



Veloxis Pharmaceuticals A/S

Improving Treatments

Improving Lives

14th Annual BIO CEO & Investor Conference

14 February 2012

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 Nulojix® (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 Veloxis Pharmaceuticals

- **NASDAQ OMX – listed pharmaceutical company (SYMBOL: VELO)**
- **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 for organ transplantation with blockbuster potential**
- **Internal formulation, development, regulatory and commercialization skills**
- **Offices in**
 - **Hørsholm, Denmark**
 - **Edison, New Jersey**



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



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 developing and commercializing in the US, partnering ex-US

Pipeline Programs

Pipeline product development and partnering to enhance the commercial potential of the Veloxis product candidates

Advance LCP-Tacro™ through clinical studies and to the market in kidney transplantation
Advance additional pipeline programs

2011 Accomplishments

- ✓ Positive results of LCP-Tacro™ Phase III “Switch” Study 3001 announced
- ✓ Enrollment in Phase III *de novo* Study 3002 progressed with target for 540 patients in 1Q 2012
- ✓ STRATO Phase IIIb study in patients experiencing neurotoxicity / tremors on tacrolimus initiated
- ✓ Plan to build commercial infrastructure to support commercialization of LCP-Tacro™ in the US announced
- ✓ Acceleration of EU filing for LCP-Tacro™ to mid 2012
- ✓ Partnership with Athena to develop, manufacture and commercialize AtorFen™ in emerging markets
- ✓ Licensing of US commercial Fenoglide® rights to Santarus

\$5B Oral-Branded Immunosuppressant Market

BRAND	Prograf / Advagraf (tacrolimus)	Neoral® / Sandimmune® (cyclosporine)	CellCept® (mycophenolate mofetil)	Myfortic® (mycophenolic acid)	Rapamune® (sirolimus)
Company	Astellas	Novartis	Roche	Novartis	Pfizer
2010 WW Brand Sales	\$1.96 B	\$870 MM	\$1.4 B	\$440 MM	\$390 MM
Growth vs PY	-13%	-5%	0%	+26%	+10%
Initial US Loss of Exclusivity	2008	2000	2009	2017	2013
	Primary Immunosuppressants		Adjunct Immunosuppressants		

The core Veloxis product uses a novel formulation of the leading transplant drug in developing a once-daily dosage drug with improved bioavailability.



Tacrolimus — Evolution and Market Dynamics

THE "GOLD STANDARD" PRIMARY IMMUNOSUPPRESSANT

- Introduced in 1992 as Prograf by Fujisawa (now Astellas)
 - Twice-daily dosing
 - Narrow therapeutic window requiring routine trough monitoring
 - Major adverse effects: tremors, diabetes, hypertension and nephrotoxicity
 - 90% of transplant recipients in the US receive tacrolimus
- Initial Prograf LoE in 2008
 - Brand maintains 45% TRx market share in the US
 - Minimal generic penetration in the EU
 - Astellas global sales of \$1.96B in 2010
 - Limited generic erosion due to physician concerns regarding predictability of switching between generic formulations for this narrow therapeutic window drug
- Advagraf developed by Astellas as a once-daily formulation of tacrolimus
 - Approved in the EU in 2007 based on noninferiority study vs cyclosporine
 - Not approved in US due to failure of noninferiority study vs Prograf
 - Data emerging suggests poor bioavailability for Advagraf vs Prograf
 - Advagraf has attained ~18% market share in EU (+32% vs PY)

LCP-Tacro™ Opportunity

**\$3B Global Calcineurin Inhibitor
(CNI) Market**



Tacrolimus

(Prograf, Advagraf, generics)

Cyclosporine

(Neoral, Sandimmune, generics)

LCP-Tacro™

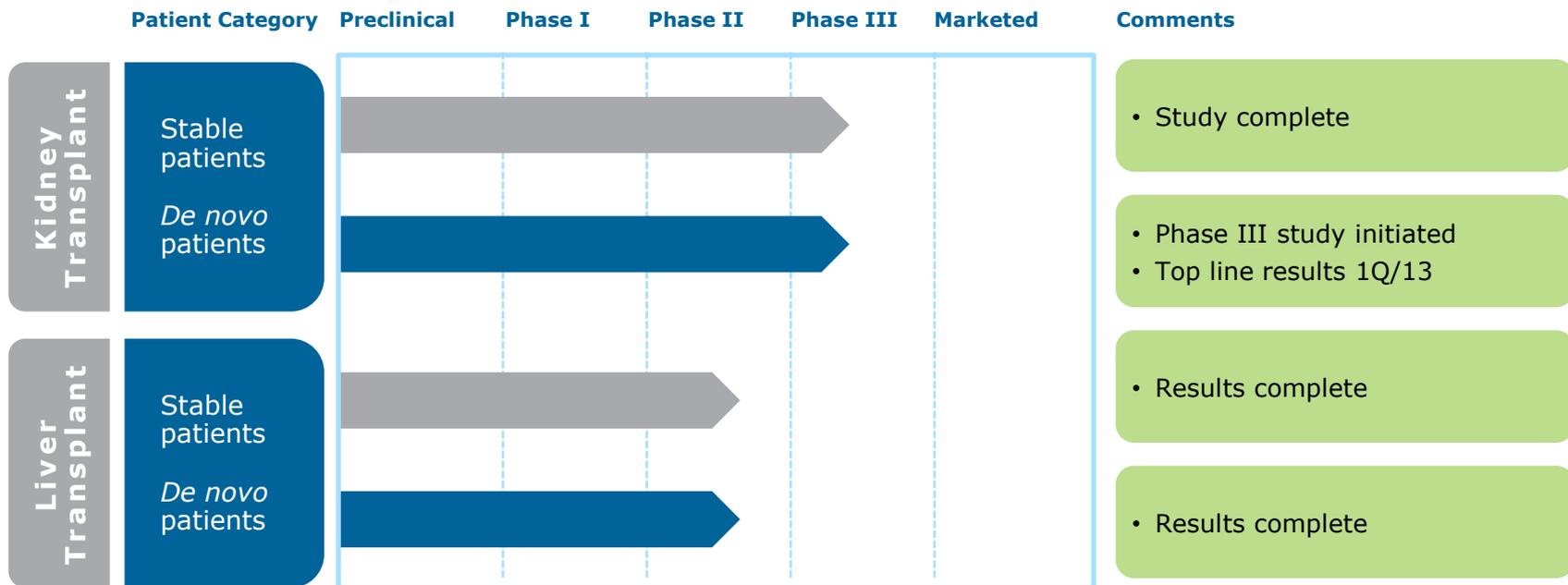
- Once-daily dosing
 - Potential improved compliance
- Improved PK (pharmacokinetic) profile
 - Reduction of tacrolimus C_{max}
 - May impact side effects (eg, tremors, DM, HT)
- Lower dosing
 - Due to improved absorption
- Not substitutable by generics, providing patients and physicians with consistency

Tacrolimus is the current “gold standard” calcineurin inhibitor.

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

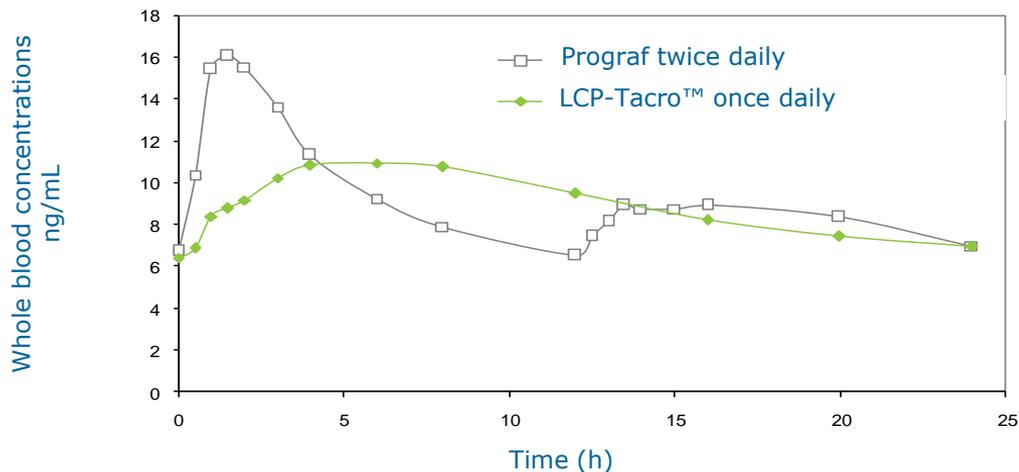


LCP-Tacro™ Development Overview



LCP-Tacro™ – Potential to be Best-in-Class

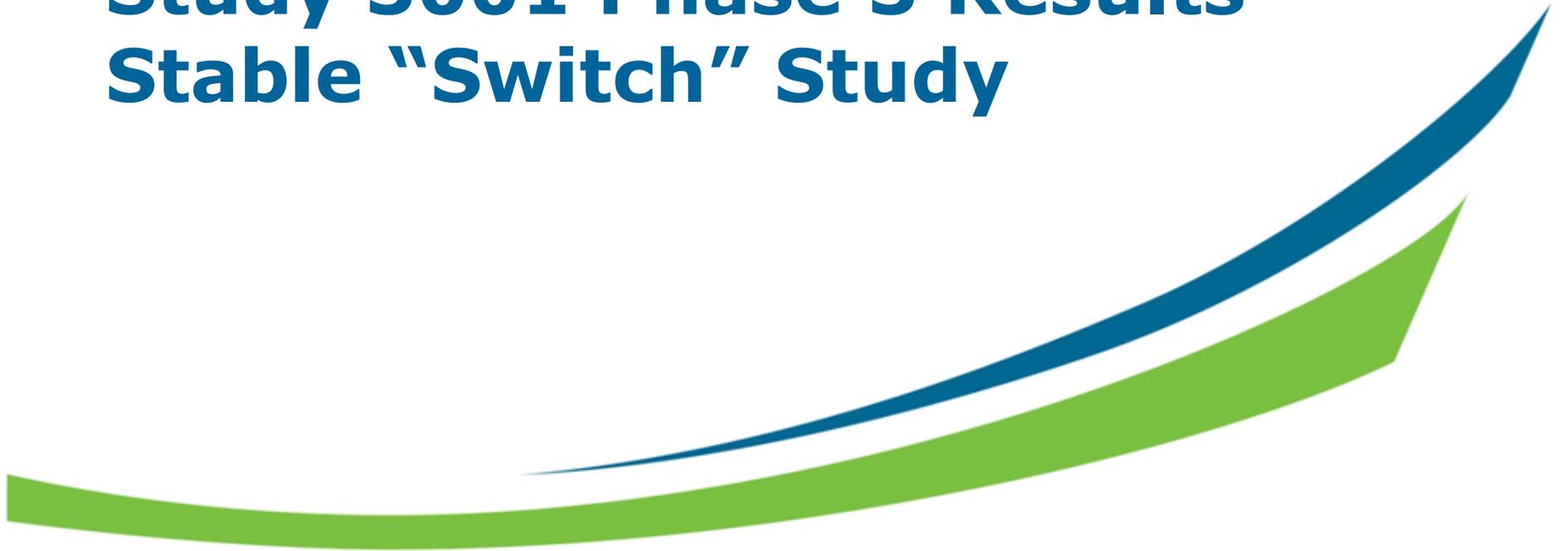
Phase II: LCP-Tacro™ vs Prograf in Stable Kidney Patients, at Steady State



- In stable kidney patients, compared to Prograf, LCP-Tacro™ has shown:
 - Desired “flat” PK profile
 - Once-daily profile
 - Approximately 30% higher bioavailability (allows dose reduction to achieve same therapeutic blood levels)

Study 3001 Phase 3 Results

Stable “Switch” Study



3001 Design

- Open-label “switch” study
 - Patients were stable, doing well on Prograf, and were “switched” in an open-label fashion to either the experimental drug (LCP-Tacro™, at a reduced dose) OR continued therapy with their known drug (Prograf, at the same dose)
- Primary endpoint
 - Treatment failure “composite”: Biopsy proven acute rejection (BPAR), graft loss, death, loss to follow-up
 - Timepoint: Month 12
- Biostatistical planning
 - Assumption: 6% composite treatment failure rate
 - Noninferiority margin of 9% for the 95% confidence interval
- Geography: US and EU

Demographics and Baseline Characteristics

	LCP-Tacro™ (N=163)	Prograf (N=163)
Age (years)	50.4	50.2
Gender (% male)	71.8	62.6
Race (% black)	22.1	20.9
Time from transplant (years)	2.1	1.8*
Diabetic (%)	37.4	32.5
Prior transplant (%)	13.5	12.3
Renal function (mL/min)	78.74	75.01
Prograf dose at entry (mg/day)	6.09	5.30 [†]

- Population generally well-matched at baseline; slightly higher Prograf dose at baseline in LCP-Tacro™ group
- Good representation of black patients

P-value between groups:

*P<0.05

†P=0.063

Primary Efficacy: Positive Results

Primary Efficacy (Local-biopsy reading)

	LCP-Tacro™ (N=162)	Prograf (N=162)
Biopsy-proven acute rejection	2 (1.2%)	2 (1.2%)
Graft loss	0	0
Death	2 (1.2%)	1 (0.6%)
Lost to follow-up	0	1 (0.6%)
Total Treatment Failures	4 (2.5%)	4 (2.5%)
Treatment difference (95% CI)		0% (-4.2,+4.2)

**Successful primary outcome:
Upper boundary of confidence interval is less than +9.0%**

Secondary Efficacy: Numerical Trend Toward Superiority With LCP-Tacro™

Secondary Efficacy
(Central biopsy reading, all data including follow-up)

	LCP-Tacro™ (N=162)	Prograf (N=162)
Biopsy-proven acute rejection*	1 (0.6%)	5 (3.1%)
Graft loss	0	1 (0.6%)
Death	3 (1.9%)	1 (0.6%)
Lost to follow-up	0	1 (0.6%)
Total Treatment Failures	4 (2.5%)	8 (4.9%)
Treatment difference (95% CI)		-2.47% (-7.53,+1.94%)

*P-value for central BPAR: P=0.214

LCP-Tacro™ Open-Label “Switch” Study Safety and Tolerability

	LCP-Tacro™ (N=162)	Prograf (N=162)
Any adverse event (AE)	83.3%	81.6%
Serious AE	22.2%	16.0%
Drug-related AE	21.6%	13.0%

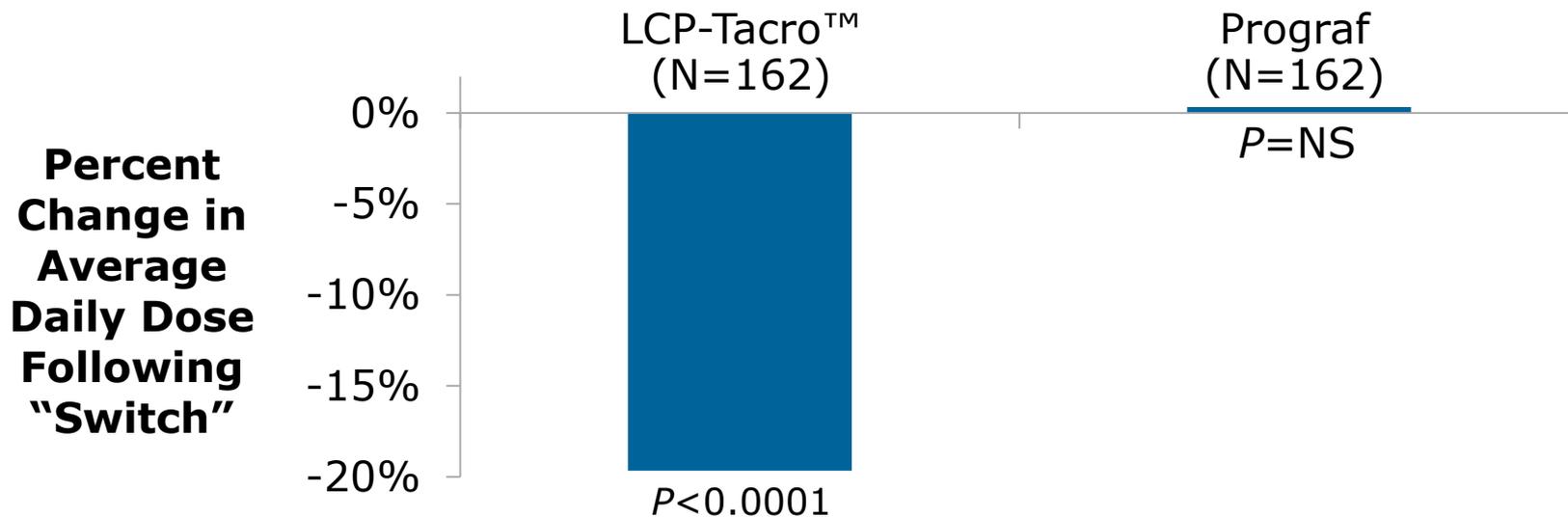
No significant differences in predefined AEs of interest:

- New-onset diabetes
- Opportunistic infection
- Malignancy
- Prespecified laboratory parameters

Numerically more GI (gastrointestinal) AEs, fewer urinary tract infections



Dose Administered



LCP-Tacro™ enabled a significant reduction in dose

Conclusions

- Successful Phase 3 results
 - Primary outcome achieved
 - Very low rate of treatment failures in both groups
 - Possible trend toward superior efficacy with LCP-Tacro™ by central biopsy results
 - Non-inferiority vs Prograf efficacy achieved in the “switch” setting
 - Actual result: 4.2% (well within the required 9% margin)
 - Comparable safety and tolerability to Prograf
 - Once-daily dosing (as opposed to twice daily), AND
 - Lower dose requirement

LCP-Tacro™ Pivotal Phase 3 Study Underway

- Study 3002 (*de novo* kidney transplant patients):
- 540 patients; double-blind non-inferiority comparison vs Prograf (1-year treatment duration)
- FDA Special Protocol Agreement obtained 3Q 2010
- Study initiated 4Q 2010
- Approximately 90 centers in US, EU, Asia and Latin America
- On schedule for full enrolment to be complete 1Q2012
- Top-line results expected 1Q 2013

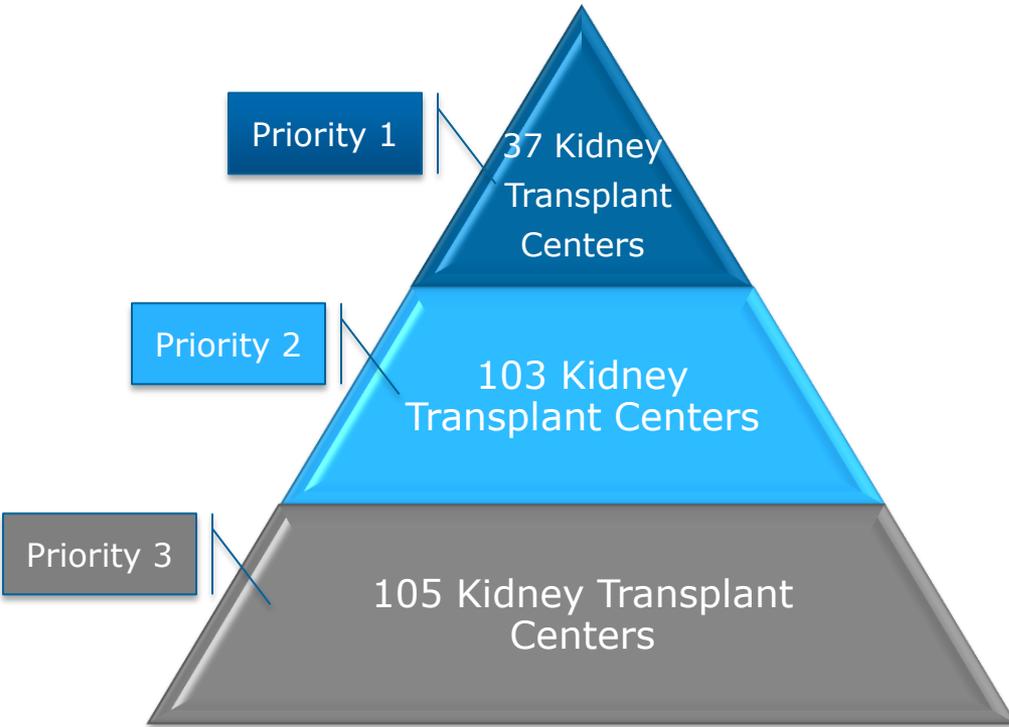
- **EU filing for LCP-Tacro™ tablets is projected for mid-2012, and FDA filing for 1H 2013.**

LCP-Tacro™ Commercial Strategy

- Veloxis to Launch and Commercialize LCP-Tacro™ in the US through its own dedicated Sales, Marketing and Medical team
 - Infrastructure build underway
- Commercialize ex-US through partner/s with suitable specialty or hospital product expertise
 - Discussions in progress

➤ **Maximize overall value for Veloxis**

US Sales Force Planned Structure

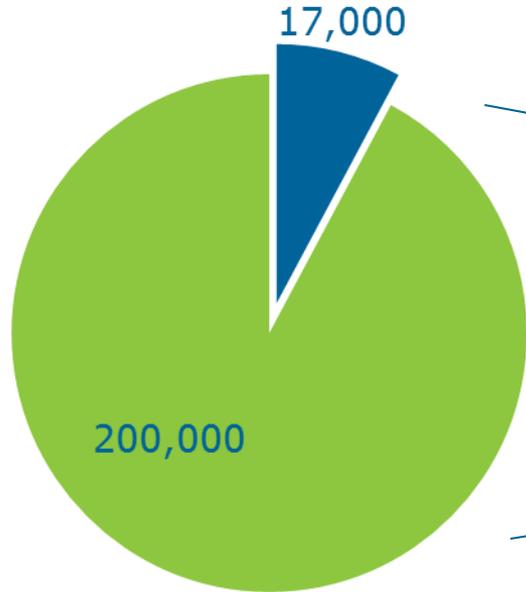


- 20 sales representatives
2 regional managers
1 head of sales
- Routine coverage of top 140 kidney transplant centers (≈80% of total volume)

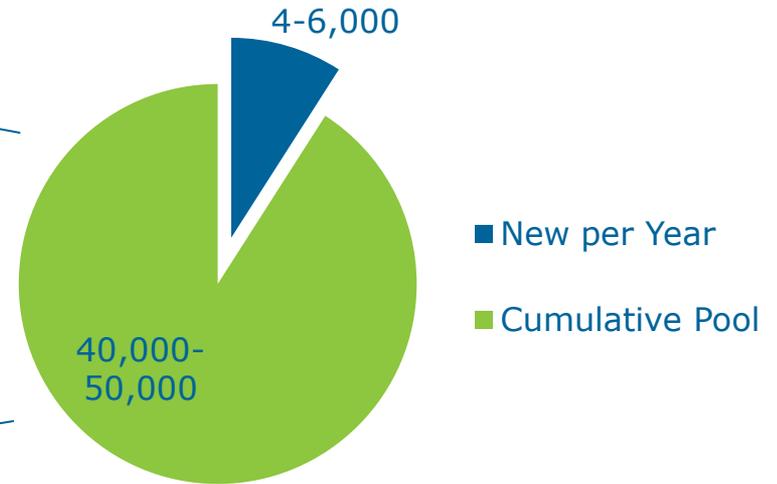
Account Type	Call Frequency
Priority 1 (>140 Transplants)	Once weekly
Priority 2 (50-140 Transplants)	Twice monthly
Priority 3 (<50 Transplants)	As needed

US Kidney Transplant Opportunity

CNI patients



Projected Peak LCP-Tacro Patients



- New per Year
- Cumulative Pool

LCP-Tacro™ — Substantial Commercial Potential

Market

- A \$3B CNI market with unmet needs
- Few existing competitors, few compounds in development
- Limited sales force and commercial resources required to promote in 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

- Develop dedicated internal US Marketing, Sales and Medical Infrastructure
- Partner Ex-US

Financials

(Million)	2009 Actual	2010 Actual	2011 Outlook	2009 Actual	2010 Actual	2011 Outlook
	DKK	DKK	DKK	USD*	USD*	USD*
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

*On the basis of an assumed USD/DKK exchange rate of 5.50.

Company Information

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Locations

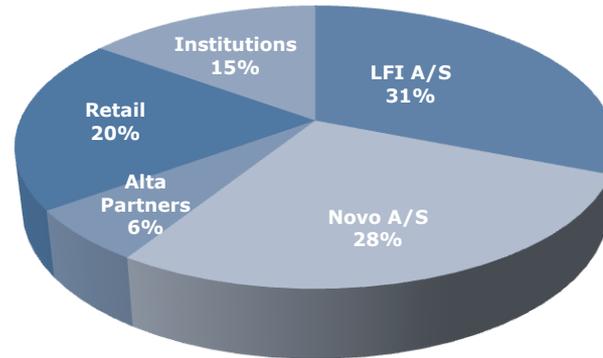
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Edison, NJ 08837
USA

Shareholders (as of 01/2012)

Geographic split (approx.):

DK based: 82%
Int. based: 18%



NASDAQ OMX: VELO



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
-

Proprietary technology platform

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

Experienced management

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



Programs with potentially high returns

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

