

Veloxis Pharmaceuticals A/S 2015 First Quarter Report

Investor Conference

William Polvino, President and CEO

Johnny Stilou, CFO

John Weinberg, COO

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Dial-in Numbers:

Denmark +45 32711660

UK +44 (0) 203427 1913

USA +1 212 444 0896

Access code 7709988

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, potential regulatory approval 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 whether the results of our Phase 3 clinical trials of ENVARSUS XR[®] meet the predetermined endpoints for such trial; our ability to complete the development of, 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 ENVARSUS XR[®] and to conduct clinical trials for ENVARSUS XR[®]; 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

- Veloxis Key Updates
- ENVARSUS XR Status Update
- Financials 1Q 2015
- Summary

Key Updates

- **U.S. Launch Planning underway**
 - On target: Veloxis expects label path clarification via Court ruling mid-year
 - Company seeking to overturn delay in approval for ENVARSUS XR in *de novo* transplant recipients
- **Clinical differentiating data rolling out**
 - Results Presented: ASERTAA study data presented at American Transplant Congress
 - ENVARSUS XR demonstrates improved pharmacokinetic profile in African-American kidney transplant recipients
 - On target: ASTCOFF PK study comparing all three major brand formulations of tacrolimus nearing completion
- **Ex-U.S. commercialization activities progressing successfully**
 - On target: Envarsus EU launch roll-outs continue in line with plans via Chiesi
 - Good pricing in initial countries
 - Good sales coverage and positive initial reception by prescribers
- **U.S. Commercial infrastructure preparations on track for product launch in 4Q2015**
 - Plans to finalize label and hire field force in 3Q
 - Launch 4Q

ENVARUS XR Status Update



U.S. Regulatory Planning

- Clarification on labeling path from U.S. district court is expected mid-year
 - All briefings have been completed as per the court schedule as defined in 1Q2015
 - NOTE: Mid-year is a target and court action could come sooner or later
- Background
 - FDA has issued Tentative Approval indicating that *de novo* indication is blocked via Astagraf XL exclusivity under Hatch-Waxman regulations
 - Veloxis maintains that there is no blocking exclusivity
 - Exclusivity currently is scheduled to expire July 2016, or Jan 2017 if pediatric extension is added
- Veloxis seeks clarity and full approval on one of the two launch indications this year

U.S. Label Clarification

Estimated* approval path



*Working assessment of outcomes and approximate timelines, subject to change

U.S. Approval Path: Comments

- Dates are target dates, and outcomes are simplified as binary
- Risk of legal appeals etc. do exist
- PDUFA cycle times are targets. Exact cycle time may be longer or shorter.

Alternate Path is Commercially Attractive

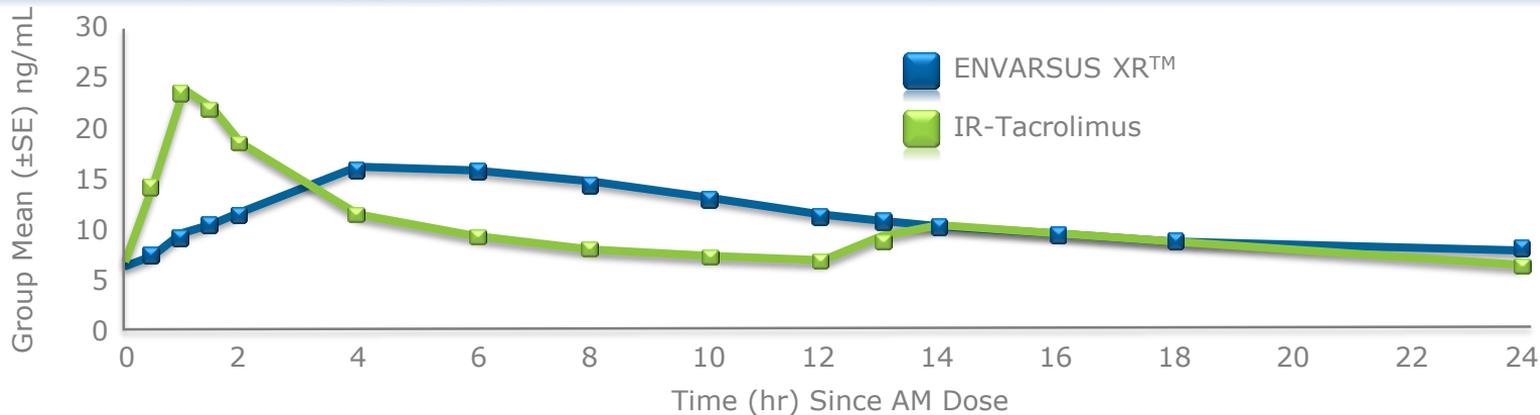
- Maintenance Population ~ 180k patients
- *De Novo* Population ~17k pre year
- More maintenance switches anticipated early in product lifecycle
 - Existing population of patients with toxicities or challenges who may benefit from switch to a novel therapy
- *De Novo* population is a steady build over time as patients are transplanted
- Maintenance labeling at launch will allow Veloxis to hire and deploy full commercial and market access teams into transplant centers and payers

ENVARUSUS XR Clinical Update – ASERTAA Study

- A Study of Extended Release Tacrolimus in African Americans
 - Phase IIIb/IV study of Envarsus in African-American (AA) kidney transplant recipients
 - Study primary elements complete
 - Results presented at American Transplant Congress in May 2015
- High unmet needs in the African-American transplant population
 - 30% of US kidney transplant recipients
 - Rapid metabolizers of tacrolimus
- Pharmacokinetic (PK) comparison of ENVARUSUS XR to twice daily immediate-release tacrolimus (IR-Tac)
 - Two sequence, cross-over design study

ENVARSUS XR benefits demonstrated in Pharmacokinetic parameters for AA patients

Group Mean Tacrolimus Plasma Concentration by Time Profile



- 20% lower dose required for ENVARSUS XR
- ENVARSUS XR is associated with a reduction in peak blood levels ($P < 0.0001$) of approximately 30%
- Reduced intra-day fluctuations by ~50% ($P < 0.0001$)
- Tacrolimus exposure was consistently maintained in the absence of dose adjustments post conversion for IR-Tac
- PK benefits most marked in high-risk rapid metaboliser patients

ENVARUSUS XR Clinical Update – Phase IIIB/IV

- **ASTCOFF Study**
A Steady-state Comparison Of all FK-506 Formulations
 - Head to head comparison of the PK profile of ENVARUSUS XR compared to Prograf twice-daily and Astagraf XL once-daily in ONE study
 - Study primary elements due to complete 2Q 2015
 - Results to be submitted for presentation at European Society for Transplantation in September, 2015
- Additional Phase IV differentiation studies in development for implementation post-approval in the U.S.
- Phase IV Activities by partner Chiesi for EU
 - STEADY Study
 - Large *de novo* study started 2Q 2015 comparing Envarsus to Standard-of-Care

ENVARUSUS XR Update – U.S. Commercial

- Commercial preparation activities continue
- U.S. commercial infrastructure on course to be ready 4Q 2015 launch
 - Key Commercial Leadership roles filled
- Sales field force hiring on hold pending court clarification
- American Transplant Congress – May 2015, Philadelphia
 - Largest Annual gathering of Transplant professionals
 - Strong Veloxis Corporate and Commercial Presence
 - 5 Abstracts on Envarsus presented
 - Strong community interest in need for novel agent in Transplant field

Envarsus Update – E.U. Commercial

- Launch Roll-Out on track through Partner Chiesi working in close collaboration with Veloxis
- First country launches Q4 2014    
 - Positive market feedback
- Staged roll out of Envarsus in remaining EU countries
 - Based on local pricing negotiation requirements
 - Most key EU countries (~13) to launch by end 2015

ENVARUSUS Update – E.U. Commercial

- Qualitative opinion of market interest in launched countries so far:
 - High interest in the unique technology, resulting in the characteristic PK profile of Envarsus
 - Consequently customers expressing interest to start using Envarsus
- Transplant centres in the launched countries called on to date by Chiesi:
 - 100% coverage of all Tx centres in first three launch countries (Germany, Netherlands, UK)

Financial Results



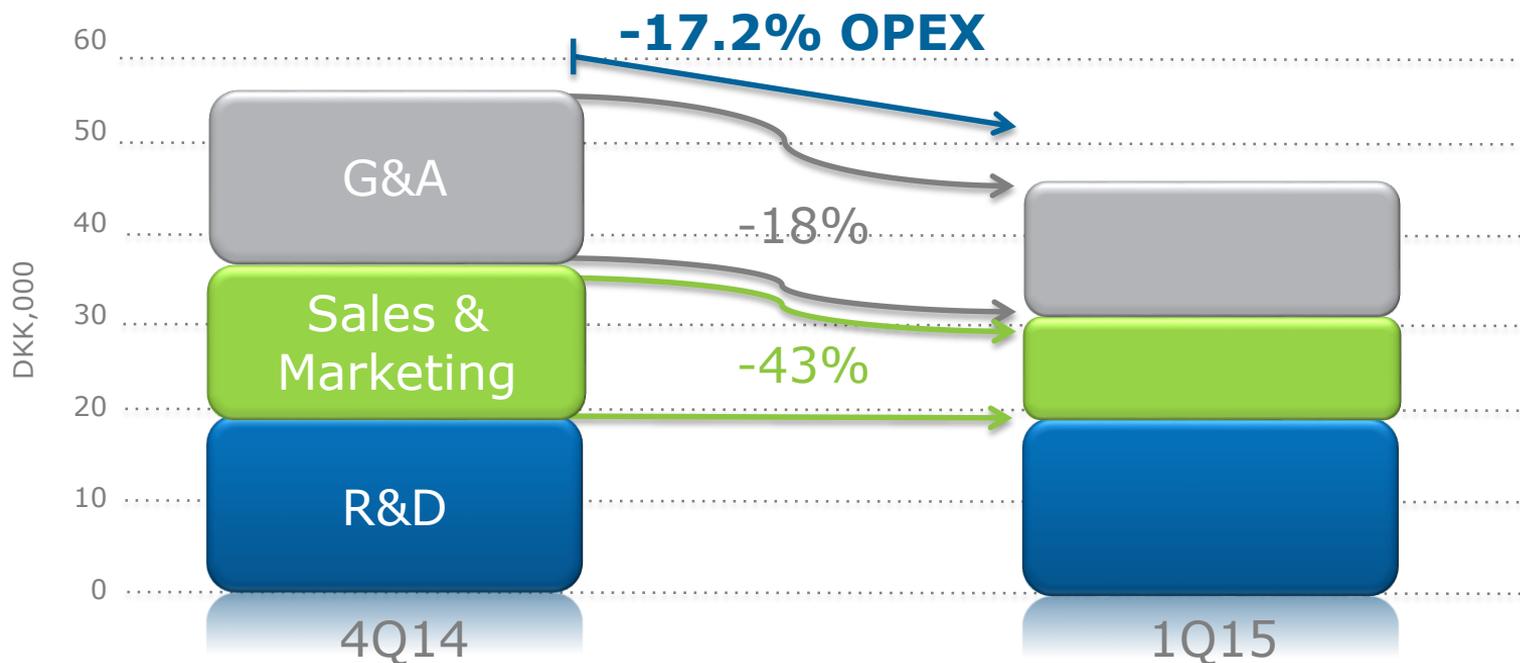
Q1 Financial Results

Interim report for the first 3 months 2015

Result and cash position in line with previously announced full year outlook

MDKK	First 3 Months		Full Year	Outlook
	2015	2014	2014	2015
Revenue	4,3	12,2	123,4	
Production costs	(4,1)	-	(3,2)	
Gross profit	0,2	12,2	120,2	
Sales and marketing	(9,8)	-	(41,3)	
Research and development	(20,8)	(26,6)	(90,1)	
General and administration	(16,0)	(7,8)	(47,4)	
Operating loss	(46,4)	(22,2)	(58,6)	(200)-(240)
Net loss	(27,0)	(20,0)	(36,3)	(195)-(235)
Cash position ending	233,6	296,2	270,4	55-95

Reductions in Costs During Launch Delay



Effective reduction in existing costs
Deferral of planned additions until approval

Summary



Summary

- ENVARSUS XR in the United States
 - Veloxis to market and sell directly in attractive U.S. market
 - Clarification on launch labeling is expected via U.S. district court mid-year
 - Anticipated Launch 4Q 2015
- Envarsus in Europe
 - Approved and successfully launched for Kidney and Liver Transplants
 - Germany, Netherlands, UK, Denmark
 - Most remaining EU countries will launch in 2015
 - Chiesi Farmaceutici marketing and selling
- Partners being identified to market in other regions
- Capital requirements resulting from delay will be met via combination of continued cash conservation plus assessment of funding options (debt, equity, deal-making)

Q & A

Thank you for your attention!

