Herantis Pharma: Herantis publishes 1H 2023 report today

Herantis Pharma Plc, Company Release, August 24, 2023, at 08:00 EEST

"During 1H 2023, the Phase 1a clinical study with subcutaneous dosing of HER-096 has progressed according to plan. We are very pleased that we now have moved into part 2 of the study with dosing of elderly healthy volunteers to assess the blood-brain barrier penetration of HER-096, safety and tolerability. Topline data of the clinical study is expected in Q4 2023, which is an important milestone on our way towards developing a disease-modifying therapy for slowing or stopping the progression of Parkinson's disease. In addition, we have been able to welcome European Innovation Council (EIC) Fund as a new investor in potential future capital raises." **said Antti Vuolanto, CEO of Herantis.**

Herantis Pharma Plc ("Herantis"), a clinical-stage biotechnology company developing disease modifying therapies for Parkinson's disease, released today the company's 1H 2023 report. The full report is attached to this release and is also available at the company's website: www.herantis.com.

A webinar (in English) will be held today at 10:00 EEST / 9:00 CEST.

Registration details: Herantis' 1H 2023 Report Webinar

Please join the webinar a few minutes in advance. You need a Zoom account to register for this event.

Business highlights January – June 2023:

- Herantis announced approval of Clinical Trial Application (CTA) for a Phase 1a study for HER-096 in February.

- In April, Herantis signed the European Innovation Council (EIC) Accelerator grant agreement. Herantis will receive €2.5 million grant funding from EIC Accelerator program and is eligible for up to €15 million in direct equity investments from the EIC Fund, the investment arm of the EIC, subject to certain customary term conditions.

- First healthy volunteer was dosed in the Phase 1a clinical study for the Parkinson's disease drug candidate, HER-096, on April 19. The Phase 1a clinical study will assess safety, tolerability, and blood-brain barrier penetration of subcutaneously administered HER-096.

Events after the reporting period:

- July 4, 2023, Herantis announced the start of recruitment of healthy volunteers for part 2 of the ongoing Phase 1a clinical study of HER-096.

- August 22, 2023, Herantis announced that dosing of the healthy volunteers in part 2 of the HER-096 Phase 1a clinical study has been started.

Key figures:

EUR thousands	January - June		Full Year
	2023	2022	2022
Other operating income	280	0	135
Payroll and related expenses	852	1 563	2 649
Depreciation and amortization	0	80	160
Other operating expenses	1 836	2 726	5 319
Profit for the period	- 1 795	- 5 665	- 9 324
Cash flow from operating activities	- 1 717	- 5 517	- 8 944

	January - June		Full Year
	2023	2022	2022
Equity ratio %	- 36.1	36.4	- 0.9
Basic and diluted loss per share EUR	- 0.11	- 0.47	- 0.64
Number of shares at end of period	16 912 394	16 909 994	16 912 394
Average number of shares	16 912 394	12 078 568	14 654 149

EUR thousands	30-Jun-23	30-Jun-22	31-Dec-22
Cash and securities[1)]	4 909	9 586	5 991
Equity	- 1 855	3 599	- 60
Balance sheet total	5 141	9 894	6 232

1) June 2023: Cash = 3 926' and Securities = 983' June 2022: Cash = 8 641' and Securities = 945' Dec 2022: Cash = 5 036' and Securities = 955'

Summary and outlook for 2023

The first healthy volunteer in Herantis' Phase 1a clinical study for HER-096 was dosed in April 2023. The Phase 1a study, which includes assessment of safety, tolerability, and blood-brain barrier penetration in healthy volunteers, is carried out in Finland. Topline data is expected in Q4 2023. Successful completion of the study would represent a significant milestone for Herantis.

2023 milestones for HER-096 are:

- Phase 1a clinical trial application (CTA) regulatory approval (targeted 1H/2023) – achieved February 20, 2023
- First HER-096 human dose in Phase 1a study (targeted 1H/2023) – achieved April 19, 2023
- Phase 1a read-out: Evidence of HER-096 safety and blood-brain barrier penetration in humans (targeted in Q4/2023)

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About Herantis Pharma Plc
Herantis Pharma Plc is a clinical-stage biotechnology company developing disease modifying therapies for Parkinson's disease. Herantis' lead product HER-096, is an advanced small synthetic chemical peptidomimetic molecule developed based on the active site of the parent CDNF protein. It combines the compelling mechanism of action of the CDNF protein with the convenience of subcutaneous administration. The ongoing Phase 1a clinical study will assess safety, tolerability, and blood-brain barrier penetration of subcutaneously administered HER-096. Top-line data is expected by Q4-2023.

The shares of Herantis are listed on the Nasdaq First North Growth Market Finland.
For more information, please visit https://www.herantis.com

Forward-looking statements
This company release includes forward-looking statements which are not historical facts but statements regarding future expectations instead. These forward-looking statements include without limitation, those regarding Herantis' future financial position and results of operations, the Company's strategy, objectives, future developments in the markets in which the Company participates or is seeking to participate or anticipated regulatory changes in the markets in which the Company operates or intends to operate. In some cases, forward-looking statements can be identified by terminology such as "aim," "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "guidance," "intend," "may," "plan," "potential," "predict," "projected," "should" or "will" or the negative of such terms or other comparable terminology.

By their nature, forward-looking statements involve known and unknown risks, uncertainties and other factors because they relate to events and depend on circumstances that may or may not occur in the future. Forward-looking statements are not guarantees of future performance and are based on numerous assumptions. The Company's actual results of operations, including the Company's financial condition and liquidity and the development of the industry in which the Company operates, may differ materially from (and be more negative than) those made in, or suggested by, the forward-looking statements contained in this company release. Factors, including risks and uncertainties that could cause these differences include, but are not limited to risks associated with implementation of Herantis' strategy, risks and uncertainties associated with the development and/or approval of Herantis' drug candidates, ongoing and future clinical trials and expected trial results, the ability to commercialize drug candidates, technology changes and new products in Herantis' potential market and industry, Herantis' freedom to operate in respect of the products it develops (which freedom may be limited, e.g., by competitors' patents), the ability to develop new products and enhance existing products, the impact of competition, changes in general economy and industry conditions, and legislative, regulatory and political factors.

In addition, even if Herantis' historical results of operations, including the Company's financial condition and liquidity and the development of the industry in which the Company operates, are consistent with the forward-looking statements contained in this company release, those results or developments may not be indicative of results or developments in subsequent periods.