

From academic invention to listed company

Neuroscience Center Annual Meeting 20 Aug 2015 Pekka Simula, CEO, Herantis Pharma Plc

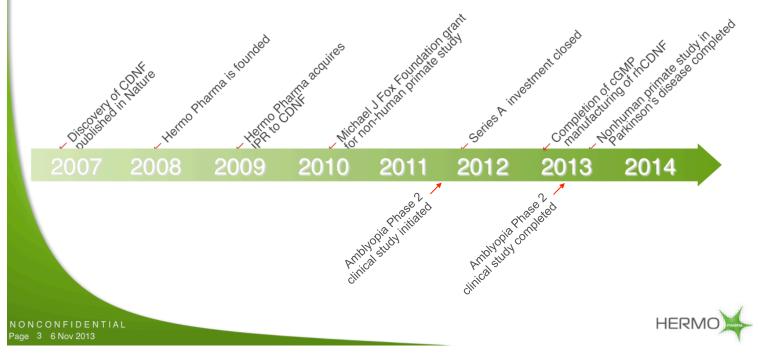
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Herantis was founded in 2008 as Hermo Pharma Ltd

Hermo Pharma - In a Nutshell

- A private biopharmaceutical company based in Helsinki, Finland
- Develops neuroscience applications originating from University of Helsinki
- Over 7 MEUR of non-dilutive funds from e.g. Michael J Fox Foundation





Founding of Hermo Pharma in 2008

- The novel neurotrophic factor CDNF, had recently been published in Nature by Professor Saarma's group
- Tekes supported an initial evaluation on the commercial potential of CDNF and other selected neuroscience-originated product candidates
- Three professors at the University of Helsinki decided to co-found Hermo Pharma to aim at commercializing the results of their research: Mart Saarma, Eero Castrén, and Heikki Rauvala
- Fourth co-founder, Dr. Henri Huttunen joined as the founding CEO

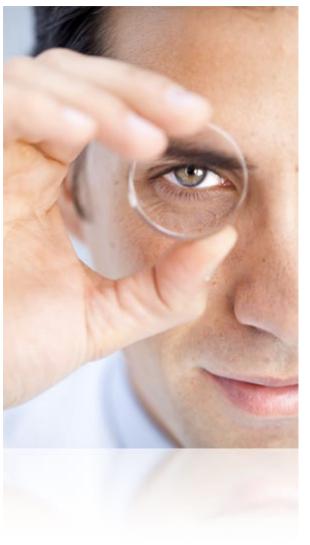


Hermo Pharma: Early years

- Negotiating all CDNF related IPR from the University of Helsinki
- After evaluating different possibilities, selecting two product candidates for further development:
 - CDNF for the treatment of Parkinson's Disease
 - Fluoxetine (an existing anti-depressant) for the treatment of Adult Amblyopia
 a.k.a. Lazy Eye
- Looking for investors to fund the planned development program



Hermo Pharma: Into the clinic and towards success!



- Funding raised from Finnvera, HYR (University Funds), and Tekes
- CDNF GMP manufacturing project started
- CDNF preclinical work continued in collaboration with University of Helsinki, also thanks to professor Saarma's funding from Michael J. Fox Foundation
- Amblyopia study launched: First-Patient-In in 2011
- New CEO was recruited
- Everything looked good!



But there were bumps on the road...

Out of cash with serious debt! Hope we'll reach the bottom! We're out Chairman vs. of gas! CEO leaving

Investors: "No more funds"

PHARMA

factor development for PD' 20/08/15

Setbacks in NFs

Amplyopia study: Negative

Fox Foundation temporarily

Stopped funding neurotrophic

Dec 2013: Looking for the silver lining with empty bank account

Conclusions: Why would we now succeed in raising Series B?

Many things have changed:

- Clear focus!
- Strong preclinical efficacy data supporting potential in <u>both</u> major unmet needs of Parkinson's Disease
 - ✓ Non-motor symptoms
 - ✓ Disease-modifying treatment
- Clear plans (budget, schedule, route of administration, regulatory acceptance, de-risking by carefully selected partners)
- CEO with track record in fund raising, working with international investors

Raising a 10 MEUR round for a preclinical biopharma company in Finland is not easy – it has probably not been done in over 10 years – but the odds could not be better.





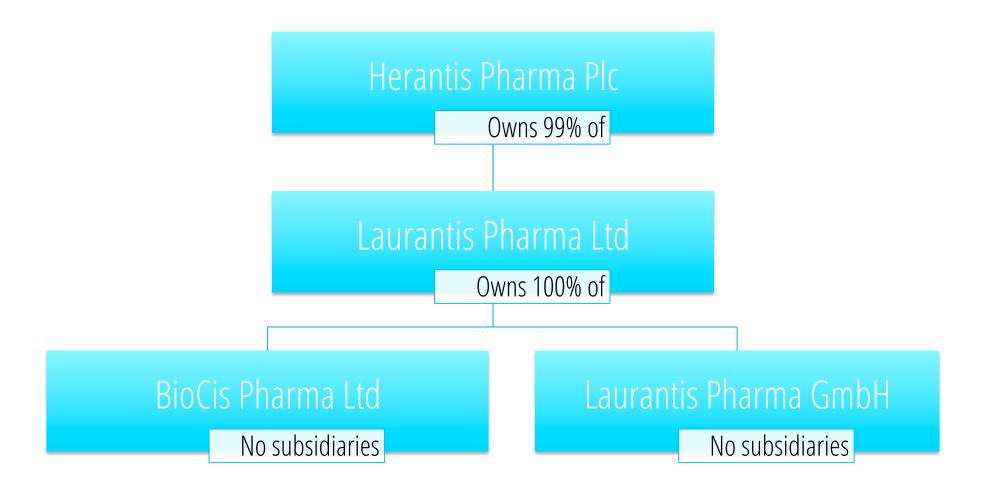


Hermo Pharma: Critical months in the turn of 2013-2014

- Several meetings with international investors in Europe and the USA: Some interest, no really strong leads struggling to find the way
- Proposal by Chairman of Laurantis Pharma on Feb 1st, 2014: Consider merger of the companies and IPO in Nasdaq First North Helsinki?
 - Challenge: Money needed ASAP; Finnish investors disappear after Midsummer
 - 3 months to complete a merger of two companies and prepare for the IPO
 - Project of a lifetime at least in craziness "impossible" was often heard
- 11 June 2014: <u>Herantis Pharma Plc</u> trading begins in Nasdaq First North Helsinki, after a successful IPO raising about 14 MEUR



Herantis group was formed in 2014





Herantis portfolio (drug candidates)

Drug candidate	Indication	Preclin	Phase 1	Phase 2	Phase 3
CDNF neuroprotective factor	Parkinson's disease	Λ	*		
CDNF neuroprotective factor	Amyotrophic lateral sclerosis (ALS)	Λ			
CDNF neuroprotective factor	Alzheimer's disease	**			
Lymfactin®	Secondary lymphedema	Λ	*		
Cis-UCA Eye Drops	Dry Eye	Λ	Λ	Λ	
Cis-UCA Emulsion Cream	Atopic dermatitis	Λ	Λ	Λ	

^{*}This stage of clinical development in planning and scheduled

^{**}Active development currently not on-going. Next steps are pending later decisions.



Herantis Pharma – organization and operations

- Agile team of 7 experts
 - Educational background in medicine, neurobiology, biochemistry, pharmaceutics...
 - Strong collaboration network. E.g. all wet lab work performed in collaboration with universities and commercial service providers (CROs)
- Focus in reaching clinical proof-of-concept
 - Manufacturing of the novel compounds in GMP
 - Required preclinical work e.g. toxicology studies to support clinical trial applications
 - Regulatory work
 - Planning, preparing, and executing clinical studies
 - The "dark side" patents, commercial partners, new sources of funding...



Herantis IPR is largely coming from academic research

Drug candidate group	# of patent families	# of patents
CDNF and MANF	5	24
Lymfactin	2	4
Cis-UCA	2	50
TOTAL	9	78

In addition, total 11 expired or abandoned patent applications



CDNF for Parkinson's disease

Based on preclinical data we believe that CDNF is the most promising compound for a <u>disease-modifying treatment</u> of Parkinson's disease.

- Parkinson's disease (PD) is a progressive neurodegenerative disease, which cannot be cured
 - Estimated seven million patients worldwide
 - Available treatments are symptomatic and only help the motor symptoms caused by disease
- CDNF is expected to relieve <u>also</u> non-motor symptoms of PD <u>and</u> slow down disease progression
 - CDNF has protected dopaminergic neurons in several preclinical studies (rodents, primates)
- First-in-human clinical study to be started in 2015
 - 18 patients, randomized, placebo-controlled
- Estimated sales of pharmaceutical products for treatment of Parkinson's disease in 2018: \$ 3.5 Bn

Figure: Illustration of a possible way to administer CDNF





Barua et al. J. Neurosci. Methods. 214: 223-232, 2013.

CDNF for ALS (Lou Gehrig's disease)

ALS is an aggressive motoneuron disease with no cure. In preclinical studies, a single CNDF injection has prolonged survival and reduced symptoms in a mouse model of ALS.



- Estimated 140,000 diagnosed cases per year worldwide
- First symptom typically weakness of limb muscles
 - Disease progression causes difficulty in moving, speaking, swallowing, and eventually breathing, leading to death
 - Huge unmet clinical need no known treatments that provide essential help
- Preclinical studies are on-going to assess the benefits of multiple dosing of rhCDNF
- Herantis' plan is to proceed to clinical development as soon as the preclinical efficacy can be confirmed



Lymfactin® for secondary lymphedema

Based on scientific studies we believe that damage to lymphatic system leading to secondary lymphedema can be treated with Lymfactin[®].

- Secondary lymphedema is a chronic progressing disease with no approved medicines
 - Estimated 15,000 18,000 patients annually in the USA as a consequence of breast cancer therapy
 - Main symptom is a permanent swelling of affected limb with significant impact on quality of life
- In preclinical models Lymfactin® has promoted new lymphatic growth in the damaged area
- Herantis' goal: Phase 1 clinical study with 24 patients launched in 2015
- Market size estimated in € hundreds of millions





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Cis-UCA Eye Drops for ocular inflammation

Based on preclinical and clinical results we believe that Cis-UCA Eye Drops is the safest and most comfortable eye drop with clear anti-inflammatory properties



- Dry eye syndrome is the most common cause of irritation in the eye
 - Estimated 45 million people in the USA and Europe suffer from dry eye syndrome
- Randomized Phase 2 clinical study completed in 3/2015, N=161
 - Cis-UCA is as safe and as well tolerated as placebo
 - While primary endpoints were not reached cis-UCA showed clear anti-inflammatory efficacy
- Herantis is looking for commercial partners to continue development of cis-UCA Eye
 Drops in dry eye and other ocular inflammatory indications



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Cis-UCA Emulsion Cream for Atopic Dermatitis

Based on clinical studies we believe that Cis-UCA Emulsion Cream is the safest antiinflammatory treatment of Atopic Dermatitis suitable for long-term use

- Phase 2 study completed in 159 patients with moderate to severe Atopic Dermatitis
- Treatment success with 5% cis-UCA superior to vehicle only
- Excellent safety profile; safe skin barrier enhancing treatment, efficacy comparable to mild corticosteroids and Elidel
- Herantis goal is to find a development partner and proceed to:
 - Optimization of the formulation to improve cis-UCA release and enhance efficacy
 - Phase 2B clinical study



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Hermo Pharma – some lessons learned

- Anyone with an exciting CV will not make a good board member
- Don't spend money you think you might get
- Life science development takes ages make sure your company will be fundable after burning the money you currently have
- For a university spin-off, continued close collaboration with academic inventors is critical for success and benefits both parties
- Look around, talk openly to different people, help them out where you can. You never know where the winner proposal comes from
- You will fail at times no matter how hard you work, no matter how smart you are. *Don't take it personally!*



FYI: Aivosairaudet (Brain diseases) seminar Nov 12th

For your information — an event that might be of interest to some of you:

- University of Helsinki, Biogen (Idec), and Herantis are arranging a Brain Disease seminar in Helsinki, 12th November, for politicians, authorities, clinicians, academia and industry
- Eventual goal is to make Finland the #1 in translational brain research
- Speakers include tier 1 politicians and e.g.
 - Dean Risto Renkonen
 - Professor Pentti Tienari
 - Bryan Traynor (NIH)
- Please contact simula@herantis.com for details

