HERANTIS PHARMA PIC Half Year Report 2021 January – June 2021

# Half Year Financial Report January 1- June 30, 2021

# HERANTIS PHARMA



Protecting the proteome from Parkinson's disease

Herantis transformed into a pure play CNS biotech company – Highlights January-June 2021

- Strategic data drive decision taken to fully focus all company resources on Herantis' CDNF and xCDNF assets, thus becoming a pure play CNS (central nervous system) biotech company.
- Selected HER-096 as the xCDNF candidate to take forward into further development for the treatment of Parkinson's Disease (PD) and other neurodegenerative diseases, an important milestone for the company. HER-096 was selected based on clear and compelling preclinical data including that it:
  - Effectively penetrates the Blood-Brain-Barrier (BBB)
  - Potently protects neurons and restores their functional phenotype
  - Significantly reduces aggregation of the toxic protein alpha-synuclein and the associated neuroinflammation
  - Restores proteostasis
- A study showing CDNF's therapeutic effects in alpha-synuclein-based animal models was published in Molecular Therapy, a leading scientific journal. This study provides new insight in how CDNF affects alphasynuclein pathology on the molecular and cellular level.
- Entered into an agreement with Nanoform Finland Plc. The collaboration provides for formulation proof-ofconcept studies to combine Herantis' CDNF therapy for Parkinson's disease, with Nanoform nanoparticle technology.
- Two presentations summarizing the results from the Phase I-II First-In-Man Clinical Trial of CDNF in PD were presented at the 15<sup>th</sup> International Conference on Alzheimer's and Parkinson's Diseases, AD/PD<sup>™</sup> 2021.
- The clinical trial results from Phase II study investigating Herantis' patented gene therapy Lymfactin<sup>®</sup>, for the treatment of Breast Cancer Related Lymphedema (BCRL), were inconclusive. The primary purpose of the trial was to determine whether there was an additional benefit of Lymfactin<sup>®</sup> treatment in combination with lymph node transfer surgery, compared to surgery alone. While both treatment groups experienced clear clinical benefits, the trial did not establish additional treatment benefit for Lymfactin<sup>®</sup> in combination with surgery, compared to surgery alone. Strategic decision taken to seek out-licensing partners for the Lymfactin<sup>®</sup> program.
- Hilde Furberg was elected to the Board of Directors
  - Hilde brings 35+ years of global leadership experience both as a Board member and through her years in global sales, marketing, strategy and management in the international Pharma/Biotech industries
  - Former European Head of Rare Disease Europe/GM and Senior VP Rare Diseases EMEA at Genzyme/Sanofi Genzyme
  - Successful R&D investor day held in June. Link to the event: <u>Herantis' Virtual R&D Investor Day 2021</u>
    - Presented novel evidence of biological and biomarker impact in humans from the CDNF Phase 1 clinical study

# Group's key figures:

EUR thousands	January	Full Year	
	2021 2020		2020
Revenue	0	0	0
Payroll and related expenses	1 284	892	2 035
Depreciation and amortization	2 640	464	927
Other operating expenses	3 947	2 747	5 199
Profit for the period	-7 939	-4 472	-9 153
Cash flow from operating activities	-5 457	-4 787	-8 561

	January	Full Year 2020	
	2021 2020		
Equity ratio %	-4.3	33.9	46.2
Basic and diluted loss per share EUR	-0.81	-0.65	-1.24
Number of shares at end of period	9 757 068	7 594 905	9 757 068
Average number of shares	9 757 068	6 851 403	7 394 001

EUR thousands	30-Jun-21	30-Jun-20	31-Dec-20
Cash and cash equivalents	7 862	9 104	13 324
Equity	-351	4 268	7 587
Balance sheet total	8 211	12 598	16 420

# Formulas used to calculate 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 weighted by the number of days each share has been outstanding during the review period.

# CEO's statement

In 2021, Herantis continued to optimize its assets and shape the company for future success as we transformed into a pure play CNS biotech company. The continued generation of strong data prompted our strategic decision to focus on our CNS assets, CDNF and xCDNF (HER-096). Following more than a decade of extensive R&D for CDNF and xCDNF, we are now reaping the fruits of those efforts.

CDNF, a protein, occurs naturally in the body and has the natural role of protecting neurons. Herantis is looking to harness the natural protective ability of CDNF and turn it into a powerful treatment for neurodegenerative diseases, such as Parkinson's disease. Recently, there has been compelling data showing that patients treated with CDNF have a strong disease relevant biomarker response. Moreover, the data suggests these biomarker changes appear to be correlated with improvements in clinical motor score parameters as well as brain imaging improvements, including in patients with recognized Parkinson's genetic mutations. The current focus for this program is to complete formulation work for intranasal and subcutaneous administration, followed by a formal program to be ready for further clinical development thereafter.

xCDNF, a synthetic molecule based on selected fragments of the parent CDNF molecule, has been successfully engineered to be able to efficiently penetrate the blood brain barrier (BBB) and while retaining its potency of CDNF. Earlier this year, we were excited to announce our preclinical candidate selection of xCDNF (HER-096), which we will take into further development. The near to mid-term priorities for this program are to complete the pre-clinical and toxicology studies with HER-096, in anticipation of potentially entering formal clinical development in humans.

Our CNS assets aim to reach the forefront of therapies for neurodegenerative diseases. This area of research, which focuses on proteostasis and protein dysregulation mechanisms of disease, is very active and holds a lot of promise for patients. Additionally, proteostasis is a significant focus area of other major pharmaceutical companies working in the space. We are in great company with these companies, whom could potentially be our future partners and collaborators.

Other key developments for the company during 1H 2021 included our decision to seek out-licensing partners for our Lymfactin<sup>®</sup> program for BCRL lymphedema. This decision was due in part to the inconclusive data from the Phase II study, as well as our data driven strategic decision to focus all resources on our CNS assets.

We are very excited for the remainder of 2021 and beyond, as we continue to refine this new chapter of Herantis, focus on our core strengths, and CNS value drivers. We look forward to achieving key milestones and generating important news flow over the next 12 - 18 months.

**Dr. Craig Cook** CEO of Herantis Pharma Plc

HERANTIS PHARMA PIC Half Year Report 2021 January – June 2021

# Review of operations January 1 – June 30, 2021

Herantis is a CNS focused biotech company with a promising portfolio of disease modifying assets CDNF (Cerebral Dopamine Neurotrophic Factor) and xCDNF (HER-096). Both assets powerfully impact a core system in the body called proteostasis, a key biological system which malfunctions in many neurodegenerative diseases. Both assets have demonstrated promising potential to significantly improve neuronal survival and thus slow or stop the progression of Parkinson's and other neurodegenerative diseases.

CDNF, Herantis' lead program, is a protein that occurs naturally in the body whose role is to protect neurons by strongly protecting and restoring proteostasis. Herantis is looking to harness this natural potential as a potent treatment for illnesses like Parkinson's disease. xCDNF, Herantis' second program, is a synthetic molecule using only the most active parts of the parent CDNF protein, specifically engineered to cross the Blood Brain Barrier (BBB) and retain the potency of CDNF.

These are the key and emerging facts about the assets:

- CDNF is safe in humans
- CDNF positively influence biology and biomarkers in humans, and this biological response correlates with motor and brain imaging improvements
- Potential genetic and biomarker patient subgroups are emerging
- Both assets modulate and restore proteostasis
- Both assets powerfully impact neuronal survival, and significantly reduce and normalize alpha-synuclein aggregates in the brain

The shares of Herantis are listed on the Nasdaq First North Growth Market Finland and Nasdaq First North Growth Market Sweden.

# Focus on CNS

Herantis announced in March that, following receipt of promising data for our CNS programs, combined with the inconclusive Lymfactin<sup>®</sup> data, the company had undertaken a comprehensive review of its programs, and made the strategic decision to focus all its efforts and resources on its CNS assets CDNF and xCDNF.

The review focused on data from its CNS assets CDNF and xCDNF, as well as on learnings from the pioneering Lymfactin<sup>®</sup> study and how best to move the program forward to address them to accurately capture treatment effect, implications for the overall program, and resourcing requirements for the Lymfactin<sup>®</sup> program in the future. As a result of this comprehensive evaluation, Herantis' Board of Directors have concluded that the best course of action for the Company is firstly to focus all activities, strategy and resources solely on the exciting CNS portfolio, and secondly to seek a suitable partner to take over further development of the innovative Lymfactin<sup>®</sup> program. The process of finding a partner for the Lymfactin<sup>®</sup> program is ongoing.

#### HERANTIS PHARMA PIC Half Year Report 2021 January – June 2021

In-line with this decision, Herantis will structure all its research and operations on neurodegenerative diseases, accelerating its programs in Parkinson's disease and other neurodegenerative diseases.

# CDNF

Generated key human data evidencing the effect of CDNF treatment on disease biomarkers in Parkinson's, including:

- biomarkers in change in response to CDNF treatment in some patients
- these changes correlated with improvements in motor function and biological dopamine signals
- some subjects found to carry important genetic mutations related to Parkinson's specifically LRRK2, GBA
- detailed biomarker profiling data supports the hypothesis of modulation of proteostasis in response to CDNF treatment

CDNF showed encouraging results in reversing motor and non-motor symptoms in animal models. Herantis reported during 2020 both 6- and 12-month read-outs from a placebo-controlled first-in-human Phase I/II clinical safety and tolerability study in PD patients and subsequent active treatment extension study. The study showed excellent tolerability for CDNF, with no dose-limiting toxicities. With this solid foundation, moving forward the company decided to pursue more patient-friendly modes of delivery such as via subcutaneous injection or intranasal application also for other neurodegenerative diseases, without the the need for a surgical device. This strategy is expected to expand the target population, accelerate clinical development, and increase the attractiveness of our CDNF-asset to partners.

# xCDNF (HER-096)

In May, Herantis announced the achievement of a significant milestone on the nomination of HER-096 (xCDNF) as the lead preclinical candidate to take it forward into further preclinical development for the treatment of Parkinson's disease (PD) and other neurodegenerative diseases.

HER-096 was selected based on clear and compelling preclinical data including that it:

- Effectively penetrates the Blood-Brain-Barrier (BBB)
- Potently protects neurons and restores their functional phenotype
- Significantly reduces aggregation of the toxic protein alpha-synuclein and the associated neuroinflammation
- Restores proteostasis

In 2018, Herantis began conducting lead optimization of several xCDNF molecular candidates to maximize their plasma half-life, BBB penetrance and potency for targeting PD. Neurodegenerative disorders such as PD are characterized by increased levels of cellular stress and the breakdown of proteostasis, which is the normal mechanism that directs the synthesis and folding of proteins, and also the removal of misfolded proteins. HER-096 has the potential to be a disease-modifying therapy, designed to be given via subcutaneous injection with no requirement for surgery.

# CDNF vs HER-096

The Herantis pipeline now comprises of two promising Parkinson's assets: CDNF, a clinical stage biological, and HER-096 a preclinical stage synthetic compound. The two assets will continue to be developed as separate projects in tandem.

CDNF is a powerful protein that occurs naturally in the body and whose normal role is to protect neurons via its ability to protect and restore a key biological system/process called proteostasis, which becomes dysfunctional in PD. Herantis is looking to harness this natural potential as a potent treatment for illnesses like PD. CDNF acts upon three key elements of proteostasis: synthesis, folding, and degradation, and can thereby reduce cellular stress and prevent formation of protein aggregates. However, as CDNF cannot readily penetrate an intact blood-brain-barrier (BBB), alternative administration routes are under development. xCDNF (HER-096) is a chemically engineered synthetic peptidomimetic version of CDNF, designed to be given via a simple subcutaneous injection with no requirement for surgery. xCDNF has been engineered with the dual aims of crossing the notoriously impermeable BBB, while retaining the potency of the parent molecule to protect neurons, both critical elements for a successful Parkinsons treatment.

# Target market

The total available market for neurodegenerative diseases is projected to reach  $\in$ 54Bn by 2026 (CAGR = 7.2%). Parkinson's diseases (PD) represents a serviceable market of  $\in$ 3.8Bn, growing to  $\in$ 5.0Bn by 2024. PD is the second most common form of neurodegeneration, affecting 7 to 10 million people worldwide, with over 60,000 new diagnoses only in the US each year. Based on the market shares of incumbent therapeutics for PD, the overall market opportunity for Herantis CDNF assets is independently estimated to be approximately  $\in$ 8Bn.

 Source:
 Parkinsons
 Foundation
 www.parkinsons.org, www.parkinsons.org, Fortune
 Business
 Insights
 <u>https://www.fortunebusinessinsights.com/industry-</u>

 reports/neurodegenerative-diseases-drugs-market-100661,
 Parkinson's
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 Market. (n.d.).
 Retrieved
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 https://www.marketsandmarkets.com/Market-Reports/parkinson-disease-treatment-market-47265247

# Employees, management, nomination committee and Board of Directors

During the review period, the company's Board of Directors comprised of Timo Veromaa (Chairman), Frans Wuite (Vice Chairman), Hilde Furberg (since April 15, 2021), Jim Phillips, Aki Prihti and Mats Thorén.

The number of employees at the end of the review period on June 30, 2021, was 13 (12).

The management team consists of CEO Craig Cook, COO Antti Vuolanto, CSO Henri Huttunen, Head of Regulatory Affairs and Compliance Sigrid Booms and CFO Tone Kvåle. Magnus Sjögren, previously CMO, has for personal reasons decided to return to his academic and medical employments but will continue his long-standing relation to Herantis as a consultant.

Herantis Pharma's Shareholders' Nomination Committee consists of four members, of which three represent the company's shareholders. The Chairman of Herantis Pharma's Board of Directors will serve as the fourth member of the Nomination Committee. The Shareholders' Nomination Committee prepares and presents to the Annual General Meeting proposals on the remuneration and members of the Board of Directors.

#### HERANTIS PHARMA Pic Half Year Report 2021 January – June 2021

The following members have been appointed to Herantis Pharma's Shareholders' Nomination Committee: Marko Berg, Helsinki University Funds (HYR) (Chairman), Pia Gisgard, Swedbank Robur, Aki Prihti, Inveni Life Sciences Fund I Ky, and Timo Veromaa, the Chairman of Herantis Pharma's Board of Directors.

# Covid-19

The company has not experienced any material impact on its operations or plans as a result of the Covid-19 pandemic so far this year. Drug development activities of the company such as the planning and preparations for preclinical and clinical projects remain ongoing. These activities will involve international collaborators whose ability to provide services could be impacted by the on-going situation. As such, there may be delays in individual subprojects.

## Summary and outlook for 2021

The new Herantis is a pure play CNS company, and the programs are fully focused on disease modifying therapeutics to address the unmet need in Parkinson's disease and other neurological illnesses. During the remainder of 2021 we will continue executing our roadmap as we aim to complete formulation activities for the new CDNF administrations routes, and continue strengthening the preclinical proof of concept data for HER-096 (xCDNF).

# Financial review January 1 – June 30, 2021

(Figures in brackets = same period 2020 unless stated otherwise)

# Accounting principles

Herantis prepares financial statements in accordance with Finnish Accounting Standards (FAS). The figures in the financial statements are unaudited. The figures are individually rounded from exact figures.

# Consolidated income statement

Herantis Group did not have material revenues in the review period or in the corresponding period previous year. The R&D expenses for the 1H of 2021 were EUR 3.0 million (EUR 2.3 million), recorded in the income statement as other operating expenses for the period. The R&D expenses were related to preclinical and CMC activities for CDNF and xCDNF (HER-096) and follow up expenses from the completed CDNF and Lymfactin<sup>®</sup> clinical studies. Depreciation and amortization for the period were EUR 2.6 million (EUR 0.5 million) whereof EUR 2.2 million relates to write-down of Lymfactin<sup>®</sup> development expenses. According to Finnish Accounting Standards (FAS), entities are required to conduct impairment tests where there is an indication of impairment of an asset. An impairment test has been performed after the company reported inconclusive data from the Lymfactin<sup>®</sup> Phase II clinical study and the strategic decision is to focus only on CDNF and xCDNF and find a partner for Lymfactin<sup>®</sup>. The process of finding a partner is ongoing.

Finance income and expenses totalled EUR -0.1 million (EUR -0.5 million). The financing expenses were mainly related to interests on loans to Business Finland in the review period. The loss for the review period was EUR -8.0 million (EUR -4.5 million).

	January	Full Year	
EUR thousands	2021	2020	2020
Revenue	0	0	0
Other operating income	0	90	90
Payroll and related expenses	1 284	892	2 035
Depreciation and amortization	2 640	464	927
Other operating expenses	3 947	2 747	5 199
Total operating expenses	7 872	4 103	8 161
Operating profit (loss)	-7 872	-4 013	-8 071
Finance income	0	0	1
Finance expenses	67	459	1 082
Total finance income and expenses	-67	-459	-1 081
Profit (loss) before taxes	-7 939	-4 472	-9 153
Profit (loss) for the financial period	-7 939	-4 472	-9 153
Consolidated profit (loss)	-7 939	-4 472	-9 153
Loss per share	-0.81	-0.65	-1.24
Basic and diluted loss per share, EUR	-0.81	-0.65	-1.24

# Consolidated balance sheet

The balance sheet of Herantis Group stood on June 30, 2021, at EUR 8.2 million (EUR 12.6 million). The consolidated balance sheet included short-term debt in the amount of EUR 5.2 million (EUR 1.1 million) and long-term loans in the amount of EUR 3.4 million (EUR 7.2 million). Majority of the total liabilities are loans from Business Finland related to development projects. No R&D expenses were capitalized during the review period. Consolidated equity was EUR -0.4 million (EUR 4.3 million).

#### HERANTIS PHARMA PIC Half Year Report 2021

Half Year Report 2021 January – June 2021

	January 1 - June 30	January 1 - June 30	31 December
EUR thousands	2021	2020	2020
ASSETS			
Non-current assets			
Intangible assets			
Development expenses	240	3 343	2 879
Intangible rights	0	0	0
	240	3 343	2 879
Tangible assets			
Machinery and equipement	0	0	0
	0	0	0
Total non-current assets	240	3 343	2 879
Current assets			
Debtors			
Short-term			
Other debtors	99	148	174
Prepayments and accrued income	11	3	42
	110	151	216
Securities	985	970	985
Cash in hand and at banks	6 876	8 134	10.000
	00/0	0 134	12 339
Total current assets	7 971	9 255	13 540
TOTAL ASSETS	8 211	12 598	16 420

HERANTIS PHARMA Plc Half Year Report 2021 January – June 2021

	January 1 -	January 1 -	31
	June 30 2021	June 30	December
EUR thousands	2021	2020	2020
LIABILITIES			
Capital and reserves			
Subscribed capital			
Subscribed capital	80	80	80
	80	80	80
Other reserves	00	00	00
Free invested equity reserve	62 490	54 490	62 490
Retained loss	-54 983	-45 830	-45 830
Loss for the financial year	-7 939	-43 030	-43 050
	-7 333	-4 472	-9 100
Total equity	-351	4 268	7 587
	-001	4 200	1 001
Creditors			
Long-term			
Loan from credit institutions	3 390	7 206	5 941
	3 390	7 206	5 941
Short-term			
Loans from credit institutions	3 810	0	1 265
Trade creditors	591	660	716
Other creditors	43	94	89
Accruals and deferred income	729	370	822
	5 172	1 124	2 892
Total liability	8 562	8 330	8 833
LIABILITIES TOTAL	8 211	12 598	16 420

#### HERANTIS PHARMA PIc Half Year Report 2021 January – June 2021

# Consolidated cash flows

The company's cash and cash equivalents for Herantis Group on June 30, 2021, amounted to EUR 7.9 million (EUR 9.1 million) and EUR 13.3 million per December 2020. The consolidated cash flow from operating activities in the review period was EUR -5.5 million (EUR -4.8 million).

	Full Year		
EUR thousands	2021	2020	2020
Cash flow from operating activities:			
Profit (loss) before income taxes	-7 939	-4 472	-9 153
Adjustments:			
Depreciation according to plan	464	464	928
Write-down Lymfactin development costs	2 176	0	0
Other financial income and expenses	67	444	1 082
Cash flow before change in working capital	-5 232	-3 565	-7 143
Change in working capital:			
Increase(-)/decrease(+) in short term interest free receivables	107	111	45
Increase(-)/decrease(+) in short term interest free liabilities	-265	-890	-381
Cash flow from operations before financial items and taxes	-5 390	-4 343	-7 478
Interest paid and other financial expenses from operation	-67	-444	-1 084
Interest received	0	0	1
Cash flow from operations before income taxes	-5 457	-4 787	-8 561
Cash flow from operating activities (A)	-5 457	-4 787	-8 561
Cash flow from investments:			
Proceeds from sale of tangible assets	0	4	4
Cash flow from investments activities (B)	0	4	4
Cash flow from financing:			
Gross proceeds from equity issue	0	6 889	14 889
Long term loans drawn	0	0	0
Short term loan repayments	-6	0	-5
Cash flow from financing activities (C)	-6	6 889	14 884
Change in cash and cash equivalents (A+B+C) incr. (+)/decr.(-)	-5 462	2 106	6 326
Cash and cash equivalents at beginning of period	13 324	6 998	6 998
Cash and cash equivalents at end of period	7 862	9 104	13 324

# Consolidated and parent company statement of changes in equity

The equity for the parent company was EUR 1.4 million (EUR 15.6 million). The loss for the period for the parent company of EUR -18.7 million (EUR -3.5 million) mainly due to write-down of shares and internal loans in Herantis' subsidiary, Laurantis, due to impairment of the asset Lymfactin<sup>®</sup>. According to Finnish Accounting Standards (FAS), entities are required to conduct impairment tests where there is an indication of impairment of an asset. An impairment test has been performed after the company reported inconclusive data from the Lymfactin<sup>®</sup> Phase II clinical study and after the strategic decision to only focus on CDNF and xCDNF and find a partner for Lymfactin<sup>®</sup>. The process of finding a partner is ongoing.

#### **HERANTIS PHARMA PIc**

Half Year Report 2021 January – June 2021

	Pare	ent	Conse	olidated
	January - June	January - June	January - June	January - June
Currency EUR	2021	2020	2021	2020
Restricted equity				
Share equity at the start of the period	80,000.00	80,000.00	80,000.00	80,000.00
Share equity at the start of the period	80,000.00	80,000.00	80,000.00	80,000.00
Restricted equity, total	80,000.00	80,000.00	80,000.00	80,000.00
Unrestricted equity				
Invested unrestricted equity reserve at the beginning of period	62,490,276.60	47,601,032.62	62,490,276.60	47,601,032.62
Issue of shares	0	6,889,240.88	0	6,889,240.88
Invested unrestricted equity reserve at the end of period	62,490,276.60	54,490,273,50	62,490,276.60	54,490,273,50
Loss from previous period, at the beginning of the period	-42,479,237.12	-35,432,148.15	-54,982,932.08	-45,830,019.90
Loss at the end of the previous period	-42,479,237.12	-35,432,148.15	-54,982,932.08	-45,830,019.90
Loss for the period	-18,667,934.50	-3,488,623.68	-7,938,825.33	-4,472,256.12
Unrestricted equity, total	1,343,104.98	15,649,501.67	-431,480.81	4,267,996.88
Equity on 30.06.2021	1,423,104.98	15,649,501.67	-351,480.81	4,267,996.88

## Share and shareholders

## Share based incentive programs

Herantis has four stock option programs: Stock option program 2010, 2014 I, 2018 I and 2021 I. The Board of Directors decided on April 19, 2021, to grant a maximum of 961,221 option rights entitling to shares to management team members and other key personnel under a new option rights program 2021 I. The new option rights program is based on the authorization granted by the Annual General Meeting held on April 15, 2021. There is a weighty financial reason to issue the option rights as they will be offered to management team members and other key personnel to increase their commitment towards long-term contribution to growing shareholder value in Herantis.

The option rights are offered without consideration. Under the new option program each option right entitles to subscribe for one ordinary share in Herantis for a subscription price of EUR 3.44 per share. The subscription price corresponds to 126% of the volume weighted average share price during 10 trading days preceding the grant date of April 19, 2021 (April 1-16, 2021). Granted share options shall vest and become exercisable over a three-year period, with 1/3 becoming exercisable from April 19, 2022, with an annual vesting of 1/3 during the second year after the grant date, and with an annual vesting of 1/3 during the third year after the grant date. The options expire on April 19, 2026, or earlier subject to customary conditions. Any shares to be subscribed for based on the option rights of the program 2021 I will not represent more than 10% of the company's outstanding shares at any time.

The main details of the stock option programs are listed in the table below:

Stock option program	Maximum number of shares <sup>1)</sup>	Subscription price per share	Decision on the stock option program made by
2010	31,600	0.00005	General Meeting 26.8.2010
2014 I	7,200	0.00005	General Meeting 20.3.2014
			General Meeting 9.4.2015,
2018 I	100,000	5.85	Board Meeting 28.8.2018
2021 I	961,221	3.44	General Meeting 15.4.2021
TOTAL	1,100,021		

<sup>1</sup> The maximum number of shares to be subscribed by stock options.

#### HERANTIS PHARMA Pic Half Year Report 2021 January – June 2021

#### Shareholder structure

The company's shares are listed at Nasdaq First North Growth Market Sweden with ticker symbol "HRNTS", and at Nasdaq First North Growth Market Finland with ticker symbol "HRTIS". The market capitalization of Herantis Pharma Plc at the end of the review period on June 30, 2021, was approximately EUR 28 million. The closing price of the company's shares in the Nasdaq First North Growth Market Finland on June 30, 2021, was 2.88 euros. The highest share price during the review period was 5.90 euros, lowest 2.50 euros, and average 3.42 euros. The trading volume of the company's share in 1H 2021 was 2,372,465 shares, corresponding to approximately 24% of all shares in the company.

According to Herantis' shareholder register dated June 30, 2021, the company had 3,804 registered shareholders. On June 30, 2021, the members of Herantis' Board of Directors and the management held in aggregate 109,036 (107,036) shares or 1.1 (1.1) percent of the company's shares. Information on managers' transactions with the company's shares is published through company releases.

Shareholders June 30, 2021	Numbers of shares	%
1 Swedbank Robur Fonder	946.435	9.7%
2 Fjärde AP Fonden	605,564	6.2%
3 Inveni Life Sciences Fund I Ky	528,134	5.4%
4 University of Helsinki Funds	515,483	5.3%
5 Nanoform Finland Oyj	432,432	4.4%
6 Pensionförsäkringsaktiebolaget Veritas	374,948	3.8%
7 Innovestor Kasvurahasto I Ky	328,500	3.4%
8 Joensuun kauppa ja kone Oy	303,181	3.1%
9 OP Finland small companies	275,891	2.8%
10 Sijoitusrahasto Säästöpankki Pienyhtiöt	260,000	2.7%
11 Nordea Nordic Small cap	232,200	2.4%
12 Mutual pension insurance company Ilmarinen	209,403	2.1%
13 Danske Bank AS Helsinki branch	209,231	2.1%
14 Saarma Mart	159,000	1.6%
15 Castrén Eero Hemminki	155,000	1.6%
16 Kaloniemi Markku Petteri	153,512	1.6%
17 Argonius Oy	145,000	1.5%
18 Rauvala Heikki Matti Eemeli	140,000	1.4%
19 Mutual pension savings bank Baltic Sea	132,907	1.4%
20 Gerako Oy	114,307	1.2%
Top 20 largest shareholders	6,221,128	63.8%
Others	3,536,624	36.2%
Total numbers of shares	9,757,752	100.0%

## Decisions by the Annual General Meeting

Herantis Pharma Plc's ("Herantis") Annual General Meeting was held in Helsinki on Thursday, April 15, 2021. Shareholders participated in the meeting and exercised their rights only by voting in advance, in addition to which they could make counterproposals and present questions in advance. The annual general meeting was arranged in accordance with an exceptional meeting procedure based on temporary legislation approved by the Finnish Parliament on October 2, 2020 to limit the spread of the Covid-19 pandemic.

The Annual General Meeting adopted the consolidated financial statements and the parent company's financial statements for the financial year January 1, 2020 – December 31, 2020, and discharged the members of the Board of Directors and the CEO from liability. The Annual General Meeting decided that, as

proposed by the Board of Directors, no dividend be paid for the financial year January 1 – December 31, 2020 and that the loss for the financial year shall be entered in the account for profit and loss.

The Annual General Meeting resolved, in accordance with the proposal by the Shareholders' Nomination Committee, that the remuneration of the Board of Directors shall be as follows:

- The remuneration payable to the members of the Board of Directors shall be EUR 18,000 annually for each member of the Board except for the Chairman of the Board who shall be paid EUR 30,000 annually and the Vice Chairman of the Board who shall be paid EUR 24,000 annually. The remuneration proposed above remains unchanged from the previous year, but it has been presented on an annual basis
- The Chairman of the Audit Committee shall receive a fixed annual fee of EUR 8,000 and each member of the Audit Committee a fixed annual fee of EUR 4,000
- The Chairman of the Remuneration Committee shall receive a fixed annual fee of EUR 4,000 and each member of the Remuneration Committee a fixed annual fee of EUR 2,000
- Board members are also reimbursed reasonable travel expenses related to the duties of the Board of Directors

In accordance with the proposal of the Shareholders' Nomination Committee, the Annual General Meeting resolved that the number of members of the Board of Directors shall be six (6) and all current members of the Board of Directors, i.e. Timo Veromaa, Mats Thorén, Frans Wuite, James Phillips, and Aki Prihti were reelected as members of the Board of Directors. Hilde Furberg was also elected as a new member of the Board of Directors, the Annual General Meeting resolved, in accordance with the proposal by the Board of Directors, that the Auditor be paid reasonable remuneration in accordance with the invoice approved by the Company.

The Annual General Meeting resolved, in accordance with the proposal by the Board of Directors, to elect the firm of authorized public accountants PricewaterhouseCoopers Oy as auditor until the end of the next Annual General Meeting. PricewaterhouseCoopers Oy has notified the company that APA Panu Vänskä will act as the responsible auditor.

The Annual General Meeting resolved to authorize the Board of Directors to resolve on issues of option rights pursuant to Chapter 10 of the Companies Act as follows:

- The Board of Herantis seeks authorization from shareholders at the Annual General Meeting to issue a maximum of 975,000 of share options and shares (representing not more than 10% of the Company's outstanding shares at any time) in total for all grants.
- The authorization covers planned future grants of options.
- The Board of Directors of Herantis believes that any option rights program created pursuant to the authorization would increase and strengthen the employees' dedication to Herantis' operations and improve loyalty to the company and that such program would be beneficial to both the shareholders and Herantis.

The authorization is valid until the close of next annual general meeting, however no longer than until June 30, 2022. Please see section "*Share based incentive programs*" above for eligibility, grant size, exercise price and vesting schedule of options issued under the authorization.

The Annual General Meeting resolved to authorize the Board of Directors to resolve on issues of shares as follows:

- The shares issued under the authorization may be new shares or treasury shares. Under the authorization, a maximum of 975,000 shares, which corresponds to approximately 10 per cent. of all of the shares currently issued and outstanding, may be issued. The shares may be issued in one or more tranches.
- Under the authorization, the Board of Directors may resolve upon issuing new shares to the Company itself. However, the Company, together with its subsidiaries, may not at any time hold more than 10 per cent. of all its registered shares.
- The Board of Directors is authorized to resolve on all terms of the share issue. The Board of Directors is authorized to resolve on a directed share issue in deviation from the shareholders' pre-emptive rights, provided that there is a weighty financial reason for the Company to do so.
- The proposed authorization does not invalidate any earlier authorizations entitling the Board of Directors to decide on share issues or issues of special rights entitling to shares.
- The authorization is valid until the close of next annual general meeting, however no longer than until June 30, 2022.

In its constitutive meeting held after the Annual General Meeting, the Board of Directors elected Timo Veromaa as Chairman of the Board and Frans Wuite as Vice Chairman of the Board. The Board of Directors also resolved on the composition of the Board Committees in its constitutive meeting. Aki Prihti was elected as the Chairman, and Mats Thorén and Hilde Furberg were elected as members of the Audit Committee. Timo Veromaa was elected as the Chairman, and Frans Wuite and James Phillips were elected as members of the Remuneration Committee.

# **Risk and uncertainties**

Herantis focuses on disease modifying therapies for debilitating neurodegenerative diseases and have and/or will have assets in preclinical and clinical development. General risks and uncertainties present in drug development also apply to this operation. 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 humans. Since Herantis develops 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 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.

#### HERANTIS PHARMA Pic Half Year Report 2021 January – June 2021

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. The company maintains clinical trial liability insurance, but the existing program may not be sufficient to cover claims and such insurance may not be available in the future on acceptable terms, if at all. The success, competitive position and future revenues will depend in part on the company's product candidates infringe upon their patents or other intellectual property.

Impairment of part or all of capitalized development expenses or assets may have a material adverse effect on the Company's business, financial condition, results of operations and future prospects as well as on the value of the Company. Resolving a patent or other intellectual property infringement claim can be costly and time consuming and may require the company to enter into royalty or license agreements, and the company cannot guarantee that it would be possible to enter into such agreements on commercially advantageous terms or at all. Currently, the company does not foresee substantial impact of the Covid-19 pandemic on its plans. However, it is possible that the company's development programs may suffer from delays if the pandemic continues. Unusual 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 a qualified senior team and other employees. A thorough assessment of the risks of Herantis is presented in the English-language information memorandum published on the company's website on 11 November 2019.

Herantis strategy is to continuously identify, minimize and mitigate potential risks, and risk assessment and management are an integrated part of Herantis' operations. 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.

# **Environmental factors**

Herantis works purposefully and systematically to reduce the environmental impact and strives not to pollute the external environment. All production and distribution activities are outsourced. Herantis' quality instructions and practices consider the environment and for example encourage the use of public transportation, limit travelling to strictly necessary business needs, and endorse the use of virtual meetings where possible. Printing and waste are minimized and recycling is organized appropriately.

# **Financial information**

These financial statements release, and its appendices are published in Finnish and in English on August 26, 2021 at 9:00 EEST/8:00 CEST on the company's website at www.herantis.com. In case of any discrepancies between the language versions, the Finnish version shall prevail.

# Certified Advisor: UB Securities Ltd, Finland: +358 9 25 380 225, Sweden: +358 40 5161400 Company website: <u>www.herantis.com</u>

# **Financial calendar**

Financial reporting 2H and FY 2021

3 March 2022

## Investor contact

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# 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.

#### HERANTIS PHARMA PIC Half Year Report 2021

January – June 2021

# **Glossary of terms**

- BBB Blood brain barrier. A border that separates the brain from blood circulation, allowing the passage of water and a selective transport of molecules important for the brains.
- BCAL Breast cancer associated lymphedema. Disease caused by injuries in the lymphatic system due to breast cancer treatments, resulting in chronic and progressive swelling of the affected arm.
- CAGR Compound Annual Growth Rate.
- CDNF Cerebral Dopamine Neurotrophic Factor. A protein naturally present in humans with neuroprotective and neuro-restorative properties. Developed by Herantis as a potential disease-modifying treatment of Parkinson's disease.
- CMC Chemistry, Manufacturing and Controls.
- CNS Central nervous system. CNS disease is a broad category of conditions in which the brain does not function as it should, limiting health and the ability to function. The condition may be an inherited metabolic disorder; the result of damage from an infection, a degenerative condition, stroke, a brain tumor or other problem; or arise from unknown or multiple factors.
- ER Endoplasmic reticulum. An organelle of cells, which is included e.g. in the folding of the proteins produced by the cells.
- HER-096 xCDNF, a synthetic peptidomimetic version of CDNF
- Lymfactin® Herantis' patented gene therapy for the treatment of secondary lymphedema based on the discovery of VEGF-C.
- PD Parkinson's disease. A neurodegenerative disease caused by the death of dopamine producing neurons in the midbrain.
- Proteostasis Is the process that regulates proteins within cells in order to maintain the health of both the the proteome and the organism itself. With ageing, and to a more pathological degree, in some disorders such as Alzheimer's, Parkinson's, the proteostasis is dysfunctional leading to misfolding and affected degradation of proteins.
- xCDNF Program developing next generation CDNF compounds. A certain part of the CDNF protein, which appears to retain the biological activity of the CDNF and to be able to penetrate the blood brain barrier.
- UPR Unfolded protein response. An important signaling system in eukaryotic cells that aims to restore proteostasis and improve cell survival under stress conditions.

pg. 19