



LifeCycle Pharma A/S

Jim New, President & CEO

Peter G. Nielsen, EVP, Pharm. Development & CMC

Johnny Stilou, VP Finance

Peter Schøtt Knudsen, Head of IR

Interim results, 2nd Quarter 2009

August 20th 2009

IMPROVING TREATMENTS
IMPROVING LIVES



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

- **Key activities in 2Q 09**
 - **Financial Results**
 - **Business Operations**
- **Latest Developments in LCP's Product Pipeline with a Focus on LCP-Tacro™**
- **Milestones 2009 and Investment Summary**



MATERIAL EVENTS DURING 2Q 2009

- LCP announces today positive interim data in the phase 2 *de novo* liver LCP-Tacro™ study – in line with previous results seen in *de novo* kidney.
- Open label, multicenter study results on a randomized clinical trial to compare the safety and efficacy of LCP-Tacro™ with that of Azathioprine in Autoimmune Hepatitis (AIH) is reported.
- Positive results from a phase 2 one year extension study for LCP-AtorFen
- Dr. Bill Polvino joins LCP as Chief Operating Officer, bolstering both management depth and experience in product development functions.
- A generic version of Prograf® was launched in the U.S. market.
- The FDA approves the use of Prograf® as the comparator drug to be used in the pivotal Phase 3 trials for LCP-Tacro™'s evaluation in *de novo* Kidney patients.
- LCP announces planned reduction in headcount to improve alignment of resource base with critical-path projects.
- Improved financial guidance and extension of cash reserves until 1Q 2011.

Overview of LCP-Tacro™ trials

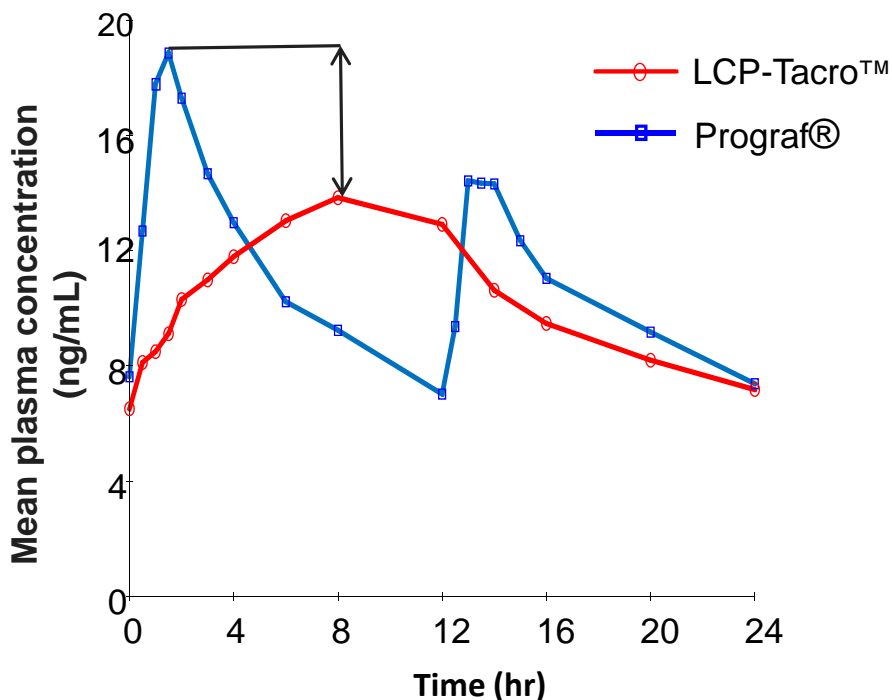
Indication	Preclinical	Phase 1	Phase 2	Phase 3	Market	Comments
Kidney Transplant						
Stable patients						<ul style="list-style-type: none"> • Enrollment commenced; expected completion, Jan. 2010 • Last patient out, 1Q 2011
De novo patients						<ul style="list-style-type: none"> ✓ Results from Phase 2, Q2 2009 • Submission of Phase 3 protocol, 2H 2009
Liver Transplant						
Stable patients						<ul style="list-style-type: none"> • Results from 12-month follow-up study, 3Q 2009
De novo patients						<ul style="list-style-type: none"> ✓ Results from Phase 2 reported today • Discussion with FDA regarding Phase 3, 4Q 2009

STUDY PROTOCOL - PK ANALYSIS OF LCP-TACRO™ IN DE NOVO LIVER PATIENTS

Study Design:

- Open-label, multicenter, prospective, parallel group study.
- 12 patients in each arm evaluating 1X/day LCP-Tacro™ and 2X/day Prograf®.
- Study duration = 14 days.
- PK Analysis on days 1,7, and 14.
- Extension phase of the study runs for 1 year.
- Study protocol allowed for daily adjustments in the dose of either LCP-Tacro™ or Prograf® to maintain a target whole blood tacrolimus trough level of 5-20 ng/ ml.

PK RESULTS OF 1X/ DAY LCP TACRO™ IN DE NOVO LIVER PATIENTS COMPARED TO 2X/ DAY PROGRAF®



- 1X/ day dosing with LCP-Tacro™ generates comparable AUC and Cmin results relative to 2X/day dosing with Prograf®.
- The Cmax for 1X/day LCP-Tacro™ is lower than both the 1st and 2nd dose for Prograf® given in the 24 hr. period.
- This result is very consistent to what has been observed in PK studies involving LCP-Tacro™ in healthy volunteers and maintenance patients.

LCP-Tacro™ Liver Indication - Next Steps

- Results on LCP-Tacro™ in stable liver transplant patients are due in 3Q 2009.
- Discussions with the FDA 2H 2009 on the phase 3 design and protocol.
- Start of phase 3 pivotals in de novo liver transplant patients is targeted for 2H 2010.

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

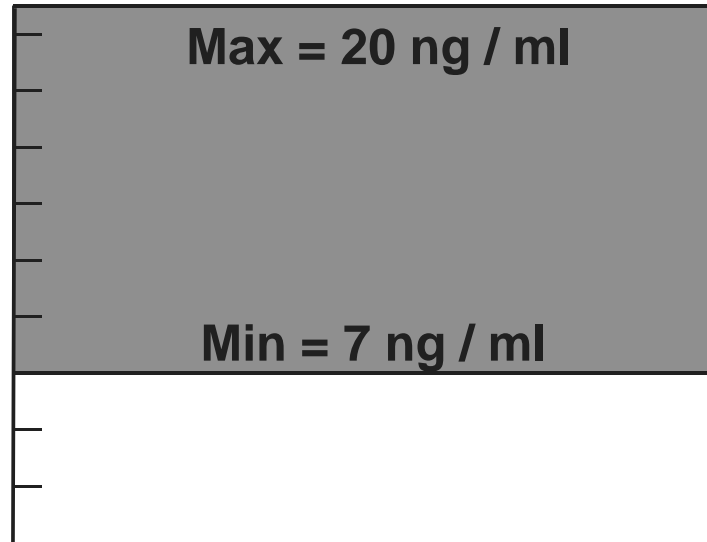
What has been observed in all PK studies involving LCP-Tacro™ to date:

- During the critical phase in the post transplant patient study, days 1-14, LCP-Tacro™ slowly rises to steady state levels in the blood.
- 1X/day dosing with LCP-Tacro™ avoids the secondary C_{max} exposure associated with the evening dose of Prograf®.
- LCP-Tacro™ has absorption throughout the GI tract due to the release properties of the MeltDose® technology, and is 30% more bioavailable than Prograf®.

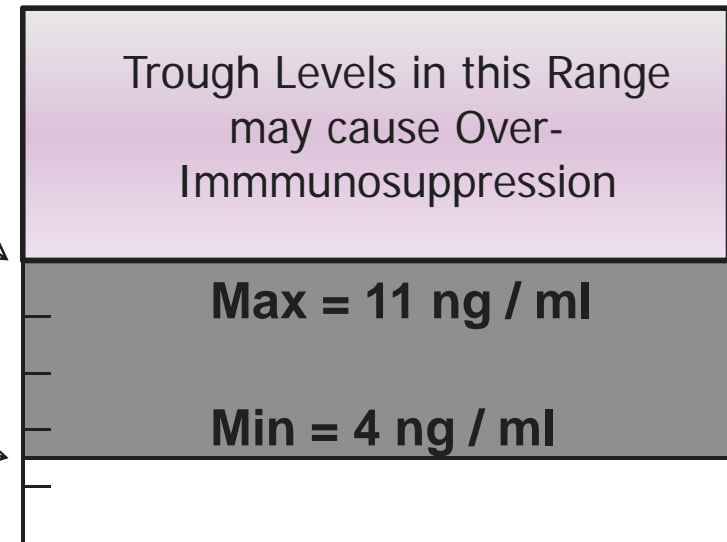
- Exposure of newly transplanted organs to peak blood levels of tacrolimus immediately following transplant may impair full restoration of the organ function.
- The C_{max} associated with each dose of Prograf® is exposing the patient to higher levels of Tacrolimus at peak than what is observed for LCP-Tacro™.
- Prograf's® absorption is principally in the duodenum, while LCP-Tacro™ travels to lower portions of the intestine providing an even distribution throughout the gut.

New Regulatory Guidance: Acceptable Blood Trough Levels for the use of Tacrolimus as an Immunosuppressant in Organ Transplant

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 vs. what 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

LCP's Market Research on Side Effects Associated with Tacrolimus Use

Adverse Event	Number of Respondents*	
	Which adverse events are you most concerned about when <u>Treating your Patients</u> with Prograf® ?	Which adverse events are Patients most concerned about when <u>Taking</u> Prograf® ?
Nephrotoxicity / Renal Function	56	36
Tremors/ Neurotoxicity	5	25
New Onset Diabetes	9	9
Hypertension	5	5

- Side effects are assumed to be intractably linked to tacrolimus use.
- If side effects are related to Cmax levels, i.e. "off-target" drug effects, then LCP-Tacro™ may offer some new benefits.

* 100 Transplant Nephrologists



LCP Tacro™'s Ph. 3 Program - Status and Update

Maintenance Kidney Transplant Patients Study 3001

- Number of patients planned for enrollment: 302.
- Number of Study Sites: 52; 19 in EU and 33 in U.S.
- Study is approx. 50% enrolled.
- Duration of therapy: 12 months.
- Last patient out: 12 months Tx is projected for Q1 2011.

De Novo Kidney Transplant Patients Study 3002

- Number of patients planned for enrollment: 540.
- Enrollment is planned to begin 1H 2010.
- Study centers will be in N. America and Europe primarily.
- Prograf® comparator drug in the phase 3 trial.
- Filing of the NDA is projected for 2Q 2012.

LCP PIPELINE UPDATE – LCP-TACRO™ IN AIH

LCP-Tacro™ in AIH

- 6 month study, with an extension of 6 months.
- A total of 13 patients were enrolled, 7 patients were randomized to LCP-Tacro™, and the other 6 patients received the comparator drug Azathioprine.

Efficacy Assessment

- Hepatic biochemical response using laboratory and histological markers as manifestation of the disease.
- Study size was too small to allow firm conclusions to be drawn about the efficacy of LCP-Tacro™ in this indication.

Results

- At 6 months, 3 of the 7 patients randomized to LCP-Tacro™ showed a complete remission.
- Another 2 LCP-Tacro™ patients, who completed the 6 month extension phase of the trial, showed a further, modest histological improvement.

Conclusions

- Small study size does not allow any conclusions on the efficacy of LCP-Tacro™ vs. the current standard of treatment involving Azathioprine.

Termination of Further Clinical Research pursuing LCP Tacro™ in AIH

- Small study size does not allow any conclusions on the efficacy of LCP-Tacro™ vs. the current standard of treatment involving Azathioprine.
- Patient recruitment and enrollment in clinical studies for LCP-Tacro™ (AIH) was very slow.
- Demonstrating superior efficacy over that of Azathioprine will be very difficult given the recalcitrant nature of the disease.

Commercial Considerations

- LCP-Tacro™ was targeted to treat approx. 35% of the AIH patient population in the U.S., this would equate to about 17,600 patients.
- Future clinical development will be high cost with uncertain timelines.
- The commercial potential in LCP-Tacro™ (AIH) is small, therefore the program in this area will be concluded.

LCP PIPELINE UPDATE – LCP-ATORFEN FOR DYSLIPIDEMIA

(continued)

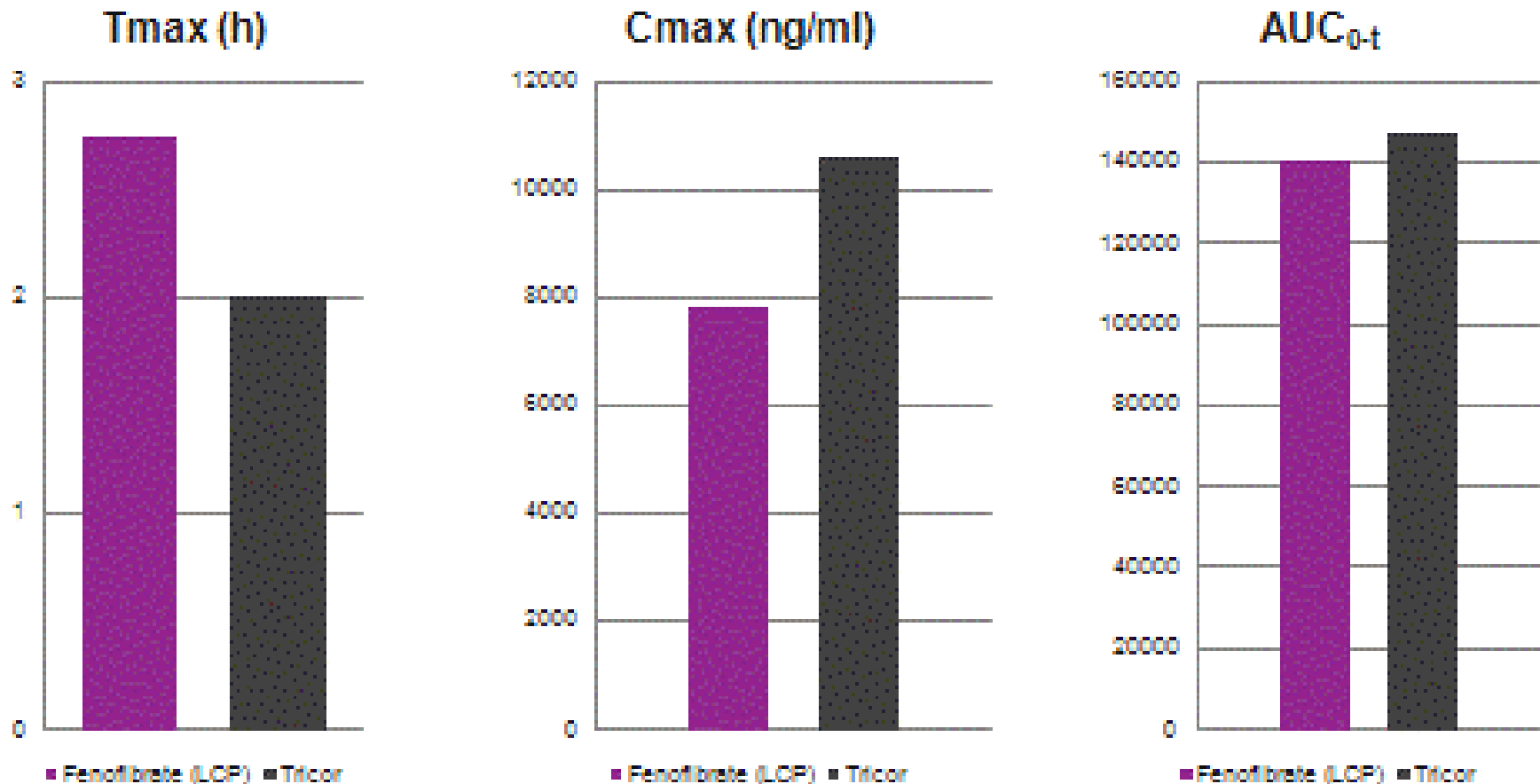


Efficacy Parameters

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

- A fixed dose, dual drug therapy approach combining Atorvastatin plus Fenofibrate leads to a loss of LDL lowering efficacy vs. standalone therapy with Atorvastatin.
- This loss of LDL lowering potency is not observed with LCP-AtorFen.

SUPERIOR PK PROFILE OF FENOFIBRATE IN ATORFEN®



A likely explanation for the full LDL lowering effect of AtorFen®, is probably due to the superior PK profile of the fenofibrate MeltDose® formulation, having a slightly later absorbance compared to e.g. TriCor®

LIFECYCLE PHARMA'S PIPELINE – 2H 2009

Product	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Market	
Immunosuppression Projects							
LCP-Tacro™	Kidney Transplant	[Progress bar]					
LCP-Tacro	Liver Transplant	[Progress bar]					
LCP-3301	Immunosuppression	[Progress bar]					
Dyslipidemia Projects							
Fenoglide™	High Triglycerides	[Progress bar]					
LCP AtorFen	Dyslipidemia	[Progress bar]					
LCP Fenog	High Triglycerides	[Progress bar]					
Preclinical Projects							
Internal projects	Undisclosed	[Progress bar]					
External partner projects	Undisclosed	[Progress bar]					

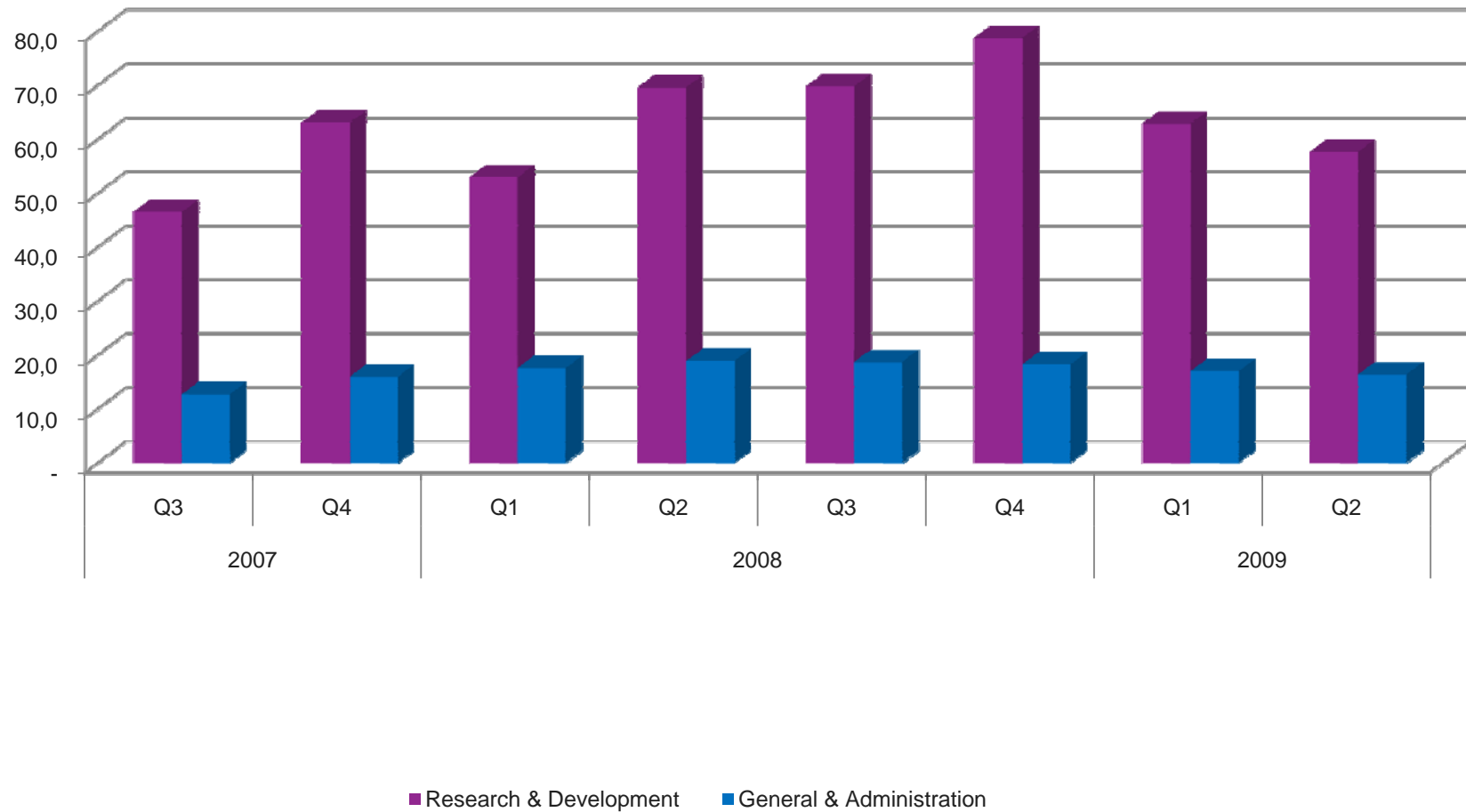
- Two new LCP product candidates have finished formulation development of the initial product prototypes.

RESULT 1ST HALF YEAR 2009

DKK '000	H1 2009	H1 2008	Year 2008
Income Statement			
Revenue	1.847	10.880	170.122
Research and development costs	(120.414)	(122.453)	(270.875)
Administrative expenses	(33.338)	(36.399)	(73.311)
Operating loss	(151.905)	(147.972)	(174.064)
Net financial income / (expenses)	7.630	7.628	24.285
Net loss for the period	(144.275)	(140.344)	(149.779)
Cash position	439.809	588.001	600.130

QUARTERLY DISTRIBUTION OF EXPENSES

MDKK



IMPROVED FULL YEAR 2009 OUTLOOK WITH 100 MDKK

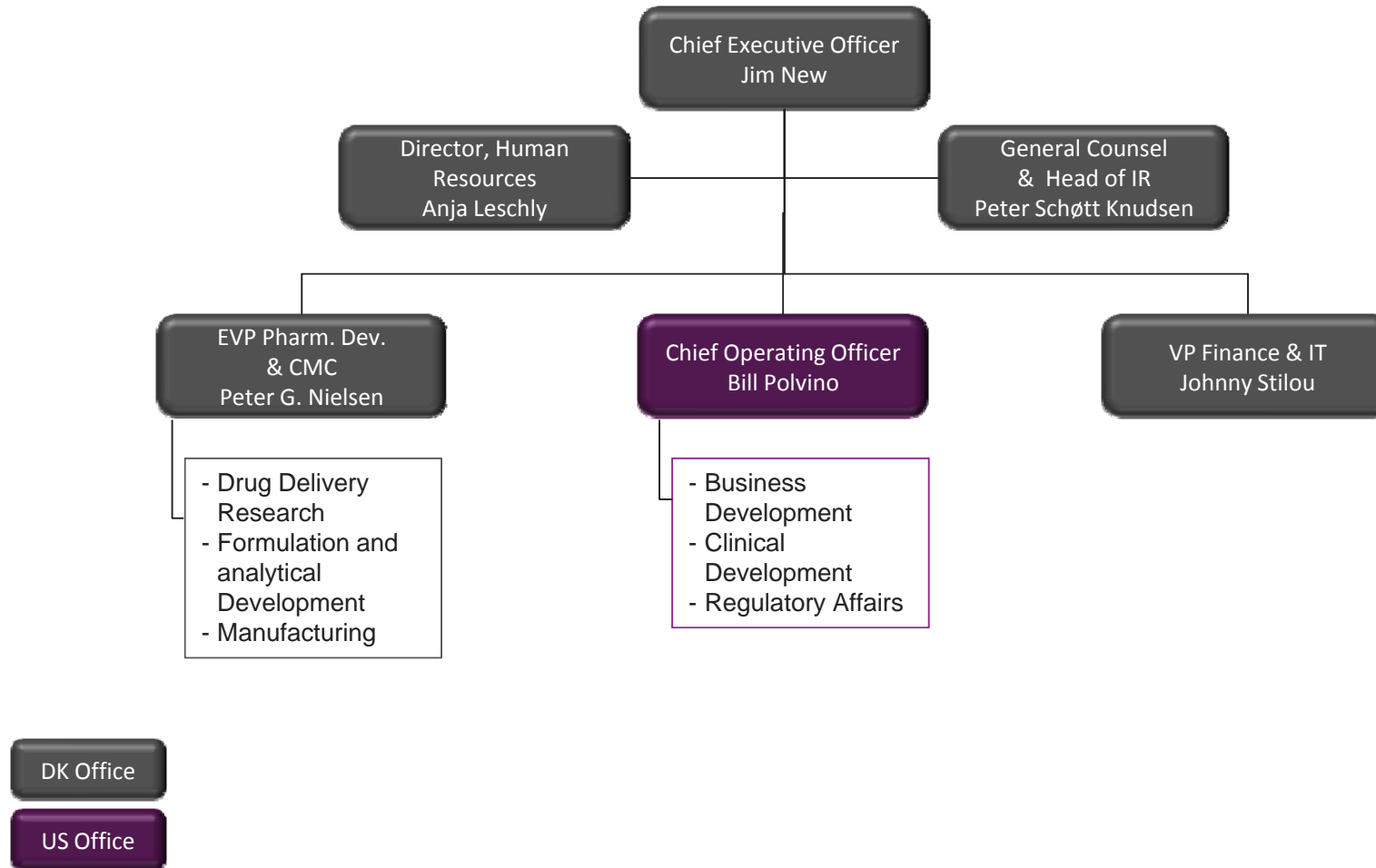
MDKK	Previous Outlook	New Outlook
Operating loss	(450 - 480)	(350 - 380)
Net profit for the period	(430 - 460)	(330 - 360)
Cash position	150 - 200	250 - 300

Full year outlook is improved with DKK 100 million due to:

- Patient enrollment rate in the LCP-Tacro™ Maintenance study.
- Start of the LCP-Tacro™ *de Novo* study.
- Limited investment in LCP-AtorFen.

The organizational changes announced today, will have limited cash effect in 2009. From 2010 our annual cost base will be reduced with approx. DKK 20 million.

MANAGEMENT TEAM AT LCP:



MILESTONES 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.
- ✓ LCP-Tacro™ Phase 2 results in Autoimmune Hepatitis.
- 12 month extension data from LCP-Tacro™ liver in stable patients (Q3 2009).
- Submit the Ph. 3 protocol to the FDA for the de novo kidney study with LCP Tacro™.



INVESTMENT SUMMARY

Commercialize
MeltDose® Technology

Recruiting key personnel to
insure the successful clinical
development of LCP Tacro™



Strong cash position

Expanding our early stage product
development portfolio through new
MeltDose® formulations and our Liquid
Loaded Tablet technology

Planning our commercial launch strategy for LCP-Tacro™



Improving Treatments
Improving Lives

Q & A

Thank you for your attention

