Veloxis Pharmaceuticals A/S
2014 First Quarter Report
Investor Conference

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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.

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Key Accomplishments

- ✓ New Drug Application (NDA) submitted to the U.S. Food and Drug Administration (FDA) seeking approval for the marketing and sale of Envarsus® for the prevention of organ rejection in kidney transplant recipients in December 2013
  - ✓ Application accepted by FDA for Review
  - ✓ Prescription Drug User Fee Act (PDUFA) Action Date is October 30, 2014
- ✓ Envarsus® granted Orphan Drug Status by FDA
- ✓ Marketing Authorization Application (MAA) for Envarsus® submitted to and accepted for review by the European Medicines Agency (EMA)
  - ✓ EMA Action on Application expected mid 2014
- ✓ Planning for commercialisation in US and EU on track

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Envarsus® Update

Envarsus® Update – Regulatory

- US NDA submitted to the FDA December 30, 2013
  - For the prevention of organ rejection in kidney transplant recipients
  - Application accepted by the FDA for review
  - PDUFA (Prescription Drug User Fee Act) action date announced as October 30, 2014
  - Orphan Drug Designation granted by the FDA in December 2013
- European MAA Filing submitted April 29, 2013
  - Acceptance of Filing received May 2013
  - Interactions ongoing with EMA as review process proceeds
  - Anticipate
    - CHMP opinion in 2Q2014
    - EMA decision in 3Q2014

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Envarsus® Update – Clinical

- Pivotal blinded phase III Study 3002 in de novo kidney transplant patients
  - Successfully completed Year 1
    - Study achieved its primary efficacy end-point of non-inferiority to Prograf, with rapid attainment of therapeutic tacrolimus blood levels
    - Similar safety and tolerability profile demonstrated
    - Once-daily dosing with lower dose requirements at steady state
  - Year 2 Extension complete
    - Data expected mid 2014
- ASERTAA (A Study of Extended Release Tacrolimus in African-Americans) Initiated
  - Phase IIIb study of Envarsus® in African-American kidney transplant recipients
  - Study on-going
  - Results expected 2015

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Envarsus® Update – Commercial

- United States
  - Commercial preparation activities underway
  - US commercial infrastructure build on course to be ready for upcoming US launch
  - Substantive presence planned at upcoming World Transplant Congress (San Francisco, July 26-31)
  - Phase IV planning activities progressing to initiate further differentiation studies
- Europe
  - Commercial planning and launch preparations proceeding via partner Chiesi in close collaboration with Veloxis

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Financial results

First three month 2014 results in line with expectations

MDKK	First three months 2014	First three months 2013	Full year 2013	Outlook 2014
Revenue	12,2	6,9	38,2	
Research and development	(26,6)	(38,9)	(146,5)	
General and Administration	(7,8)	(7,8)	(27,8)	
Operating loss	(22,2)	(39,8)	(136,1)	(60) - (90)
Net loss	(20,0)	(35,7)	(139,3)	(55) - (85)
Cash position ending	296,2	456,2	328,7	230 - 270

Summary

Summary

- Envarsus® remains on target
  - US and EU Regulatory Filings under review by FDA and EMA
  - FDA and EMA Regulatory Actions anticipated during 2014
- Commercial opportunity attractive and commercial planning progressing
  - US Commercial infrastructure build and launch planning on track
  - European partnership with Chiesi in place and operating well
- Financing in place to support development, differentiation and commercialization activities through initial Envarsus® launch

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Q & A

Thank you for your attention!