



Veloxis Pharmaceuticals A/S

Annual General Meeting 2012

18 April 2012
Hørsholm, Denmark

Welcome

By Chairman of the Board of Directors

Kim Bjørnstrup

Agenda

1. Report by the Board of Directors on the Company's activities during the year.
2. Presentation of the audited Annual Report for approval.
3. Resolution on covering of losses as per the adopted Annual Report.
4. Approval of the fee to the Board of Directors.
5. Proposal to change the age limit for Directors from 70 to 75 years.
6. Election of members of the Board of Directors.

Agenda (continued)

7. Election of auditor.
8. Proposal for authorization for the Company to acquire own shares.
9. Proposal to adopt a capital decrease by writing down the nominal value of the Company's shares from DKK 1 to DKK 0.1 per share.
10. Proposal for authorization for the chairman of the Annual General Meeting.

Agenda Item 1

**Report on the Company's activities
during the year 2010**

**By President & CEO
Bill Polvino**

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 III candidate for organ transplantation with blockbuster potential**
- **Internal formulation, development, regulatory and commercialization skills**
- **Offices in**
 - **Hørsholm, Denmark**
 - **Edison, New Jersey**



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



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 (e.g. tremors, DM, HT)
- Lower dosing
 - Due to improved absorption
- Not substitutable by generics, providing patients and physicians with consistency

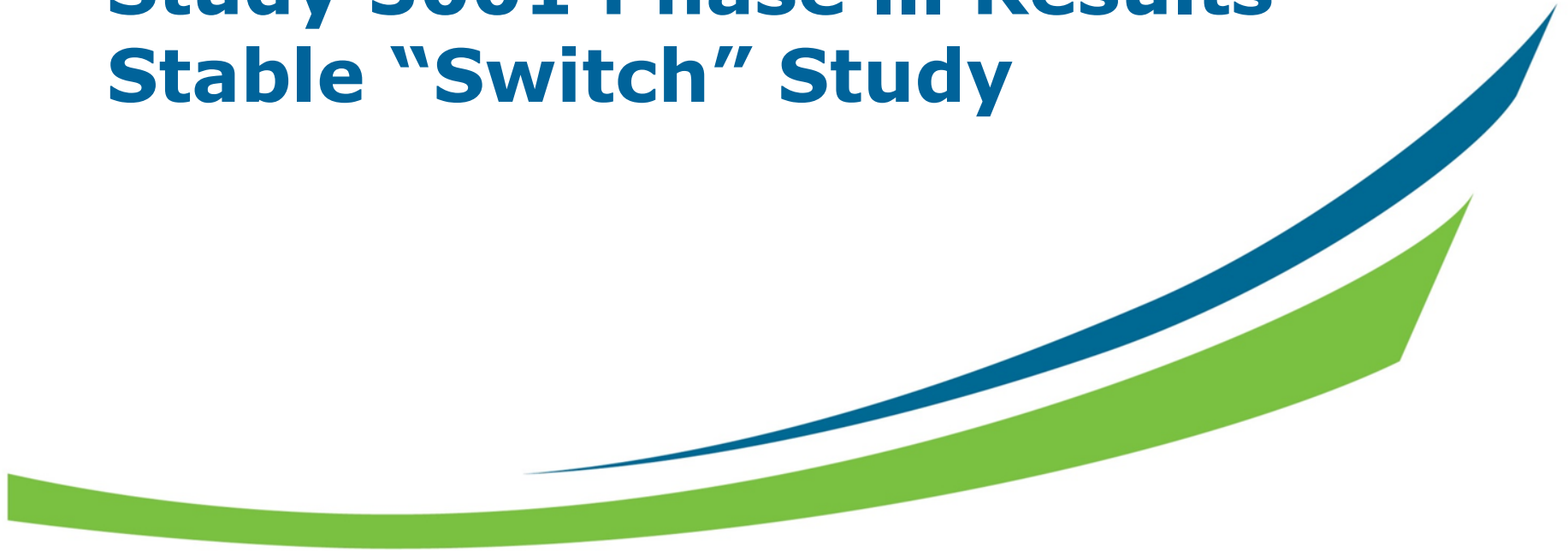
Tacrolimus is the current “gold standard” calcineurin inhibitor.

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



Study 3001 Phase III 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
- Geography: US and EU

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%**

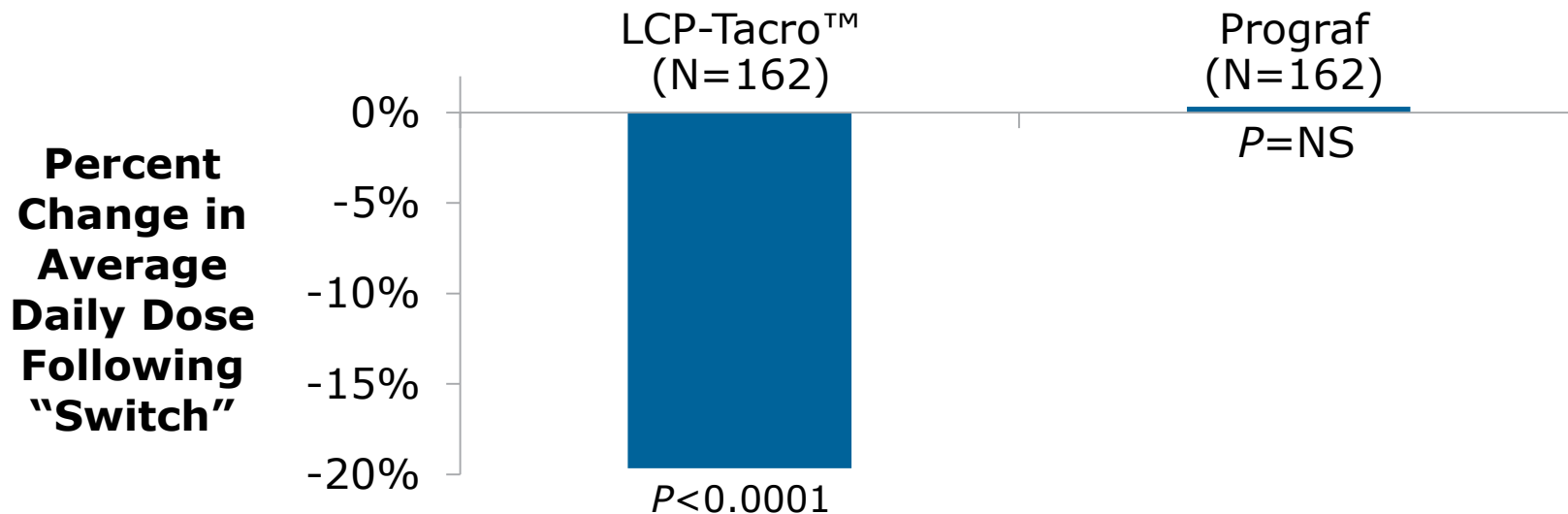
Secondary Efficacy: Numerical Trend Toward Superiority With LCP-Tacro™

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

Dose Administered



LCP-Tacro™ enabled a significant reduction in dose

Conclusions

- Successful Phase III 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 II 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 80 centers in US, EU, Asia and Latin America
- Full enrollment achieved March 2012
- Top-line results expected Mid-2013

- **EU filing for LCP-Tacro™ tablets is projected for mid-2012, and FDA filing for 2H 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**

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)	2010 Actual	2011 Actual	2012 Outlook	2010 Actual	2011 Actual	2012 Outlook
	DKK	DKK	DKK	USD*	USD*	USD*
Revenue	1,5	-	-	0,3	-	-
Research and development costs	(210,4)	(222,1)	-	(38,3)	(40,4)	-
Administrative expenses	(52,2)	(47,8)	-	(9,5)	(8,7)	-
One-off restructuring costs	(10,9)	-	-	(2,0)	-	-
Operating loss	(272,0)	(269,9)	(220) - (250)	(49,5)	(49,1)	(40,0) - (45,5)
Net loss	(274,2)	(252,6)	(220) - (250)	(49,9)	(45,9)	(40,0) - (45,5)
Year-end cash position	531,5	297,7	40 - 80	96,6	54,1	7,3 - 14,5

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

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 leading global pharmaceutical companies
-



Proprietary technology platform

- MeltDose® is proven clinically and 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 and commercial needs
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Agenda Item 2

Presentation of the audited Annual Report for approval.

The Board of Directors proposes that the presented audited annual report is approved.

Agenda Item 3

Resolution on covering of losses as per the adopted annual report.

The Board of Directors proposes that the year's net loss of DKK 252.6 million be carried forward by transfer to accumulated deficit.

Agenda Item 4

Approval of the fee to the Board of Directors.

The Board of Directors proposes that the general meeting approves the fee to the Board of Directors for the financial year 2012. The Board of Directors proposes that the Board of Directors receives an identical remuneration as in 2011.

Consequently, the Board of Directors proposes that board members receive a fixed cash fee of DKK 150,000 each and that the chairman receives DKK 450,000.

In addition, the chairman of a board sub-committee receives DKK 75,000 per year.

Further, members of the Board of Directors may receive incentive-based remuneration under the company's general guidelines for incentive pay to its members of the Board of Directors and executive management, cf. article 19 of the articles of association.

The Board of Directors proposes that the chairman of the board of directors be granted 150,000 warrants and that all other board members be granted 50,000 warrants each. Each board member may decide to receive cash payment instead of warrants corresponding to DKK 1 per warrant.

Agenda Item 5

Proposal to change the age limit for directors from 70 to 75 years.

Article 16(3) of the Company's articles of association stipulates that members of the Board of Directors shall retire from the Board of Directors at the annual general meeting following immediately after his attaining the age of 70.

In order to maintain and attract experienced and qualified board members, the Board of Directors proposes that the age limit be raised to 75 years.

Consequently, article 16(3) of the articles of association is proposed to be amended to the following wording:

"Any board member shall retire from the Board of Directors at the Annual General Meeting following immediately after his attaining the age of 75."

Agenda Item 6

Election of members of the Board of Directors.

All board members elected by the general meeting are up for election.

The Board of Directors proposes re-election of the entire current Board of Directors consisting of:

- *Kim Bjørnstrup*
- *Thomas Dyrberg*
- *Kurt Anker Nielsen*
- *Anders Götzsche*
- *Mette Kirstine Agger*
- *Edward Penhoet*

For a description of the qualifications of the nominated candidates, see exhibit 1 to the notice to convene the general meeting.

Agenda Item 7

Election of auditor.

The Board of Directors proposes re-election of PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab as the Company's auditor.

Agenda Item 8

Proposal for authorization for the Company to acquire own shares.

The Board of Directors requests the general meeting to grant an authorisation until the next Annual General Meeting for the company to acquire the Company's own shares for up to 10 per cent of the Company's share capital at any time, provided that the acquisition, in accordance with the Danish Companies Act section 197, can be financed by the funds that may be distributed as extraordinary dividends. The payment may not divide from the stock price at NASDAQ OMX Copenhagen A/S with more than 10 per cent at the time of purchase.

Agenda Item 9

Proposal to adopt a capital decrease by writing down the nominal value of the Company's shares from nominally DKK 1 to DKK 0.1 per share.

Proposal from the Board of Directors to adopt a capital decrease by nominally DKK 407,288,232 from nominally DKK 452,542,480 to nominally DKK 45,254,248 to transfer to a special reserve fund by writing down the nominal value of the Company's shares from nominally DKK 1 to nominally DKK 0.1 per share, and consequently amendment of the Company's articles of association.

The Board of Directors proposes to decrease the capital by nominally DKK 407,288,232 from nominally DKK 452,542,480 to nominally DKK 45,254,248.

The capital decrease shall be made by transfer to a special reserve fund, see the Danish Companies Act section 188(1(3)).

The capital decrease shall take place at the rate of 100 corresponding to a price of DKK 407,288,232.

The capital decrease shall be made by writing down the nominal value of all the Company's shares as the nominal value of all shares shall be decreased by nominally DKK 0.9 from nominally DKK 1 to nominally DKK 0.1.

Before the execution of the capital decrease a notice will be given to the creditors of the company, requesting them to file their claims against the company, if any, within four weeks in accordance with the law. The request will be published in the Danish Business Authority's IT system.

The Board of Directors proposes that the authorizations to increase the share capital in the articles of association articles 9 and 9A are not decreased even though a capital decrease is proposed.

Further, the Board of Directors proposes to amend the Company's articles of association as a consequence of the capital decrease and write-down of the nominal value per share.

Agenda Item 10

Proposal for authorization for the chairman of the Annual General Meeting.

The Board of Directors proposes that the chairman of the Annual General Meeting, with the right of substitution, be authorized to register the resolutions passed by the general meeting with the Danish Business Authority and to make such alterations as the Danish Business Authority may require for registration or approval.

Thank you!

