

Company Announcement no. 18/2014

To: NASDAQ OMX Copenhagen A/S

Hørsholm, Denmark, 20 August, 2014

Veloxis Pharmaceuticals announces financial results for the first six months of 2014

Highlights:

- On 28 July the European Commission granted marketing authorization for Envarsus® for the prevention of organ rejection in adult kidney and liver transplant patients in the European Union (EU).
- Following the European marketing authorization Veloxis will receive a milestone payment of USD 15 million from our European partner Chiesi in the third quarter 2014 which is in line with expectations. The payment will be recognized fully as income in the third quarter 2014.
- Envarsus® XR for the prevention of organ rejection in kidney transplant patients is under regulatory review by the U.S. FDA and has a PDUFA action date of October 30, 2014.
- The once-daily Envarsus® XR (tacrolimus extended-release tablets), an investigational new drug under FDA review for the prevention of organ rejection in adult kidney transplant patients, has demonstrated a lower treatment failure rate in African-Americans compared with twice-daily tacrolimus (Prograf®).
- The two-year results of the pivotal Phase 3 clinical trial, Study 3002, of Envarsus® XR in *de novo* kidney transplant patients continued to demonstrate non-inferiority compared to tacrolimus capsules (Prograf®; Astellas Pharma).
- Veloxis reported a net loss of DKK 53.1 million for the first half of 2014 compared to a net loss of DKK 80.5 million for the same period in 2013. The reported net loss is in line with expectations and the financial outlook for 2014 is maintained.
- For the first half of 2014, Veloxis' research and development costs amounted to DKK 51.0 million compared to DKK 81.7 million during the same period in 2013.
- On 30 June, 2014, Veloxis had cash and cash equivalents of DKK 264.2 million.

Outlook for 2014

Veloxis maintains its 2014 outlook with an operating loss of DKK 60-90 million and a net loss of DKK 55-85 million for the financial year 2014.

As at 30 June 2014, the Company's cash position equaled DKK 264.2 million, and as at 31 December 2014, the Company's cash position is expected to be in the range of DKK 230-270 million.

Conference call

A conference call will be held tomorrow, 21 August, 2014 at 2:00 PM CET (Denmark); 1:00 PM GMT (London), 8:00 AM EST (New York).

To access the live conference call, please dial one of the following numbers:

+45 32 72 80 18 (Denmark)

+44 (0) 1452 555 131 (UK)

+1 866 682 8490 (USA)

Access code 89298792

Following the conference call, a recording will be available on the company's website <http://www.veloxis.com>.

Research & development update

Envarsus® in kidney transplant patients

Veloxis has conducted two Phase III studies of Envarsus® in kidney transplant recipients as the basis for its development programme for Envarsus® as a once-daily agent for the prophylaxis of organ rejection in kidney transplantation. The first of these studies, the 3001 Study, was a non-inferiority study performed in 326 stable kidney transplant recipients, and was successfully completed in 2011, meeting its primary efficacy and safety endpoints when compared to Prograf® (tacrolimus, Astellas Pharma Inc.). The second study, Study 3002 was a randomized, double-blind, multicenter study that compared once-daily Envarsus® against twice-daily Prograf® in 543 *de novo* adult kidney transplant patients and met its primary efficacy and primary safety endpoints. The primary endpoint of the study was a composite endpoint of treatment failure (biopsy-proven acute rejection, graft failure, loss to follow up or death) that was evaluated after a 12-month treatment period to demonstrate the non-inferiority of Envarsus® compared to Prograf®. The treatment failure rate for Envarsus® was 18.3% compared to 19.6% for Prograf®, and the difference between the treatments was well within the 10% pre-specified non-inferiority margin. The primary safety analyses were the differences between Envarsus® and Prograf® treatment groups at Month 12 (Day 360) with respect to the incidence of adverse events (AEs) and the incidence of predefined potentially clinically significant laboratory measures including: fasting plasma glucose; platelet count; white blood cell (WBC) count; aminotransaminases; total cholesterol; low density lipoprotein (LDL) cholesterol; triglycerides; and estimated glomerular filtration rate (eGFR). In all instances, there were no statistically significant differences between the two treatments. Specifically, renal function was similar between the two groups at 12 months, as was the incidence of malignancy, infections and new onset diabetes during this period. On June 29, 2014, Veloxis announced the results of the second year of blinded therapy in this study and the results were similar to the one-year results with Envarsus® continuing to demonstrate non-inferiority to Prograf® on the primary endpoint at the two year time point.

In addition to the pivotal Phase III studies, Veloxis is conducting a series of Phase IIIb/IV studies to further evaluate potential differences in clinical profile provided by Envarsus®' unique PK profile. The first study is the STRATO (Switching kidney TRAnsplant patients with Tremor to LCP-tacrO) study of Envarsus® in kidney transplant recipients experiencing drug-induced tremors. The STRATO study was designed to explore whether a conversion of patients who have symptomatic tremor from treatment with standard immediate release twice-daily tacrolimus capsules to extended release once-daily Envarsus® tablets leads to a measurable improvement in tremor. Results from this study

demonstrated that patients switched to Envarsus® demonstrated a statistically significant improvement in hand tremors based on improvement in the FTM Tremor rating scale. Additionally, both the patient- and physician-reported global assessments demonstrated significant overall improvements following the switch to Envarsus®.

Additionally, the ASERTAA (A Study of Extended Release Tacrolimus in African-Americans) Phase IIIb study of Envarsus® in kidney transplant recipients is ongoing. The ASERTAA study is designed to compare the pharmacokinetics of Envarsus® given once-daily to generic twice daily tacrolimus capsules in stable African-American renal transplant patients. Results from this study are anticipated to be available in 2015.

Envarsus® Regulatory Strategy

On 29 April, 2013 a Marketing Authorization Application (MAA) was submitted by Veloxis to the European Medicines Agency (EMA) seeking approval to market Envarsus® for the prevention of organ rejection in transplant patients in the European Union. On 28 July, 2014, it was announced that the European Commission granted marketing authorization for Envarsus® for the prevention of organ rejection in adult kidney and liver transplant patients in the European Union (EU). The EU marketing authorization is based on review of the favourable results of the Envarsus® Phase III 3001 study in stable kidney transplant patients and 3002 study in *de novo* kidney transplant recipients as well as data from an extensive Phase I and II clinical program, which included both kidney and liver transplant patients.

Veloxis submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for the marketing and sale of Envarsus® in the US for the prevention of organ rejection in kidney transplant recipients on 30 December, 2013. The FDA has accepted for standard review the NDA for Envarsus® and has set a target review date under the Prescription Drug User Fee Act (PDUFA) of 30 October, 2014.

In addition, the FDA granted Envarsus® Orphan Drug status for prophylaxis of organ rejection in patients receiving allogeneic kidney transplants. The designation is to encourage the development of drugs that may provide significant benefit to patients suffering from rare diseases.

Envarsus® Commercial Strategy

In the US Veloxis is planning to launch and commercialize Envarsus® XR through its own dedicated marketing and sales organization. The hiring and building of the marketing and sales infrastructure is on-going with activities on target to support a launch of Envarsus® XR for the indication of prophylaxis of kidney transplant rejection in the first quarter of 2015.

In the EU, Chiesi Farmaceutici S.p.A., through an exclusive distribution agreement with Veloxis, will commercialize Envarsus®, with initial country launches anticipated for the fourth quarter of 2014.

Financial Highlights

	YTD 2014 DKK'000	YTD 2013 DKK'000	Q2 2014 DKK'000	Q2 2013 DKK'000	Year 2013 DKK'000
Income Statement					
Revenue	24,412	13,736	12,206	6,868	38,148
Sales and marketing costs	(13,653)	-	(13,653)	-	-
Research and development costs	(51,044)	(81,719)	(24,420)	(42,772)	(146,512)
Administrative expenses	(17,732)	(14,611)	(9,983)	(6,834)	(27,771)
Operating loss	(58,017)	(82,594)	(35,850)	(42,738)	(136,135)
Net financial income / (expenses)	1,905	1,654	1,228	(2,253)	(4,426)
Loss before tax	(56,112)	(80,940)	(34,622)	(44,991)	(140,561)
Tax for the period	2,989	485	1,495	241	1,250
Net loss for the period	(53,123)	(80,455)	(33,127)	(44,750)	(139,311)
Balance Sheet					
Cash and cash equivalents	264,240	399,743	264,240	399,743	328,652
Total assets	276,493	409,371	276,493	409,371	348,863
Share capital	166,252	166,057	166,252	166,057	166,057
Total equity	231,649	334,686	231,649	334,686	279,042
Investment in property, plant and equipment	117	-	(169)	-	1,055
Cash Flow Statement					
Cash flow from operating activities	(67,126)	(96,290)	(33,577)	(51,165)	(157,747)
Cash flow from investing activities	(117)	-	169	-	(1,055)
Cash flow from financing activities	684	(2,506)	-	(2,555)	(3,227)
Cash and cash equivalents at period end	264,240	399,743	264,240	399,743	328,652
Financial Ratios					
Basic and diluted EPS	(0.03)	(0.05)	(0.02)	(0.03)	(0.08)
Weighted average number of shares	1,661,684,858	1,660,130,437	1,662,527,283	1,660,572,426	1,660,353,248
Average number of employees (FTEs)	23	28	23	27	26
Assets/equity	1.19	1.22	1.19	1.22	1.25

The interim report has not been audited or reviewed by the company's independent auditors.

Revenue

For the first half of 2014 Veloxis recognized deferred revenue of DKK 24.4 million as revenue compared to DKK 13.7 million in the same period of 2013. Deferred revenue consist of up-front and milestone payments under Veloxis' distribution agreement with Chiesi Farmaceutici S.p.A. and is recognized in the income statement based on planned development periods.

Sales and marketing costs

For the first half of 2014, Veloxis' sales and marketing costs amounted to DKK 13.7 million. This reflects the hiring and building of the marketing and sales infrastructure in the US along with activities to support a launch of Envarsus® XR in the first quarter of 2015.

Research and development costs

For the first half of 2014, Veloxis' research and development costs amounted to DKK 51.0 million compared to DKK 81.7 million during the same period in 2013. Research and development costs are mainly attributable to the phase III trial in Envarsus® (*de novo* patients, Study 3002). The reduction in cost is associated with the overall reduction in study activity as the study is approaching finalization.

Administrative expenses

For the first half of 2014, Veloxis' administrative cost amounted to DKK 17.7 million compared to DKK 14.6 million during the same period in 2013.

Compensation costs

For the first half of 2014, a total of DKK 5.0 million was recognized as share-based compensation. The cost is included in R&D and G&A. The comparable cost for 2013 was DKK 5.2 million.

In the second quarter of 2014, a total of 236,782 warrants have been cancelled, a total of 196,328 warrants have expired and a total of 250,000 warrants at a strike price of DKK 1.14 were granted to other employees.

As of 30 June, 2014, there were a total of 98,964,371 warrants outstanding at an average strike price of DKK 0.70. Members of the Board of Directors held 589,584 warrants at an average strike price of DKK 1.43. Members of the Executive Management held 61,279,081 warrants at an average strike price of DKK 0.51, while other current and former employees held 37,095,706 warrants at an average strike price of DKK 1.02.

Please refer to Veloxis' latest annual report for additional details on the Company's warrant programs.

Operating loss

Veloxis' operating loss for the first half of 2014 was DKK 58.0 million compared to DKK 82.6 million in the corresponding period of 2013.

Financial income

During the first half of 2014, the Company recognized net financial income of DKK 1.9 million compared to net financial income of DKK 1.7 million in the corresponding period of 2013. The income is mainly due to unrealized currency gain following an increase in the USD / DKK currency rate during the first half of 2014.

Net loss

Veloxis' net loss for the first half of 2014 was DKK 53.1 million compared to DKK 80.5 million in the corresponding period of 2013.

Cash flow

As per 30 June, 2014, the balance sheet reflects cash and cash equivalents of DKK 264.2 million compared to DKK 328.7 million as per 31 December, 2013. This represents a decrease of DKK 64.5 million primarily related to the Company's operating activities for the period.

Balance sheet

As per 30 June, 2014, total assets were DKK 276.5 million compared to DKK 348.9 million at the end of 2013.

Shareholders' equity equalled DKK 231.6 million as of 30 June, 2014, compared to DKK 279.0 million at the end of 2013.

Significant risks and uncertainties

Veloxis faces a number of risks and uncertainties related to operations, research and development, commercial and financial activities. For further information about risks and uncertainties, we refer to the Annual Report for 2013. As of the date of this Interim Report, there have been no significant changes to Veloxis' overall risk profile since the publication of the Annual Report for 2013.

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The forward looking statements and targets contained herein are based on the current view and assumptions of the Executive Management and the Board of Directors of Veloxis Pharmaceuticals A/S. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. Veloxis Pharmaceuticals A/S expressly disclaim any obligation or undertaking to update or revise any forward looking statements, targets or estimates contained in this interim report to reflect any change in events, conditions, assumptions, or circulations on which any such statements are based unless required by applicable law.

About Envarsus® and tacrolimus

Tacrolimus is a leading immunosuppression drug used for the prevention of transplant allograft rejection after organ transplantation. Envarsus (tacrolimus prolonged release tablets) has received marketing authorization in the EU for prophylaxis of organ rejection in kidney and liver transplant recipients. In the US Envarsus, known as Envarsus XR (tacrolimus extended-release tablets), is an investigational new drug under FDA review that is being developed as a once daily tablet version of tacrolimus for prophylaxis of kidney transplant rejection. Envarsus XR has received orphan drug designation in the US. Upon approval, Veloxis plans to commercialize Envarsus XR in the US through its own sales force and in the EU through its partnership with Chiesi Farmaceutici SpA.

About Veloxis Pharmaceuticals

Based in Hørsholm, Denmark, with an office in New Jersey, Veloxis Pharmaceuticals A/S, or Veloxis, is a specialty pharmaceutical company. The company's lead product candidate is Envarsus® XR for immunosuppression, specifically organ transplantation. Veloxis' unique, patented delivery technology, MeltDose®, can improve absorption and bioavailability at low scale up costs. Veloxis has a lipid lowering product, Fenoglide®, currently on the U.S. market that is commercialized through partner Salix, Inc. Veloxis is listed on the NASDAQ OMX Copenhagen under the trading symbol OMX: VELO.

For further information, please visit <http://www.veloxis.com>.

Executive Management's and the Board of Directors' Statement on the Interim Report

The Executive Management and the Board of Directors have considered and adopted the Interim Report for the 6 months ended 30 June 2014 of Veloxis Pharmaceuticals A/S.

The Interim Report is prepared in accordance with International Accounting Standard No. 34 (IAS 34), "Interim Financial Reporting" and additional Danish disclosure requirements for financial reporting of listed companies.

We consider the applied accounting policies to be appropriate and, in our opinion, the Interim Report gives a true and fair view of the assets and liabilities, financial position, results of the operation and cash flow of the group for the period under review. Furthermore, in our opinion the management review includes a fair review of the development and performance of the business and the financial position of the group, together with a description of the material risks and uncertainties the group faces.

Hørsholm, 20 August, 2014

Executive Management

Dr. William J. Polvino
President & CEO

Johnny Stilou
Executive Vice President & CFO

Board of Directors

Kim Bjørnstrup
(Chairman)

Thomas Dyrberg
(Deputy Chairman)

Anders Götzsche

Mette Kirstine Agger

Interim Report
for the 6 Months Ended 30 June, 2014
(20 August, 2014)



Financial Highlights
Quarterly Numbers in DKK

	Q2 2014 DKK'000	Q1 2014 DKK'000	Q4 2013 DKK'000	Q3 2013 DKK'000	Q2 2013 DKK'000	Q1 2013 DKK'000
Income Statement						
Revenue	12,206	12,206	12,206	12,206	6,868	6,868
Sales and marketing costs	(13,653)	-	-	-	-	-
Research and development costs	(24,420)	(26,624)	(29,546)	(35,247)	(42,772)	(38,947)
Administrative expenses	(9,983)	(7,749)	(6,457)	(6,703)	(6,834)	(7,777)
Operating loss	(35,850)	(22,167)	(23,797)	(29,744)	(42,738)	(39,856)
Net financial income / (expenses)	1,228	677	(1,425)	(4,655)	(2,253)	3,907
Loss before tax	(34,622)	(21,490)	(25,222)	(34,399)	(44,991)	(35,949)
Tax for the period	1,495	1,494	522	242	241	244
Net loss for the period	(33,127)	(19,996)	(24,700)	(34,157)	(44,750)	(35,704)
Balance Sheet						
Cash and cash equivalents	264,240	296,237	328,652	380,179	399,743	456,216
Total assets	276,493	305,373	348,863	388,982	409,371	465,939
Share capital	166,252	166,252	166,057	166,057	166,057	166,057
Total equity	231,649	261,538	279,042	302,307	334,686	377,276
Investment in property, plant and equipment	(169)	285	1,055	-	-	-
Cash Flow Statement						
Cash flow from operating activities	(33,577)	(33,550)	(47,417)	(14,040)	(51,165)	(45,125)
Cash flow from investing activities	169	(285)	(1,055)	-	-	-
Cash flow from financing activities	-	684	(319)	(401)	(2,555)	48
Cash and cash equivalents at period end	264,240	296,237	328,652	380,179	399,743	456,216
Financial Ratios						
Basic and diluted EPS	(0.02)	(0.01)	(0.01)	(0.02)	(0.03)	(0.02)
Weighted average number of shares	1,662,527,283	1,660,833,074	1,660,572,426	1,660,572,426	1,660,572,426	1,659,683,537
Average number of employees (FTEs)	23	22	23	26	27	29
Assets/equity	1.19	1.17	1.25	1.29	1.22	1.24

Income statement and statement of comprehensive income

Income Statement		Consolidated			
(DKK'000)	YTD 2014	YTD 2013	Q2 2014	Q2 2013	Year 2013
Revenue	24,412	13,736	12,206	6,868	38,148
Sales and marketing costs	(13,653)	-	(13,653)	-	-
Research and development costs	(51,044)	(81,719)	(24,420)	(42,772)	(146,512)
Administrative expenses	(17,732)	(14,611)	(9,983)	(6,834)	(27,771)
Operating loss	(58,017)	(82,594)	(35,850)	(42,738)	(136,135)
Financial income	5,949	9,872	2,758	1,000	1,243
Financial expenses	(4,044)	(8,218)	(1,530)	(3,253)	(5,669)
Loss before tax	(56,112)	(80,940)	(34,622)	(44,991)	(140,561)
Tax for the period	2,989	485	1,495	241	1,250
Net loss for the period	(53,123)	(80,455)	(33,127)	(44,750)	(139,311)
Basic and diluted EPS	(0.03)	(0.05)	(0.02)	(0.03)	(0.08)
Weighted average number of shares	1,661,684,858	1,660,130,437	1,662,527,283	1,660,572,426	1,660,353,248

Statements of comprehensive income		Consolidated			
(DKK'000)	YTD 2014	YTD 2013	Q2 2014	Q2 2013	Year 2013
Net loss for the period	(53,123)	(80,455)	(33,127)	(44,750)	(139,311)
Other comprehensive income: <i>Items that may be subsequently reclassified to profit or loss:</i>					
Currency translation differences, net of tax	75	(277)	49	(149)	(390)
Other comprehensive income for the period	75	(277)	49	(149)	(390)
Total comprehensive income for the period	(53,048)	(80,732)	(33,078)	(44,899)	(139,701)

Balance sheet

Assets	Consolidated		
	(DKK'000)	30 June 2014	30 June 2013
Patent rights and software	441	1,981	494
Intangible assets	441	1,981	494
Property, plant and equipment	3,098	2,634	3,333
Leasehold improvements	-	39	-
Property, plant and equipment	3,098	2,673	3,333
Non-current assets	3,539	4,654	3,827
Inventories	2,224	-	-
Other receivables	5,765	3,964	15,170
Prepayments	725	1,010	1,214
Receivables	6,490	4,974	16,384
Cash	264,240	399,743	328,652
Cash and cash equivalents	264,240	399,743	328,652
Current assets	272,954	404,717	345,036
Assets	276,493	409,371	348,863

Interim Report
for the 6 Months Ended 30 June, 2014
(20 August, 2014)



Balance sheet

Equity & Liabilities	Consolidated		
(DKK'000)	30 June 2014	30 June 2013	31 Dec. 2013
Share capital	166,252	166,057	166,057
Special reserve	407,289	407,289	407,289
Translation reserves	2,043	2,081	1,968
Retained earnings/loss	(343,935)	(240,741)	(296,272)
Equity	231,649	334,686	279,042
Finance lease	-	721	-
Trade payables	17,738	20,179	13,026
Deferred revenue	12,206	34,340	36,617
Other payables	14,900	19,445	20,178
Current liabilities	44,844	74,685	69,821
Liabilities	44,844	74,685	69,821
Equity and liabilities	276,493	409,371	348,863

Cash flow statements

Cash Flow Statement	Consolidated				
(DKK'000)	YTD 2014	YTD 2013	Q2 2014	Q2 2013	Year 2013
Operating loss	(58,017)	(82,594)	(35,850)	(42,738)	(136,135)
Share-based payment	4,971	5,243	3,188	2,310	8,568
Depreciation and amortization	405	681	203	341	1,315
Write-down	-	-	-	-	1,243
Changes in working capital	(14,699)	(19,587)	(1,334)	(11,083)	(35,294)
Cash flow from operating activities before interest	(67,340)	(96,257)	(33,793)	(51,170)	(160,303)
Interest received	214	48	214	-	1,243
Interest paid	-	58	-	76	(39)
Corporate tax received	-	-	-	-	1,352
Corporate tax paid	-	(139)	2	(71)	-
Cash flow from operating activities	(67,126)	(96,290)	(33,577)	(51,165)	(157,747)
Purchase of property, plant and equipment	(117)	-	169	-	(1,055)
Cash flow from investing activities	(117)	-	169	-	(1,055)
Installments on bank borrowings and finance lease	-	(2,944)	-	(2,555)	(3,665)
Proceeds from issuance of shares, net	684	438	-	-	438
Cash flow from financing activities	684	(2,506)	-	(2,555)	(3,227)
Increase/(decrease) in cash	(66,559)	(98,796)	(33,408)	(53,720)	(162,029)
Cash at beginning of period	328,652	496,834	296,237	456,216	496,834
Exchange gains/(losses) on cash	2,147	1,705	1,411	(2,753)	(6,153)
Cash at end of period	264,240	399,743	264,240	399,743	328,652

Statement of changes in equity

Consolidated Equity							
	Number of Shares	Share Capital DKK'000	Share Premium DKK'000	Special Reserves DKK'000	Translation Reserves DKK'000	Retained Earnings DKK'000	Total DKK'000
Equity as of 1 Jan. 2013	1,659,322,426	165,932	-	407,289	2,358	(165,842)	409,737
Net loss for the year						(80,455)	(80,455)
Other comprehensive income for the year					(277)		(277)
Total comprehensive income					(277)	(80,455)	(80,732)
Warrant exercises	1,250,000	125	313				438
Share-based payment						5,243	5,243
Transfer of retained earnings			(313)			313	-
Equity as of 30 June 2013	1,660,572,426	166,057	-	407,289	2,081	(240,741)	334,686
Net loss for the year						(58,856)	(58,856)
Other comprehensive income for the year					(113)		(113)
Total comprehensive income					(113)	(58,856)	(58,969)
Share-based payment						3,325	3,325
Equity as of 31 Dec. 2013	1,660,572,426	166,057	-	407,289	1,968	(296,272)	279,042
Net loss for the year						(53,123)	(53,123)
Other comprehensive income for the year					75		75
Total comprehensive income					75	(53,123)	(53,048)
Warrant exercises	1,954,857	195	489				684
Share-based payment						4,971	4,971
Transfer of retained earnings			(489)			489	-
Equity as of 30 June 2014	1,662,527,283	166,252	-	407,289	2,043	(343,935)	231,649

Notes

1. Accounting policies

The interim report is prepared in compliance with International Accounting Standard No. 34 (IAS 34), "Interim Financial Reporting" and in accordance with the NASDAQ OMX Copenhagen's financial reporting requirements for listed companies.

There have been no changes in accounting policies used for the interim report compared to the accounting policies used in the preparation of Veloxis Pharmaceuticals' annual report for 2013.