



Improving Treatments  
Improving Lives

# LifeCycle Pharma A/S

*IMPROVING TREATMENTS*  
*IMPROVING LIVES*

March 2011

# FORWARD LOOKING STATEMENTS

This presentation contains forward looking statements. All statements other than statements of historical facts included in this presentation are forward-looking statements that are subject to certain risks, trends and uncertainties that could cause actual results and achievements to differ materially from those expressed in such statements. These risks, trends and uncertainties are in some instances beyond our control.

Words such as “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “will” and other similar expressions identify forward-looking statements, although not all forward-looking statements contain these identifying words. In particular, any statements regarding clinical trial results and potential regulatory approval for LCP-Tacro are considered forward-looking statements. These forward-looking statements involve substantial risks and uncertainties and are based on our assessment and interpretation of the currently available data and information, current expectations, assumptions, estimates and projections about our business and the biopharmaceutical and specialty pharmaceutical industries in which we operate.

Important factors that may affect our ability to achieve the matters addressed in these forward-looking statements include, but are not limited to whether the results of our Phase 3 clinical trials of LCP-Tacro meet the predetermined endpoints for such trial; our ability to complete the development of, obtain regulatory approval for, and commercialize, LCP-Tacro; our ability to hire and retain personnel in a competitive industry; our reliance on third parties to manufacture LCP-Tacro and to conduct clinical trials for LCP-Tacro; competition from existing therapies and therapies that are currently under development, including Prograf® (tacrolimus), Advagraf® (tacrolimus), and belatacept; whether we are able to obtain additional financing, if needed; risks of maintaining protection for our intellectual property; risks of an adverse determination in intellectual property litigation; and risks associated with stringent government regulation of the biopharmaceutical industry.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements, which speak only as of the date hereof. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. We do not have a policy of updating or revising forward-looking statements and, except as required by law, assume no obligation to update any forward-looking statements.

# ABOUT LIFECYCLE PHARMA (LCP)

- NASDAQ–OMX-listed pharmaceutical company (SYMBOL: LCP)
- Recently completed successful \$85m financing
- Clinical and market stage company using its proprietary technology to:
  - Create optimized drug products from known active ingredients
  - Develop LCP-Tacro™ a Phase 3 candidate with blockbuster potential
- Internal formulation, development, regulatory and commercialization skills
- Offices in
  - Hørsholm, Denmark
  - Edison, NJ



# EXPERIENCED MANAGEMENT TEAM

## Executive and senior management



**William J. Polvino**  
President and CEO



**Edward E. Koval, MBA**  
SVP, Business Dev. and Strategic Corporate Dev.



**Anja A. Leschly**  
VP, Human Resources and Communications



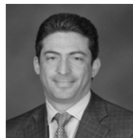
**Tim Melkus, MBA**  
SVP, Development Operations



**Peter G. Nielsen**  
EVP, Pharmaceutical Development and CMC

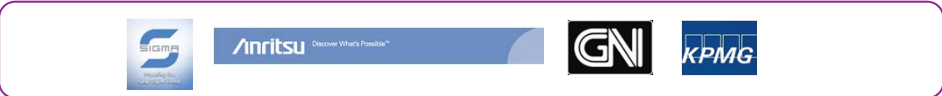


**Johnny Stilou, M.Sc. (Econ)**  
Chief Financial Officer



**John D. Weinberg, MD, MBA**  
SVP, Commercial Ops. and Investor Relations

## Prior experience



# HIGHLIGHTS

## LCP-Tacro™

- Significant sales potential
  - Potential “best-in-class” profile
  - Optimized, branded version of the #1 transplant drug
  - Funded through to Regulatory submissions in 2013
- 

## Experienced management

- Executive and senior management group with expertise, experience and proven track-record from global leading pharmaceutical companies
- 



## Proprietary technology platform

- MeltDose® is proven clinically & commercially with Fenoglide®
  - Low cost / transferable
  - Patent protected
  - Applicable in multiple therapeutic areas
- 

## Programs with potentially high returns

- No New Chemical Entity risk
  - Late stage efforts
  - Focused on established markets with unmet medical & commercial needs
-

# STRATEGY

Leverage the Company's proprietary MeltDose technology in therapeutic areas with established commercial potential

## LCP-Tacro™ for Transplant

Maximize the full value of the LCP-Tacro program by funding in-house through the completion of Phase III and to NDA/MAA submission\*

## Pipeline Programs

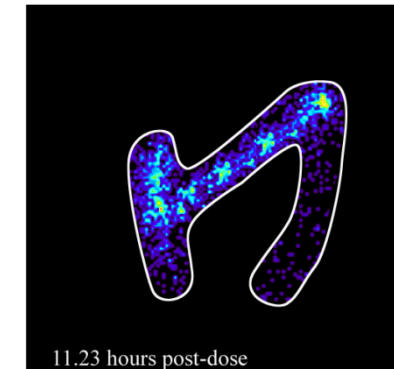
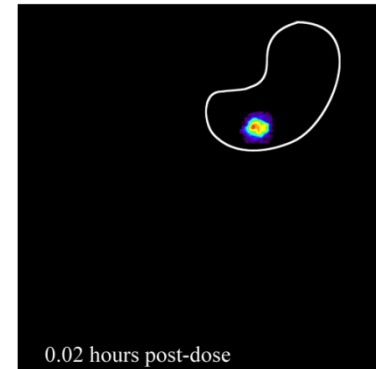
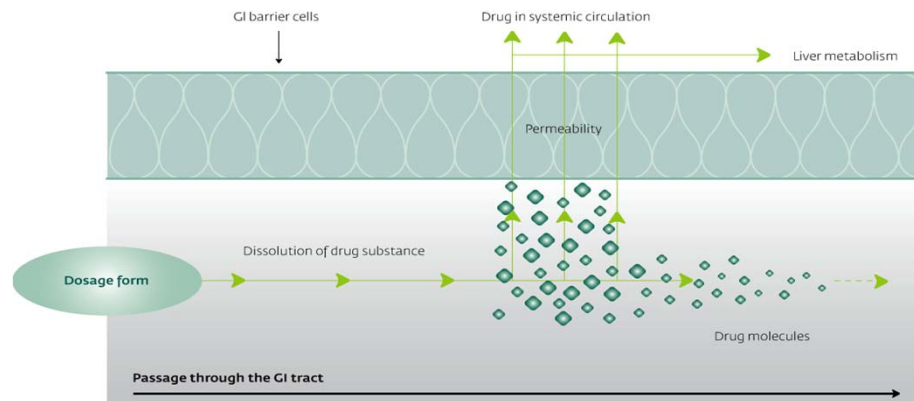
Pipeline product development and partnering to enhance the commercial potential of LCP's product candidates

Advance LCP-Tacro through clinical studies in kidney transplantation  
Advance additional pipeline programs

\*\$85m financing 4Q2010

# MELTDOSE® TECHNOLOGY <sup>1)</sup>

## Improving GI (gastrointestinal) absorption of poorly soluble drugs



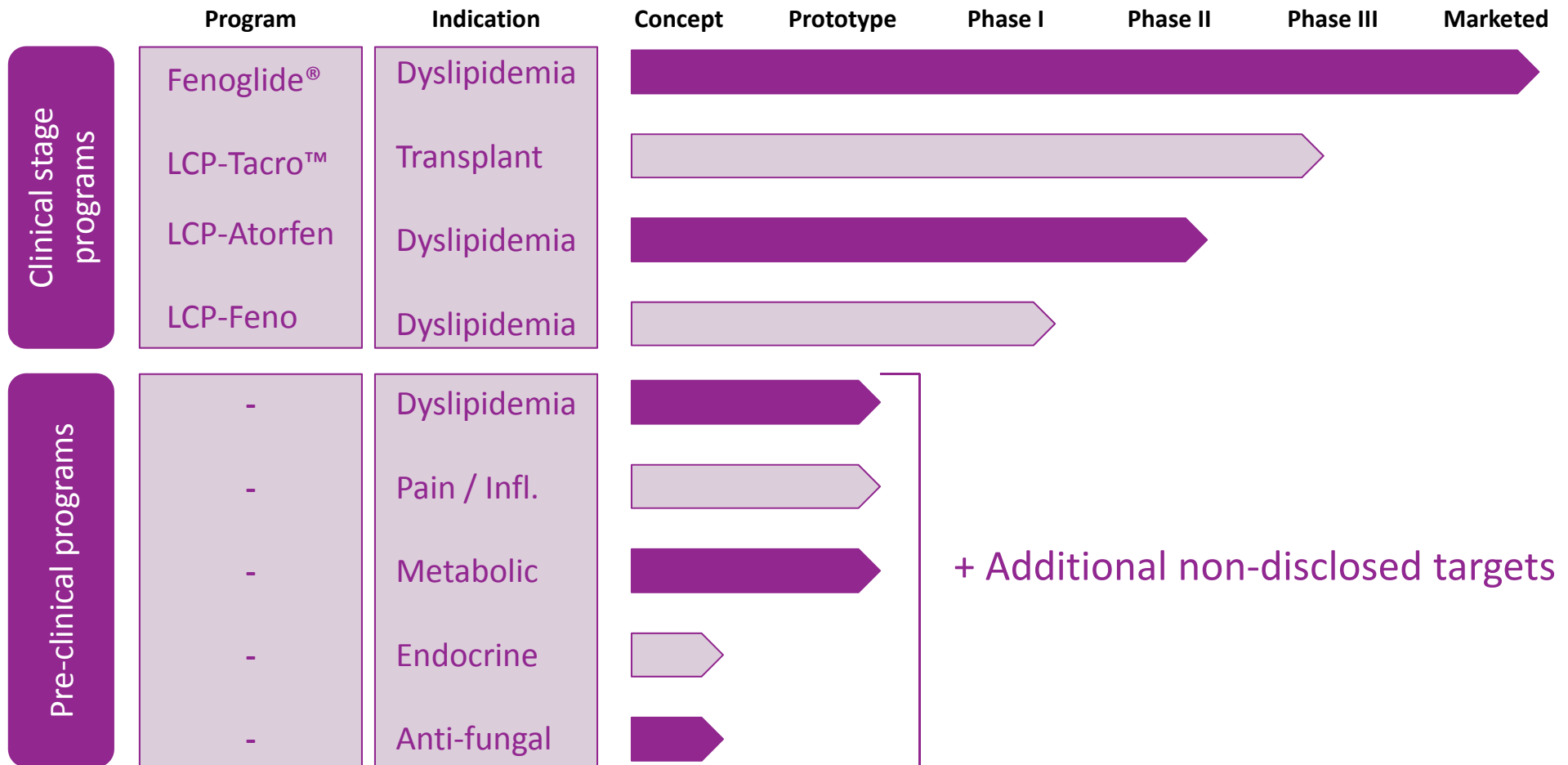
- MeltDose® enhances the bioavailability of compounds with low water solubility
- Allows the company to create improved versions of marketed drugs
- Validated in clinical studies and received regulatory approval (Fenoglide® in the U.S.)

- Sustained delivery and absorption
- Scintigraphy of LCP-Tacro™ just after dosing to the stomach, and showing continued absorption in the lower gastrointestinal tract

***Poor solubility causes low and variable absorption. MeltDose® is an enabling, proprietary technology that generates improved products with better, consistent absorption***

<sup>1)</sup> MeltDose® is LCP's proprietary technology

# PIPELINE – MULTIPLE OPPORTUNITIES IN EARLY DEVELOPMENT





Improving Treatments  
Improving Lives

# LCP-TACRO™

The Next “Gold Standard” in Transplantation

# \$5B ORAL IMMUNOSUPPRESSANT MARKET

BRAND	Prograf / Advagraf (tacrolimus)	Neoral / Sandimmune (cyclosporin)	CellCept (mycophenolate mofetil)	Myfortic (mycophenolic acid)	Rapamune (sirolimus)
Company	Astellas + Generics	Novartis + Generics	Roche + Generics	Novartis	Pfizer
MOA	Calcineurin Inhibitor	Calcineurin Inhibitor	Anti-metabolite	Anti-metabolite	mTOR Inhibitor
2009 WW Sales of Branded Products	<b>\$2.0 B</b>	<b>\$950 MM</b>	<b>\$1.4 B</b>	<b>\$390 MM</b>	<b>\$350 MM</b>

Primary Immunosuppressants

Adjunct Immunosuppressants

LCP's core product uses a novel formulation of the leading transplant drug in developing a once-daily dosage drug with improved bioavailability

# LCP-TACRO™ OPPORTUNITY

USDbn 3 global calcineurin inhibitor market <sup>1)</sup>

LCP-Tacro™

## Tacrolimus

(Prograf®, Advagraf®, generics)

## Cyclosporine

(Neoral®, Sandimmune®, generics)

- Once-daily dosing
- Improved PK (pharmacokinetics) profile
- Lower dosing
- Not automatically substitutable by generics, providing patients and physicians with consistency

Tacrolimus is the current “gold standard” calcineurin inhibitor

LCP-Tacro™ offers the potential to supplant tacrolimus as the standard therapy

<sup>1)</sup> Astellas Pharma's Annual Report 2009 and Novartis Pharmaceuticals Annual Report 2009

# RATIONALE FOR LCP-TACRO™ DEVELOPMENT

## Challenges with tacrolimus

### Absorption

- Absorption of tacrolimus from Prograf® capsules characterized by high inter- and intra-patient variability

### Dose adjustment

- Dose adjustments based on measurement of trough levels required to assure therapeutic concentrations
- Wide peak/trough fluctuation and diurnal variability

### Daily dosing

- Twice-daily dosing
- Incorrect dosing can result in either kidney toxicity or organ rejection

### Side effects

- Include diabetes, tremors, hypertension

## Potential benefits of LCP-Tacro™

- MeltDose® technology improves systemic absorption and may reduce variability
- Bioavailability of LCP-Tacro™ is greater than Prograf®

- Opportunity for reducing the dose administered
- Limited peak/trough fluctuation
- Reliable absorption/exposure
- Potential for fewer dose changes, and improved compliance

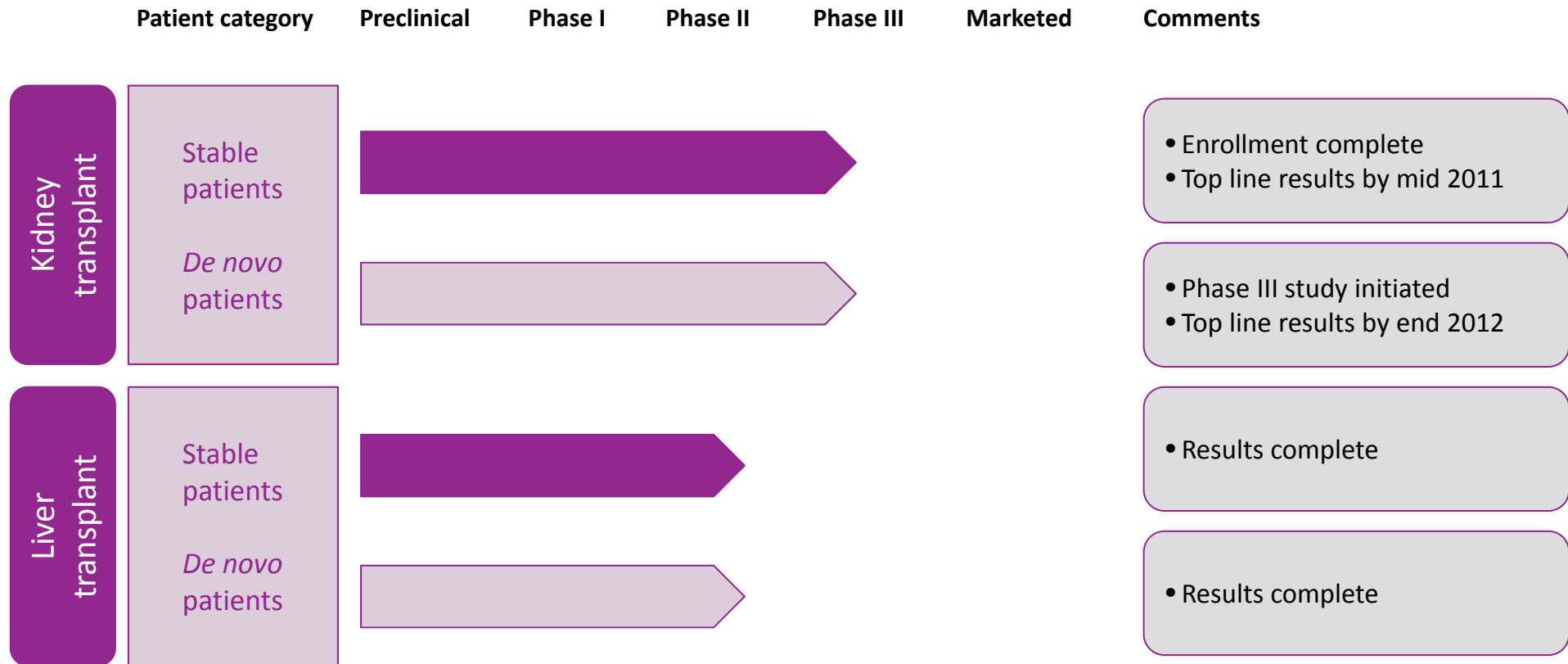
- Once-daily dosing aligns with physician and patient preference
- Physicians desire to have a primary immunosuppressant that cannot be substituted by the pharmacy

- Therapeutic exposure with reduced Cmax may improve side effect profile

LCP-Tacro™ development rationale

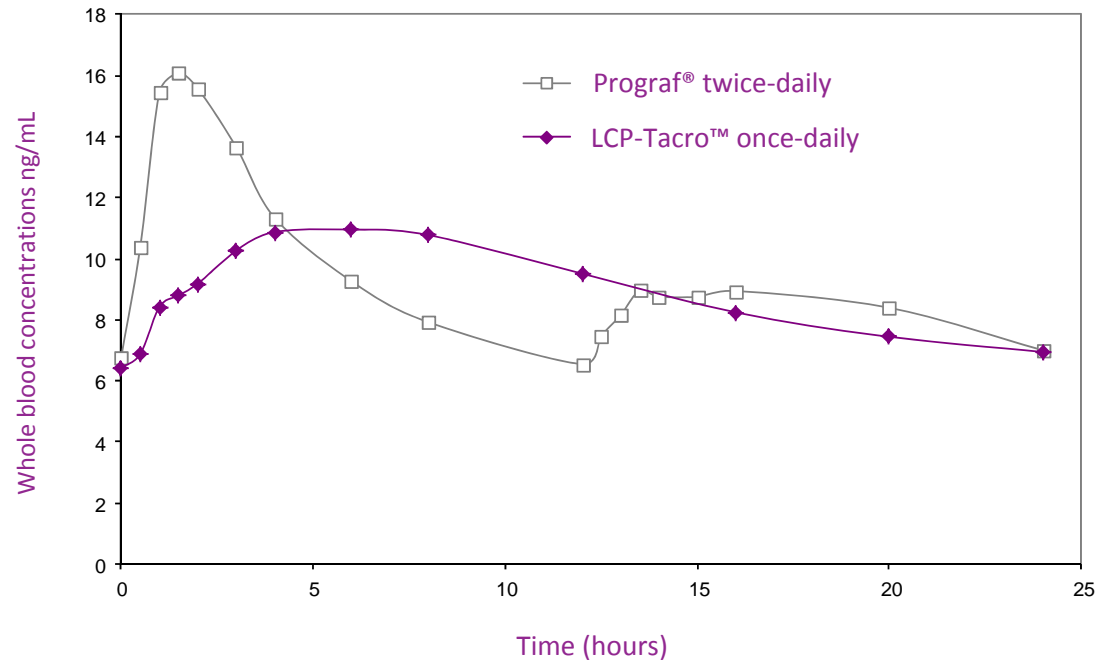
**Better pharmacokinetics and easier dosing may result in better patient outcomes**

# LCP-TACRO™ DEVELOPMENT OVERVIEW



# LCP-TACRO™ - POTENTIAL TO BE BEST-IN-CLASS

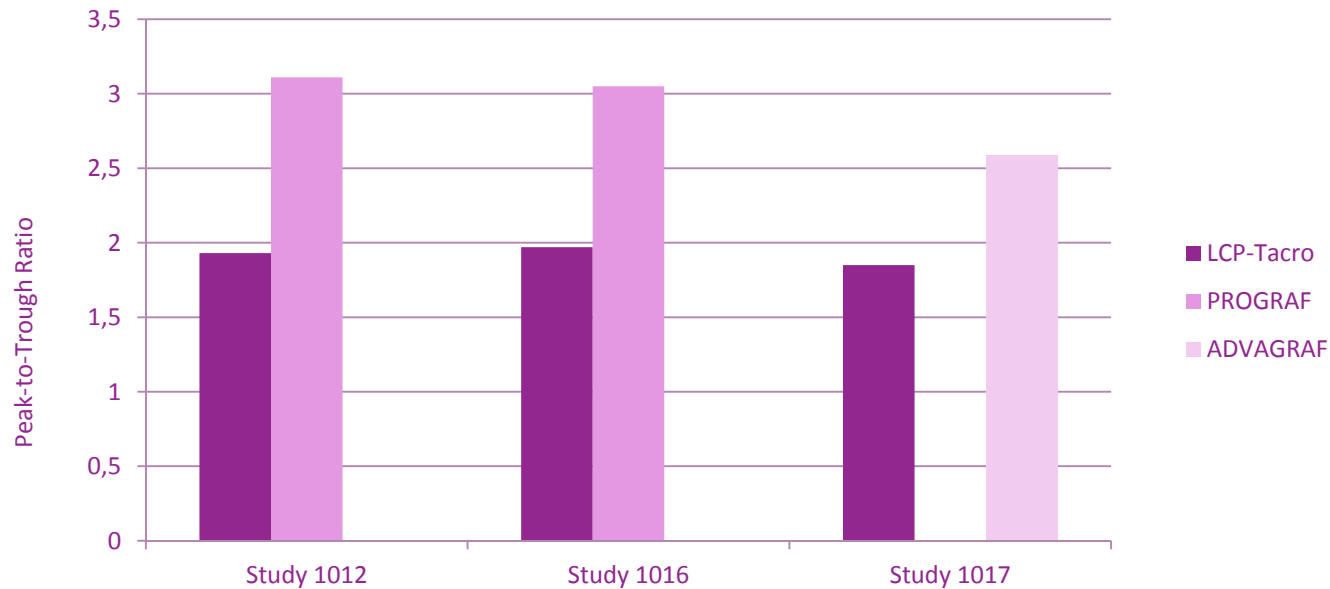
## Phase II: LCP-Tacro™ vs. Prograf® in stable kidney patients, at steady-state



- In stable kidney patients, compared to Prograf®, LCP-Tacro™ has shown:
  - Desired “flat” PK profile
  - Once-daily profile
  - Approximately 40% higher bioavailability (allows dose reduction to achieve same therapeutic blood levels)

# LCP-TACRO™ - CONSISTENT REDUCTION IN PEAK CONCENTRATION WITH SMOOTH, FLAT BLOOD LEVELS

## Phase I: Consistent improvement vs. competitors



- Compared to Advagraf® and Prograf®, LCP-Tacro™ has shown:
  - Consistent reduction in peak concentrations
  - Superior extended release profile

# LCP-TACRO™ – EXTENSIVE PHASE II PROGRAM COMPLETE

## Overview of Phase II Studies

Study no.	Study 2011	Study 2012	Study 2012E <sup>1)</sup>	Study 2016	Study 2017	Study 2018
Country	US	US	US	US, Canada	US	US
Patient population	Stable kidney transplant	Stable liver transplant	Stable liver (12 month extension of Study 2012)	Auto-immune hepatitis	<i>De novo</i> kidney transplant	<i>De novo</i> liver transplant
Comparator	Prograf®	Prograf®	None	None	Prograf®	Prograf®
Enrollment (patients)	60	57	49	13	63	58
Enrollment status	Closed	Closed	Closed	Closed	Closed	Closed

1) Safety and efficacy study extension offered to patients who successfully completed study 2012

# PRIMARY EFFICACY DATA – PHASE II

Phase II <i>de novo</i> Kidney Transplant (Study 2017)		
	LCP-Tacro™ (N=32)	Prograf® (N=31)
	n (%)	n (%)
Death	0	0
Graft failure	0	0
Acute rejection	1 (3.13%)	2 (6.45%)
Loss to follow-up	1 (3.13%)	1 (3.23%)
<b>Composite endpoint for treatment failure</b>	<b>2 (6.25%)</b>	<b>3 (9.68%)</b>

LCP-Tacro™ demonstrated favorable efficacy and safety in 52-week study

# LCP-TACRO™ ONGOING PHASE III KIDNEY PROGRAM

- Study 3001 (**stable** kidney transplant patients):
  - Fully enrolled
  - Conversion from Prograf® to LCP-Tacro™ at a 30% lower dose
  - Open-label comparison vs. Prograf® (one-year treatment duration)
  - 326 patients randomized
  - Results by mid 2011
- Study 3002 (**de novo** kidney transplant patients):
  - Double-blind comparison vs. Prograf® (one-year treatment duration)
  - Special Protocol Agreement obtained 3Q2010
  - 540 patients targeted
  - Study initiated 4Q2010

➤ NDA/MAA filing for LCP-Tacro™ tablets is projected for 1Q 2013

➤ 505(b)2 Regulatory route

# LCP-TACRO™ - COMMERCIALIZATION

## Market

- A \$3Bn market with unmet needs; expected to increase in the future
- Few existing competitors, few compounds in development
- Limited sales force and commercial resources required to promote to this specialty market

## Product

- A differentiated product able to attain significant pricing
- Positioned to be the optimized, branded primary immunosuppressant
- Proprietary technology for LCP-Tacro™

## Strategy

- Opportunity to commercialize independently or with partner, regionally or globally
- ~20 sales reps needed to cover U.S. market

LCP can choose to commercialize LCP-Tacro independently or through a partner

# EXPECTED NEWS FLOW – LCP-TACRO™

2011	2012	2013
<b>Mid:</b> Top-line results Phase III stable kidney patients	<b>Q4:</b> Last patient last visit in Phase III <i>de novo</i> kidney patients	<b>Q1:</b> NDA (New Drug Application) submission ( <i>de novo</i> kidney patients) with the FDA
<b>Q4:</b> Complete enrollment in Phase III <i>de novo</i> kidney patients	<b>Q4:</b> Top-line results in Phase III <i>de novo</i> kidney patients	

# FINANCIALS

(Million)	2009 Actual	2010 Actual	2011 Outlook	2009 Actual	2010 Actual	2011 Outlook
	DKK	DKK	DKK	USD <sup>1)</sup>	USD <sup>1)</sup>	USD <sup>1)</sup>
Revenue	2,5	1,5	-	0,5	0,3	-
Research and development costs	(210,1)	(210,4)	-	(38,2)	(38,3)	-
Administrative expenses	(62,4)	(52,2)	-	(11,3)	(9,5)	-
One-off restructuring costs	(9,5)	(10,9)	-	(1,7)	(2,0)	-
Operating loss	(279,5)	(272,0)	(250) - (280)	(50,8)	(49,5)	(45,5) - (50,9)
Net loss	(271,0)	(274,2)	(250) - (280)	(49,3)	(49,9)	(45,5) - (50,9)
Year-end cash position	333,4	531,5	250 - 300	60,6	96,6	45,5 - 54,5

1) On the basis of an assumed USD/DKK exchange rate of 5.50

# COMPANY INFORMATION

## Contacts

CFO (EU)  
Johnny Stilou, CFO  
Tel. +45 20 55 38 52  
E-mail: JST@lcpharma.com

Investor Relations (US):  
John Weinberg, MD  
Tel. +1 732 321 3208  
E-mail: JDW@lcpharma.com

## Locations

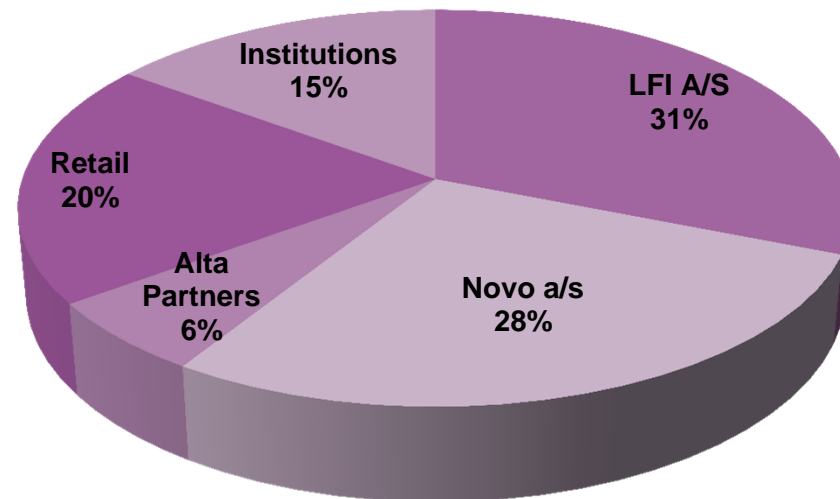
LifeCycle Pharma A/S  
Kogle Allé 4  
DK-2970 Hørsholm  
Denmark

LifeCycle Pharma Inc.  
499 Thornall Street, 3rd Floor  
Edison, NJ 08837  
USA

## Shareholders (as of 12/2010)

Geographic split (approx.):

DK based: 76%  
Int. based: 24%



NASDAQ-OMX: LCP

# HIGHLIGHTS

## LCP-Tacro™

- Significant sales potential
  - Potential “best-in-class” profile
  - Optimized, branded version of the #1 transplant drug
  - Funded through to Regulatory submissions in 2013
- 

## Experienced management

- Executive and senior management group with expertise, experience and proven track-record from global leading pharmaceutical companies
- 



## Proprietary technology platform

- MeltDose® is proven clinically & commercially with Fenoglide®
  - Low cost / transferable
  - Patent protected
  - Applicable in multiple therapeutic areas
- 

## Programs with potentially high returns

- No New Chemical Entity risk
  - Late stage efforts
  - Focused on established markets with unmet medical & commercial needs
-



Improving Treatments  
Improving Lives

Q & A

Thank you for your attention

