



Improving Treatments  
Improving Lives

# LIFECYCLE PHARMA A/S

**Carnegie Nordic Health Care Seminar March 2010**

**March 23, 2010 - Stockholm**

**Peter Schøtt Knudsen, Head of IR**

# 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

- **LCP in Brief**
- **LCP's Pipeline**
- **LCP-Tacro™**
- **LCP & Dyslipidemia**
- **Milestones**
- **Summary**



# LCP IN BRIEF

## ■ About

LifeCycle Pharma A/S is a specialized pharmaceutical company applying a unique proprietary drug formulation technology to improve the absorption and therapeutic value of pharmaceutical products

## ■ Products

Our most advanced product is LCP-Tacro™ for the treatment of transplant organ rejection in Phase 3 clinical trials

## ■ Public Company

Listed on the NASDAQ OMX Copenhagen under the trading symbol (OMX: LCP) with a market cap of approx 60 million USD

## ■ Offices

Our Headquarters and R & D Operations are located in Hørsholm, Denmark with a subsidiary in NYC. We are approximately 45 employees

## ■ Management



William Polvino  
*Chief Executive Officer*



Peter G. Nielsen  
*Executive Vice President of  
Pharmaceutical Development  
and CMC*



Peter Schøtt Knudsen  
*General Counsel, Head of  
Legal Affairs & Investor  
Relations*

# BUSINESS STRATEGY

- Maximize commercialization potential of product candidates
  - Create value in LCP-Tacro™ program through continued development
  - Seek strategic partnerships for LCP products and technologies
- Apply proprietary MeltDose® and LLT technology platform broadly for other major therapeutic areas with established commercial potential

# KEY FOCUS – NEAR TERM

- **Advance LCP-Tacro™ into the pivotal Phase 3 program**
  - ✓ Design the final protocol for the program
  - Ensure regulatory alignment with FDA and EMEA
- **Focus and strengthen the organization**
  - ✓ Organization focused and aligned with overall strategy
  - ✓ Key hires in place: - Tim Melkus, SVP Dev. Operation  
- Ron Guido, VP Reg. Affairs
- **Build IP and enter into partnerships**
  - ✓ Patent re Fenoglide® in the U.S.
  - ✓ Patent re LCP-Tacro™ in Europe
  - Continue to seek partners for LCP-AtorFen (worldwide)
  - Assess partnering opportunities for LCP-Tacro™

# LCP'S PIPELINE





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# LCP-TACRO™



**Gail received a kidney transplant from her friend Paula.  
They are both doing great.**

# LCP-TACRO™ – PRODUCT OVERVIEW

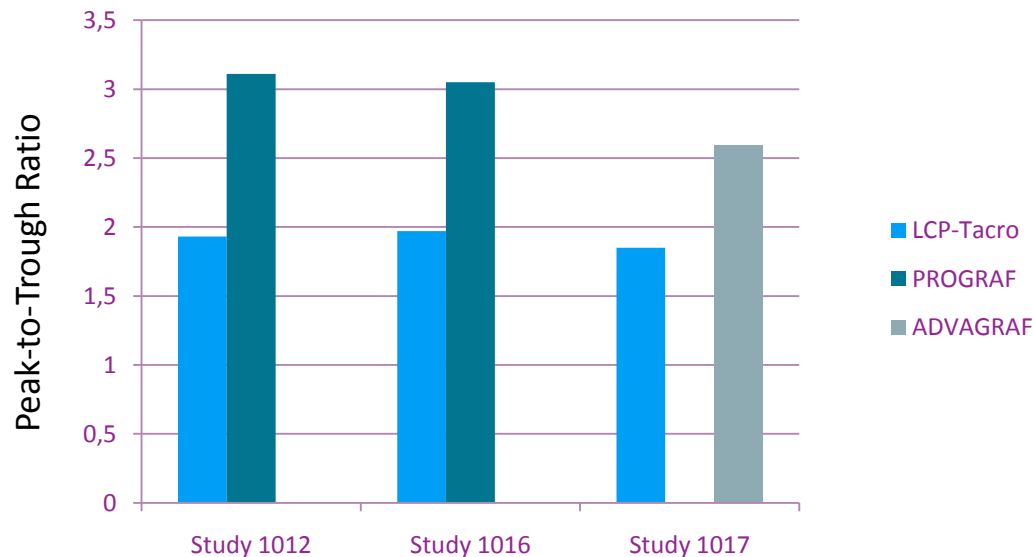
- Once-daily version of tacrolimus with improved bioavailability and reduced variability under development for kidney and liver transplantation
  - Potential superiority vs. market-leader Prograf® (potential for reduced side effects)
- Demonstrated superiority over Advagraf®, the only once-daily tacrolimus product, in a Phase I head-to-head clinical study
  - Higher bioavailability
  - Flatter pharmacokinetic profile / reduced variability
  - Potential for administration at lower doses
- LCP retains worldwide marketing rights to LCP-Tacro™

# STATUS - LCP-TACRO™ CLINICAL TRIALS

Indication	Preclinical	Phase 1	Phase 2	Phase 3	Market	Comments
<b>Kidney Transplant</b>						
<b>Stable patients</b>						<ul style="list-style-type: none"> <li>✓ Enrollment finalized in Jan 2010</li> <li>• Last patient out, 1Q 2011</li> </ul>
<b>De novo patients</b>						<ul style="list-style-type: none"> <li>✓ Results from Phase 2, Q2 2009</li> <li>✓ Submitted Phase 3 protocol, Q4 09</li> <li>• Enroll first patient around mid 10</li> </ul>
<b>Liver Transplant</b>						
<b>Stable patients</b>						<ul style="list-style-type: none"> <li>✓ Results from 12-month follow-up study, 3Q 2009</li> </ul>
<b>De novo patients</b>						<ul style="list-style-type: none"> <li>✓ Results from Phase 2, Q3 2009</li> <li>• On-going discussion with FDA regarding Phase 3</li> </ul>

# CLINICAL PK PROFILE OF LCP-TACRO™

## Phase 1: Consistent improvement in Peak-to-Trough ratios vs. competitors



Compared to Advagraf® and Prograf®, LCP-Tacro™ shows:

- Reduction in peak concentrations relative to trough
- Superior extended release profile

## Phase 2: LCP-Tacro™ vs. Prograf® in stable kidney patients



In patients, compared to Prograf®, LCP-Tacro™ shows:

- Desired "flat" PK profile
- Confirmed once-daily profile

**LCP-Tacro™ can be "Best-in-Class"!**

# CONTROLLED RELEASE PROPERTIES OF LCP-TACRO™ ARE ADVANTAGED BY THE MELTDOSE® TECHNOLOGY

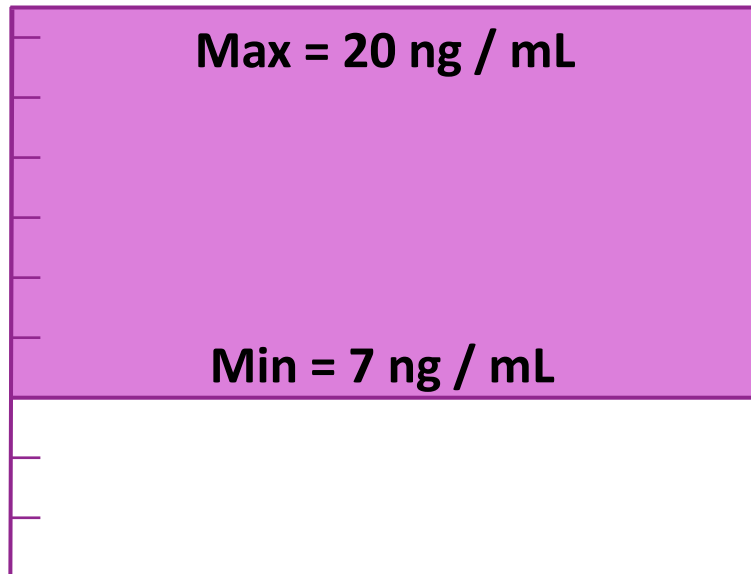
- LCP-Tacro™ results are due to MeltDose® technology
  - LCP-Tacro™ is absorbed throughout the GI tract due to the release properties obtained by using the MeltDose® technology, and is 30% more bioavailable than Prograf®
  - Reduced variability, lower dose
  - Flatter PK profile
- Consistent immunosuppression, with potential reduction in side effects
- Once-daily dosing vs. twice-daily for Prograf®

# LCP-TACRO – STATUS OF CLINICAL STUDIES

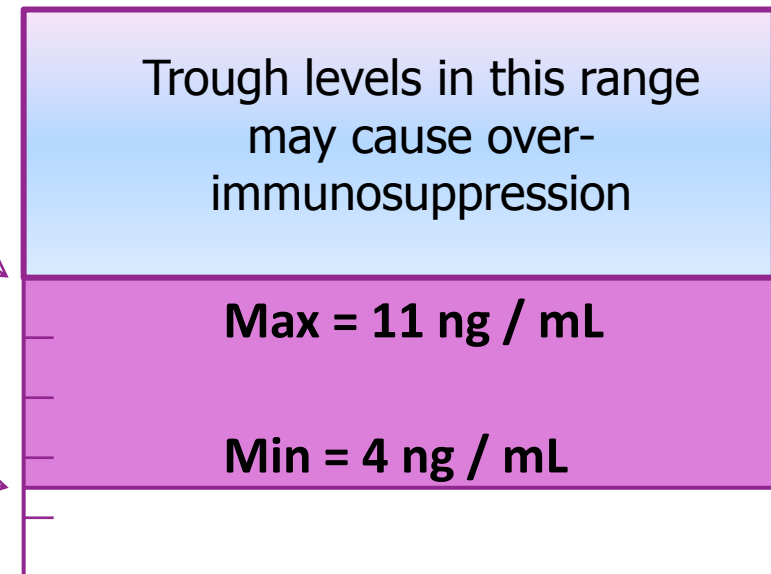
- Phase 2 clinical studies for stable kidney and liver transplant patients completed March and July 2008. An extension phase for liver patients finalized in September 2009.
- Positive interim Phase 2 results for de novo kidney and liver transplant patients (April 2009 and August 2009).
  - Extension phase for the Phase 2 clinical study expected completed in H1 2010 for de novo kidney patients and H2 2010 for de novo liver patients.
- Enrolment completed in January 2010 for the phase 3 stable kidney patients
  - 326 patients enrolled in 53 centres in the U.S. and Europe
  - Phase 3 clinical study expected completed in H1 2011
- Phase 3 program expected to begin around mid 2010
  - Approximately 540 de novo kidney transplant patients
  - 52 week study

# NEW REGULATORY GUIDELINE SUPPORTS LCP-Tacro™

## Original Prograf® Labeling



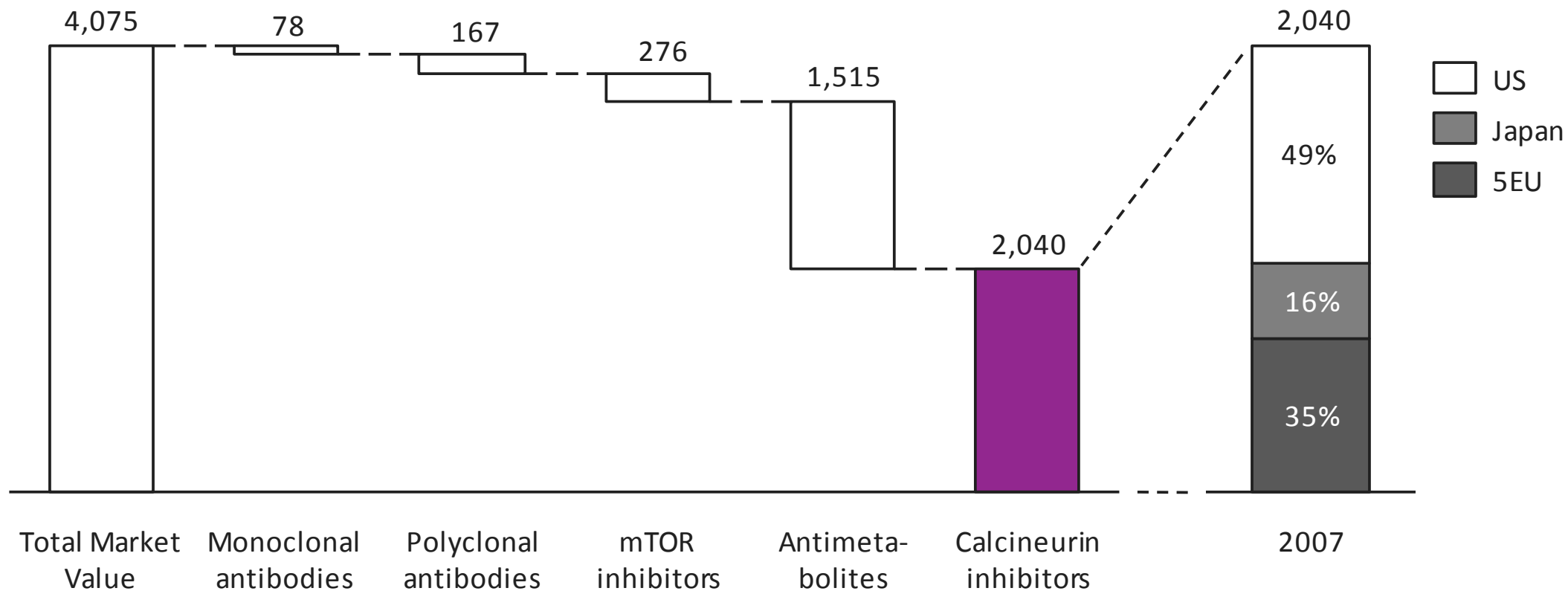
## Revised Prograf® Labeling



- Symphony Study (NEJM, 2007, 357:2562-2575) showed that lower doses of Prograf® in combination with Cellcept® were consistent with good immunosuppression control in transplant patients
- Prograf® product label was revised in May 2009 to allow lower doses to be used than was recommended in the original product label

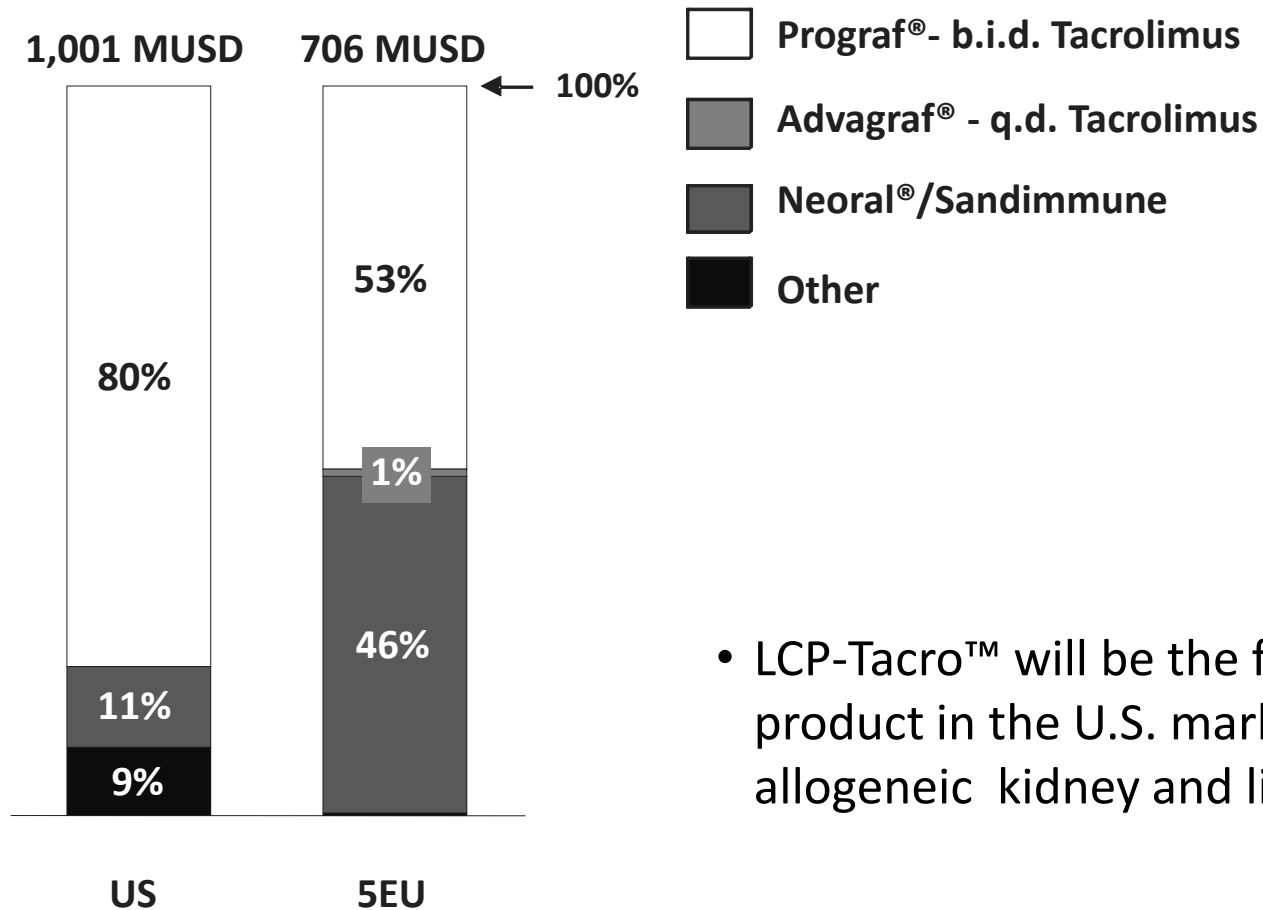
Revised regulatory guidance on allowing lower daily trough levels for tacrolimus in transplant patients is adequately suited to LCP-Tacro™'s gentle controlled release profile

# IMMUNOSUPPRESSANT SALES<sup>1</sup>



<sup>1</sup> Source: Datamonitor, Immunosuppressants in the seven Major Markets (US, Japan, England, France, Germany, Spain and Italy) in 2007 (mUSD)

# Sales within the Calcineurin Inhibitor Class (2007)

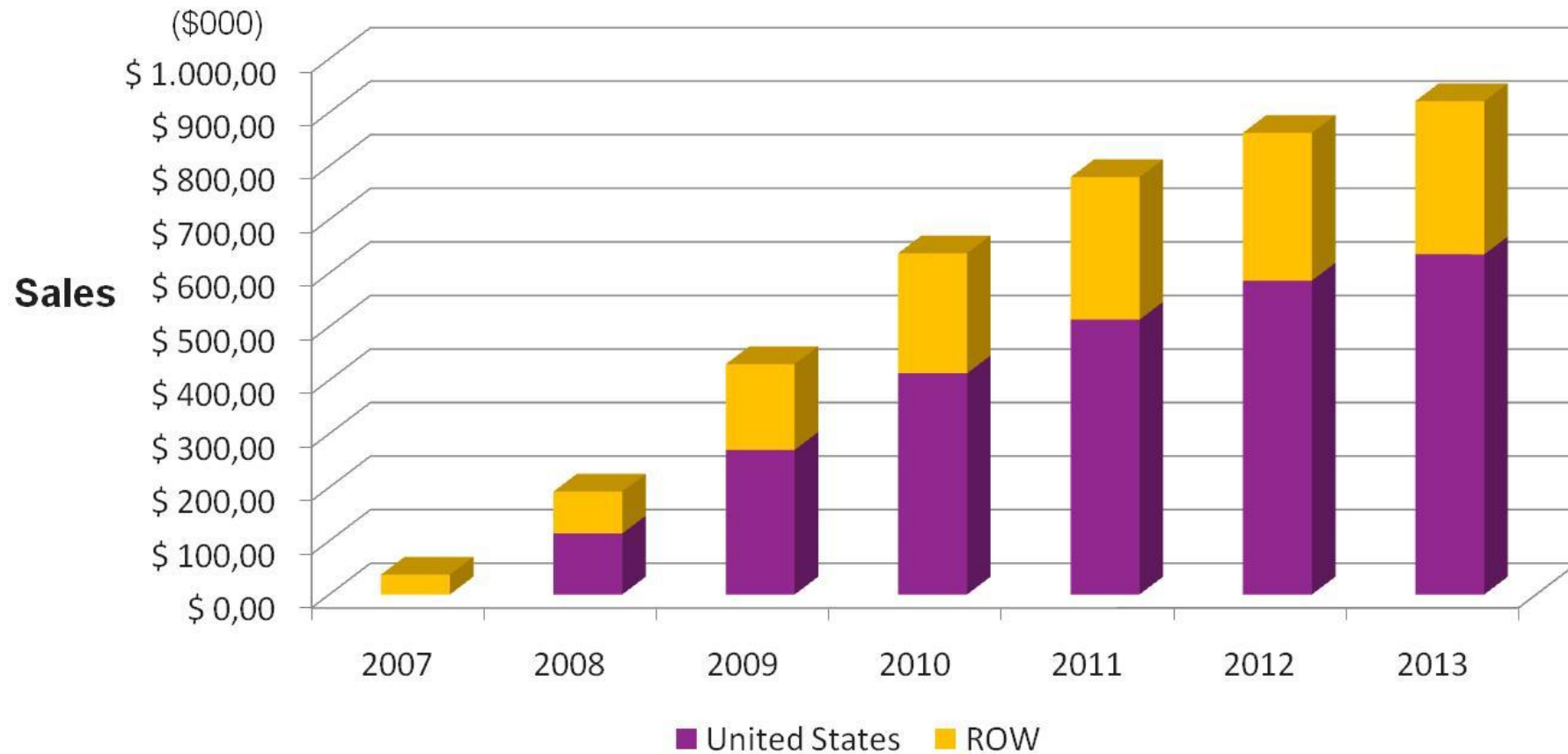


- LCP-Tacro™ will be the first once-daily tacrolimus product in the U.S. market for treatment of allogeneic kidney and liver transplant patients.

Note: 5EU: Germany, the United Kingdom, France, Italy and Spain. Advagraf® is not sold in the U.S.

Source: Datamonitor

# Projected Sales of Advagraf® on worldwide markets



- The NDA submission for Advagraf® is withdrawn from the FDA in February 2009
- LCP-Tacro™ is now the lead candidate to be the only once-daily tacrolimus-based immunosuppressant in the organ transplant market

Source: Datamonitor, Astellas Company Reports



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# LCP – DYSLIPIDEMIA



# FENOGLIDE®: MARKETED IN THE U.S.

- Fenoglide® provides patients with the lowest dose of fenofibrate without any significant food effect, on the market
- Fenoglide® is patent protected
- Launched in the U.S. in February 2008 by partner Sciele Pharma (a Shionogi Company)
- The royalty stream sold to Cowen Healthcare Royalty Partners in August 2008 for up to 105 mUSD, including an upfront payment of 29 mUSD
- In 2009, worldwide sales of fenofibrate drugs were approximately USD 2.34bn <sup>1)</sup>



1) IMS; all rights reserved

# LCP-ATORFEN

- Comparison to statin monotherapy vs. statin/fibrate combo:



- Unique combination with the lowest dose of fenofibrate with atorvastatin using the MeltDose<sup>®</sup> technology
- Partnering activities continue to be pursued
- In the US, the combined sales of atorvastatin and fenofibrates were appr. 10.5 billion USD in 2009

(IMS; all rights reserved)

Efficacy Parameters						
Product	hs-CRP	TC	LDL-C	HDL-C	TG	ApoB
<b>Statin Monotherapy Studies</b>						
Lipitor <sup>®</sup> 40mg <sup>(1)</sup>	-34.0%	-37.4%	- 43.1%	+ 6.5%	-28.9%	- 35.7%
Crestor <sup>®</sup> 20mg <sup>(2)</sup>	-29.9%	- 37.3%	- 45.0%	+10.3%	-25.6%	-39.6%
<b>Combination Therapy Studies</b>						
LCP-AtorFen 40/100mg <sup>(1)</sup>	-37.2% **(3.2 mg/dL)	-35.9% *(252.0 mg/dL)	-42.5% *(156.2 mg/dL)	+ 19.7% *(43.3 mg/dL)	-49.1% *(265.7 mg/dL)	-40.5% *(144.9 mg/dL)
Atorvastatin 40mg <sup>(2)</sup> + Trilipix 135mg	-42.9% **(0.26 mg/dL)	-34.6% *(269.4 mg/dL)	-35.4% *(158.4 mg/dL)	+12.6% *(38.0 mg/dL)	-42.1% *(282.6 mg/dL)	-37.1% *(149.1 mg/dL)

\* Baseline mean

\*\* Baseline median

Sources: 1) LCP-AtorFen Phase 2 study data; 2) Am. J. Cardiology 2008;





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# FINANCIALS/ MILESTONES 2010



Lotte is a kidney transplant patient  
living an active and productive life

# ANNUAL REPORT 2009

MDKK	Actual		Outlook
	2009	2008	2010
Revenue	2,5	170,1	
Research and development	(220,6)	(270,9)	
General and Administration	(51,9)	(73,3)	
One-off restructuring cost	(9,5)	-	
Operating loss	(279,5)	(174,1)	(260) - (290)
Net loss	(271,0)	(149,8)	(260) - (290)
Cash position year-end	333,4	600,1	50 - 100

# MILESTONES IN 2010

- ✓ Patent granted for LCP-Tacro™ in Europe
- ❑ Results from extension Phase 2 in LCP-Tacro™ in *de novo* kidney
- ❑ Results from extension Phase 2 in LCP-Tacro™ in *de novo* liver
- ❑ Regulatory alignment with EMEA
- ❑ Regulatory FDA re phase 3 for LCP-Tacro™
- ❑ Initiate enrolment of the Phase 3 *de novo* kidney study with LCP-Tacro™



# INVESTMENT HIGHLIGHTS

Experienced  
management with  
proven track record

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Marketed product

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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  
products

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# COMPANY INFORMATION

## IR Contact:

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Denmark

## LifeCycle Pharma Inc.

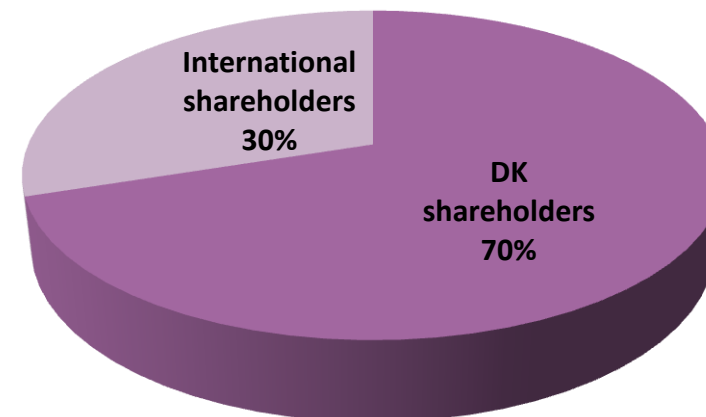
100 Park Avenue, 13th floor  
New York, NY 10017  
USA

## Analyst Coverage

Danske Equities: Thomas Bowers  
Carnegie: Carsten Lønborg  
Madsen  
Morgan Stanley: Karl Bradshaw  
SEB Equity Cap.: Gustaf Vahlne  
Metha Partners: Devesh Singh

## Shareholders

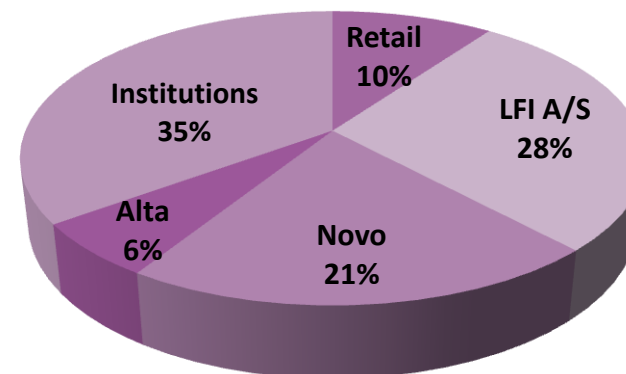
### Geographical split



### Major shareholders

Over 55% of LCP's shares are owned by 3 major shareholders:

- LFI A/S (Lundbeck Foundation)
- Novo A/S
- Alta Partners





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**Q & A**

**Thank you for your attention**

