



# **Veloxis Pharmaceuticals A/S**

## **Third Quarter 2012 Report**

### **Investor Conference**

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# Forward-Looking Statements

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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 Company financing, clinical trial results, potential regulatory approval and commercialization 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.

# Agenda

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- LCP-Tacro™ Status Update
- Financials 3Q 2012
- Corporate Financing
- Summary
- Q & A

# LCP-Tacro™



# LCP-Tacro Update – Clinical

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- Pivotal phase III Study 3002 in de novo kidney transplant patients
  - Progressing according to plan
  - Enrollment of 543 patients completed March 2012
  - Top line 1-year data expected mid-2013
- STRATO Phase IIIb/IV study in Tremor patients
  - Study actively enrolling
  - Preliminary data expected 4Q 2012
  - Designed to assess potential of once-daily LCP-Tacro to reduce tremor in patients who have this side effect while receiving twice-daily tacrolimus

# LCP-Tacro Update – Regulatory

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- European MAA Filing projected for 2013
  - Precise 2013 timing to be decided in collaboration with EMA rapporteur and commercial partner
- Filing in the US with the FDA remains on track for 2H 2013

# LCP-Tacro Update – Partnership

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- Partnership announced with Chiesi Farmaceutici S.p.A. for Europe, Turkey and CIS countries
  - Chiesi is a fully integrated European Pharmaceutical company focused on special care products
  - Chiesi will be responsible for the commercialization and distribution of LCP-Tacro
- Veloxis will receive up-front and milestone payments of up to USD 47.5 million
  - Milestone payments are subject to the achievement of certain regulatory milestones and sales targets
- Veloxis will supply product to Chiesi for sale at a transfer price at a pre-agreed double-digit percentage of the product's sales price
  - Chiesi is committed to certain minimum purchases during the term of the agreement

# Financial results





# 3Q 2012 results in line with full year expectations

| MDKK                       | First nine months |         | Full year | Outlook<br>2012 |
|----------------------------|-------------------|---------|-----------|-----------------|
|                            | 2012              | 2011    | 2011      |                 |
| Revenue                    | -                 | -       | -         |                 |
| Research and development   | (168,8)           | (160,3) | (222,1)   |                 |
| General and Administration | (26,7)            | (36,4)  | (47,8)    |                 |
| Restructuring cost         | (21,4)            | -       | -         |                 |
| Operating loss             | (216,9)           | (196,7) | (269,9)   | (240) - (270)   |
| Net loss                   | (216,2)           | (184,4) | (252,6)   | (240) - (270)   |
| Cash position ending       | 86,7              | 348,3   | 297,7     | 490 - 530       |

# Corporate Financing



# Corporate Financing

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## To finance Veloxis through initial launch of LCP-Tacro

- The Company conducted a rights issue offering to raise gross proceeds of 422 MDKK
- The financing was supported by LFI A/S and Novo A/S
- Completed 13 November 2012

# Summary



# Summary

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- LCP-Tacro remains on target
  - Clinical development and differentiation programs progressing according to plan
  - Filings projected for US and EU in 2013
  - Commercial opportunity highly attractive and commercial planning progressing
  - European partnership deal completed
- Financing in place to support development, differentiation and commercialization activities through initial launch of LCP-Tacro

# Major milestones and anticipated newsflow

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## Completed

- ✓ Phase III “switch” study results reported Jun 2011
- ✓ Phase IIIb/IV STRATO tremor study initiated Jan 2012
- ✓ Phase III “de novo” study complete enrollment Mar 2012
- ✓ European Partnership Oct 2012

## Upcoming

- STRATO results end-2012
- Phase III “de novo” results mid-2013
- MAA submission: 2013
- NDA submission: 2H2013

**Q & A**

**Thank you for your attention!**

