Herantis Pharma Plc

Company release August 29, 2018 at 9:00am

Drug development progresses in randomized trials

Herantis Pharma Plc's half year financial report January 1 - June 30, 2018 (unaudited)

Highlights in January-June 2018 (compared with January-June 2017):

- Herantis Pharma's ("Herantis") investigational drug CDNF's clinical Phase 1-2 study for the treatment of Parkinson's disease expanded with two additional sites at the university hospitals in Helsinki and Lund in addition to the first site in Stockholm based on a favorable safety evaluation by the independent data safety monitoring board.
- Herantis completed the patient enrolment in the Phase 1 study of Lymfactin gene therapy for breast cancer associated secondary lymphedema and announced positive interim data in April.
- Herantis announced in June the initiation of Phase 2 study for Lymfactin® gene therapy in secondary lymphedema associated with the treatment of breast cancer. The main goal of the study is to evaluate the therapeutic effect of Lymfactin®.
- Revenue was €0.0 (0.0) thousand
- Cash flow from operations was €-1.8 (-0.9) million
- Earnings per share were €-0.36 (-0.49)
- Cash and cash equivalents on June 30, 2018 amounted to €4.0 (2.2) 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	1-6/2018	1-6/2017	1-12/2017
Revenue	0.0	0.0	0.0
Personnel expenses	682.3	575.1	1,024.1
Depreciation and amortization	601.2	611.2	1,216.6
Other expenses for business operations	1,348.3	891.1	1,928.1
Profit for the period	-1,764.7	-2,027.9	-2,164.5
Cash flow from operations	-1,803.8	-949.5	-2,599.0

	1-6/2018	1-6/2017	1-12/2017
Equity ratio %	24.7	-5.1	35.3
Earnings per share €	-0.36	-0.49	-0.51
Number of shares at the end of period	4,918,305	4,118,305	4,918,305
Average number of shares	4,918,305	4,118,305	4,322,653

€ thousands	30 Jun 2018	30 Jun 2017	31 Dec 2017
Cash and cash equivalents	3,965.1	2,218.8	5,511.5
Equity	2,325.7	-453.0	4,090.4
Balance sheet total	9,424.9	8,918.3	11,572.6

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 2018

The company does not expect essential revenues in 2018. The company continues to invest in its ongoing development programs in Secondary Lymphedema (LE) and Parkinson's disease (PD). The company's current financing is expected to be sufficient for completing the first placebo-controlled clinical studies with both CDNF and Lymfactin® drug candidates.

Outlook for 2018

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 partners for its drug development programs. Thanks to its financing situation, the company can continue its drug development through the end of the first placebo-controlled studies before entering into any collaboration agreements, if considered appropriate for shareholder value.

The main objectives for 2018 are the launch of a Phase 2 clinical study with Lymfactin® and the completion of patient recruitment in the Phase 1-2 clinical study with CDNF. Both of these drug candidates are based on leading science in their fields and aim at a breakthrough in the treatment of severe diseases.

Pekka Simula, CEO:

We are really pleased with rapid progress in our clinical development. Both of our drug candidates, CDNF in PD and Lymfactin® in LE, are now in randomized placebo-controlled clinical studies.

The development of our drug candidate Lymfactin® advances toward clinical proof-of-concept. We completed patient recruitment in the Phase 1 safety study in February 2018, then rapidly obtained regulatory approvals for a Phase 2 study and were able to enroll the first Phase 2 patient already in June. The Phase 2 study will provide information about the efficacy of Lymfactin® in the treatment of breast cancer associated LE, a disease that has no approved pharmacological treatments, with Lymfactin® aiming to be a curative therapy.

The Phase 1-2 randomized placebo-controlled clinical study of our drug candidate CDNF is progressing well and the three participating university hospitals in Sweden and Finland are actively recruiting patients. The study will collect safety data and preliminary signals of efficacy in the treatment of PD. CDNF aims at stopping the progression of Parkinson's disease while the available treatments can only alleviate its motor symptoms.

We continue discussions with potential partners related to further development and commercialization of our drug candidates. Herantis' position in discussions is strengthened by having both drug candidates in clinical proof-of-concept studies.

REVIEW OF OPERATIONS JANUARY 1–JUNE 30, 2018

Herantis' drug development

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

Lymfactin® for breast cancer associated lymphedema

Surgery or trauma can damage lymphatic system, 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 LE is a chronic, progressive disease that severely affects the patient's quality of life. Current treatments such as compression garments, 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 human growth factor called VEGF-C, which is the natural trigger for 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 the research at a National Centre of Excellence at the University of Helsinki led by Professor Kari Alitalo.

Lymfactin® is currently in a Phase 2 clinical study in patients with breast cancer associated LE. Herantis announced in February 2018 that the Phase 1 study had completed patient enrollment and Lymfactin® had been safe and well tolerated. In June 2018 the company also announced that the randomized double-blind placebo-controlled Phase 2 study had been started. The Phase 2 study will recruit 40 patients, half of whom will receive the investigational drug Lymfactin® while the other half will receive placebo. Herantis believes that if Lymfactin® is proven efficacious in breast cancer associated LE it may also be suitable for the treatment of other types of LE. The company estimates the market for Lymfactin® in breast cancer associated LE at approximately €500 million in the USA and Europe.

CDNF neuroprotective factor for Parkinson's disease

Herantis develops its drug candidate CDNF for the treatment of PD, a slowly progressing neurodegenerative disease affecting estimated 7 million patients worldwide. Known treatments of PD only alleviate the motor symptoms of the disease but have no effect on its progression or cause: the death of dopaminergic neurons in the brain.

CDNF, a protein naturally present in humans, is a potent neuroprotective factor. It was discovered in the long-term academic research led by Professor Mart Saarma at the University of Helsinki. In preclinical disease models CDNF has broadly alleviated the symptoms of PD 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 approximately €6 million for CDNF research and development including the Phase 1-2 clinical study. The grant became effective 1 Jan 2017. The Phase 1-2 study assesses the safety and signals of efficacy of CDNF in 18 patients with Parkinson's disease at three university hospitals in Sweden and Finland. In February 2018, Herantis announced the favorable safety evaluation by an independent data safety monitoring board and their recommendation to continue the study as planned, including the start of patient recruitment also in Helsinki and Lund.

Potential drug development programs

Herantis has been granted a patent in the USA for the use of MANF in the treatment of neurological diseases including PD, epilepsy, and ischemic brain

injury. MANF is the only known neuroprotective factor similar to Herantis' patented CDNF. Herantis will inform separately if it launches a formal drug development program of MANF.

The European Medicines Agency EMA and the US Food and Drug Administration FDA have granted an Orphan Drug Designation for Herantis' CDNF for the treatment of ALS based on the preliminary preclinical results on its possible efficacy. Decisions on starting a development program have not been made and no funding is allocated.

FINANCIAL REVIEW JANUARY 1–JUNE 30, 2018

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 €1.1 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 studies with Lymfactin® for the treatment of breast cancer associated LE and CDNF for the treatment of PD. The group's R&D expenses for the corresponding period in the previous year, €0.7 million, were recorded as the review period's expenses in the profit and loss statement.

The profit for the review period was €-1.8 (-2.0) million.

Financing and capital expenditure

The company's cash and cash equivalents on June 30, 2018 amounted to €4.0 (2.2) million.

In addition, the company has R&D loans previously granted by Business Finland to be drawn in the amount of €1.1 million. During the review period Herantis drew €0.3 million of the granted 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.

The company estimates that its current funding will suffice approximately to the end of 2019.

The consolidated cash flow from operations in the review period was €-1.8 (-0.9) million.

Acquisitions and directed share issues

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

Affiliate companies

Opia Games Ltd, a partially owned affiliate of Herantis, has been liquidated during the review period. The liquidation didn't have financial implications for Herantis.

Balance sheet

The consolidated balance sheet on June 30, 2018 stood at €9.4 (8.9) million.

At the end of the review period on June 30, 2018 the consolidated balance sheet included short-term debt in the amount of €1.4 (1.4) million, long-term loans in the amount of €5.7 (7.9) million, and capital loans in the amount of €0.0 (0.1) million. Financing earnings and expenses totaled €0.1 (0.0) million.

Business Finland decided in January 2018 to waive a total of €692,458 of loan principal, which was granted for the Amblyopia drug development project terminated in 2013. Also, the loan interest was waived.

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

Equity

Consolidated equity on June 30, 2018 was €2.3 (-0.5) million. The change is the result of the share issue and consolidated loss of the review period.

Personnel, management, and administration

The number of personnel at the end of the review period on June 30, 2018 was 9 (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 2018

Herantis' ordinary Annual General Meeting (AGM) was held in Helsinki on April 11, 2018.

The AGM adopted the annual accounts for financial year 2017 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, 2017, 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 €1,500 per month, with the exception of its Chairman, whose remuneration shall be €2,500 per month. 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

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. For instance, the production, stability, safety, efficacy, and regulatory aspects of drug candidates involve risks, the realization of which can render the commercialization of the drug candidate impossible or significantly delayed. One common challenge in drug development is that preclinical disease models may not accurately simulate the real disease. Promising preclinical results do therefore not guarantee that the drug candidate is efficacious in real patients.

Since Herantis develops biological drugs based on novel scientific research and their mechanisms differ from known drugs, the risks and uncertainties can be considered greater than in the development of conventional drugs. Further, the company has not commercialized any drug candidates, it does not have any history of profitable operations, and it has not so far closed any commercialization agreements pursuant to its strategy.

Drug development requires significant investments. Since Herantis is a pre-revenue company it must finance its drug development programs from external sources such as grants, R&D loans, or equity investments. Factors

such as delays in the company's development programs or a weak financial market can impact the company's ability to raise funding and continue its operations.

Even if the safety and efficacy of a drug candidate was established in clinical studies its commercialization involves risks such as pricing or reimbursement, organizing a sales network, competition from other emerging treatments, unexpected adverse events in long-term use, strength of the company's patents, patent infringement claims raised against the company and other factors.

Usual business risks and uncertainties are also relevant to the operations of Herantis, such as data protection risks, dependencies on subcontractors and other third parties, and the ability to recruit and keep the necessary senior team and other employees.

Herantis has protected its operations against risks to its best ability and is not aware of any such risks or uncertainties, which would essentially differ from the usual risks and uncertainties in its business.

Shares and shareholders

The market capitalization of Herantis Pharma Plc at the end of the review period on June 30, 2018 was approximately €34.2 million. The closing price of the company's share on June 30, 2018 was €6.95. The highest share price during the review period was €7.50, lowest €5.40, average €6.14, and trading volume amounted to 2.0% of the shares in the company.

According to Herantis' shareholder register dated on June 30, 2018, the company had 917 registered shareholders.

On June 30, 2018 the members of Herantis' Board of Directors and the CEO held in aggregate 69,089 (53,366) shares including shares held through their controlled companies, which equaled 1.4 (1.3) 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

In July Herantis announced the initiation of a non-invasive CDNF development program to broaden the application of CDNF in Parkinson's disease and potentially other neurodegenerative disorders. In conjunction, Herantis and the University of Helsinki signed a licensing agreement granting Herantis worldwide, exclusive rights for the therapeutic application of a non-invasive CDNF approach based on a modification of the natural CDNF.

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 2018

The financial statements release January 1 – December 31, 2018 will be published 28 Feb 2019.

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, 2018
Statement of cash flow January 1–June 30, 2018
Statement of changes in equity

Distribution: Nasdaq, principal media, Herantis' web site

More information:

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Herantis Pharma in brief:

Herantis Pharma Plc is an innovative drug development company focused on regenerative medicine and unmet clinical needs. Our clinical stage assets CDNF and Lymfactin® are based on globally leading scientific research in their fields. They both aim at breakthrough in the treatment of severe diseases: CDNF in neurodegenerative diseases such as Parkinson's disease; and Lymfactin® in breast cancer associated lymphedema with potential also in other lymphedemas. The shares of Herantis are listed on the First North Finland marketplace run by Nasdaq Helsinki stock exchange.

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CONSOLIDATED INCOME STATEMENT

Currency EUR	01/01/18 30/06/18	01/01/17 30/06/17	01/01/17 31/12/17
NET TURNOVER	0,00	0,00	0,00
Other operating income	117 538,46	75 000,00	225 130,91
Raw materials and services			
External Services	0,00	0,00	0,00
Staff expenses			
Wages and salaries	-565 182,30	-476 179,56	-853 812,46
Social security expenses			
Pension expenses	-93 140,81	-72 927,15	-132 343,74
Other social security expenses	-23 975,83	-25 996,84	-37 903,51
	-682 298,94	-575 103,55	-1 024 059,71
Depreciation and reduction in value			
Depreciation according to plan	-484 672,22	-494 681,32	-984 495,78
Depreciation from consolidation difference	-116 573,99	-116 573,99	-233 147,98
	-601 246,21	-611 255,31	-1 217 643,76
Other operating charges	-1 348 257,45	-891 121,58	-1 928 138,42
OPERATING PROFIT (LOSS)	-2 514 264,14	-2 002 480,44	-3 944 710,98
Income from other investments held as non-current assets	0,00	0,00	2 024 306,27
Financial income and expenses			
Other interest and financial income			
From others	778 364,51	33 744,32	65 133,61
Interest and other financial expenses			
For others	-28 817,93	-59 121,76	-309 244,89
	749 546,58	-25 377,44	-244 111,28
PROFIT (LOSS) BEFORE APPROPRIATIONS AND TAXES	-1 764 717,56	-2 027 857,88	-2 164 515,99
PROFIT (LOSS) FOR THE FINANCIAL YEAR	-1 764 717,56	-2 027 857,88	-2 164 515,99
CONSOLIDATED PROFIT (LOSS)	-1 764 717,56	-2 027 857,88	-2 164 515,99

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CONSOLIDATED BALANCE SHEET

Currency EUR	30/06/18	30/06/17	31/12/17
A S S E T S			
NON-CURRENT ASSETS			
Intangible assets			
Development expenses	5 198 672,65	6 126 377,65	5 662 525,15
Intangible rights	60 000,50	136 920,30	80 000,00
Consolidation difference	194 289,28	427 437,26	310 863,27
	5 452 962,43	6 690 735,21	6 053 388,42
Tangible assets			
Machinery and equipment	5 741,81	7 655,63	6 562,03
	5 741,81	7 655,63	6 562,03
Investments			
Participating interests	1 162,50	1 162,50	1 162,50
	1 162,50	1 162,50	1 162,50
	5 459 866,74	6 699 553,34	6 061 112,95
CURRENT ASSETS			
Debtors			
Short-term			
Other debtors	87 040,60	67 514,34	90 510,37
Prepayments and accrued income	7 828,30	6 495,27	18 953,14
	94 868,90	74 009,61	109 463,51
Securities	3 696 616,72	1 780 513,51	5 311 395,32
Cash in hand and at banks	173 579,98	364 259,95	90 596,48
	3 965 065,60	2 218 783,07	5 511 455,31
ASSETS TOTAL	9 424 932,34	8 918 336,41	11 572 568,26

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CONSOLIDATED BALANCE SHEET

Currency EUR	30/06/18	30/06/17	31/12/17
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	37 656 176,82	32 976 176,82	37 656 176,82
Retained earnings (loss)	-33 645 796,82	-31 481 280,83	-31 481 280,84
Profit (loss) for the financial year	-1 764 717,56	-2 027 857,88	-2 164 515,99
	2 325 662,44	-452 961,89	4 090 379,99
CAPITAL LOANS	0,00	98 300,00	0,00
CREDITORS			
Long-term			
Loans from credit institutions	5 705 002,65	7 867 172,65	6 022 471,65
	5 705 002,65	7 867 172,65	6 022 471,65
Short-term			
Loans from credit institutions	444 250,00	419 793,00	547 250,00
Other income advances	0,00	600 000,00	0,00
Trade creditors	367 847,38	171 440,72	278 278,29
Other creditors	64 997,31	83 220,19	29 666,72
Accruals and deferred income	517 172,56	131 371,74	604 521,60
	1 394 267,25	1 405 825,65	1 459 716,61
	7 099 269,90	9 272 998,30	7 482 188,26
LIABILITIES TOTAL	9 424 932,34	8 918 336,41	11 572 568,26

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FUNDS STATEMENT

Currency EUR	01/01/18 30/06/18	01/01/17 30/06/17	01/01/17 31/12/17
Cash flow from operating activities			
Profit (loss) before appropriatiosn and taxes	-1 764 717,56	-2 027 857,88	-2 164 515,99
Corrections:			
Depreciation According to plan and amortization	484 672,22	494 681,32	984 495,78
Depreciation from consolidation difference	116 573,99	116 573,99	233 147,98
Unrealized exchange rate profits and losses	-368,97	2 864,26	3 705,00
Bankruptcy of a subsidiary	0,00	0,00	-2 024 306,27
Other financial income and expenses*	-749 546,58	22 513,18	240 406,28
Cash flow before change in working capital	-1 913 386,90	-1 391 225,13	-2 727 067,22
Change in working capital:			
Increase(-)/decr.(+) in short-term interest-free receivables	14 594,61	-8 803,83	-44 277,78
Increase(+)/decr.(-) in short-term interest-free liabilities	37 550,64	476 465,15	416 459,07
Cash flow from operations before financial items and taxes	-1 861 241,65	-923 563,81	-2 354 885,93
Interest paid and pmts for other financ. exp. from operat.	-28 448,96	-59 703,02	-309 244,89
Financial income received from operations	85 906,51	33 744,32	65 133,61
Cash flow from operations before appropriations and taxes	-1 803 784,10	-949 522,51	-2 598 997,21
Cash flow from operating activities (A)	-1 803 784,10	-949 522,51	-2 598 997,21
Cash flow from investments:			
Investments in tangible and intangible assets	0,00	0,00	0,00
Financial resources lost in bankruptcy of a subsidiary	0,00	0,00	-32,96
Acquisition of subsidiary's shares	0,00	0,00	0,00
Cash flow from investments (B)	0,00	0,00	-32,96
Cash flow from financing:			
Share issue	0,00	0	4 680 000,00
Long-term loans drawn	271 989,00	274 821,00	516 547,00
Long-term loan repayments	0,00	-10 000,00	-25 000,00
Cash flow from financing (C)	271 989,00	264 821,00	5 171 547,00
Change in cash and cash equivalents(A+B+C) incr.(+)/decr.(-)	-1 531 795,10	-684 701,51	2 572 516,83
Cash and cash equivalents at beginning of period	5 401 991,80	2 829 474,97	2 829 474,97
Cash and cash equivalents at end of period	3 870 196,70	2 144 773,46	5 401 991,80

*Other financial income and expenses include 692,458.00 Eur of Business Finland loans that were waived during the reporting period

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STATEMENT OF CHANGES IN EQUITY

EUR

	Share capital	Other funds	Retained earnings	Equity total
Equity on Dec 31, 2017	80 000	37 656 177	-27 672 379	10 063 798
Profit/loss for the period			-771 521	
Issue of shares for cash				
Equity on Jun 30, 2018	80 000	37 656 177	-28 443 900	9 292 277

	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, 2016	80 000	32 976 177	-25 125 874	7 930 303
Profit/loss for the period			-2 546 505	
Issue of shares for cash		4 680 000		
Equity on Dec 31, 2017	80 000	37 656 177	-27 672 379	10 063 798