Company Announcement no. 11/2014

To: NASDAQ OMX Copenhagen A/S

Hørsholm, Denmark, 14 May, 2014

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

Highlights:

- The U.S. Food and Drug Administration (FDA) has accepted for standard review the company's New Drug Application (NDA) for Envarsus® for the prevention of organ rejection in adult kidney transplant patients. The FDA has set a target review date under the Prescription Drug User Fee Act (PDUFA) of October 30, 2014.

- The Company has previously reported that the MAA for Envarsus® had been accepted by the European Medicines Agency (EMA). A CHMP opinion is expected in 2Q 2014 and regulatory action on the application is expected in 3Q 2014.

- Veloxis reported a net loss of DKK 20.0 million for the first quarter of 2014 compared to a net loss of DKK 35.7 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 quarter of 2014, Veloxis' research and development costs amounted to DKK 26.6 million compared to DKK 38.9 million during the same period in 2013.

- On 31 March, 2014, Veloxis had cash and cash equivalents of DKK 296.2 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 31 March 2014, the Company's cash position equaled DKK 296.2 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, 15 May, 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 35440957

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. Patients are participating in a 12-month extension period on treatment for follow-up safety and efficacy assessments.

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. The MAA submission was based on the favourable results of the Envarsus® Phase III 3001 Study in stable kidney transplant patients and data from an extensive Phase I and II clinical programme and has been accepted for review by the EMA. The review of the MAA is on-going and Veloxis expects to receive a decision on the application in 3Q 2014.

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 December 30, 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 October 30, 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.

Financial Highlights

	Q1 2014 DKK'000	Q1 2013 DKK'000	Year 2013 DKK'000
Income Statement			
Revenue	12,206	6,868	38,148
Research and development costs	(26,624)	(38,947)	(146,512)
Administrative expenses	(7,749)	(7,777)	(27,771)
Operating loss	(22,167)	(39,856)	(136,135)
Net financial income / (expenses)	677	3,907	(4,426)
Loss before tax	(21,490)	(35,949)	(140,561)
Tax for the period	1,494	244	1,250
Net loss for the period	(19,996)	(35,704)	(139,311)
Balance Sheet			
Cash and cash equivalents	296,237	456,216	328,652
Total assets	305,373	465,939	348,863
Share capital	166,252	166,057	166,057
Total equity	261,538	377,276	279,042
Investment in property, plant and equipment	285	-	1,055
Cash Flow Statement			
Cash flow from operating activities	(33,550)	(45,125)	(157,747)
Cash flow from investing activities	(285)	-	(1,055)
Cash flow from financing activities	684	48	(3,227)
Cash and cash equivalents at period end	296,237	456,216	328,652
Financial Ratios			
Basic and diluted EPS	(0.01)	(0.02)	(0.08)
Weighted average number of shares	1,660,833,074	1,659,683,537	1,660,353,248
Average number of employees (FTEs)	22	29	26
Assets/equity	1.17	1.24	1.25

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

Revenue
For the first quarter of 2014 Veloxis recognized deferred revenue of DKK 12.2 million as revenue compared to DKK 6.9 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.

Research and development costs
For the first quarter of 2014, Veloxis' research and development costs amounted to DKK 26.6 million compared to DKK 38.9 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 quarter of 2014, Veloxis' administrative cost amounted to DKK 7.7 million compared to DKK 7.8 million during the same period in 2013.

Compensation costs
For the first quarter of 2014, a total of DKK 1.8 million was recognized as share-based compensation. The cost is included in R&D and G&A. The comparable cost for 2013 was DKK 2.9 million.

In the first quarter of 2014, a total of 4,382,843 warrants have been cancelled, a total of 1,954,857 warrants have been exercised at an exercise price of DKK 0.35, and a total of 15,647,781 warrants were granted to Executive Management at a strike price of DKK 0.95, a total of 6,408,249 warrants at a strike price of DKK 0.95 was granted to Senior Management and a total of 911,726 warrants at a strike price of DKK 0.95 was granted to other employees.

As of 31 March, 2014, there were a total of 99,147,481 warrants outstanding at an average strike price of DKK 0.73. 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 37,278,816 warrants at an average strike price of DKK 1.08.

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

Operating loss
Veloxis' operating loss for the first quarter of 2014 was DKK 22.2 million compared to DKK 39.8 million in the corresponding period of 2013.

Financial income
During the first quarter of 2014, the Company recognized net financial income of DKK 0.7 million compared to net financial income of DKK 3.9 million in the corresponding period of 2013. The income is mainly due to unrealized currency gain following a slight increase in the USD / DKK currency rate during the first quarter of 2014.

Net loss
Veloxis' net loss for the first quarter of 2014 was DKK 20.0 million compared to DKK 35.7 million in the corresponding period of 2013.

Cash flow

As per 31 March, 2014, the balance sheet reflects cash and cash equivalents of DKK 296.2 million compared to DKK 328.7 million as per 31 December, 2013. This represents a decrease of DKK 32.5 million primarily related to the Company's operating activities for the period.

Balance sheet

As per 31 March, 2014, total assets were DKK 305.4 million compared to DKK 348.9 million at the end of 2013.

Shareholders' equity equalled DKK 261.5 million as of 31 March, 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.

For more information, please contact:

John D. Weinberg
EVP, Chief Operating Officer
Mobile: +1 732 321 3208
Email: jdw@veloxis.com

Johnny Stilou
EVP, Chief Financial Officer
Mobile: +45 21 227 227
Email: jst@veloxis.com

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 transplantation. Envarsus® is an investigational drug that is being developed as a once-daily tablet version of tacrolimus with improved bioavailability, consistent pharmacokinetic performance and reduced peak-to-trough variability when compared to currently approved tacrolimus products. Transplant patients need to maintain a minimum blood level of tacrolimus for the prevention of transplant allograft rejection, but excessive levels may increase the risk of serious side effects such as nephrotoxicity, tremor, diabetes, high blood pressure, and opportunistic infections. Therefore, tacrolimus levels need to be managed carefully, and transplant patients are typically obliged to make frequent visits to the hospital for monitoring and dose adjustments after receiving a new organ.

About Veloxis Pharmaceuticals

Based in Hørsholm, Denmark, with an office in New Jersey, Veloxis is a specialty pharmaceutical company. The company's lead product candidate is Envarsus® 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 Santarus, 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 3 months ended 31 March 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, 14 May, 2014

Executive Management

Dr. William J. Polvino	Johnny Stilou
President & CEO	Executive Vice President & CFO

Board of Directors

Kim Bjørnstrup	Thomas Dyrberg
(Chairman)	(Deputy Chairman)
Anders Götzsche	Mette Kirstine Agger

Financial Highlights
Quarterly Numbers in DKK

	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	6,868	6,868
Research and development costs	(26,624)	(29,546)	(35,247)	(42,772)	(38,947)
Administrative expenses	(7,749)	(6,457)	(6,703)	(6,834)	(7,777)
Operating loss	(22,167)	(23,797)	(29,744)	(42,738)	(39,856)
Net financial income / (expenses)	677	(1,425)	(4,655)	(2,253)	3,907
Loss before tax	(21,490)	(25,222)	(34,399)	(44,991)	(35,949)
Tax for the period	1,494	522	242	241	244
Net loss for the period	(19,996)	(24,700)	(34,157)	(44,750)	(35,704)
Balance Sheet					
Cash and cash equivalents	296,237	328,652	380,179	399,743	456,216
Total assets	305,373	348,863	388,982	409,371	465,939
Share capital	166,252	166,057	166,057	166,057	166,057
Total equity	261,538	279,042	302,307	334,686	377,276
Investment in property, plant and equipment	285	1,055	-	-	-
Cash Flow Statement					
Cash flow from operating activities	(33,550)	(47,417)	(14,040)	(51,165)	(45,125)
Cash flow from investing activities	(285)	(1,055)	-	-	-
Cash flow from financing activities	684	(319)	(401)	(2,555)	48
Cash and cash equivalents at period end	296,237	328,652	380,179	399,743	456,216
Financial Ratios					
Basic and diluted EPS	(0.01)	(0.01)	(0.02)	(0.03)	(0.02)
Weighted average number of shares	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)	22	23	26	27	29
Assets/equity	1.17	1.25	1.29	1.22	1.24

Income statement and statement of comprehensive income

Income Statement	Consolidated		
(DKK'000)	**Q1 2014**	**Q1 2013**	**Year 2013**
Revenue	12,206	6,868	38,148
Research and development costs	(26,624)	(38,947)	(146,512)
Administrative expenses	(7,749)	(7,777)	(27,771)
Operating loss	**(22,167)**	**(39,856)**	**(136,135)**
Financial income	3,191	8,872	1,243
Financial expenses	(2,514)	(4,965)	(5,669)
Loss before tax	**(21,490)**	**(35,949)**	**(140,561)**
Tax for the period	1,494	244	1,250
Net loss for the period	**(19,996)**	**(35,704)**	**(139,311)**
Basic and diluted EPS	(0.01)	(0.02)	(0.08)
Weighted average number of shares	1,660,833,074	1,659,683,537	1,660,353,248

Statements of comprehensive income	Consolidated		
(DKK'000)	**Q1 2014**	**Q1 2013**	**Year 2013**
Net loss for the period	**(19,996)**	**(35,704)**	**(139,311)**
Other comprehensive income:			
Items that may be subsequently reclassified to profit or loss:			
Currency translation differences, net of tax	26	(128)	(390)
Other comprehensive income for the period	26	(128)	(390)
Total comprehensive income for the period	**(19,970)**	**(35,832)**	**(139,701)**

Balance sheet

Assets	Consolidated		
(DKK'000)	**31 Mar. 2014**	**31 Mar. 2013**	**31 Dec. 2013**
Patent rights and software	468	2,103	494
Intangible assets	**468**	**2,103**	**494**
Property, plant and equipment	3,442	2,814	3,333
Leasehold improvements	-	79	-
Property, plant and equipment	**3,442**	**2,893**	**3,333**
Non-current assets	**3,910**	**4,996**	**3,827**
Other receivables	4,350	3,267	15,170
Prepayments	876	1,460	1,214
Receivables	**5,226**	**4,727**	**16,384**
Cash	296,237	456,216	328,652
Cash and cash equivalents	**296,237**	**456,216**	**328,652**
Current assets	**301,463**	**460,943**	**345,036**
Assets	**305,373**	**465,939**	**348,863**

Balance sheet

Equity & Liabilities	Consolidated		
(DKK'000)	**31 Mar. 2014**	**31 Mar. 2013**	**31 Dec. 2013**
Share capital	166,252	166,057	166,057
Special reserve	407,289	407,289	407,289
Translation reserves	1,994	2,230	1,968
Retained earnings/loss	(313,997)	(198,300)	(296,272)
Equity	**261,538**	**377,276**	**279,042**
Finance lease	-	3,275	-
Trade payables	8,250	20,448	13,026
Deferred revenue	24,412	41,208	36,617
Other payables	11,173	23,732	20,178
Current liabilities	**43,835**	**88,663**	**69,821**
Liabilities	**43,835**	**88,663**	**69,821**
Equity and liabilities	**305,373**	**465,939**	**348,863**

Cash flow statements

Cash Flow Statement	Consolidated		
(DKK'000)	**Q1 2014**	**Q1 2013**	**Year 2013**
Operating loss	**(22,167)**	**(39,856)**	**(136,135)**
Share-based payment	1,782	2,933	8,568
Depreciation and amortization	202	340	1,315
Write-down	-	-	1,243
Changes in working capital	(13,365)	(8,504)	(35,294)
Cash flow from operating activities before interest	**(33,548)**	**(45,087)**	**(160,303)**
Interest received	-	48	1,243
Interest paid	-	(18)	(39)
Corporate tax received	-	-	1,352
Corporate tax paid	(2)	(68)	-
Cash flow from operating activities	**(33,550)**	**(45,125)**	**(157,747)**
Purchase of property, plant and equipment	(285)	-	(1,055)
Cash flow from investing activities	**(285)**	**-**	**(1,055)**
Installments on bank borrowings and finance lease	-	(389)	(3,665)
Proceeds from issuance of shares, net	684	437	438
Cash flow from financing activities	**684**	**48**	**(3,227)**
Increase/(decrease) in cash	**(33,151)**	**(45,077)**	**(162,029)**
Cash at beginning of period	328,652	496,834	496,834
Exchange gains/(losses) on cash	736	4,459	(6,153)
Cash at end of period	**296,237**	**456,216**	**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						(35,704)	(35,704)
Other comprehensive income for the year					(128)		(128)
Total comprehensive income					(128)	(35,704)	(35,832)
Warrant exercises	1,250,000	125	313				438
Share-based payment						2,933	2,933
Transfer of retained earnings			(313)			313	-
Equity as of 31 Mar. 2013	**1,660,572,426**	**166,057**	**-**	**407,289**	**2,230**	**(198,300)**	**377,276**
Net loss for the year						(103,606)	(103,606)
Other comprehensive income for the year					(262)		(262)
Total comprehensive income					(262)	(103,606)	(103,868)
Share-based payment						5,634	5,634
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						(19,996)	(19,996)
Other comprehensive income for the year					26		26
Total comprehensive income					26	(19,996)	(19,970)
Warrant exercises	1,954,857	195	489				684
Share-based payment						1,782	1,782
Transfer of retained earnings			(489)			489	-
Equity as of 31 Mar. 2014	**1,662,527,283**	**166,252**	**-**	**407,289**	**1,994**	**(313,997)**	**261,538**

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.