



# **Veloxis Pharmaceuticals A/S 2014 Third Quarter Report Investor Conference**

**William Polvino, President and CEO**  
**Johnny Stilou, CFO**  
**John Weinberg, COO**

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Dial-in Numbers:  
Denmark +45 32728018  
UK +44 (0) 1452 555131  
USA +1 866 6828490  
Access code 28069222

# 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 clinical trial results, potential regulatory approval for Envarsus® (formerly LCP-Tacro™), and commercial forecasts 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 Envarsus® meet the predetermined endpoints for such trial; our ability to complete the development of, obtain regulatory approval for, and commercialize, Envarsus®; our ability to hire and retain personnel in a competitive industry; our reliance on third parties to manufacture Envarsus® and to conduct clinical trials for Envarsus®; competition from existing therapies and therapies that are currently under development, including Prograf® (tacrolimus), Advagraf®/Astagraf® (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.

# Key Updates

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- US FDA issues “Tentative Approval” for Envarsus® XR
  - For the prophylaxis of transplant rejection in adult kidney recipients
  - Veloxis working with FDA to address the Approval timing delay
- EU Partner Chiesi preparing for first country launches in Fourth Quarter 2014
- Planning for commercialization in US continues

# Envarsus<sup>®</sup> Update



# Envarsus® Update – Clinical

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- ASERTAA (A Study of Extended Release Tacrolimus in African-Americans) Initiated
  - Phase IIIb/IV study of Envarsus® in African-American kidney transplant recipients
  - Study on-going in several US transplant centres
  - Results expected 2015
- Additional Phase IV differentiation studies in development for implementation post-approval in the US
- Phase IV Study in development by partner Chiesi for EU

# Envarsus® XR Update – Commercial

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- United States
  - Commercial preparation activities continue
  - US commercial infrastructure on course to be ready for potential 2015 launch
    - Key Commercial Leadership roles filled
  - Sales field force hiring on hold pending FDA decisions appeal
- Europe
  - Commercial planning and launch preparations on track
  - Partner Chiesi working in close collaboration with Veloxis
  - Staged roll out of Envarsus in EU countries
    - Based on local pricing negotiation requirements
  - First country launches Q4 2014



# Financial results



# First nine month 2014 results in line with expectations

## Full year result improved

MDKK	First nine months		Full year 2013	Outlook 2014
	2014	2013		
Revenue	120,2	26,0	38,2	
Sales and marketing	(24,0)	-	-	
Research and development	(70,5)	(117,0)	(146,5)	
General and Administration	(28,0)	(21,3)	(27,8)	
Operating result	(2,3)	(112,3)	(136,1)	(40) - (70)
Net result	12,9	(114,6)	(139,3)	(20) - (50)
Cash position ending	310,6	380,2	328,7	255 - 285

# Summary



# Summary

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- Envarsus XR
  - Approved in EU
    - Initial launches in Q4 by Chiesi
  - Tentative approval in US
- Veloxis will update the investor community with material developments as they occur

**Q & A**

**Thank you for your attention!**

