips, Aki Prihti, Timo Veromaa and Frans Wuite, The Managing Director for the company was Pekka Simula.

Ordinary Annual General Meeting 2017

Herantis' ordinary Annual General Meeting (AGM) was held in Helsinki on April 11, 2017.

The AGM adopted the annual accounts for financial year 2016 and resolved to discharge the members of the Board of Directors and the Managing Director from liability. In accordance with the proposal by the Board of Directors, the AGM resolved that no dividend be paid for the financial period January 1–December 31, 2016, and that the loss for the period be recorded on the profit and loss account.

The AGM resolved that the remuneration for the members of the Board of Directors shall be €1,000 per month, with the exception of its Chairman, whose remuneration shall be €2,000 per month. It was further resolved that the Board members shall be eligible to subscribe for stock options under the Stock option program 2014 I, according to the rules of which the Board members can be granted stock options for each full 12-month period as a Board member. Board members are also reimbursed reasonable travel expenses related to Board of Director's duties.

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

The firm of authorized public accountants PricewaterhouseCoopers Oy was appointed Herantis Pharma Plc's Auditor for the term ending at the closing of the next AGM, with Mr. Martin Grandell, APA, as the responsible auditor.

Share based incentive program

During the review period the company cancelled a total of 96,625 stock option rights that would have entitled to the subscription of 96,625 new shares in the company. The share subscription period of these stock option rights, which belonged to the stock option programs 2014 II and 2014 III had expired.

Herantis has three stock option programs: Stock option program 2010, Stock option program 2014 I, and Stock option program 2016 I, whereby stock

options have been offered to key 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
2016 I	70,000	€ 2.92	General Meeting 9.4.2015, Board Meeting 19.5.2016
TOTAL	**158,400**	**-**	**-**

[1] The maximum remaining number of shares to be subscribed for with stock options.

Risks and uncertainties

Herantis is a drug development company and the general risks and uncertainties present in drug development also apply to its operations. Further, Herantis develops novel biological drugs based on novel scientific research and with mechanisms different from currently approved drugs. Therefore the risks and uncertainties can be considered larger than in conventional drug development.

The significant risks and uncertainties in Herantis' business operations are described in the IPO prospectus dated May 12, 2014 that is available on the company's website at www.herantis.com. The medical risk related to the cis-UCA eye drop is partly realizing as the efficacy of the drug candidate proved weaker in the Phase 2 clinical studies than expected on the basis of preclinical studies.

Shares and shareholders

The market capitalization of Herantis Pharma Plc at the end of the review period on June 30, 2017 was €29.0 million. The closing price of the company's share on June 30, 2017 was €7.05. The highest share price during the review period was €9.30, lowest €2.66, average €4.63, and trading volume amounted to 6.0% of the shares in the company.

According to Herantis' shareholder register dated on June 30, 2017, the company had 799 registered shareholders.

On June 30, 2017 the members of Herantis' Board of Directors and the CEO held in aggregate 53,366 (49,866) shares including shares held through their controlled companies, which equaled 1.3 (1.2) percent of the company's total

stock. Information on insider trading with the company's shares is published on the company's website.

Events after the review period

No essential updates have taken place after the review period.

Accounting policies

These financial statements have been prepared according to good accounting practice, local legislation and the rules of the First North market. The figures in the half-year report are not audited. The figures are individually rounded from exact figures.

Financial information 2017

The financial statements release will be published 28 Feb 2018.

In case of any discrepancies between the language versions of this half-year financial report the Finnish version shall prevail.

Herantis Pharma Plc

Board of Directors

APPENDICES

Profit and loss statement and Balance sheet January 1–June 30, 2017
Statement of cash flow January 1–June 30, 2017
Statement of changes in equity

Distribution: Nasdaq, principal media

More information:

Herantis Pharma Plc, Pekka Simula, CEO, telephone +358 40 7300 445
Company website: www.herantis.com
Certified Advisor: UB Securities Oy, telephone +358 9 25 380 246

Herantis Pharma in brief:

Herantis Pharma Plc is an innovative drug development company focused on regenerative medicine and unmet clinical needs. Our first-in-class assets are based on globally leading scientific research in their fields: CDNF for disease modification in neurodegenerative diseases, primarily Parkinson's and ALS; and Lymfactin® for breast cancer associated lymphedema, with potential also in other types of lymphedema. The shares of Herantis are listed on the First North Finland marketplace run by Nasdaq Helsinki Ltd.

Herantis Pharma Oyj
Viikinkaari 4
00790 Helsinki

CONSOLIDATED INCOME STATEMENT

Currency EUR	01/01/17 30/06/17	01/01/16 30/06/16	01/01/16 31/12/16
NET TURNOVER		25 291,91	25 291,91
Other operating income	75 000,00	0,00	29,28
Raw materials and services			
External Services			-27 088,64
Staff expenses			
Wages and salaries	-476 179,56	-436 738,20	-766 051,48
Social security expenses			
Pension expenses	-72 927,15	-74 861,29	-129 008,71
Other social security expenses	-25 996,84	-33 319,77	-47 085,48
	-575 103,55	-544 919,26	-942 145,67
Depreciation and reduction in value			
Depreciation according to plan	-494 681,32	-494 572,68	-990 092,88
Depreciation from consolidation difference	-116 573,99	-104 381,99	-212 827,98
	-611 255,31	-598 954,67	-1 202 920,86
Other operating charges	-891 121,58	-1 427 198,01	-2 273 345,55
OPERATING PROFIT (LOSS)	-2 002 480,44	-2 572 868,67	-4 420 179,53
Financial income and expenses			
Other interest and financial income			
From others	33 744,32	32 958,24	78 199,47
Interest and other financial expenses			
For others	-59 121,76	-57 572,90	-82 528,51
	-25 377,44	-24 614,66	-4 329,04
PROFIT (LOSS) BEFORE APPROPRIATIONS AND TAXES	-2 027 857,88	-2 597 483,33	-4 424 508,57
PROFIT (LOSS) FOR THE FINANCIAL YEAR	-2 027 857,88	-2 597 483,33	-4 424 508,57
CONSOLIDATED PROFIT (LOSS)	-2 027 857,88	-2 597 483,33	-4 424 508,57

Herantis Pharma Oyj
Viikinkaari 4
00790 Helsinki

CONSOLIDATED BALANCE SHEET

Currency EUR	30/06/17	30/06/16	31/12/16
A S S E T S			
NON-CURRENT ASSETS			
Intangible assets			
Development expenses	6 126 377,65	7 054 082,65	6 590 230,15
Intangible rights	136 920,30	196 391,24	166 655,52
Consolidation difference	427 437,26	591 497,24	544 011,25
	6 690 735,21	7 841 971,13	7 300 896,92
Tangible assets			
Machinery and equipment	7 655,63	6 891,21	8 749,23
	7 655,63	6 891,21	8 749,23
Investments			
Participating interests	1 162,50	1 162,50	1 162,50
	1 162,50	1 162,50	1 162,50
	6 699 553,34	7 850 024,84	7 310 808,65
CURRENT ASSETS			
Debtors			
Short-term			
Other debtors	67 514,34	88 309,52	41 606,58
Prepayments and accrued income	6 495,27	10 067,48	23 599,20
	74 009,61	98 377,00	65 205,78
Securities	1 780 513,51	3 004 913,40	2 047 288,94
Cash in hand and at banks	364 259,95	628 989,24	782 186,03
	2 218 783,07	3 732 279,64	2 894 680,75
	8 918 336,41	11 582 304,48	10 205 489,40

Herantis Pharma Oyj
Viikinkaari 4
00790 Helsinki

CONSOLIDATED BALANCE SHEET

Currency EUR	30/06/17	30/06/16	31/12/16
ASSETS TOTAL			
L I A B I L I T I E S			
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	32 976 176,82	32 976 176,82
Retained earnings (loss)	-31 481 280,83	-27 056 772,27	-27 056 772,27
Profit (loss) for the financial year	-2 027 857,88	-2 597 483,33	-4 424 508,57
	-452 961,89	3 401 921,22	1 574 895,98
CAPITAL LOANS	98 300,00	98 300,00	98 300,00
CREDITORS			
Long-term			
Loans from credit institutions	7 867 172,65	7 626 229,65	7 919 291,65
	7 867 172,65	7 626 229,65	7 919 291,65
Short-term			
Loans from credit institutions	419 793,00	0,00	102 853,00
Other income advances	600 000,00	0,00	0,00
Trade creditors	171 440,72	280 464,63	186 074,28
Other creditors	83 220,19	44 223,69	177 757,93
Accruals and deferred income	131 371,74	131 165,29	146 316,55
	1 405 825,65	455 853,61	613 001,76
	9 272 998,30	8 180 383,26	8 532 293,41
LIABILITIES TOTAL	8 918 336,41	11 582 304,48	10 205 489,40

Herantis Pharma Oyj
Viikinkaari 4
00790 Helsinki

FUNDS STATEMENT

Currency EUR	01/01/17 30/06/17	01/01/16 30/06/16	01/01/16 31/12/16
Cash flow from operating activities			
Profit (loss) before appropriatiosn and taxes	-2 027 857,88	-2 597 483,33	-4 424 508,57
Corrections:			
Depreciation According to plan and amortization	494 681,32	494 572,68	990 092,88
Depreciation from consolidation difference	116 573,99	104 381,99	212 827,98
Unrealized exchange rate profits and losses	2 864,26	1 321,31	-278,97
Other financial income and expences	22 513,18	23 293,35	4 608,01
Cash flow before change in working capital	-1 391 225,13	-1 975 235,31	-3 217 258,67
Change in working capital:			
Increase(-)/decr.(+) in short-term interest-free receivables	-8 803,83	7 867,39	40 377,01
Increase(+)/decr.(-) in short-term interest-free liabilities	476 465,15	-122 376,24	125 372,66
Cash flow from operations before financial items and taxes	-923 563,81	-2 089 744,16	-3 051 509,00
Interest paid and pmts for other financ. exp. from operat.	-59 703,02	-53 681,26	-60 339,73
Financial income received from operations	33 744,32	30 387,91	76 188,55
Cash flow from operations before appropriations and taxes	-949 522,51	-2 113 037,51	-3 035 660,18
Cash flow from operating activities (A)	-949 522,51	-2 113 037,51	-3 035 660,18
Cash flow from investments:			
Investments in tangible and intangible assets	0,00	-6 588,61	-10 378,61
Capital expenditure on other investments	0,00	0,00	-60 960,00
Cash flow from investments (B)	0,00	6 588,61	-71 338,61
Cash flow from financing:			
Long-term loans drawn	274 821,00	212 970,00	395 915,00
Long-term loan repayments	-10 000,00	0,00	0,00
Cash flow from financing (C)	264 821,00	212 970,00	395 915,00
Change in cash and cash equivalents(A+B+C) incr.(+)/decr.(-)	-684 701,51	-1 906 656,12	-2 711 083,79
Cash and cash equivalents at beginning of period	2 829 474,97	5 540 558,76	5 540 558,76
Cash and cash equivalents at end of period	2 144 773,46	3 633 902,64	2 829 474,97

Herantis Pharma Oyj
Viikinkaari 4
00790 HELSINKI

STATEMENT OF CHANGES IN EQUITY
€

	Share capital	Other funds	Retained earnings	Equity total
Equity on Dec 31, 2016	80 000	32 976 177	-25 125 874	7 930 303
Profit/loss for the period			-1 156 786	
Issue of shares for cash		0		
Equity on Jun 30, 2017	80 000	32 976 177	-26 282 660	6 773 517

	Share capital	Other funds	Retained earnings	Equity total
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 earnings	Equity total
Equity on Dec 31, 2015	80 000	32 976 177	-22 397 093	10 659 084
Profit/loss for the period			-2 728 780	
Issue of shares for cash		0		
Equity on Dec 31, 2016	80 000	32 976 177	-25 125 873	7 930 304