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Improving Lives

# Annual Report 2009 – Investor conference

William Polvino, President & CEO

Johnny Stilou, VP Finance

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# 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's Strategy**
- **LCP's Pipeline**
- **LCP-Tacro™**
- **LCP & Dyslipidemia**
- **Financial Results 2009**
- **Milestones**
- **Summary**



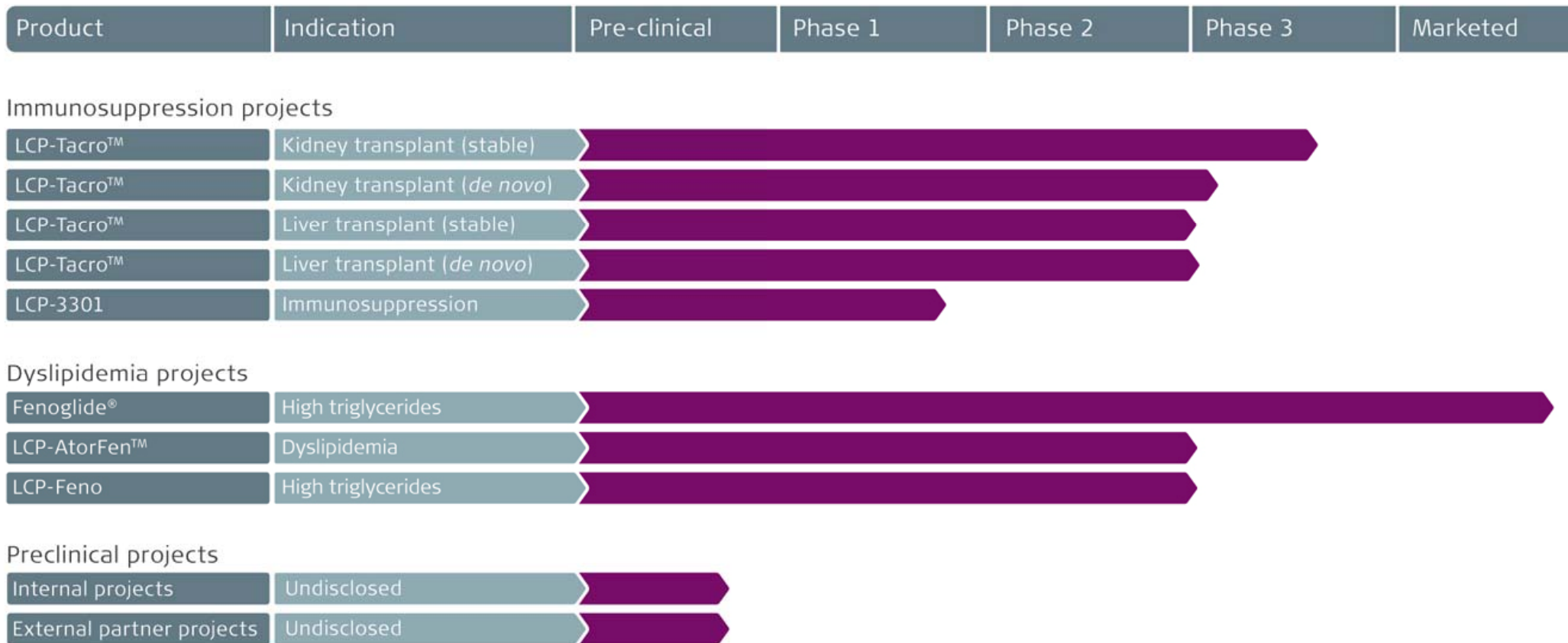
# BUSINESS STRATEGY

- 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 partner for LCP-AtorFen (worldwide)
  - Assess partnering opportunities for LCP-Tacro™

# LCP'S PIPELINE





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# LCP-TACRO™



Confide

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)
- Patent now issued in Europe re LCP-Tacro™
- LCP retains worldwide marketing rights to LCP-Tacro™
- Total world-wide market size for tacrolimus based products continue to stay at a very robust level despite generic competition in the U.S.:
  - In 2009 the total market was appr. 2 billion USD (compared to 1.9 billion in 2008)<sup>1</sup>

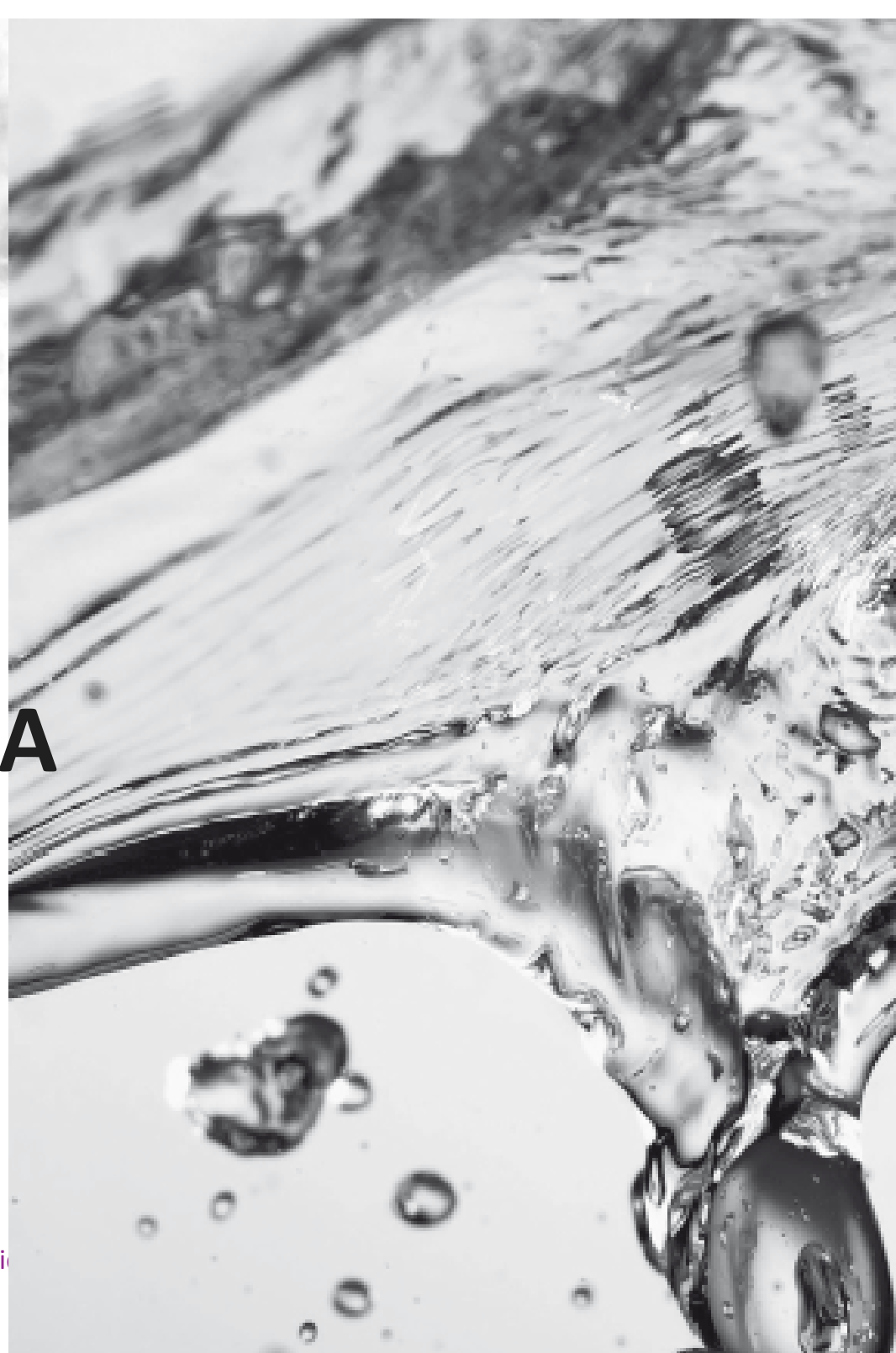
# LCP-TACRO – STATUS OF CLINICAL STUDIES

- Phase 2 clinical studies for stable kidney and liver transplant patients completed March and July 2008. An extension phase for liver patients finalized in Sept 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



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# LCP – DYSLIPIDEMIA



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# LCP-ATORFEN

- 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
- Positive Phase 2 data in May 08, confirmed in extension phase in May 2009.
- Solid commercial potential:
  - In the U.S. alone, combined sales of atorvastatin and fenofibrate were approximately USD 10.5bn in 2009 (IMS; all rights reserved).
- End of Phase 2 meeting held with the FDA, protocol for the phase 3 prepared as well as clinical supplies for the phase 3.
- Partnering discussions ongoing with several parties.

# 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 now patent protected.
- Launched in the U.S. in February 2008 by partner Sciele Pharma (a Shionogi Company). Sales has since launched continued a steady growth.
- The royalty stream sold to Cowen Healthcare Royalty Partners in August 2008 for up to 105 mUSD, including an upfront payment of 29 mUSD. No milestones expected in 2010.
- In 2009, worldwide sales of fenofibrate drugs were approximately USD 2.34bn. <sup>1)</sup>





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# FINANCIALS/ MILESTONES 2010



co

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

# ANNUAL REPORT 2009

MDKK	Actual		Outlook 2010
	2009	2008	
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

# ACHIEVEMENT IN 2009

- ✓ Positive results from Phase 2 LCP-Tacro™ in de novo kidney
- ✓ Positive results from LCP-AtorFen Phase 2 extension studies reports results
- ✓ Positive results from Phase 2 LCP-Tacro™ in de novo liver patients
- ✓ Positive 12 month extension data from LCP-Tacro™ liver in stable patients
- ✓ Patent granted in the U.S. re Fenoglide®
- ✓ Submitted the Ph. 3 protocol to the FDA for the de novo kidney study with LCP-Tacro™



# 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 enrollment 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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# INVESTOR RELATIONS

- **IR contact**

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- **Financial calendar**

21 Apr 10: AGM

12 May 10: 1Q10

18 Aug 10: 1H10

10 Nov 10: 3Q10

- **About our shares**

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

- **Share capital**

As of 31 December 2009 LCP had a registered share capital of DKK 56.6 mio shares with a nominal value of DKK 1 per share. LCP has only one share class and all shares have equal voting rights.

- **Ownership structure**

As of 31 December 2009, a total of 3,935 of LCP's shareholders were registered in the shareholder register. The following shareholders have reported ownership of 5 % or more of the company's shares:

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



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Q & A

Thank you for your attention

