



Veloxis Pharmaceuticals A/S

Third Quarter 2013 Report

Investor Conference

William Polvino, President and CEO
Johnny Stilou, CFO
John Weinberg, CCO

14-November-2013, 4pm CET

Dial-in Numbers:
Denmark +45 32 72 80 18
UK +44 (0) 1452 555131
USA +1 866 682 8490
Conference ID: 96780245

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 Envarsus® (formerly 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 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.

Agenda

- Envarsus[®] Status Update
- Financials 3Q 2013
- Summary

Envarsus® Status Update



Envarsus® Update – Regulatory

- European MAA Filing submitted April 29, 2013
 - Based on Phase I, II and Study 3001
 - Acceptance of Filing received May 2013
 - Interactions ongoing with EMA as review process proceeds
 - Anticipate EMA decision in 2014
- Preparations for 2013 US New Drug Application submission to the FDA continue
 - Based on Phase I, II and Studies 3001 and 3002

Envarsus® Update – Commercial

- US
 - Commercial preparation activities underway
 - US commercial infrastructure build in 2014
 - Phase IV planning activities progressing to initiate further differentiation studies
- Europe
 - Commercial planning and preparation proceeding via partner Chiesi

Financial results



First nine months 2013 results

Improved full year outlook

MDKK	First nine months		Full year 2012	Outlook 2013 Improved	Outlook 2013 Previous
	2013	2012			
Revenue	26,0	-	6,9		
Research and development	(115,0)	(168,8)	(210,7)		
General and Administration	(23,3)	(26,7)	(36,9)		
Restructuring cost	-	(21,5)	(21,5)		
Operating loss	(112,3)	(217,0)	(262,2)	(160) - (190)	(170) - (200)
Net loss	(114,6)	(216,2)	(262,7)	(160) - (190)	(170) - (200)
Cash position ending	380,2	86,7	496,8	310 - 340	270 - 310

Summary



Summary and Upcoming Events

- Veloxis is on target for major Envarsus® milestones in 2013
 - EU Regulatory Filing Submitted – April 2013
 - Tremor study differentiation results positive – May 2013
 - Phase III Pivotal study results positive in de novo kidney transplant – June 2013
 - US Regulatory Filing projected - Late 2013
- Commercial opportunity attractive and commercial planning progressing
 - European partnership with Chiesi in place and operating
- Financing in place to support development, differentiation and commercialization activities through initial Envarsus® launch

Q & A

Thank you for your attention!

