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Helsinn – Building Quality Cancer Care Together

- A world-leading company focused on cancer supportive care
- A comprehensive portfolio of therapies treating several indications including: chemotherapy-induced nausea and vomiting, pain and inflammation and gastroenterology
- Our products are sold in more than 90 countries worldwide via more than 69 partners
- Growing global footprint, with a state-of-the-art R&D facility in Biasca, Switzerland, a world-class production plant in Dublin, Ireland and a growing presence in both the US and China
- Privately held, founded in 1976 by Dr. Gabriele Braglia, headquartered in Lugano, Switzerland, now with more than 560 employees
- Ultimate focus: “to build better todays for every person affected by cancer” via a quality portfolio of innovative cancer-care therapies and via direct connection within the cancer care community
Helsinn’s Senior Executive Team

Our People build Helsinn’s growth

Riccardo Braglia
Group Chief Executive Officer, Board Member & US Chairman

Giorgio Calderari
Group General Manager & Chief Operating Officer & US Board Member

Luigi Caletti
Group Chief Financial Officer, Board Member & US Board Member

Waldo Mossi
Local General Manager, Chemical Business, Helsinn Advanced Synthesis, Switzerland

Padraig Somers
Local General Manager, Pharma Business, Helsinn Birex Pharmaceuticals, Ireland

William Mann
Local President & CEO, & Board Member US Pharma Business, Helsinn Therapeutics (U.S.), Inc

Andrea Meoli
Chief Commercial Officer

Sergio Cantoreggi
Chief Scientific Officer

Roberto De Ponti
Senior Director, Head of Corporate Business Development

Matteo Missaglia
Senior Director, General Counsel, Corporate Legal Affairs

Daniele Bonadeo
Senior Director, Head of Corporate Technical Affairs
Helsinn’s Business

Helsinn Group’s US operations:
Helsinn Therapeutics US Inc., Bridgewater, NJ, USA

Helsinn Group’s development, manufacturing and supply chain platform for finished drug products:
Helsinn Birex Pharmaceuticals Ltd., Dublin, Ireland

Helsinn Group’s Global Headquarters
Helsinn Healthcare SA, Lugano, Switzerland

Helsinn Group’s development & manufacturing facility for Active Pharmaceutical Ingredients:
Helsinn Advanced Synthesis SA, Biasca, Switzerland

Helsinn’s representative office: Beijing, China
Helsinn’s Business Strategy

- Helsinn seeks to be a world-leader in cancer supportive care
- We in-license, develop, manufacture and commercialize the highest quality pharmaceutical products and medical devices to improve the health and quality of life of people with cancer
- Industry high (68%) historical commercialization success rate
- Proven expertise in:
  - CINV
  - Pain and inflammation
  - Gastroenterology
Helsinn’s Partners Worldwide

- Aché
- Alliance Pharma
- Angelini
- Aspen Pharma Pty
- Atco Lab.
- Azevedos
- Biotoscan
- Boehringer Ingelheim
- Bonifar D.O.O.
- Chengda Pharmaceutical
- Chugai Pharma Marketing
- CJ Healthcare
- Corporation CSC
- Dara Biosciences
- Eisai
- Específicos Stendhal
- Eurofarma
- Fannin Ltd.
- Fidia
- Galenica
- Gen İlaç
- Grüenthal
- GSK
- Harvester Trading Company
- Hemas
- Holling Bio Pharma
- Indochina Healthcare
- Italfarmaco
- JW Pharmaceuticals
- Kampar
- Lab. Ergo-Maroc
- Lab. Rubio
- Lab. Silesia
- Lee’s Pharma
- Mantecorp
- Merck & Co.
- Mundipharma
- Naturalia
- Norgine
- Novamed
- Novventure
- Nycomed
- Onko Koçsel İlaç
- Ono Pharmaceutical
- Pfizer
- Pharmasolutions
- Pharmaswiss/Valeant
- Pierre Fabre/Robapharm
- P.T. Kalbe Farma
- Quality Pharma Eirl
- Rafa Laboratories
- Restore Medica
- Riemser Arzneimittel AG
- Riso Pharma Tech
- Roche
- Sobi
- Specialised Therapeutics
- Stada Arzneimittel
- Sulikaj
- Taiho
- Taiwan Major Chem. & Co.
- Thorne Research
- Tramedico
- Treasure Mountain
- UCB Pharma
- Vifor Pharma
- Vifranco Pharma Co.
- Widepharma
Financials
Helsinn’s 2013 Financial Highlights

- 550 employees (309 in CH + 241 abroad) of which 26% in R&D
- Profitable, free cash flow generation and well capitalized
- Turnover invested in R&D in the last 5 years (2009-2013) approx. 28% (approx. 447 million USD)

* Compounded Annual Growth Rate
Historic financial charts
Profitability, R&D figures and number of employees

EBITDA in Million USD

R&D Expenses in Million USD

Headcounts at YE
Helsinn current portfolio and expected sales

- **Aloxi 219.1 M**
- **Akynzeo 81.9 M**
- **Oxaproxin 0.9 M**
- **Nimesulide 24.1 M**
- **Integrative Care 12.1 M**
- **Klean Prep 6.1 M**
- **Gelclair 8.1 M**
- **Klean Prep Lax 3.5 M**
- **Anamorelin 395.1 M**
- **Elsiglutide 124.7 M**
- **Netupitant IV 124.5 M**

**Development Stage vs. Year of Peak Sales (B2B+B2C) - CHF**
Our Cancer Supportive Care
Cancer supportive care focus areas:

- Chemotherapy-induced nausea and vomiting
- Cachexia and Anorexia
- Oral Mucositis
- Hand and Foot Syndrome
- Cancer induced pain
- Diarrhea
- Pre colonoscopy treatment
- Supplements and Nutraceuticals
- Medical Devices
- Alternative Therapies
Corporate Business Development Framework & Licensing-in Strategy

**THERAPEUTIC FOCUS:**
- Cancer Care
- Niche Oncology Indications
- Orphan Drugs
- Pain/Inflammation
- Gastrointestinal

**2015 PRIORITIES ARE:**
- Seeking regulatory approval in the US and Europe for Anamorelin
- Licensing in quality clinical stage projects
- Building out US commercial products in Cancer Supportive Care and Oncology
- Continuing to drive international expansion through targeted distribution agreements
- M&A small size commercial unit focused on oncology or acute care

**CHEMOTHERAPY INDUCED DIARRHOEA**
- CACHEXIA, SARCOPENIA
- ORAL MUCOSITIS
- HAND & FOOT SYNDROME
- BRAIN EDEMA
- CANCER INDUCED PAIN
- SUPPLEMENTS/MEDICAL FOODS
- MEDICAL DEVICES / WOUND HEALING

**PRE-COLONOSCOPY TREATMENT**
- OPIOID-INDUCED BOWEL DYSFUNCTION
- SUPPLEMENTS/MEDICAL FOODS
Helsinn’s Commercialized Products

**PALONOSETRON**
1. Chemotherapy-Induced Nausea and Vomiting (CINV)
2. Post-Operative Nausea and Vomiting (PONV)

**NETUPITANT-PALONOSETRON FIXED DOSE COMBINATION**
Chemotherapy-Induced Nausea and Vomiting (CINV)

**GELCLAIR®**
Oral mucositis

**KLEAN-PREP®**
Bowel preparation prior to Colonoscopy and Surgery

**NIMESULIDE**
(eg. Aulin® Mesulid® Nimed®)
Pain and Inflammation

**OXAPROZIN**
(Duraprox® Walix®)
Pain and Inflammation

*Registered Trademark of Helsinn Healthcare SA
Akynzeo is approved by FDA only Approval pending in other Countries
WW Sales Data in USD from September '03 to September '14

USD 4,698 M
Akynzeo, netupitant and palonosetron fixed-dose combination, oral formulation approved by FDA in October 2014 and launched in USA
Successor product of Aloxi

Oral formulation:
Approved by FDA
Under review by EMA

i.v. formulation:
Under development

*Registered Trademark of Helsinn Healthcare SA
Akynzeo is approved by FDA only Approval pending in other Countries
**Indication:** AKYNZEO is a fixed combination of Netupitant, a substance P/neurokinin 1 (NK1) receptor antagonist, and Palonosetron, a serotonin-3 (5-HT3) receptor antagonist indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Oral Palonosetron prevents nausea and vomiting during the acute phase and Netupitant prevents nausea and vomiting during both the acute and delayed phases after cancer chemotherapy.

**Dosage and administration:** 1 hour prior to the start of chemotherapy; no limitations in terms of frequency of administration

**Contraindications:** None

**Warning and precautions:** Hypersensitivity reactions and serotonin syndrome

**Adverse reactions (incidence ≥ 2%):** Headache and constipation

**Drug interactions:** Caution when co-administered with CYP3A4 substrates

**Specific populations:** Avoid use in severe hepatic or renal impairment patients
AKYNZEO Launch Strategy:

AKYNZEO is the ONLY antiemetic synergistically targeting 2 key CINV pathways in 1 fixed dose

AKYNZEO achieved 90% complete response rates preventing of nausea and vomiting for up to 5 days

AKYNZEO has demonstrated efficacy in Cis & AC based regimens that is sustained across multiple cycles

Demonstrated safety profile in more than 1000 patients receiving over 4500 chemotherapy cycles

AKYNZEO is easy to be administered. Only one capsule, about 1 hour before chemotherapy

*Registered Trademark of Helsinn Healthcare SA
Akynzeo is approved by FDA only Approval pending in other Countries
Development pipeline

Research and Development
Helsinn’s Product Development

- Integrated discovery/preclinical and clinical organizations
- R&D capabilities validated by continuous program successes and repeated licensing to partners
- Effective management of product development
- Revenues invested in R&D in the last 5 years approx. 25%
- Two main phase III programs on NCE recently completed:

### Research

**Focus on the Ghrelin receptor**

Strategic collaboration with state of the art and cost-effective Chinese CROs since 2008

New ghrelin receptor antagonists and agonists discovered and promoted to preclinical and clinical development, respectively. Ghrelin inverse agonists program at Lead Optimization stage

### Development

<table>
<thead>
<tr>
<th>NETUPITANT - PALONOSETRON</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>oral fixed-dose combination</td>
<td>Under development phase II in Japan and phase III in China</td>
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<tr>
<td>i.v. fixed-dose combination</td>
<td>Under review by EMA</td>
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<table>
<thead>
<tr>
<th>ANAMORELIN</th>
<th>Status</th>
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<tbody>
<tr>
<td></td>
<td>Data presented at ESMO 2014 FDA and EMA submissions under preparation</td>
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<table>
<thead>
<tr>
<th>PALONOSETRON Pediatric</th>
<th>Status</th>
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<tbody>
<tr>
<td></td>
<td>Approved by FDA in May 2014 Under EMA review</td>
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</table>

<table>
<thead>
<tr>
<th>ELSIGLUTIDE</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Entering Phase IIb</td>
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</table>
## Helsinn’s Development Pipeline

### Cancer Care

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Indication</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>NETUPITANT-PALONOSETRON FIXED DOSE COMBINATION ORAL</td>
<td>Chemotherapy-Induced Nausea and Vomiting</td>
<td>Under review by EMA</td>
</tr>
<tr>
<td>NETUPITANT-PALONOSETRON FIXED DOSE COMBINATION IV</td>
<td>Chemotherapy-Induced Nausea and Vomiting</td>
<td>Under review by EMA</td>
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<tr>
<td>NETUPITANT-PALONOSETRON FIXED DOSE COMBINATION ORAL CHINA AND KOREA</td>
<td>Chemotherapy-Induced Nausea and Vomiting</td>
<td>Under review by EMA</td>
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<tr>
<td>PALONOSETRON</td>
<td>Chemotherapy-Induced Nausea and Vomiting in Pediatrics</td>
<td>Approved by FDA</td>
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<tr>
<td>ANAMORELIN</td>
<td>Anorexia-Cachexia in NSCLC* patients</td>
<td>Approved by FDA</td>
</tr>
<tr>
<td>ANAMORELIN CHINA</td>
<td>Anorexia-Cachexia in NSCLC* patients</td>
<td>Under review by EMA</td>
</tr>
<tr>
<td>ELSGLUTIDE</td>
<td>Chemotherapy-Induced Diarrhea</td>
<td>Under review by EMA</td>
</tr>
<tr>
<td>GHRELIN RECEPTOR AGONIST 1</td>
<td>Chemotherapy-Induced Neuropathic Pain</td>
<td>Under review by EMA</td>
</tr>
<tr>
<td>GHRELIN RECEPTOR AGONIST 2</td>
<td>Cancer Anorexia/Cachexia</td>
<td>Under review by EMA</td>
</tr>
</tbody>
</table>

### Gastroenterology

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Indication</th>
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<tbody>
<tr>
<td>PEG 3350-BASED OTC LAXATIVE</td>
<td>Constipation</td>
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### Metabolism

<table>
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<tr>
<th>Therapy</th>
<th>Indication</th>
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</thead>
<tbody>
<tr>
<td>GHRELIN RECEPTOR ANTAGONIST</td>
<td>Obesity</td>
</tr>
<tr>
<td>GHRELIN RECEPTOR INVERSE AGONISTS</td>
<td>Obesity</td>
</tr>
</tbody>
</table>

*NSCLC: Non Small Cell Lung Cancer

---

**2011 - 2013**

**2011 - 2013**

<table>
<thead>
<tr>
<th>Clinical Trials</th>
<th>Patients Tested</th>
<th>Clinical Centers</th>
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<tbody>
<tr>
<td>Phase 1</td>
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<td></td>
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<tr>
<td>Phase 2</td>
<td>4</td>
<td></td>
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<tr>
<td>Phase 3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Phase 4</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

Epidemiological studies: [Update 22-5-19](#)
Elsiglutide (ZP1846), is a once-daily, subcutaneously administered glucagon-like peptide 2 (GGLP-2) analog. It is an investigational drug being evaluated for the prevention of chemotherapy-induced diarrhea (CID).

**Development status:** Phase IIa completed, entering Phase IIb

**Aminoacids Sequence:**
H-HGEGSFSSELSTILDALAARDFIAWLIATKITDKKKKKK-NH2
What is Cancer Anorexia-Cachexia Syndrome (CACS)?

Cancer anorexia-cachexia syndrome (CACS) is a multifactorial condition defined by an ongoing loss of body weight (mainly skeletal muscle mass, with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment. (ref: Fearon K et al, Lancet Oncol. 2011 May;12(5):489-95)

- Loss of appetite
- Anorexia
- Reduced food intake
- Muscle wasting
- CACS
- Weight loss
- Anaemia
- Weakness
- Fatigue
- Altered metabolism
- Early satiety
What is the Impact of Cachexia in the Cancer Journey?

Over 50% of cancer patients develop cachexia
- In some tumour types that increases to 80%

CACS has serious implications for people with cancer
- Shortened survival time
- Reduced ability to tolerate treatments
- Reduced response to therapy

Up to 30% of cancer deaths are directly related to CACS
Why is an Effective Treatment for CACS so Important?

A significant **unmet need** exists as there is no present standard of care and current treatments have limited efficacy.

---

"With no new treatments for cachexia to emerge in the last 40 years and phase III seemingly a tough barrier to cross, a success story is sorely needed."

---

**Synovate 2011**

*Base: All respondents (541 Oncologists from 13 countries)*

Q2ii: Thinking about your typical approach to the management of cancer cachexia, what does this usually consist of?
Anamorelin Phase III clinical studies have been completed for the treatment of cancer anorexia-cachexia syndrome (CACS) in patients with non-small cell lung cancer (NSCLC)

Development status: FDA and EMA submissions under preparation

Anamorelin is a novel, orally available, selective ghrelin receptor agonist (GRA) that mimics the appetite-enhancing and anabolic effects of the ghrelin hormone
Lean Body Mass

Change from baseline over 12 weeks in:
- Lean body mass (measured by dual-energy X-ray absorptiometry)
- Hand grip strength of the non-dominant hand
- 477 patients per study

ROMANA 1

Median change:
ANAM: 1.10 kg (95% CI: 0.76, 1.42)
Placebo: -0.44 kg (95% CI: -0.88, 0.20)

ROMANA 2

Median change:
ANAM: 0.75 kg (95% CI: 0.51, 1.00)
Placebo: -0.96 kg (95% CI: -1.27, -0.46)
Body Weight

**ROMANA 1**

Mean change from baseline (kg)

- ANAM: 2.20, N = 283
- Placebo: 0.14, N = 141

**p<0.0001**

**ROMANA 2**

Mean change from baseline (kg)

- ANAM: 0.95, N = 267
- Placebo: -0.57, N = 135

**p<0.0001**

ANAM: Anamorelin
FAACT Anorexia/Cachexia Domain

**ROMANA 1**

<table>
<thead>
<tr>
<th></th>
<th>Mean change from baseline</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Placebo</td>
<td>1.92</td>
<td></td>
</tr>
<tr>
<td>ANAM</td>
<td>4.12</td>
<td>0.0004</td>
</tr>
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</table>

N = 141

N = 282

**ROMANA 2**

<table>
<thead>
<tr>
<th></th>
<th>Mean change from baseline</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>1.34</td>
<td></td>
</tr>
<tr>
<td>ANAM</td>
<td>3.48</td>
<td>0.0016</td>
</tr>
</tbody>
</table>

N = 133

N = 266

ANAM: Anamorelin; FAcCT: Functional Assessment of Anorexia-Cachexia Treatment
Phase 3 Anamorelin data – Strong KOL and media endorsement

Helsinn published positive Phase III on Anamorelin at ESMO 2014

Data was strongly endorsed by KOLs on the trial, including Professor David Currow, Flinders University, Adelaide

Press coverage of the drug was positive, highlighting improvements delivered on lean body mass in patients with cancer anorexia-cachexia
The Lead Optimization Program: the GHRELIN PLATFORM

GHRELIN RECEPTOR ANTAGONISTS

One ghrelin receptor antagonist + several back-up compounds with potential utility in obesity and other metabolic diseases

Development status: Early pre-clinical (pre-IND) development

GHRELIN RECEPTOR AGONISTS

Two novel ghrelin agonists

Development status: Late pre-clinical (pre-IND) development
International Growth
Helsinn’s Strategy in US

Vision to become a leading specialty company with direct sales in the U.S. market by 2016

**R&D Focused company**
- Developing clinical and preclinical stage products
- Leveraging Helsinn’s API and finished product manufacturing capabilities

**Integrated Specialty company with direct sales**
- Integrated R&D and commercial organization
- Portfolio in cancer care and other opportunistic areas tailored to the US market
- Currently co-detailing Emesis franchise product with Eisai

**B2B Model**
- R&D Focused company

**B2C Model**
- Integrated Specialty company with direct sales
“Building the Future”
Step-wise Build-up of U.S. Commercial Organization

Additions to portfolio include:

- Elsiglutide and other compounds acting on the ghrelin receptor under development by Helsinn
- Additional compounds acquired through licensing and acquisition

2013
- 20 people in Commercial

2013
- Initiate co-detailing of oral netupitant-palonosetron fixed-dose combination

2014
- Akynzeo* netupitant/palonosetron co-detailing of oral netupitant-palonosetron fixed-dose combination

2015
- Anamorelin launch First Helsinn launch of product in the US Phase 2 of sales & marketing build-up
- Initiate co-promotion of netupitant-palonosetron fixed-dose combination

2016
- Akynzeo* netupitant/palonosetron co-detailing of oral netupitant-palonosetron fixed-dose combination

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Akynzeo is approved by FDA only Approval pending in other Countries
The China Presence

PRESENCE IN CHINA FROM 2012

- Representative office in Beijing from 3rd quarter 2012
- Country manager on-board with more than 10 years experience in China
- Development and regulatory activities for new generation products:
  - IND for oral Netupitant-Palonosetron Fixed Dose Combination approved, Phase III ongoing.
  - Anamorelin IND approved in October 2014
- Working towards direct sales in China from 2016-17

COORDINATION OF EXISTING ACTIVITIES

- Lead optimization R&D programs at Shanghai discovery labs
- Chemical supply chain management with a J-V partner
- Licensing partnership with Mundipharma
Summary and Upcoming Milestones
Helsinn is leveraging its wide cancer supportive care network
2014 Milestones

- FDA Approval and Co-detailing of Akynzeo, Netupitant-Palonosetron oral fixed-dose combination in USA
- FDA Approval of Aloxi pediatric formulation
- One year co-detailing of Aloxi and Halaven with Eisai
- Completion of Anamorelin phase III and preparation of regulatory submissions
- Preparing our second-generation ghrelin agonist to be ready for phase I
- Targeting the acquisition of a commercial drug or a company in USA - now close to finalisation
- Complete worldwide licensing agreement for Netupitant-Palonosetron oral fixed-dose combination and for Anamorelin
- 12 FDA inspections in 2014
- 340 million US$ sales target, 20% in R&D and with 600 people
Helsinn at a glance

- Focused on Quality of Life products in cancer supportive care
- Private, well-established company with profitability, positive cash flow, no bank debt
- Broad product portfolio of marketed products
- Unique R&D pipeline of technologies and new products
- Internationally diversified into new business models and virgin territories (e.g. US sales and China)
- Family run company with strong management team

A GLOBAL LEADER COMPANY IN CANCER CARE