



# **Veloxis Pharmaceuticals A/S 2015 Third Quarter 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 potential future regulatory approvals for ENVARSUS XR® (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 our ability to obtain regulatory approval for, and commercialize, ENVARSUS XR®; our ability to hire and retain personnel in a competitive industry; our reliance on third parties to manufacture and distribute ENVARSUS XR®; competition from existing therapies and therapies that are currently under development, including Prograf® (tacrolimus), Advagraf® /Astagraf XL® (tacrolimus), generic tacrolimus products, 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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- Veloxis Key Updates
- ENVARUSUS XR Status Update
- Financials 3Q 2015
- Summary

# Key Updates

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- U.S. FDA approval achieved
  - Envarsus XR is indicated for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations
- Envarsus XR granted U.S. orphan drug exclusivity for the approved indication
- U.S. commercial infrastructure preparations on track for product launch
  - Majority of Field Force hired, on-board, trained and active in the field
- EU commercialization activities progressing successfully
  - Envarsus EU launch roll-outs continue in line with plans via Chiesi
    - Nine Countries launched to date
    - Good sales coverage and positive initial product uptake
- Sponsored Level 1 American Depositary Receipt (ADR) program established in the U.S.
  - The ADR trades under the symbol VXPZY.



# ENVARUS XR Status Update



# U.S. Regulatory Update

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- On July 10, 2015 U.S. FDA approved marketing authorization of Envarsus XR (tacrolimus extended-release tablets)
  - Indicated for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants
- On August 14, 2015, U.S. orphan drug exclusivity granted
  - For prophylaxis of organ rejection in patients who convert from immediate-release tacrolimus
  - Entitles Veloxis to a waiver of the FDA prescription drug user fees for Envarsus XR
  - Potential tax incentives
  - U.S. orphan indication exclusivity protection for up to seven years



# ENVARSUS XR Update –U.S. Commercial



- Commercial preparation activities on track and ready to launch
- Majority of US Commercial Team hired and fully trained
  - Sales team of 18 FTEs
    - Competitive size compared with other transplant companies
    - From all major transplant Companies: Astellas, BMS, Novartis, Pfizer, Roche
    - Cumulative 130 years of experience commercializing Transplant products
  - Targeting top 140 key Transplant Centers (80% of Transplants)
  - Actively engaged with potential customers
- Promotional materials finalized and being utilized
- Patient support programs complete
- Payer interactions proceeding well
  - Unique J-code issued by the Centers for Medicare and Medicaid Services (CMS) for 2016 onwards
- Medical support functions in place and operational
- Product shipped to U.S. Warehouse
  - Supply Chain ready for distribution



# Envarsus Update – E.U. Commercial

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- Launch Roll-Out continues successfully through partner Chiesi
  - Close collaboration with Veloxis
- Nine countries now launched
  - Including Germany, France and UK
  - Full coverage of all transplant centres in initial launch countries
  - Good initial uptake
- Additional key markets to launch in 4Q 2015 into 2016
  - Based on local pricing negotiation requirements
- Two Phase IV studies enrolling actively across E.U.

# Financial Results



# First nine month 2015 results in line with expectations

MDKK	First nine months		Full year	Outlook 2015
	2015	2014	2014	
Revenue	13,0	120,2	123,4	
Production costs	(7,5)	-	(3,2)	
Gross profit	5,5	120,2	120,2	
Sales and marketing	(40,9)	(24,0)	(41,3)	
Research and development	(56,0)	(70,5)	(90,1)	
General and Administration	(40,4)	(28,0)	(47,4)	
Operating loss	(131,8)	(2,3)	(58,6)	(175) - (205)
Net loss	(114,3)	12,9	(36,3)	(155) - (185)
Cash position ending	157,6	310,6	270,4	100 - 130

# Summary



# Summary

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- ENVARSUS XR in the United States
  - FDA Approval and Orphan Drug Status received
  - Veloxis ready to market and sell directly in the attractive U.S. market
  - Initial market uptake is expected to be gradual but steady as patients are switched from existing therapies
- Envarsus in Europe
  - Approved and successfully launched for Kidney and Liver Transplants
  - Chiesi Farmaceutici marketing and selling
- Partners being identified to market in other regions
- Funding options (debt structures) to address future capital requirements are being actively assessed
  - Likely to reflect cost terms similar to high-yield bond



**Q & A**

**Thank you for your attention!**

