Herantis Pharma Plc

Company release August 28, 2019 at 9:00am

Herantis Pharma Plc announces half year financial report January 1 - June 30, 2019 (unaudited)

- **Randomized clinical studies in Parkinson's and lymphedema proceed as planned**
- **Pipeline expansion with next generation xCDNF**

Highlights January-June 2019

- In March, Herantis Pharma Plc ("Herantis" or "Company") issued 1,111,982 new shares for the subscription price of €5.20 per share in a directed issue, as authorized by the Extraordinary General Meeting.
- In March, Herantis announced that its randomized Phase 2 Lymfactin® clinical study, AdeLE, was expanded within Sweden to include Karolinska University Hospital in Stockholm, and Uppsala University Hospital.
- In April, the Company announced 12-month follow-up results from the Phase 1 study with the Company's gene therapy, Lymfactin®, concluding that the treatment continued to be safe and well-tolerated in all patients without severe adverse events.
- In May, 32,000 new shares were issued as a result of share subscriptions by stock options.
- Im May, Timo Veromaa was nominated as the Vice Chairman of the Company.
- Revenue was €0.0 (in the corresponding period in 2018: €0.0) thousand.
- Cash flow from operations was €-2.7 (-1.8) million.
- Earnings per share were €-0.60 (-0.36).
- Cash and cash equivalents on June 30, 2019 amounted to €5.6 (4.0) million.
- The Company's financial position in the last half-year period is solid and there have not been any exceptional events.

Key figures

€ thousands	1-6/2019	1-6/2018	1-12/2018
Revenue	0.0	0.0	0.0
Personnel expenses	747.1	682.3	1,243.9
Depreciation and amortization	562.2	601.2	1,202.5
Other expenses for business operations	1,729.2	1,348.3	2,654.3
Profit for the period	-3,318.9	-1,764.7	-4,179.7
Cash flow from operations	-2,746.8	-1,803.8	-3,732.2

	1-6/2019	1-6/2018	1-12/2018
Equity ratio %	24.0	24.7	-1.2
Earnings per share €	-0.60	-0.36	-0.85
Number of shares at the end of period	6,062,287	4,918,305	4,918,305
Average number of shares	5,544,814	4,918,305	4,918,305

€ thousands	30 Jun 2019	30 Jun 2018	31 Dec 2018
Cash and cash equivalents	5,599.4	3,965.1	2,185.5
Equity	2,374.1	2,325.7	-89.3
Balance sheet total	9,894.7	9,424.9	7,147.5

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 2019

Herantis does not expect meaningful revenues in 2019. The company continues to invest in its ongoing drug development programs in the treatment of Parkinson's disease and secondary lymphedema as well as in the development of xCDNF: the next generation, non-invasive CDNF.

Outlook for 2019

Herantis' long-term goal is to significantly increase its business through commercialization agreements for its drug candidates. The company continues to discuss collaboration opportunities with potential partners for its drug development programs.

The main objectives for 2019 are to present topline results of the Phase 1-2 clinical study of CDNF, advance patient recruitment in the Phase 2 clinical study with Lymfactin®, select a lead molecule for the formal development of the next generation xCDNF, and secure financing for the company's planned operations through the end of 2020.

Pekka Simula, CEO:

"As a team, Herantis' focus is on the successful execution of two randomized, placebo-controlled, multi-center clinical studies in Parkinson's disease and lymphedema. We are also seeking strategically to expand our pipeline and advance corporate development discussions."

"Our CDNF program aims to be the first disease-modifying treatment of Parkinson's disease. We have completed patient recruitment in the first clinical study with CDNF and expect initial results at the end of the year. While available data suggest further potential in additional neurodegenerative diseases, the current invasive administration of CDNF may limit its applicability in other indications. Therefore, there has been a lot of interest in our non-invasive next generation CDNF, xCDNF, which is currently in preclinical development in lead selection stage. The data we have accumulated on xCDNF continues to support moving forward with full speed. Our objective is to select a lead molecule by the end of this year. While xCDNF is still at an early stage of development, it holds a very exciting promise for the treatment of several neurodegenerative diseases."

"As we build value through both the Parkinson's and lymphedema clinical programs, we continue discussions with potential partners related to further development and commercialization of our drug candidates. Thanks to the successful funding round in early 2019, adding the global healthcare fund Swedbank Robur Medica from Sweden as our major shareholder, we can evaluate all partnering opportunities from a position of strength and therefore optimize the potential for building shareholder value."

REVIEW OF OPERATIONS JANUARY 1-JUNE 30, 2019

Herantis' drug development

Herantis develops drugs based on leading scientific research, aiming for breakthroughs in the treatment of severe diseases. The Company's strategy is to obtain rights to early stage drug candidates, develop them into the clinical stage, and when considered beneficial, negotiate commercialization agreements with larger pharmaceutical companies on their late stage development and marketing.

In the review period, the drug development of Herantis proceeded according to plan with the ongoing placebo-controlled clinical studies of CDNF and

Lymfactin®, the favorable safety data from Phase 1 study with Lymfactin®, and progress toward xCDNF lead molecule selection.

CDNF for the treatment of Parkinson's disease

Herantis develops its drug candidate, CDNF, for the treatment of Parkinson's disease. Parkinson's is a slowly progressing neurodegenerative disease that cannot be cured. An estimated 7 million people worldwide have Parkinson's disease. Currently available treatments only alleviate the motor symptoms of the disease and their efficacy is typically reduced with disease progression. Herantis strives for significant improvement over the current treatments.

Scientific research has shown that CDNF, a natural human protein discovered by Professor **Mart Saarma's** group at the University of Helsinki, is a promising neuroprotective drug candidate. It efficiently protects dopaminergic neurons, restores the function of already degenerated neurons, and alleviates both motor and non-motor symptoms in Parkinson's disease models. Based on preclinical data, CDNF may even stop disease progression. Herantis has patented CDNF internationally.

Herantis has advanced CDNF into a Phase 1-2, randomized, placebo-controlled clinical study, that evaluates safety and initial efficacy of CDNF compared to a placebo in patients with Parkinson's disease. The study is conducted at three university hospitals in Finland and Sweden, and its topline results are expected to be announced in 2019.

CDNF is a protein that does not penetrate the blood-brain barrier, a semipermeable border in the human brain that protects our brain from harmful substances in blood circulation but also prevents many pharmaceutical substances from reaching the brain. Therefore, in the first clinical study, CDNF is administered directly into the brain via a sophisticated medical device. As of the end of June 2019, the medical device has been implanted in 17 patients in the CDNF study and patient recruitment has been completed.

xCDNF: Next generation CDNF for easier administration

To enable a less invasive administration of CDNF, Herantis acquired intellectual property rights from the University of Helsinki in 2018 and formally launched a development program of CDNF-derived peptides that penetrate the blood-brain barrier. Based on early scientific data, the xCDNF peptides are as efficacious as CDNF yet suitable for a much simpler subcutaneous administration, similar to the common insulin dosing by patients with diabetes. The development of xCDNF is currently in lead selection stage. Herantis has not yet announced a timeline or target indication of a possible clinical development program with xCDNF.

Lymfactin® for the treatment of secondary lymphedema

Injuries of the lymphatic system caused, e.g., by an accident, surgery, or illness can lead to secondary lymphedema. Common symptoms are

permanent swelling of the affected limb, thickening and hardening of skin, limited limb mobility, pain, and increased sensitivity to infections. Secondary lymphedema is a chronic, progressive disease that often severely decreases the patient's quality of life. Currently available treatments such as compression garments, special massages, and exercise may relieve the symptoms in some patients, but they do not address the cause the disease.

Professor **Kari Alitalo's** group at the University of Helsinki discovered the human growth factor, VEGF-C, which is necessary for the development of lymphatic vessels. Herantis' drug candidate, Lymfactin®, is based on this scientific breakthrough. It is the first and only clinical stage gene therapy aimed at repairing the lymphatic system.

Lymfactin® is currently in a Phase 2 clinical study, AdeLE, to evaluate safety and efficacy in patients with breast cancer associated lymphedema (BCAL) compared to placebo. Altogether, 40 patients are planned to be recruited in the study and results are expected by the end of 2020. The previous Phase 1 study was conducted in 15 BCAL patients and 12-month follow-up data, announced in April 2019, demonstrated Lymfactin® treatment was safe and well-tolerated.

If the safety and efficacy of Lymfactin® are established in the treatment of breast cancer associated lymphedema, it may be applicable also for the treatment of other secondary lymphedemas.

FINANCIAL REVIEW JANUARY 1-JUNE 30, 2019

Income from business operations, R&D expenses

Herantis group did not have meaningful revenues in the review period or in the corresponding period in the previous year.

The R&D expenses for the review period were €1.4 million, recorded in the profit and loss statement as an expense for the period. The R&D expenses for the review period mainly comprised of the clinical studies with Lymfactin® for the treatment of breast cancer associated lymphedema and CDNF for the treatment of PD. The group's R&D expenses for the corresponding period in the previous year, €1.1 million, were recorded as the review period's expenses in the profit and loss statement.

The profit for the review period was €-3.3 (-1.8) million.

Financing and capital expenditure

The company's cash and cash equivalents on June 30, 2019 amounted to €5.6 (4.0) million.

In addition, the Company has R&D loans previously granted by Business Finland to be drawn in the amount of €0.6 million at the end of the review period. During the review period Herantis drew €0.3 million of the granted loans.

Furthermore, the European Union has awarded the Company a grant of €6.0 million for the project TreatER. The TreatER project comprises 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 2020 for the ongoing development programs.

The consolidated cash flow from operations in the review period was €-2.7 (-1.8) million.

Acquisitions and directed share issues

The Company reported on March 12, 2019 that the Board of Directors of Herantis had decided on a directed share issue of 1,111,982 new shares in aggregate, at a per-share subscription price of €5.20, to certain institutional investors and a limited number of investors other than qualified investors as well as to certain directors of the Company.

The share capital was not increased, but instead the entire subscription price of €5,782,306.40 was recorded in the invested unrestricted equity reserve of the Company. As a result of the share subscriptions, the number of shares in Herantis increased to 6,030,287 shares.

Herantis reported on May 28, 2019 that 32,000 new shares of the Company had been subscribed with option rights of the option programs 2010 and 2014. The share capital was not increased but instead the entire subscription price of €1.60 was recorded in the invested unrestricted equity reserve of the Company. As a result of the share subscriptions, the number of shares in Herantis increased to 6,062,287 shares.

Balance sheet

The consolidated balance sheet of Herantis stood at €9.9 (9.4) million on June 30, 2019.

At the end of the review period on June 30, 2019, the consolidated balance sheet included short-term debt in the amount of €1.0 (1.4) million, long-term loans in the amount of €6.5 (5.7) million, and capital loans in the amount of €0.0 (0.0) million. Financing earnings and expenses totaled €-0.4 (0.7) million. The increase of the financing expenses was mainly related to the funding round in the review period.

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

Equity

Consolidated equity on June 30, 2019 was €2.4 (2.3) 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, 2019 was 9 (9) persons.

During the review period, the Company's Board of Directors comprised Pekka Mattila (Chairman), Timo Veromaa (Vice Chairman) Jim Phillips, Aki Prihti, and Frans Wuite, and from March 12, 2019, Ingrid Atteryd Heiman. The Managing Director for the company was Pekka Simula.

Ordinary Annual General Meeting 2019

Herantis' ordinary Annual General Meeting ("AGM") was held in Helsinki on April 11, 2019.

The AGM adopted the annual accounts for the financial year 2018 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, 2018, and that the loss for the period be recorded on the profit and loss account.

The AGM resolved that the remuneration payable to the members of the Board of Directors shall be €1,500 per month except for the Chairman of the Board who shall be paid €2,500 monthly, and a possibly elected Vice Chairman of the Board who shall be paid €2,000 monthly. Board members are also reimbursed for reasonable travel expenses related to Board of Director's duties. Six members were elected to the Board of Directors: Ingrid Atteryd Heiman, Pekka Mattila, James (Jim) Phillips, Aki Prihti, Timo Veromaa, and Frans Wuite.

The Annual General Meeting decided that the Auditor will be paid 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.

Share based incentive program

Herantis has four stock option programs: Stock option program 2010, Stock option program 2014 I, Stock option program 2016 I, and Stock option program 2018 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	35,600	€ 0.00005	General Meeting 26.8.2010
2014 I	20,800	€ 0.00005	General Meeting 20.3.2014
2016 I	70,000	€ 2.92	General Meeting 9.4.2015, Board Meeting 19.5.2016
2018 I	100,000	€ 5.85	General Meeting 9.4.2015, Board Meeting 28.8.2018
TOTAL	**226,400**	**-**	**-**

[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.

The risks and uncertainties associated with Herantis' operations are described in more detail in the Company's Annual Report for 2018.

Shares and shareholders

The market capitalization of Herantis Pharma Plc at the end of the review period on June 30, 2019 was approximately €35.5 million. The closing price of the company's share on June 28, 2019 was €5.85. The highest share price during the review period was €6.00, lowest €4.80, average €5.43, and trading volume amounted to 1.3% of the shares in the company.

According to Herantis' shareholder register dated on June 30, 2019, the company had 947 registered shareholders.

On June 30, 2019 the members of Herantis' Board of Directors and the CEO held in aggregate 107,792 (69,089) shares including shares held through their controlled companies, which equaled to 1.8% (1.4%) 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 2019

The financial statements release January 1 - December 31, 2019 will be published 27 Feb 2020.

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, 2019
Statement of cash flow January 1-June 30, 2019
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	01/01/19 30/06/19	01/01/18 30/06/18	01/01/18 31/12/18
NET TURNOVER	0,00	0,00	0,00
Other operating income	112 528,35	117 538,46	230 100,24
Raw materials and services			
External Services	0,00	0,00	0,00
Staff expenses			
Wages and salaries	-623 468,38	-565 182,30	-1 033 104,09
Social security expenses			
Pension expenses	-99 444,33	-93 140,81	-172 736,23
Other social security expenses	-24 230,75	-23 975,83	-38 029,09
	-747 143,46	-682 298,94	-1 243 869,41
Depreciation and reduction in value			
Depreciation according to plan	-484 470,18	-484 672,22	-969 345,49
Depreciation from consolidation difference	-77 715,29	-116 573,99	-233 147,98
	-562 185,47	-601 246,21	-1 202 493,47
Other operating charges	-1 729 233,42	-1 348 257,45	-2 654 272,99
OPERATING PROFIT (LOSS)	-2 926 034,00	-2 514 264,14	-4 870 535,63
Income from other investments held as non-current assets	0,00	0,00	3 036,87
Financial income and expenses			
Other interest and financial income			
From others	13,87	778 364,51	767 645,57
Reduction in value of financial expenses	18 822,66	0,00	-19 178,29
Interest and other financial expenses			
For others	-411 733,14	-28 817,93	-60 635,31
	-392 896,61	749 546,58	687 831,97
PROFIT (LOSS) BEFORE APPROPRIATIONS AND TAXES	-3 318 930,61	-1 764 717,56	-4 179 666,79
PROFIT (LOSS) FOR THE FINANCIAL YEAR	-3 318 930,61	-1 764 717,56	-4 179 666,79
CONSOLIDATED PROFIT (LOSS)	-3 318 930,61	-1 764 717,56	-4 179 666,79

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CONSOLIDATED BALANCE SHEET

Currency EUR	30/06/19	30/06/18	31/12/18
A S S E T S			
NON-CURRENT ASSETS			
Intangible assets			
Development expenses	4 270 967,65	5 198 672,65	4 734 820,15
Intangible rights	19 997,50	60 000,50	40 000,00
Consolidation difference	0,00	194 289,28	77 715,29
	4 290 965,15	5 452 962,43	4 852 535,44
Tangible assets			
Machinery and equipment	4 306,36	5 741,81	4 921,54
	4 306,36	5 741,81	4 921,54
Investments			
Participating interests	0,00	1 162,50	0,00
	0,00	1 162,50	0,00
	4 295 271,51	5 459 866,74	4 857 456,98
CURRENT ASSETS			
Debtors			
Short-term			
Other debtors	127 511,92	87 040,60	93 704,42
Prepayments and accrued income	0,00	7 828,30	10 839,55
	127 511,92	94 868,90	104 543,97
Securities	985 243,95	3 696 616,72	1 466 421,29
Cash in hand and at banks	4 486 624,28	173 579,98	719 105,72
	5 599 380,15	3 965 065,60	2 290 070,98
ASSETS TOTAL	9 894 651,66	9 424 932,34	7 147 527,96

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CONSOLIDATED BALANCE SHEET

Currency EUR	30/06/19	30/06/18	31/12/18
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	43 438 484,82	37 656 176,82	37 656 176,82
Retained earnings (loss)	-37 825 463,62	-33 645 796,82	-33 645 796,83
Profit (loss) for the financial year	-3 318 930,61	-1 764 717,56	-4 179 666,79
	2 374 090,59	2 325 662,44	-89 286,80
CAPITAL LOANS	0,00	0,00	0,00
CREDITORS			
Long-term			
Loans from credit institutions	6 500 840,65	5 705 002,65	5 878 418,65
	6 500 840,65	5 705 002,65	5 878 418,65
Short-term			
Loans from credit institutions	135 861,00	444 250,00	507 461,00
Other income advances	0,00	0,00	0,00
Trade creditors	393 715,19	367 847,38	199 608,19
Other creditors	67 209,67	64 997,31	27 556,54
Accruals and deferred income	422 934,55	517 172,56	623 770,37
	1 019 720,41	1 394 267,25	1 358 396,10
	7 520 561,06	7 099 269,90	7 236 814,75
LIABILITIES TOTAL	9 894 651,66	9 424 932,34	7 147 527,96

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FUNDS STATEMENT

Currency EUR	01/01/19 30/06/19	01/01/18 30/06/18	01/01/18 31/12/18
Cash flow from operating activities			
Profit (loss) before appropriatiosn and taxes	-3 318 930,61	-1 764 717,56	-4 179 666,79
Corrections:			
Depreciation According to plan and amortization	484 470,18	484 672,22	969 345,49
Depreciation from consolidation difference	77 715,29	116 573,99	233 147,98
Unrealized exchange rate profits and losses	0,00	-368,97	0,00
Bankruptcy of a subsidiary	0,00	0,00	-3 036,87
Other financial income and expences	392 896,61	-749 546,58	-687 831,97
Cash flow before change in working capital	-2 363 848,53	-1 913 386,90	-3 668 042,16
Change in working capital:			
Increase(-)/decr.(+) in short-term interest-free receivables	-22 967,95	14 594,61	-17 225,16
Increase(+)/decr.(-) in short-term interest-free liabilities	32 924,31	37 550,64	-61 531,51
Cash flow from operations before financial items and taxes	-2 353 892,17	-1 861 241,65	-3 746 798,83
Interest paid and pmts for other financ. exp. from operat.	-392 910,48	-28 448,96	-60 635,31
Financial income received from operations	13,87	85 906,51	75 187,57
Cash flow from operations before appropriations and taxes	-2 746 788,78	-1 803 784,10	-3 732 246,57
Cash flow from operating activities (A)	-2 746 788,78	-1 803 784,10	-3 732 246,57
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	0,00
Acquisition of subsidiary's shares	0,00	0,00	7 165,78
Cash flow from investments (B)	0,00	0,00	7 165,78
Cash flow from financing:			
Share issue	5 782 308,00	0	0,00
Long-term loans drawn	250 822,00	271 989,00	508 616,00
Long-term loan repayments	0,00	0,00	0,00
Cash flow from financing (C)	6 033 130,00	271 989,00	508 616,00
Change in cash and cash equivalents(A+B+C) incr.(+)/decr.(-)	3 286 341,22	-1 531 795,10	-3 216 464,79
Cash and cash equivalents at beginning of period	2 185 527,01	5 401 991,80	5 401 991,80
Cash and cash equivalents at end of period	5 471 868,23	3 870 196,70	2 185 527,01

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STATEMENT OF CHANGES IN EQUITY

	Share capital	Other funds	Retained earnings	Equity total
Equity on Dec 31, 2018	80 000	37 656 177	-29 834 613	7 901 564
Profit/loss for the period			-2 230 511	
Issue of shares for cash			5 782 308	
Equity on June 30, 2019	80 000	37 656 177	-26 282 816	11 453 361

	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 June 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, 2017	80 000	37 656 177	-27 672 379	10 063 798
Profit/loss for the period			-2 162 234	
Issue of shares for cash				
Equity on Dec 31, 2018	80 000	37 656 177	-29 834 613	7 901 564