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# Handelsbanken

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Executive Vice President and Chief Financial Officer

June 2008

# FORWARD LOOKING STATEMENTS

This presentation contains forward looking statements. The words “believe”, “expect”, “anticipate”, “intend”, “will”, “may”, “would”, “could” and “plan” and similar expressions identify forward looking statements. All statements other than statements of historical facts included in this presentation, including, without limitation, those regarding our financial position, business strategy, plans and objectives of management for future operations (including development plans and objectives relating to our products), are forward looking statements.

Such forward looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance, achievements or industry results to be materially different from any future results, performance, achievements or industry results expressed or implied by such forward looking statements.

Such forward looking statements are based on numerous assumptions regarding our present and future business strategies and the environment in which we will operate in the future.

The important factors that could cause our actual results, performance, achievements or industry results to differ materially from those in the forward looking statements include, among others, risks associated with product discovery, development and commercialization, uncertainties related to the outcome of clinical trials, slower than expected rates of patient recruitment, unforeseen safety issues resulting from the administration of our products in patients, uncertainties related to product manufacturing, the lack of market acceptance of our products, our ability to manage growth, the competitive environment in relation to our business area and markets, our ability to attract and retain suitably qualified personnel, the unenforceability or lack of protection of our patents and proprietary rights, our relationships with affiliated entities, changes and developments in technology which may render our products obsolete, and other factors.

Further, certain forward looking statements are based upon assumptions of future events which may not prove to be accurate. The forward looking statements in this document speak only as at the date of this presentation.

# AGENDA

- Introduction to LCP
- Product Pipeline & Presentation of Products
- Presentation of Drug Delivery Platform
- Highlights 2008
- Expected Milestones 2008-2009



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# INTRODUCTION TO LCP

History ● Strategy ● Shareholders ● Overview

# HISTORY OF LCP

2002

- ✓ Meldose® technology platform – a spin out from Lundbeck A/S

2003

- ✓ Initiation of clinical studies of tracrolimus and fenofibrate

2006

- ✓ Commercialization agreement for LCP-Feno with Sandoz (US) and Mylan (EU)
- ✓ EU patent for the Meldose® technology
- ✓ New Drug Application (NDA) for Fenoglide
- ✓ Listing on the OMX Nordic Exchange Copenhagen raising more than DKK 500 million

2007

- ✓ Establishment of an affiliate in New York
- ✓ Agreement with Sciele Pharma to market Fenoglide in North America and Mexico
- ✓ US patent for Meldose® technology
- ✓ FDA approved Fenoglide

2008

- ✓ Sciele Pharma launched Fenoglide in the US
- ✓ Completed follow-up offering raising more than DKK 400 million

# BUSINESS STRATEGY

- Build a fully integrated specialty pharmaceutical company, focused on transplantation and certain cardiovascular indications
- Maximize commercialization potential of product candidates
  - Retain commercial rights to transplant products in certain markets (e.g. U.S.)
  - Out license cardiovascular products
- Apply proprietary MeltDose<sup>®</sup> technology platform broadly for other major therapeutic areas with established commercial potential

# BUSINESS STRATEGY

- Evolve into a fully integrated specialty pharmaceutical company
- Rapidly develop a portfolio of differentiated products
- Meet unique needs of key therapeutic markets and patient populations



Transplantation

**Develop own sales and marketing expertise and sales force**

Cardiovascular Disease

**Outlicense selected best-in-class products to strategic partners**



# LCP OVERVIEW

**Emerging specialty pharmaceutical company currently focused on two major therapeutic areas with established commercial potential**

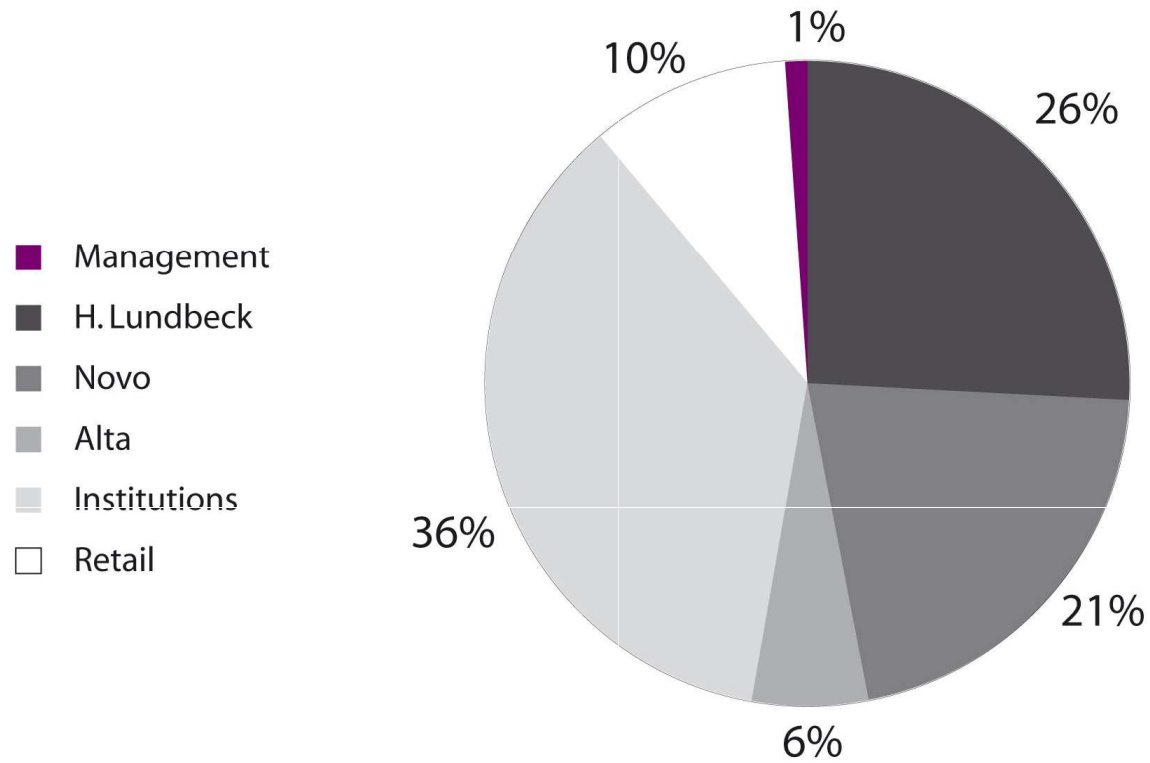
## Transplantation

- Focus on immunosuppressant organ in transplantation and autoimmune disorders, such as AIH
- **Lead product, LCP-Tacro, is a potential best-in-class, once-daily version of tacrolimus**
  - Positive Phase II results for kidney transplantations (Mar 08)
  - Positive Phase II interim results for liver transplantations (Jan 08), final results expected 2Q08
  - 2007 worldwide sales of Prograf® reached USD 1.6bn <sup>1)</sup>

## Cardiovascular Disease

- Focus on the treatment of dyslipidemia
- **First marketed product, Fenoglide™**, launched in the U.S. in February 2008 by partner Sciele Pharma for dyslipidemia
- **LCP-AtorFen Phase II** clinical studies were finalized in May, 2008. The studies verify that the product is safe and well-tolerated for dyslipidemia, and the principle of using a statin/fenofibrate combination has been confirmed as well as the application of our MeltDose® technology

# SHAREHOLDER INFORMATION



Split between shareholders:

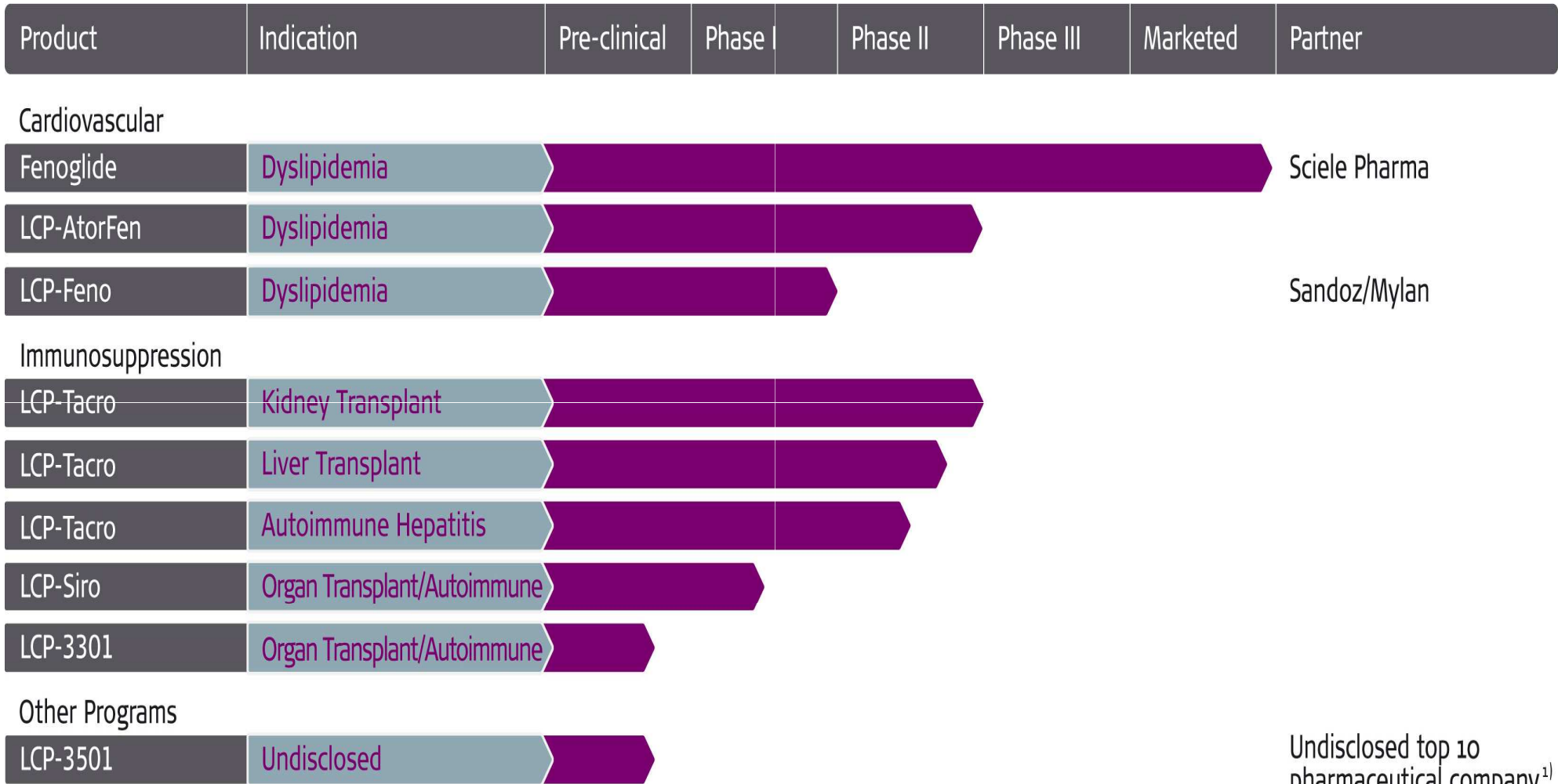
- DK shareholders ~ 70%
- Foreign shareholders ~ 30%



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# PRODUCT PIPELINE & PRESENTATION OF PRODUCTS

# DIVERSE LATE-STAGE PRODUCT PIPELINE



Undisclosed top 10 pharmaceutical company<sup>1)</sup>

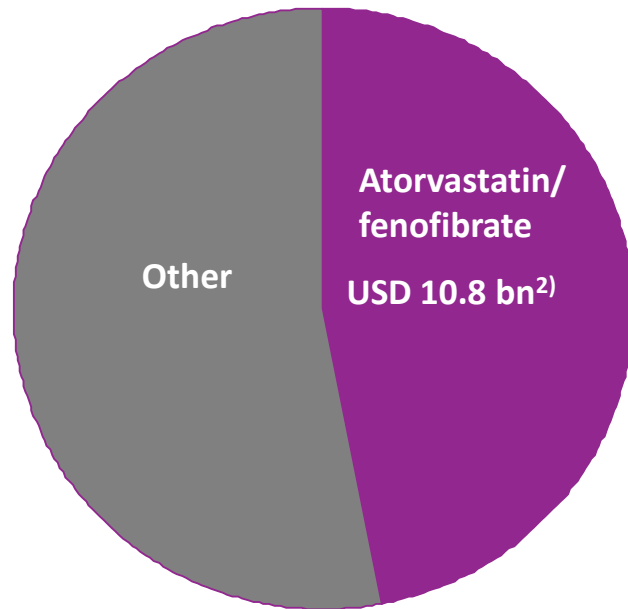


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# CARDIOVASCULAR

Market Information & Product Presentation

# THE CARDIOVASCULAR MARKET



## U.S. Dyslipidemia Market, 2006 By drug type (USD 21bn)<sup>2)</sup>

### Market Players in Dyslipidemia<sup>3)</sup>

- Pfizer (Lipitor<sup>®</sup> – atorvastatin) (\$8.3B)
- Sciele Pharma (Triglide<sup>®</sup> – fenofibrate) (\$20M)<sup>4)</sup>
- Abbott (Tricor<sup>®</sup> – fenofibrate) (\$1.2B)
- Oscient (Antara<sup>®</sup> – fenofibrate) (\$43.7M)

# Fenoglide™ MARKETED IN THE U.S.

- Fenoglide™ provides patients with the lowest dose of fenofibrate without any significant food effect on the market
- Launched in the U.S. in February 2008 by our partner, Sciele Pharma
- Marketed by more than 400 sales reps across Sciele Pharma's diabetes and cardiovascular sales force
  - LCP to receive milestones plus tiered royalty on percentage basis
- In 2006, worldwide sales of fenofibrate drugs were approximately USD 1.7bn <sup>1)</sup>



# LCP-ATORFEN - PHASE II

- Fixed-dose combination of atorvastatin and fenofibrate
  - Comprehensive control in single, once-daily tablet without food effect
  - Potential for low effective doses with documented safety
- Phase II clinical studies were finalized in May 2008
  - 220 patients with mixed dyslipidemia
  - LCP-AtorFen vs. Lipitor® (atorvastatin) and Tricor® (fenofibrate)
- AtorFen Phase II clinical studies confirm
  - the product is safe and well-tolerated for dyslipidemia
  - the application of our MeltDose® technology for producing convenient fixed-dose combination products of statin/fenofibrate within a single tablet
- Significant commercial potential
  - In the US alone, combined sales of atorvastatin and fenofibrate were approximately USD 10.8bn in 2006 <sup>1)</sup>
- LCP expects to find a partner for Phase III



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# TRANSPLANTATION

## IMMONUSUPPRESSION

Market Information & Product Presentation

# THE IMMUNOSUPPRESSION MARKET

- The immunosuppression (organ transplant) market is approximately **USD 3.3bn** <sup>1)</sup>
- Annual Growth Rate is approximately 3% until 2015 <sup>1)</sup>
- Prograf® (tacrolimus) worldwide sales of approximately USD 1.6bn (2007) <sup>2)</sup>

Overview of Major Immunosuppression Drugs						
<b>Brand name</b>	Prograf®	CellCept®	Rapamune®	Neoral®	Myfortic®	N/A
<b>Generic name</b>	tacrolimus	mycophenolate mofetil	sirolimus	cyclosporine	mycophenolic acid	azathioprine
<b>Market share<sup>1)</sup></b>	31%	29%	7%	23%	1%	4%
<b>Maker</b>	Astellas	Roche	Wyeth	Novartis / generic	Novartis	Various / generic
<b>Approved indications</b>	Kidney, liver, heart	Kidney, liver, heart	Kidney	Kidney, liver, heart	Kidney	Kidney

■ Competitor products to LCP existing portfolio

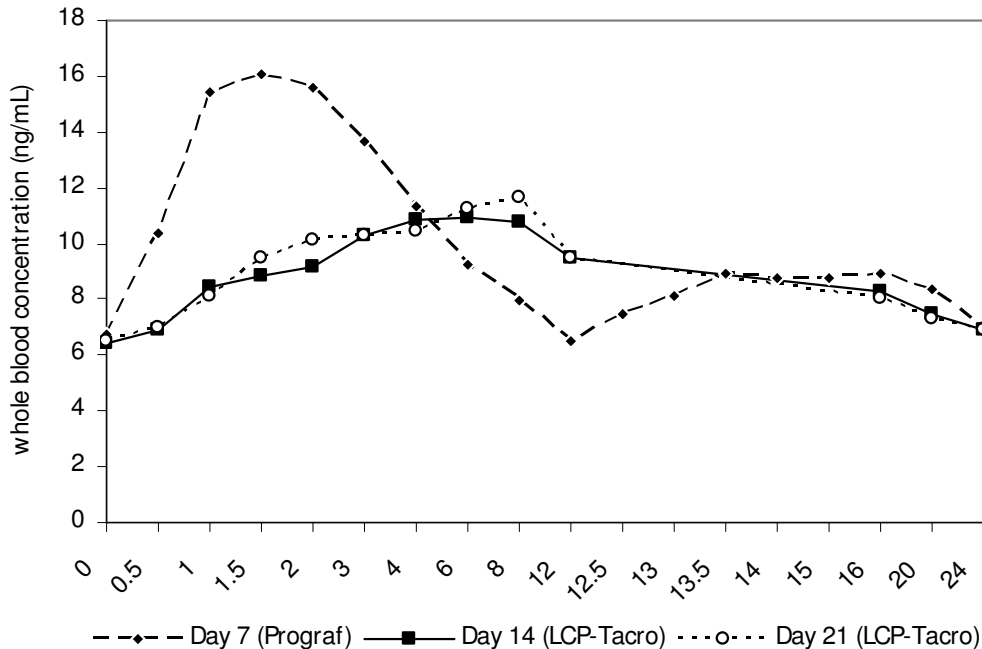
# LCP-TACRO

- Once-daily version of tacrolimus with improved bioavailability and reduced variability for kidney transplantation, liver transplantation, and autoimmune hepatitis
- Demonstrated superiority over Advagraf<sup>®</sup>, the only once-daily tacrolimus product in a Phase I head-to-head clinical study
- Results of Phase II for LCP-Tacro Kidney:
- 46 patients were successfully switched from Prograf<sup>®</sup> to LCP-Tacro
  - Rate of conversion between Prograf<sup>®</sup> to LCP-Tacro: 0.66 – 0.80 (mg. LCP-Tacro/mg. Prograf<sup>®</sup>)
  - Approximately 40% higher bioavailability compared to Prograf<sup>®</sup>
  - Lower C<sub>max</sub> (at peak) and a reduced peak-to-trough ratio
  - No serious adverse effects related to LCP-Tacro
  - End-points reached: switching, conversion rates, bioavailability, and pharmacokinetic parameters
- LCP retains worldwide marketing rights to LCP-Tacro

# LCP-TACRO – POTENTIALLY BEST-IN-CLASS PROFILE

## Once Daily Profile (Phase II Results vs Prograf)

Mean dose uncorrected whole blood concentrations of tacrolimus in patients on days 7, 14, and 21 (LCP-Tacro vs. Prograf®)



Once-daily profile confirmed

~ 40% higher bioavailability

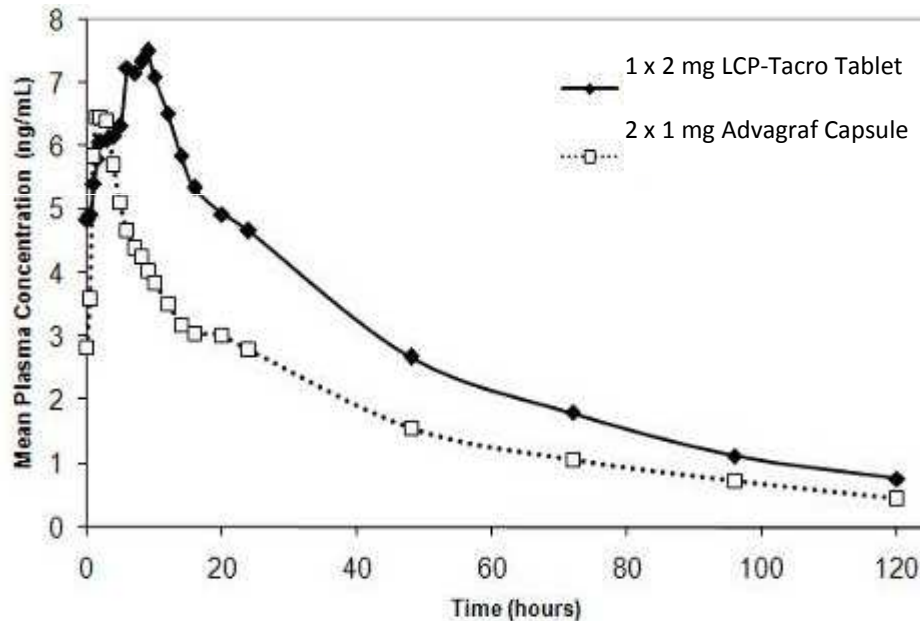
30 % dose reduction possible

Superior peak-to-trough ratio

# LCP-TACRO – POTENTIALLY BEST-IN-CLASS PROFILE

## Once Daily Profile (Phase I results vs Advagraf)

Linear Time Concentration Plot, Dose-  
Uncorrected. (LCP-Tacro vs. Advagraf®)



Once-daily profile confirmed

~ 50% higher bioavailability

Lower dose compared to Advagraf possible

# LCP-TACRO – STATUS OF CLINICAL STUDIES FOR TRANSPLANTATION

- Positive interim Phase II results for liver transplant patients (1Q08)
  - Phase II study expected to be completed in 2Q08
- Phase III program expected to begin in 2H08
  - Approximately 1,000 kidney and liver transplant patients
  - Switch studies with Prograf® as comparator, as well as *de novo* kidney and *de novo* liver transplant studies versus Prograf®

# LCP-TACRO – AUTOIMMUNE HEPATITIS - PHASE II

- Phase II study initiated in January 2008
- Expected to enroll up to 60 patients in up to 12 centers throughout the U.S. and Canada
- LCP-Tacro could potentially offer a safe and effective alternative to patients with autoimmune disorders
- Top-line Phase II results expected in early 2009

## **Market Information:**<sup>1)</sup>

- Prevalence of AIH is 17 cases per 100,000 persons per year
- Equates to a US patient population around 50,000
- Frequency of AIH among patients with chronic liver disease in North America is between 11-23%

# EARLY-STAGE IMMUNOSUPPRESSION PRODUCT CANDIDATES

- LCP-Siro:
  - Active ingredient is sirolimus, which is marketed by Wyeth under the brand name Rapamune® (2007 sales of USD 290m) <sup>1)</sup>
  - Phase I studies ongoing involving healthy volunteers, data expected in 2H08
  - LCP-Siro is expected to demonstrate improved bioavailability compared to Rapamune®
- LCP-3301: once-daily dosage form of another immunosuppressive agent for the prevention of rejection after organ transplantation and for the treatment of autoimmune diseases
  - Preclinical studies ongoing, Phase I to commence in 2H08

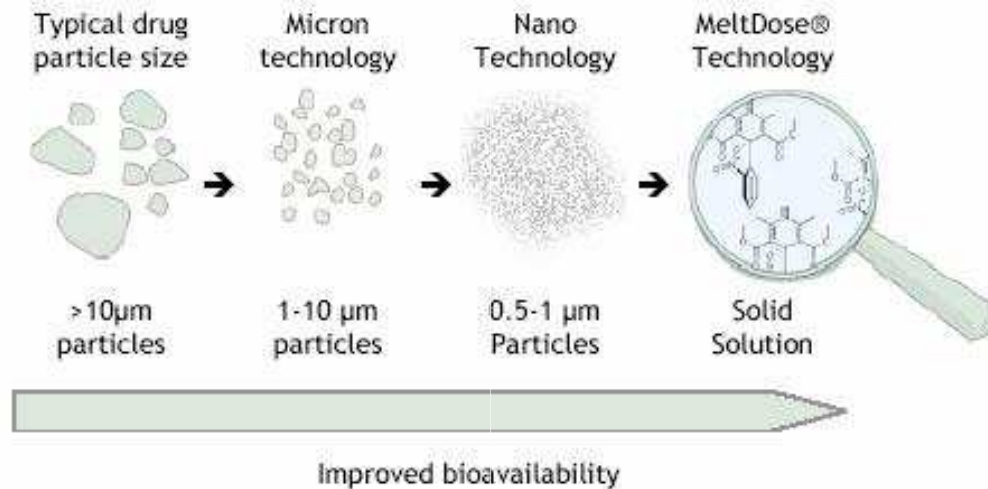


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# DRUG DELIVERY PLATFORM

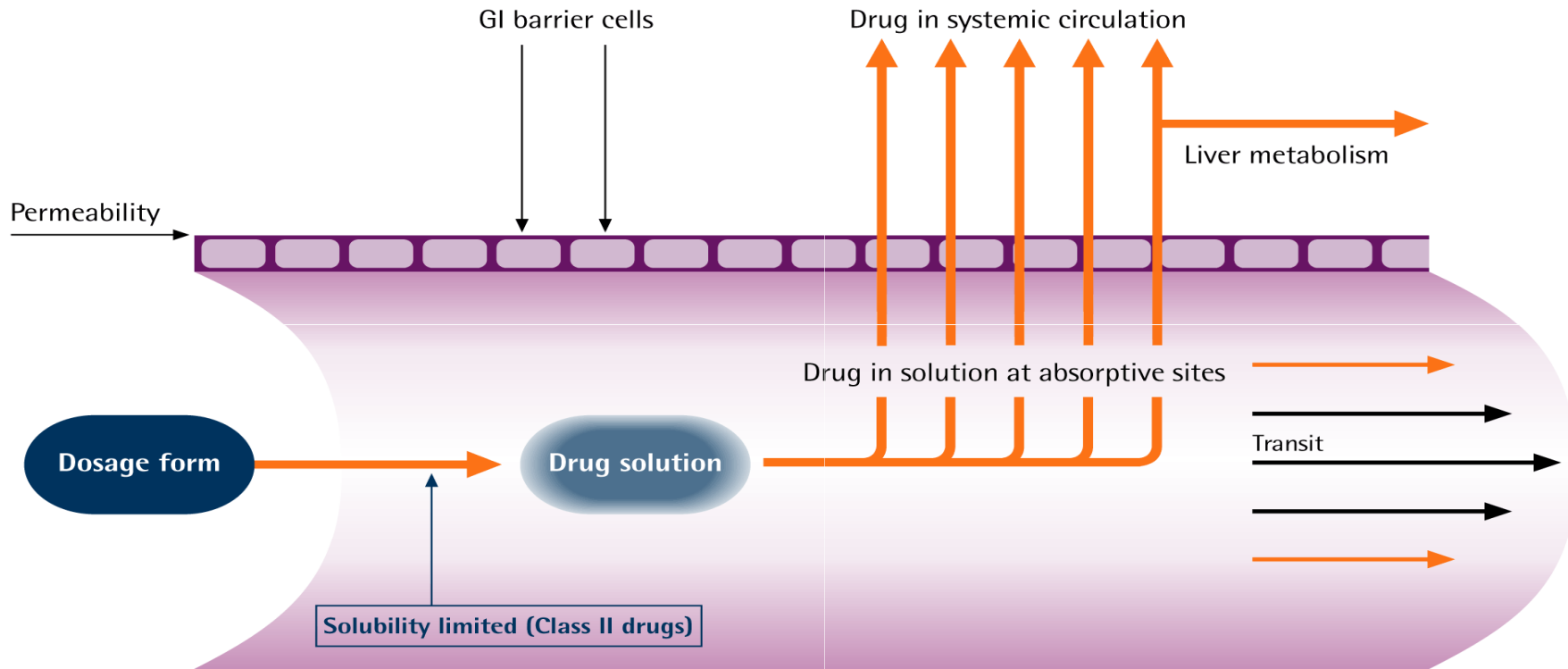
# PROPRIETARY MELTDOSE® TECHNOLOGY

- MeltDose® is our proprietary drug delivery platform for the improvement of absorption and bioavailability in oral therapeutics
  - Clinically and commercially validated
  - Permits a low-risk profile for our product candidates
- Potential clinical benefits include decreased inter- and intra-individual variability, reduction of food-effect, reduction in peak to trough ratio, reduction of administration frequency and API use

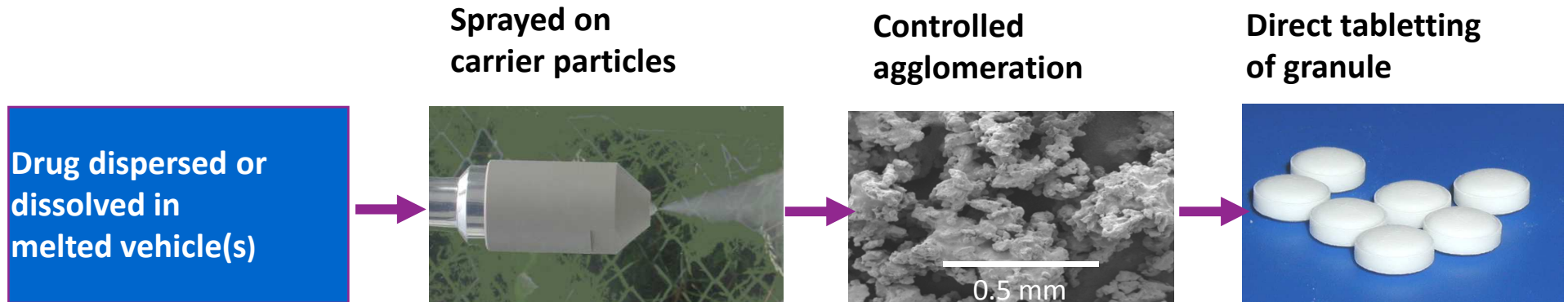


# SOLUBILITY/DISSOLUTION RATE

- MeltDose® improves drug solubility/dissolution rate significantly and therefore facilitates GI tract absorption



# MELTDOSE® TECHNOLOGY PROCESS



## Broad and validated patent portfolio

- 1 issued EU-patent on MeltDose® technology
- 105 patent applications
- Sandoz and Merck have conducted extensive IP due diligence with positive outcome



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# HIGHLIGHTS 2008

# SUCCESSFUL COMPLETION OF OFFERING

Rights issue was 99.62% subscribed with 23,987,771 new shares at DKK 17 per share



Gross proceeds from the rights issue was DKK 408.8 million

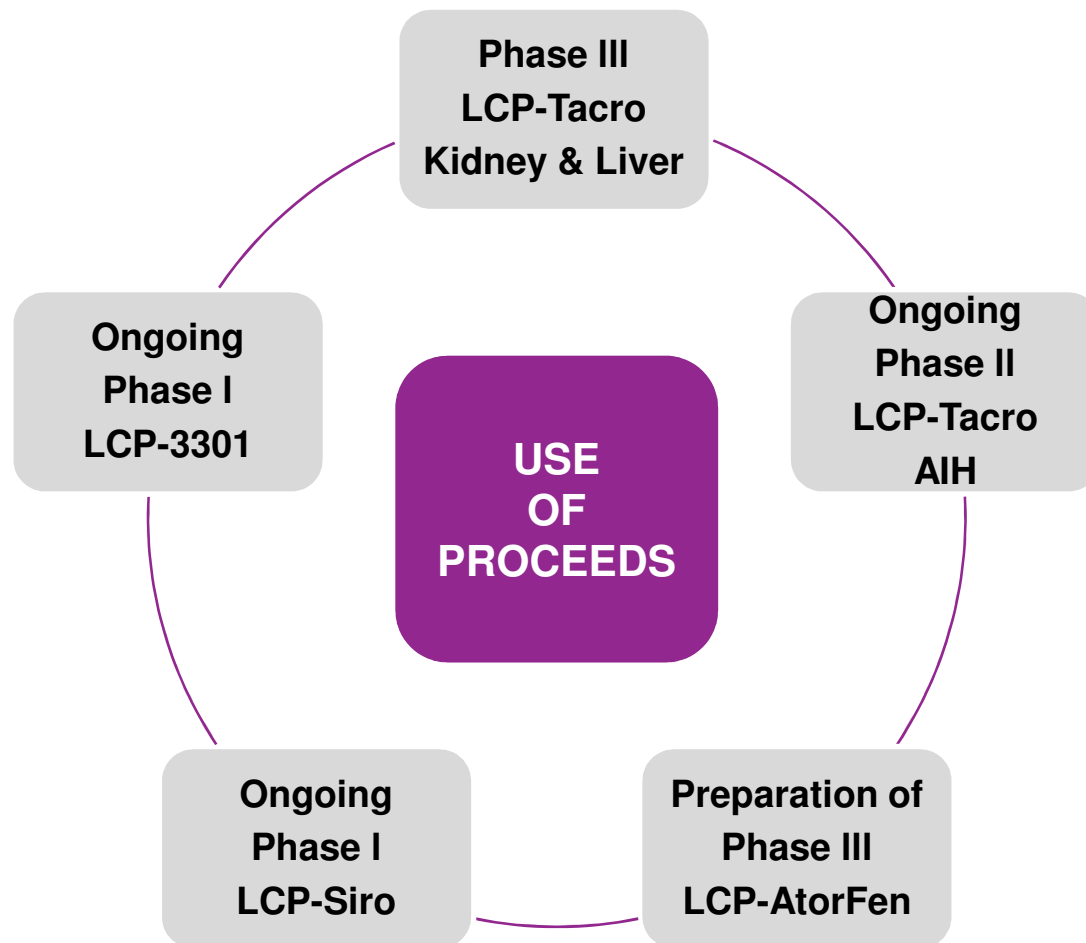


Net proceeds was DKK 375.4 million



LCP's share capital totals DKK 56,092,945

# USE OF PROCEEDS



# RESULT – Q1 2008

	Q1 2008 DKK'000	Q1 2007 DKK'000	Year 2007 DKK'000	Outlook 2008 MDKK
<b>Income Statement</b>				
Revenue	2,928	3,789	64,705	
Research and development costs	(52,916)	(32,096)	(183,608)	
Administrative expenses	(17,545)	(10,400)	(54,033)	
Operating loss	(67,533)	(38,707)	(172,936)	(260 - 290)
Net financial income / (expenses)	2,323	3,605	12,697	
Net loss for the period	(65,210)	(35,102)	(160,239)	(250 - 280)

- Cash ultimo Q1: DKK 265.5 Million
- Proceeds from offering: DKK 375 Million
- Expected cash end of 2008: DKK 445-485 Million



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# EXPECTED MILESTONES 2008-2009

# EXPECTED MILESTONES 2008-2009

- ✓ Launch of Fenoglide™ in the U.S. by Sciele Pharma (February)
- ✓ Results from completed Phase II studies of LCP-Tacro in kidney transplant patients (March)
- ✓ Results from Phase II studies of LCP-AtorFen for the treatment of dyslipidemia (May)
- Results from Phase II studies of LCP-Tacro in liver transplant patients (Q2)
- Initiation of Phase III studies for LCP-Tacro in kidney and liver transplant patients (2H, 2008)
- Presentation of Phase III studies for LCP-AtorFen for the treatment of dyslipidemia (2H, 2008)
- Phase I studies results for LCP-Siro for organ transplantation and autoimmune diseases (2H, 2008)
- LCP expects to find a partner for AtorFen Phase III (H1, 2009)
- Top-line results for LCP-Tacro Autoimmune Hepatitis Phase II (H1, 2009)

# INVESTMENT HIGHLIGHTS

Experienced management with proven track record

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Marketed product generating revenues

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Diverse late-stage pipeline with low risk profile

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Validated MeltDose<sup>®</sup> technology platform

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Worldwide commercialization rights retained for potentially best-in-class product candidates

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# COMPANY INFORMATION

## ▪ IR Contact

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## ▪ About our Shares

LifeCycle Pharma's (LCP) shares were admitted to trading and official listing on the OMX Nordic Exchange Copenhagen on 13 November 2006. The symbol is LCP and the securities identification code (ISIN) is DK0060048148.

## ▪ Share Capital

Our registered share capital is currently DKK 56,092,945 with a nominal value of DKK 1 per share. LCP has only one share class and all shares have equal voting rights.

## ▪ Ownership Structure

The following shareholders have reported ownership of 5 % or more of the company's shares:

- H. Lundbeck A/S
- Novo A/S
- Alta Partners